Veranex

Panel Discussion

FDA's Regulation on LDTs: Current Impact and Future Implications

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Speakers

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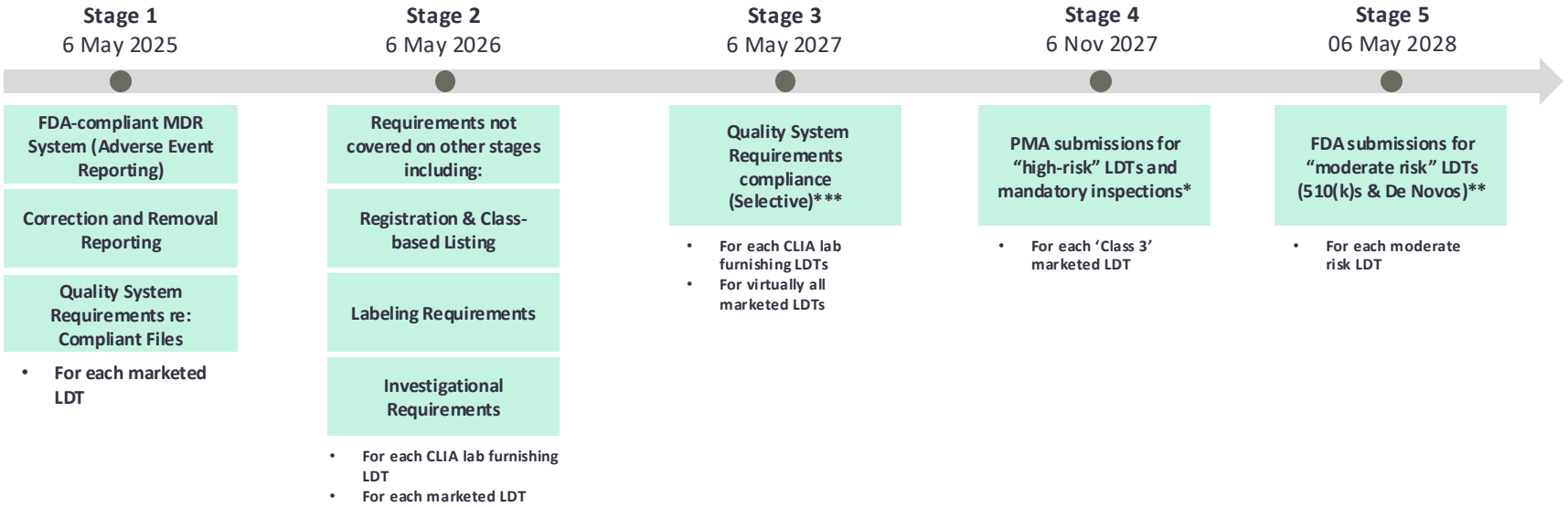
Final rule rollout features major changes to regulatory requirements for LDT and RUO tests, including full QMS requirements for LDTs by May 2027

Final Rule has similar timeline as the proposed Rule, and the FDA will phase out enforcement discretion for virtually all LDTs in five stages over four years from the date of final publication

Timeline applies to all LDTs unless an exception applies. In the Final Rule, FDA expands the list of tests that will be eligible for some form of continued enforcement discretion (i.e., "grandfathering")



*Unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion
**To streamline the process, labs can utilize the FDA's Third-Party review program for submissions
*** Select QSR elements such as design controls, purchasing controls, acceptance activities, CAPA, and records
https://www.federalregister.gov/documents/2024/05/06/2024-08935/medical-devices-laboratory-developed-tests
MDR: Medical Device Reporting

Reactions to the Proposed FDA Oversight of LDTs

April 29, 2024
FDA's Final Rule Announced

May 6, 2024
FDA's Final Rule Published

May 17, 2024
Congressmen and Senator introduced Resolution in the U.S. Senate

May 29, 2024
ACLA filled a lawsuit against FDA

May 30, 2024
ARUP Files Declaration to Support Lawsuit Challenging the FDA's Rule to Regulate LDTs

July 15, 2024
House committee tells FDA to suspend lab developed test rule

August 19, 2024
AMP filled a lawsuit against FDA

PRESS RELEASES

Reps. Finstad and Crenshaw, Sen. Paul Introduce Resolution to Repeal Harmful FDA Rule Limiting Access to Laboratory Developed Tests

May 17, 2024

WASHINGTON, D.C. – U.S. Congressmen Brad Finstad (MN-01) and Dan Crenshaw (TX-02) introduced a resolution under the Congressional Review Act (CRA) to repeal *Medical Devices: Laboratory Developed Tests* (LDTs), a rule that was recently finalized by the Food and Drug Administration (FDA). U.S. Senator Rand Paul (R-KY) introduced the resolution in the U.S. Senate. The final rule, published May 6th, seeks to impose burdensome regulations on the creation and implementation of laboratory developed tests (LDTs), limiting patients' access to critical diagnostic testing.

Oftentimes LDTs are the only or most reliable option available within the U.S. healthcare system that provide timely results to patients with rare diseases and conditions. Specifically, implementation of FDA's rule would:

- Impose regulatory burdens that hinder the development and deployment of new and improved lab-developed tests;
- Increase regulatory requirements that will lead to delays in patients' access to critical diagnostic tests;
- Potentially hinder collaborative efforts in clinical care that rely on the flexibility provided by LDTs; and,
- Negatively impact small and medium-sized laboratories, which will face economic challenges with complying with the rule as written.

