June 26, 2020

The Honorable Lamar Alexander
Chairman
Senate Committee on Health Education Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Alexander:

On behalf of the National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB), thank you for your work in addressing the current COVID-19 pandemic and for your leadership in working to prepare our nation for the next pandemic. We appreciate the opportunity to respond to your white paper, "Preparing for the Next Pandemic." However, we offer the important caveat that many of the recommendations and comments below must still be addressed in response to the current pandemic. COVID-19 is far from over, and we need leadership from Congress and the Administration to improve our current response and ensure we are working with a coordinated approach. **To that end, we first and foremost urge you and your colleagues to pass an additional COVID-19 relief package that has dedicated funding available to the clinical laboratories working on the ground to increase testing capacity around the country.**

Members of NILA and AAB work in regional and community independent and clinical laboratories across the United States performing clinical laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care providers. NILA and AAB members serve a wide variety of communities and patient populations that are **not** priorities for the largest independent clinical laboratories, including rural areas, underserved inner city neighborhoods, small and mid-sized cities and municipalities, community and critical access hospitals, skilled nursing facilities, adult homes, group homes, and patient rehab centers. The laboratory response to COVID-19 and any future pandemic is of critical importance, and regional and community laboratories must be part of this response.

Responding to a future public health or other type of national emergency [e.g., bioterrorism or biowarfare, natural disasters (fires, earthquakes, hurricanes, tsunamis, etc.), nuclear accidents or nuclear attacks, cyber warfare, or supply chain interruptions] requires upfront investment in community and regional laboratories **before**, not *during* the next crisis. Unfortunately, recent cuts in Medicare laboratory reimbursement rates following the Protecting Access to Medicare Act (PAMA) have hampered the ability of many community and regional clinical laboratories to respond to the COVID-19 pandemic. Further, we urge you to include regional and community laboratories in your planning for future national emergencies and provide ongoing investment in laboratory infrastructure so that community and regional laboratories are able to quickly respond to future public health emergencies.

The following comments respond to the recommendations that most closely align with NILA and AAB's areas of expertise and offer additional insight on how Congress and the Administration can better utilize the services of community and regional clinical laboratories in future public health emergencies.

Tests Treatments and Vaccines—Accelerate Research and Development

Recommendation 1.4: Engage and partner with the private sector early to develop diagnostic tests, ensure flexibility to develop and use laboratory-developed tests in a public health emergency, and ensure that the stockpile is better prepared to address diagnostic needs.

Accurate and reliable clinical diagnostic tests are critical to the nation's response to any public health emergency or pandemic. As your white paper states, several missteps in response to COVID-19, including lack of available testing supplies, slowed the U.S. response. NILA and AAB support this recommendation and urge the federal government to partner early with community and regional clinical laboratories to quickly respond to future public health emergencies, while also protecting the public from unreliable or inaccurate test results.

During the COVID-19 public health emergency, the Food and Drug Administration (FDA) relaxed its oversight of clinical laboratory tests through emergency use authorization (EUA) 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 took advantage of the pandemic and the federal government's focus on speedy access to testing, to market inaccurate, unreliable, and in some cases fraudulent tests that threatened 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. Unfortunately, the federal government's oversight of these tests during the COVID-19 pandemic was inadequate to 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 number of tests—is the primary focus in future public health emergencies. To do so, the federal government should require emergency use authorization (EUA) 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 EUA 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 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 (PT) 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 CLIA-approved Proficiency Testing 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, AAB's CLIA-approved Proficiency Testing program offered to quickly develop a **free** emergency COVID-19 proficiency testing program if CMS would provide positive COVID-19 specimens, but we received no response. We urge the federal government to partner with proficiency testing programs 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, make certain that proficiency testing programs have access to needed specimens, and **require** participation in a CLIA-approved proficiency testing program as a condition of the emergency use authorization.

In addition to molecular testing, serology testing has emerged both as a tool for public health surveillance and a source of regulatory concern for future public health emergencies. To date, serology testing has primarily been discussed as a way to permit non-essential businesses to reopen, but the efficacy of serology tests for this purpose remains unclear. Serology testing for antibodies may be an important tool to respond to a future pandemic, but it must be approached carefully. We encourage the federal government to require manufacturers to obtain an EUA and for CMS to require proficiency testing for all molecular and serologic tests. Further, the intended use for all serology tests should be clearly stated and communicated to the public. In order for serology testing to fulfill its intended purpose in the country's response to a pandemic, available testing must be accurate and reliable.

