March 27, 2023

The Honorable Bernie Sanders
Chair
Health, Education, Labor, and Pensions Committee
U.S. Senate
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member
Health, Education, Labor, and Pensions Committee
U.S. Senate
Washington, DC 20510

The Honorable Bob Casey
Health, Education, Labor, and Pensions Committee
U.S. Senate
Washington, DC 20510

The Honorable Mitt Romney
Health, Education, Labor, and Pensions Committee
U.S. Senate
Washington, DC 20510

Dear Chair Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney,

On behalf of the National Independent Laboratory Association (NILA), thank you for the opportunity to provide comments on the upcoming reauthorization of the Pandemics and All Hazards Preparedness Act (PAHPA). 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 are a critical component of our nation's public health preparedness and response. NILA members perform laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care professionals and have consistently provided these services to patients despite regulatory ambiguity, severe supply shortages, and workforce challenges.

NILA is grateful for your consideration of the comments below. As you work to reauthorize PAHPA, we urge you to consider policies that will help sustain community and regional clinical laboratories as part of our nation's critical laboratory infrastructure. In recent years the United States has been focused on combating infectious disease, but a future public health emergency could involve threats that are not linked to pathogenic organisms. We must be prepared to respond to toxic spills, radiation leaks and contamination, natural disasters, biological warfare, and the proliferation of drugs, particularly opioids and fentanyl. Community and regional laboratories play a critical role in responding to these types of disasters and emergencies.

Program Effectiveness
The Strategic National Stockpile (SNS)

Community and regional clinical 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 filled an extensive gap in testing when national laboratories were overwhelmed. Despite providing essential testing capacity, many community and regional clinical laboratories struggled to access needed testing supplies—including swabs, reagents, Personal Protective Equipment (PPE), and test kits—to

adequately serve their communities. Additionally, state governments often failed to distribute supplies equally among laboratories and 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 community and regional clinical laboratories to fend for themselves or go underutilized, limiting testing capacity and hampering pandemic response.

Many community and regional clinical laboratories were also forced to place large supply orders with upfront payment and with no guarantee that ordered stock would be utilized. In the future, a more transparent supply distribution process that accounts for the entire laboratory industry and considers 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 reach all laboratories that are responding to the public health emergency. Distribution and stockpiling plans should recognize the diversity of public health threats that could impact the nation and recognize the upfront capital investments that community and regional laboratories need to respond to the threat.

One reason for stockpiling medical countermeasures is that the commercial supply chain is currently not optimized to dispense a product at the right time or in the right amount during a public health emergency. We learned from COVID-19 that this is true of the diagnostic testing supply chain. And, while the SNS was designed for a mass response, it failed to acknowledge that a clinical laboratory is a key health care provider in the event of a pandemic. Currently, though statute does not preclude it, the SNS has no requirement or funding to store clinical laboratory testing supplies.

The SNS must store crucial laboratory supplies and be widely advertised to stakeholders so that clinical laboratories and officials understand the routes required to access the SNS when disaster occurs. Necessary supplies that should be made available to clinical laboratories through the SNS include surgical gloves, protective gowns, plastics (including pipette tips), and viral transport media.

In addition to adding diagnostic testing supplies to the SNS, NILA recommends a transparent and open process for maintaining and disseminating the contents of the SNS. Further, to ensure the supplies are available and in working order in the event of an emergency, the SNS must be funded for routine inventory and replacement of laboratory supplies. First, there should be periodic review of the contents of the SNS to ensure that supplies are not depleted, have not expired, and are in working order for deployment when necessary. Second, guidance should be disseminated regarding the process by which the Secretary will deploy the contents of the SNS. The full scope of laboratory infrastructure, including community and regional clinical laboratories, must be considered in such guidance to ensure the greatest testing capacity possible when responding to a public health emergency.

Last, in the early days of the COVID-19 pandemic laboratories were faced with decisions about obtaining very expensive PCR testing platforms (many over $500,000), but were uncertain about the volume of testing that would materialize, the level of reimbursement, and whether funding for the equipment would be obtainable. Consideration of these circumstances slowed laboratories' ability to react to the pandemic. We understand the federal government provided funding for a number of laboratories to bring equipment in house to facilitate rapid testing. In an emergency there should be a transparent funding mechanism available to help a greater number of diverse laboratories, including community and regional clinical laboratories, to borrow the capital needed to quickly obtain needed equipment to grow testing capacity. Funding should also be provided to maintain that equipment for use should another pandemic occur. This could be carried out via a partnership program between the SNS and participating clinical laboratories.

