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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

HEIDI PURCELL, M.D., *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., *et al.*,

Defendants.

CIVIL ACTION

Case No. 1:17-cv-00493-JAO-RT

PLAINTIFFS' BRIEF REQUESTING THAT THE COURT RETAIN JURISDICTION DURING REMAND

After eight years of litigation spanning two discrete agency reviews, this Court granted summary judgment to Plaintiffs on their claim that the U.S. Food and Drug Administration's ("FDA") decision to maintain the Mifepristone Risk Evaluation and Mitigation Strategy ("REMS") in 2023 was arbitrary and capricious in violation of the Administrative Procedure Act ("APA"). Order Granting Pls.' Mot. for Summ. J. and Denying Defs.' Cross Mot. for Summ. J., at 4, 78 (Oct. 30, 2025), ECF No. 253 [hereinafter "Order Granting Summ. J."]. Noting that Plaintiffs "do not currently seek vacatur of the restrictions," the Court remanded to FDA "to reconsider the mifepristone REMS in accordance with this order and the law." *Id.* at 3, 78. Given this Court's unique familiarity with the REMS statutory scheme and the 25-year history of FDA's regulation of mifepristone, and "mindful of the likelihood of further litigation," *Prometheus Radio Project v. Fed. Commc'ns Comm'n*, 824 F.3d 33, 60 (3d Cir. 2016), Plaintiffs respectfully request that the Court retain jurisdiction over this matter during the agency remand.

I. Factual Background

Plaintiffs initiated this litigation in October 2017, challenging FDA's 2016 decision to maintain a REMS for mifepristone as, *inter alia*, arbitrary and capricious. Compl. (Oct. 3, 2017), ECF No. 1. The parties submitted cross-motions for summary judgment in December 2019, which were mooted by a stay of proceedings from January 2020 to March 2021 pending developments in other relevant litigation. *See*

Order Denying Defs.' Mot. to Stay Proceedings at 2-3 (Aug. 8, 2023) [hereinafter "Order Denying Stay"], ECF No. 191. In April 2021, Plaintiffs submitted a second motion for summary judgment. ECF. No. 141. Shortly before Defendants' response and cross-motion was due, "FDA notified Plaintiffs that it was undertaking a fresh review of the mifepristone REMS and would consider any relevant data and evidence submitted by Plaintiffs during that review." Order Denying Stay at 4. On that condition, "the parties jointly agreed to stay this action pending the FDA's 2021 review . . . and the Court ordered so." *Id.*; ECF Nos. 148, 149.

In early 2023, FDA updated its mifepristone regulations and the Court lifted its stay. ECF Nos. 157, 158. Plaintiffs filed an amended and supplemental complaint challenging the agency's decision to maintain a REMS, to maintain two of the three Elements to Assure Safe Use ("ETASU"), and to add a new ETASU. Am. & Suppl. Compl. (Apr. 10, 2023), ECF No. 169. Plaintiffs raised APA and constitutional claims, alleging—among other violations—that "FDA expressly omitted from its analysis much of the data and evidence provided by the *Chelius* Plaintiffs . . . . even though it is relevant to [the statutory requirements for a REMS]." *Id.* at 46-47.

From October 2024 to August 2025, the Parties briefed and argued cross-motions for summary judgment. ECF Nos. 221-234, 236-252. Although Plaintiffs had pleaded a request that the Court direct FDA to vacate the REMS, *see* Corrected 2d Am. & Suppl. Compl. at 92-93, ECF No. 212, Plaintiffs' motion took a more

"modest approach . . . in the first instance," Tr. of Summ. J. H'rg at 6:22-7:18 (Aug. 22, 2025), "ask[ing] the Court to remand the matter to the FDA with instructions to address the statutorily-mandated factors and consider relevant evidence the Agency allegedly disregarded." Order Granting Summ. J. 3; *accord* ECF No. 221.

