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 OPPOSITION TO DEFENDANTS' MOTION TO STAY

Plaintiffs filed this suit nearly three years ago seeking relief against the Food and Drug Administration's ("FDA") 2023 decision imposing burdensome and unjustified restrictions on the prescribing and dispensing of mifepristone (the "2023 REMS Decision"). Now, over ten months after cross-motions for summary judgment were argued, and six months after FDA announced it would be reviewing its 2023 REMS Decision, the Government asks this Court to stay the case pending the outcome of that open-ended review process. As described below, granting a stay would be both inefficient and prejudicial to Plaintiffs, particularly if other litigations challenging the 2023 REMS Decision remain active. On the other hand, the Government faces no prejudice from allowing this case to continue. For these reasons, Plaintiffs oppose a stay.

BACKGROUND

On May 8, 2023, Plaintiffs filed this suit, challenging certain requirements for prescribing and dispensing mifepristone in the 2023 REMS Decision as violative of the Administrative Procedures Act ("APA"). As this Court is aware, these claims have been extensively briefed and argued in this case, first at the preliminary injunction stage and, following a roughly five-month stay pending the Supreme Court's decision in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S.

367 (2024) ("*Alliance*"), in cross-motions for summary judgment. This Court heard argument on the latter motions on May 19, 2025.

Four months later, on September 19, 2025, the FDA and U.S. Department of Health and Human Services issued a letter stating that FDA would conduct a review to determine whether modifications to the 2023 REMS Decision are necessary. *See* Ex. 1 to Defs.' Mot. to Stay Proceedings, ECF No. 92-1. At the time, cross-motions for summary judgment were pending not only in this case, but also in another challenge to the 2023 REMS Decision, *see Purcell v. Kennedy*, No. CV 17-00493 (D. Haw. 2017). Yet FDA did not then seek a stay of either litigation. In late October 2025, the *Purcell* court issued its decision "declar[ing] the 2023 REMS Decision unlawful under the APA and remand[ing] the matter to the Agency to reconsider the mifepristone REMS[.]" *Purcell*, 2025 WL 3101785, at *28 (D. Haw. Oct. 30, 2025). At no time prior to this motion did the Government seek a stay of this case based on its announced or court-ordered review of the mifepristone REMS.

In early 2026, FDA updated its website with information about the timing of its "saftey [sic] study on mifepristone." FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, Ques. 37 (rev. Feb. 2, 2026).[1] FDA stated that "studies like these . . . often take approximately a year or more to conduct," but "[t]he current agency plan is to have this study done sooner than that timeframe." *Id.* Defense counsel has since clarified that FDA's representation speaks only to the timing of "the study that it's doing, which is part of the [mifepristone] review – it's not the whole review" and that the Government "do[es]n't have a timeframe to put on" the review itself. Tr. of Mot. Hr'g at 33:21-34:1, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La. Feb. 24, 2026) (attached as Exhibit A). *See also* Mot. at 3-4.

[1] Available at https://perma.cc/8F8G-5TWJ.

ARGUMENT

"Courts adjudicating motions to stay balance three factors: (1) 'the interests of judicial economy,' (2) 'the hardship and inequity to the moving party in the absence of a stay,' and (3) 'the potential prejudice to the non-moving party in the event of a stay.'" *Fitzgerald v. Wildcat*, No. 3:20-CV-44, 2021 WL 1936799, at *1 (W.D. Va. May 13, 2021) (quoting *Stinnie v. Holcomb*, 396 F. Supp. 3d 653, 658 (W.D. Va. 2019)); *see also BAE Sys. Ordnance Sys., Inc. v. Fluor Fed. Sols., LLC*, No. 7:20-CV-00587, 2021 WL 6134685, at *1 (W.D. Va. Dec. 29, 2021). "The party seeking a stay must justify it by clear and convincing circumstances outweighing potential harm to the party against whom it is operative." *Williford v. Armstrong World Indus., Inc.*, 715 F.2d 124, 127 (4th Cir. 1983). All three factors weigh in favor of denying a stay.

