January 27, 2022

Dear Congressmen Hudson, Banks, and Cole:

On behalf of the National Independent Laboratory Association (NILA), thank you for the opportunity to respond to the Health Future Task Force Security Subcommittee's Request for Information (RFI). 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. NILA is eager to contribute its "lessons learned" to policymakers interested in improving our ongoing response to the COVID-19 pandemic and adequately preparing for future public health emergencies. Below are responses to the RFI questions most relevant to NILA and its members.

Pandemic Preparedness

1. In its Public Health Emergency Medical Countermeasures Enterprise Multi Year Budget: Fiscal Years 2018-2022, the Department of Health and Human Services acknowledged the Strategic National Stockpile (SNS) "faces the challenge of maintaining a stockpile of [medical countermeasures] against a plethora of low-probability, high-consequence threats, while continuing to develop important countermeasures against other threats, and maintaining the capacity to rapidly respond to novel threats like emerging or re-emerging infectious diseases."

a. *What steps can Congress take to ensure the sustainability of our medical countermeasure (MCM) response capabilities?*
b. *Are there additional flexibilities and authorities the SNS needs to adequately stockpile MCMs and to act nimbly in response to emerging infectious diseases and during public health emergencies?*
c. *To stretch scarce Federal resources further, what additional authorities or flexibilities does the SNS require to transfer expiring stockpile items to other Federal agencies, State governments, or non-governmental entities and use profits from these transfers to acquire new MCMs?*
d. *What challenges does the SNS face when distributing MCMs to State and local partners? What steps can Congress take to fix these challenges?*

Community and regional labs 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 independent 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.

2. The Coronavirus Aid, Relief, and Economic Security (CARES) Act explicitly required the SNS to maintain, in addition to already enumerated items, supplies of "personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile."

a. *Are there other products and MCMs Congress should explicitly require the SNS to stock?*
b. *What challenges might the Federal government encounter to maintaining this stockpile?*
c. *Are the SNS's current annual review procedures sufficient for evaluating inventory needs and manufacturing, procurement, and deployment challenges?*
d. *Should additional Federal (or even non-Federal) entities be included in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which provides input on SNS stockpiling decisions? Are there shortcomings in the SNS's coordination with current PHEMCE members? If so, how best can these shortcomings be fixed?*

The strategic national stockpile should stock all necessary laboratory equipment—including swabs, reagents, PPE, test kits, testing platforms, and other associated products—necessary to respond to a wide array of public health threats. The laboratory community, including community and regional independent laboratories, should be included in SNS stockpiling planning and decision-making. These communities are best positioned to understand what materials will be needed by laboratories to adequately respond to future public health emergencies.

3. The COVID-19 pandemic highlighted the efficacy of removing inefficient regulatory barriers that may stall public health and recovery responses. While many federal barriers to the immediate risk were addressed, long-term impediments remain that could discourage State, local, and private sector investment in pandemic preparedness.

a. *What regulatory barriers could be modified, consolidated, harmonized, or repealed to better ensure Federal and State public health agencies are better situated to quickly adapt and efficaciously respond to protect public health in a future PHE?*
b. *What barriers exist that impede private sector investment in resources and capabilities – such as early warning systems, vaccine development, and domestic manufacturing – which could prove beneficial in future pandemics and public health emergencies?*
c. *What regulatory barriers and burdens could be allayed, consolidated, repealed, or otherwise modified that would better situate local communities to remain economically viable and resilient in the face of future public health emergencies?*
d. *What revisions and updates to public health and communicable disease law may be required in light of issues raised during the public health response to the COVID-19 pandemic?*

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 labs closed, or otherwise altered their business models to serve fewer Medicare beneficiaries. This contraction in the laboratory market has 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 independent laboratories. Laboratories are now working to mitigate staffing shortages, while many are also providing increased wages to meet the increase in the minimum wage for federal contractors to $15 per hour effective in January 2022. For those community and regional laboratories that remain, these rate reductions have also hampered their ability to purchase needed supplies, leading to slower test results and inconsistent access to testing in many communities. A comprehensive plan to respond to the next public health emergency must consider the adequacy and sustainability of non-emergency laboratory infrastructure. Without adequate investment in pre-emergency infrastructure, the nation will be left without the tools necessary to quickly respond to future public health threats.

