August 23, 2021

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Michael Bennet
U.S. Senate
261 Russell Senate Building
Washington, DC 20510

The Honorable Larry Bucshon, MD
U.S. House of Representatives
1005 Longworth House Office Building
Washington, DC 20515

The Honorable Richard Burr
U.S. Senate
217 Russell Senate Office Building
Washington, DC 20510

Dear Congresswoman DeGette, Congressman Bucshon, Senator Bennet, and Senator Burr:

On behalf of the National Independent Laboratory Association (NILA), thank you for the opportunity to submit comments in response to the introduction of H.R.4128/S.2209, the VALID Act of 2021. NILA represents regional and community clinical laboratories across the United States that perform laboratory testing for physicians, hospitals, skilled nursing facilities, and other health care professionals. NILA members serve a wide variety of communities and patient populations, many of whom are inadequately 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. As it is currently written, NILA is concerned that the VALID Act of 2021 could slow down, or even prohibit, access to essential diagnostics.

Laboratory-developed tests (LDTs) serve an irreplaceable role in patient care. Manufactured and commercialized in vitro diagnostic (IVD) test kits do not cover the full spectrum of human diseases and can quickly become outdated. LDTs fill these gaps and provide critical knowledge to health care practitioners. LDTs are developed and used by professional laboratory personnel who provide expert analyses; they are also inherently different from Food and Drug Administration (FDA)-regulated IVD tests, many of which are initially created as LDTs. LDTs are frequently more accurate, reliable, and relevant to timely patient care than FDA-approved IVDs. Laboratory innovation through LDTs has also made the nation's response to COVID-19 possible. To protect access to these essential diagnostic tools, and to ensure that community and regional laboratories can continue to provide innovative laboratory services to patients, NILA urges you to modify the VALID Act of 2021 to address several concerns including unnecessary registration requirements; unaffordable user fees; and duplicative regulatory requirements.

Our concerns are further outlined below, and we have also included a white paper on LDTs with more background information on how NILA members and their patients use LDTs.

Registration Requirements

The VALID Act of 2021 would require laboratories to register all current and future LDTs with the FDA, regardless of risk to the patient or use in the field. For community and regional laboratories that specialize in LDTs with no IVD equivalent, this requirement will be extraordinarily burdensome—with thousands of tests requiring initial registration and updates in perpetuity. Registration requirements for existing LDTs, without regard to risk or need for oversight, serve little purpose except to create a catalog of tests that will be difficult for patients to understand, cost prohibitive for laboratories to administer, and challenging for the FDA to maintain.

There is no compelling reason to extend registration requirements to tests that pose little risk to patients and that are performed safely and accurately in the field—especially those that have been in use for years already. In the face of these regulatory burdens, laboratories will narrow their test menus to avoid the burden of maintaining these administrative records, limiting the testing options available to clinicians and their patients. Further, laboratories could choose not to make updates and improvements to existing LDTs if it triggers a burdensome new registration. A more appropriate, tailored approach would limit registration requirements to only those tests not yet in use and those that pose the highest risk to patients or have a limited record of use in the field.

User Fees

The VALID Act of 2021 also proposes to fund oversight activities through user fees that will be challenging for regional and community laboratories to pay. Such user fees would both impose unsustainable costs on community and regional laboratories and facilitate anticompetitive behavior within the laboratory and IVD industry. Following implementation of the Protecting Access to Medicare Act (PAMA), laboratories have suffered severe cuts to reimbursement rates. PAMA-related cuts have weakened the nation's laboratory infrastructure and devastated community and regional independent laboratories who serve communities not reached by the largest independent laboratories. Without Congressional action, further cuts will go into effect in January 2022, exacerbating this crisis. As a result, many community and regional laboratories cannot afford the user fees required to bring innovative LDTs to market. Requiring these fees will slow innovation in the laboratory sector and accelerate the existing trend of laboratory consolidation and closure.[1]

User fee agreements will also advantage traditional IVD manufacturers and large laboratories at the expense of patients and smaller entities. If existing FDA user fee arrangements are predictive of a future state for LDT user fee negotiations, FDA will primarily negotiate with large, national interest groups with more limited opportunities for patients and other industry participants. As a result, large national industry groups will have a disproportionate influence on the development of these user fee agreements, representing the interests of their members and not the needs of patients or the laboratory industry as a whole. Both the cost and the negotiation of user fees are likely to entrench existing market players and further consolidate market power. If Congress wishes to further regulate the laboratory industry, the cost for these activities should be authorized and federally funded to avoid advantaging laboratory industry participants with outsized influence on federal regulators.

[1] See U.S. Clinical Laboratory Forecast & Trends, 2020-2022: Independent Lab Closure, 1995-2020 (showing a rise in independent lab closures between 2011-2020).

