February 4, 2022

The Honorable Patty Murray
Chair, U.S. Senate Committee on Health, Education, Labor & Pensions
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member, U.S. Senate Committee on Health, Education, Labor & Pensions
217 Russell Senate Office Building
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr:

On behalf of the National Independent Laboratory Association (NILA), thank you for the opportunity to comment on the PREVENT Pandemics Act discussion draft. NILA commends you on the development of this bipartisan framework to help the nation be better prepared for the next pandemic. We have all learned a lot from our response to the COVID-19 pandemic—NILA and its members are no exception, and we look forward to working with you to improve the ongoing response to the COVID-19 pandemic and adequately prepare for future public health emergencies.

NILA represents community, regional, and health system laboratories that serve a wide variety of communities and patient populations—many of whom are not served by large independent clinical laboratories. NILA member laboratories across the United States have been invaluable to the nation's COVID-19 response by performing laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care professionals. NILA member laboratories have provided these services despite continuous regulatory ambiguity, severe supply shortages, and workforce challenges.

Our comments are outlined below in the order in which sections appear in the discussion draft.

Title I: Strengthening Federal and State Preparedness

Section 101. Comprehensive review of the COVID-19 response

Clinical laboratories have much to offer as part of a comprehensive review of the COVID-19 response. The federal government must recognize that the strength and sustainability of the nation's laboratory infrastructure *before* a public health emergency occurs directly impacts the ability of laboratories to effectively respond *during* a public health emergency.

Following years of Medicare CLFS cuts, the first three years of the implementation of the Protecting Access to Medicare Act (PAMA) resulted in an additional 30% reduction in reimbursement for many common laboratory tests. Because of these ongoing cuts, many community laboratories closed or otherwise altered their business models to serve fewer Medicare beneficiaries. This contraction in the laboratory market limited the laboratory testing options of many communities and slowed the nation's response to the COVID-19 pandemic. The convergence of continuing Medicare CLFS rate cuts and mounting labor costs has devastated regional and community laboratories. Laboratories are now working to mitigate staffing shortages, while many are also incurring additional costs to meet the

increase in the minimum wage for federal contractors to $15 per hour effective in January 2022. These rate reductions have also hampered the ability of those community and regional laboratories that remain to purchase needed supplies, leading to slower test results and inconsistent access to testing in many communities.

Another challenge for community and regional laboratories is the large initial investments that laboratories may have to make to respond to public health emergencies. Molecular and serology tests are performed on a wide variety of testing platforms. Many community and regional laboratories, particularly given ongoing cuts to Medicare reimbursement rates following the enactment of PAMA, lack the resources necessary to invest between $250,000 and $1,000,000 in a new testing platform at the outset of a public health emergency to respond to a new or emerging threat. For community and regional laboratories to respond effectively to new public health threats in the future, laboratories must be able to rely upon government and private payers to adequately reimburse them for the collection, transportation, and testing services that they provide. The federal government should also ensure that community and regional laboratories have access to upfront capital so that laboratories can invest in the testing platforms required to respond to public health emergencies. Without both adequate reimbursement and upfront capital investment, laboratories are unlikely to be able to respond quickly to future public health emergencies.

While we outline these ideas here, **NILA strongly recommends that the National Task Force on the Response of the United States to the COVID-19 Pandemic interview and consult with clinical laboratories of all sizes** not just the large, national laboratories who were often the public face of the COVID-19 response. NILA member laboratories working locally in states and communities played an essential role in the response and offered capacity when national laboratories could not alone meet demand.

Section 103. Public health and medical preparedness and response coordination
Future pandemic preparedness response coordination must include community and regional laboratories. The current Memorandum of Understanding on testing surge capacity during emergency response was only executed between the Centers for Disease Control and Prevention (CDC), the American Clinical Laboratory Association (ACLA), the Association of Public Health Laboratories, and the Council of State and Territorial Epidemiologists—excluding the input of community and regional laboratories not represented by the ACLA. This led to a concentration of testing at large national laboratories, which could not keep up with the demand, resulting in extended wait times for COVID-19 test results even though additional testing capacity existed at several regional and community laboratories. **Future pandemic response should coordinate among all actors in the laboratory industry.**

To avoid concentration and inefficient allocation of test volume in the future, NILA recommends the establishment of a "Clinical Laboratory Ready Reserve" to guard against atrophy following the current pandemic and ensure that there is national capacity and capability to ramp up a widespread and coordinated lab testing response within ten days of a new infectious disease outbreak or bioterror attack. This would be accomplished through a federally supported network of clinical laboratories, of all sizes and from all regions of the nation, that would participate on a voluntary basis. This new entity could be an extension of the Medical Reserve Corps, led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR).

