



May 21, 2021

By Electronic Mail

Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Policy for Laboratory Developed Tests

Dear Secretary Becerra:

On behalf of the American Clinical Laboratory Association (ACLA), I am reaching out about the critical role that clinical laboratories play in our nation's health care system and to initiate a dialogue with you regarding the policies of the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) regarding laboratory developed tests (LDTs).¹ This dialogue is needed to ensure that all laboratories, including the laboratories that have been, and continue to be, on the front lines of the nation's response to the COVID-19 pandemic, have an appropriate, clear, and predictable regulatory system, so that they may continue to meet our nation's current demands for accurate and reliable COVID-19 testing, and, more broadly, can meet the needs of our health care system going forward.

ACLA believes that a clear and consistent policy for LDTs that reflects alignment among stakeholders is critical to a robust COVID-19 response. We are concerned that regulatory policies for diagnostics, in particular LDTs, have repeatedly shifted over the last year, and this changing landscape has been especially disruptive to the laboratories that have been so instrumental to the pandemic response. More broadly, while the COVID-19 pandemic highlighted the crucial role clinical laboratories play during a public health emergency, laboratory diagnostics are critical to the every-day health of our nation and it should not be lost in the COVID-19 pandemic discussions that the millions of tests administered every day have a profound impact on medical care, from finding cancer in time to treat it to identifying childhood diseases in order to correct them before a lifetime of illness. Shifting regulatory policies inhibit development of the cutting edge diagnostics that are needed to address the needs of our health care system, including clinical laboratory tests to diagnose and optimize the treatment of a variety of diseases. In the interest of spurring innovation and speeding access to accurate and reliable diagnostics, HHS must avoid the implementation of inappropriate and counterproductive regulation of LDTs as medical devices. Rather, we encourage HHS to address the important legal and policy questions regarding FDA oversight of LDTs by engaging with FDA staff, Congress, the laboratory industry, and other stakeholders in a transparent process to develop a diagnostics-specific statutory framework for the long term.

As you are aware, ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that help identify and prevent infectious, acute, and chronic disease. ACLA members both develop and perform LDTs, in addition to purchasing and performing tests with in vitro diagnostic test kits (IVDs). Over the past

¹ As background, LDTs are diagnostic test services that are developed, validated and performed by laboratories certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Laboratory services, including the performance of LDTs, are subject to extensive controls under CLIA, and are subject to ongoing inspection and accreditation requirements, which affirm the quality of the laboratory's services.

thirty years, the clinical laboratory industry has been at the forefront of significant advances in molecular and genetic diagnostics. These powerful tools have advanced medical knowledge through increasing levels of accuracy and precision in both screening and diagnostic tests never before contemplated or achievable, and, thereby, are able to better guide diagnosis and prevention or treatment decisions. Through this innovation, clinical laboratories have played a critical role in reducing medical costs and increasing the quality of patient care.

Most recently, ACLA members were among the first laboratories to validate and scale novel tests for the SARS-CoV-2 virus. Since then, our members have worked around the clock to perform more than 124 million PCR tests for COVID-19 while adapting platforms and workflows, navigating supply constraints, and working creatively and collaboratively to meet patients' evolving health needs. ACLA members are uniquely qualified to rapidly develop, validate and perform the high-quality diagnostic tests that are needed for a pandemic response. Given this expertise, it is no surprise that when FDA needed an accurate and reliable COVID-19 test to utilize with its own employees as they return to the workplace, the Agency selected an LDT developed by an ACLA member.

In the midst of the 24-7 response to the COVID-19 pandemic, on August 19, 2020, HHS announced a new policy regarding FDA's authority over LDTs. This unexpected policy change led to confusion about the process for laboratories developing and performing COVID-19 tests. Nevertheless, even following that announcement, ACLA members continued to collaborate with FDA to ensure the availability of existing tests and the development and deployment of additional COVID-19 tests. Numerous public health officials have recognized the critical role of clinical laboratories during the pandemic. For example, CDC Director Dr. Rochelle Walensky recently remarked that: "We like to say the laboratory is the sharp end of the spear in this emergency response. Laboratories are our eyes and ears during a public health crisis. Strong clinical and commercial laboratories are the foundation for accurate and timely disease diagnosis, prevention and control and are vital to improve the health and safety of Americans."²

