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

NOTICE OF SUPPLEMENTAL AUTHORITY

Defendants respectfully submit this Notice of Supplemental Authority regarding a final disposition (attached hereto as Exhibit A) in *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash. July 8, 2025), a case which involves the same legal issues relating to the same agency action as the one before this Court. The district court granted FDA's cross-motion for summary judgment, denied the plaintiffs' summary judgment motion, and vacated the preliminary injunction it had previously entered. Ex. A at 10-11. The court explained that "under a deferential review, it appears FDA fully considered the important aspect of the issues in this case and came to a reasonable conclusion." Ex. A at 10.

July 16, 2025

Respectfully submitted,

/s/ Noah T. Katzen
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Certificate of Service

I certify that the foregoing was served on all counsel of record via ECF on July 16, 2025.

/s/ Noah T. Katzen
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EXHIBIT A

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, STATE OF OREGON, STATE OF ARIZONA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF ILLINOIS, ATTORNEY GENERAL OF MICHIGAN, STATE OF NEVADA, STATE OF NEW MEXICO, STATE OF RHODE ISLAND, STATE OF VERMONT, DISTRICT OF COLUMBIA, STATE OF HAWAII, STATE OF MAINE, STATE OF MARYLAND, STATE OF MINNESOTA, and COMMONWEALTH OF PENNSYVLANIA, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs, UNITED STATES	NO. 1:23-CV-3026-TOR ORDER ON MOTIONS FOR SUMMARY JUDGMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES, and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

BEFORE THE COURT are Plaintiffs' Motion for Summary Judgment (ECF No. 156) and Defendants' Cross-Motion for Summary Judgment (ECF No. 171). The Court has determined that oral argument is unnecessary. The Court has fully reviewed the record and files herein and is fully informed. For the reasons discussed below, Defendants' Cross-Motion for Summary Judgment (ECF No. 171) is **granted**.

BACKGROUND

This case concerns federal regulation of mifepristone used in connection with the termination of early pregnancy. ECF No. 35. Plaintiffs seek a remand to the FDA. The following facts are generally undisputed for purposes of resolving the instant motion.

In 1992, Subpart H regulations authorized the Food and Drug Administration ("FDA") to require conditions "needed to assure safe use" for certain drugs. Final Rule, 57 Fed. Reg. 58,942, 58,958 (December 11, 1992) (codified at 21 C.FR. § 314.520). In September 2000, FDA approved

mifepristone[1] under Subpart H, concluding that mifepristone is safe and effective for medical termination of intrauterine pregnancy through 49 days' gestation when used in a regimen with the already-approved drug, misoprostol. ECF No. 35 at 21, ¶ 85. FDA's restrictions on mifepristone included requiring (1) an in-person dispensing requirement where the drug could only be dispensed in a hospital, clinic, or medical office, by or under the supervision of a certified provider who at the time could only be a physician, (2) providers attest to their clinical abilities in a signed form kept on file by the manufacturer, and agree to comply with reporting and other REMS requirements, and (3) prescribers and patients review and sign a form with information about the regimen and risks and that the prescriber provide copies to the patient and patient's medical record. *Id.* at 24, ¶ 87.

From 1992 to February 2002, seven New Drug Applications ("NDA"), including Mifeprex, were approved subject to these conditions, in contrast to the 961 NDAs with no additional restrictions from January 1993 to September 2005. ECF No. 35 at 24–25, ¶ 88.

[1] As referenced herein, mifepristone is the drug used for early termination of pregnancy, such as Mifeprex and the generic drug. This Order does not impact mifepristone as used in Korlym, a drug used to treat Cushing's syndrome.

The Food and Drug Administration Amendments Act of 2007 effectively replaced Subpart H with the REMS statute codified at 21 U.S.C. § 355-1. Pub. L. No. 110-85, tit. IX, § 901. All drugs previously approved under Subpart H, including Mifeprex, were deemed to have a REMS in place. Pub. L. No. 110-85, tit. IX, § 909(b). Under the Federal Food, Drug and Cosmetic Act ("FDCA"), a new drug cannot be marketed and prescribed until it undergoes a rigorous approval process to determine that it is safe and effective. 21 U.S.C. § 355.

