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:

9 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.* (Final judgment entered—case closed)
  - *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.* (Final judgment entered—case closed)
  - *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.* (Voluntarily dismissed—case closed)

- 2 Public Records Cases seeking access to information on FDA's review of mifepristone
  - *The Center for Reproductive Rights v. U.S. Department of Health and Human Services, et al.*
  - *American Civil Liberties Union v. U.S. Food and Drug Administration*

3 cases filed to restrict current access:

- **Three FDA Decisionmaking Cases** 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.*
  - *Louisiana et al. v. U.S. Food and Drug Administration et al*.
  - *Florida et al. v. U.S. Food and Drug Administration et al.*

The Mifepristone Litigation Tracker was last updated in December 2025.

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
Florida et al. v. U.S. Food and Drug Administration et al., Case No. 7:25-cv-00126	U.S. District Court for the Northern District of Texas	December 9, 2025 Texas	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 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.	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	The case is currently pending in the U.S. District Court.

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				mifepristone's administration via telehealth) and limitations on which health care providers can prescribe mifepristone.	
The Center for Reproductive Rights v. U.S. Department of Health and Human Services, et al., Case No. 25-03023	U.S. District Court for the District of Columbia	September 5, 2025 Washington, D.C.	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 decision-making. 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.	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	The case is currently pending in U.S. District Court. FDA and HHS have not yet answered CRR's complaint.

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				and effective, but has been largely debunked by the medical community for its flawed information and lack of peer review. Both FDA and HHS have said FDA is currently reviewing mifepristone, without providing any transparency to the public on what that review entails. medical community for its flawed information and lack of peer review.	
American Civil Liberties Union v. U.S. Food and Drug Administration, Case No. 25-03736	U.S. District Court for the District of Maryland	November 13, 2025 Maryland	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.	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	The case is currently pending in U.S. District Court. FDA has not yet answered ACLU's complaint.

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				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.	
Louisiana et al. v. U.S. Food and Drug Administration et al., Case No. 6:25-cv-01491	U.S. District Court for the Western District of Louisiana	October 6, 2025 Louisiana	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 the FDA's 2023 Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, which removed the requirement of in-person dispensation for mifepristone, is unlawful under the Administrative Procedure Act 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	This case could impact the ability to access mifepristone via telehealth by requiring the reinstatement of in-person dispensing only. This would drastically impact access to medication abortion nationwide, as nearly one in four of all abortions are	The case is currently pending in the U.S. District Court. On December 1, 2025, the court granted the defendant's motion for extension of time to respond to complaint. The deadline to respond is now January 12, 2026.

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
			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.	accessed via telehealth.	
GenBioPro v. Raynes et al., Case No. 23-2194 (Final judgment entered—case closed.)	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	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.	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. The court held that West

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			GenBioPro's claims regarding the counseling and waiting period requirements since they are not currently in effect. GenBioPro appealed the decision to the U.S. Court of Appeals for the Fourth Circuit.		Virginia's law prohibiting abortion is not preempted by or in conflict with federal regulation of abortion medication safety. It reasoned that FDA "has never been authorized to 'regulate the practice of medicine' or mandate that specific drugs be available." The court further noted, however, that its decision does not mean "FDA lacks any preemptive effect. States are certainly not free to dilute federal safety standards where they have been clearly established." Final judgment was entered—this case is now closed.

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
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. 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	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). Although *GenBioPro, Inc. v. Raynes* is now closed (see above), this case currently remains pending.

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
			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 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.	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.	On October 30, 2025, the court granted plaintiffs' motion for summary judgement and denied defendant's cross-motion. The court ruled that the FDA acted arbitrarily and capriciously in violation of the Administrative Procedure Act because it failed to consider relevant evidence and failed to provide adequate reasoning as to why it was restricting mifepristone access. The matter was remanded to the Agency to reassess the REMS in accordance with the court's order and the law.

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
					On December 6, 2025, the court dismissed plaintiff's equal protection claims without prejudice. Plaintiff's brief is now due December 19, 2025, and defendant's reply is due January 5, 2025.
Washington et al. v. U.S. Food and Drug Administration et al., Case No. 1:23-cv-03026 (Final judgment entered—case closed.)	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 providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than those who prescribe, dispense, or use other medications.	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. FDA may continue to require the patient agreement form, which the States assert presents privacy risks for patients and providers.	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.