The FDA's initial policy decision during the COVID-19 public health emergency to not require emergency use authorization for serology tests, while intended to speed products to market, resulted in the marketing and use of unreliable and inaccurate serology tests. NILA and AAB recommend that the federal government avoid missteps like this in the future by maintaining adequate external monitoring of serology and molecular tests during future public health emergencies. Efforts to publicly communicate the accuracy and reliability of tests, such as the current partnership between the FDA, NCI, and other agencies to work with the private sector to publicly share serology test performance data as part of validation studies, should be replicated in future public health emergencies. This type of partnership is valuable to community laboratories so that they can adequately assess the reliability and accuracy of the serology tests that are marketed outside of the non-emergency FDA approval processes. These partnerships, however, are not a substitute for adequate oversight and proficiency testing of molecular and serology tests. Proficiency testing, unlike other types of evaluations, assesses the use of tests "in the field," and gauge the accuracy and reliability of tests as performed by laboratorians for patients. To avoid the health and public safety risks that accompany inaccurate and inadequately evaluated molecular and serological tests, the federal government should require proficiency testing during public health emergencies so that health care providers, public health professionals, and laboratories can accurately assess the impact of a public health threat on a given community.

Disease Surveillance—Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases

Recommendation 2.1: Ensure timely communication between health professionals, states, the CDC, and the public, as appropriate, of case data and information regarding how emerging infectious diseases affect populations, including who is at higher risk for severe disease and death, to help inform state and local response and address any potential disproportionate impact on minority populations.

As your white paper correctly identifies, the communication of accurate and timely data to public health agencies is essential to understanding how an infectious disease is impacting a given community. Community laboratories play an important role in this data transmission, yet need access to the technology infrastructure necessary to quickly communicate testing results to public health laboratories. NILA and AAB urge the federal government to invest in community laboratory infrastructure **before** the next public health emergency so that community laboratories are better positioned to respond. **The recent draconian cuts in Medicare reimbursement rates under PAMA severely hamper that ability.**

The federal government should also be prepared to respond nimbly to a situation in which a public health threat disproportionately impacts different communities. COVID-19 has disproportionately impacted older Americans, particularly those in skilled nursing facilities, group homes, assisted living facilities, nursing homes, and patient rehab centers. These facilities, due to the small profit margins and higher specimen collection risks, are primarily served by regional and community laboratories, **not** the largest independent clinical laboratories. In this and future pandemics, the federal government must invest the time, attention, and funding necessary to deploy resources to all kinds of laboratories—including community and regional laboratories—to ensure adequate access to testing and accurate disease surveillance. A "one-size-fits-all" approach that only includes the largest independent clinical laboratories will inevitably neglect some of the most vulnerable communities and hamper the nation's timely response to public health threats. The shortcomings of a "one-size-fits-all" approach were made evident during the current pandemic following the over reliance on the largest independent clinical laboratories, which resulted in patients waiting up to two weeks for COVID-19 test results because the largest independent clinical laboratories were unable to respond adequately to the surge in testing demand.

In this and in future public health emergencies, the federal government should focus on community-tailored solutions that support the community and regional laboratories that serve older Americans and other communities not adequately served by the largest independent clinical laboratories. These solutions will require investment in community and regional laboratories that continue to struggle under reimbursement rate reductions following the enactment of PAMA. These rate reductions have already weakened the nation's laboratory infrastructure and reduced access to testing in settings not served by the largest independent clinical laboratories. Community and regional laboratories are central to providing services to rural and underserved communities; without investment in these laboratories before the next public health emergency, the federal government risks leaving many communities without access to needed testing services.

Stockpiles, Distribution, and Surges – Rebuild and Maintain Federal and State Stockpiles and Improve Medical Supply Surge Capacity and Distribution

Recommendation 3.2: States should establish distribution plans and procedures to better inform and communicate with health care providers that request supplies. The Strategic National Stockpile should provide states, territories, and tribes with guidance on best practices to coordinate and distribute medical supplies, including procedures to request resources from the federal stockpile.

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. Community and regional laboratories must be included in state distribution plans that oversee the allocation of essential supplies. Throughout the COVID-19 public health emergency, community laboratories have struggled to access needed testing supplies—including swabs, reagents, Personal Protective Equipment (PPE), and test kits—to adequately serve their communities. Additionally, supplies that have been made available by state governments have not always been distributed equally among laboratories. 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 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.

Additionally, the federal government must recognize that the strength and sustainability of the nation's laboratory infrastructure ***before*** a public health emergency directly impacts the ability of laboratories to effectively respond *during* a public health emergency. Following years of cuts to Medicare's Clinical Laboratory Fee Schedule, the first three years of the implementation of PAMA resulted in an additional 30% cut to many common laboratory tests. Because of these ongoing cuts, many community and regional laboratories have 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. For those community and regional clinical laboratories that remain, these rate reductions have also hampered their ability to purchase and stockpile 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.

Recommendation 3.4: The federal government, states, and the private sector must work more effectively together to distribute tests, treatments, and vaccines. Plans should be established in advance for how the federal government, states, and the private sector will coordinate to assess needs and distribute newly developed tests, treatments, or vaccines.

