



Mifepristone Related Litigation

As of September 9, 2026

State of Louisiana et al. v. FDA and HHS

(Status: Ongoing | Location: Louisiana Western | Last Update: 9/9/2026)

On October 6th, 2025, the State of Louisiana sued the Food and Drug Administration and the Department of Health and Human Services, seeking to permanently withdraw the current rules that allow the sending of abortion medications through the mail. The Risk Evaluation and Mitigation Strategy (REMS) for mifepristone removed a requirement that the medication be dispensed in person in a medical facility in 2023. The state of Louisiana challenged the changes the FDA made to REMS as arbitrary and capricious, a violation of the Comstock Act, and an infringement on Louisiana's state sovereignty. The case was filed on October 6th, 2025. In January 2026, the FDA requested a stay in the case while the agency completed its ongoing review of the safety of abortion medications. On February 3, 2026, two makers of abortion medications (GenBioPro and Danco Laboratories) filed a motion to intervene, which was granted during a hearing on February 24. On April 8, 2026, the judge ruled in favor of Louisiana, reinstated the in-person dispensing requirement but granted the Department of Justice's request to stay the litigation until the FDA review is complete, but requested an update on the review no later than October 7, 2026. Louisiana appealed and on May 1, 2026 the 5th Circuit reversed the stay reinstating the in-person requirement. In an emergency appeal filed by GenBioPro and Danko on May 6th, they asked the Supreme Court to reinstate the stay to prevent disruption of access to Mifepristone. On May 14th, the Supreme Court granted the stay, which allows the use of Mifepristone according to the current FDA requirements to continue while the U.S. Court of Appeals for the Fifth Circuit considers the merits of the case.

The Fifth Circuit expedited the case and oral arguments were heard on September 9, 2026. The next step will be a decision by the 5th Circuit, and the case could again be appealed to the United States Supreme Court during the 2026-2027 term, depending on the decision and the results of the FDA review. A report on the status of this review is due to LA federal court on October 7, 2026.

Florida et al. v. U.S. Food and Drug Administration et al.

(Status: Ongoing | Location: Texas Northern; District Court | Last Update: 10/9/2025)

In December of 2025, the states of Florida and Texas brought a suit against the FDA on their approval of medication abortion drugs as safe and effective. The states challenge FDA's 2000



original approval of Mifepristone, FDA’s decisions to relax restrictions on Mifepristone in 2016, 2021, and 2023, and FDA’s recent approvals of the generic form of Mifepristone. They also assert that the agency’s subsequent changes to the regulation of this medication violate the Administrative Procedure Act; the Food, Drug, and Cosmetic Act; the Comstock Act; and the Pediatric Research Equity Act. In the spring of 20026 Danco and GenBioPro moved to intervene and to dismiss the case while the Department of Justice moved to stay the case pending ongoing litigation in Louisiana v. FDA. On August 31, 2026 a decision was issued by the district court judge denying the motions to dismiss, and finding that the states had standing to sue. The judge stayed the ruling until the sooner of December 1, 2026 or the completion of the FDA’s mifepristone review.

Bryant v. Moore (Previously Bryant v. Stein)

(Status: Ongoing | Location: North Carolina; United States Court of Appeals for the Fourth Circuit | Last Update: 9/9/2026)

In January 2023, Dr. Amy Bryant, a North Carolina physician, filed a lawsuit challenging state-imposed restrictions on the provision of and patient access to mifepristone. Dr. Bryant contended that North Carolina’s regulations, which included requirements such as in-person dispensing and physician-only administration, were preempted by federal law, specifically, the FDA’s updated Risk Evaluation and Mitigation Strategy (REMS) for mifepristone. On April 30, 2024, the court determined that certain state-imposed restrictions—namely, those requiring in-person prescribing, dispensing, and administration of mifepristone, as well as physician-only prescribing—were preempted by federal law and therefore invalid. However, the court upheld other state requirements, including mandatory in-person consultations, ultrasounds, and a 72-hour waiting period, finding that these did not conflict with FDA’s regulations. Following this decision, both parties filed appeals. On December 3, 2024, the 4th US Circuit Court of Appeals placed this case on hold pending a decision in GenBioPro v. Sorsaia/Raynes discussed below. Following the conclusion of that case, briefing in this case was completed in May 2026, and oral arguments will be held on October 28, 2026.

