

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

CLERKS OFFICE US DISTRICT COURT
AT CHARLOTTESVILLE, VA
FILED

July 23, 2026

LAURA A. AUSTIN, CLERK

BY: /s/ Nik Sams
DEPUTY CLERK

WHOLE WOMAN'S HEALTH
ALLIANCE, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Civil Action No.: 3:23-CV-00019

By: Hon. Robert S. Ballou
United States District Judge

ORDER

For the reasons set forth in the accompanying Memorandum Opinion, Plaintiffs' motion for summary judgment is **DENIED** as to Count I and **GRANTED** as to Count II. Defendants' cross-motion for summary judgment is **GRANTED** as to Count I and **DENIED** as to Counts II, III, and IV. The Court **DECLARES** the 2023 REMS unlawful under the Administrative Procedure Act as arbitrary and capricious. Before remanding the matter to the FDA to reconsider the mifepristone REMS in accordance with this order and the law, the Court must first resolve the pending constitutional claims.

Plaintiffs did not seek summary judgment on their constitutional claims and because the Court denies Defendants' cross-motion on these claims, they remain pending. However, arbitrary and capricious agency action necessarily lacks any rational basis. As such, Plaintiffs' constitutional claims appear to be coextensive with their successful APA challenge to the 2023 REMS. Given this unique posture, the Court **DIRECTS** the parties to file a joint status report within 10 days of this order setting forth their positions on how this case should proceed as to the

constitutional claims. The remand order will be entered following determination of the status of the constitutional claims.

It is so **ORDERED**.

Entered: July 23, 2026

Robert S. Ballou

Robert S. Ballou
United States District Judge