The Mifepristone Litigation and Federal Action Tracker

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The **Mifepristone Litigation Tracker** and **Mifepristone Federal Action Tracker** provide timely, regularly updated information on the current status of litigation and federal administrative actions that could shape regulation of and access to mifepristone.

The **Mifepristone Litigation Tracker** contains **12 cases** that could affect access to mifepristone, **8** of which remain active. The **Mifepristone Federal Action Tracker** contains **7 citizen petitions** filed since January 1, 2025, that could affect regulation of mifepristone, **6** of which remain open.

Mifepristone Is a Safe and Effective Medication Used for Abortion

Mifepristone is commonly used in medication abortion, which accounts for nearly two-thirds of all abortions in the United States. The U.S. Food and Drug Administration (FDA) approved mifepristone in 2000, and its safety has been rigorously tested—decades of studies analyzing hundreds of thousands of patient outcomes have conclusively proven that mifepristone is safe and effective. Based on this overwhelming safety record, FDA has, over the last decade, lifted some prior restrictions on how the medication is administered. These FDA decisions have allowed a broader group of health care providers to administer mifepristone, including by telehealth, increasing access to the medication. Despite FDA's recent removal of some restrictions, mifepristone is far more regulated than other medications with similar safety profiles. Many states have also imposed laws and policies restricting access to mifepristone beyond FDA's regulations.

Litigation and Federal Action Could Affect Access to Mifepristone Nationwide

Despite mifepristone's record of safety and effectiveness, anti-abortion activists have pursued various strategies to ban or undercut access to it. In recent years, anti-abortion activists have brought litigation challenging FDA's original approval of mifepristone and recent decisions relaxing some of the restrictions on the medication. At the same time, because mifepristone is still subject to more rigorous restrictions than other drugs with a similar safety profile, health care providers and advocacy organizations have challenged regulations of mifepristone that create unnecessary barriers to access. The outcome of these cases could affect access to mifepristone throughout the country—stay updated through the **Mifepristone Litigation Tracker**.

The federal government may also independently take administrative and agency actions, apart from its involvement in any litigation, that could affect regulation of and access to mifepristone. FDA may modify the current regulations governing mifepristone, including in response to the citizen petition process, by which people may issue formal requests for the agency to take action. There's reason to keep an eye on federal actions related to mifepristone—despite an overwhelming body of gold standard science definitively establishing the safety and effectiveness of mifepristone, the federal government recently announced FDA is conducting a new review of mifepristone prompted by a report that has been denounced by more than 260 expert researchers as methodologically flawed and unreliable. Stay updated on the federal government's actions related to mifepristone since January 1, 2025, through the **Mifepristone Federal Action Tracker**.

The Mifepristone Litigation Tracker

The Mifepristone Litigation Tracker was last updated in August 2026.

Current mifepristone litigation includes the below categories of cases. Click on a case category to learn more.

3 Cases to Restrict Access:

- **3 FDA Decisionmaking Cases** challenging FDA's decisions approving mifepristone and removing prior restrictions on it, including the in-person dispensing requirement

9* Cases to Protect or Expand Access:

- **3* FDA Decisionmaking Cases** addressing whether current FDA regulations on mifepristone are overly burdensome and restrictive given mifepristone's safety and effectiveness
- **2* Federal Preemption Cases** addressing whether federal law preempts (supersedes) and invalidates additional state restrictions on mifepristone beyond FDA's regulations
- **1 State Law Case** addressing whether additional state restrictions on mifepristone are invalid under state law
- **1* Due Process Case** seeking to prevent any enforcement of a court decision suspending FDA approval of mifepristone without due process
- **2 Public Records Cases** seeking access to information on FDA's review of mifepristone

**Including recently closed cases, in which final judgment was entered.*

Cases to Restrict Access

3 FDA Decisionmaking Cases challenging FDA's decisions removing prior restrictions on mifepristone, including the in-person dispensing requirement, and seeking to reimpose those restrictions

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

   Case number: 7:25-cv-00126

   Court: U.S. District Court for the Northern District of Texas

   Date Filed: December 9, 2025

   Summary of Challenge: Florida and Texas filed suit challenging FDA's 2000 original approval of mifepristone, FDA's decisions in 2016, 2021, and 2023 relaxing prior restrictions on mifepristone, and FDA's 2019 and 2025 approvals of the generic form of the drug. Florida and Texas claim FDA's decisions were not supported by adequate evidence and do not comply with the Comstock Act and thus violate the Administrative Procedure Act (APA). The States seek to rescind the original and generic approvals of mifepristone, and reimpose restrictions on mifepristone that FDA has determined are medically unnecessary, including the pre-2021 requirement that it be dispensed in-person, and the pre-2016 restrictions requiring three office visits, limiting prescription of mifepristone to only certified physicians, indicating it could only be used for pregnancies up to 7 weeks (rather than 10 weeks), and requiring the reporting of all serious non-fatal adverse events to FDA.

   What's at Stake: This case could rescind FDA approval of mifepristone, drastically impacting access throughout the country. The case could also affect access to mifepristone by imposing burdensome restrictions on mifepristone FDA has determined are medically unnecessary, including requirements for in-person dispensing and office visits (which would prohibit mifepristone's administration via telehealth) and limitations on which health care providers can prescribe mifepristone.