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and related strategy, implementation plan, and budget plan

The National Academies of Science, Engineering, and Medicine (NASEM) released a report in 2021, *Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise*, that makes several recommendations that would improve the PHEMCE and support community and regional clinical laboratories.

First, NILA agrees with the recommendation to incorporate the perspectives of nonfederal and private-sector partners and stakeholders in the PHEMCE Strategy and Implementation Plan, and its associated multiyear budget, with clearly specified roles, objectives, accountability, benchmarks, timelines, and budget requirements. The initial reliance on public health laboratories and missteps at the Centers for Disease Control and Prevention (CDC) slowed detection of the SARS-CoV-2 virus, limiting opportunities for identification and containment. Incorporating the perspectives of nonfederal and private-sector partners and stakeholders will lessen the likelihood that the same types of delays and missteps will occur in future public health emergencies and will allow the federal government to utilize the skill and capacity of private entities, such as community and regional clinical laboratories, sooner.

NILA also supports the recommendation to develop and maintain an advisory committee of representative medical countermeasures partners and stakeholders to benefit from their expertise and to ensure transparency in the diverse aspects of PHEMCE activities. Transparency in the PHEMCE response to future public health emergencies is an urgent priority. Throughout the first year of the pandemic, NILA and its community and regional laboratory members received inconsistent communications from federal partners, even after highlighting dire supply shortages. Information received from the federal government on how laboratories could obtain supplies was incomplete and inaccurate, and it became clear that some laboratories were receiving prioritized access to needed supplies, while others with capacity to test were left out of the distribution chain. A committee of partners and stakeholders could advise PHEMCE more quickly on challenges facing laboratories during future public health emergencies and avoid the types of inconsistent communication and inappropriate prioritization of laboratory equipment that occurred during the current public health emergency.

Third, NILA agrees with the recommendation to establish a mechanism for transparent communications both across the government and with nonfederal and private-sector partners and stakeholders. As stated above, communication from the federal government in the first year of the pandemic was inconsistent and frequently challenging for laboratories to follow. While a diverse set of stakeholders make up PHEMCE, it should not be the responsibility of private stakeholders to navigate this bureaucracy. Rather, the federal government should centralize information in a way that is useful to stakeholders, minimizing the need for stakeholders to seek out and process information from multiple sources.

Lastly, there should be clearly defined authorities, roles, and responsibilities among the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), PHEMCE, and nonfederal and private-sector partners and stakeholders. Increased focus on identifying the authorities, roles, and responsibilities – particularly between the federal government and private-sector partners and stakeholders – will improve future public health responses.

Emergency Use Authorizations (EUA) and related authorities

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 COVID-19 pandemic, NILA members struggled to obtain timely information on EUA applications, limiting the ability of community and regional clinical laboratories to deliver innovative products to market under emergency use authorization. Improved processes and increased transparency in these processes will benefit laboratories and the communities they serve by providing patients more testing options.

FDA needs sufficient resources to allocate to EUA review when emergencies occur. Just as clinical laboratories need a stockpile of supplies to tap into during an emergency, FDA should "stockpile" expertise in the form of outside experts who have the skills and knowledge to review validation data and recommend whether tests meet the necessary analytical standards. Without the staff and capacity to review EUA applications, a unique test performed in a small laboratory may not come to the surface because it is considered low priority by the FDA as it triages work in times of emergency. This has the potential to stifle innovation that can come from small, highly complex laboratories.

The Medical Reserve Corps (MRC)

Future pandemic responses should be coordinated 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 COVID-19 pandemic and to ensure that there is national capacity and capability to ramp up a widespread and coordinated laboratory 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 ASPR.

Participating laboratories would be encouraged to maintain in reserve (i) testing equipment, (ii) personnel, and (iii) expertise and know-how. Seminars, exercises and "tabletop" drills or contests would be held at least annually, whereupon sequences of novel pathogens or other analytes 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 could be awarded to those laboratories that demonstrate the ability to deploy accurate testing in the shortest amount of 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.

