AMERICAN CLINICAL LABORATORY ASSOCIATION

February 4, 2022

The Honorable Patty Murray, Chair
The Honorable Richard Burr, Ranking Member
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Via E-mail: HELPPandemicbill@help.senate.gov

Re: Comments from the American Clinical Laboratory Association Regarding the PREVENT Pandemics Act Discussion Draft

Dear Chair Murray and Ranking Member Burr,

The American Clinical Laboratory Association (ACLA) and its members are pleased to provide these initial comments on the discussion draft of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act ("the Discussion Draft"). As the nation continues to fight the COVID-19 pandemic, we applaud the Senate HELP Committee's efforts to strengthen our public health infrastructure to prepare for, and ideally prevent, the next potential public health emergency. Your leadership throughout the pandemic has been appreciated by our members—clinical laboratories on the front lines of the nation's response. In the interest of supporting a robust, nimble, and responsive American public health framework, ACLA offers these initial comments on the Discussion Draft. In the coming weeks, we also hope to provide you with additional technical comments in the form of a redline to the legislative text in the Discussion Draft.

I. INTRODUCTION

Since the earliest days of the COVID-19 pandemic, ACLA members have taken unprecedented steps to rapidly validate novel COVID-19 tests and scale testing capacity to meet the pressing public health needs facing American families and workers. Since March 2020, our members collectively have performed more than 181 million COVID-19 PCR tests, and as the pandemic continues to evolve and new variants emerge, clinical laboratories continue to be uniquely qualified and suited to rapidly develop and validate tests that meet patients' health needs and evolving circumstances. Accurate, reliable, and available tests are critical to safe returns to work, school and daily life, and deploying the full range of testing options is fundamental to slowing and mitigating the spread of COVID-19 within our communities. Clinical laboratories, which report data to public health authorities, also play an essential role in our public health response by providing data needed for trending cases at a population level, as well as other data needed to support population health assessment. For the last two years, ACLA members have taken an "all hands on deck" approach to stemming the spread of COVID-19. ACLA and its members remain committed to supporting the response to this emergency and any future public health emergencies. We also remain deeply concerned about the disproportionate

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impact of COVID-19 on underserved communities, and our members take their role in providing tests to these communities very seriously.

We applaud Congress and the Administration for critical actions taken to mandate coverage of and protect access to COVID-19 testing, as clear coverage mandates without cost sharing have been critical to making testing accessible to Americans. Strong coverage and reimbursement (including through Medicare) allowed for a dramatic expansion in laboratory testing capacity and expansion of patient access through testing innovations such as at-home testing. However, the COVID-19 pandemic (particularly in the earliest weeks) has exposed significant systemic barriers that hamper clinical laboratories' ability to support the country in fully responding to public health emergencies. For example, the federal government deprioritized standing up testing in private-sector clinical laboratories for weeks in the early days of the pandemic, instead focusing on the test in development by the Centers for Disease Control and Prevention (CDC). This delay inhibited private-sector laboratories, the nation's largest source of laboratory capacity, from fully assisting with the pandemic response for more than a month. 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 front-end federal funding was made available to directly support the rapid expansion of laboratory capacity, including for the performance of the tests. While we cannot understate the continued importance and success of strong coverage and reimbursement for COVID-19 testing, we believe additional policies and programs should be added to strengthen our national clinical laboratory response capability, particularly in the earliest days of a potential public health threat.

We are pleased to see that the Discussion Draft takes a forward-looking approach and proposes several long-term improvements to the public health framework. Nonetheless, we see significant opportunities for improvement to ensure that the strengths of private-sector clinical laboratories are appropriately leveraged in this effort. As such, ACLA's comments focus on two key issues: (1) increasing opportunities for early collaborations between the government and clinical laboratories, and (2) standardizing public health data reporting. Our comments on these topics cover several specific provisions of the Discussion Draft, including sections: 102 (regarding the CDC Director's Strategic Plan), 211 (regarding modernization of biosurveillance capabilities), 213 (regarding public health data availability and access), 304 (regarding access to diagnostic tests), 401 (regarding manufacturing surge capacity), 402 through 405 (regarding the Strategic National Stockpile), and 508 (regarding communications with the Food and Drug Administration (FDA)). ACLA also provides comments regarding section 504 (regarding Third Party EUA Test guidance).

We are encouraged by many provisions in the Discussion Draft that take important steps to address these and other topics critical to our nation's public health framework, and we ask the HELP Committee to consider the following comments and recommendations. With these suggestions, we believe the Discussion Draft will more fully address the needs of the healthcare sector in responding to the current and future pandemics.