Duplicative Regulatory Requirements

Laboratories use a CLIA-mandated process, called proficiency testing, to ensure the validity and accuracy of clinical diagnostic laboratory tests, including LDTs. This CLIA-mandated process ensures that all tests performed in a laboratory—both IVDs and LDTs—are analytically valid and capable of performing accurately and reliably. The vast majority of LDTs, and more than 83% of LDTs offered by NILA members, simply identify and/or quantify the presence or absence of a substance, infectious agent, chemical, or other property. Far fewer LDTs use sophisticated proprietary software, algorithms or probabilistic assessments to direct clinical care. As a result, most LDTs pose low risk to patients and fall within the traditional regulatory authority of CLIA and existing state laws that apply to laboratories. As proposed, the VALID Act would duplicate certain CLIA and state regulatory requirements without regard to the risk level of the LDT. Federal regulation should, instead, avoid duplication of existing regulations and limit the burdens placed on laboratories and tests that are the least risk to patients.

As proposed, the VALID Act of 2021 would discourage innovation and competition and impose costs that community and regional laboratories cannot afford. These requirements are likely to unintentionally restrict patient access to breakthroughs in laboratory innovation and slow the speed at which laboratories can respond to emerging public health threats. FDA oversight of LDTs is also likely to create perverse incentives for laboratories to avoid bringing new products to market, or delay needed upgrades to existing tests. Congress should not permit federal regulation to be used as a tool to limit competition in the laboratory market—yet, as proposed, the VALID Act of 2021 will advantage larger entities with more staff and capital over regional and community laboratories that serve the communities that are a low priority for these larger entities. Large laboratories and IVD manufacturers cannot and do not provide testing to all communities or produce tests that cover the full spectrum of human diseases. Community and regional laboratories, and the LDTs they create, are essential to patient care.

Appended to this letter is a white paper on LDTs that NILA hopes will be informative as you consider revisions to the VALID Act of 2021. As you consider modifications to the VALID Act, we urge you to ensure that any regulation of laboratories and LDTs is proportional to the risk borne by patients and allows for innovation in the laboratory market. Failure to do so will ultimately undermine patient access to needed laboratory services.

Sincerely yours,

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.
Executive Director
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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.

Laboratory Developed Tests – Irreplaceable Tools for Innovative Patient Care

Clinical laboratory tests provide the information necessary for physicians and other health care providers to make treatment decisions for their patients. Laboratories that perform complex clinical testing must meet stringent regulatory requirements under the federal Clinical Laboratory Improvement Amendments (CLIA). In addition, a number of states also regulate clinical laboratories. Laboratories also adhere to established professional society and laboratory practice guidelines and obtain certifications and/or accreditations as appropriate for their particular discipline. These regulations, guidelines, and certifications ensure that patients receive reliable and accurate laboratory testing services.

What is an in vitro diagnostic test?

In vitro diagnostic (IVD) tests are used to analyze specimens from the human body, including blood, urine, tissue, nasopharyngeal samples, or saliva. These tests are manufactured and sold to laboratories by third-party vendors. Manufacturers produce and market IVD tests, which are typically performed on manufacturer-specific platforms (instruments), to diagnose, prevent, or manage the treatment of specific diseases. IVDs can be used in a number of settings, including clinical laboratories, physician offices, hospitals, and even at home—for example, an over the counter pregnancy test. IVD tests and test components are considered medical devices and are therefore regulated by the Food and Drug Administration (FDA) under a risk-based framework.

What are Laboratory Developed Tests (LDTs)?

Laboratory Developed Tests (LDTs) are testing processes that are created, validated, and performed in a single CLIA-certified laboratory and are not marketed for sale or use in other laboratories. LDTs play a significant role in patient care. The vast majority of LDTs simply detect and/or quantify the presence of something in the human body, such as a virus, antibody, or toxic chemical, to aid in the detection of a disease or health condition or to monitor a drug treatment or therapy. Some LDTs—like those used for early cancer detection or cancer risk factors—look for genetic variations and require automated instrumentation or software-based algorithms to determine an individual's risk for a disease or disorder.

The Value of LDTs: Pandemic Response

LDTs made the nation's COVID-19 response possible. Early mistakes in the development of an IVD for SARS-CoV-2 led to weeks long delays in access to authorized COVID-19 test kits. In response, laboratories stepped up and developed LDTs, allowing physicians and their public health partners to identify COVID-19 positive patients and respond to the novel SARS-CoV-2 virus – and demonstrating the value of LDTs in a public health emergency.

Why do patients need LDTs?

Manufactured and commercialized IVDs do not nearly cover the full spectrum of human diseases. LDTs are needed to fill these gaps and provide critical knowledge to health care practitioners. Because LDTs are developed and used by professional laboratory personnel who provide expert analyses, LDTs are inherently different from FDA-regulated IVD tests.

