June 26, 2020

Via e-mail: *PANDEMICPREPAREDNESS@HELP.SENATE.GOV*

American Clinical Laboratory Association

Senator Lamar Alexander of Tennessee
Chairman, U.S. Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Re: Preparing for the Next Pandemic: A White Paper

Dear Chairman Alexander:

The American Clinical Laboratory Association (ACLA) is pleased to provide these initial comments on your white paper, *Preparing for the Next Pandemic*. As always, ACLA stands ready to answer any questions on our comments and to collaborate with your staff on improving the public health framework to ensure that the United States is well-prepared to respond to the next pandemic. ACLA appreciates your efforts in addressing this important topic and considering these comments.

I. INTRODUCTION

ACLA is a trade association representing the nation's leading providers of clinical laboratory services, including regional and national laboratories. ACLA members have performed over half of all COVID-19 testing in the United States, including over 14.5 million PCR tests as of June 24, 2020. Its diverse membership includes a broad array of laboratories: large national independent laboratories, reference laboratories, esoteric laboratories, hospital laboratories, and nursing home laboratories. ACLA members both develop and perform laboratory developed test services (LDTs), in addition to purchasing and performing tests with in vitro diagnostic test kits (IVDs).

As part of the country's ongoing response to the COVID-19 pandemic, private-sector laboratories have taken unprecedented steps to rapidly scale testing capacity and provide a range of new tests to meet the pressing public health needs facing American families and workers. Many independent laboratories, hospital laboratories, and academic medical center laboratories have joined public health laboratories to provide molecular and serologic COVID-19 testing – an indication of both the scale of the crisis and the capabilities of our combined response.

The COVID-19 pandemic has exposed significant systemic barriers that hamper the private sector's ability to support the country in fully responding to public health emergencies. For example, the Centers for Disease Control and Prevention (CDC) deprioritized standing up testing in private-sector clinical laboratories for weeks, instead focusing on the agency's own test. This delay inhibited private-sector laboratories from fully assisting with the pandemic response for more than a month, instead of leveraging the nation's largest source of laboratory capacity (i.e., private-sector clinical laboratories). Even when private-sector clinical laboratories were called upon to dramatically expand their testing capacity, critical test validation resources were held up by unclear government channels, and no federal funding was made available to support the rapid expansion of laboratory capacity nor the performance of the tests. While Congress has since taken action to mandate coverage and Medicare and many other payers have

established reimbursement, gaps and disparities remain and, to-date, private-sector labs have not received direct federal support for the expanded capacity investments, despite Congress appropriating substantial funds to support testing activities broadly.

As we continue to respond to the COVID-19 pandemic and safely reopen the economy, laboratories face a constantly shifting landscape on several fronts, including test ordering guidance, coverage interpretation, reimbursement rules, and vastly expanded data reporting requirements. Despite the shifting landscape, clinical laboratories have committed upfront investments to rapidly expand testing capacity, all while resources are scarce within the laboratory ecosystem amidst a backdrop of year-over-year cuts to Medicare reimbursement for clinical laboratory services through CMS's flawed implementation of a market-based fee schedule under the *Protecting Access to Medicare Act* (PAMA) and a worsening economic environment resulting from national social and economic lockdowns.

This week, the Administration also significantly undermined the goal of ensuring that every American has access to COVID-19 testing, with the issuance of guidance for group health plans and health insurance issuers from the Departments of Labor, Treasury, and Health & Human Services (HHS) on June 23, 2020 ("Tri-Agency Guidance").[1] The June 23rd Tri-Agency Guidance stands in contrast to the statutory coverage mandates in the *Families First Coronavirus Response Act* ("FFCRA") and the *Coronavirus Aid, Relief, and Economic Security Act* ("CARES Act"). As Chairman Lamar Alexander and Chairman Roy Blunt stated in an April 8, 2020 letter to HHS Secretary, Alex Azar, coverage applies to "both the diagnosis of COVID-19 or SARS-COV-2 and the detection of antibodies to SARS-COV-2."[2] Likewise, an earlier guidance on April 11, 2020 indicated that both molecular *and* serology testing for COVID-19 must be covered by group health plans and health insurance issuers.[3]

The new Tri-Agency Guidance undermines the broad coverage goals of the FFCRA and CARES Act, by creating significant gaps and disparities in access to COVID-19 testing when such testing is deemed to be for surveillance or "return to work" purposes and creates uncertainty around coverage of serology with the deletion of the coverage clarification from the April 11th guidance.[4] In addition to hindering the pandemic testing effort, the new coverage gaps could further exacerbate disparities in the response. For example, while some individuals may still retain access to testing due to employer funded return-to-work programs, others, such as individuals working in nursing homes and restaurants, will face barriers to access necessary testing.