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.

6. The National Academies of Sciences, Engineering, and Medicine (NASEM) released a study report in November 2021, Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise, that provides recommendations for a re-envisioned Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). Four priority areas of improvement emerged from committee deliberations: (1) articulating PHEMCE's mission and role and explicating the principles guiding PHEMCE's operating principles and processes, (2) revising PHEMCE operations and processes, (3) collaborating more effectively with external public and private partners, and (4) navigating legal and policy issues. Please provide feedback and responses to relevant recommendations in this report.

Four recommendations in the NASEM report are of particular relevance to independent laboratories.

- Incorporate the perspectives of nonfederal and private-sector partners and stakeholders in the PHEMCE Strategy and Implementation Plan and associated multiyear budget with clearly specified roles, objectives, accountability, benchmarks, timelines, and budget requirements.
    - NILA agrees that the incorporation of nonfederal and private-sector partners and stakeholders is important for future strategy and planning. The initial reliance on public

health laboratories and missteps at the Centers for Disease Control and Prevention 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 allow the federal government to utilize the skill and capacity of private entities, like community and regional independent laboratories, sooner.

- Develop and maintain an advisory committee of representative MCM partners and stakeholders to both benefit from their expertise and 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 distribution. 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 at times during the current public health emergency.
- 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.
- Develop, document, and clearly define authorities, roles, and responsibilities among 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. As discussed in more detail below, the governing memorandum of understanding on surge testing between the CDC and private-sector stakeholders and partners failed to include community and regional laboratories, excluding more than half of the independent laboratory market from plans for surge testing response. 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.

7. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has historically focused on and invested in strong public-private partnerships, pairing together the foundation and support of the U.S. federal government (USG) with the expertise and on-the-ground, in-the-field experience of the private sector. Throughout the COVID-19 pandemic, we have relied on the success of public-private partnerships such as Operation Warp Speed and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).

a. What regulatory barriers could be modified, consolidated, harmonized, or repealed to ensure these public-private partnerships continue to be supported and best utilized to both prepare for and respond to future pandemic and public health emergencies?
b. Are there other barriers that exist that impede private sector interest and investment in public-private partnerships?
c. How can the U.S. federal government better support, encourage, and invest in promoting and advancing public-private partnerships with the private sector?
d. Please identify any specific gaps in issue areas or programs that would benefit from additional support and promotion of public-private partnerships.

Future public-private partnerships on pandemic planning and surge testing capacity must include community and regional independent laboratories. The current Memorandum of Understanding on testing surge capacity needs during emergency response was only executed between CDC and the American Clinical Laboratory Association, Association of Public Health Laboratories, and the Council of State and Territorial Epidemiologists, excluding the input of community and regional independent laboratories not represented by the American Clinical Laboratory Association. 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 a number of 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 – will be key to future pandemic response.

To avoid concentration and inefficient allocation of test volume in the future, a "Clinical Laboratory Ready Reserve" should be established to guard against atrophy following the current pandemic and ensure that there is national capacity and capability to ramp up a muscular, 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 independent and academic clinical labs, of all sizes and from all regions of the US, 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 labs 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 labs 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 labs who demonstrate the ability to deploy accurate testing in the shortest time.

Matching funds would also be provided to encourage labs 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 again be needed. Grants would also be provided to help labs 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.

9. Please share any brief additional comments or recommendations that were not properly addressed with the above prompted questions.

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 Food and Drug Administration (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. While access to testing is critical, NILA became increasingly concerned about the accuracy, reproducibility, and reliability of some of these tests. Unfortunately, during the COVID-19 response, some clinical laboratory test manufacturers have taken advantage of the pandemic and the federal government's focus on speedy access to testing to market fraudulent tests that threaten lives and resources. As more rapid and point-of-care tests were marketed, it was critical to evaluate the accuracy and reliability of these tests during the pandemic and, unfortunately, the federal government's oversight of these tests during the COVID-19 pandemic was inadequate to fully protect the public. Inaccurate or unreliable testing represents a public health threat, particularly in a time of emergency.