Community and regional clinical laboratories have been deeply involved in the response to COVID-19 and will be on the front lines of future public health emergencies. Throughout the COVID-19 pandemic, community and regional clinical laboratories have struggled to gain access to testing supplies that have been allocated to the states. The U.S. will need an "all hands on deck" approach to respond successfully to future pandemics. Community and regional clinical laboratories must be included in state and federal distribution plans in order to maximize the ability of health care workers to provide clinical laboratory tests to as many individuals as possible. **The largest independent clinical laboratories do not have the capacity to reach all areas of the country.** Further, many of their specimens are transported by air to core testing facilities. This model has certain weaknesses—such as an airport or air travel shutdown as happened during 9/11. Most community and regional clinical laboratories do not ship specimens by air

and can provide supplemental and alternative testing capacity in states and regions that need them most. However, this can only happen if the federal government provides emergency funding and resources to ensure that community and regional clinical laboratories have the capacity and resources needed, and are prepared, to offer the tests.

Another challenge for community and regional clinical laboratories is the large initial investments that laboratories may need to make in order to respond to public health emergencies. Molecular and serology tests are performed on a wide variety of testing platforms. Many community and regional clinical laboratories, particularly in light of 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 molecular testing platform at the outset of a public health emergency. For community and regional clinical 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 laboratories for the collection, transportation, and testing services that laboratories provide. The federal government should also make certain that community and regional clinical laboratories have access to the upfront capital needed to invest in the testing platforms required to perform the tests needed to be able to quickly respond to future public health emergencies. Without both adequate reimbursement and upfront capital investment, community and regional clinical laboratories are unlikely to be able to respond quickly to future public health emergencies.

Recommendation 3.5: Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.

The Strategic National Stockpile is a critical resource in responding to a pandemic. However, its functionality depends on resources being maintained and replenished regularly. We agree that to be prepared for the next public health emergency the federal government must make maintenance of the Strategic National Stockpile a priority. Laboratory testing supplies such as swabs, reagents, and personal protective equipment must be included in future federal stockpiling efforts to ensure that diagnostic testing can be swiftly ramped up in a time of emergency. The federal government must also make certain that the Strategic National Stockpile is stocked to respond to a wide variety of public health emergencies—not just a viral threat such as COVID-19. From bioterrorism to natural disasters to the ongoing opioid epidemic, the materials in the Strategic National Stockpile must reflect the diversity of potential public health threats that the nation may face. Oversight and accountability of the Strategic National Stockpile must include evaluation of whether the stockpile has the supplies necessary to respond to a wide variety of public health threats.

Recommendation 3.6: Better leverage the support provided by FEMA and their emergency management experience and assets by improving a coordinated process between HHS and FEMA to more rapidly distribute supplies to states, health care providers, and other entities on the front lines, while utilizing HHS expertise with respect to public health and medical care and medical supplies.

We agree that improved interagency coordination will allow for a better emergency response. As HHS and FEMA work together to improve the speed of supply distribution, we ask that community and regional laboratories be among the health care entities that receive access to necessary supplies as soon as they are available. As with the state testing plans described above, supply distributions to states,

Recommendation 3.6: Better leverage the support provided by FEMA and their emergency management experience and assets by improving a coordinated process between HHS and FEMA to more rapidly distribute supplies to states, health care providers, and other entities on the front lines, while utilizing HHS expertise with respect to public health and medical care and medical supplies.

We agree that improved interagency coordination will allow for a better emergency response. As HHS and FEMA work together to improve the speed of supply distribution, we ask that community and regional laboratories be among the health care entities that receive access to necessary supplies as soon as they are available. As with the state testing plans described above, supply distributions to states, health care providers and others must account for the variety of entities that perform testing and respond to public health emergencies, including community and regional clinical laboratories. The federal government should also include non-profit and professional associations, such as AAB and NILA, in future public health emergency planning and response. Early engagement with these entities will give the federal government access to the expertise necessary to plan for future public health emergencies and access to the laboratories best positioned to respond to those emergencies when they inevitably arrive. Finally, there must be transparency in how supplies/reagents are allocated and distributed to discourage hoarding by "preferred" providers and to encourage sharing among all the entities involved.

Again, thank you for your leadership in preparing our nation to respond to the next pandemic. The COVID-19 pandemic will not be the last time we face an infectious threat of this nature and we must do all we can to ensure that the U.S. is equipped to protect the health and livelihoods of all individuals in this country when the time comes. Working in community and independent laboratories, NILA and AAB members will be on the front lines of the next infectious disease to emerge. We encourage you to consider the critical role community and independent labs have played in pandemic response so far and to ensure these labs are positioned to respond fully to the next pandemic. If you have questions regarding any of the information provided above, please contact AAB and NILA's Washington Representative, Erin Morton, at emorton@dc-crd.com.

Sincerely yours,

Mark S. Birenbaum, Ph.D.
Executive Director
American Association of Bioanalysts (AAB) and the
National Independent Laboratory Association (NILA)