July 16, 2021

The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
United States House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

On behalf of the National Independent Laboratory Association (NILA), thank you for your leadership in drafting the Cures 2.0 Act. We are grateful for the opportunity to provide comments on the discussion draft.

Members of NILA work in regional and community independent and clinical laboratories across the United States performing clinical 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 largest independent laboratories—including rural areas, underserved inner city neighborhoods, mid- and small-sized cities and municipalities, congregate facilities, and critical access hospitals. The laboratory response to COVID-19 and any future pandemic is of critical importance and regional and community labs must be part of this response.

We support the goals of Section 102 of the Cures 2.0 draft, including addressing strategies for testing and urge you to consider the role that regional and community independent laboratories play in this strategy and any public health emergency. The COVID-19 pandemic demonstrated that a national testing strategy is essential to prepare for future public health emergencies. Accurate and reliable clinical diagnostic tests are critical to the nation's response to a public health emergency or pandemic. We cannot expect to prepare our nation's laboratory infrastructure *during* the next crisis like we tried to do with COVID-19. We are pleased that the draft Cures 2.0 legislation addresses the need for a National Strategy to Prevent and Respond to Pandemics, including development of strategies for clinical laboratory testing. We must use the lessons learned during the COVID-19 response to inform this strategy and ensure our laboratories and the broader public health community are sufficiently prepared to respond to the next threat to our nation's health. However, before we can address the next pandemic, we need to ensure the stability of our clinical laboratory infrastructure. For that, the federal government must make upfront investment in community and regional laboratories.

Unfortunately, recent cuts in Medicare laboratory reimbursement rates following the Protecting Access to Medicare Act (PAMA) slowed the ability of many community and regional laboratories to respond to the COVID-19 pandemic. Unless Congress takes action, further cuts will follow next year. Further cuts

will continue to erode laboratory preparedness for the next public health emergency, putting both laboratories and the public at risk. We urge Congress to act to repair the flawed implementation of PAMA that has the potential to decimate the laboratory industry and its ability to respond to an emergency. Further, we ask you to include regional and community laboratories in any planning for future pandemics and to provide ongoing investment in non-emergency laboratory infrastructure so that laboratories are able to quickly respond to future public health emergencies. Community and independent laboratories will continue to be a significant resource as our nation responds to future public health emergencies.

As you well know, Laboratory Developed Tests (LDTs) were an essential component of the COVID-19 response and should be considered as part of any future testing strategy for a pandemic response. 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. 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." It is imperative that the federal government avoid making the same mistakes that hampered access to accurate COVID-19 LDTs.

As you consider this issue, and Representative DeGette's recently introduced VALID Act, the COVID-19 example should serve as a warning about the risks of imposing additional regulatory barriers to accurate and reliable clinical laboratory testing. 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 exclusive FDA oversight of LDTs will hinder innovation and ensure that many regional and community clinical laboratories will not be able to develop and use their LDTs for patients. We look forward to working more with Representative DeGette and the other sponsors of the VALID Act to ensure that we are not creating a duplicative regulatory structure that fails to recognize the unique nature of clinical laboratory tests as processes rather than products.

Again, thank you for the opportunity to provide comment on the Cures 2.0 Discussion Draft. If you have questions or would like to discuss these comments further, please contact NILA's Washington Representative, Erin Morton at emorton@dc-crd.com.

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.