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II. PUBLIC-PRIVATE COLLABORATIONS TO IMPROVE RESPONSE AND CAPACITY

Private-sector clinical laboratories are uniquely qualified to rapidly develop, validate, and perform high-quality diagnostic tests that are necessary for identifying the threat and scope of infectious diseases. Yet the country's current system focuses on government laboratories and government-controlled supplies. Private-sector laboratories are tapped for assistance "as-needed," often later than would be most useful and dependent on distribution of federally stockpiled materials to meet increased demand in short order. Federal, state, and local governments should instead leverage clinical laboratory expertise at every stage of the preparation and response process, and ensure that laboratories are well positioned to rapidly respond to surges that create sharp increases in demand for clinical testing services. This requires earlier and sustained engagement with clinical laboratories to support their ability to maintain on-site testing capacity. This means readily available personnel, equipment, and reserves of supplies, all of which are needed to immediately respond to sharp increases in testing demand. It is critical that this engagement with clinical laboratories start well before an outbreak progresses to a pandemic and a public health emergency has been declared.

Thus, ACLA has advocated for legislation that establishes and funds public-private preparedness collaborations, whereby private-sector clinical laboratories with appropriate expertise are a critical element of pandemic response planning, preparedness training, proactive data monitoring, and the early testing response, both for emerging pathogen threats and larger epidemics and pandemics.[1] Such partnerships should include support for maintaining needed laboratory capacity in a near-ready-state to respond to urgent demands for increased testing.

ACLA appreciates that the Discussion Draft encourages these types of partnerships, and we commend the efforts in the Discussion Draft to ensure laboratory supplies are available to meet the country's testing demands. The following sections describe ACLA's support for various provisions and identify key places where provisions could be made more explicit and strengthened with regard to laboratory capacity.

A. Earlier Government Engagement with Private-Sector Clinical Laboratories

The federal government's early response to the COVID-19 pandemic lacked appropriate engagement with private-sector clinical laboratories. Although the federal government engaged laboratories in early discussions about the progress of the virus, the CDC ultimately focused on a single CDC-developed test, and it was not until three weeks after the CDC's test was authorized—and nearly a month after the emergency was declared—that FDA issued its first COVID-19 testing policy to expedite the development of additional clinical laboratory diagnostic tests. Even once private laboratories were called upon to expand their capacity in short order given the emergency, the process was clouded by unclear communication channels with key

[1] ACLA Comments to the U.S. Senate Committee on Health, Education, Labor and Pensions, *Preparing for the Next Pandemic: A White Paper* (June 29, 2020), https://www.acla.com/acla-comments-on-chairman-lamar-alexanders-pandemic-response-white-paper-2.

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federal agencies. The "one test approach," combined with uncoordinated communication, squandered precious weeks of the nation's first wave response to the virus which could have otherwise been utilized to rapidly validate, scale, and deploy multiple tests within multiple clinical laboratories in parallel partnership with the federal government.

This experience demonstrates why private-sector laboratories must be key, early partners with the federal government in preparing for and responding to public health emergencies. For this reason, ACLA strongly supports the provisions in the PREVENT Pandemic Act Discussion Draft that encourage formal relationships between private industry and government agencies to prepare for public health emergencies—before a pandemic is upon us. As noted below, some provisions in the Discussion Draft also could be strengthened along these lines:

- **Section 102 -** Strategic Plan for Public Health Preparedness: Section 102 proposes to add a new section to the Public Health Service Act (PHSA) related to CDC Director authority.[2] ACLA supports the portion of the section that directs the CDC Director to develop a "Strategic Plan" that sets forth strategic priorities and objectives for, among other things, "enhancing global and domestic public health capacity, capabilities, and preparedness, including public health data, surveillance, and laboratory capacity and safety."[3] Importantly, the provision requires the Director to describe how the plan will incorporate "partnerships with private sector entities" to achieve these objectives.[4] This provision appropriately considers laboratory capacity as a key element of our nation's public health readiness strategy, and recognizes the importance of leveraging private-sector laboratories in the planning stages of our public health preparedness strategy.

- **Section 211 -** Strategic Plan for Situational Awareness System: ACLA supports the provisions in section 211 that amend PHSA § 319D in ways that encourage more public-private collaborations—including with clinical laboratories—to modernize the interoperable network of systems for nationwide public health situational awareness.[5]

- **Section 211** - State Grant Program Situational Awareness System: Section 211 also amends an existing grant program for state health situational awareness systems by requiring states to incorporate "public-private partnerships" in their grant applications.[6] The health situational awareness systems created by the states are already expected to be developed "in collaboration with . . . clinical laboratories,"[7] but this provision

[2] Discussion Draft § 102, at 23-31 (called "Appointment and Authority of the Director of the Centers for Disease Control and Prevention").