In 2011, FDA issued a new REMS for Mifeprex incorporating the same restrictions under which the drug was approved eleven years earlier. *Id.*, ¶ 90; ECF No. 51-2. In 2013, FDA reviewed the existing REMS and reaffirmed the restrictions in place. ECF No. 35 at 25, ¶ 91.

In 2015, Mifeprex's manufacturer submitted a supplemental NDA proposing to update the label to reflect evidence-based practices across the country – namely, the use of 200 mg of mifepristone instead of 600 mg. *Id.*, ¶ 92. In July 2015, the manufacturer submitted its REMS assessment, proposing minor modifications. *Id.* This submission prompted a review of the Mifeprex label and REMS by FDA. *Id.* at 26, ¶ 93. As part of the review, FDA received letters from more than 40 medical experts, researches, advocacy groups, and professional associations who asked, *inter alia*, that the REMS be eliminated in their entirety. *Id.* One letter asked FDA

to "[e]liminate the REMS and ETASU (Elements to Assure Safe Use), including eliminating the certification and patient agreement requirements. *Id.* at 27, ¶ 95.

In 2016, FDA found "no new safety concerns have arisen in recent years, and that the known serious risks occur rarely," and that "[g]iven that the number of … adverse events appear to be stable or decreased over time, it is likely that … serious adverse events will remain acceptably low." *Id.* at 30, ¶ 100. Following this review, FDA changed Mifeprex's indication, labeling, and REMS, including increasing the gestational age limit from 49 to 70 days, reducing the number of required in-person clinic visits to one, finding at-home administration of misoprostol safe, finding no significant differences in outcomes based on whether patients had a follow-up phone call or in person or based on the timing of those appointments, and allowing a broader set of healthcare providers to prescribe mifepristone. *Id.*, ¶ 101. However, FDA still required that mifepristone be administered in a clinic setting. *Id.*

In 2019, FDA approved a different manufacturer's abbreviated NDA for a generic version of mifepristone and established the Mifepristone REMS Program, which covered both Mifeprex and the generic drug. *Id.* at 32, ¶ 103; ECF No. 51-3. In May 2020, American College of Obstetricians and Gynecologists ("ACOG") sued FDA, challenging the Mifepristone REMS Program's in-person dispensing requirement in light of the COVID-19 pandemic. ECF No. 35, ¶ 104. In that

case, the district court temporarily enjoined FDA from enforcing the in-person dispensation requirements under the REMS in light of the COVID-19 pandemic. *American College of Obstetricians and Gynecologists v. United States Food and Drug Administration*, 472 F. Supp. 3d 183 (D. Md. 2020).

In April 2021, FDA suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-person dispensing requirement had been enjoined, the availability of mifepristone by mail showed no increases in serious patient safety concerns. *Id.*, ¶ 105.

On May 7, 2021, FDA announced it would review whether the Mifepristone REMS Program should be modified. ECF No. 51-4. FDA reviewed materials between March 29, 2016 and July 26, 2021, as well as publications found on PubMed and Embase and those provided by "advocacy groups, individuals, plaintiffs in *Chelius v. Becerra*, 1:17-493-JAO-RT (D. Haw.), application holders, and healthcare providers and researchers. *Id.* at 10–11.

On December 16, 2021, FDA announced its conclusions regarding the Mifepristone REMS Program. ECF No. 51-5. On January 3, 2023, FDA accepted these conclusions by approving the supplemental applications proposing conforming modifications. ECF Nos. 51-8; 51-11. The 2023 REMS removed the in-person dispensing requirement and added a pharmacy-certification requirement.

ECF Nos. 51-4, 51-5. The FDA maintained the Prescriber and Patient Agreement Form requirements. *Id.*

DISCUSSION

The Court may grant summary judgment in favor of a moving party who demonstrates "that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In ruling on a motion for summary judgment, the court must only consider admissible evidence. *Orr v. Bank of America, NT & SA*, 285 F.3d 764, 773 (9th Cir. 2002). The party moving for summary judgment bears the initial burden of showing the absence of any genuine issues of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to identify specific facts showing there is a genuine issue of material fact. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Id*. at 252.

