BRETT A. SHUMATE
Assistant Attorney General

JAMES W. HARLOW
Acting Assistant Director

NOAH T. KATZEN (D.C. Bar No. 1006053)
Trial Attorney
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L St., NW
Washington, DC 20005
Tele: 202-305-2428
Noah.T.Katzen@usdoj.gov

Attorney for Defendants

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, *et al*., Plaintiffs, v. ROBERT F. KENNEDY, JR., *et al*., Defendants.	CIV. NO. 1:17-00493-JAO-RT **DEFENDANTS' BRIEF IN OPPOSITION TO THE COURT RETAINING JURISDICTION DURING REMAND**

This case has ended. On October 30, 2025, this Court granted summary judgment to Plaintiffs and declared the January 2023 REMS Modification decision arbitrary and capricious under the Administrative Procedure Act. *See* ECF No 253. The Court then dismissed the remaining equal protection claims on December 6, 2025. *See* ECF No. 257. Now, on remand, FDA will review the REMS in light of the Court's opinion, the evidence before the agency, and the governing statutory and regulatory standards. In short, Plaintiffs' challenge to the January 2023 REMS Modification has been fully resolved, and no further relief from that action is possible. Nothing remains but for the Court to enter final judgment and close the case.

Plaintiffs, however, seek to deviate from the normal course, asking this Court to retain jurisdiction during the remand to the agency. Yet none of the circumstances justifying such ongoing supervision of the Executive Branch are present here. And Plaintiffs' mere desire to expedite a hypothetical challenge to FDA's post-remand actions will not suffice. Accordingly, this Court should decline Plaintiffs' request to retain jurisdiction.

ARGUMENT

When a court sustains a challenge to agency action, the "norm" is to remand to the agency without retaining jurisdiction. *Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d 37, 41 (D.D.C. 2008); *accord Amos v. Menik*, No. CV DKC 24-42, 2025

WL 3200681, at *2 (D. Md. Nov. 17, 2025); *Flores v. United States*, No. 11-12119, 2015 WL 3887537, at *4 (E.D. Mich. June 24, 2015). The Ninth Circuit follows this approach. *See, e.g.*, *Ctr. for Biological Diversity v. EPA*, No. 20-73146, 2022 WL 2805090, at *1 (9th Cir. Jul. 18, 2022) (remanding to agency without vacatur and without retaining jurisdiction); *Idaho Conservation League v. EPA*, 820 F. App'x 627, 628-29 (9th Cir. 2020) (same); *Cal. Communities Against Toxics v. EPA*, 688 F.3d 989, 993-94 (9th Cir. 2012) (per curiam) (same).

Although a court has "discretion" to retain jurisdiction during a remand, that "is 'typically reserved for cases alleging unreasonable delay of agency action or failure to comply with a statutory deadline, or for cases involving a history of agency noncompliance with court orders or resistance to the fulfillment of legal duties.'" *N. Alaska Envt'l Ctr. v. Haaland*, Case No. 3:20-cv-00187, 2022 WL 1556028, at *7 n.90 (D. Alaska May 17, 2022) (quoting *Baystate*, 587 F. Supp. at 41); *see also Mercy Gen. Hosp. v. Azar*, 410 F. Supp. 3d 63, 82 (D.D.C. 2019); *Navajo Nation v. Azar*, 302 F. Supp. 3d 429, 441 (D.D.C. 2018). Authorities on which Plaintiffs rely (*see* ECF No. 258, at 3-5) fit that mold: *Cobell v. Norton*, 240 F.3d 1081, 1109 (D.C. Cir. 2001) (retaining jurisdiction based on "a record of agency recalcitrance and resistance to the fulfillment of its legal duties"); *Cook Inletkeeper v. EPA*, 400 Fed. App'x 239, 241 (9th Cir. 2010) (history of delay); *Nat'l Ass'n of Regul. Util. Comm'rs v. U.S. Dept. of Energy*, 680 F.3d 819, 826

(D.C. Cir. 2012) (agency had shown "disposition to delay"); *Prometheus Radio Project v. FCC*, 824 F.3d 33 (3d Cir. 2016) (third remand of the same issue in twelve years of litigation).[1]

Here, however, FDA has not unlawfully withheld or unreasonably delayed action or shown any disposition to flout court orders or legal obligations. Plaintiffs accuse FDA of "violating both the APA and its commitment to Plaintiffs and the Court" by failing to review certain data and evidence submitted by Plaintiffs in connection with the 2021 REMS review. ECF No. 258, at 4. For starters, that ignores how the 2023 REMS Modification actually afforded partial relief to Plaintiffs. *See* ECF No. 212, ¶ 190. While the Court has disagreed with FDA's assessment that it had reviewed all relevant evidence, ECF No. 253, at 76, this finding of a run-of-the-mill APA error does not justify the unusual retention of jurisdiction.