[3] *Id.* at 26.

[4] *Id.* at 27.

[5] *Id.* § 211, at 73 (called "Modernizing Biosurveillance Capabilities and Infectious Disease Data Collection").

[6] *Id.* at 73-74; PHSA § 319D(d)(1)-(2).

[7] *See* PHSA § 319D(d)(1).

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appropriately encourages state governments to consider clinical laboratories and the private sector in the earliest planning stages.

- **Section 304** - Government Contracts for Diagnostic Tests: ACLA supports the portion of section 304 that proposes a new section of the PHSA to allow the Secretary of Health and Human Services (HHS) to contract with "private entities" to "increase capacity in the rapid development, validation, manufacture, and dissemination of diagnostic tests" to "address an emerging infectious disease" in a declared public health emergency or "that has significant potential to cause such a public health emergency."[8] This is the kind of upfront investment that is necessary for supporting the earlier development of diagnostic tests. One issue for the HELP Committee to consider is whether the language could be strengthened to make more explicit that investments can be made well in advance of an emergency to ensure appropriate preparations are in place.

  Another issue is that this provision, as drafted, could be interpreted as limited to supporting the manufacture and distribution of test kits. It is important to be explicit that the provision also supports both (a) professional laboratory services required to perform those tests, and (b) laboratory developed tests that are a vital component of the public health response. Such contracts should support laboratory funding to retain, reserve, and train personnel; maintain equipment and facilities; and stock test and personnel supplies to quickly bring testing services online and adequately perform a significant volume of tests in the earliest stages of a response.

  Although ACLA agrees that early investment in the manufacture and distribution of test kits is important, the first manufactured test kits often can be performed only by sophisticated clinical laboratories. For this reason, clinical laboratory capacity must be supported and leveraged hand-in-hand with test development and manufacturing capacity so that all sectors of the nation's testing infrastructure, end-to-end, are deployed together for full effectiveness. Furthermore, as we saw with the COVID-19 pandemic, sophisticated clinical laboratories are best suited to quickly leverage existing clinical expertise and available infrastructure to rapidly develop and validate novel tests in the face of an emerging threat. Therefore, early investment in the development and validation of diagnostics tests *must* include laboratory services and laboratory developed tests.

- **Section 508** - FDA Communications: ACLA supports section 508, which directs FDA to develop a report and plan for best practices for communicating with external stakeholders outside of guidance documents, and requires clinical laboratories to be consulted in the development of such best practices.[9] As we have learned from the past two years, public health emergencies pose ever-evolving challenges, and an "all hands on deck" approach requires effective and consistent communication with regulated industry. ACLA welcomes the opportunity to work with FDA on establishing protocols for effective

[8] Discussion Draft § 304, at 125-26 (called "Accessing Specimen Samples and Diagnostic Tests").

[9] *Id.* § 508, 182-85 (called "Improving FDA Guidance and Communication").

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communication so we can work together productively before and during public health emergencies.

B. Support for Laboratory Testing Capacity

A critical pillar of pandemic preparedness is ensuring that clinical laboratories are maintained in a state of near-readiness to rapidly—and sustainably—respond in the face of an emerging threat. Entering the third year of the COVID-19 pandemic, the United States continues to face disruptions in the accessibility of necessary supplies that cause downstream interruptions in laboratory testing capacity. The current pandemic aside, many parts of the country suffer from a shortage of personnel who are trained and qualified to direct and staff clinical laboratories, further limiting testing capacity. With regard to testing supplies, we have learned that redundancies in the supply chain are necessary so that our healthcare response network does not become strained from a single point of failure. Thus, we are pleased to see that the Discussion Draft makes efforts to improve the country's state of readiness by building strong systems that can help anticipate and respond to potential supply chain disruptions and rapid increases in demand for testing. However, we believe some of these provisions also can be improved by providing more direct support for laboratory capacity.