   Current Status: The case is currently pending in the U.S. District Court. On March 13, 2026, mifepristone manufacturers Danco Laboratories, LLC, and GenBioPro, Inc. filed separate motions to intervene. Additionally, on March 13, FDA and the other federal government defendants filed a motion to dismiss and a motion to stay, arguing that the court should stay litigation pending FDA's ongoing regulatory review of mifepristone. On April 10, 2026, the motions to intervene were granted and GenBioPro and Danco filed separate motions to dismiss. On April 24, 2026, Plaintiff States filed a response to the motions to dismiss, stating that the case should be stayed for a reasonable amount of time, and the motions to dismiss should be denied. On August 30, 2026, the District Court stayed the case until the sooner of December 1, 2026, or the completion of FDA's regulatory review of mifepristone.

2. ***Louisiana et al. v. U.S. Food and Drug Administration et al.***

Case number: 26-30203

Court: U.S. Court of Appeals for the Fifth Circuit (on appeal from U.S. District Court for the Western District of Louisiana)

Date Filed: October 6, 2025

Summary of Challenge: Plaintiffs are the State of Louisiana and Louisiana resident Rosalie Markezich, who claims she was coerced by a former partner to take medication abortion that he ordered in her name and received by mail. Plaintiffs argue that FDA's 2023 REMS for mifepristone, which removed the requirement of in-person dispensing, is unlawful under the APA because it is arbitrary and capricious and because it violates the Comstock Act and is thus contrary to law. They allege that as a result of the REMS, Louisiana suffers sovereign and economic harms and Markezich suffered physical and emotional harms. Plaintiffs request that the 2023 REMS be held unlawful, stayed, set aside, vacated, and permanently enjoined under the APA.

What's at Stake: This case could reinstate the prior in-person dispensing requirement, drastically affecting access to medication abortion nationwide, as nearly one in four of all abortions are accessed via telehealth.

Current status: The case is currently pending in the U.S. Court of Appeals for the Fifth Circuit. On December 17, 2025, Plaintiffs filed a motion for preliminary injunction, requesting the court withdraw mifepristone's 2023 REMS and impose restrictions requiring in-person dispensing. On January 27, 2026, the Government filed a motion to stay all proceedings, arguing that a decision in the case would interfere with or be unnecessary given FDA's ongoing review of mifepristone's REMS. The court granted motions to intervene filed by Danco Laboratories, L.L.C. and GenBioPro, manufacturers of mifepristone, which both filed motions to dismiss for failure to state a claim and lack of jurisdiction.

On April 7, 2026, the court granted the Government's motion to stay proceedings while FDA conducts its regulatory review of mifepristone. The court denied Plaintiffs' request for a preliminary injunction and GenBioPro's and Danco's motions to dismiss without prejudice to refiling when the stay is lifted. While the court concluded that Plaintiffs have standing and are likely to succeed on the merits of their 2023 REMS challenge, it reasoned that allowing FDA to complete its regulatory review would best serve the public interest. Plaintiffs appealed the ruling and filed a motion to stay or enjoin FDA's 2023 REMS. On May 1, 2026, the Fifth Circuit Court of Appeals issued an order granting Plaintiffs' request to reimpose the requirement that mifepristone prescriptions be filled only in person at clinics, medical offices, or hospitals. The manufacturers requested the U.S. Supreme Court stay the Fifth Circuit's order. On May 14, the U.S. Supreme Court granted a stay of the Fifth Circuit's order for the remainder of the appeals process (disposition of the appeal in the Fifth Circuit and disposition of a petition of writ of certiorari to and judgment from the Supreme Court). The case is now pending before Fifth Circuit, and oral argument took place on September 9, 2026.

3. ***Missouri et al. v. U.S. Food and Drug Administration et al.***

Case number: 4:25-cv-01580

Court: U.S. District Court for the Eastern District of Missouri (transferred from U.S. District Court for the Northern District of Texas)

Date Filed: November 18, 2022

Summary of Challenge: Missouri, Kansas, and Idaho (the States) seek to revive a prior case, *Alliance for Hippocratic Medicine, et al., v. FDA*, in which the States had intervened. In June 2024, the Supreme Court held that the plaintiffs in *AHM v. FDA*—anti-abortion doctors and activists who never prescribed and never experienced harm related to mifepristone—lacked standing, and all claims in *AHM v. FDA* were dismissed. In October 2024, the States filed an amended complaint in the same federal district court in Texas that presided over *AHM v. FDA*.

The States claim FDA decisions in 2016, 2021, and 2023 relaxing prior restrictions on mifepristone and FDA's 2019 approval of the generic form of the drug were not supported by adequate evidence and as a result violate the APA. The States seek to rescind the 2019 generic approval and reimpose restrictions on mifepristone that FDA has determined are medically unnecessary, including the pre-2021 requirement that it be dispensed in-person, and the pre-2016 restrictions requiring three office visits, limiting prescription of mifepristone to only certified physicians, indicating it could only be used for pregnancies up to 7 weeks (rather than 10 weeks), and requiring the reporting of all serious non-fatal adverse events to FDA. The States also seek an order prohibiting provision of mifepristone to adolescents.

What's at Stake: This case could affect access to mifepristone by imposing burdensome restrictions on mifepristone FDA has determined are medically unnecessary, including requirements for in-person dispensing and office visits (which would prohibit mifepristone's administration via telehealth) and limitations on which health care providers can prescribe mifepristone. The case could also affect adolescent access to mifepristone.