Private-sector laboratories have stepped up to the unprecedented challenge by shouldering the upfront costs of rapidly expanding test capacity, and continue to face difficulties in obtaining reimbursement for tests performed as part of the nation's pandemic response. Ultimately, to ensure that Americans are protected and the economy successfully reopens, and to prevent and mitigate the spread of the virus, both tests to diagnose the presence of the virus and tests for

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[1] *FAQs About Families First Coronavirus Response Act, and Coronavirus Aid Relief, and Economic Security Act Implementation*, Part 43; June 23, 2020; ("June 23 Tri-Agency Guidance") https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf.

[2] Letter from Chairman Lamar Alexander and Chairman Roy Blunt, U.S. Senate, to Secretary Alex Azar, U.S. Department of Health and Human Services (April 8, 2020); https://www.help.senate.gov/imo/media/doc/Senate%20Letterhead%20Alexander%20Blunt%20Letter%20to%20Azar%204%208%202020.pdf.

[3] *See FAQs About Families First Coronavirus Response Act, and Coronavirus Aid Relief, and Economic Security Act Implementation*, Part 42; April 11, 2020; Q4, p. 5; https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-42.pdf.

[4] *See* June 23 Tri-Agency Guidance, Q5, p. 6.

contact tracing, surveillance, and return to work and school must be widely available. Testing is critical to support a comprehensive response to this pandemic, yet the Tri-Agency Guidance creates coverage gaps that, left unfilled, undermine state and national efforts to limit virus spread and reopen our economy.

To address the current pandemic, ACLA urges the following immediate actions by Congress and the Administration to keep the economy open, bolster our preparedness for COVID-19 this coming flu season, strengthen our national pandemic response systems for the future, and keep Americans safe.

To keep the economy open in our current response:

- Congress and the Administration should provide clarity for when third-party payers, the government, or other responsible parties must provide reimbursement for all types of COVID-19 testing, whether for diagnostic, screening, or surveillance purposes. Such clarity must include dedicated federal funding to reimburse for tests when there is no other responsible payor. Laboratories have rapidly expanded capacity to meet the unprecedented demand caused by the pandemic. As of June 24th, ACLA member laboratories have performed over 14.5 million PCR COVID tests. But, laboratories need certainty that they will be reimbursed for the tests that they perform as part of the nation's response.
- HHS should work rapidly to further educate providers and those administering specimen collection sites on appropriate test ordering guidelines, particularly around the need to collect expanded demographic data during the patient encounter. ACLA recognizes and supports the critical need for additional patient demographic information to be reported, particularly race and ethnicity. This data is absolutely critical to respond to the disparate impact of COVID-19 on minority and underserved communities. However, that information must be included with the test order if laboratories are to be able to provide demographic information to public health authorities. ACLA is already working on its own outreach to professional societies and organizations representing physicians, nurses and pharmacies.

To strengthen future responses and guarantee a robust and innovative national laboratory network, Congress and the Administration should:

- Establish and fund public-private preparedness collaborations through the CDC, whereby private-sector clinical laboratories with appropriate expertise are a critical element of pandemic response planning, proactive data monitoring, and the early testing response, both for emerging pathogen threats and larger epidemics and pandemics.
- Establish and fund a standardized national public health data reporting system so that federal, state, and local public health authorities have timely access to actionable and accurate public health data, while minimizing burden on reporting by health care providers.
- Eliminate further cuts to Medicare clinical laboratory reimbursement under PAMA, until the Clinical Laboratory Fee Schedule (CLFS) can be properly reformed into a truly market-based system.

We know that the Committee recognizes that the current response demands an all-hands-on-deck approach, and ACLA remains a committed partner in the current response and in preparing for future public health emergencies.

Looking ahead to ensure that our nation is adequately prepared for the next pandemic, changes to the public health framework are necessary. Such changes must leverage the strengths of private-sector clinical laboratories, public health laboratories, and federal, state, and local governments. Below, ACLA describes key reforms that should be made to the public health framework to better position the United States to respond to the next pandemic. These reforms guide our comments on the recommendations and questions outlined in the white paper.

II. THE PUBLIC HEALTH INFRASTRUCTURE MUST BE REFORMED TO MAKE PRIVATE-SECTOR CLINICAL LABORATORIES A KEY GOVERNMENT PARTNER FOR PANDEMIC PREPARATION AND RESPONSE

Availability of diagnostic and screening tests is essential to managing a pandemic response in a way that avoids severe economic lockdowns. Without testing, it is impossible to know the scale of the outbreak, which hampers the country's ability to fight the virus by taking containment measures, such as isolation and contact tracing, and mitigation measures, such as equipping hospital systems with necessary supplies. Testing for an emerging pathogen poses unique challenges, since tests cannot be developed before the pathogen has been identified. Thus, once the threat of an infectious disease pandemic is identified, time is of the essence.

Private-sector clinical laboratories–particularly CLIA-certified, high-complexity laboratories—are uniquely qualified to rapidly develop, validate, and perform high-quality diagnostic tests that are necessary for managing a pandemic response. Private-sector clinical laboratories are armed with the personnel, scientific expertise, and experience necessary to respond quickly and develop new tests. In the commercial sector, laboratories also have the most capacity, established supply chains, and operational systems to quickly and efficiently conduct large-scale testing of specimens from all over the country, 24 hours a day and 7 days a week. However, the current public health framework does not adequately recognize or leverage the power of the private laboratory industry to respond to a pandemic, particularly in the earliest phases.