1. Manufacturing Supply Chain

Ensuring that laboratories have adequate supplies and materials is a critical first step in providing support for laboratory capacity. Even when optimally staffed, laboratories can only perform those tests for which they have adequate supplies. That is why we strongly support the provisions in section 401 of the Discussion Draft that support improving manufacturing surge capacity and capabilities for products that are important to the public health response.[10]

Section 401 amends PHSA § 319L such that the authority of the HHS Secretary ("the Secretary") to support advanced research and development of products that are important to the public health response also includes "activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities."[11] For example, the Secretary would be required or permitted to, among other things:

- Incorporate "manufacturing surge capacity and capabilities" in the Secretary's strategic plan for countermeasure research, development, and procurement, required under PHSA § 319L(b);

- "[E]stablish[] and maint[ain] domestic manufacturing surge capacity and capabilities" based on such plan, under PHSA § 319L(c)(2);

[10] *Id.* § 401, at 126-34 (called "Warm Base Manufacturing Capacity for Medical Countermeasures").

[11] *Id.*

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- Facilitate communication between HHS and relevant persons regarding "manufacturing surge capacity and capabilities," under PHSA § 319L(c)(4)(A);

- "[A]ward contracts, grants, and cooperative agreements" to "support, maintain, and improve domestic manufacturing surge capacity and capabilities" under PHSA § 319L(c)(4)(B);

- "[A]ward contracts, grants, and cooperative agreements" to "improve manufacturing capacities and capabilities for medical countermeasures" under PHSA § 319L(c)(4)(D); and

- "[M]ake payments for activities necessary to maintain domestic manufacturing surge capacity and capabilities" under PHSA § 319L(c)(5)(H).

These provisions appropriately provide support to help manufacturers sustain capacity to provide important medical supplies, including supplies for laboratory tests. However, as we discuss in the following section, we urge the HELP Committee to include "laboratory testing capacity and capabilities" in these provisions, as well. As explained above, laboratories can only perform diagnostic testing services to the extent that they are adequately staffed and have appropriate supplies. Therefore, inclusion of laboratory testing capacity and capabilities is vital.

2. Laboratory Reserve and Surge Capacity

New infectious diseases and strains of such diseases drive dramatic increases in demand for testing. We have seen this play out repeatedly with new waves of COVID-19 caused by emerging SARS-CoV-2 variants, recently with the Omicron variant. To quickly meet rapid increases in demand that are associated with emerging threats, laboratories need adequate levels of trained laboratory professionals, as well as sufficient sample collection materials, testing supplies, personal protection equipment, instruments, and space. Clinical laboratories maintain appropriate staffing and supply levels to support usual operations, but cannot reasonably support excess staffing and excess supply in a non-emergency setting when the demand for testing is not at public health emergency surge levels. Unfortunately, once an emerging threat is identified and demand for testing surges, it takes valuable time to hire or transfer laboratory professionals and secure additional supplies, both of which are likely to be more difficult to secure during an emergency.

This is akin to the system we currently have with the Strategic National Stockpile (SNS). Under the SNS framework, the federal government amasses materials that are sequestered for later distribution if and when a need arises. The approach is not well-suited to address laboratory capacity problems, however, because laboratory developed tests and laboratory services are not products that can be stockpiled. Moreover, clinical laboratories cannot provide services with materials alone; they also need trained laboratory professionals and adequate space to perform tests. There must be an ongoing effort to maintain investment in laboratory capacity that can meet the testing surges during a public health emergency.

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A "reserve capacity" approach is better suited to ensure clinical laboratories are prepared to meet testing demands during nationwide crises. Under a "reserve capacity" approach, the focus would not be only on amassing supplies for later distribution by the federal government, but would also support the ability of laboratories to maintain on-site capacity sufficient to respond to emerging public health crises across the country. As envisioned by ACLA, a "reserve capacity" approach for clinical laboratories would involve funds for maintaining laboratory surge capacity and other upfront investments to support laboratory resources. ACLA plans to provide suggestions in our forthcoming redline that would accomplish the following:

- Infrastructure Funding: ACLA supports adding a new section to the Discussion Draft that authorizes to be appropriated funds for contracts with private-sector clinical laboratories for additional infrastructure to ensure clinical laboratory capacity, in addition to programs to support the renovation, expansion, and modernization of state and local laboratory infrastructure. The Secretary would use these funds to provide grants or contracts for both private- and public-sector laboratories to increase and enhance testing and response capacity, hire and retain sufficient personnel to readily respond to increased public demand for testing in an outbreak, and make other changes to modernize laboratories as the Secretary deems important for maintaining public health. This kind of upfront investment would allow private-sector laboratories to be better prepared for surges at the start of a pandemic and during periodic surges in demand caused by new variants and other circumstances.