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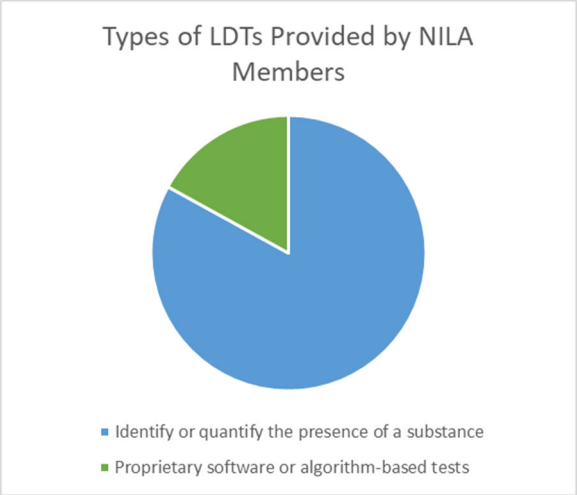
The expertise of experienced laboratory professionals are required to design, develop, validate, perform, and improve LDTs. Laboratory professionals design LDTs and set their analytic parameters. Laboratory professionals also consult with the treating practitioner, who uses his or her medical judgment to care for the patient. As technology evolves and new infectious agents emerge, laboratory professionals are able to rapidly validate and implement novel LDTs—often well before commercial, FDA-approved IVDs are available—that aid in medical care and help respond to public health emergencies, like COVID-19 and the Zika virus.

The Value of LDTs: Catching Up to Designer Drugs

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 fueling the ongoing opioid epidemic. LDT technologies allow laboratories to respond immediately to the novel threat posed by these substances and facilitate emergency treatment of patients and swift public health response. Without LDTs, public health officials and physicians would not have access to tests that can identify new, dangerous substances – leaving the public at risk and slowing opportunities to save lives.

In addition, LDTs are frequently more accurate, reliable, and relevant to patient care than FDA-approved IVDs. Because IVD tests must undergo FDA approval, test manufacturers have a disincentive to improve or refine IVD tests because modifications to an existing IVD test may require additional regulatory review. Because LDTs do not require FDA approval, laboratories are able to safely and accurately modify existing LDTs to improve their performance, meet the needs of patients, and respond to emerging threats.



The vast majority of LDTs identify and/or quantify the presence or absence of a substance, infectious agent, chemical, or other property. More than 83% of LDTs offered by NILA-member laboratories simply identify or quantify the presence of a substance. Only a few LDTs use sophisticated proprietary software, algorithms or probabilistic assessments to direct clinical care. As a result, most LDTs pose low risks to patients and fall within the traditional regulatory authority (CLIA, state regulations) that already apply to laboratories.

How are laboratories, IVDs and LDTs regulated?

The Centers for Medicare and Medicaid Services (CMS) regulates most clinical laboratory testing through the Clinical Laboratory Improvement Amendments (CLIA). CLIA holds laboratories and their staff to specific standards, while allowing laboratory professionals to use their professional judgment in performing tests. Under CLIA, CMS regulates clinical laboratories and the testing processes that they execute, including LDTs. While FDA oversight of IVDs focuses only on a manufacturer's test kit or instrument, CLIA regulates the quality and performance of IVDs and LDTs in the field. Specifically, CLIA assesses the ability of a test to accurately detect and measure the substance of interest. Prior to releasing the result of any LDT, a laboratory must establish the LDT's analytical validity (the tests ability to measure accurately and reliably a substance or organism of interest) within that specific laboratory environment. The analytical validity of LDTs is also reviewed by CMS, or an agency acting on CMS'

behalf, as part of a biennial survey process. States also impose their own requirements on laboratories and LDTs to ensure the analytical validity of laboratory tests.

How does proficiency testing help laboratories ensure the validity and accuracy of LDTs?

Laboratories use a CLIA-mandated process, called proficiency testing, to ensure the validity and accuracy of clinical diagnostic laboratory tests, including LDTs. Proficiency testing is an external quality control measure to evaluate the performance of tests in a laboratory. Required under CLIA, laboratories must enroll in an HHS-approved proficiency testing program. On a scheduled basis, a set of unknown samples are forwarded to a laboratory to analyze through their regular testing process. Results are reported back to the proficiency testing program and graded to monitor the laboratory's performance and the accuracy of the test when performed "in the field." In the absence of externally available proficiency tests, CLIA requires a laboratory performing an LDT to develop another means of "challenging" the test to demonstrate its validity and accuracy.