GenBioPro v. Sorsaia/Raynes

(Status: Decision Issued | Location: West Virginia; United States Court of Appeals for the Fourth Circuit | Last Update: 07/15/2025)

GenBioPro, Inc. v. Raynes is a case in which GenBioPro (the manufacturer of generic mifepristone) challenged West Virginia’s abortion ban, arguing it is preempted by the Federal Food, Drug, and Cosmetic Act (FFDCA) and FDA’s regulation of mifepristone. A judge from the



U.S. District Court for the Southern District of West Virginia ruled that the abortion ban was not preempted by the FFDCA as a result of its ancillary restrictions on the sale of the abortion pill. GenBioPro appealed the district court's decision to the U.S. Court of Appeals for the Fourth Circuit. On July 15, 2025, a three-judge panel of the Fourth Circuit upheld the district court's opinion, rejecting GenBioPro's arguments. In a 2-1 ruling, the majority held that neither the FFDCA nor the 2007 Food and Drug Administration Amendments Act (FDAAA) that codified the Risk Evaluation and Mitigation Strategy (REMS) provisions under the FFDCA, preempted the West Virginia abortion ban. The decision suggests states may ban FDA-approved drugs if ancillary to other broad state health and safety laws. Judge Benjamin's dissent warned that West Virginia's law effectively nullifies federal drug approvals and intrudes into the FDA's domain. No appeal of this decision was taken.

Purcell v. Kennedy (Previously Purcell v. Becerra and Chelius v. Becerra)
(Status: Ongoing | Location: Hawaii; District Court | Last Update: 12/6/2025)

Purcell v. Kennedy is an ongoing federal lawsuit initiated in October 2017 in the U.S. District Court for the District of Hawaii. The plaintiffs, including Dr. Heidi Purcell, the Society of Family Planning, and the California Academy of Family Physicians, challenge the U.S. Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, a medication used for early abortion and miscarriage management. The plaintiffs argue that the REMS imposes unnecessary and burdensome restrictions on mifepristone, making it difficult to access and prescribe, despite its established safety and efficacy. They contend that by singling out mifepristone for undue limitations not applied to other medications with comparable safety profiles, these restrictions violate the Equal Protection Clause of the U.S. Constitution and the Administrative Procedure Act. In response to the lawsuit, the FDA announced in April 2021 that it would undertake a comprehensive review of the REMS for mifepristone. Subsequently, in January 2023, the FDA updated the REMS, removing the in-person dispensing requirement but maintaining and adding other restrictions, such as special certification for prescribers and pharmacies. The plaintiffs assert that these remaining restrictions continue to impede access to mifepristone and have persisted with their legal challenge. On October 30th 2025, the federal district judge ruled that the 2023 REMS for mifepristone was arbitrary and capricious and required a new review by FDA consistent with the court's determinations that the REMS were overly restrictive.

(cont'd)

Whole Woman's Health Alliance et al. v. U.S. Food and Drug Administration et al.



(Status: Ongoing | Location: Virginia; District Court | Last Update: 9/9/2026)

On May 8, 2024, the Center for Reproductive Rights filed a lawsuit in federal district court in Virginia, on behalf of independent abortion providers in Virginia, Montana, and Kansas. The Plaintiffs argue that the FDA violated the Equal Protection Clause of the US Constitution and the Administrative Procedure Act by maintaining Mifepristone requirements that make the drug difficult to access and prescribe. On August 21, 2023, the federal court denied CRR's request for a preliminary injunction. On October 23, 2024, the Plaintiffs sought summary judgment that the 2023 Mifepristone REMS were unlawful. In July 2026 the district court judge ruled that the 2023 REMS decision maintaining some restrictions was arbitrary and capricious given that FDA had "steadfastly found, over the past quarter century, that mifepristone is a safe and effective medication" and ordered the FDA to reconsider the rules.

Texas v. Carpenter

(Status: Ongoing | Location: Texas District Court in Collin County | Last Update: 10/31/2025)

Attorney General Ken Paxton from Texas sued Dr. Margaret Daley Carpenter from New York for providing mifepristone to a Texas resident via telemedicine, asserting this violates Texas abortion law. Dr. Carpenter sent a 20-year-old female medication abortion pills. On July 16, 2024, she asked the biological father to take her to the hospital due to a hemorrhage or severe bleeding, where he found out that she was pregnant and had taken the abortion pills to terminate the pregnancy. Dr. Carpenter is the founder of the Abortion Coalition for Telemedicine (ACT) and is covered by New York state's shield laws, which protect people from legal consequences for providing, receiving, or facilitating abortion-related reproductive health care. Shield laws are designed to limit the ability of anti-abortion states to enforce their restrictions outside of their borders. In October 2025, the New York Supreme Court judge dismissed the case, saying "Dr. Carpenter's conduct falls squarely within the definition of 'legally protected health activity,'" and that New York state acted legally when it did not file a case against Dr. Carpenter. It is expected that the case will be appealed up to the highest state court in New York (the Court of Appeals) and could eventually be heard by the Supreme Court of the United States. Both parties have completed briefing on the request for a stay and are awaiting a decision from the judge.

