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 Honorable Robert Ballou

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

On January 3, 2023, Defendant U.S. Food and Drug Administration ("FDA" or "the Agency") issued a decision subjecting mifepristone—a prescription medication that millions of U.S. patients have used to end an early pregnancy—to a set of medically unjustified restrictions that reduce patient access to this essential medication and burden the healthcare delivery system. Plaintiffs move this Court for an order (1) granting summary judgment in their favor on the first and second causes of action in their Complaint,[1] Dkt. 1, (2) declaring the 2023 Risk Evaluation and Mitigation Strategy for mifepristone ("2023 Mifepristone REMS") unlawful under the Administrative Procedure Act ("APA"), as both beyond FDA's statutory authority and limitations and arbitrary and capricious and (3) either vacating the 2023 Mifepristone REMS in its entirety or remanding it to the FDA with instructions to reconsider the REMS, including its Elements to Assure Safe Use ("ETASU").

[1] The third and fourth causes of action in Plaintiffs' Complaint further allege that FDA's 2023 REMS Decision is unlawful under the under the APA as "contrary to constitutional right," 5 U.S.C. § 706(2)(B), and under the Equal Protection Clause because it singles out clinicians who prescribe, and pharmacists who dispense, medication abortion for onerous restrictions to which clinicians and pharmacists prescribing other, less safe drugs are not subject. Plaintiffs are not moving for summary judgment on these two claims.

As explained in greater detail in the accompanying Memorandum of Law, FDA's 2023 Mifepristone REMS, which maintained the Prescriber Certification and Patient Agreement ETASUs and added a new Pharmacy Certification ETASU, exceeds FDA's statutory authority and limitations because the Agency did not address statutory criteria that Congress directed FDA "shall" consider in approving or modifying a REMS or ETASU.

The 2023 Mifepristone REMS is also arbitrary and capricious because: (a) FDA refused to examine unquestionably relevant data, including statements from the nation's leading medical professional societies explaining why the REMS and ETASU are unnecessary in light of existing professional and ethical standards governing healthcare providers; (b) FDA's decision was unreasoned, relying on speculative assumptions and faulty logic; and (c) FDA failed to address evidence that FDA improperly regulates mifepristone—which medical experts agree is safer than Tylenol and penicillin—more stringently than other, more harmful products.

Plaintiffs make this Motion pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 56 and in accordance with the scheduling order stipulated to by the parties and entered by the Court. *See* Dkts. 56, 57. Summary judgment is supported by the accompanying Memorandum of Law, by the relevant portions of the administrative record to be filed on April 1, 2025, and by any reply or other submissions that Plaintiffs file in further support of their motion. Oral argument is scheduled for May 8, 2025 at 10:00 AM. Dkt. 58.

Plaintiffs respectfully request that the Court enter an Order (a) declaring that FDA's 2023 Mifepristone REMS, including its ETASU, exceed FDA's statutory authority and limitations and are arbitrary and capricious; (b) either vacating the 2023 Mifepristone REMS or remanding it to FDA for reevaluation in accordance with the specific directives set forth in the proposed Order attached

to this Motion as Exhibit A; and (c) awarding Plaintiffs their costs, expenses and reasonable attorneys' fees pursuant to 28 U.S.C. § 2412.

DATED: October 23, 2024

Respectfully submitted,

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