IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; WHOLE WOMAN'S HEALTH, on behalf of itself, its staff, and its patients; WHOLE WOMAN'S HEALTH OF THE TWIN CITIES, LLC, on behalf of itself, its staff, and its patients; BLUE MOUNTAIN CLINIC, on behalf of itself, its staff, and its patients; HELEN WEEMS, APRN-FNP on behalf of herself and her patients; ALL FAMILIES HEALTHCARE, on behalf of itself, its staff, and its patients; and TRUST WOMEN FOUNDATION, on behalf of itself, its staff, and its patients, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services, Defendants.	Case No. 3:23-cv-00019-NKM

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs Whole Woman's Health Alliance, Whole Woman's Health, Whole Woman's Health of the Twin Cities, LLC, Blue Mountain Clinic, Helen Weems, All Families Healthcare, and Trust Women Foundation ("Plaintiffs"), each on behalf of itself, its staff, and its patients, respectfully move for a preliminary injunction pursuant to Fed. R. Civ. P. 65.

The Complaint in this action seeks declaratory and injunctive relief against the Risk Evaluation and Mitigation Strategy for mifepristone promulgated by the U.S. Food and Drug Administration ("FDA") in 2023 (the "2023 REMS") because it exceeds FDA's statutory authority;

is contrary to law; is arbitrary and capricious; and is an equal protection violation. In this motion, Plaintiffs seek narrow preliminary relief enjoining Defendants from deviating from the status quo of provision of mifepristone under the 2023 REMS during the pendency of this litigation. This relief is necessary to ensure some modicum of clarity around, and continued patient access to, mifepristone: a safe, effective, and essential medication that has been repeatedly targeted by anti-abortion activists who have been emboldened by FDA's overregulation of mifepristone through the REMS. *See, e.g.*, *All. for Hippocratic Med. v. FDA*, No. 2:22-CV-223-Z (N.D. Tex.) (the "*Alliance* Case").

Plaintiffs satisfy all of the required elements for preliminary injunctive relief. *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 20 (2008); *League of Women Voters of N.C. v. North Carolina*, 769 F.3d 224, 236 (4th Cir. 2014). First, Plaintiffs are likely to succeed on the merits of their claims that the 2023 REMS violates the Administrative Procedure Act. The FDA has consistently and correctly concluded that mifepristone is safe and effective, while continuing to saddle it with a uniquely burdensome regulatory scheme, which disrupts patients' access to mifepristone with no justification. These restrictions have become increasingly irrational as decades of research and experience show mifepristone to be one of the safest medications available in the United States, as attested by all mainstream medical organizations to have opined about mifepristone. Second, the recent chaos surrounding mifepristone and its regulation—driven by years of stigma generated by the REMS—subjects Plaintiffs and their patients to irreparable harm. For example, from one development to another in the *Alliance* Case, Plaintiffs experienced repeated whiplash with respect to their provision of mifepristone, with resulting harm to patients. Finally, the balance of the equities and the public interest favor granting a preliminary injunction, as injunctive relief would

alleviate this chaos and confusion and promote timely access to essential reproductive healthcare in the states where Plaintiffs provide care.

WHEREFORE, Plaintiffs respectfully request that this Court issue a preliminary injunction preventing the Defendants, and their officers, agents, servants, employees, attorneys, and any persons in active concert or participation, from altering the status quo and their rights, as they relate to the January 2023 Risk Evaluation and Mitigation Strategy promulgated by the FDA under 21 U.S.C. § 355-1 in the states of Virginia, Montana, and Kansas, where Plaintiffs operate, pending a decision on the merits.

This motion is supported by a memorandum of law and the declarations of Amy Hagstrom-Miller, Nicole Smith, Helen Weems, and Rebecca Tong, which will be filed contemporaneously.

DATED: May 8, 2023

Respectfully submitted,

/s/ Gail Deady
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Attorneys for Whole Woman's Health Alliance; Whole Woman's Health; Whole Woman's Health of the Twin Cities; Blue Mountain Clinic; Helen Weems; All Women's Health; and Trust Women Foundation

**Pro Hac Vice* Application Pending

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of May, 2023, I filed the foregoing document with the Clerk of Court using the CM/ECF system, and I hereby certify that I will mail by United States Postal Service Certified Mail the document to the following non-CM/ECF participants:

United States Department of Health & Human Services
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Chief Counsel, Food and Drug Administration
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I also hereby certify that on this 8th day of May, 2023, the foregoing document will be hand served to:

U.S. Attorney Christopher Kavanaugh
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