Participating laboratories would be encouraged to maintain in reserve (i) testing equipment, (ii) personnel, and (iii) expertise and know-how. To do seminars, exercises and "tabletop" drills or contests would be held at least annually, whereupon sequences of novel pathogens would be distributed along with positive specimens (controls), and laboratories and diagnostic kit manufacturers would practice and even compete to develop and validate assays in as short a time as possible. In addition to modest yearly stipends, cash prizes would be awarded to those laboratories who demonstrate the ability to deploy accurate testing in the shortest time.

Matching funds would be needed to encourage laboratories to maintain in good working condition "dual use" but excess equipment (e.g., PCR thermocyclers, extractors, liquid handling robots, etc.) that could be repurposed should mass screening be needed. Grants would also be provided to help laboratories maintain a cadre of skilled part-time laboratory technicians ready to be deployed in an emergency. These arrangements would be modeled much like a volunteer fire department. Diagnostic kit and instrument manufacturers would also be recruited and incentivized to participate as part of the Reserves.

Title II: Improving Public Health Preparedness and Response Capacity

Section 212. Genomic sequencing, analytics, and public health surveillance of pathogens
NILA supports this section and encourages the CDC to continue to expand its genomic sequencing work with additional clinical laboratories including regional and community laboratories.

Title III: Accelerating Research and Countermeasure Discovery

Section 304. Accessing specimen samples and diagnostic tests
NILA strongly supports Section 304. Early access challenges to COVID-19 specimens and delays at CDC made it difficult for many community and regional laboratories to start testing for COVID-19. We know now that state public health laboratories do not have the capacity to respond to a pandemic of this size and future planning must include the entire laboratory community—especially community and regional laboratories.

The reliance on public health laboratories and the CDC assay at the beginning of the pandemic greatly hampered the pandemic response. The initial problems with CDC's first COVID-19 diagnostic tests created several problems for laboratories that impeded the initial response to the pandemic. It delayed access to the data laboratories needed to develop their own tests. It also prolonged the period when public health laboratories were the primary laboratories performing COVID-19 diagnostic tests, limiting access to testing services for patients. More planning to secure early access by public and private entities to specimen samples is needed to identify when and how private entities can supplement public health testing and test development capacity and provide additional expertise. Failure to do so early in the COVID-19 pandemic led to undetected and uncontrolled spread of COVID-19.

Title IV: Modernizing and Strengthening the Supply Chain for Vital Medical Products

Community and regional laboratories play a critical role in pandemic response and, like other health care providers, need uninterrupted access to the supplies necessary to carry out testing and transport of

specimens. Throughout the COVID-19 public health emergency, community laboratories have struggled to access needed testing supplies—including swabs, reagents, PPE, and test kits—to adequately serve their communities. Additionally, state governments have not distributed supplies equally among laboratories, and state governments have made inconsistent and non-transparent decisions regarding the allocation of resources. Prioritization of supplies for the largest, national laboratories at the expense of community and regional laboratories, left many NILA laboratories to fend for themselves or go underutilized, limiting testing capacity and hampering pandemic response.

Many community and regional laboratories were also forced to place large supply orders with upfront payment and no guarantee that ordered stock would be utilized. In the future, a more transparent supply distribution process that accounts for the entire laboratory industry—rather than favoring some actors over others and considering where additional laboratory capacity could absorb more testing if supplies were available—would help NILA laboratories to better respond to the needs of their communities. Future distribution plans should also ensure that needed supplies consider and reach all laboratories that are responding to the public health emergency. Distribution and stockpiling plans should also recognize the diversity of public health threats that could impact the nation and recognize the upfront capital investments that may be needed by community and regional laboratories to adequately respond.

Specifically, NILA supports several provisions of the PREVENT Pandemics Act, which will ensure the Strategic National Stockpile (SNS) is robust and mitigate disruptions to the medical supply chain in the event of a pandemic.

Section 402. Supply chain considerations for the Strategic National Stockpile
NILA supports the assessment of supply chain vulnerabilities within the SNS' annual Threat-Based Review requirements. NILA additionally supports consideration of the effect that any modification to the SNS would have on the availability of ancillary medical supplies, especially those used in laboratory testing.

Section 403. Strategic National Stockpile equipment maintenance
NILA supports requirements that the contents of the SNS be periodically reviewed both to ensure that supplies are not depleted and that they are unexpired and in working order for deployment when necessary.

Section 404. Improving transparency and predictability of processes of the Strategic National Stockpile
NILA supports the dissemination of guidance regarding the process by which the Secretary will deploy the contents of the SNS. The full scope of laboratory infrastructure, including community and regional laboratories, must be considered in such guidance to ensure the greatest capacity possible in responding to a pandemic. Community and regional laboratories must also be included in annual meetings convened to consider the maintenance and use of the SNS.