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 do so, the federal government should require emergency use authorization for *all* tests deployed during a public health emergency and laboratory participation in proficiency testing for both molecular and serology tests as a condition of performing emergency use authorized tests. Accurate and reliable tests underpin the nation's ability to address and control any pandemic. In the push to increase testing capacity, it is important to note that *more* testing capacity does not always equate to *reliable* or *accurate* testing capacity. Indeed, inaccurate molecular or serology tests can have dangerous consequences for the public. A false negative on a molecular COVID-19 test will allow infected individuals to unknowingly continue to spread the virus, potentially resulting in more hospitalizations and deaths. And a false positive molecular test result could unnecessarily require individuals to remain in quarantine, prevent them from interacting with their loved ones or returning to the workforce, and cause undue mental stress and anxiety. Serology tests are also subject to false positive and false negative results. Where a false negative molecular COVID-19 test may lead an individual to unknowingly infect more people, a false positive serology test may cause people to take unwarranted risks in exposing themselves to infection, believing incorrectly that the false positive test result means they are immune to infection by the COVID-19 virus. As FDA and CLIA continue to regulate clinical tests and the laboratories that perform them, the need for sufficient testing capacity must be balanced with the need for accurate and reliable test results to avoid these dangerous consequences.

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, including molecular and serology tests, in a laboratory where they are used to provide clinical laboratory test results to physicians and patients. During the current pandemic, and in future pandemics, a PT program should be immediately established and funded to evaluate laboratory performance and the accuracy of tests performed "in the field." At the beginning of this pandemic, the American Association of Bioanalysts (AAB) offered its services to the federal government at no cost to create a COVID-19 proficiency testing program to assist the nation's response to the pandemic, but received no response. We urge the federal government to partner with proficiency testing programs, like AAB's, early in future public health emergencies to ensure that emergency use authorized tests are subject to rigorous external quality control. The federal government

should also support proficiency testing by underwriting the cost of laboratory participation in these programs during a public health emergency and make certain that proficiency testing programs have access to needed specimens.

Public Health

8. The beginning of the COVID-19 pandemic illustrated the insufficiency of States' public health laboratory testing capacity and surveillance activities. What specific problems contributed to the challenges many States encountered? Which problems remain to be addressed by Congress, and what solutions might Congress pursue to enhance public health laboratory testing capacity and surveillance?

The insufficiency of States' public health laboratory testing capacity demonstrates the need for future planning that incorporates the entire laboratory community—including community and regional independent laboratories. During national public health emergencies, it is unrealistic to expect public health agencies or laboratories to be able to respond on their own. The reliance on public health laboratories 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 needed for laboratories 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. The CDC's initial challenges also harmed the trust between the laboratory industry and the CDC, calling into question the competence of the administration's response to the pandemic and creating confusion in the laboratory community. More planning is needed to identify when and how private entities can supplement testing and test development capacity and provide additional expertise. Failure to do so early in the pandemic led to undetected and uncontrolled spread of COVID-19.

11. The COVID-19 pandemic highlighted the need for agile, adaptable public health agencies unencumbered by activities and actions beyond the scope of their core mission.

a. *What reforms can be made to modernize and streamline Federal public health agencies?*
b. *What reforms, if any, are needed to Federal public health agencies to ensure an unencumbered, agile, and adaptable public health response? What actions covered by such agencies fall outside the scope of their core missions and should be moved, repealed, streamlined, or otherwise addressed?*

Collaboration between public health agencies and community and regional independent laboratories has been challenging throughout the pandemic. As noted above, initial missteps at the CDC and elsewhere hampered pandemic response. Additionally, the imposition of burdensome data reporting requirements during an emergency response imposed additional costs on laboratories. Unlike other areas of health technology, there has been little incentivization or investment in the laboratory information technology sector. 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 under tremendous financial constraints. Both 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 enough without additional investments in the private clinical laboratory infrastructure. As we have seen with COVID-19, it is not just public health laboratories

reporting results to public health departments—independent labs, including NILA members, are now responsible for a much higher volume of public health reporting than before. NILA supports independent laboratories' role in this regard but feels strongly that federal investments should be made in independent laboratories, as well as public health departments, to ensure that there is interoperability and consistency in reporting. Incentive payments to independent 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.

Thank you again for the opportunity to respond to this RFI. The National Independent Laboratory Association and its members would welcome the opportunity to discuss these responses further. Should you have any questions, please contact NILA representative Erin Morton at emorton@dc-crd.com.

Sincerely yours,

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