- Revitalizing the Private Laboratory Workforce: ACLA also supports adding a new section that promotes support for laboratory professionals such as funding for laboratory technician training programs and setting compensation for laboratory services at adequate rates. Clinical laboratories cannot perform tests without the expertise of laboratory staff, but staff shortages will inherently limit laboratory capacity to perform tests, particularly during public health emergencies. The Discussion Draft provides support in the form of loan repayment for laboratory professionals employed by public health agencies under **section 221**,[12] but this exclusive focus on the public health laboratories fails to acknowledge the parallel value of clinical laboratories that also serve a vital public health purpose. Therefore, ACLA's proposals here aim to provide much-needed support to build up the laboratory workforce across the country, including professionals that support commercial clinical laboratories.

- Surge Capacity Payments: As discussed in the previous subsection,[13] **section 401** of the Discussion Draft amends the provisions of PHSA § 319L on strategic planning, coordination, and eligibility for contracts, grants, and agreements to include manufacturing surge capacity.[14] For the reasons described above, ACLA recommends that the HELP Committee amend this section to include laboratory services surge

[12] *Id.* § 221, at 93-99 (called "Improving Recruitment and Retention of the Frontline Public Health Workforce").

[13] *See supra* Section II.B.1.

[14] Discussion Draft § 401, at 126-34.

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capacity and capabilities, as well (or alternatively, add a new section specific to laboratory capacity). This change would make clinical laboratories more explicitly eligible for government contracts and awards, and allow the Secretary to make payments to laboratories to maintain surge capacity levels of staffing, space, and supplies.[15] Again, ACLA also supports a grant program that aids clinical laboratories during periods of low demand for testing so that laboratories can maintain necessary staffing and resources, including before an emergency, in the event of a testing surge caused by a pandemic.

- On-Site Reserve Capacity: In addition to the SNS, ACLA recommends authorizing the government to partner with private-sector laboratories to ensure that a six-month reserve of testing supplies is maintained on-site at major laboratories across the country. The supplies would be rotated through the laboratory's regular inventory and be supported through contract arrangements with the CDC. Ensuring the reserve supply is available on-site, and kept evergreen by rotating supply for commercial operations, eliminates many of the distribution challenges faced with the COVID-19 pandemic. Certain testing supplies are manufacturer-specific and not interchangeable with equipment or supplies from different manufacturers. As such, on-site stockpiles allow individual laboratories to ensure that supplies match the equipment operated in that same individual laboratory.

In addition to these "reserve-capacity" proposals, we encourage the HELP Committee to improve the efficiency of the process for distributing supplies from the SNS. As we saw with the COVID-19 pandemic, the SNS was disastrously strained in delivering necessary supplies across the country during a national-scale emergency.[16] To the extent that states and localities could get supplies, private-sector laboratories then had to navigate negotiating separately with states and localities for access to those supplies.

ACLA appreciates that the Discussion Draft makes improvements to strengthen the supply chains and communications related to SNS,[17] but it ultimately could do more to address the capacity challenges that clinical laboratories face. Therefore, ACLA recommends that the Secretary be required to coordinate distributions from the stockpile to more large-scale, regional recipients, rather than to individual state and local governments. ACLA recommends the following:

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[15] *Cf. id.* at 130, 131-32.

[16] *See, e.g.*, Goldstein et al., *Desperate for Medical Equipment, States Encounter a Beleaguered National Stockpile*, Washington Post (Mar. 28, 2020), https://www.washingtonpost.com/national/health-science/desperate-for-medical-equipment-states-encounter-a-beleaguered-national-stockpile/2020/03/28/1f4f9a0a-6f82-11ea-aa80-c2470c6b2034_story.html.

[17] *See* Discussion Draft § 402, at 134-35 (adding an assessment of supply chains to the SNS Annual Threat-Based Review); *id.* § 403, at 135-36 (amending PHSA § 319F-2(a)(3) to ensure that the stockpile supplies are adequately maintained); *id.* § 404, at 136-37 (directing the Secretary to provide guidance on how the SNS contents are distributed); *id.* § 405, at 138-41 (authorizing the Secretary to enter into contracts with manufacturers to maintain the stockpile).

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- **Section 404**: SNS Distributions to Large-Scale Entities: Section 404 directs the Secretary to issue guidance on how the SNS contents are distributed to states, territories, tribes and "other applicable entities" under PHSA § 319F-2(a).[18] ACLA proposes that this section be amended to require the Secretary to include in their guidance that large-scale, private entities—such as clinical laboratories that operate nationally—can directly receive contents from the SNS during nationwide public health emergencies. This will reduce the burden on private-sector laboratories with nationwide operations to negotiate separately with each state and locality to access necessary supplies.

