July 7, 2023

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

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

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

The Honorable Mitt Romney
Health, Education, Labor, and Pensions Committee
U.S. Senate
Washington, D.C. 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 discussion draft of the reauthorization of the Pandemics and All Hazards Preparedness Act (PAHPA). NILA represents a diverse range of community, regional, and health system laboratories that cater to various communities and patient populations, including those not served by large independent clinical laboratories. NILA member laboratories are located throughout the United States and are vital to the nation's readiness for, and response to, public health emergencies. Despite facing regulatory uncertainty, severe supply shortages, and workforce challenges, NILA member laboratories have consistently offered essential laboratory testing services to physicians, hospitals, skilled nursing facilities (SNFs), and underserved patient communities.

NILA sincerely appreciates your consideration of the following comments. As you undertake the reauthorization of PAHPA, we urge you to prioritize policies that support the sustainability of our nation's laboratory infrastructure, including community and regional clinical laboratories. While the United States has primarily focused on combating infectious diseases in recent years, future public health emergencies may encompass hazards unrelated to pathogenic organisms. It is imperative that we are prepared to respond to various threats such as toxic spills, radiation leaks and contamination, natural disasters, biological warfare, and the increasing prevalence of drugs, particularly opioids and fentanyl. Community and regional clinical laboratories play a pivotal role in addressing all types of disasters and emergencies that may present a threat to public health.

Title II—FEDERAL PLANNING AND COORDINATION

Section 202: The Strategic National Stockpile

NILA is concerned about the absence of provisions requiring the inclusion of essential laboratory supplies in the Strategic National Stockpile (SNS). Severe shortages of laboratory supplies during the COVID-19 pandemic hindered diagnostic capacity throughout the country, potentially contributing to the spread of the disease in many communities. The SNS must store crucial laboratory supplies and be widely advertised to stakeholders so that clinical laboratories and officials understand the procedures 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. As such, allocating dedicated federal funding for the storage of clinical laboratory testing supplies is necessary. Adequate storage infrastructure is also essential to ensure the availability and integrity of critical testing materials, particularly during extended emergencies or periods of heightened demand. Including a specific authorization of funding for this purpose would contribute to the resilience of clinical laboratories and bolster the nation's overall preparedness.

SNS distribution plans should ensure that needed supplies reach all laboratories that are responding to a public health emergency. Disparities in the allocation of resources can hinder the ability of community and regional clinical laboratories to effectively respond to emergencies. We urge the inclusion of measures that promote equitable distribution of supplies and resources to support all laboratories in their preparedness efforts.

NILA acknowledges the inclusion in the discussion draft of a requirement to enhance tracking of the contents of the SNS, which aligns with comments we submitted in response to the Committee's March 2023 Request for Information (RFI). Again, NILA recommends a transparent and open process for maintaining and disseminating the contents of the SNS. To ensure supplies are available and in working order in the event of an emergency, the SNS must be funded for routine inventory and replacement of supplies. 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. The discussion draft lacks explicit language regarding the frequency of this tracking. It is crucial to establish clear guidelines on how often the contents of the SNS will be inventoried to ensure efficient and effective management and preparedness.

Last, we recommend the integration of streamlined communications to enhance decision transparency by state governments. Improved communication channels between state authorities, federal officials, and laboratories can facilitate timely and coordinated responses during emergencies, enabling more effective utilization of resources and better overall preparedness.

Section 204: Public Health Emergency Medical Countermeasures Enterprise

NILA supports the inclusion of a requirement for the Secretary to share information, including that related to logistics, deployment, distribution, dispensing, and use of countermeasures, with relevant stakeholders. This information sharing must extend to laboratories, including community and regional clinical laboratories, who are on the front lines of public health response. However, the discussion draft does not include a mechanism for considering the

perspectives of non-federal and private stakeholders in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) strategy and implementation plan, a recommendation put forth by the National Academies of Science, Engineering, and Medicine (NASEM) and supported by NILA. NASEM also calls for an advisory committee comprising representative medical countermeasures partners and stakeholders. Such a committee would provide a valuable platform for collaboration, information exchange, and shared decision-making among relevant parties, and clear definitions of authorities, roles, and responsibilities among the Office of the Assistant Secretary for Preparedness and Response (ASPR), PHEMCE, and nonfederal and private-sector partners. NILA strongly supports these NASEM recommendations cited in our March 2023 RFI response to foster efficient coordination and enable effective utilization of resources and expertise across sectors.