Clinical laboratories from the private sector should be utilized proactively as a key collaborative partner with the federal and state governments. As such, they should be included not only in the earliest discussions with CDC and other public health officials regarding planning and implementation of pandemic preparedness and response strategy, but also in the early stages of test development and distribution of protocols and materials to develop such tests. Our nation's response mindset must shift fundamentally from overly relying on government laboratories and test development, with as-needed support from private-sector laboratories, to a strategy that leverages the strengths and testing capacity of the private-sector clinical laboratory industry from the very beginning, even before the threat of a pandemic emerges. ACLA's vision of clinical laboratories as a true partner in preparing for and responding to public health emergencies, however, requires upfront and ongoing investment and collaboration from the federal government and public health officials.

a. Private-sector clinical laboratories must be involved in pandemic response from the beginning.

From the earliest days of the pandemic, private-sector laboratories engaged with U.S. health department officials to offer our services in developing and performing tests. Beginning in January 2020, ACLA member laboratories participated in a regular dialogue with the CDC, public health laboratories, and epidemiologists to share information regarding the progression of the virus and the government's developing response. Despite the regular communication, however, the government's first call-to-action that enabled private-sector clinical laboratories to provide testing capacity to respond to the worsening pandemic did not come until February 29, 2020, when FDA issued a guidance streamlining introduction, under limited conditions, by

high-complexity laboratories of validated LDTs for the identification of the virus causing COVID-19. Under that guidance, high-complexity laboratories could immediately introduce, upon notification to the FDA, validated LDTs for the identification of the virus causing COVID-19, utilizing procedures developed under the Clinical Laboratory Improvement Amendments (CLIA), pending approval of an application for an FDA emergency use authorization (EUA), which was to be submitted within 15 days of the notification.

One justification offered for delaying the involvement of private-sector clinical laboratories was that public health laboratories had sufficient capacity to perform the number of tests needed. While public health laboratories are a critically important part of our public health infrastructure, they are not equipped with the capacity for national-scale testing required in a pandemic. In contrast, laboratories in the private-sector are accustomed to performing tests and providing results rapidly for thousands and thousands of tests on a daily basis.

Another justification offered for delaying involvement of the private sector was that the FDA needed to review *all* tests developed by clinical laboratories in response to a pandemic. This demonstrates a critical flaw in the framework: in the absence of a public health emergency, FDA does not review LDTs developed by licensed and certified laboratory practitioners in clinical laboratories; however, FDA is required to review such tests once a public health emergency is declared, thereby slowing down test development and distribution precisely at the time when we need it the most.

This flaw is a remnant of the mindset that clinical laboratories and commercial manufacturers of diagnostics are interchangeable entities performing identical functions, and as such, are subject to the same regulations.[5] But they are not, and they do not – something the current pandemic has clearly shown. Commercial manufacturers make and distribute IVD ***products*** and are regulated by the FDA. Without FDA approval of an IVD, there is no assurance of the product's accuracy. In contrast, clinical laboratories provide ***services*** by developing, validating, and performing LDTs. In the absence of a public health emergency, FDA does not review individual LDTs developed by clinical laboratories, but that does not mean laboratories are unregulated or the accuracy and reliability of LDTs is unknown. Rather, clinical laboratories have been regulated for decades by the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) and under state law. Under CLIA, laboratories are certified to perform high-complexity, moderate-complexity, and/or "CLIA waived" tests. To maintain certification, laboratories are required to be staffed by personnel meeting certain educational and training requirements, and the laboratories must have quality management systems in place, in addition to undergoing regular inspections and, where applicable, proficiency testing to demonstrate the accuracy of the laboratories' tests. It was precisely these quality and validation requirements under CLIA that allowed public health laboratories to detect the flaws in the original CDC kit distributed in February. The quality checks required under CLIA prevented the testing of patients with a flawed test, which would have set back the nation's response even further.

The FDA's recognition of the accuracy and reliability of LDTs for COVID-19 serology tests is evidenced by its policy on those tests, which allows CLIA-certified high-complexity laboratories to offer and use the tests when they have been validated by the laboratory, and which does not require the laboratories to seek EUAs for the tests. Although FDA initially extended such policy

[5] *See, e.g.*, Christopher Weaver, Betsy McKay and Brianna Abbott, *America Needed Tests. The Government Failed. --- A series of blunders blinded the U.S. to the outbreak's scale,* WALL STREET JOURNAL (Mar. 19, 2020) (quoting a CDC email that stated the CDC's work with public-health laboratories was meant to fill "the short-term gap until experienced commercial diagnostic **manufacturers** come to market") (emphasis added).

to commercial manufacturers of serology tests, it ultimately retracted this policy and required commercial manufacturers—not laboratories—to submit EUAs for serology tests after discovering that several of the commercially manufactured tests—which were subject to *no* regulatory oversight and were required to comply with *no* quality standards—were unreliable. The updated policy explains:

> FDA has become aware that a concerning number of commercial serology tests are being promoted inappropriately, including for diagnostic use, or are performing poorly based on an independent evaluation by the NIH, indicating that greater FDA oversight of commercial serology tests is important to protect the public health.[6]

Since the policy was updated, FDA has warned that fifty of these manufactured tests should not be used.[7] The updated policy continues to permit CLIA-certified, high-complexity laboratories to develop and distribute serology tests without FDA review, however, which recognizes that clinical laboratories can reliably develop and perform accurate tests.

