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The National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB) filed an Amicus Brief in support of the American Clinical Laboratory Association (ACLA) and the Association for Molecular Pathology (AMP) in their Lawsuits Against the Food and Drug Administration's (FDA's) Final Rule on Laboratory Developed Tests (LDT)

The National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB) along with the American Society for Clinical Pathology, the American Society for Microbiology, the Association for Diagnostics & Laboratory Medicine, and the Infectious Disease Society of America submitted an Amicus Brief on October 7, 2024, in support of the American Clinical Laboratory Association (ACLA) and the Association for Molecular Pathology (AMP) in their lawsuits against the Food and Drug Administration (FDA). ACLA and AMP filed lawsuits against the FDA over the Final Rule on Laboratory Developed Tests (LDTs), which classifies and regulates LDTs as medical devices. The ACLA and AMP lawsuits were subsequently consolidated into a single action. ACLA and AMP are suing the FDA as they state the FDA does not have authority to regulate LDTs as medical devices.

NILA and AAB assert that the FDA Final Rule is unreasonable on several grounds. Among NILA and AAB's arguments is that Congress has not authorized the FDA to regulate LDTs; rather, Congress established the Clinical Laboratory Improvement Amendments (CLIA) to regulate LDTs. NILA and AAB argue that the FDA is overstepping its authority through this Final Rule.

NILA and AAB also emphasize that the FDA Final Rule will make LDTs—tests that are critically necessary and relied upon for years by treating physicians—inaccessible to patients because of the increased administrative and financial burdens that FDA's Final Rule will have upon laboratories that develop LDTs. The impact of the Final Rule will fall disproportionately on community and regional clinical laboratories, especially those with niche specialties, and clinical laboratories that support rural and other medically underserved communities. With fewer laboratories producing LDTs, access to these essential tests will be limited for patients.

"It is about accessibility" says Mark Birenbaum, PhD, executive director of AAB and NILA. "Many of our members are concerned about limiting their testing menu and halting research on new LDTs. We don't want to see a crisis in patient access occur because of these new regulations."

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About NILA and AAB: *NILA represents community, regional, and specialty clinical laboratories across the U.S., providing essential testing services to diverse patient populations. AAB, established in 1956, includes clinical laboratory professionals dedicated to supporting community and specialty laboratories in delivering critical diagnostic services.*