Judicial Economy: The interests of judicial economy are not served by granting a belated stay request in a case where dispositive motions have been briefed, argued, and under consideration for over ten months. As an initial matter, the Government provides no explanation as to why a stay serves judicial economy *now*—over six months after its announced review of the mifepristone REMS. The Government did not raise these concerns with the *Purcell* court when it was considering dispositive motions on the APA challenge there, and it has not raised these concerns with this Court in the many months since. Nor does the existence of other challenges to the 2023 REMS Decision justify a stay at this time, *see* Defs.' Mot. to Stay Proceedings, ECF No. 92, at 2-3 ("Mot."), given that such cases have been pending throughout the course of this litigation, *see* Defs.' Combined Mem. in Supp. of Cross-Mot. for Summ. J. and in Opp. To Pls.' Mot. for Summ. J., ECF No. 70, at 36 n.11 (listing other litigations seeking relief against the 2023 REMS).[2]

[2] Indeed, other than while the Supreme Court was considering *Alliance*, the Government has never sought a stay of this case based on the existence of other litigations related to the 2023 REMS Decision, which include the following: *Washington v. FDA*, No. 1:23-CV-3026, 2025 WL 1888794

Moreover, while the Government claims that the outcome of FDA's review "could" eliminate any need for judicial review, *see* Mot. at 4, the opposite could as easily be true: this Court's summary judgment decision could provide important guidance to the FDA regarding its stated rationales for the 2023 REMS Decision, which would inform its ongoing review. Indeed, it would be far more efficient for FDA to take this Court's decision into account during its current review, as opposed to waiting months or more for FDA to conclude its review only for it to potentially issue a new REMS decision with similar or identical deficiencies; in such a circumstance, the parties would then have to relitigate the same issues and, depending on this Court's decision, FDA might then have to conduct yet *another* review of its mifepristone REMS. That is particularly inefficient where, as here, cross motions for summary judgment are fully briefed and argued and have been *sub judice* for many months. *See, e.g.*, *Valley Forge Ins. Co. v. Aquawood*, *LLC*, No. CV 24-3769, 2025 WL 2396671, at *3 (D. Minn. Aug. 18, 2025) (affirming denial of stay and finding that "[i]ssuing a decision in due course on a fully briefed, potentially dispositive motion will not squander efforts already expended but rather will promote judicial economy."); *Skinner v. Armet Armored Vehicles, Inc.*, No. 4:12-CV-00045, 2015 WL 540156, at *5 (W.D. Va. Feb. 10, 2015) (finding "indefinite stay" would be "contrary to" the court's "policy of efficient and expeditious resolution of cases" (citation omitted)).

Hardship to Movant: Defendants identify no hardship that they would suffer if denied a stay. This case consumes no Defendant resources given that dispositive motions are briefed and no deadlines loom. FDA also cannot establish why receiving a decision while it is conducting a REMS

(E.D. Wash. 2023) (judgment issued July 8, 2025); *Purcell,* No. CV 17-00493 (judgment issued Jan. 21, 2026); *Missouri v. FDA*, No. 4:25-cv-580 (E.D. Mo. 2025) (on remand from *Alliance*, 602 U.S. 367 (2024)) (Amended Complaint filed Jan. 16, 2025 and Supplemental Complaint filed Dec. 19, 2025); *Louisiana*, No. 6:25-cv-01491 (Complaint filed Oct. 6, 2025); *Florida v. FDA*, No. 7:25-cv-126 (N.D. Tex. 2025) (Complaint filed Dec. 9, 2025).

review would be harmful. If Plaintiffs succeed on their summary-judgment motion, this Court's decision would provide useful guidance to FDA about its legal obligations, which would bear on any future REMS under consideration. And if FDA prevails, a decision would impose no additional obligations on its pending review.

Prejudice to Non-Moving Parties: Finally, a stay would prejudice Plaintiffs, especially if other litigations related to the 2023 REMS Decision proceed. In such circumstances, Plaintiffs—who filed the complaint in this case long before any of the other pending complaints—may be impacted by decisions in those later cases to which they are not parties while being deprived of their ability to vindicate their rights in the case in which they are. *Cf. Allied-Gen. Nuclear Servs. v. Commonwealth Edison Co.*, 675 F.2d 610, 611 n.1 (4th Cir. 1982) ("Ordinarily, when multiple suits are filed in different Federal courts upon the same factual issues, the first or prior action is permitted to proceed to the exclusion of another subsequently filed.").

More broadly, Plaintiffs have expended significant resources litigating this case and have been seeking relief from the challenged restrictions for years. Granting a stay would further delay such relief, forcing Plaintiffs to continue complying with the restrictions for, at least, the duration of FDA's ongoing review, which could take upwards of a year, *see supra* at 2-3. *See, e.g.*, *Dynport Vaccine Co. LLC v. Lonza Biologics, Inc.*, No. CV JKB-14-2921, 2015 WL 5768707, at *2 (D. Md. Jan. 10, 2015) ("an indeterminate stay . . . will surely prejudice [plaintiff's] efforts to achieve prompt resolution of the instant case"); *Fisher v. United States*, No. CV 3:13-MC-08, 2013 WL 6074076, at *5 (E.D. Va. Nov. 18, 2013) (finding stay that could last "months" a "significant period of delay [that] may prejudice the Respondents").

