AMERICAN CLINICAL LABORATORY ASSOCIATION

August 7, 2023

Shalanda Young
Director
Office of Management and Budget
1650 Pennsylvania Avenue, NW
Washington, DC 20503

Christopher Spiro
Associate Director, Health Programs
Office of Management and Budget
1650 Pennsylvania Avenue, NW
Washington, DC 20502

Re: ACLA Meeting on FDA Proposed Rule to Regulate Laboratory Developed Tests

Dear Director Young and Associate Director Spiro:

We look forward to meeting with members of your office tomorrow, August 8th. In advance of that discussion, we wanted to outline some of the topics that we hope to discuss with your office in our meeting.

The American Clinical Laboratory Association (ACLA) is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, 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 among others COVID and monkeypox), and they frequently innovate new areas of science. LDTs developed by ACLA members play a unique and critical role in delivering healthcare to patients. There are countless examples of tests that are available only as LDTs – or that were pioneered as LDTs before IVDs became available. As just two of many examples, testing for fentanyl and xylazine rely on LDTs since there are no such FDA-cleared or -approved tests available.

Laboratories that offer LDTs have long been subject to federal and state regulation, including rigorous accreditation standards. Even with that existing regulatory oversight, last year ACLA closely collaborated with FDA, Congress, and other stakeholders to develop and refine legislation, the VALID Act, that would have provided FDA with statutory authority to regulate LDTs. ACLA believes that if FDA is to regulate LDTs, legislation is necessary to establish a system with appropriate clarity and predictability. The VALID Act included provisions that were tailored to the regulation of diagnostic tests, including LDTs. ACLA remains committed to working constructively with FDA and Congress on a legislative solution to establish a diagnostic-specific regulatory framework.

Notwithstanding Congress's decision not to enact legislation granting FDA authority over LDTs, FDA has announced that it plans to regulate LDTs using its preexisting authority under the Food, Drug and Cosmetic Act (FDCA) for devices. ACLA has significant policy and legal concerns with FDA regulation of LDTs under the agency's existing device authority.

First, FDA's medical device authority is ill-suited for laboratory diagnostics because it was never

intended for that purpose. The medical device framework was designed for products that are manufactured and distributed to third parties, not LDTs, which are services developed and performed by the same laboratory. The device framework is rigid and cannot account for the dynamic nature of laboratory diagnostics which rely on the expertise of laboratory professionals. In fact, LDTs are subject to frequent modifications to adjust and fine-tune their performance. New targets emerge and laboratories frequently use novel combinations of multiple markers to identify diseases and conditions. The medical device framework is not suitable for this pace of change; premarket review of all such changes would ground laboratory services to a halt. To account for this, the VALID Act would have included Technology Certification, a novel program that could have allowed for modifications to enhance and improve test performance as science changes. FDA does not have the authority under device law to establish such a Technology Certification program.

Second, device regulation could undermine access to critical tests and slow innovation. The device clearance/approval process would add months or years to the development lifecycle for new diagnostics, and will restrict modifications that improve the accuracy or scope of existing tests. These added administrative costs would be imposed at the very time when reimbursement for testing is being cut. Device regulation would lead to laboratories being forced out of business or investing less in research and development.

Third, device regulation would interfere with the practice of medicine. Turning laboratories into device manufacturers would restrict the ability of laboratory medical directors from practicing the art and science of laboratory medicine. Moreover, consultations between ordering physicians and laboratory directors would be regulated and restricted by the FDCA (*e.g.,* restricting discussion about off-label uses of tests).

Fourth, FDA/CDRH lacks the expertise and capacity to regulate LDTs given its current resources and focus. FDA cannot keep up with its existing regulatory responsibilities. To add tens of thousands of new tests to FDA's responsibility would overwhelm the regulatory system and negatively impact patients. For context, New York's clinical laboratory program, which requires approval of LDTs offered to New York residents, lists over 10,000 LDTs approved by the state.

All of these issues arise in a situation where there is no public health problem to be solved. In fact, every day, physicians and patients successfully rely on LDTs to make more informed medical decisions, leading to better patient outcomes and lower costs for our health care system.

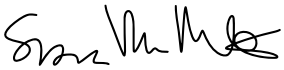
Compounding these problems, FDA's legal authority to regulate LDTs is weak, at best. The FDCA provides FDA with jurisdiction over tangible medical products that are distributed in interstate commerce. But LDTs are neither tangible products, nor are they distributed in interstate commerce. Rather, LDTs are professional services provided by laboratories. The history of the FDCA and the Clinical Laboratory Improvement Amendments (CLIA) makes clear that Congress never granted FDA authority over LDTs – not to mention the fact that Congress considered and rejected FDA authority over LDTs just last year. Even the HHS General Counsel in 2020 took the position that FDA had questionable legal authority to regulate LDTs. And finally, recent jurisprudence – including but not limited to the strengthening of the "major questions" doctrine – suggests that courts would look skeptically at FDA actions to regulate LDTs based on

a novel interpretation of existing statutes. Given this highly doubtful authority, if FDA moves forward with this effort, the agency would likely face numerous lawsuits.

The appropriate course of action is to renew the push for a legislative solution. At minimum, FDA should utilize other tools for public engagement, such as workshops and updated concept papers, before moving to regulations that carry the force of law (as it is doing with other complex topics, such as AI in devices, etc.).

We look forward to engaging with your office and staff tomorrow.

Warm regards,



Susan Van Meter
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