Current status: On August 22, 2025, Texas and Florida moved to intervene and on September 19, 2025, the state of Louisiana and an individual resident moved to intervene. On September 30, 2025, Judge Kacsmaryk granted defendant's motion to dismiss for lack of venue and transferred the case to the Eastern District of Missouri. On October 23, 2025, the case was transferred and assigned to Judge Cristian M. Stevens. On March 6, 2026, FDA and the other federal government defendants filed a motion to stay, or alternatively, a motion to dismiss, stating that judicial review should be stayed until FDA completes its regulatory review of mifepristone. Mifepristone manufacturers Danco and GenBioPro, which had previously intervened as defendants in the case, filed motions to dismiss on March 6, 2026, and March 13, 2026, respectively. On April 10, 2026, GenBioPro and Danco filed reply briefs requesting that the court dismiss the complaints. On the same day, FDA and other government defendants filed a reply brief requesting that the court stay or dismiss the case. From May 5, 2026, through May 19, 2026, the parties filed supplemental briefs addressing the Fifth Circuit's decision in *Louisiana v. FDA*.

Cases to Protect or Expand Access

3 FDA Decisionmaking Cases addressing whether current FDA regulations on mifepristone are overly burdensome and restrictive given mifepristone's safety and effectiveness

1. ***Purcell et al. v. Kennedy et al.*** (Final judgment entered—case closed.)

   Case number: 1:17-00493

   Court: U.S. District Court for the District of Hawaii

   Date Filed: October 13, 2017

   Summary of Challenge: Plaintiffs—a health care provider, Society of Family Planning, and the California Academy of Family Physicians—challenge FDA's current set of restrictions (the Risk Evaluation and Mitigation Strategy (REMS)) on mifepristone as unduly burdensome and arbitrarily restrictive given mifepristone's safety and effectiveness. Plaintiffs argue that these restrictions—which require patients to certify they have decided to take mifepristone to end their pregnancy and limit who can prescribe and dispense the drug by requiring providers and pharmacies to undergo a special certification process—delay care, deter qualified providers and pharmacies from prescribing and dispensing mifepristone, and impede research and training on mifepristone at academic institutions. Plaintiffs assert claims under the equal protection guarantee of the Fifth Amendment and the APA, alleging they are treated differently from other similarly situated parties without a sufficient state interest, and that FDA's imposition of the REMS was not based on a reasoned decision or rational basis.

   What's at Stake: The case could affect access by eliminating or leaving intact current restrictions on mifepristone that impede access by limiting the health care professionals who can prescribe it and the pharmacies that can dispense it. The case could also determine whether FDA may continue to require the patient agreement form, which plaintiffs assert presents privacy risks for patients and providers.

   Current status: On October 30, 2025, the court granted plaintiffs' motion for summary judgment and denied defendant's cross-motion. The court ruled that FDA acted arbitrarily and capriciously in violation of the APA because it failed to consider relevant evidence and failed to provide adequate reasoning as to why it was restricting mifepristone access. The court remanded the matter to FDA to reassess the REMS in accordance with the court's order and the law. On December 6, 2025, the court dismissed Plaintiffs' constitutional claims without prejudice. On January 21, 2026, the court declined to retain jurisdiction over the matter pending remand to FDA, issuing its final decision.

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

   Case number: 3:23-cv-00019

   Court: U.S. District Court for the Western District of Virginia

   Date Filed: May 8, 2023

   Summary of Challenge: Abortion providers in Virginia, Montana, and Kansas challenge FDA's current mifepristone REMS as unduly burdensome and arbitrarily restrictive given mifepristone's safety and effectiveness. The providers argue that the current restrictions are unnecessary barriers that make it more difficult to access care. Plaintiffs argue that FDA violated the APA by imposing the REMS against evidence showing the restrictions are unnecessary, and violated the equal protection guarantee of the Fifth Amendment by treating providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than those who prescribe, dispense, or use other medications.

   What's at Stake: The case could affect access by eliminating or leaving intact current restrictions on mifepristone that impede access by limiting the health care professionals who can prescribe it and the pharmacies that can dispense it. The case could also determine whether FDA may continue to require the patient agreement form, which plaintiffs assert presents privacy risks for patients and providers.

   Current status: The case is currently pending in federal district court in Virginia. In October 2024, plaintiffs filed a motion for summary judgment. In December 2024, defendants filed a cross-motion for summary judgment, arguing that plaintiffs' claims should be dismissed on the merits, and that plaintiffs lack standing and did not administratively exhaust their claims by first raising them with FDA. The court held oral argument on the motions for summary judgment on May 19, 2025. In March 2026, defendants moved for the court to stay litigation while FDA completes its regulatory review of mifepristone. In April 2026, plaintiffs filed a response in opposition to defendants' motion to stay proceedings. On July 23, 2026, the court issued a ruling finding that FDA's 2023 REMS modification was arbitrary and capricious because the agency failed to consider relevant data, analyze restrictions with reference to the mandated statutory factors, or provide a reasonable justification for the modification. On September 2, 2026, the court issued an order remanding the 2023 REMS modifications to FDA for reconsideration and directing the parties to submit briefing on whether the court should retain jurisdiction of the case during agency remand, which all parties submitted by October 9, 2026.

