UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*, Plaintiffs, v. FOOD AND DRUG ADMIN., *et al.*, Defendants.	Case No. 3:23-cv-00019-RSB

MOTION TO STAY PROCEEDINGS

Protecting the health and safety of pregnant women is of paramount importance. To that end, on September 19, 2025, the Secretary of Health and Human Services and the Commissioner of Food and Drugs announced that FDA is reviewing the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone. Ex. 1 (Letter to State Attorneys General (Sept. 19, 2025)). The Secretary and the Commissioner explained that this review—which will include a study undertaken by FDA itself—is "informed by the lack of adequate consideration underlying prior REMS approvals." *Id.* at 1. FDA's review is rooted in the agency's commitment "to protecting the health and safety of pregnant women" and "ensur[ing] . . . decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence." *Id.* at 2. Because this ongoing review

will culminate in a decision that may moot Plaintiffs' lawsuit, Defendants respectfully move this Court for a stay of litigation while the administrative review occurs.[1]

"[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). In exercising its "broad discretion to stay proceedings," *Clinton v. Jones*, 520 U.S. 681, 706 (1997), a court "must weigh competing interests and maintain an even balance," *Landis*, 299 U.S. at 254-55. "The grant or denial of a request to stay proceedings calls for an exercise of the district court's judgment 'to balance the various factors relevant to expeditious and comprehensive disposition of the causes of the action on the court's docket.'" *Maryland v. Universal Elections, Inc.*, 729 F.3d 370, 375 (4th Cir. 2013) (quoting *United States v. Ga. Pac. Corp.*, 562 F.2d 294, 296 (4th Cir. 1977)). Here, that balance favors a stay.

In deciding to launch a new review of the mifepristone REMS, FDA recognized that restrictions on mifepristone are hotly contested legal and scientific issues that have been the subject of litigation for many years. One district court has upheld FDA's 2023 approval of supplemental applications modifying the REMS (the "2023 REMS Modification"). *Washington v. FDA*, No. 1:23-cv-3026-TOR, 2025 WL 1888794 (E.D.

[1] Plaintiffs currently oppose a stay but have stated that they may reconsider if stays are issued in other cases with mifepristone-related challenges. FDA has moved for a stay in *Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA, ECF No. 50, 50-1 (W.D. La.), *Missouri v. FDA*, No. 4:25-cv-1580-CMS, ECF No. 293 (E.D. Mo.), and *Florida v. FDA*, No. 7:25-cv-126-O, ECF No. 20 (N.D. Tex.).

Wash. July 8, 2025). Another ruled that the 2023 REMS Modification was arbitrary and capricious because it failed to consider relevant evidence and applied the incorrect statutory standard; that court issued a remand to FDA for reconsideration of the REMS. *Purcell v. Kennedy*, Civ. No. 17-00493-JAO-RT, 2025 WL 3101785, at *28 (D. Haw. Oct. 30, 2025). The Fifth Circuit expressed concerns about FDA's easing of REMS restrictions. *See All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 249-51 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367 (2024). And three other district courts have yet to weigh in. *See Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA, (W.D. La.); *Missouri v. FDA*, No. 4:25-cv-1580-CMS (E.D. Mo.); *Florida v. FDA*, No. 7:25-cv-126-O (N.D. Tex).

Given this widespread debate over the safety of mifepristone, FDA has concluded that the best path forward is to conduct a new review of the mifepristone REMS based on all the evidence before the agency. As noted above, that evidence will include FDA's own study, which it "is taking care to do . . . properly and in the right way." FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*.[2] At this time, "FDA continues to work on the collection of the robust and timely data that is necessary for a well-controlled study with adequate statistical power." *Id.* Although studies like these "often take approximately a year or more to conduct," FDA plans to complete the study "sooner than that timeframe." *Id.* And once FDA has analyzed the data from that study (as well as all other evidence

[2] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (item No. 37).

before the agency), it will decide whether "substantive changes to the REMS" are warranted. *Id.*

While the review occurs, the Court should exercise its inherent power to stay this litigation. "[U]nder [the] regulatory scheme," the scientific issues Plaintiffs raise here "have been placed within the special competence of" FDA. *United States v. W. Pac. R. Co.*, 352 U.S. 59, 64 (1956). It thus makes good sense for the Court to let FDA apply its "expert and specialized knowledge," *id.*, including by considering matters—such as the Canadian study—that Plaintiffs failed to exhaust, ECF No. 71-1, at 15-18. The interests of judicial efficiency also support a stay because FDA's review will necessarily result in a new decision that could supersede the 2023 REMS Modification and thereby obviate any need to adjudicate Plaintiffs' current arguments. Any party adversely affected by the new agency decision on mifepristone may seek judicial review at that time.

On the other side of the ledger, deferring judicial review until FDA's review is complete will not prejudice Plaintiffs. In oral argument on the cross motions for summary judgment, Plaintiffs clarified that they seek only a remand without vacatur. Ex. 2, 5/19/2025 Tr. at 23. But the judgment in *Purcell* already ensures that FDA will do precisely that as part of its ongoing review. Given that FDA is undertaking the very review Plaintiffs ask this Court to order, there is no reason for this Court to reach the issues in this case at this time.

Granting a stay while an agency reviews the matter under litigation is par for the course. *Purcell* is a case in point. There, the plaintiffs originally challenged the REMS that existed before the 2023 REMS Modification. After FDA announced a REMS review

in May 2021, the *Purcell* court stayed the litigation. *See Chelius v. Becerra*, No. 1:17-cv-493-JAO-RT, ECF No. 149 (D. Haw. May 7, 2021) (staying and administratively closing case).[3] The case remained stayed until after the 2023 REMS Modification. *Id.*, ECF No. 158 (D. Haw. Feb. 28, 2023) (reopening case). The Court should take a similar course here to allow FDA to complete its review of the mifepristone REMS.