III. STANDARDIZING PUBLIC HEALTH DATA REPORTING

ACLA also recognizes that access to patient data is essential to understanding health disparities in infection and mortality rates. As noted above, ACLA remains deeply concerned about the disproportionate impact of COVID-19 on underserved communities, and our members take their role in providing test results and other pertinent information to these communities and public health authorities very seriously. Clinical laboratories provide critical data for population health monitoring. In addition to providing important results to individuals, clinical laboratories are uniquely positioned to share test information with public health authorities. That is why ACLA supports a system that is designed to effectively and efficiently capture data on a national scale. To that end, it is critical that the system operates on a uniform set of standards that is practically achievable for entities required to collect and report data, particularly during a public health emergency. Although ACLA appreciates some steps the Discussion Draft takes to improve the public health data reporting process, we believe the legislation needs to go further to comprehensively respond to the operational and health information technology issues that impede the collection and reporting of public health data.

A. The Critical Need for Uniformity

As we have advocated for in the past, ACLA supports a data reporting system that has national uniformity. Today, laboratories performing COVID-19 testing must respond to numerous duplicative data requests from all levels of government: federal, state, local, tribal, and even private health information exchanges. Many states require reporting of additional data elements that are not consistent with current requirements under HHS guidance. For example, New Jersey has proposed requiring reporting of gender identity and sexual orientation of patients with test results for COVID-19 and other reportable test results, despite the lack of a standard for reporting such data. Further, laboratories have to grapple with cumbersome and potentially conflicting HIPAA and patient privacy issues when health information exchanges request patient information.

Together, these differing reporting requirements and formats create a patchwork system that needlessly generates overlapping health data and unnecessarily duplicative burdens and costs to accomplish the single, national goal of accurate, actionable public health data. This

[18] *Id.* § 404, at 136-37 (called "Improving Transparency and Predictability of Processes of the Strategic National Stockpile").

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burden layers piles onto clinical laboratories which are already expending tremendous resources to meet the testing demand of an emergency, and it reduces the laboratories' ability to perform at optimal capacity. These pressures ultimately slow and duplicate data entry, and therefore can delay access to the data needed to effectively monitor public health by various governmental authorities.

ACLA supports provisions of the Discussion Draft that propose improvements to the current system by promoting information sharing across all levels of government. For example:

- **Section 211** - Strategic Plan for Situational Awareness System: As discussed previously,[19] section 211 tasks the Secretary with improving coordination and collaboration between federal, state, and local governments, clinical laboratories, and other entities to modernize the interoperable network of systems for nationwide public health situational awareness.[20]

- **Section 213** - CDC Public Health System Standards: Section 213 amends PHSA § 2823(a)(2) to direct the Secretary, acting through the CDC Director, to use existing authority for adopting data and technology standards for CDC public health systems to include "reporting test orders and results electronically, including from laboratories."[21]

- **Section 213** - Study on Clinical Laboratory Reporting: Section 213 also authorizes a study that will, among other things, examine the extent to which laboratories are using standards for ordering and reporting test results, trends in laboratory compliance, existing challenges clinical laboratories face in data reporting, and other relevant areas.[22]

At a high level, ACLA also supports the portions of section 213 of the Discussion Draft that provide the Secretary with authority to carry out activities to improve public health data and information sharing. However, as described in Section III.B., below, we have significant concerns regarding the particulars of these proposals.

Furthermore, while this provision empowers the Secretary to establish federal data reporting standards to increase uniformity, the existence of standards alone does not prevent other levels of government from continuing to make duplicative and differing data requests that bog down laboratories in disparate, duplicative, and inconsistent reporting requirements. To avoid diverting limited laboratory resources to a patchwork of reporting obligations, the Discussion Draft should establish a single standard that can be applied across the country and provide needed information as rapidly as possible to public health agencies. Below are ACLA's proposals to do this:

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[19] *See supra* Section II.A.

[20] Discussion Draft § 211, at 73; PHSA § 319D(c)(6).

[21] Discussion Draft § 213, at 80 (called "Supporting Public Health Data Availability and Access").

[22] *Id.* at 81-82.

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- National Reporting System: ACLA proposes a uniform, national reporting system. Under such a system, public health data would be reported by appropriate entities depending on their access to and control over the requested data to one national public health authority, which would then make such data available to the CDC and state and local authorities simultaneously. This streamlined system will improve access to accurate and timely data to inform the nation's response efforts while also relieving the burdens created under the patchwork system we have today.

