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

The Mifepristone Litigation Tracker

To date, mifepristone litigation includes:

7 cases filed to protect or expand current access:

- **Three FDA Decisionmaking Cases** addressing whether current FDA regulations on mifepristone are overly burdensome and restrictive given mifepristone's safety and effectiveness
  - *Purcell et al. v. Kennedy et al.*
  - *Washington et al. v. U.S. Food and Drug Administration et al.*
  - *Whole Woman's Health Alliance et al. v. U.S. Food and Drug Administration et al.*

- **Two Federal Preemption Cases** addressing whether federal law preempts (supersedes) and invalidates additional state restrictions on mifepristone beyond FDA's regulations
  - *GenBioPro v. Raynes et al.*
  - *Bryant v. Moore*

- **One State Law Case** addressing whether additional state restrictions on mifepristone are invalid under state law
  - *Birthmark Doula Collective v. State of Louisiana*

- **One Due Process Case** seeking to prevent any enforcement of a court decision suspending FDA approval of mifepristone without due process
  - *GenBioPro v. U.S. Food and Drug Administration, et al.*

1 case filed to restrict current access:

- **One FDA Decisionmaking Case** challenging FDA's decisions removing prior restrictions on mifepristone, including the in-person dispensing requirement, and seeking to reimpose those restrictions
  - *Missouri et al. v. U.S. Food and Drug Administration et. al.*

The Mifepristone Litigation Tracker was last updated in July 2025.

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
GenBioPro v. Raynes et al., Case No. 23-2194	U.S. Court of Appeals for the Fourth Circuit (on appeal from U.S. District Court for the Southern District of West Virginia)	January 25, 2023 West Virginia	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 authorized only 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.	This case could affect access to mifepristone by deciding whether 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	On July 15, 2025, the U.S. Court of Appeals for the Fourth Circuit affirmed the decision below, leaving the state's abortion ban in effect. The court held that federal regulation of mifepristone under the Food and Drug Administration Amendments Act (FDAA) did not preempt the field of abortion regulation and did not create a conflict that made it impossible for plaintiff to comply with both the state law and federal law. It held that West Virginia's law prohibiting abortion is not preempted by or in conflict with federal regulation of abortion medication safety. It found that the FDA

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			GenBioPro appealed the decision to the U.S. Court of Appeals for the Fourth Circuit.		"has never been authorized to 'regulate the practice of medicine' or mandate that specific drugs be available." The court further noted that its decision does not mean "FDAA lacks any preemptive effect. States are certainly not free to dilute federal safety standards where they have been clearly established."
Bryant v. Moore, Case No. 24-1617	U.S. Court of Appeals for the Fourth Circuit (on appeal from U.S. District Court for the Middle District of North Carolina)	January 25, 2023 North Carolina	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.	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.	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) (see above).

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			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. Plaintiff, the defendant state Attorney General (who agrees with plaintiff that the state laws are preempted), and several legislative leaders (who have intervened as defendants in the case and argue that the state laws are not preempted) have all appealed the district court's judgment to the U.S. Court of Appeals for the Fourth Circuit.		
Purcell et al. v. Kennedy et al., Case No. 1:17-00493	U.S. District Court for the District of Hawaii	October 13, 2017 Hawaii	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	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	The case is currently pending in federal district court in Hawaii. In October 2024, plaintiffs filed a motion for summary judgment. In December 2024, defendants filed a cross-motion for summary judgment,

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			certification process—delay care, deter qualified providers and pharmacies from prescribing and dispensing mifepristone because of the burdens related to certification, and impede research and training on mifepristone at academic institutions. Plaintiffs assert claims under the equal protection guarantee of the Fifth Amendment and the Administrative Procedure Act, 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.	determine whether FDA may continue to require the patient agreement form, which plaintiffs assert presents privacy risks for patients and providers.	arguing that plaintiffs' claims should be dismissed on the merits, and that plaintiffs lack standing. Oral argument on the motions for summary judgment is scheduled for August 22, 2025.
Washington et al. v. U.S. Food and Drug Administration et al., Case No. 1:23-cv-03026	U.S. District Court for the Eastern District of Washington	February 23, 2023 Washington	17 states and Washington, D.C. (the States) challenge FDA's mifepristone REMS as unduly burdensome and arbitrarily restrictive given mifepristone's safety and effectiveness. The States 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—are unnecessary barriers that make it more difficult to access care. The States argue that FDA violated the Administrative Procedure Act by imposing the REMS against evidence showing the restrictions are unnecessary, and violated the equal protection guarantee of the Fifth Amendment by treating	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 the States	On July 8, 2025, the court issued a decision in which it granted defendant's cross-motion for summary judgment and dismissed the case. Based on the record before it, the court found that the FDA's review and decision regarding the mifepristone REMS was reasonable, not arbitrary or capricious, and did not ignore any