The Government posits that Plaintiffs face no prejudice because they "seek only a remand" and "FDA is undertaking th[at] very review." Mot. at 4. But Plaintiffs request more than a general

remand order. Contemplating the likelihood of another "agency review," Plaintiffs emphasized that "it's particularly important . . . to issue an opinion that tells the FDA . . . [that] [a]ny REMS that you issue are going to have to make a determination based upon four statutory factors . . . because those are exclusive statutory factors[.]" May 19, 2025 Tr. of Proceedings at 24:7-9, 24:20-25:1 (attached as Exhibit B). *See also id.* at 23:11-16 (Plaintiffs "ask[] the Court . . . to issue a declaration that spells out what the FDA's obligations are in considering any modification to the REMS, and remand[] the case to FDA to reperform the 2023 review in adherence to those statutory requirements."). Without that specific instruction from this Court, Plaintiffs face prejudice, because there is no assurance that the FDA's pending review will correct the deficiencies raised in this suit. *See supra* at 4.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendants' Motion for a Stay.

Dated: April 6, 2026

Respectfully submitted,

/s/ *Linda C. Goldstein*
Linda C. Goldstein (*pro hac vice*)
Gail M. Deady
Virginia Bar Number: 82035
CENTER FOR REPRODUCTIVE RIGHTS
199 Water Street, 22nd Floor
New York, New York 10038
Telephone: (917) 637-3600
Fax: (917) 637-3666
Email: gdeady@reprorights.org
Email: lgoldstein@reprorights.org

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of April, 2026, I filed the foregoing document with the Clerk of Court using the CM/ECF system.

/s/ *Gail M. Deady*
Gail M. Deady
Virginia Bar Number: 82035
Linda C. Goldstein (pro hac vice)
CENTER FOR REPRODUCTIVE RIGHTS
199 Water Street, 22nd Floor
New York, New York 10038
Telephone: (917) 637-3600
Fax: (917) 637-3666
Email: gdeady@reprorights.org
Email: lgoldstein@reprorights.org

Counsel for Plaintiffs

EXHIBIT A

09:29:03

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

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STATE OF LOUISIANA ET AL	CASE NO. 6:25-cv-01491
VERSUS	JUDGE DAVID C. JOSEPH
U.S. FOOD & DRUG ADMINISTRATION ET AL	MAGISTRATE JUDGE DAVID J. AYO

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TRANSCRIPT OF MOTION HEARING PROCEEDINGS
HEARD BEFORE THE HONORABLE DAVID C. JOSEPH
UNITED STATES DISTRICT JUDGE
FEBRUARY 24, 2026

APPEARANCES:

FOR THE PLAINTIFF STATE OF LOUISIANA AND ROSALIE MARKEZICH:	LA DEPARTMENT OF JUSTICE 1885 N. Third Street Baton Rouge, LA 70802 (BY: J. BENJAMIN AGUINAGA, Esquire) (BY: CAITLIN A. HUETTEMANN, Esquire) ALLIANCE DEFENDING FREEDOM 44180 Riverside Parkway Lansdowne, VA 20176 (BY: ERIN M. HAWLEY, Esquire)
FOR THE DEFENDANT U.S. FOOD & DRUG ADMINISTRATION:	CIVIL DIVISION FEDERAL PROGRAMS BRANCH 1100 L Street NW Room 12002 Washington, DC 20005 (BY: NOAH T. KATZEN, Esquire)
FOR THE MOVANT DANCO LABORATORIES LLC:	HOGAN LOVELLS 555 13th Street NW Washington, DC 20004 (BY: ALEXANDER V. SVERDLOV, Esquire) (BY: JESSICA L. ELLSWORTH, Esquire) MOST & ASSOCIATES 201 St. Charles Avenue Suite 2500 #9685 New Orleans, LA 70170 (BY: WILLIAM B. MOST, Esquire)

APPEARANCES:

FOR THE MOVANT GENBIOPRO INC.:	ARNOLD & PORTER 601 Massachusetts Avenue NW Washington, DC 20001 (BY: DAPHNE O'CONNOR, Esquire) (BY: ROBERT J. KATERBERG, Esquire)
	ADCOCK LAW 8131 Oak Street Unit 100 New Orleans, LA 70118 (BY: JOHN N. ADCOCK, Esquire)
OFFICIAL COURT REPORTER:	BETH DELATTE, FCRR, CCR, RPR Certified Court Reporter Registered Prof. Reporter 800 Lafayette Street Room 3105 Lafayette, LA 70501

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY. TRANSCRIPT PRODUCED BY COMPUTER.

10:43:47 standing. Thank you.

10:43:49 **THE COURT:** How long will the review of the 2023 REMS
10:43:53 last?