3. ***Washington et al. v. U.S. Food and Drug Administration et al.*** (Final judgment entered—case closed)

   Case number: 1:23-cv-03026

   Court: U.S. District Court for the Eastern District of Washington

   Date Filed: February 23, 2023

   Summary of Challenge: 17 states and Washington, D.C. (the States) challenge FDA's mifepristone REMS as unduly burdensome and

restrictive given mifepristone's safety and effectiveness. The States argue that the current restrictions are unnecessary barriers that make it more difficult to access care. The States argue that FDA violated the APA by imposing the REMS against evidence showing the restrictions are unnecessary, and violated the equal protection guarantee of the Fifth Amendment by treating providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than those who prescribe, dispense, or use other medications.

What's at Stake: The case affects access by leaving intact current restrictions on mifepristone that impede access by limiting the health care professionals who can prescribe it and the pharmacies that can dispense it. The case could also determine whether FDA may continue to require the patient agreement form, which the States assert presents privacy risks for patients and providers.

Current status: On July 8, 2025, the court issued a final decision granting defendant's cross-motion for summary judgment and dismissing the case. Based on the record before it, the court found that FDA's review and decision regarding the mifepristone REMS was reasonable, not arbitrary or capricious, and did not ignore any laws or regulations. The court's decision did not reach plaintiffs' equal protection claim. Final judgment was entered—this case is now closed.

2 Federal Preemption Cases addressing whether federal law preempts (supersedes) and invalidates additional state restrictions on mifepristone beyond FDA's regulations

1. ***GenBioPro v. Raynes et al.*** (Final judgment entered—case closed.)

   Case number: 23-2194

   Court: U.S. Court of Appeals for the Fourth Circuit (on appeal from U.S. District Court for the Southern District of West Virginia)

   Date Filed: January 23, 2025

   Summary of Challenge: GenBioPro, a manufacturer of generic mifepristone, argues that federal law preempts West Virginia laws banning abortion in almost all cases and banning prescription of mifepristone by telemedicine because Congress only authorized FDA to impose restrictions on access to mifepristone. GenBioPro also challenges as preempted West Virginia restrictions on mifepristone requiring counseling and a waiting period that are not currently in effect but would be reimposed if the state's general abortion ban were struck down. GenBioPro argues that the state's ban and restrictions also burden interstate commerce in violation of the U.S. Constitution's Commerce Clause.

   The district court granted defendants' motion to dismiss GenBioPro's claim related to West Virginia's general abortion ban, reasoning that the ban restricts *when* an abortion may be performed rather than *how* mifepristone may be prescribed and thus is not in conflict with or preempted by FDA's regulations. The court also concluded that the general abortion ban does not violate the Commerce Clase because it does not impede the flow of mifepristone nationally. The court dismissed GenBioPro's claims regarding the counseling and waiting period requirements since they are not currently in effect.

   What's at Stake: This case affects access to mifepristone by deciding that states may impose burdensome restrictions on

mifepristone beyond FDA's regulations, including by banning mifepristone for its approved use in almost all circumstances and barring prescription via telehealth or otherwise making it more difficult to access.

Current Status: On July 15, 2025, the U.S. Court of Appeals for the Fourth Circuit affirmed the district court's decision, leaving the state's abortion ban in effect. Final judgment was entered—this case is now closed.

2. ***Bryant v. Moore***

Case number: 24-1617

Court: U.S. Court of Appeals for the Fourth Circuit (on appeal from U.S. District Court for the Middle District of North Carolina)

Date Filed: January 25, 2025

Summary of Challenge: Plaintiff, a medical provider in North Carolina, asserts that federal law preempts North Carolina laws imposing additional restrictions on mifepristone beyond FDA's requirements. The district court ruled that some of the challenged state-imposed restrictions—including laws requiring in-person prescribing, dispensing, and administering of mifepristone, prohibiting providers other than physicians from prescribing mifepristone, mandating the scheduling of an in-person follow-up appointment, and requiring non-fatal adverse event reporting to FDA—were preempted by federal law and invalid because FDA had implemented and then later affirmatively rejected and removed these restrictions. The district court upheld other challenged state requirements for an in-person advance consultation, ultrasounds, an in-person examination, blood type testing, and adverse event reporting to state health authorities, concluding that these provisions were not expressly considered and rejected by FDA or "focus more on the practice of medicine and a patient's informed consent," and thus are not preempted.

What's at Stake: This case could affect access to mifepristone by deciding whether states may impose burdensome restrictions on mifepristone beyond FDA's regulations, including those barring administration via telehealth or otherwise making mifepristone more difficult to access.

Current Status: The case is currently pending before the U.S. Court of Appeals for the Fourth Circuit. The parties have filed briefs, but the case is temporarily suspended pending a decision by the U.S. Court of Appeals for the Fourth Circuit in *GenBioPro, Inc. v. Raynes* (Case No. 23-2194). Although a decision in *GenBioPro, Inc. v. Raynes* was issued and the case is now closed (see above), this case currently remains pending. On April 27, 2026, the parties filed supplemental briefs addressing the *GenBioPro v. Raynes* decision. Oral argument was held on October 28, 2026.