However, even FDA's policies that expedited availability of tests from private-sector clinical laboratories was delayed. The Secretary of HHS declared a public health emergency on January 31, 2020, and the CDC received an EUA for its SARS-CoV-2 diagnostic test only four days later. But it was not until February 29, 2020—over three weeks after the CDC test was authorized and nearly a month after the emergency was declared—that FDA issued its first COVID-19 testing policy that expedited the development and distribution of SARS-CoV-2 molecular diagnostic tests by clinical laboratories. The problems with the CDC test are well documented,[8] and Americans would have benefitted from having alternative tests available during the earliest days, weeks, and months of the pandemic.

Before the next pandemic, our public health framework should be reorganized to tap into the unique capabilities and strengths of the private sector, which can skillfully and efficiently develop and deploy novel testing at a wide scale in response to a pandemic. In line with this, ACLA recommends that public health authorities should continue to act as the "boots on the ground"—tracking cases, conducting follow-up, and implementing containment measures. Private-sector clinical laboratories are well suited, however, to function as the "testing arm" of the system whenever a substantial volume of testing is needed. Private-sector laboratories are located throughout the United States and already operate advanced logistics, including quick airport access, to ensure the speedy performance of tests for patients throughout the country. Laboratories from the private sector should be a key, upfront partner with the federal government in preparing for and responding to public health emergencies, not an afterthought. As such, draft test protocols and control and validation materials should be shared with designated clinical laboratory partners, concurrently with CDC test development and sharing and distribution with public health laboratories.

To have maximum impact, this collaboration should be activated *before* the threat of another pandemic arises. Private-sector clinical laboratories should be engaged in the government's processes for planning, implementing, and beta testing the public health response framework,

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[6] FDA Guidance, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency* at 7 (May 11, 2020) (citations and footnotes omitted).
[7] FAQs on Testing for SARS-CoV-2: "What Tests Should No Longer Be Distributed for COVID-19?", *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#nolonger-ivd (last visited June 26, 2020).
[8] *See, e.g.*, Shawn Boburg, et al., *Inside the coronavirus testing failure: Alarm and dismay among the scientists who sought to help*, THE WASHINGTON POST (April 5, 2020).

including by monitoring emerging data regarding new pathogens *before* those pathogens create a public health emergency. The federal government should build on efforts, such as the memorandum of understanding between ACLA, CDC, the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE), to strengthen coordination between private industry and public health agencies, establish clear lines of communication, and clarify and streamline regulatory processes for diagnostic testing in emergencies.[9]

This upfront collaboration can be established through government contracts periodically awarded by the CDC to high-complexity laboratories. The contracts should include requirements for expertise, laboratory capacity, communication and data reporting, joint training requirements, protections for government intellectual property, and other routine contractual protections. In return, the contracted laboratories should receive regular funding to retain and reserve personnel, equipment, test supplies, and facilities necessary to quickly bring new tests and substantial capacity online when called upon to respond to an emerging pathogen threat.

While no preparedness model can fully guarantee the prevention of a nationwide pandemic, a substantially larger, fully coordinated, public-private response in the earliest stages will give the United States the best opportunity for prevention, mitigation, and containment.

b. The public health framework should encourage maintenance of on-site "reserves" that are ready for rapid deployment, rather than sequestration of "stockpiled" materials.

The scale of the COVID-19 pandemic put immense strain on the ability of the Strategic National Stockpile to respond quickly and broadly enough to meet regional and local needs across the country. The strain demonstrated the need for additional failsafe stockpiles to support the health care infrastructure, particularly in a national-scale emergency. From personal protective equipment (PPE) to ventilators to testing supplies, shortages across the country prevented healthcare workers and laboratory professionals from responding to the COVID-19 crisis with necessary speed. The public health infrastructure should be structured to enable quick response in an emergency. Therefore, ACLA urges the Committee to direct HHS to revisit the "stockpile" approach, wherein designated materials are sequestered for later distribution, and, instead, consider adding support for the maintenance of on-site "reserve" capacities that enable our health system to rapidly respond to emerging threats.

Supporting reserve capacity means making upfront and ongoing investments to ensure that our health system has the resources it needs to rapidly respond to novel health threats. This includes an ongoing investment in the materials, technology, trained personnel, and facilities needed to respond in a public health emergency. Indeed, it is impossible to stockpile trained expertise or facility capacity—such resources must be maintained through ongoing investment.