CONCLUSION

For the foregoing reasons, the Court should stay this case until FDA completes its ongoing review of the mifepristone REMS.

March 23, 2026

Respectfully submitted,

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[3] *Chelius* was later renamed *Purcell v. Kennedy*.

EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

September 19, 2025

Dear Attorneys General:

Thank you for your letter of July 31, 2025, regarding the review of mifepristone by the Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services (HHS). We write to provide an update on this review.

As you noted, the FDA first approved Mifeprex (mifepristone) in September 2000 for medical termination of pregnancy (abortion) through seven weeks gestation. In 2016, the FDA extended this window to ten weeks gestation, and relaxed certain other requirements under the drug's Risk Evaluation and Mitigation Strategy (REMS). Most recently, in 2023, the FDA modified the REMS program again by removing the in-person dispensing requirement.

Since its original approval, the FDA has received reports of serious adverse events in patients who took mifepristone. As with all approved drugs, when the FDA receives new information regarding adverse events, the agency reviews the new information and, as appropriate, takes necessary action. The FDA continuously reviews reports of adverse events to determine, among other things, whether they are known risks or whether they are signals of emerging safety concerns.

Under the Food and Drug Administration Amendments Act, the Secretary is authorized to require a REMS when "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a). For drugs that are "inherent[ly] toxic[] or potential[ly] harmful[]," the Secretary "may require that the [REMS] include such elements as are necessary to assure safe use of the drug." *Id.* § 355-1(f)(1). The Secretary is also authorized to require modifications to an existing REMS when he, among other things, "determines that 1 or more goals or elements should be added, modified, or removed from the [current REMS] to … ensure the benefits of the drug outweigh the risks of the drug." *Id.* § 355-1(g)(4)(B).

HHS is committed to studying the adverse consequences reported in relation to mifepristone to ensure the REMS are sufficient to protect women from unstated risks. Therefore, through the FDA, HHS will conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary. HHS's decision to do so is informed by the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered.

To that end, HHS—through the FDA—is conducting its own review of the evidence, including real-world outcomes and evidence, relating to the safety and efficacy of the drug. Given the 2016 FDA decision to eliminate the REMS requirement for certified prescribers to report non-fatal serious adverse events to the mifepristone sponsors, this review will contribute to the understanding of the drug's safety profile.

Recent studies—such as the study by the Ethics and Public Policy Center (EPPC), which you highlighted in your letter—indicate potential dangers that may attend offering mifepristone without sufficient medical support or supervision. FDA's own data collected between 2000 to 2012 indicated 2,740 adverse events, including 416 events involving blood loss requiring transfusions. Since then, safeguards for women regarding the administration of mifepristone have been significantly reduced.

The concerns you have raised in your letter merit close examination. This Administration will ensure that women's health is properly protected by thoroughly investigating the circumstances under which mifepristone can be safely dispensed.

* * *

HHS and FDA remain committed to protecting the health and safety of pregnant women. This review will help ensure that the FDA's decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence.

Thank you again for your continued engagement in this matter. We will keep you informed as the FDA's review of mifepristone progresses.

Sincerely,

/s/

Robert F. Kennedy, Jr.
Secretary

/s/

Martin A. Makary, MD, MPH
Commissioner of Food and Drugs

Exhibit 2

make sure I understand how I get there procedurally, if I agree with you. I know that the government or the FDA, if I agree with you, wants to brief remedies later. I want to understand now what the net effect would be, if I agree with you, where does that leave this drug. If I issue an opinion tomorrow that says the plaintiffs are right, and the FDA failed in its obligation with issue to these REMS, for whatever reason, what are you asking me to do? What's the next sentence that goes in that opinion? What are you asking the Court to do?

MS. GOLDSTEIN: What we're asking the Court to do at this point, Your Honor, is to issue a declaration that spells out what the FDA's obligations are in considering any modification to the REMS, and remanding the case back to FDA to reperform the 2023 review in adherence to those statutory requirements.

THE COURT: Would the REMS stay in place under what the plaintiffs are asking me to do during that process?

MS. GOLDSTEIN: Yes, Your Honor. We have tried to identify any situation where this court -- where there was precedent for vacating the REMS in their entirety during a review, and we have been unable to identify any precedents. You know, it would not be a prohibitory injunction. It would be a mandatory injunction because there's never been a case where mifepristone was available in the United States without

some form of restriction.

THE COURT: For whatever it's worth category, I agree, because I think that would then require the Court to make it some type of a determination on the record that I think is an agency determination with respect to the issues of approval of a drug without a REMS strategy.

MS. GOLDSTEIN: To be clear, Your Honor, we fully expect we're going to be back here before you after any agency review. This is particularly clear not just because of the administrative record which is before you, but also because of the political climate, withdrawing approval of mifepristone. We're at a minimum restoring the in-person dispensing requirement. Those were both parts of Project 2025 which has been a blueprint for the current administration. The secretary of Health and Human Services, Robert F. Kennedy, Jr., appeared before the Senate Health Committee just last week, last Wednesday, and said that he had asked Commissioner Makary to do a complete review of mifepristone. That wasn't so that the remaining ETASU could be removed. So that's why we think it's particularly important, Your Honor, to issue an opinion that tells the FDA in no uncertain terms you have never complied with the 355-1(a) requirements. Any REMS that you issue are going to have to make a determination based upon four statutory factors and only those statutory factors because those are