- National Standard with Preemption: In the alternative, ACLA proposes that once a national standard for data reporting has been established, states and localities should be explicitly preempted from creating data reporting standards that are different from or broader than the federal reporting standard. This would ensure uniformity in the kinds of requests to which data reporting entities must respond and would promote consolidation of data reporting. With input from state, local, and tribal public health officials, as well as stakeholders like clinical laboratories, the Secretary can design a single reporting standard that satisfies the public health data needs without sacrificing laboratory resources during emergencies. Such an approach will also lead to more timely reporting.

- Directives for Uniformity: At minimum, ACLA encourages the HELP Committee to consider adding directives for state and local authorities to take steps to align their reporting standards with the federal standard. As it stands, the Discussion Draft does not appear to impose any requirements that state and local officials work to standardize their requirements with each other or the federal government.

ACLA will be providing legislative text for these alternative proposals in its forthcoming redline.

B. Development of Feasible Standards for Data Reporting

ACLA supports appropriate efforts to establish data reporting standards at the federal level. However, it is critical that the established standards are feasible and are directed toward entities best suited to achieve the objectives in the most effective and efficient manner, based on their access to and control over the requested data. Therefore, ACLA offers the following suggestions on section 213:

- **Section 213** - Updates to External Entity Agreements: Section 213 gives the Secretary authority to update memoranda of understanding, data use agreements, and contracts to "improve appropriate access, exchange, and use of public health data" between federal agencies, state health departments, laboratories, and other external entities to monitor declared or potential public health emergencies.[23] ACLA urges the HELP Committee to ensure that clinical laboratories are consulted as part of the Secretary's development of updated memoranda, agreements and contracts. Moreover, the Secretary should be

[23] *Id.* at 85.

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required to provide commitments necessary to afford the external entity with appropriate protections related to data sharing, such as around data privacy.

- **Section 213** - Secretary Activities for Availability of Public Health Data: Section 213 adds a new section to the PHSA that authorizes the Secretary to undertake "activities to improve the availability of appropriate and applicable public health data related to communicable diseases, and information sharing between the [CDC Director], [ASPR], and . . . public health officials, which may include such data from . . . clinical laboratories."[24] ACLA has several comments on this provision of section 213.

  First, this section provides little detail regarding what "activities" the Secretary is authorized to undertake or what public health data is "appropriate and applicable." Therefore, it seems plausible that the Secretary might use this authority to require clinical laboratories to report demographic data that laboratories do not collect as the data is not pertinent to the performance of the test.[25] ACLA recommends that the Secretary should be required to follow the Administrative Procedures Act in developing the "activities" or standards to improve public health data. This will ensure that the Secretary's authority in this area has adequate input from external experts as to practical and technical considerations. ACLA also recommends that the Secretary's ability to create new data standards should be limited to data collection performed "in a manner consistent with the technical and operational capabilities of such providers." This would mitigate concerns over a new, impractical standard forcing some entities to refrain from aiding in the public health response. Consideration should also be given to the distinct differences in the feasibility to obtain timely and accurate data between different types of tests and test access points. For example, it may be less feasible to obtain timely and accurate test data from at-home patients who use tests obtained over-the-counter as compared to obtaining data from a clinical laboratory for laboratory-based tests ordered by a health care provider.

  Second, this provision directs the Secretary to "work with [state, local, and tribal] officials and relevant stakeholders to provide information on the content, form, and manner in which such data may most effectively support" government responses to

[24] *Id.* at 86-87.

[25] Only very limited demographic data is part of a standard test requisition, and it is usually not needed to perform the test. Furthermore, at present, ordering providers have no incentive to collect and report additional demographic data to clinical laboratories as part of the test order. Indeed, for this reason, it has been difficult for laboratories to accurately report the numerous demographic data elements currently required by public health authorities for the COVID-19 public health emergency. *HHS Guidance: COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115*, Health & Human Servs., at 2-4 (last updated June 8, 2021), https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf. These are the very "challenges related to collection and reporting of demographics" that the Office of the National Coordinator for Health Information Technology is likely to find if it conducts its study on clinical laboratories as required in the Discussion Draft under section 213. Discussion Draft § 213, at 81-82.

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communicable diseases.[26] As a practical matter, this provision appears to only require the Secretary to inform clinical laboratories or other reporting entities of the data requirements, rather than consult with them on what requirements make sense from a practical and technical standpoint. As a reporting entity, clinical laboratories are well positioned to provide input to the Secretary on the best ways to implement new demographic requirements or standards changes that are workable and provide important information for public health officials.