Nor do Plaintiffs "offer[]" any other "compelling reason to deviate from the usual course of remanding . . . without retaining jurisdiction." *Shawnee Tribe v.*

[1] Other authorities cited by Plaintiffs either provide no reasoning, *Tex. Ass'n of Mfrs. v. CPSC*, 989 F.3d 368, 390 (5th Cir. 2021), or involve remands in which the agency could have provided further explanation of its decision and did not necessarily have "to conduct further proceedings," *Cent. Maine Power Co. v. FERC*, 252 F.3d 34, 48 (1st Cir. 2001). Here, by contrast, the remand requires more than further explanation of the action already taken: among other things, it requires FDA to consider evidence and statutory provisions that the Court found the agency previously did not consider. ECF No. 253, at 40, 76.

Yellen, Case No. 1:20-cv-01999 (APM), 2023 WL 9468248, at *2 (D.D.C. Oct. 3, 2023). Their alleged need to expedite future review, ECF No. 258, at 5, is hardly exceptional. There is *always* a possibility that a successful APA plaintiff will want to challenge an agency's post-remand action. That challenge, however, must be raised in a "separate APA action." *Heartland Reg'l Med. Ctr. v. Leavitt*, 415 F.3d 24, 30 (D.C. Cir. 2005).

Plaintiffs suggest this case is unusual because Plaintiffs "declin[ed] to seek vacatur." ECF No. 258, at 5. But the Ninth Circuit frequently remands to an agency without vacatur *and* without retaining jurisdiction. *See Ctr. for Biological Diversity*, 2022 WL 2805090, at *1; *Idaho Conservation League*, 820 F. App'x at 628-29; *Cal. Communities Against Toxics*, 688 F.3d at 993-94.

Moreover, Plaintiffs *could not* have sought vacatur because that relief would not have redressed their injuries. The normal "effect of vacatur is to 'reinstate the rules previously in force.'" *HIV & Hepatitis Policy Inst. v. HHS*, No. 22-cv-2604 (JDB), 2023 WL 10669681, at *3 (D.D.C. Dec. 22, 2023) (quoting *Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 757 (D.C. Cir. 1987)); *cf. Hewitt v. United States*, 606 U.S. 419, 431 (2025) ("By operation of legal fiction, the law acts as though the vacated order never occurred."). Here, the pre-2023 REMS was *more* stringent than the 2023 modification that Plaintiffs believed too strict. Thus, the remand without vacatur that the Court ordered was the only relief from the

challenged agency action that Plaintiffs could have obtained. *See Washington v. FDA*, 668 F. Supp.3d 1125, 1143 (E.D. Wash. 2023) ("[E]njoining the 2023 REMS and returning to the status quo would eliminate the ability of pharmacies to provide the drug, thereby reducing its availability. This runs directly counter to Plaintiffs' request."), *preliminary injunction vacated*, No. 1:23-cv-3026-TOR, 2025 WL 188794 (E.D. Wash. July 8, 2025).

Finally, Plaintiffs' efficiency concerns are overblown. *See* ECF No. 258, at 5. FDA's ongoing review of mifepristone will result in a new agency action on the basis of a new administrative record. If Plaintiffs believe further litigation in this District is appropriate, they can file a new complaint and a Notice of Related Case. *See* LR40.2 (including "completed civil actions" as potential related cases). But, of course, it is hardly a foregone conclusion that Plaintiffs will resume litigation over the mifepristone REMS or that this District would be the appropriate forum for such litigation. These uncertainties, combined with the minimal burden to Plaintiffs of commencing a new civil action, render the retention of jurisdiction particularly inappropriate here.

CONCLUSION

For the foregoing reasons, the Court should decline to retain jurisdiction during the remand to FDA and should instead enter final judgment.

Dated: January 5, 2026

Respectfully submitted,

/s/ Noah T. Katzen
NOAH T. KATZEN
Federal Programs Branch
Civil Division
U.S. Department of Justice

Attorney for Defendants