Section 408. Action reporting on stockpile depletion
NILA supports requirements for the Secretary to report regularly on the contents of the SNS during a public health emergency. This reporting will provide transparency and visibility into supply availability and provide up-to-date information for manufacturers and health care providers on supply limitations.

Section 410. Grants for State strategic stockpiles
During the COVID-19 pandemic the federal government's dissemination of necessary laboratory testing supplies to states was lacking. Community and regional laboratories were often unable to access testing supplies, resulting in lost testing capacity during key surges of the virus. NILA supports the authorization of grants to states for strategic stockpiles of supplies to increase the availability of critical laboratory testing supplies during an emergency so long as those stockpiles are available to all types of clinical laboratories called upon to respond to a national or state public health emergency.

Title V: Enhancing Development and Combatting Shortages of Medical Products

NILA applauds the inclusion in the PREVENT Pandemics Act of provisions that would require the Food and Drug Administration (FDA) to work more effectively with the public and require testing supply manufacturers to plan for and guard against future supply shortages. Repeated policy changes throughout the first year of the pandemic were challenging for laboratories and were frequently poorly communicated to the laboratory community. As noted above, supply shortages significantly hampered the nation's response to COVID-19 pandemic. Protecting against and minimizing future shortages will lessen the likelihood that additional shortages will occur.

In addition, NILA supports the use of third-party evaluation to ensure the accuracy and validity of in vitro diagnostics. Accurate and reliable clinical diagnostic tests are critical to the nation's response to any public health emergency or pandemic. During the COVID-19 public health emergency, the FDA relaxed its oversight of clinical laboratory tests through emergency use authorization regulations. As a result, the number of available COVID-19 tests expanded significantly in the race to increase testing capacity with some developers deploying tests with subpar accuracy, reproducibility, and reliability. The federal government should learn from the early missteps of the COVID-19 pandemic to ensure that accurate and reliable testing—rather than the absolute volume of testing—is the primary focus in future public health emergencies. To ensure accurate and reliable testing in future public health emergencies, frequent and routine proficiency testing (PT) should be required for all laboratories running emergency use authorized clinical laboratory tests during a public health emergency or pandemic. Proficiency testing is an external quality control measure to evaluate the performance of tests in a laboratory where they are used to provide clinical laboratory test results to physicians and patients. Expanded use of PT programs in future public health emergencies will protect the public from testing that is unreliable, inaccurate, or unreproducible.

Section 504. Third party test evaluation during emergencies
NILA supports the ability of the Secretary to, as appropriate, consult with external persons to evaluate the validity, accuracy, and reliability of in vitro diagnostic products. This provision should be implemented to allow consultation with existing proficiency testing programs with experience evaluating the reliability, accuracy, and reproducibility of tests.

Section 507. Increasing EUA decision transparency
NILA supports increasing transparency regarding emergency use authorization (EUA) decisions. Publication of decisions regarding EUA decisions in the Federal Register and on the FDA's website will give test developers greater transparency into the agency's decision-making and provide consumers with more consistent access to a list of authorized technologies, including in vitro diagnostics.

Section 508. Improving FDA guidance and communication

NILA strongly supports the development of consistent, more transparent processes for development, issuance, and use of FDA guidance documents and communications between the FDA and external stakeholders. Throughout the pandemic, NILA members have struggled to get timely information on EUA applications, limiting the ability of community and regional laboratories to bring innovative products to market under emergency authorization. Improved processes and increased transparency regarding these processes will benefit both laboratories and the communities they serve by giving patients more testing options.

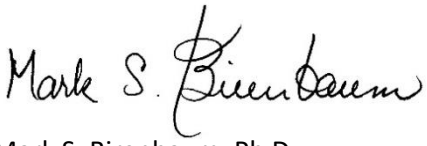
Section 515. Strengthening medical device supply chains

Section 516. Preventing medical device shortages

NILA strongly supports Sections 515 and 516 of the PREVENT Pandemics Act. Section 506J of the Food, Drug and Cosmetics Act currently requires developers of clinical chemistry products, hematology products, microbiology products, needles and syringes, personal protective equipment, and testing supplies and equipment to alert the FDA when shortages occur but stops short of requiring manufacturers of these products to prepare for and prevent future shortages. By expanding the circumstances under which shortage notifications are required (Section 516) and requiring manufacturers to implement risk management plans (Section 515), community and regional laboratories will be able to better anticipate future shortages and hopefully experience fewer shortages of these critical supplies.

Thank you for the opportunity to comment on the discussion draft of the PREVENT Pandemics Act. Please contact NILA's Washington representative, Erin Morton, with any questions at emorton@dc-crd.com.

Sincerely yours,



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