AMERICAN CLINICAL LABORATORY ASSOCIATION

March 4, 2024

Shalanda Young
Director
Office of Management and Budget
1650 Pennsylvania Avenue, NW
Washington, DC 20500

Neera Tanden
Director
Domestic Policy Council
1600 Pennsylvania Avenue NW
Washington, DC 20500

Re: FDA Regulation of Laboratory Developed Tests

Dear Director Young and Director Tanden:

I am writing regarding FDA's plan to promulgate a final rule that would subject laboratory developed tests (LDTs) to regulation as medical devices. This rule—rushed through the administrative process despite its sweeping implications for the nation's healthcare system—would have a devastating impact on clinical laboratories and the patients they serve. We request a meeting with you and your colleagues to discuss this rule and explain why it is deeply misguided from both substantive and process perspectives.

I represent the American Clinical Laboratory Association (ACLA), which is the national trade association for leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members provide testing services to patients in every state and territory in the U.S. The services laboratories provide inform 70 percent of clinical decisions, improve patient outcomes, and advance the next generation of personalized care. ACLA member laboratories are at the forefront of developing tests to respond to emerging health issues, including during the COVID-19 and MPox public health emergencies, and other unmet medical needs. Many of the most meaningful advances in diagnosing diseases and conditions achieved over the past several decades—from groundbreaking BRCA testing for ovarian/breast cancer to tests for fentanyl with xylazine, which are essential to addressing the ongoing and devastating opioid public health emergency—are the result of innovation by clinical laboratories. The testing services these laboratories provide are also critical to ensuring health equity and access for underserved communities, including for patients with rare diseases.

Last August, after FDA announced its intent to issue a proposed rule that would regulate laboratory developed tests as medical devices, ACLA met with the Office of Management and Budget and the Domestic Policy Council. During that meeting and in related discussions with the FDA and HHS, ACLA encouraged the Administration to reengage with Congress and stakeholders to advance appropriate legislation. The goal of legislation should be to create a diagnostics-specific regulatory framework that would avoid harming patients, laboratories, and the broader economy. Appropriate legislation would recognize the unique characteristics of diagnostics, the essential role of clinical laboratories, and the existing statutory authority for regulation under the Clinical Laboratory Improvement Amendments, and it would also protect patient access to essential laboratory developed testing services while fostering innovation through mechanisms that keep pace with scientific advancements. ACLA collaborated closely with FDA, Members of Congress, and other stakeholders to advance and improve diagnostics regulatory reform legislation, commonly known as the VALID Act, which would have provided FDA with new legal authority and established an appropriate regulatory framework specifically

designed for diagnostic tests. Although that legislation has not yet been enacted by Congress, it was reintroduced in the current Congress and remains a viable option. ACLA continues to believe that carefully crafted legislation is essential to providing FDA the authorities and tools necessary to regulate the dynamic universe of laboratory developed tests, including appropriate tools to handle the volume and breadth of diagnostic tests, without causing harm to patients, the nation's healthcare system, or the broader economy.

Instead of continuing to work with Congress and stakeholders to advance legislation, FDA chose to act unilaterally and, despite the serious harm and disruptions that will result, is attempting to regulate laboratory developed testing services under the existing medical device framework. As ACLA explained at length in our comments to FDA's docket (available here), FDA's proposal is ill-considered, both from a legal and a public policy perspective. In addition to our comments, more than 6000 comments were submitted to that docket by other stakeholders. Notwithstanding the numerous deficiencies and the significant public engagement on this topic, FDA has announced plans to finalize this rule by April 2024. Given that FDA rulemaking typically is measured in years, not months, this timeline also raises process concerns, notably that FDA does not intend to fairly consider public comments before moving forward with a rule that would cause immense disruptions and harm by fundamentally reshaping a key pillar of our health care system.

We have numerous concerns with FDA finalizing this rule, including:

- Regulating laboratory developed testing services as medical devices would divert resources and impede innovation that is essential to economic growth. It would also harm patients by slowing the next generation of diagnostics to fight cancer, infectious diseases and pandemics, neurological conditions such as Alzheimer's, cardiovascular diseases, scores of rare adult and pediatric diseases for which laboratory developed tests are the only available diagnostic option, and numerous other disease categories. Forcing laboratories to invest in a backwards-looking exercise to justify existing diagnostic tests—many of which have been relied on by physicians for decades—would draw scarce resources away from advancing innovative tests, improving existing tests, or investing resources in diagnostics critical to fighting the next pandemic.

