

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

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' REQUEST FOR THE COURT TO
RETAIN JURISDICTION DURING THE REMAND**

This case is over. All claims that Plaintiffs asserted in their challenge to the January 2023 REMS Modification decision have been resolved, and the Court has remanded the matter to FDA. ECF Nos. 95, 100. 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. No further relief from the challenged agency action is possible.

Like the court in *Purcell v. Kennedy*, this Court should follow the "norm" and decline to retain jurisdiction over the remand. *See* 1:17-cv-00493-JAO-RT, ECF No. 262 (D. Haw. Jan. 21, 2026) (attached hereto as Exhibit A). Plaintiffs propose to deviate from that standard course (ECF No. 101), but no circumstance that could justify such ongoing supervision of the Executive Branch is present. Plaintiffs' unfounded "belie[f]" that

FDA will yield to “political pressure” and “ignore” the statutory factors this Court directed it to consider does not suffice. *See id.* at 1-2.

ARGUMENT

I. The Court Should Not Retain Jurisdiction During Remand

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. Meink*, 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). “Although courts have discretion to maintain jurisdiction pending agency remand, it’s not the norm.” *Purcell*, 1:17-cv-00493-JAO-RT, ECF No. 262, at 2 (internal citation omitted). That discretion “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 Env’tl 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).

The Court should follow the norm here. FDA has not unlawfully withheld or unreasonably delayed agency action. Nor has it shown any disposition to flout court orders or its legal obligations. Indeed, after Judge Otake remanded to FDA to reconsider the mifepristone REMS on similar grounds to the ones this Court adopted,

she declined to retain jurisdiction because “the Court gleans no recalcitrance or bad faith on the part of the Agency.” *Purcell*, 1:17-cv-00493-JAO-RT, ECF No. 262, at 3.

II. Plaintiffs’ Unfounded Speculation Does Not Justify Departing From The Norm

Notably, Plaintiffs do not cite any traditional basis for retaining jurisdiction. They do not allege that FDA has unreasonably delayed or unlawfully withheld agency action. Nor do they allege that FDA has acted in bad faith. Lacking such a record, Plaintiffs speculate that FDA *will* act in bad faith *in the future*. According to Plaintiffs, there has been “political pressure on FDA to make the mifepristone REMS *more* onerous.” ECF No. 101 at 2. Because of this, Plaintiffs “believe there is grave risk” that on remand FDA will “ignore the statutory factors that this Court has directed it to consider.” *Id.* at 1.

Plaintiffs cite no precedent for retaining jurisdiction based on speculation about “political interference with the reconsideration.” *Id.* at 5. Instead, the cases they cite either involve a demonstrated history of delay or bad faith, *see Alvarez Lagos v. Barr*, 927 F.3d 236, 257 (4th Cir. 2019) (retaining jurisdiction because the matter “ha[d] already been the subject of three agency opinions and one remand from this court”); *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”); *American Academy of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019) (retaining jurisdiction and imposing a deadline based on a history of delay), or do not explain their reasoning, *see Tex. Ass’n of Mfrs. v. CPSC*, 989 F.3d 368, 390 (5th Cir. 2021).

Moreover, Plaintiffs' "belie[f]" is not enough to ascribe bad faith to the Executive Branch. *See United States v. Chem. Found., Inc.*, 272 U.S. 1, 14-15 (1926) ("The presumption of regularity supports the official acts of public officers and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties."). Plaintiffs offer no "clear evidence" – only unfounded speculation. ECF No. 101 at 2-4. That some outside of FDA have called for increasing restrictions on mifepristone is neither here nor there, just as it is irrelevant that others have called for *reducing* restrictions on mifepristone.¹ The existence of such opposing requests does not mean that FDA will yield to pressure in either direction.² Indeed, it is commonplace for government officials to express their own policy views on matters pending before federal agencies. It does not follow that such "political pressure" portends disregard of statutory constraints. And while Plaintiffs contend FDA's own statements are somehow improper, the agency's promises to "conduct[] a review of mifepristone," "work[] with the professional career scientists at the Agency who review" the relevant data, and

¹ *See, e.g.*, <https://www.regulations.gov/document/FDA-2025-P-0377-0001> (American College of Obstetricians and Gynecologists, et al.); <https://www.regulations.gov/document/FDA-2025-P-1576-0001> (Andrea Joy Campbell, Attorney General of Massachusetts and the Attorneys General for 3 other states); <https://www.regulations.gov/document/FDA-2025-P-2162-0001> (GenBioPro, Inc.); <https://www.regulations.gov/document/FDA-2025-P-3287-0001> (Nicholas Brown, Attorney General of Washington and the Attorneys General for 18 other states).