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			providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than those who prescribe, dispense, or use other medications.	assert presents privacy risks for patients and providers.	laws or regulations. The decision did not reach plaintiffs' equal protection claim. Plaintiffs have 30 days from the entry of the order to appeal.
GenBioPro v. U.S. Food and Drug Administration et al., Case No. 8:23-cv-01057	U.S. District Court for Maryland	April 19, 2023 Maryland	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 Administrative Procedure Act, the All Writs Act, and the due process guarantee of the Fifth Amendment. GenBioPro asserts that any enforcement action characterizing its mifepristone as misbranded and without an effective drug approval based on federal court rulings that did not provide a constitutionally adequate procedure for suspending drug approval would be unlawful.	The case could affect access to mifepristone by determining whether court decisions may suspend its approval.	This case was stayed while the Supreme Court resolved *Alliance for Hippocratic Medicine v. FDA*, and remains stayed until August 15, 2025, awaiting the Texas federal district court's decision on pending motions to dismiss *Missouri v. FDA*, Case No. 2:22-cv-00223.

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Whole Woman's Health Alliance et al. v. U.S. Food and Drug Administration et al., Case No. 3:23-cv-00019	U.S. District Court for the Western District of Virginia	May 8, 2023 Virginia	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 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—are unnecessary barriers that make it more difficult to access care. Plaintiffs argue that FDA violated the Administrative Procedure Act 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.	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.	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. The court has not yet issued a decision.

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Missouri et al. v. U.S. Food and Drug Administration et al., Case No. 2:22-cv-00223	U.S. District Court for the Northern District of Texas	November 18, 2022 Texas	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 U.S. 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 Administrative Procedure Act. 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.	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.	Defendants have moved to dismiss this case, arguing that it should be dismissed or transferred because the States have no connection to the Texas district in which they filed their complaint. Defendants additionally argue that the case should be dismissed because the States haven't demonstrated they suffered any injury as a result of FDA's decisions, failed to first raise their claims through FDA's review process, and some of the claims are barred by the statute of limitations. The parties have completed briefing on defendants' motion to dismiss. Next, Judge

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					Kacsmaryk, who previously ruled in favor of the anti-abortion doctors and activists in *AHM v. FDA*, will decide whether to dismiss the case.
Birthmark Doula Collective v. State of Louisiana, Case No. C-7552171	Louisiana State Trial Court (19th Judicial District Court)	October 31, 2024 Louisiana	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.	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.	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 that plaintiffs' challenge can proceed.

The Mifepristone Federal Action Tracker

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

Date	Summary of Action	What's at Stake	Current Status
June 5, 2025	California, Massachusetts, New York, and New Jersey file a Citizen Petition requesting FDA eliminate the current REMS for mifepristone or in the alternative, cease enforcing the restrictions as unnecessary.	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.	FDA acknowledged receipt of the petition on June 6, 2025. FDA must respond to the petition within 180 days by granting or denying the request, or saying it needs more time to respond.
May 14, 2025	U.S. Health Secretary Robert F. Kennedy Jr. testifies before the Senate Health, Education, Labor and Pensions Committee that he has 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	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.	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)

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	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.		
May 12, 2025	An individual, James Brinkruff, files 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.	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.	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.
March 6, 2025	Dr. Marty Makary (then-nominee, now head of the FDA), states during his confirmation hearing that he would review whether FDA should re-impose an in-person dispensing requirement for mifepristone.	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.	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	FDA may decide to eliminate or leave intact current restrictions on mifepristone that impede access by limiting the health care professionals	FDA acknowledged receipt of the petition on February 4, 2025. FDA must respond to the petition

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	submit 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.	who can prescribe it and the pharmacies that can dispense it. FDA may also determine whether to continue to require the patient agreement form.	within 180 days by granting or denying the request, or saying it needs more time to respond.
January 29, 2025	Robert F. Kennedy Jr. (then-nominee, now Secretary of Health) states 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."	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.	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 submit 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 had also filed a Citizen Petition in December 2024, requesting that FDA refrain from modifying	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.	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.

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	the approved usage of mifepristone to include miscarriage care.		Citing the same reasons, FDA denied the petition filed by Students for Life of America on May 21, 2025.