Section 205: Pilot Program for Public Health Data Availability

NILA acknowledges the efforts to centralize data and adopt uniform standards for reporting data through an interoperable network. However, we note the draft does not include incentives for community and regional clinical laboratories to adopt updated technology and ensure interoperability with public health data systems. NILA firmly believes that federal investments should be made not only in public health departments but also in community and regional independent clinical laboratories that play an essential role in public health response. Incentives for such laboratories to improve public health data reporting could play a crucial role in encouraging the adoption of technology that streamlines reporting processes and improves the consistency, accuracy, and interoperability of the collected data. Such incentives would facilitate the necessary investments in laboratory information technology and alleviate the financial burdens faced by laboratories, especially those already under significant financial constraints.

Moreover, during a public health emergency, each state's Department of Health may require a unique and individual interface and/or electronic format for laboratory data reporting. Therefore, many clinical laboratories must add staff and pay for additional interface software to report data across many different states. Uniform data standards are necessary to improve the ability of laboratories 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.

TITLE IV—STRENGTHENING BIOSECURITY

Section 404: Supporting research and laboratory surge capacity

NILA supports the inclusion of this provision that will shore up research and laboratory surge capacity through the establishment and maintenance of regional biocontainment laboratories. These laboratories play a crucial role in conducting biomedical research to enhance preparedness and response to biological agents. However, to truly enhance laboratory surge capacity we must expand access to novel pathogen specimens beyond public health laboratories. We learned from the COVID-19 pandemic that state public health laboratories alone do not have the capacity to respond to a pandemic of the magnitude of COVID-19. Future pandemic and all-hazards 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. Better planning is necessary to secure early access by public and private entities to specimen samples to 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. This is a critical step in ensuring laboratory surge capacity for all types of public health emergencies.

It is also essential to address the need for more consistent and transparent processes for the development, issuance, and use of Food and Drug Administration (FDA) guidance documents. Throughout the COVID-19 pandemic, NILA members faced challenges in obtaining timely information on Emergency Use Authorization (EUA) applications. This limitation hindered the ability of community and regional clinical laboratories to deliver innovative research and products under EUA, ultimately impacting their capacity to respond effectively. To address this issue FDA must establish processes that ensure laboratories receive timely and transparent information on EUA applications. Access to such information will enable laboratories to actively contribute to the development and deployment of innovative testing solutions during public health emergencies, ultimately serving patients and communities by providing broader testing options.

TITLE V—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

Section 510: Volunteer Medical Reserve Corps.

In previous comments, including NILA's response to the Committee's March 2023 RFI, NILA has recommended the establishment of a Clinical Laboratory Ready Reserve. The creation of such an entity is crucial to guard against atrophy following the COVID-19 pandemic and to ensure national capacity and capability to rapidly scale up a coordinated laboratory testing response within a short timeframe in the event of a new infectious disease outbreak, bioterror attack, or disaster.

The Clinical Laboratory Ready Reserve would be a federally supported network of clinical laboratories of all sizes and from all regions of the nation participating on a voluntary basis. Laboratories would maintain reserve capacity of testing equipment, personnel, and expertise. By conducting seminars, exercises, and drills, laboratories and diagnostic kit manufacturers would continuously practice and compete to develop and validate assays in the shortest possible time for novel pathogens or analytes. As the Committee continues to develop the PAHPA reauthorization we request that you consider the inclusion of language to establish a Clinical Laboratory Ready Reserve. NILA suggests the following language, which follows existing language around the "Earlier Development of Diagnostic Tests" that was included in the PREVENT Pandemics bill that passed as part of the FY 2023 omnibus legislation (new language is in bold).

> *(b) EARLIER DEVELOPMENT OF DIAGNOSTIC TESTS.—Title III of the Public Health Service Act is amended by inserting after section 319A (42 U.S.C. 247d–1) the following:*
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> *"SEC. 319B. EARLIER DEVELOPMENT OF DIAGNOSTIC TESTS. …*

The Secretary may contract with qualified academic, hospital-based, and independent clinical laboratories to build private sector laboratory testing capacity in, during, or outside of a national public health emergency including support for:

1. ***Hiring and training qualified laboratory personnel that could be deployed as part of a surge laboratory workforce as appropriate;***
2. ***The purchase and maintenance of laboratory equipment, including testing platforms, reagents, and other testing supplies;***
3. ***Maintaining a ready reserve of clinical laboratory capacity outside of public health emergencies;***
4. ***Training exercises during non-emergency settings to ensure emergency readiness and coordination with state public health laboratories.***

NILA remains committed to working collaboratively with Congress and other stakeholders to ensure the continued preparedness and resilience of our nation's health care system. By prioritizing policies and investments that support community and regional clinical laboratories, promote transparency and collaboration, and facilitate effective reporting and data interoperability, we can enhance our nation's ability to respond to future public health emergencies.

Again, thank you for the opportunity to provide comments on the reauthorization of PAHPA. If you have questions or wish to discuss these comments further, please contact NILA's Washington representative, Erin Morton, at emorton@dc-crd.com.

Sincerely yours,

Mark S. Birenbaum, PhD
Executive Director
National Independent Laboratory Association