1 State Law Case addressing whether additional state restrictions on mifepristone are invalid under state law

1. ***Birthmark Doula Collective v. State of Louisiana***

Case number: C-7552171

Court: Louisiana State Trial Court (19th Judicial District Court)

Date Filed: October 31, 2024

Summary of Challenge: Plaintiffs—birth workers and other medical professionals, advocates, and a pregnant person—challenge a Louisiana law classifying mifepristone and misoprostol, safe medications with no risk of abuse or dependence, as controlled dangerous substances. Plaintiffs argue that this classification delays access to the medication, risking the health and safety of patients, including those carrying pregnancy to term and experiencing miscarriages. Plaintiffs assert that the law discriminates based on physical condition, thereby violating Louisiana's constitutional right to equal protection. Plaintiffs also argue that the legislature violated state constitutional requirements (the single object requirement and germane amendment rule) in amending a bill introduced to create the crime of coerced abortion to add the unrelated matter of classifying mifepristone and misoprostol as controlled substances.

What's at Stake: This case could impact emergency care for pregnant people in Louisiana. Classification of mifepristone and misoprostol as controlled dangerous substances delays access to care, posing a particular threat to the health and safety of people experiencing obstetric emergencies.

Current Status: The case is currently pending in Louisiana trial court. On May 15, 2025, the court held a hearing on defendants' motion requesting dismissal of the case and ruled on June 10, 2025 that plaintiffs' challenge can proceed.

1 Due Process Case seeking to prevent any enforcement of a court decision suspending FDA approval of mifepristone without due process

1. ***GenBioPro v. U.S. Food and Drug Administration et al.*** (voluntarily dismissed – case closed.)

Case number: 23-01057

Court: U.S. District Court for Maryland

Date Filed: April 19, 2023

Summary of Challenge: GenBioPro, a manufacturer of generic mifepristone, filed suit in April 2023 to prevent other federal court rulings (including those issued by the district court and Fifth Circuit in *Alliance for Hippocratic Medicine v. FDA*) from stripping FDA approval of generic mifepristone without following the required statutory and regulatory procedures for suspension of a drug's approval. GenBioPro argues that suspending approval of mifepristone without proper process would violate the APA, the All Writs Act, and the due process guarantee of the Fifth Amendment.

What's at Stake: The case could have affected access to mifepristone by determining whether court decisions may suspend its approval.

Current status: This case was originally stayed while the Supreme Court resolved *Alliance for Hippocratic Medicine v. FDA*. It was further stayed in light of a pending decision in *Missouri v. FDA*, Case No. 2:22-cv-00223, on motions to dismiss the case. On November 14, 2025 GenBioPro voluntarily dismissed the case without prejudice. The court dismissed the case without prejudice on November 17, 2025.

2 Public Records Cases seeking access to information on FDA's review of and communications related to mifepristone

1. ***The Center for Reproductive Rights v. U.S. Department of Health and Human Services, et al.***

Case number: 25-03023

Court: U.S. District Court for the District of Columbia

Date Filed: September 5, 2025

Summary of Challenge: The Center for Reproductive Rights (CRR) filed suit to compel FDA and HHS to comply with the Freedom of Information Act (FOIA) and produce information responsive to CRR's request regarding FDA's decision to review mifepristone, the process FDA will follow to review the medication, whether information from third parties will be considered during the review, and the influence HHS leadership may exert over FDA's review of mifepristone and decisionmaking. CRR submitted its FOIA request in July 2025. HHS and FDA were required to notify CRR within 20 days of receiving the request of whether they would produce responsive records or their reasons for withholding them but failed to do so.

What's at Stake: Both FDA and HHS have said FDA is currently reviewing mifepristone, without providing any transparency to the public on what that review entails. Disclosure of the information CRR requests may shed light on the scope of FDA's review and the sources of information FDA is considering, including whether it is considering an Ethics and Public Policy Center (EPPC) report that purports to undercut the longstanding determination that mifepristone is safe and effective, but has been largely debunked by the medical community for its flawed information and lack of peer review.

Current Status: The case is currently pending in U.S. District Court. HHS and FDA answered CRR's amended complaint on January 16, 2026, claiming—among other defenses—that they need additional time to search for records because of exceptional circumstances. In April, the court adopted the following schedule, which stated that an interim status report is due May 5, 2026, and defendants will provide plaintiffs with the estimated total number of pages of potentially responsive records to be processed by June 15, 2026. A joint status report was submitted on June 30, 2026, detailing the production of documents from FDA and HHS. The next joint status reports were submitted on August 31, 2026 on October 30, 2026, with additional status reports due every sixty days thereafter.

2. ***American Civil Liberties Union v. U.S. Food and Drug Administration***

Case number: 25-03736

Court: U.S. District Court for the District of Maryland

Date Filed: November 13, 2025

Summary of Challenge: ACLU filed suit to compel FDA to comply with FOIA and produce information responsive to ACLU's request regarding FDA's review of and communications related to mifepristone. Plaintiff submitted its FOIA request on August 1, 2025. FDA was required to notify ACLU within 20 days of receiving the request of whether it would produce responsive records or its reasons for withholding them but failed to do so.

What's at Stake: Both FDA and HHS have said FDA is currently reviewing mifepristone, without providing any transparency to the public on what that review entails. Disclosure of the information ACLU requests may shed light on the scope of FDA's review and the sources of information FDA is considering, including whether it is considering an Ethics and Public Policy Center (EPPC) report that purports to undercut the longstanding determination that mifepristone is safe and effective, but has been largely debunked by the medical community for its flawed information and lack of peer review.