This shift in mindset is especially critical in the context of clinical laboratories. As noted above, LDTs are not products, and they cannot be stockpiled, especially for use in the context of an emerging pathogen that, by its very definition, has only recently emerged. Rather, in responding to an emerging pathogen, partner laboratories, including private-sector partners, need immediate access to sample collection and testing materials, PPE, instruments, highly-trained personnel, and testing space. With regard to materials, PPE and instruments, ACLA

[9] *See* ACLA Blog, *During emergencies and in everyday life, labs support public health goals* (June 6, 2019); https://www.acla.com/during-emergencies-and-in-everyday-life-labs-support-public-health-goals/.

recommends that such laboratories partnered with the government should have reserve supplies that would support six months of operations. The supplies should be maintained in an inventory that is rotated and supported through the contract arrangements with the CDC, as discussed above.

However, clinical laboratories cannot provide services with materials alone. The knowledge base and expertise of trained laboratory professionals is critical to the success of any response effort. Therefore, the government also must have the foresight to continuously invest in our country's laboratory professionals, for example, by funding laboratory technician training programs, and by setting compensation for laboratory services at adequate rates to ensure laboratory professionals can be adequately compensated for their work.

Additionally, in responding to a pandemic, laboratories require space to conduct large quantities of tests. Like laboratory professionals, laboratory *space* also cannot be stockpiled. Therefore, the government must continuously invest in maintaining and growing this country's private-sector partner facilities through contracts and/or grants, such as the arrangements discussed above. *See* section a, *supra*.

To the extent that materials remain in central stockpiles, however, ACLA urges the federal government to coordinate distribution of materials from the stockpile directly to large-scale recipients (i.e. capable of serving populations in multiple states). In the current pandemic, private-sector laboratories with nationwide operations were required to negotiate separately with states and local governments, each with its own support needs. Dealing with this type of disarray diverted crucial resources from responding to the actual emergency at hand.

This piecemeal approach fails to recognize that private-sector operations are not limited by state borders. Samples may be collected in one state and transported for testing by a laboratory in a different state. Therefore, allocating testing supplies to states on the basis of state resident need is not always the most efficient means of ensuring tests reach those residents. Rather, the government's approach to distributing testing supplies should account for the capacity of laboratories in the private sector to run large-scale testing, including acceptance of samples from other states. This would remove unnecessary redundancy and streamline the ability to deploy national testing at a large scale.

c. The federal government should commit to establishing a national public health reporting system that enables uniform reporting across the country.

ACLA supports the establishment of a national public health reporting system that enables uniform reporting across the country and improved access to data to inform response efforts. Currently, laboratories performing COVID-19 testing are receiving numerous duplicative data requests from all levels of government: federal, state, local, and even private health information exchanges. These multiple data feeds generate duplicative and overlapping public health data—placing additional cost and burden on private-sector laboratories that already are expending tremendous resources to comply with new regulatory requirements as they simultaneously expand testing capacity. While today's system appropriately prioritizes the state or local authorities who are responsible for taking action, the current patchwork system is inefficient, resource-intensive, and time-consuming. Instead, ACLA proposes a uniform, national reporting system, by which actionable public health data is reported by laboratories to one national public health authority, and is then available, once reported, to the CDC and the specific state and local authorities simultaneously. This streamlined system will improve access to accurate and timely data to inform the nation's response efforts and support a better understanding of health disparities, particularly in infection and mortality rates. Technology with the proper security

must be deployed, so that data reporting can be consolidated without compromising or delaying the delivery of accurate data to the ground for action. ACLA is committed to being a partner in the effort to reform the nation's public health data reporting system.

III. RESPONSES TO WHITE PAPER PROPOSALS AND QUESTIONS: HIGH PRIORITY

1. 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.*

ACLA agrees that LDTs must be included in any response to an emerging pathogen. Furthermore, private-sector laboratories should be fully engaged *before* the threat of another public health emergency arises, and certainly before another public health emergency is declared. As noted above, LDTs typically are not reviewed by FDA, but upon declaration of a public health emergency, LDTs must be authorized through FDA's EUA process, thus slowing down development and distribution of diagnostic tests, just when more tests and capacity is needed the most. *See* section II.a, *supra*. Therefore, ACLA encourages early and ongoing engagement by the federal government with the private sector—before declaration of a public health emergency—to ensure seamless and rapid development of LDTs for use in a public health emergency.

ACLA also encourages the government to shift away from the "stockpile" mindset and shift toward a "reserve" mindset. Rather than relying only on a central stockpile that sequesters product from the market, ACLA encourages investment in reserve systems that ensures private-sector laboratories are equipped with the materials, equipment, personnel and space to ramp-up testing on a moment's notice in the event of another pandemic. *See* section II.b, *supra*.

