May 12, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Kennedy:

The undersigned medical professional organizations urge the Trump Administration *not* to appeal a recent U.S. District Court opinion vacating a U.S. Food and Drug Administration (FDA) rule claiming oversight of Laboratory Developed Tests (LDTs).

In the case, **American Clinical Laboratory Association et al. vs. FDA**, plaintiffs challenged a rule fast tracked by the Biden Administration giving FDA oversight authority of LDTs. **In his decision, Judge Sean D. Jordon of the U.S. District Court (Texas, Eastern Division), ruled that "FDA's final rule exceeds its authority and is unlawful.**" Jordon wrote that "…the text, structure, and history of the [Federal Food, Drug, and Cosmetic Act] FDCA and [Clinical Laboratory Improvement Amendments] CLIA make clear that FDA lacks the authority to regulate laboratory-developed test services." He also stated, "*FDA's asserted jurisdiction over laboratory-developed test services as "devices" under the FDCA defies bedrock principles of statutory interpretation, common sense, and longstanding industry practice*."

LDTs are laboratory testing services developed by and used within a single laboratory and include modifications of commercial, FDA-approved tests. These services are often developed by laboratories because no existing, FDA-approved test meets patient needs. LDTs are already closely regulated by the Centers for Medicare and Medicaid Services (CMS) per the Clinical Laboratory Improvement Amendments (CLIA) of 1988. This statute sets federal standards for laboratory testing of human specimens to assess patient health and to diagnose, prevent, or treat disease. As a result, *the FDA's rule would have imposed a cumbersome, expensive, time-consuming and duplicative oversight process that would likely prevent most clinical laboratories—including those at academic medical centers—from providing these quality testing services to their patients*.

During President Donald Trump's first term, U.S. Health and Human Service (HHS) Secretary Alex Azar blocked the FDA from claiming oversight authority over LDTs. **Secretary Azar's decision** was based on a legal opinion drafted by HHS General Counsel Robert Charrow arguing that FDA lacked statutory authority to provide oversight over LDTs.

The undersigned organizations, some of whom submitted an amicus brief (See **here** and **here**) on behalf of the plaintiffs, believe that FDA's oversight of LDTs would fundamentally undermine patient access to quality care by imposing expensive and duplicative oversight burdens on clinical laboratories without improving patient outcomes.

As noted in the Judge's decision, "the final rule will initially impact nearly 80,000 existing tests offered by almost 1,200 laboratories, and it will also affect about 10,013 new tests offered every year going forward. The estimated compliance costs for laboratories across the country will total well over $1 billion per year, and over the next two decades, FDA projects that total costs associated with the rule will range from $12.57 billion to $78.99 billion. FDA acknowledges that the enormous increased costs to laboratories may cause price increases and reduce the amount of revenue a laboratory can invest in creating and modifying tests." This flawed rule would massively undermine patient access to testing services, including where no alternative commercial diagnostic is available.

In declining to appeal Jordon's decision, the Trump Administration would be sending a clear signal to the FDA and Congress that LDTs require a different oversight approach—one that is nimble and free of FDA's excessive bureaucratic and costly requirements. *CLIA offers the only realistic regulatory oversight program that can provide effective oversight while ensuring that patients are able to access these lifesaving and innovative testing services*.

We appreciate your consideration of our concerns and would be happy to answer any questions.

Sincerely,

American College of Medical Genetics and Genomics
American Society for Clinical Pathology
Association for Academic Pathology
Association for Diagnostics & Laboratory Medicine

cc: Heather Flick Melanson, HHS, OS
Stefanie Spear, HHS, OS
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