Under the APA, a court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary [and] capricious … or otherwise not in accordance with law [or] in excess of statutory … authority, or limitations." 5 U.S.C. § 706(2)(A), (C). Courts must uphold an agency action unless it (1) "relied on factors which Congress has not intended it to consider," (2) "entirely

failed to consider an important aspect of the problem," (3) "offered an explanation for its decision that runs counter to the evidence before the agency," or (4) the "decision is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Turtle Island Restoration Network v. U.S. Dep't of Commerce*, 878 F.3d 725, 732–33 (9th Cir. 2017) (internal quotation marks omitted). Additionally, a decision is arbitrary and capricious if it is internally inconsistent with the underlying analysis. *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1141 (9th Cir. 2015). Review is "at its most deferential" regarding an agency's scientific determinations within its area of expertise. *Baltimore Gas & Elec., Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1982).

Regulations are valid if they are "consistent with the statute under which they are promulgated." *United States v. Larionoff*, 431 U.S. 864, 873 (1977). Under the FDCA, a new drug cannot be marketed and prescribed until it undergoes a rigorous approval process to determine that it is safe and effective. 21 U.S.C. § 355. For certain drugs, a risk evaluation and mitigation strategy (REMS) is required when the agency determines, after considering six factors, it is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). An existing REMS may be modified or removed to "ensure the benefits of the drug outweighs the risks of the drug [or] minimize the burden on the

health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B).

Moreover, a REMS may include elements that are necessary to assure safe use [ETASU] due to a drug's "inherent toxicity or potential harmfulness" if the drug has "been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug." 21 U.S.C. § 355-1(f)(1)(A). A "serious adverse drug experience" is one that results in:

> death; an adverse drug experience that places the patient at immediate risk of death…; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or a congenital anomaly or birth defect; or based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent [such] an outcome.

21 U.S.C. § 355-1(b)(4)(A). If the FDA determines ETASU is required, the ETASU shall:

> not be unduly burdensome on patient access to the drug, considering in particular – patients with serious or life-threatening diseases or conditions; patient who have difficulty accessing health care (such as patients in rural or medically underserved areas); and patients with functional limitations; and to the extent practicable, so as to minimize the burden on the health care delivery system – conform with [ETASU] for other drugs with similar, serious risks; and be designed to be compatible with established distribution, procurement, and dispensing systems from drugs.

21 U.S.C. § 355-1(f)(2)(C)–(D).

Now that the Court has a full record, it is not the Court's role to review the scientific evidence and decide whether mifepristone's benefits outweigh its risks without REMS and/or ETASU. That is precisely FDA's role. However, based on the present record, FDA did assess whether mifepristone qualifies for REMS and ETASU based on the criteria set forth under 21 U.S.C. § 355-1(g)(4)(B). Even under a deferential review, it appears FDA fully considered the important aspect of the issues in this case and came to a reasonable conclusion.

The Court cannot find, based on the full record before it, that the FDA was arbitrary and capricious in its decision. The FDA did not ignore the laws that apply nor the regulations. The FDA reviewed materials between March 29, 2016 and July 26, 2021, not the subsequent Canadian study.

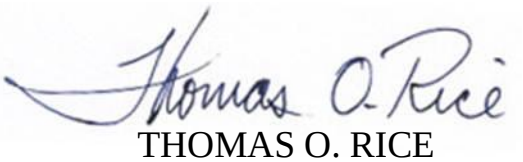
Defendants argue Plaintiffs lack standing, have not exhausted their administrative claims, and cannot assert Constitutional claims. Given this Court's disposition of the case, these issues are now moot.

ACCORDINGLY, IT IS HEREBY ORDERED:

1. The Preliminary Injunction (ECF No. 80) is **VACATED**.
2. Defendants' Cross-Motion for Summary Judgment (ECF No. 171) is **GRANTED**.
3. Plaintiffs' Motion for Summary Judgment (ECF No. 156) is **DENIED**.

The District Court Executive is directed to enter this Order and Judgment accordingly, and furnish copies to counsel, and **CLOSE** the file.

DATED July 8, 2025.



THOMAS O. RICE
United States District Judge