Question 3*: What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?*

CDC should immediately establish an ongoing collaboration with a set of both public health and private-sector clinical laboratories that are CLIA-certified to perform high-complexity testing to guarantee capacity across the country at the beginning of the next pandemic. The collaboration should enable CDC, public health laboratories, and private-sector clinical laboratories to resolve any "red-tape" issues that would otherwise prevent a rapid ramp-up of testing. In particular, the collaboration should address material transfer, intellectual property issues, availability of control materials and test components, and service performance reimbursement. The collaboration also should ensure that private-sector laboratories are part of the government's processes for planning, implementing, and beta testing the public health response framework, and that private-sector laboratories are involved in monitoring emerging data regarding new pathogens *before* those pathogens create a public health emergency.

Additionally, the federal government should halt any further cuts to the Medicare Clinical Laboratory Fee Schedule (CLFS) under PAMA. The current pandemic has made clear the importance of having a strong network of laboratories across our country. The government should stop starving the nation's laboratory infrastructure and, instead,

invest in ensuring that American clinical laboratories remain innovative and equipped to provide the highest levels of laboratory personnel, quality, efficiency, and patient access.

***Question 7**: How can Congress and HHS make sure CDC and FDA are working more closely with the private sector on diagnostic tests to detect emerging diseases?*

Congress and HHS should ensure that an HHS representative is engaged full-time in preparing for, coordinating, and responding to public health emergencies. This representative should ensure that: (1) there is more timely communication from HHS regarding the need for surge testing capacity, and (2) CDC, FDA, and CMS are aligned on guidance issued to health care providers, health plans, response partners and the public, including with regard to test ordering, the availability of tests, and their coverage and reimbursement.

***Question 9**: What are the lessons learned from the current fast tracking of tests, treatments, and vaccines to make them available even more rapidly?*

Clinical laboratories have a unique and vital role to play in ensuring the early availability of diagnostic tests – one that is distinct from that of manufacturers of in vitro diagnostic devices. In particular, high-complexity laboratories operating under CLIA provide a critical level of expertise and safeguards to ensure that accurate and reliable tests are brought to market. These laboratories provide in-field expertise to identify testing issues earlier, in addition to responding to supply chain issues which accompany the rapid-scaling of a new test. As such, private-sector laboratories should be recognized as a vital resource, distinct from device manufacturers. *See* section II.**Error! Reference source not found.**, *supra*.

***Question 10**: Are additional or more predictable liability protections needed to incentivize manufacturers of medical products that are not approved or cleared by the FDA for use during a certain emergency to scale up manufacturing capacity?*

Yes. Clinical laboratories should be immune from civil liability for services provided in good faith in response to a pandemic or emerging pathogen.

2. 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 inform state and local response and address any potential disproportionate impact on minority populations.*

ACLA agrees with this recommendation. ACLA supports continued efforts to improve access to information to inform the nation's COVID-19 response and to better understand health disparities in infection and mortality rates. To accomplish more timely and robust communication, including regarding race and ethnicity information, ACLA strongly urges HHS to provide clear direction to clinicians who order COVID-19 testing so that those clinicians can collect and include complete patient information in test orders submitted to laboratories when forwarding patient specimens. As laboratories typically do not interact with patients, laboratories can report only the demographic information that is provided by ordering clinicians. The ordering clinician and/or the specimen collection site both directly interact with the patient, and these

interactions represent the single best opportunity to collect the most fulsome patient data possible to inform the public health response and build scientific and medical understanding of the disease. Although HHS guidance states that laboratories can search for missing information in a health information exchange or other data source, it is not reasonable or practical to expect laboratories to hunt down information that is not provided when they are already expending tremendous resources to expand testing capacity, perform tests, and report results in a timely manner.

Additionally, as described above, the United States should adopt a uniform public health reporting system. *See* section II.c, *supra*.

Question 1*: What other barriers, in addition to limited testing capacity, and insufficient and outdated technology, make it difficult to detect and conduct public health surveillance of emerging infectious diseases?*

In the context of COVID-19, delayed cooperation with private-sector laboratories delayed our ability to assist in developing the necessary testing capacity to respond to this pandemic. Private-sector laboratories should be considered a collaborative partner of the government, and be included in the earliest discussions with CDC and other public health officials regarding planning and implementing a pandemic response strategy. The mindset must shift from the strategy of reliance on public health laboratory capacity and test development, with as-needed support from private-sector laboratories, to a strategy that leverages the strengths of the private sector from the beginning. *See* section II.a, *supra*.

Moreover, this public-private partnership needs to be established *before* the threat of a pandemic arises. In the context of COVID-19, even once the private sector was called upon to join the response, several logistical issues had to be worked out *before* our laboratories could launch testing. These included issues related to intellectual property and material transfer, among others. One of the biggest bottlenecks to testing ramp-up by private-sector clinical laboratories was the availability of testing materials, including materials needed to validate the CDC test. To prevent this barrier to rapid ramp-up of testing capacity in the future, CDC should establish a collaborative relationship with a set of private and public sector, high-complexity clinical laboratories immediately, so that these types of issues can be ironed out in advance of the next pandemic. The collaboration also should ensure that the broad expertise of the private sector is part of the government's processes for planning, implementing, and beta testing the public health response framework. Further, both public health and private-sector clinical laboratories should be included in monitoring emerging data regarding new pathogens *before* those pathogens create a public health emergency.