² Nor does the Attorney General's statement about ensuring "that the *Dobbs* decision becomes permanent in every single state" somehow commit FDA to any specific, future action on the mifepristone REMS. ECF No. 101 at 4. That Executive Branch officials may hold policy views with which Plaintiffs disagree cannot rebut the presumption of regularity.

“conduct a study of the safety of the current REMS” to “determine whether modifications are necessary,” are evidence of *good* faith, not bad. ECF No. 101 at 2-4.

CONCLUSION

If, following FDA’s review, Plaintiffs believe they are entitled to relief from new agency action, they may seek to challenge that action in a “separate APA action.” *Heartland Reg’l Med. Ctr. v. Leavitt*, 415 F.3d 24, 30 (D.C. Cir. 2005). But they have demonstrated no reason for the Court to take the unusual step of retaining jurisdiction over this now-concluded APA action. The Court should decline to do so.

October 2, 2026

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General

ERIC D. BECKENHAUER
Assistant Branch Director

/s/ Noah T. Katzen
NOAH T. KATZEN
Assistant Branch Director
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L St., NW
Washington, DC 20005
202-305-2428
Noah.T.Katzen@usdoj.gov

Counsel for Defendants

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, ET AL.,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his
official capacity as SECRETARY, U.S.
D.H.H.S., ET AL.,

Defendants.

CIV. NO. 17-00493 JAO-RT

ORDER DECLINING TO RETAIN
JURISDICTION PENDING
REMAND

ORDER DECLINING TO RETAIN JURISDICTION PENDING REMAND

On October 30, 2025, the Court granted Plaintiffs’¹ Motion for Summary Judgment and accordingly denied Defendants’ Cross Motion for Summary Judgment on Plaintiffs’ Administrative Procedure Act Challenge to the 2023 REMS Decision. *See generally* ECF No. 253 (“MSJ Order”). As relief, the Court declared the 2023 REMS Decision unlawful and remanded the matter to the FDA to reconsider the mifepristone REMS in accordance with the MSJ Order and the law. *See id.* at 78. The Court, however, did not vacate the mifepristone REMS and ETASUs pending remand. *See id.* The MSJ Order also did not fully dispose of Plaintiff’s constitutional challenge to the 2023 REMS Decision, so the Court

¹ The Court uses the defined terms from its October 30, 2025 Order.

ordered the parties to file a joint status report on how the case would proceed. *See id.*

In that joint status report, Plaintiffs requested voluntary dismissal of the constitutional claims without prejudice, *see* ECF No. 256 at 2, which the Court granted, ECF No. 257. The parties also asked the Court for leave to file briefs regarding whether the Court should maintain jurisdiction over the case pending remand to the FDA. *See* ECF No. 256 at 2–3. The Court allowed the briefing, and the parties timely filed their respective briefs. *See* ECF Nos. 257–60.

Plaintiffs broadly argue that the Court should maintain jurisdiction over this long-running dispute because of the Court’s familiarity with the case and in order to expedite any future review. *See* ECF No. 258 at 5–6. Defendants oppose the request and ask the Court to follow the more “typical” practice of declining continued jurisdiction pending agency remand. *See* ECF No. 259 at 3–6.

Although courts have discretion to maintain jurisdiction pending agency remand, *see Cobell v. Norton*, 240 F.3d 1081, 1109 (D.C. Cir. 2001), it’s not the norm and is instead “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 fulfillment of legal duties,” *Baystate Med. Ctr. v. Leavitt*, 587 F.3d 2d 37, 41 (D.D.C. 2008) (citations omitted). Here, while the litigation and the administrative challenges

have been lengthy, the Court gleans no indication of recalcitrance or bad faith on the part of the Agency. *See Baystate Med. Ctr.*, 587 F.2d at 41 n.5 (commenting that length of administrative proceedings did not demonstrate the agencies' resistance to following the law). As such, the Court will follow the typical practice and declines to retain jurisdiction over the matter pending remand.

IT IS SO ORDERED.

DATED: Honolulu, Hawai'i, January 21, 2026.



A handwritten signature in black ink, appearing to read "Jill A. Otake", written over a horizontal line.

Jill A. Otake
United States District Judge

CIV. NO. 17-00493 JAO-RT, *Purcell, et al. v. Kennedy, et al.*, ORDER
DECLINING TO RETAIN JURISDICTION PENDING REMAND