IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

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

PLAINTIFFS' MEMORANDUM IN SUPPORT OF
RETAINING JURISDICTION PENDING REMAND TO FDA

On July 23, 2026, this Court granted Plaintiffs summary judgment on Count II of their Complaint, holding that FDA's decision to impose a REMS and ETASU on mifepristone in 2023 was arbitrary and capricious. ECF No. 95. The Court summarized FDA's shortcomings as follows:

> The explanation for the REMS and ETASUs imposed by the FDA in 2023 does not identify the risk alleviated by the restrictions. Nor does the FDA explain how, without these restrictions, prescribing the drug becomes an intolerable risk which would require withdrawal of the drug from the market. The FDA failed to reasonably justify its 2023 REMS modification decision, disregarding substantial contrary evidence from the medical community and comparative regulatory data, and inadequately addressing the burdens imposed on providers and patients."

Id. at 47. On September 2, 2026, this Court issued its order remanding the 2023 REMS "to the FDA for reconsideration consistent with the Court's July 23, 2026, Memorandum Opinion and the law, including the statutory factors set forth in 21 U.S.C. §355-1(a)(1), (f)(1)–(2), and (g)(b)(4)." ECF No. 100 at 1.

Plaintiffs believe there is a grave risk that, on remand, FDA will ignore the statutory factors that this Court has directed it to consider. Even before this Court's remand, FDA had started to conduct a review of the mifepristone REMS. That review was instigated and driven by ideologically-driven politicians and lawmakers from states that have banned abortion who disagree

with a different aspect of FDA's 2023 REMS decision: its formal elimination of the in-person dispensing requirement. The political pressure on FDA to make the mifepristone REMS *more* onerous is considerable:

Date	Event
April 28, 2025	Senator Josh Hawley (R. Mo.) sends a letter to then-FDA Commissioner Martin Makary urging him to "revisit and restore the FDA's longstanding safety measures regarding mifepristone."[1]
June 2, 2025	Then-FDA Commissioner Martin Makary responds to Senator Hawley, saying that he is "committed to conducting a review of mifepristone and working with the professional career scientists at the Agency who review this data."[2]
July 31, 2025	Kansas Attorney General Kris Kobach and at least 20 other Republican attorneys general send a letter to Health and Human Services ("HHS") Secretary Robert F. Kennedy, Jr. and then-FDA Commissioner Makary calling for FDA to "consider reinstating safety protocols" from the 2011 REMS or, alternatively, to withdraw mifepristone from the market.[3]
Sept. 19, 2025	HHS Secretary Kennedy and then-FDA Commissioner Makary respond to the Republican attorneys general, informing them that "through the FDA, HHS will conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary."[4]

[1] Letter from Sen. Josh Hawley to Comm'r Martin Makary (Apr. 28, 2025) (https://www.hawley.senate.gov/wp-content/uploads/2025/04/2025-04-28-Hawley-FDA-Letter-to-Makary.pdf).

[2] Image posted by Sen. Josh Hawley (@HawleyMO), X, *Letter from Comm'r Makary* (Jun. 2, 2025), https://x.com/HawleyMO/status/1929696353010987013.

[3] Landon Mion, *More than 20 GOP attorneys general call on RFK Jr, FDA to reinstate safeguards for abortion drugs*, Fox News (Aug. 13, 2025), https://www.foxnews.com/politics/more-than-20-gop-attorneys-general-call-rfk-jr-fda-reinstate-safeguards-abortion-drugs.

[4] ECF No. 92-1 at 1.

Date	Event
Dec. 10, 2025	Senator Hawley sends another letter to then-FDA Commissioner Makary demanding a "specific timeline" for completion of FDA's mifepristone review.[5]
May 12, 2026	Makary resigns as Commissioner of FDA. The press reports that one factor contributing to his "rocky tenure" at FDA was anti-abortion groups' accusation that he was "slow-walking" the mifepristone review.[6] The press also reports that "[w]ithin hours of his appointment," Acting FDA Commissioner Kyle Diamantas reached out to "several anti-abortion leaders" to assure them that "he is morally opposed to the procedure."[7]
Aug. 19, 2026	President Trump nominates Heidi Overton to succeed Makary as FDA Commissioner. While working at the America First Policy Institute, Dr. Overton co-authored a paper on "Risking Two Lives: The Dangerous Rise of Chemical Abortion," in which she opined that mifepristone posed "a serious threat to women's health."[8]
Aug. 27, 2026	The Senate Committee on Health, Education, Labor & Pensions issues a report titled "Mifepristone Without Guardrails: An Investigation Into How Chemical Abortion Drug Makers Are Putting Mothers and Babies At Risk" (the "Senate HELP Report").[9] The Senate HELP Report

[5] Letter from Sen. Josh Hawley to Comm'r Martin Makary (Dec. 10 2025) at 2 (https://www.hawley.senate.gov/wp-content/uploads/2025/12/Hawley-Letter-to-Makary-12.10.25.pdf).