Against the background of this extraordinary commitment to the public health, we urge the Biden Administration to engage with the laboratory community rather than shift existing regulatory expectations without our input and expertise. As you may be aware, ACLA has a long-standing position, predating the previous administration, that FDA does not have the statutory authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act, and that even if such authority exists, it can only be implemented following notice-and-comment rulemaking pursuant to the Administrative Procedure Act. Moreover, even if LDTs could be regulated as devices, ACLA strongly believes that from a public policy perspective, doing so would be inappropriate and counter to the best interests of the public health. In particular, regulating LDTs as medical devices would create duplicative and sometimes conflicting regulatory obligations for laboratories that are already subject to regulations under CLIA and state law to which IVD manufacturers are not subject.

We are in agreement with senior FDA officials that the best way to move forward to address these important and complicated legal and policy questions is through comprehensive legislation specifically designed for the oversight of diagnostics.³ Ever-shifting policy announcements and reversals would be detrimental to the laboratory industry's efforts to provide a consistent supply of accurate and reliable COVID-19 tests and

² [Remarks](#) at ACLA 2021 Annual Meeting (March 11, 2021).

³ FDA officials have long acknowledged that the regulation of LDTs should be addressed by comprehensive legislation. For example, Dr. Jeffrey Shuren and Dr. Janet Woodcock [wrote](#) in February 2020 that "The FDA is committed to continuing to work with Congress on a broader legislative solution to the oversight of in vitro clinical tests generally (including LDTs), which would modernize our regulation of these tests." Then-FDA Commissioner Dr. Scott Gottlieb [stated](#) in 2018 that "As I've said before, I believe comprehensive legislation is the right way to address these issues."

undermine the important public health role of LDTs on a host of other fronts, such as precision medicine. Building upon interactions between the FDA and the clinical laboratory community throughout the pandemic, HHS should engage with stakeholders to understand the lessons learned from this experience, and work collaboratively to advance legislation to establish an appropriate, modernized regulatory framework for clinical laboratory diagnostics, including LDTs.

For several years, ACLA has been actively engaging with Congress, FDA and the stakeholder community to develop and improve legislative proposals for a new statutory framework for diagnostic regulation, including the VALID Act. As ACLA has previously expressed, we believe that any new framework for diagnostic regulation should be guided by the following key principles. First, the regulation of diagnostic tests must balance government oversight with the need for flexibility and innovation, and must ensure timely responses to emerging public health threats. To achieve this balance, legislation should: apply standards appropriate to diagnostics and their modification and avoid application of the current medical device framework or other duplicative, overlapping or conflicting requirements; take into account the differences between IVDs and LDTs; and acknowledge the fact that laboratories are already subject to extensive regulation under CLIA and state law. Second, the framework must be risk-based and calibrate the level of regulatory oversight to the risk that a test may present. Third, legislation should include appropriate transition and grandfathering provisions to ensure continued access to existing diagnostic tests, many of which are the gold standard in clinical practice. Finally, to promote transparency and accountability, the legislation should require FDA to implement the new system through notice-and-comment rulemaking. With your support, we believe that a legislative solution will lead to regulatory certainty and help laboratories continue to meet the needs of our health care system before, during, and after public health emergencies.

We commend the successful efforts of the administration to close insurance coverage gaps for COVID-19 testing and to make investments to expand our nation's sequencing capacity, and its extraordinary actions to accelerate access to COVID-19 vaccines. These collective efforts have been critical to significantly lowering rates of COVID-19 across the country and readying the nation for return to normal work and life patterns. To continue this progress, ACLA stands ready to engage with you and your staff to discuss the complex factors and considerations for the regulation of diagnostic tests. Toward that end, we would appreciate the opportunity to schedule a meeting to discuss the soundest path forward on LDT regulation and developing a comprehensive new legislative framework for diagnostics. Please do not hesitate to contact me with any questions at 202-637-9466 or jkhani@acla.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Julie Khani', written in a cursive style.

Julie Khani
President, ACLA

Cc: Dr. Janet Woodcock, Acting FDA Commissioner
Dr. Jeffrey Shuren, Director, CDRH, FDA