The Value of LDTs: Better Allergen Testing

LDTs are frequently more accurate than existing IVDs. Unlike LDTs, IVDs are developed with wide commercialization in mind, meaning that the quality may be lower than tests developed by laboratories. As a result, laboratories frequently create their own LDTs to achieve more precise or specific results. For example, laboratories have developed LDTs to detect more than 400 different allergens, most of which are not available from IVD manufacturers. These unique tests help physicians devise better treatments for patients. Laboratories have improved the quality of allergen results with LDT technologies that manufacturers have been reluctant to adopt due in part to the regulatory burden of FDA review.

Most laboratories that offer LDTs use CLIA-approved proficiency testing programs to ensure that the tests they offer are accurate and reliable. This CLIA-mandated process ensures that all tests performed in a laboratory—both IVDs and LDTs—are analytically valid and capable of performing accurately and reliably. Physicians and other qualified healthcare providers then use their clinical expertise to determine which tests are needed to diagnose a disease or monitor a patient's health and then they evaluate the test results in light of the patient's symptoms. Proficiency testing gives confidence to medical providers that, when they order tests for their patients, they will receive reliable and accurate results.

What would FDA regulation of LDTs mean for patients and laboratories?

Historically, the FDA has not regulated LDTs, deferring to CLIA to oversee the development and performance of LDTs. The advent of more sophisticated LDTs, however, has raised questions about whether existing CLIA regulations are adequate to regulate LDTs that use proprietary algorithms or machine learning technology. Current proposals to extend FDA authority to regulate all LDTs, while intended to provide additional assurances to patients, are likely to cause unintended consequences that will limit access to care and impose ill-conceived regulatory burdens.

Restricted Access to Innovative Technologies.

FDA regulation of LDTs may unintentionally restrict patient access to breakthroughs in laboratory technology and discourage laboratory innovation that improves patient health and safety. Duplicative regulations on LDTs are likely to make the development of LDTs prohibitively expensive for all but the largest clinical laboratories, restricting patient access to innovative technology and advances in the diagnosis and treatment of cancer and other diseases. In addition, FDA oversight of LDTs is also likely to create perverse incentives for laboratories to avoid bringing new products to market, or delay needed upgrades to existing tests, for fear of

needing to wade through additional FDA regulatory requirements that prevent improvements to tests from reaching patients more quickly, thus inadvertently leading to less accurate test results.

Duplicative Requirements & Regulatory Delay.
Current proposals to impose FDA regulation on the development and use of LDTs fail to recognize the existing protections that CLIA and state law provide against patient harm. Laboratory innovation moves faster than government regulators—meaning FDA regulation of LDTs will inevitably lead to delayed access to innovative diagnostic technologies. Even outside the strain of a pandemic, FDA review is frequently criticized as burdensome, slow, and costly. Adding numerous LDTs to FDA's portfolio—even just test registration—will be costly to the FDA, the laboratory industry, and patients. FDA resources are better focused on assessing the safety and efficacy of treatments and devices, and physicians and other primary health care providers are best equipped to use their clinical judgment to assess the clinical relevance of the information they request from laboratories. Policy makers should reserve additional oversight, if any, for those tests that pose the highest risk of harm to patients and that most clearly fall outside the purview of existing safety protections provided by CLIA and state laws.

Unnecessary Regulatory Burden.
Current proposals to regulate LDTs will also impose significant administrative burdens on laboratories with no obvious tie to patient safety. Requirements that laboratories register existing LDTs with the FDA, for example, serve little purpose except to create a catalog of tests that will be difficult for patients to understand, costly for laboratories to populate, and challenging for the FDA to maintain. Additionally, the FDA has proposed a fee per test on laboratories performing LDTs to self-fund this proposed program. Such fees will stifle innovation, especially for infrequently ordered, but necessary tests, such as those used to help diagnose or guide treatment of orphan diseases.

There is no compelling reason to extend registration requirements to tests that pose little risk to patients and that are performed safely and accurately in the field. Registration requirements are particularly challenging for smaller community and regional clinical laboratories, some of whom specialize in providing LDTs that other laboratories choose not to provide. In the face of these regulatory burdens, some laboratories may choose to narrow their test menus, limiting the testing options available to clinicians and their patients. A more appropriate, tailored approach would limit registration requirements to only those tests that pose the highest risk to patients or have a limited record of use in the field.

How can policymakers avoid stifling innovation and limiting access to needed care?

To avoid an unnecessary regulatory burden and increased costs for both patients and providers, policymakers should avoid imposing requirements that duplicate existing state and federal safeguards. In addition, lawmakers should not create test registration requirements for LDTs that present a low risk to patient safety or public health—particularly for those tests already relied upon by providers and patients. Finally, regulatory approaches to LDTs should be clear, transparent, consistent, and not impose undue costs on laboratories or patients.

Laboratories take seriously their obligation to provide reliable, accurate testing services to clinicians and patients. By taking a more tailored approach to regulating LDTs, Congress can avoid unnecessary costs and delays to innovation and patient care.