(cont'd)

State of Washington, Oregon, et al., v. FDA



(Status: Decision Issued | Location: Washington; District Court | Last Update: 07/08/2025)

In February 2023, a coalition of 17 states and the District of Columbia, led by Washington and Oregon, filed a lawsuit against the FDA in the U.S. District Court for the Eastern District of Washington. The plaintiffs argued that the FDA's mifepristone REMS imposed unnecessary restrictions on the drug despite its established safety profile. On April 7, 2023, U.S. District Judge Thomas O. Rice issued an injunction preventing the FDA from “altering the status quo and rights as it relates to the availability of Mifepristone” under the 2023 REMS in the plaintiff states and DC, thereby maintaining existing access to the medication in those jurisdictions.” Subsequently, a group of Republican-led states sought to intervene in the case, aiming to impose additional restrictions on Mifepristone. However, in July 2024, the Ninth Circuit Court of Appeals denied their intervention, ruling that these states lacked the legal standing to participate in the lawsuit. In September 2024, the Ninth Circuit declined to grant a rehearing *en banc*. On July 8, 2025, the court issued a decision in which it granted FDA’s cross-motion for summary judgment and dismissed the case. In the ruling, the judge stated, “The Court cannot find, based on the full record before it, that the FDA was arbitrary and capricious in its decision. The FDA did not ignore the laws that apply nor the regulations.”

State of Missouri, et al., v. FDA (Formerly AHM, et al., v. FDA)

(Status: Ongoing | Location: Texas Northern District Court in Amarillo | Last Update: 10/23/2025)

In June 2024, the Supreme Court issued a unanimous decision in *Alliance for Hippocratic Medicine v. Food and Drug Administration (FDA)*. The Court ruled the plaintiffs lacked the necessary legal standing to challenge the FDA's regulation of mifepristone, including the 2016 and 2023 REMS modifications (notably, the Supreme Court did not consider the original challenge to the mifepristone approval, which the Fifth Circuit found was time-barred). In November 2023, Missouri, Kansas, and Idaho filed a motion seeking to intervene in the case. In November 2024, the states sought leave to file an amended complaint that would remove the original plaintiffs and leave the state attorneys general to pursue the case. These states argued the FDA's guidelines for mifepristone infringed on state sovereignty and public health policies, as each state had established restrictions or regulations around abortion. In November 2024, the Biden administration and Danco Laboratories (the manufacturer of branded mifepristone) filed a motion to dismiss the complaint. However, on January 16, 2025, Texas federal judge Matthew Kacsmaryk issued a ruling permitting the attorneys general from Missouri, Kansas, and Idaho to continue litigating the case. On May 5, 2025, the Trump Administration followed the legal course also taken by the Biden Administration, asking Judge Kacsmaryk to dismiss the lawsuit, arguing that Missouri, Kansas, and Idaho have no connection to the Texas district in



which they filed their complaint. On September 30th, Judge Kacsmaryk dismissed the case on standing grounds for Texas, Louisiana, and Florida, but allowed transfer to the Eastern District of Missouri, a court overwhelmingly dominated by Trump-appointed judges. On October 23, 2025, the case was officially transferred to the Eastern District of Missouri to Judge Cristian Stevens as case number 4:25-cv-01580.

Birthmark Doula Collective v. State of Louisiana

(Status: Filed Lawsuit | Location: Louisiana; District Court | Last Update: 10/31/24)

In *Birthmark v. Louisiana*, filed in October 2024, the plaintiffs challenged Louisiana's Act 246, which reclassifies mifepristone and misoprostol as controlled dangerous substances under the state's controlled substances law. The plaintiffs argue that the reclassification imposes stringent regulations, potentially delaying access to these essential medications during critical emergencies, thereby endangering patients' lives. They contend that Act 246 violates the Louisiana Constitution's equal protection guarantee by discriminating against individuals based on their physical conditions. The Birthmark Doula Collective initiated the lawsuit, along with healthcare professionals and individuals directly affected by the law. They assert that the legislation contributes to the stigmatization of reproductive healthcare and could lead to increased surveillance and criminalization of healthcare providers and patients. The plaintiffs seek a declaratory judgment and a permanent injunction to prevent the enforcement of Act 246, aiming to ensure uninterrupted access to these critical medications for both patients and healthcare providers.

For more information, please contact info@emaaproject.org.