Third, a subsection of section 213 titled "Decreased Burden" requires the Secretary to "make reasonable efforts to limit reported public health data to the minimum necessary information needed to accomplish the intended public health surveillance purpose."[27] This provision is particularly important, and it must be implemented in a meaningful way. Standard data reporting requirements directed toward clinical laboratories must be reasonably related to clinical testing performed by the laboratories; otherwise, clinical laboratories cannot be reasonably expected to have such data to report. This is because clinical laboratories often have no direct relationship, interaction, or communication with the patients whose specimens the laboratories are testing. Instead, laboratories are typically reliant on the health care providers ordering the test to provide any necessary demographic data at the time the patient specimen is collected. If the ordering provider does not provide the relevant data with the test order, then the laboratory has no such data to report. The ordering provider's patient encounter is the single-best opportunity to obtain accurate and fulsome patient-specific data.

To the extent that public health authorities seek to collect demographic data to which clinical laboratories typically do not have direct access and that is often not directly related to nor necessary for clinical testing, we recommend that ordering providers or public health authorities be the sole entities engaged for collecting and reporting such data. Physicians and other healthcare providers typically have dramatically more regular and direct relationships, and lines of communications with patients as compared to clinical laboratories. These providers with direct treatment relationships already have case reporting obligations to public health entities, and the requested data may be relevant to their treatment of the patient. The Discussion Draft also should require HHS to provide guidance to ordering providers about their data collection and reporting obligations, particularly for those who manage non-traditional specimen collection settings like drive-thru testing sites.

IV. THIRD PARTY EMERGENCY USE AUTHORIZATION

Regarding section 504 (Third Party Test Evaluation During Emergencies), ACLA greatly appreciates the HELP Committee's recognition that a third-party review program could be helpful in the context of a public health emergency, when FDA is flooded with requests for

[26] Discussion Draft § 213, at 87.

[27] *Id.*

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emergency use authorization (EUA) for diagnostic tests. However, significant changes to section 504 are needed to make the program productive for FDA and test developers.

Section 504 of the Discussion Draft proposes to amend section 565 of the Federal Food, Drug and Cosmetic Act (FDCA) to authorize FDA to "consult with persons" or "enter into cooperative agreements or contracts with persons" for the evaluation of "in vitro diagnostic products" that are submitted for emergency use authorization.[28] As proposed, such persons must submit written recommendations to the Secretary "regarding the validity, accuracy, and reliability" of the in vitro diagnostic products, as well as "whether the relevant criteria under [section 564(c)(2)] for issuance of authorization . . . are met."[29] The draft provision completely defers to FDA to propose via guidance "considerations concerning conflicts of interest, compensation arrangements, and information sharing" for such persons.[30] There are several issues with this proposal as currently written.

First, the proposal does not expressly address FDA's action after a third-party review, and we are worried that—without clarity as to the process—the current language could turn diagnostic EUAs into essentially a two-step process (i.e., a third-party review then a similar review by FDA), potentially slowing down the introduction of tests when time is most of the essence. Instead, any third-party review program should include language that expressly provides for the process following third-party review, i.e., a direction to FDA to act on the recommendation. If an EUA test developer devotes time and resources toward the third-party review, the test developer should have confidence that the third-party review will not be duplicated by FDA, requiring additional time and resources that are limited during a public health emergency. ACLA further recommends that, if FDA does not act on a third-party review, the recommendation would serve as an authorization if the section 564 criteria are met, subject to FDA having all of its usual ability to revise or revoke EUAs under section 564.

Second, it is not appropriate for the text to blankly defer to FDA regarding which "persons" with which it may engage for purposes of this program, and FDA should not be able to implement this provision through guidance alone. Rather, it is critical that substantive criteria related to who may participate in this program be established through notice-and-comment rulemaking.

Finally, to operationalize a third-party review program, the recommendation should be based on criteria aligned with those required for emergency use authorization under section 564 of the FDCA. As proposed, the written recommendation regarding the test relates to the test's "validity, accuracy and reliability" in addition to "whether the relevant criteria . . . for issuance of authorization . . . are met." The standard for an EUA is that a product "may be effective," and this should be the sole basis for any third-party review recommendation.

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[28] *Id.* § 504, at 170-71 (called "Third Party Test Evaluation During Emergencies").

[29] *Id.*

[30] *Id.*

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ACLA plans to provide additional suggestions for this third-party review program in its forthcoming redline.

V. CONCLUSION

Thank you for the opportunity to submit these comments and our forthcoming redlines of the legislative text in the Discussion Draft. 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 emergency preparedness and response activities. Your leadership on these critical public health issues is appreciated, and we look forward to further engaging with you to help our nation prepare for and hopefully prevent the next pandemic.

If you have any questions, please reach out to me at tsparkman@acla.com.

Sincerely,

Tom Sparkman
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