10:43:54 **MR. KATZEN:** I don't have a timeline I can give Your
10:43:57 Honor. I think the current plan is for FDA to try to complete the
10:44:01 study it's undertaking in less than -- in sooner than a year, but I
10:44:06 can't put a timeframe on the review as a whole.

10:44:08 **THE COURT:** So that was announced last September, is that
10:44:15 right, by the secretary?

10:44:15 **MR. KATZEN:** It was confirmed last September. It may
10:44:17 have been mentioned publicly before that, as well, but it was
10:44:21 certainly stated in the September --

10:44:23 **THE COURT:** So by this September, you think the review
10:44:26 would be complete?

10:44:27 **MR. KATZEN:** By this September?

10:44:30 **THE COURT:** Right.

10:44:30 **MR. KATZEN:** I can't make any representations about the
10:44:32 time --

10:44:32 **THE COURT:** You said within a year and it was announced
10:44:35 last September.

10:44:36 **MR. KATZEN:** I'm sorry. I'm sorry. In January of this
10:44:37 year, FDA said on its website that it expects to have the study
10:44:44 that it's doing, which is part of the review -- it's not the whole
10:44:48 review itself -- have the study complete in sooner than a year.
10:44:52 That's the current plan of the agency. But the review itself, I

10:44:57 don't have a timeframe to put on that.

10:44:59 **THE COURT:** So the review has begun? It began last

10:45:02 month?

10:45:03 **MR. KATZEN:** The study is part of the review, and they're

10:45:05 in the data collection phase of the study. FDA, yes. FDA is

10:45:09 beginning its review -- begun its review.

10:45:11 **THE COURT:** What are they currently doing as part of

10:45:15 their review?

10:45:16 **MR. KATZEN:** I can't talk specifically about what they

10:45:18 are doing. I can say there's three different kind of work streams.

10:45:22 One is the study. Well, maybe four different work streams. The

10:45:24 study, there's just the review of all evidence before --

10:45:26 **THE COURT:** Why can't you talk specifically about it?

10:45:28 Because you don't know? Or because you're not supposed to talk

10:45:30 about it?

10:45:31 **MR. KATZEN:** No, no. This is my understanding of what,

10:45:33 in general, the agency is doing. I can't review all their

10:45:37 deliberative processes. I can't, you know, get ahead of the agency

10:45:42 on anything; but I can tell you --

10:45:43 **THE COURT:** Well, you can say generally what they're

10:45:46 doing. You're telling me to defer to the agency process. I'm

10:45:49 asking you: What are they doing?

10:45:52 **MR. KATZEN:** Yeah, I think I am going to answer this

10:45:54 question. They are conducting a study. They are reviewing all

10:45:59 evidence before the agency. They are reviewing citizen petitions

EXHIBIT B

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

WHOLE WOMAN'S HEALTH ALLIANCE, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	)	CIVIL ACTION NO. 3:23-cv-00019-RSB CROSS-MOTIONS FOR SUMMARY JUDGMENT

TRANSCRIPT OF PROCEEDINGS

Charlottesville, Virginia

May 19, 2025

1:00 p.m.

BEFORE: THE HONORABLE ROBERT S. BALLOU
United States District Judge

APPEARANCES:

CENTER FOR REPRODUCTIVE RIGHTS
BY: LINDA CEILIA GOLDSTEIN, ESQ.
GAIL MARIE DEADY, ESQ.
Counsel for the Plaintiffs

DEPARTMENT OF JUSTICE - CIV
BY: NOAH T. KATZEN, ESQ.
JAMES HARLOW, ESQ.
Counsel for the Defendants

Reported by: Frank R. Austin, RPR, CSR, RMR, CRR

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

exclusive statutory factors, and you have to comply with (f)1 and (f)2. That's important because of the Canadian study, because the Canadian study shows that mifepristone can be safely and effectively prescribed and dispensed by any health care provider and by any pharmacy without any increase in serious adverse events or other complications. So in light of that study it is impossible, we would submit, for FDA to conclude that mifepristone would have to be withdrawn from the market without the three ETASU that we're challenging here.

Similarly we'd have to consider the (f)2 factors on burden which FDA -- there were a dozen -- I counted them -- a dozen studies on the burdens imposed by the prescriber certification in patient agreement ETASU which FDA didn't look at because they weren't safety data. Well, they weren't pretending to be safety data. They were burden data. Burden is one of the things that FDA has to consider under 355-1(f)2.

I believe I have been through the statutory framework. Unless Your Honor has any more questions on that, I'd like to proceed to arbitrary and capricious.

THE COURT: Yes, ma'am. I thought we had been there.

MS. GOLDSTEIN: We have been there a little bit with the Canadian study. And I just wanted to make a few points,