Current Status: The case is currently pending in U.S. District Court. FDA answered ACLU's complaint on January 20, 2026, claiming—among other defenses—that it needs additional time to search for records because of exceptional circumstances. The parties submitted a joint status reports on July 31, 2026 on October 30, 2026.

The Mifepristone Federal Action Tracker

The Mifepristone Federal Action Tracker covers federal actions since January 1, 2025, and was last updated in August 2026.

- **July 15, 2026**: During a Senate Confirmation Hearing, acting Attorney General Todd Blanche pledged his support to restrict access to mifepristone in the United States, stating that FDA and HHS were taking a careful look at mifepristone's safety, despite decades of reliable evidence that shows its safety and efficacy. He also committed to reviewing the Comstock Act, which the Biden administration concluded does not prohibit the mailing of medication abortion.
    - **What's at Stake:** A federal ban on mifepristone would affect abortion access throughout the country—mifepristone is commonly used in medication abortion, which now accounts for over two-thirds of abortions in the United States.
    - **Current Status:** FDA's review of mifepristone is ongoing.
- **June 5, 2026**: In two different letters, fourteen Republican Attorneys General and sixteen Republican Congress members demanded that the U.S. Environmental Protection Agency (EPA) add mifepristone to its Contaminant Candidate List (CCL), which is a list of water contaminants that occur in public water systems and are not subject to EPA drinking water regulations.
    - **What's at Stake:** Despite no research indicating that mifepristone contaminates drinking water at concerning levels, adding mifepristone to CCL could open it up to additional federal investigation efforts to assess its already cataloged safety and potential regulation under the Safe Drinking Water Act.
    - **Current Status:** The deadline to submit comments for CCL 6 was June 5, 2026. EPA is expected to finalize the list of substances on CCL 6 by November 17, 2026.
- **June 4, 2026:** FDA launched a study on the safety of mifepristone. FDA officials stated that the full study may take about six months to complete. On October 7, 2026, FDA submitted a status report in the *Louisiana v. FDA* case stating that it expects to complete the study by March 2027.
    - **What's at Stake:** If FDA were to impose restrictions on mifepristone's administration, many people may be unable to access the medication, especially in areas that already lack reproductive health resources.
    - **Current Status:** FDA's review of mifepristone is ongoing.
- **March 18-April 14, 2026:** On March 18, 2026, U.S. Senator Josh Hawley sent letters to Danco Laboratories and GenBioPro, both manufacturers of mifepristone, stating that he was opening investigations into their business practices via the Senate Judiciary Committee on Crime and Counterterrorism. On March 25, 2026, U.S. Senator Bill Cassidy and other Senate Republicans sent letters to Danco, GenBioPro, and Evita, manufacturers of medication abortion, as well as the FDA, demanding detailed records regarding compliance with

mifepristone's REMS. On April 14, 2026, U.S. Senator Josh Hawley sent a letter to the U.S. Department of Justice (DOJ), asking the DOJ to open an investigation into Danco Laboratories.

  - **What's at Stake:** These efforts are part of a broader strategy to impose burdensome restrictions on and limit access to mifepristone, despite its established safety record.
  - **Current Status:** Senator Cassidy's letter requests a response by April 8, 2026, and Senator Hawley's letter requests a response by April 24, 2026.

- **March 11, 2026:** U.S. Senator Josh Hawley introduced legislation in the U.S. Senate that would ban mifepristone federally by withdrawing FDA's approval of the drug.
  - **What's at Stake:** If Congress were to withdraw FDA approval of mifepristone, it would affect abortion access throughout the country—mifepristone is commonly used in medication abortion, which now accounts for over two-thirds of abortions in the United States.
  - **Current Status:** The bill has been introduced in the U.S. Senate.
- **January 14, 2026**: The U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP) held a hearing examining the safety of medication abortion.
  - **What's at Stake:** Proponents of the HELP hearing have urged FDA to impose burdensome restrictions on mifepristone, including requiring that it be administered in person rather than through telehealth. If these restrictions were imposed, many people would be unable to access the medication, especially in areas that already lack reproductive health resources. The scientific evidence is clear and long-settled: studies over the past 25 years have shown that mifepristone is safe, including when administered via telehealth.
  - **Current Status:** FDA's review of mifepristone is ongoing.
- **December 9, 2025:** Bloomberg reported according to key sources that FDA has postponed reviewing the safety of mifepristone until after the 2026 midterm elections at FDA administrator Martin A. Makary's request.
  - **What's at Stake:** The reporting suggests FDA's review process is driven by political considerations rather than science. The public should have information on governmental action that could affect access to abortion.
  - **Current Status:** U.S. Health Secretary Robert F. Kennedy Jr. and Martin A. Makary stated in September 2025 that FDA review of the safety of mifepristone was ongoing. On December 10, 2025, Senator Josh Hawley sent a letter to Martin A. Makary seeking the prompt review of mifepristone in light of the reports that review will be delayed until after the 2026 midterms.
- **September 30, 2025:** FDA approved a new generic mifepristone by Evita Solutions, LLC. It may be used up to 70 days after the last menstrual period to terminate early pregnancy.

- **What's at Stake:** The approval may increase supply of and access to mifepristone in the country, despite a recent announcement by U.S. Health Secretary Robert F. Kennedy Jr. and FDA administrator Martin A. Makary that the agency is reviewing the safety of mifepristone.
- **Current Status:** Senator Josh Hawley wrote a letter to FDA commissioner Martin A. Makary expressing his concern about the recent mifepristone approval and asking for an explanation for the decision to approve the medication.