Gaps in Current Activities & Capabilities
Laboratory Data Reporting

New and burdensome data reporting requirements during the COVID-19 emergency response imposed significant costs on laboratories. Unlike other areas of health technology, there has been little incentive or investment in laboratory information technology. As a result, many laboratories lacked the required technology and manpower early in the pandemic to respond to new public health data reporting mandates, further slowing the pandemic response, and imposing additional costs on laboratories already

under tremendous financial constraints. Public health information systems and independent clinical laboratory infrastructure need financial investments to allow all laboratories to receive and communicate patient data to public health authorities more effectively. While public health departments need investments to build an infrastructure that will allow for more streamlined reporting and consistency across state reporting requirements, this is not sufficient without additional investments in the private clinical laboratory infrastructure. As we have seen with COVID-19, not just public health laboratories report results to public health departments—community and regional clinical laboratories are now responsible for a much higher volume of public health reporting than before.

NILA supports the role of community and regional clinical laboratories in this regard but believes strongly that federal investments should be made in community and regional clinical laboratories, as well as public health departments, to ensure interoperability. Incentive payments to community and regional clinical laboratories for public health data reporting could also support the adoption of technology that would streamline reporting and improve the consistency and accuracy of the data collected. Each state's Department of Health requires a unique and individual interface and/or electronic reporting format. Therefore, many clinical laboratories have to add staff and pay for additional interface software to report data across many different states. Importantly, inconsistent reporting requirements across fifty states and the federal government, as well as requirements to report data that laboratories do not always have, hinder laboratories' ability to report data. Uniform data standards would improve the ability to report important data. A centralized data repository to which laboratories could provide data that is subsequently made available to interested state and federal parties would create efficiencies. Important public health data, including demographic and race and ethnicity data, may be better collected from the ordering clinician who has access to the patient's records, which laboratories often do not.

Novel Pathogen Testing

We learned from the COVID-19 pandemic that state public health laboratories do not have the capacity to respond to a pandemic of the magnitude of COVID-19. Future planning must include the entire laboratory community—particularly community and regional clinical laboratories—to ensure the full capacity of our nation's laboratory infrastructure is utilized. The reliance on public health laboratories and the CDC assay at the beginning of the COVID-19 pandemic greatly hampered the pandemic response. The initial problems with CDC's first COVID-19 diagnostic tests created difficulties 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 many 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 the virus.

Laboratory Developed Tests

Many NILA 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 and preparedness. 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 in vitro diagnostic test kits, LDTs can be developed rapidly in response to emerging public health threats, including pandemics. For example, LDTs continue to detect the rash of synthetic fentanyl 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 impeding opportunities to save lives.

NILA has concerns about the Verifying Leading-edge IVCT Development (VALID) Act as introduced in the 117th Congress. The VALID Act creates a costly new oversight and registration requirement for LDTs that will burden community and regional clinical laboratories, limit patient access to critical diagnostic testing, and hinder preparedness. As drafted, 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.

Our nation's community and regional clinical laboratories are a critical component in the overall clinical laboratory infrastructure that is necessary to respond to pandemics and other emerging threats to health. Legislation as far-reaching as the VALID Act should be considered under the regular committee process, with opportunity for hearings and amendments. Should the committee consider including the VALID Act in the PAHPA reauthorization, we urge you to ensure the legislation is reviewed thoroughly during the committee process and that comments from all stakeholders are taken into consideration.

Partnerships

Again, community and regional clinical laboratories are an essential part of our nation's health care and response infrastructure. Future pandemic planning exercises should be more transparent and incorporate a broader array of nonfederal and private-sector partners, like NILA, to avoid inhibiting laboratory testing capacity in future public health emergencies. During the COVID-19 pandemic, limited partnerships between the federal government and the largest publicly traded clinical laboratories led to a concentration of testing at large national laboratories, which could not keep up with the demand, and resulted in extended wait times for COVID-19 test results. Additional testing capacity existed at regional and community laboratories. Future pandemic response and public-private partnerships should coordinate among all actors in the laboratory industry. More efficient allocation of samples among laboratories and utilization of all clinical laboratories—not just the largest national laboratories—is a key to an effective pandemic response.

Sincerely yours,

Mark S. Birenbaum

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