- Regulating laboratory developed tests as medical devices would undermine health equity. There are numerous examples of testing services that are developed for underserved patient groups, including tests for diseases that disproportionately impact certain racial or ethnic communities, or which are designed to serve subpopulations, such as children. Adding the cost and burden of ill-fitting FDA regulation under the medical-device framework would stifle investment in and development of these diagnostic tests, as many do not generate sufficient revenue to support the expense of FDA approval or clearance as medical devices.

- Regulating laboratory developed tests as medical devices would unnecessarily increase health care costs and undermine access. FDA regulation would add significant time and expense to developing and offering novel diagnostics, not to mention the post-market costs imposed by medical-device regulation (reporting, quality systems, etc.), most of which is ill-suited for laboratory services and/or duplicative of existing requirements for laboratories. These added costs would be imposed at the same time that reimbursement for laboratory testing is subject to cuts—current law will result in up to 15 percent

reductions in Medicare payment for about 800 clinical laboratory tests, absent congressional intervention.

These and other harms arise in large part because laboratory developed tests are not medical devices. They are instead health care services—methods of using instruments, reagents, and tools to derive diagnostic information that have tremendous utility to treating clinicians, patients, and public health. Subjecting these highly skilled professional services to a regulatory system intended for mass-manufactured products makes little sense. The differences between medical devices and laboratory testing services are seen every day. Consider the cancer space: Physicians routinely turn to the professional testing services provided by clinical laboratories because FDA-approved medical devices serve different purposes and are often unable to keep pace with scientific advances. FDA regulation would curtail that pace of evolution and improvement, to the detriment of patient care.

It is all but certain that FDA would become a bottleneck that would curtail patient access to necessary testing services. By FDA's own estimates in its proposed rule (which are likely low), the number of premarket approval applications (PMAs) required in the first year of regulation would be more than the cumulative number of PMAs processed by FDA in the entire 45+ year history of FDA premarket review. That would be on top of a similarly large flood of de novo classification requests and a significantly larger avalanche of 510(k)s. FDA does not have resources to deal with all of these demands, and there are not enough qualified regulatory and scientific professionals for FDA to ramp up its resources, especially given that laboratories would be vying to hire the same professionals to support their additional regulatory workload.

ACLA continues to urge the Administration to work with Congress and stakeholders, including our association, to craft an appropriate, diagnostic-specific framework. The consequences of regulating essential and dynamic laboratory developed testing services with a framework designed for manufactured products will be felt immediately by the economy and by patients and providers, who will lose access to the testing services they need. Accelerating rulemaking belies the fact that there is no systemic public-health problem to be solved. In our comments, ACLA demonstrates that FDA's justification for its rule is built on anecdotes, unproven allegations from lawsuits, outdated studies, and cherry-picked examples that fail to paint a balanced or accurate picture. FDA's reliance on flawed and unreliable information led to FDA dramatically understating the far-reaching costs and seriously overstating the benefits of regulating laboratory services as medical devices. This approach should not be acceptable for a regulatory action that would impact an entire industry and the millions of patients it serves.

As ACLA discussed in our comments, FDA's attempt to regulate laboratory developed tests as medical devices also suffers from fatal legal flaws and raises serious constitutional questions. In short, laboratory developed tests do not meet the definition of a "device" in the Food, Drug, and Cosmetic Act, and, as a result, FDA does not have jurisdiction to regulate them. This understanding is confirmed by the legislative history and overall structure of the relevant statutory scheme.

Given the serious consequences for patients, the economy, and our healthcare system as a whole, rather than rush a misguided rule through the administrative process, FDA should, at a minimum, utilize other tools for public engagement, such as issuing a request for information (RFI) to collect reliable information to inform its regulatory proposals. FDA should also return to the

legislative table to develop a regulatory system that accounts for the unique features of diagnostics and appropriately preserves innovation and access to critical tests. ACLA is committed to working with the Agency, Congress, and other stakeholders to craft such legislation.

We look forward to engaging with you and your staff on these important topics.

Sincerely,

Susan Van Meter
President
American Clinical Laboratory Association

Cc: William Morice, President and CEO, Mayo Collaborative Services, Mayo Cinic Laboratories
Scott Danzis, Partner, Covington & Burling LLP