- **September 19, 2025:** U.S. Health Secretary Robert F. Kennedy Jr. and FDA administrator Martin A. Makary announced that FDA is conducting a review of mifepristone.
  - **What's at Stake:** If FDA were to impose restrictions on mifepristone's administration, many people may be unable to access the medication, especially in areas that already lack reproductive health resources.
  - **Current Status:** HHS and FDA issued a letter indicating that review of mifepristone is ongoing.
- **August 20, 2025:** Sixteen states and Washington D.C. ("Petitioner States") filed a Citizen Petition to join the "Multistate Citizen Petition" that California, Massachusetts, New York, and New Jersey filed in June 2025.
  - **What's at Stake:** This petition seeks to ensure access to mifepristone generally and increase access in the Petitioner States. In addition to joining the Multistate Citizen Petition (see June 5 filing detailed below), the Petitioner States request that FDA remove the Mifepristone REMS Program or choose not to enforce the Mifepristone REMS Program in the Petitioner States. The Petitioner States also submit additional evidence in support of this Petition that illustrates the importance of medication abortion in their states and the negative impact restrictions would have.
  - **Current Status:** FDA acknowledged receipt of the Petition on August 21, 2025. On February 10, FDA issued an interim response letter stating that given the complexity of the request, a decision had not yet been reached.
- **August 13, 2025:** The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) resubmitted a Citizen Petition requesting that FDA deny approval of mifepristone for miscarriage management and impose additional restrictions on mifepristone's administration through its REMS. AAPLOG previously submitted a similar Petition in January 2025, which was denied by FDA in June 2025.
  - **What's at Stake:** Currently, mifepristone is commonly prescribed off-label for miscarriage management. In all areas of medicine, "off-label" use of medications to reflect evolutions in evidence-based practice is permissible, common, and necessary to ensure that clinical care is not undermined by scientifically outdated labeling. Imposition of stricter restrictions than currently exist for mifepristone's use, including to treat miscarriages—as requested by this petition—would unnecessarily limit access and burden providers and patients.
  - **Current Status:** On January 16, 2026, FDA denied AAPLOG's Petition, stating that any decision on a potential pending application must follow the procedural requirements of FDA's approval process. FDA stated that the request to impose additional restrictions on mifepristone through its REMS raised "complex scientific and policy issues" that could not be resolved within the 150-day Citizen

Petition review timeframe, but FDA would consider the issues raised by the Petition when making determinations as part of its ongoing regulation of drugs containing mifepristone. FDA previously denied a similar Petition filed by AAPLOG in January 2025.

- **July 3, 2025:** GenBioPro filed a Citizen Petition to request that absent new peer-reviewed studies or robust scientific evidence, FDA take no action that would restrict patient access to mifepristone or increase the burdens associated with prescribing or dispensing mifepristone. Additionally, GenBioPro requested that any changes meet all rules and procedures afforded by law and regulation and that FDA permit GenBioPro to continue to distribute and ship mifepristone until such procedures have been completed.
    - **What's at Stake:** This petition seeks to ensure FDA does not act without adhering to its rules and procedures and only acts in reliance on robust scientific or clinical evidence. If FDA takes action to restrict, modify, or withdraw approval of mifepristone, in the absence of robust scientific or clinical evidence for doing so, it would create unnecessary burdens on patients who rely on the ability to access safe and effective medication through telehealth. Patients in rural or remote areas may be especially impacted, along with those who are unable to travel long distances to acquire the medication because of work or child care needs.
    - **Current Status:** FDA acknowledged receipt of the Petition on July 7, 2025. FDA must respond to the Petition within 180 days by granting or denying the request, or saying it needs more time to respond. On December 17, 2025, FDA issued an interim response letter stating that given the complexity of the request, a decision has not yet been reached.
- **June 5, 2025:** California, Massachusetts, New York, and New Jersey filed a Citizen Petition requesting FDA eliminate the current REMS for mifepristone or in the alternative, cease enforcing the restrictions as unnecessary.
    - **What's at Stake:** According to a representative of the states, in response to the filing of this petition, FDA will need to consider the ample scientific research of mifepristone's safety and effectiveness, including newer research, and it cannot change its current regulation of mifepristone while the petition is pending. In response to the Petition, FDA may decide to eliminate or leave intact current restrictions on mifepristone that impede access by limiting the health care professionals who can prescribe it and the pharmacies that can dispense it. FDA may also determine whether to continue to require the patient agreement form.
    - **Current Status:** FDA acknowledged receipt of the Petition on June 6, 2025. On August 20, 2025, Arizona, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, Oregon, Rhode Island, Vermont, Washington, the District of Columbia, and Josh Shapiro in his official capacity as Governor of the Commonwealth of Pennsylvania filed a petition to join the multistate Citizen Petition and submit additional evidence in support of it. On November 25, FDA issued an interim response letter stating that given the complexity of the request, a decision had not yet been reached.
- **May 14, 2025:** U.S. Health Secretary Robert F. Kennedy Jr. testified before the Senate Health, Education, Labor and Pensions Committee that he had ordered FDA administrator Martin A. Makary to conduct a "complete review" of mifepristone regulations. In response to a question from Senator Hawley, Kennedy agreed that FDA review of mifepristone is necessary in part because of a recent report on mifepristone released by anti-abortion activists that was not peer-reviewed or published in a medical journal. (Hearing on Fiscal Year 2026 Department of Health and Human Services Budget, May 14, 2025, 1:48:15-1:50:40) In contrast, more than one hundred scientific studies conducted over the last 30 years have conclusively proven mifepristone's safety.