Finally, the absence of a uniform, national public health reporting system makes data-sharing unnecessarily difficult. Testing is critical for identifying infected individuals, but what we *do* with testing information is of equal importance. Currently, clinical laboratories are struggling to comply with various cumbersome requests for data from different levels of government. This slows data entry and, ultimately, data access by the public health officials conducting public health surveillance. A uniform, national public health reporting system that streamlines reporting would speed access to accurate and up-to-date information. *See* section II.c, *supra*.

Question 3*: What privacy protections should accompany new technology? Would these technologies be utilized and maintained by HIPAA-covered entities or others?*

Clinical laboratories in the private sector need front-end clarification of HIPAA exceptions and compliance to appropriately protect patient privacy.

Looking forward, the government should establish a uniform, national public health reporting system. Currently, laboratories performing COVID-19 testing are inundated with requests for patient information in the context of COVID-19 reporting requirements, repeatedly triggering HIPAA and patient privacy considerations. A uniform, national public health reporting system could alleviate these redundancies because the data would be entered only once, in a uniform manner, and then pushed down to states and localities for local response measures. *See* section II.c, *supra*.

ACLA understands that CDC currently requests de-identified data because CDC computers do not have the appropriate security systems in place to receive identified data that are required by local health departments. Therefore, to implement a national public health reporting system, CDC needs the necessary resources to update its computer systems to enable them to accept identified data in a secure fashion. Such data could then be pushed down to state and local health authorities.

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

Recommendation 3.1*: Utilize existing authorities to build public-private partnerships, such as vendor managed inventory contracts with manufacturers and distributors, to create excess medical supplies managed by private sector partners that could be needed for the next pandemic or public health emergency. Additionally, the Strategic National Stockpile could contract with manufacturers to maintain manufacturing capability for certain products, such as N95 masks or other personal protective equipment, to rapidly manufacture supplies needed for a future pandemic.*

ACLA urges the government to rethink its approach to "stockpiling" supplies, particularly with regard to laboratories. Laboratory testing services are not commodities that can be stockpiled—they are procedures that require trained professionals and expertise. Therefore, ACLA recommends a public-private partnership between the government and private-sector laboratories that ensures a sustained commitment to investing in maintaining laboratories in a "ready state," which includes ensuring that there are sufficient numbers of highly-trained laboratory professionals. *See* section II.b, *supra*.

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.*

To the extent that materials remain in a central stockpile, ACLA urges the federal government to coordinate distribution of materials from the stockpile directly to large-scale (multi-state) recipients, such as private-sector clinical laboratories with the capacity and scale to serve multi-state and national populations. *See* section II.b, *supra*.

4. Public Health Capabilities – Improve State and Local Capacity to Respond

Question 1*: What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?*

A total shift in approach with regard to the following is necessary:

(1) The role of private-sector clinical laboratories. Private-sector clinical laboratories must be seen as a partner in preparing for and responding to a pandemic. *See* section II.a, *supra*.

(2) The "stockpile" approach. Laboratory testing services cannot be stockpiled. There must be an investment to maintain reserve capacity within private-sector laboratory partners so that tests can be developed and deployed at scale without delay. *See* section II.b, *supra*.

(3) Public health reporting. Instead of all laboratories reporting to various state and local public health authorities, as well as some national health authorities, there should be a uniform, national public health reporting system that makes the data available to states and localities. *See* section II.c, *supra*.

IV. RESPONSES TO WHITE PAPER PROPOSALS AND QUESTIONS: ADDITIONAL COMMENTS

1. Tests, Treatments, and Vaccines – Accelerate Research and Development

Recommendation 1.2*: Congress and the administration should continue to support NIH research and its academic partnerships, which have provided key infrastructure to rapidly pivot to COVID-19 research and clinical trials.*

and

Recommendation 1.3*: Congress and the administration must work together to implement the Medical Countermeasure Innovation Partner program so tests, treatments, and vaccines can quickly be identified, researched, and developed for the next pandemic.*

ACLA agrees that Congress and the administration should continue to support NIH research and its academic partnerships, but private-sector clinical laboratories must be included in such partnerships. Historically, research and academic partnerships have focused on engaging manufacturers. However, as noted above, clinical laboratories that perform services are *not* manufacturers. *See* section II.a, *supra*. Private-sector clinical laboratories have distinct capabilities that should be part of the larger conversation around tests, treatments, and vaccines. Therefore, ACLA urges Congress to consider, when drafting legislative language to support research and academic partnerships, that the language should be broad enough to include private-sector clinical laboratories developing and performing LDTs as key stakeholders.

Likewise, programs such as the Medical Countermeasure Innovation Partner program must be implemented in a way that considers the role that private-sector clinical laboratories play in developing scientific knowledge to respond to an emerging pathogenic threat.

