

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN CLINICAL LABORATORY ASSOCIATION, ET AL. v. U.S. FOOD AND DRUG ADMINISTRATION, ET AL.	§ § § § § § § § § §	CASE NO. 4:24-CV-479-SDJ
ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL. v. U.S. FOOD AND DRUG ADMINISTRATION, ET AL.	§ § § § § § § § § §	CASE NO. 4:24-CV-824-SDJ

FINAL JUDGMENT

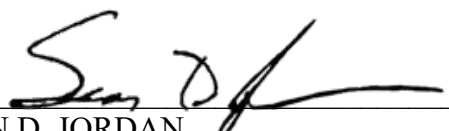
For the reasons set forth in the Court’s Memorandum Opinion and Order on this date, (Dkt. #93), it is **CONSIDERED, ORDERED,** and **ADJUDGED** that Plaintiffs’ Motions for Summary Judgment, (Dkt. #20, #27), are **GRANTED.** Defendants’ Cross-Motion for Summary Judgment, (Dkt. #54), is **DENIED.** The Court thus enters Final Judgment in favor of Plaintiffs the American Clinical Laboratory Association (“ACLA”), HealthTrackRX Indiana, Inc., and HealthTrackRX, Inc. (collectively, “HealthTrackRX”), the Association for Molecular Pathology (“AMP”) and Michael Laposata, M.D., and against Defendants, United States Department of Health and Human Services, the Food and Drug

Administration, Robert F. Kennedy, Jr., and Sara Brenner, M.D. in their official capacities.

It is further **ORDERED, ADJUDGED, and DECREED** that:

1. Final Judgment is entered in favor of Plaintiffs ACLA and HealthTrackRX on Count I in the Complaint in Cause Number 4:24-cv-479. (Dkt. #1 at ¶¶ 131–137). Final Judgment is also entered for Plaintiffs AMP and Dr. Laposata on Count I in the Complaint in Cause Number 4:24-cv-824 (Dkt. #1 at ¶¶ 122–152).
2. The Court does not reach Plaintiffs ACLA and HealthTrackRX’s Count II in the Complaint in Cause Number 4:24-cv-479 (Dkt. #1 at ¶¶ 138–142). Nor does the Court reach Plaintiffs AMP and Dr. Laposata’s Count II in the Complaint in Cause Number 4:24-cv-824 (Dkt. #1 at ¶¶ 153–159).
3. The Court **VACATES** and **SETS ASIDE**, in its entirety, the FDA’s Final Rule titled Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286 (May 6, 2024) (to be codified at 21 C.F.R. § 809). The Court remands this matter to the Secretary of Health and Human Services for further consideration.
4. The Court **DENIES** all other requested relief. Any pending motions are **DENIED** as **MOOT**.
5. The Clerk is directed to close these consolidated actions.

So ORDERED and SIGNED this 31st day of March, 2025.


SEAN D. JORDAN
UNITED STATES DISTRICT JUDGE