- **What's at Stake:** If FDA were to impose additional restrictions on mifepristone, whether reimposing prior restrictions or creating new ones, it could decrease access throughout the country, including in states where abortion is legal.
- **Current Status:** Kennedy indicated FDA review of mifepristone is ongoing. (Hearing on Fiscal Year 2026 Department of Health and Human Services Budget, May 14, 2025, 1:48:15-1:50:40). The timeline and parameters of FDA's review of mifepristone are unclear. CRR and ACLU have filed lawsuits to enforce FDA's obligation under the Freedom of Information Act to produce information about its review of and communications related to mifepristone.

- **May 12, 2025:** An individual, James Brinkruff, filed a Citizen Petition requesting immediate suspension of the approval of mifepristone for medication abortion, an FDA study of mifepristone when used via telehealth, and imposition of requirements for in-person dispensing and a follow-up appointment.
  - **What's at Stake:** If FDA were to suspend approval of mifepristone for medication abortion, it would severely affect access to abortion throughout the country—medication abortion is currently used in nearly two-thirds of all abortions in the United States. Imposing additional restrictions on mifepristone would also decrease access throughout the country, including in states where abortion is legal.
  - **Current Status:** FDA acknowledged receipt of the Petition on May 14, 2025. FDA must respond to the Petition within 180 days by granting or denying the request, or saying it needs more time to respond. On November 7, 2025, FDA issued an interim response letter stating that given the complexity of the request, a decision had not yet been reached.
- **March 6, 2025:** Dr. Marty Makary (then-nominee, now head of the FDA), stated during his confirmation hearing that he would review whether FDA should re-impose an in-person dispensing requirement for mifepristone.
  - **What's at Stake:** FDA's imposition of an in-person dispensing requirement for mifepristone would significantly decrease access, particularly for rural and underserved communities, and those who can't travel or take time away from work.
  - **Current Status:** Kennedy has since indicated that FDA review of mifepristone is ongoing. (Hearing on Fiscal Year 2026 Department of Health and Human Services Budget, May 14, 2025, 1:48:15-1:50:40)
- **January 31, 2025:** The American College of Obstetricians and Gynecologists, Society of Family Planning, and Society for Maternal-Fetal Medicine submitted a Citizen Petition requesting FDA eliminate the current REMS for mifepristone or in the alternative refrain from taking any action that would further reduce patient access to mifepristone or increase the burdens associated with prescribing or dispensing mifepristone.
  - **What's at Stake:** FDA may decide to eliminate or leave intact current restrictions on mifepristone that impede access by limiting the health care professionals who can prescribe it and the pharmacies that can dispense it. FDA may also determine whether to continue to require the patient agreement form.

- **Current Status:** FDA acknowledged receipt of the Petition on February 4, 2025. FDA must respond to the Petition within 180 days by granting or denying the request, or saying it needs more time to respond. On July 28, 2025, FDA issued an interim response letter stating that given the complexity of the request, a decision had not yet been reached.

- **January 29, 2025:** Robert F. Kennedy Jr. (then-nominee, now Secretary of Health) stated during his confirmation hearing: "President Trump has asked me to study the safety of mifepristone. He has not yet taken a stand on how to regulate it. Whatever he does, I will implement those policies."
  - **What's at Stake:** If FDA were to impose additional restrictions on mifepristone, whether reimposing prior restrictions or creating new ones, it could decrease access throughout the country, including in states where abortion is legal.
  - **Current Status:** Kennedy has since indicated that FDA review of mifepristone is ongoing. (Hearing on Fiscal Year 2026 Department of Health and Human Services Budget, May 14, 2025, 1:48:15-1:50:40)

- **January 7, 2025:** American Association of Pro-Life Obstetricians and Gynecologists submitted a Citizen Petition noting that there had been news reports that mifepristone's manufacturer had planned to apply to add miscarriage management as an indication for mifepristone, and requesting that if FDA approve that indication it establish a REMS prohibiting telehealth, requiring an in-person follow-up appointment with an ultrasound, and requiring reporting of all adverse events. Students for Life of America also filed a Citizen Petition in December 2024, requesting that FDA refrain from modifying the approved usage of mifepristone to include miscarriage care.
  - **What's at Stake:** Currently, mifepristone is commonly prescribed off-label for miscarriage management. In all areas of medicine, "off-label" use of medications to reflect evolutions in evidence-based practice is permissible, common, and necessary to ensure that clinical care is not undermined by scientifically outdated labeling. Imposition of stricter restrictions than currently exist for mifepristone's use to treat miscarriages—as requested by this petition—would unnecessarily limit access and burden providers and patients.
  - **Current Status:** On June 4, 2025, FDA denied the Petition filed by American Association of Pro-Life Obstetricians and Gynecologists, stating that to the extent there is any pending application to add miscarriage management as an approved indication for mifepristone, FDA had not issued a final determination to approve it and consideration of the issues presented in the Petition outside FDA's approval process would be procedurally improper. Citing the same reasons, FDA denied the Petition filed by Students for Life of America on May 21, 2025.