

## FIFTH CIRCUIT COURT OF APPEALS PANEL GRANTS STAY IN CASE CHALLENGING FDA REGULATION OF MIFEPRISTONE

**5/14/2026 UPDATE:** On May 14, 2026, the U.S. Supreme Court extended a stay preserving telehealth access to mifepristone while the Fifth Circuit considers a challenge to regulations permitting pharmacies, including mail-order pharmacies, to dispense the drug directly to patients. The order maintains the existing regulatory framework for mifepristone, allowing prescribing via telehealth and dispensing by retail and mail order pharmacies to continue during the ongoing litigation.

**5/4/2026 UPDATE:** Shortly after this alert was published, the Supreme Court granted an administrative stay of the Fifth Circuit's order. This means that, while the Supreme Court reviews Danco's and GenBioPro's emergency requests that the Fifth Circuit's stay be vacated, mifepristone is available under the **2023 REMS**, which permits dispensing of mifepristone directly to patients by certain pharmacies, including by certain mail-order pharmacies. We will continue to follow this litigation and will provide further updates as they are available.

---

On May 1, 2026, the Fifth Circuit Court of Appeals (the "Fifth Circuit") issued an **opinion** in the ongoing litigation regarding the U.S. Food & Drug Administration's ("FDA") regulation of mifepristone, a drug approved for use in medically induced abortions and routinely used "off-label" to treat early miscarriages. Ruling in favor of the State of Louisiana, the Fifth Circuit issued a stay of 2023 regulations by the FDA, which permitted mifepristone to be dispensed by certain pharmacies, including certain mail-order pharmacies. Defendant drug manufacturers **Danco** and **GenBioPro** have each submitted emergency applications to the Supreme Court of the United States (the "Supreme Court") requesting that the Fifth Circuit's stay be vacated and that the order be administratively stayed while the Supreme Court considers the emergency applications.

### BACKGROUND

In 2000, the FDA approved mifepristone for the medical termination of pregnancy subject to a number of restrictions, including, among others, that: (i) mifepristone could be used for termination of pregnancy only through seven weeks' gestation; (ii) only physicians could prescribe mifepristone; and (iii) dispensing and administration of mifepristone and of a related drug, misoprostol, and a follow-up appointment, must each occur at separate, in-person doctor's-office visits. These restrictions were later included in the first Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, which was approved by the FDA in 2011.

In 2016, the FDA amended the mifepristone REMS by: (i) permitting use of mifepristone for termination of pregnancy through ten weeks' gestation; (ii) allowing non-physician prescribers to prescribe mifepristone; and (iii) removing the requirements that misoprostol administration and the follow-up visit occur in person (the "2016 REMS"). In 2019, the FDA approved a generic version of mifepristone.

More recently, in 2021, the FDA announced that, as a result of the COVID-19 pandemic, it would not enforce the in-person dispensing requirement for mifepristone. The FDA formalized this change with an **updated mifepristone REMS** in January 2023, which also expanded access to mifepristone by allowing certain pharmacies, including large chains and mail-order companies, to dispense mifepristone directly to patients with a prescription from a certified provider (the "2023 REMS").

### STATUS OF LITIGATION

As those following this litigation will recall, in 2024, in separate but related litigation, the Supreme Court rejected a challenge to the 2016 REMS and 2023 REMS, overturning a stay (which never went into effect) imposed by the Fifth Circuit. A previous alert on that decision is available [here](#). Importantly, the Supreme Court's 2024 decision was based on the plaintiff states' lack of standing and did not address the merits of the challenge.

This new lawsuit was filed in 2025 by the State of Louisiana, which argues that it has standing because the 2023 REMS allows for "streams of mifepristone by mail into Louisiana for the express purpose of causing thousands of abortions in Louisiana every year," in violation of Louisiana's general ban on abortion.

In April 2026, a federal District Court in Louisiana granted a stay of litigation while the FDA completes an ongoing review of the mifepristone regulation, which began in September 2025. The State of Louisiana appealed to the Fifth Circuit, which granted a stay of the 2023 REMS, meaning that pharmacies, including large chain and mail-order companies, may no longer dispense mifepristone directly to patients with a prescription from a certified provider.

Intervenor-defendant pharmaceutical companies Danco and GenBioPro, which manufacture mifepristone, have submitted emergency applications to the Supreme Court requesting that the stay be vacated and that the order be administratively stayed as the Supreme Court considers the emergency applications.

## LOOKING AHEAD AND PRACTICAL TAKEAWAYS

For the time being, and unless the Supreme Court intervenes, the 2023 REMS are stayed, meaning that mifepristone may not be dispensed directly to patients by pharmacies – including, but not limited to, mail order pharmacies. In other words, at present, mifepristone may be dispensed to patients only in certain health care settings, by or under the supervision of a certified prescriber.

Health care providers and pharmacies should continue to closely monitor ongoing developments, including action by the Supreme Court and state law actions related to the prescribing of mifepristone, and should further review current policies and procedures related to the prescribing and dispensing of mifepristone to ensure consistency with the stay and state law.

Hall Render is actively tracking the ongoing litigation and regulatory activity related to mifepristone as well as related state law issues. If you have questions regarding mifepristone or need assistance in reviewing and updating practices related to mifepristone use, please contact:

- [Jennifer Skeels](mailto:jскеels@hallrender.com) at (317) 977-1497 or [jsкеels@hallrender.com](mailto:jскеels@hallrender.com); or
- [Todd Nova](mailto:tnova@hallrender.com) at (414) 721-0464 or [tnova@hallrender.com](mailto:tnova@hallrender.com);
- [Cait Bell-Butterfield](mailto:cbell-butterfield@hallrender.com) at (919) 228-2408 or [cbell-butterfield@hallrender.com](mailto:cbell-butterfield@hallrender.com);
- [Camilla Moreno Jimenez](mailto:cjimenez@hallrender.com) at (317) 429-3679 or [cjimenez@hallrender.com](mailto:cjimenez@hallrender.com); or
- Your primary Hall Render contact.

*Hall Render blog posts and articles are intended for informational purposes only. For ethical reasons, Hall Render attorneys cannot—outside of an attorney-client relationship—answer specific questions that would be legal advice.*