December 9, 2022

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Chuck Schumer
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
Washington, DC 20510

Dear Speaker Pelosi, Leader Schumer, Leader McCarthy, and Leader McConnell,

On behalf of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), we urge you to exclude the Verifying Leading-edge IVCT Development (VALID) Act from any end-of-year legislative package. Although this legislation would create sweeping changes that could slow innovation and restrict patient access to essential diagnostic testing, the VALID Act was not considered in regular order and there has been no deliberative process to repair the legislation's flaws.

NILA represents regional and community independent clinical laboratories across the United States that perform laboratory testing for physicians, hospitals, skilled nursing facilities, and other health care professionals. AAB, founded in 1956, is a professional association representing clinical laboratory directors, owners, managers, supervisors, medical laboratory technicians, and physician office laboratory technicians.

NILA members serve a wide variety of communities and patient populations, many of whom are not adequately served by the largest national laboratories—including rural areas, underserved urban areas, mid- and small-sized cities and municipalities, congregate facilities, and critical access hospitals. Many NILA and AAB members use laboratory-developed tests (LDTs) to provide expansive diagnostic test menus for providers and patients—particularly of tests for which test kits are not available on the commercial market.

LDTs serve an irreplaceable role in patient care. Manufactured and commercialized in vitro diagnostic (IVD) test kits cover only a small fraction of clinically-ordered tests. Additionally, test kits can quickly become outdated. Unlike IVDs, LDTs can be developed rapidly in response to emerging public health threats. For example, LDTs continue to detect the rash of synthetic fentanyls and other drugs fueling the ongoing opioid epidemic. Without LDTs, public health officials and physicians will not have access to tests that can identify new and dangerous substances, identify emerging infectious agents, and provide other clinically important information, thus leaving the public at risk and slowing opportunities to save lives.

As written, the VALID Act creates a costly new oversight and registration requirement for LDTs, which will burden smaller community and regional clinical laboratories and limit patient access to critical diagnostic testing. These requirements will cause many laboratories to drop tests from their menus, denying physicians and their patients essential laboratory testing services. In its current form, the VALID Act would be a major obstacle to community and regional clinical laboratories that have already suffered damage from reimbursement cuts under the Protecting Access to Medicare Act, made significant investments to respond to the COVID-19 pandemic, and are now facing dramatic increases in costs for reagents, equipment, supplies and laboratory personnel due to a very high inflation rate and a persistently low unemployment rate.

Legislation as far-reaching as the VALID Act should be considered under the regular committee process, with opportunity for hearings and amendments to repair flawed and unworkable language. Again, we urge you to ensure that the VALID Act is excluded from any legislative vehicle considered by Congress before the adjournment of the 117th Congress. If you have questions or would like to discuss further, please reach out to AAB and NILA's Washington representative, Meghan Riley at mriley@dc-crd.com.

Sincerely yours,

Mark S. Birenbaum, Ph.D.
Administrator