***Question 1**: What incentives can the federal government offer to the private sector to encourage development of more medical countermeasures with no commercial market?*

The federal government should ensure that private-sector clinical laboratories have access to Biomedical Advanced Research and Development Authority (BARDA) grants so that clinical laboratories can develop LDTs and assist with clinical research. Additionally, private-sector clinical laboratory access to research and development tax credits would encourage development of more medical countermeasures.

Additionally, an important incentive the federal government can offer is funding to support the maintenance of private-sector clinical laboratory "reserves" so that private-sector partner laboratories can respond quickly when a new pathogen emerges. *See* section II.b, *supra*. As noted above, a key challenge with testing for an emerging pathogen is that tests for the pathogen cannot be developed before the pathogen has been identified. Yet, an effective national response requires, as an initial step, the development of new diagnostic tests that can be deployed rapidly and efficiently. Therefore, the federal government must invest in ensuring that private-sector clinical laboratories are consistently equipped with the proper resources, including materials, instruments, trained personnel, and space.

***Question 5**: How can the United States build manufacturing systems that can rapidly respond to new threats, whether naturally occurring or manmade?*

ACLA encourages the United States to build strong systems that can help the country anticipate supply chain needs and respond efficiently to ensure the adequacy of supply chains. Having a robust supply chain built up is critical to ensuring that the United States can deliver a durable response.

2. Disease Surveillance – Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases

***Recommendation 2.3**: The Departments of Health and Human Services, Homeland Security, and Transportation should coordinate to improve access to passenger contact information by appropriate public health officials to inform public health responses to infectious diseases, like measles and COVID-19, with necessary privacy protections in place. CDC should, in coordination with state health officials, review and improve the systems used to communicate such information to states.*

ACLA agrees that there should be better coordination across agencies to ensure a more unified federal response.

***Recommendation 2.4**: Congress should pass the Public Health Data Systems Modernization Act, included in the Lower Health Care Costs Act, to modernize our nation's biosurveillance systems.*

Instead of modernizing several different systems that are part of the current patchwork approach, ACLA urges the United States to commit to establishing a uniform, national public health reporting system that pushes data down to states and localities. *See* section II.c, *supra*.

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

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.*

To the extent that materials remain in a central stockpile, ACLA agrees that the federal government should coordinate distribution of materials from the stockpile directly to large-scale (multi-state) recipients. The federal government should *not* mandate capacity allocations, however. *See* section II.b, *supra*.

Question 2*: How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?*

The United States must invest in maintaining reserves in healthcare facilities, including private-sector clinical laboratories, to enable those facilities to rapidly respond instead of waiting for distributions from the stockpile. Moreover, because laboratory capacity and experience cannot be stockpiled as a commodity, the United States must invest in maintaining capacity and trained personnel that are required for clinical laboratories to develop and scale testing in a rapid fashion. *See* section II.b, *supra*.

Question 5*: Could states and hospital systems establish their own vendor managed inventory programs with manufacturers and distributors? Should the federal government or states contribute to such hospital stockpiles?*

Yes. In order to be positioned to respond quickly, health systems, including private-sector clinical laboratories, must have resources on-hand, including sample collection and testing materials, PPE, instruments, highly-trained laboratory professionals and space. To ensure the availability of such resources in the event of an emergency, upfront and continuing investments are required. *See* section II.b, *supra*.

4. Public Health Capabilities – Improve State and Local Capacity to Respond

Recommendation 4.2*: Ensure that the United States does not lose the gains made in telehealth.*

During the pandemic, several state and federal regulators have implemented emergency measures that expand access to telehealth, resulting in safer interactions for both patients and providers during the COVID-19 pandemic. ACLA agrees that some of these telehealth measures should be made permanent, and that the United States should protect the gains made in this area.

5. Who is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency

Recommendation 5.1*: Congress must clarify who is in charge and has the ability and authority to keep a continued focus on preparedness for pandemics and other major public health threats when other priorities may seem more pressing, and improve how federal*

agencies will coordinate during a pandemic. These roles and responsibilities must also be clearly communicated to states and local governments so they can include this information in their own preparedness planning.

AND

Recommendation 5.2*: A key lesson from Crimson Contagion and COVID-19 is that plans and systems cannot be improved upon if they are not practiced. More training is needed, as well as more opportunities to exercise plans and processes nationwide.*

> ACLA agrees with these recommendations. A clear line of command is required to manage a pandemic response. Additionally, ACLA supports the use of public-private tabletop exercises, which give the government and industry the opportunity to train for a pandemic response and build lines of communication.

V. CONCLUSION

In closing, thank you for the opportunity to submit these comments. ACLA and ACLA member laboratories remain committed to responding to the pandemic, protecting patient health, and serving as a resource in your efforts to bolster our nation's preparedness response.

If you have follow-up questions, please reach out to Tom Sparkman at tsparkman@acla.com.

Sincerely,

Julie Khani
President