June 11, 2021

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

Re: FDA Regulation of Laboratory Developed Tests

Dear Secretary Becerra:

This letter follows those recently forwarded to you by the House Energy and Commerce Committee Democrats[1] as well as various trade associations[2] on the topic of FDA regulation of laboratory developed tests (LDTs). For the reasons outlined below we respectfully discourage immediate expansion of FDA's authority to regulate LDTs and instead recommend a period of stakeholder engagement and discussion—including with representatives of regional and community clinical laboratories—to ensure that any updates to existing clinical laboratory regulations are done in a clear and predictable way that protects patients while not harming innovation.

The National Independent Laboratory Association (NILA) represents regional and community clinical laboratories across the United States that perform laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care professionals. NILA members serve a wide variety of communities and patient populations, many of whom are not adequately served by the large national laboratories—including rural areas, underserved urban areas, mid- and small-sized cities and municipalities, congregate facilities, and critical access hospitals.

A recent article in the *Yale Law Journal* outlined the FDA's role in slowing the introduction of COVID-19 tests in the first few weeks of the pandemic and the resulting deaths and spread of the disease stemming from those delays.[3] This report concluded that the FDA-imposed delays "potentially foreclosed opportunities to arrest widespread community transmission of the disease" and was "possibly the deadliest regulatory overreach in U.S. history."[4]

[1] Letter from Rep. Frank Pallone, Jr., Chairman, Rep. Anna Eshoo, and Rep. Diana DeGette, House Committee on Energy and Commerce, to Xavier Becerra, Secretary, U.S. Department of Health and Human Services (May 11, 2021).
[2] Letters from the American Assoc. for Clinical Chemistry, and American Clinical Laboratory Association (both dated May 21, 2021).
[3] See citations n.1 in "Deadly Delay: The FDA's Role in America's COVID-19 Testing Debacle," *The Yale Law Journal,* July 29, 2020
[4] Ibid. pp. 78 & 79

The COVID-19 example should serve as a warning about what could happen if the FDA moves forward to require immediate and full premarket approval of LDTs. This shift would be especially unfortunate as clinical laboratory testing has experienced unprecedented levels of innovation and advancement since the novel coronavirus first entered the United States. Requiring immediate and exclusive FDA oversight of LDTs will hinder innovation and ensure that many regional and community labs will not be able to develop and use their LDTs for patients.

FDA approval or authorization does not necessarily ensure high quality. There are examples of FDA approved or cleared tests that have been recalled for quality or accuracy problems. Many NILA members offer LDTs because their LDTs have higher accuracy than in-vitro diagnostic test kits that are approved by the FDA, and many NILA members develop LDTs because no acceptable FDA-approved diagnostic test kits exist on the market. Regional and community laboratories have been at the forefront of significant innovations that improve accuracy and precision in both screening and diagnostic clinical laboratory tests that reduce healthcare costs and improve the quality of patient care.

Under current CLIA regulations that have been in place for decades, laboratory test services, including the performance of LDTs, are subject to extensive controls and ongoing inspection and accreditation requirements from CMS, and many states also regulate the quality of a clinical laboratory's testing products and processes.

NILA encourages HHS to carefully review the implications of total FDA oversight of LDTs before moving forward. We welcome the opportunity to engage in further dialogue with you and your colleagues at the FDA and CMS to ensure we are working towards a clear and straightforward regulatory pathway that is not duplicative of existing processes, is not unduly burdensome, and does not hinder innovation.

Thank you for considering our perspective and recommendations.

Sincerely yours,

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.
Executive Director
National Independent Laboratory Association

The National Independent Laboratory Association (NILA) is a trade association for community, regional, and health system clinical laboratories. NILA serves as a platform for laboratory owners and senior executives to share business expertise, focus on legislative and regulatory issues, work together to address industry concerns, and to improve the operations of NILA's member laboratories.