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
					Final judgment was entered—this case is now closed.
GenBioPro v. U.S. Food and Drug Administration et al., Case No. 8:23-cv-01057 (Voluntarily dismissed—case closed.)	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 have affected access to mifepristone by determining whether court decisions may suspend its approval.	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 of the case without prejudice. The court dismissed the case without prejudice on November 17, 2025.
Whole Woman's Health Alliance et al.	U.S. District Court for the Western	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	The case could affect access by eliminating or leaving intact current restrictions on	The case is currently pending in federal district court in Virginia.

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
v. U.S. Food and Drug Administration et al., Case No. 3:23-cv-00019	District of Virginia		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.	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.	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.
Missouri et al. v. U.S. Food and Drug	U.S. District Court for the Eastern	November 18, 2022	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	This case could affect access to mifepristone by	On August 22, 2025, Texas and Florida moved to intervene

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Administration et al., Case No. 4:25-cv-01580	District of Missouri (transferred from U.S. District Court for the Northern District of Texas)	Texas	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.	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.	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.
Birthmark Doula Collective v.	Louisiana State Trial Court (19th	October 31, 2024	Plaintiffs—birth workers and other medical professionals, advocates, and a pregnant person—challenge a Louisiana law classifying mifepristone	This case could impact emergency care for pregnant	The case is currently pending in Louisiana trial court. On May 15,

Case	Court	Date and Location Filed	Summary of Challenge	What's at Stake	Current Status
State of Louisiana, Case No. C-7552171	Judicial District Court)	Louisiana	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.	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.	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.

The Mifepristone Federal Action Tracker

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

Date	Summary of Action	What's at Stake	Current Status
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.	The reporting suggests FDA's process lacks transparency and is driven by politics rather than science. The public should have information on governmental action that could affect access to abortion.	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.	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.	Senator Josh Hawley wrote a letter to FDA commissioner Martin A. Makary expressing his concern for 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 the FDA is conducting a review of mifepristone.	If FDA were to change or roll back mifepristone approval, many individuals may be unable to access the drug or find it even more challenging to access, especially in areas that already have a dearth in access to reproductive health resources.	The letter indicated 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.	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 5th 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	FDA acknowledged receipt of the petition on August 21, 2025. FDA must respond to the petition within 180 days by granting or denying the request, or saying it needs more time to respond.

Date	Summary of Action	What's at Stake	Current Status
		additional evidence in support of this Petition that illustrates the importance of medication abortion in their states and the negative impact restrictions would have.	
August 13, 2025	The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) resubmits a Citizen Petition that was previously denied to request that the FDA deny approval of mifepristone for miscarriage management. AAPLOG previously submitted a similar Petition in January 2025, which was denied by FDA in June 2025.	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.	FDA acknowledged receipt of the petition on August 21, 2025. FDA must respond to the petition within 180 days by granting or denying the request, or saying it needs more time to respond.
July 3, 2025	GenBioPro files 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 requests that any change meet all rules and procedures afforded by law and regulation and that FDA will permit GenBioPro to continue to distribute and ship mifepristone until such procedures have been completed.	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.	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.
June 5, 2025	California, Massachusetts, New York, and New Jersey file a Citizen Petition requesting	According to a representative of the states, in response to the filing of this petition, FDA will	FDA acknowledged receipt of the petition on June 6, 2025. FDA must

Date	Summary of Action	What's at Stake	Current Status
	FDA eliminate the current REMS for mifepristone or in the alternative, cease enforcing the restrictions as unnecessary.	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.	respond to the petition within 180 days by granting or denying the request, or saying it needs more time to respond. 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. 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 a recent report on mifepristone released by	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). 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

Date	Summary of Action	What's at Stake	Current Status
	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.		Freedom of Information Act to produce information about its review of and communications related to mifepristone.
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. 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), 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 submit a Citizen Petition requesting FDA eliminate the current REMS for mifepristone	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	FDA acknowledged receipt of the petition on February 4, 2025. FDA must respond to the petition within 180 days by granting or denying the

Date	Summary of Action	What's at Stake	Current Status
	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.	dispense it. FDA may also determine whether to continue to require the patient agreement form.	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) 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 the approved usage of mifepristone to include miscarriage care.	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. Citing the same reasons, FDA denied the petition filed by Students for Life of America on May 21, 2025.