[6] Matthew Perrone and Seung Min Kim, *Marty Makary resigns as Trump's FDA chief*, PBS News (May 12, 2026), https://www.pbs.org/newshour/health/ap-report-marty-makary-resigning-as-trumps-fda-chief.

[7] Alice Miranda Ollstein and David Lim, *Acting FDA leader tries to explain past Planned Parenthood work to abortion opponents*, Politico (May 15, 2026), https://www.politico.com/news/2026/05/15/new-fda-leader-rushes-to-reassure-anti-abortion-leaders-they-still-have-questions-00923657.

[8] Matias Perttula and Heidi Overton, *Issue Brief - Risking Two lives—The Dangerous Rise of Chemical Abortion*, America First Policy Institute (Feb. 27, 2023), https://www.americafirstpolicy.com/issues/issue-brief-risking-two-livesthe-dangerous-rise-of-chemical-abortion.

[9] Staff of S. Comm. On Health, Education, Labor & Pensions, 119th Cong., "Mifepristone Without Guardrails: An Investigation Into How Chemical Abortion Drug Makers Are Putting Mothers and Babies at Risk" (Aug. 2026), https://www.help.senate.gov/imo/media/doc/mifepristone_report_finalpdf.pdf.

Date	Event
	concludes that ""FDA should step in to institute more stringent REMS requirements that provide sufficient guardrails to discourage inappropriate use of products approved with ETASU."[10]

Notably, unlike this Court's order, ECF No. 100 at 1, neither the Senate HELP Report nor the missives from Senator Hawley to FDA mention the statutory standards that cabin FDA's authority to issue a REMS or ETASU—exacerbating the risk that FDA will continue to ignore them.

The pressure campaign on FDA extends beyond Congress all the way to the White House. Last month, Attorney General Blanche reassured a group of faith leaders that the Department of Justice was "working hand-in-hand with HHS and the FDA and the White House and President Trump's team to get permanent solutions so that the *Dobbs* decision becomes permanent in every single state."[11]

This Court has the authority to retain jurisdiction over this case pending the completion of FDA's review. "[F]ederal courts regularly retain jurisdiction until a federal agency has complied with its legal obligations, and have the authority to compel regular progress reports in the meantime." *Cobell v. Norton*, 240 F.3d 1081, 1109 (D.C. Cir. 2001) (retaining jurisdiction in light of "record of agency recalcitrance and resistance to the fulfillment of its legal duties"); *Texas Association of Manufacturers v. United States Consumer Product Safety Commission*, 989 F.3d 368, 372 (5th Cir. 2021) (retaining jurisdiction where agency had "procedurally erred" by promulgating a rule without allowing for notice-and-comment); *Alvarez Lagos v. Barr*, 927 F.3d

[10] *Id*. at 36.

[11] Audio recording posted by Jessica Valenti, Substack, *No, Todd Blanche Didn't Promise a National Abortion Ban—But He Did Vow Something Else* (Aug. 5, 2026), https://jessica.substack.com/p/todd-blanche-abortion-ban?utm_source=substack&utm_medium=email; *see also* Kelcie Moseley-Morris, *AG nominee tells faith leaders he will take action to restrict abortion drug access*, Stateline (Aug. 4, 2026), https://stateline.org/2026/08/04/ag-nominee-tells-faith-leaders-he-will-take-action-to-restrict-abortion-drug-access.

236 (4th Cir. 2019) (retaining jurisdiction where claims had already been the subject of three agency decisions); *American Academy of Pediatrics v. Food and Drug Administration*, 399 F. Supp. 3d 479, 487 (D. Md. 2019) (retaining jurisdiction after remand to FDA to ensure that "if the need arises, further action could be taken by the Court."). Given the very real possibility of political interference with the reconsideration of the 2023 REMS that this Court has mandated FDA to conduct, Plaintiffs respectfully request that this Court retain jurisdiction in the event FDA fails to adhere to this Court's instructions or otherwise violates the Administrative Procedure Act on remand.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court retain jurisdiction while the 2023 REMS Decision is on remand to the FDA.

Dated: September 18, 2026

Respectfully submitted,

/s/ Linda C. Goldstein
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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of September, 2026, I filed the foregoing document with the Clerk of Court using the CM/ECF system.

/s/ Linda C. Goldstein
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