In a 79-page decision, the Court granted summary judgment to Plaintiffs, concluding that FDA "fail[ed] to provide a reasoned explanation for its restrictive treatment of the drug, which was compounded by its decision to limit the scope of information it considered when evaluating the REMS." Order Granting Summ. J. 4; *accord id.* at 78. The Court remanded to FDA with directions to consider and address the statutory factors and categories of relevant evidence identified in the Order. *Id.*

The remand comes against the backdrop of Defendants' announcements earlier this year, in response to political pressure by anti-abortion politicians and advocates, that FDA is conducting a new mifepristone REMS review.[1]

II. Argument

"[F]ederal courts regularly retain jurisdiction until a federal agency has

[1] *See, e.g.*, Letter from Robert F. Kennedy, Jr., Sec'y, Dep't of Health & Hum. Servs., and Martin A. Makary, Comm'r, FDA, to Attorneys General 1 (Sept. 19, 2025), https://perma.cc/Q57U-MSHX; Alejandra O'Connell-Domenech, FDA Commissioner Pledges to Investigate Mifepristone, THE HILL (June 3, 2025), https://thehill.com/policy/healthcare/5330774-marty-makary-fda-mifepristone-review/ [https://perma.cc/3SNS-DGT7]; Susan Rinkunas, RFK Jr Orders Mifepristone Review as Anti-Abortion Groups Push for Ban, GUARDIAN (May 14, 2025), https://perma.cc/L3R9-32BW.

complied with its legal obligations." *Cobell v. Norton*, 240 F.3d 1081, 1086, 1109 (D.C. Cir. 2001) (district court's order remanding to the Interior and Treasury Departments while retaining jurisdiction was "well within the district court's equitable powers"); *see, e.g.*, *Cook Inletkeeper v. E.P.A.*, 400 F. App'x 239, 242 (9th Cir. 2010); *Nat'l Ass'n of Regul. Util. Comm'rs v. U.S. Dep't of Energy*, 680 F.3d 819, 820, 826 (D.C. Cir. 2012); *Texas Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 390 (5th Cir. 2021).

It is appropriate for the Court to retain jurisdiction here. Plaintiffs have been urging FDA to eliminate the mifepristone REMS for nearly a decade, across two distinct agency reviews. *See* Corrected Second Am. & Suppl. Compl. at 32-36 (describing Society of Family Planning's ("SFP") letter to FDA in February 2016). When the Court stayed this litigation again pending FDA's 2021 review, it did so on the condition that FDA "commit[ted] to review any relevant data and evidence submitted by the Plaintiffs." ECF 148, 149. But FDA failed to consider that relevant evidence, violating both the APA and its commitment to Plaintiffs and the Court. Order Granting Summ. J. at 63-76 (finding, *inter alia*, that "FDA 'excluded' most of the sources Plaintiffs submitted," even those that were "clearly relevant"); *see Washington v. U.S. Dep't of the Navy*, No. 19-CV-1059-RAJ, 2024 WL 3843811, at *1 (W.D. Wash. Aug. 16, 2024) ("history of agency noncompliance with court orders or resistance to the fulfillment of legal duties" supports retaining jurisdiction,

though "not a prerequisite" (internal quotation marks and citations omitted)), *appeal dismissed*, No. 24-6357, 2025 WL 227700 (9th Cir. Jan. 6, 2025).

In declining to seek vacatur, Plaintiffs afforded the agency yet another opportunity to correct its errors. However, in the interest of equity, Plaintiffs respectfully request that this Court "retain jurisdiction over this case so that any further review [of agency non-compliance] would be expedited." *Nat'l Ass'n of Regul. Util. Comm'rs*, 680 F.3d at 820. This Court's detailed knowledge of 21 U.S.C. § 355-1 and the voluminous multi-decade administrative record, *see, e.g.*, Joint Appendix, Vol. A, at 3-27, ECF 240-1 (evidence from 2000), positions it well to "review whatever decision [the agency] makes on reconsideration in response to [the Court's] mandate, assuming that the decision remains contested." *Cent. Maine Power Co. v. F.E.R.C.*, 252 F.3d 34, 48 (1st Cir. 2001) (citations omitted). Retaining jurisdiction while FDA reviews the REMS for the *third* time since SFP's 2016 letter is critical to prevent prejudice to Plaintiffs and their members. "Rarely does a trilogy benefit from a sequel"—but if the Court's summary judgment order does not "bring[] this saga to its conclusion," Plaintiffs should be able to have any "further litigation" promptly heard by this Court. *Prometheus Radio Project*, 824 F.3d at 60.

III. Conclusion

For the foregoing reasons, Plaintiffs respectfully request that the Court retain jurisdiction over this matter while it is on remand with FDA.

Respectfully submitted,

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