"Minnesota's First District is home to some of the most cutting-edge medical innovation in the world. With new technologies emerging every day, diagnostic testing is more advanced than ever before, largely thanks to laboratory developed tests," said Rep. Finstad. "This harmful rule from FDA will stifle the development of new methods of testing, delay access to patient care, and impact many of the laboratories that we depend on in southern Minnesota for accurate, timely diagnostic testing. I am proud to introduce this resolution with Rep. Crenshaw to protect LDTs from overregulation and strengthen the relationship between medical innovation and patient care."

"This rule is the biggest unilateral expansion of FDA regulation in recent years. Unelected bureaucrats are saying they know better than the diagnostic developers and clinicians that make Houston a capitol for medical innovation," said Rep. Crenshaw. "This is a clear case of unreasonable, overregulation that will cost billions of dollars and put lives at risk by stifling medical innovation. I'm proud to cosponsor this legislation to revoke the rule so that Congress prevents executive overreach and reasserts its role as the first branch of government."

"This is yet another brazen power grab by the FDA under the direction of President Biden," said Dr. Paul. "Unnecessary regulations on lab developed tests threaten to delay critical diagnostics and undermine healthcare innovation. This CRA is a step towards preserving the innovation and flexibility needed to address emerging medical challenges and safeguard patient health."

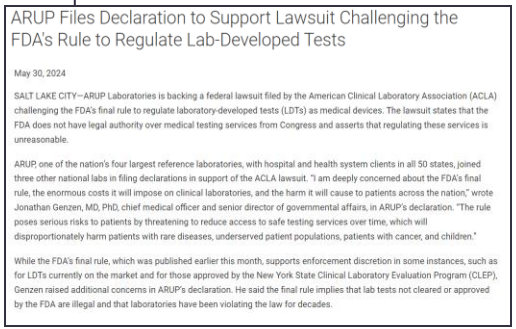
ACLA CHALLENGES FDA'S FINAL RULE TO REGULATE LABORATORY DEVELOPED TESTING SERVICES AS MEDICAL DEVICES

May 29, 2024 | Categories: Public Health Preparedness and Infrastructure, Value of Clinical Labs: The Power of Knowing, ACLA News, ACLA In The News, Featured News, ACLA Press Releases, Regulatory Issues

Washington, D.C. – Today the American Clinical Laboratory Association (ACLA) and its member company, HealthTrackRx, filed a lawsuit against the U.S. Food and Drug Administration (FDA) in the United States District Court for the Eastern District of Texas, challenging the Agency's May 6, 2024, Final Rule, which inappropriately seeks to regulate professional laboratory testing services as medical devices under the *Federal Food, Drug, and Cosmetics Act* (FDCA).

Congress has never granted FDA authority to regulate the professional testing services that laboratories provide, which are federally regulated by the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA).

For years, ACLA has worked collaboratively with Congress, FDA and other stakeholders to develop legislation that would establish an appropriate regulatory framework for diagnostics. Rather than continue that dialogue, FDA chose instead to act unilaterally and impose an ill-fitting device regime on laboratory testing services. Given the far-reaching negative impacts on our nation's laboratory community, ACLA believes it must bring this lawsuit to clarify that FDA's Final Rule exceeds its authority. The lawsuit challenges the Final Rule because FDA has exceeded its statutory authority and acted arbitrarily and capriciously in violation of the *Administrative Procedure Act*.



ARUP Files Declaration to Support Lawsuit Challenging the FDA's Rule to Regulate Lab-Developed Tests

May 30, 2024

SALT LAKE CITY—ARUP Laboratories is backing a federal lawsuit filed by the American Clinical Laboratory Association (ACLA) challenging the FDA's final rule to regulate laboratory-developed tests (LDTs) as medical devices. The lawsuit states that the FDA does not have legal authority over medical testing services from Congress and asserts that regulating these services is unreasonable.

ARUP, one of the nation's four largest reference laboratories, with hospital and health system clients in all 50 states, joined three other national labs in filing declarations in support of the ACLA lawsuit. "I am deeply concerned about the FDA's final rule, the enormous costs it will impose on clinical laboratories, and the harm it will cause to patients across the nation," wrote Jonathan Genzen, MD, PhD, chief medical officer and senior director of governmental affairs, in ARUP's declaration. "The rule poses serious risks to patients by threatening to reduce access to safe testing services over time, which will disproportionately harm patients with rare diseases, underserved patient populations, patients with cancer, and children."

While the FDA's final rule, which was published earlier this month, supports enforcement discretion in some instances, such as for LDTs currently on the market and for those approved by the New York State Clinical Laboratory Evaluation Program (CLEP), Genzen raised additional concerns in ARUP's declaration. He said the final rule implies that lab tests not cleared or approved by the FDA are illegal and that laboratories have been violating the law for decades.

AMP Association for Molecular Pathology

Association for Molecular Pathology
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Association for Molecular Pathology Files Lawsuit Against FDA to Challenge Final Rule on Regulation for Laboratory Developed Testing Procedures

Drastic policy change will stifle diagnostic innovation, impose billions of unnecessary dollars in healthcare mandates, and threaten patient access to essential medical procedures

ROCKVILLE, Md. – August 19, 2024 – The Association for Molecular Pathology (AMP), the premier global

House committee tells FDA to suspend lab developed test rule

Lawmakers said the final rule carries "the risk of greatly altering the United States' laboratory testing infrastructure."

Published July 15, 2024

ACLA: American Clinical Laboratory Association
ARUP Laboratories is a national nonprofit and academic reference laboratory
AMP: Association of Molecular Pathology

Thank you!

Amit Kumar Jain

Vice President

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