March 29, 2023

The Honorable Bernard Sanders,
Chair
Health, Education, Labor, and Pensions Committee
US Senate
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member
Health, Education, Labor, and Pensions Committee
US Senate
Washington, DC 20510

The Honorable Robert P. Casey, Jr.
Health, Education, Labor, and Pensions Committee
US Senate
Washington, DC 20510

The Honorable Mitt Romney
Health, Education, Labor, and Pensions Committee
US Senate
Washington, DC 20510

Dear Chairman Sanders, Ranking Member Cassidy, and Senators Casey and Romney:

The American Association for Clinical Chemistry (AACC) offers the following comments on the *"Pandemic and All-Hazards Preparedness Act*" (PAHPA). We are pleased that the Senate Health, Education, Labor & Pensions (HELP) Committee is taking the necessary steps to reauthorize this measure and ensure that the United States is better prepared to deal with national emergencies, such as COVID-19, in the future.

Over the past several years, the healthcare community has worked closely with the government to combat the COVID-19 pandemic that has plagued our nation and the world. Clinical laboratories developed and performed tests on an unprecedented scale to diagnose, triage, and treat those individuals affected by the virus. From the onset of the pandemic, AACC surveyed clinical laboratories performing COVID-19 testing to gain insight into the problems they were encountering.

Our last complete survey, taken early in 2022, identified challenges facing the laboratory community that were consistent throughout the pandemic. The results were from 43 laboratories, which cumulatively performed more than 100,000 COVID tests daily. The findings from these laboratories indicated that:

Supply Issues

- 73% were struggling to obtain supplies (e.g., reagents, test kits);
- 45% were unable to obtain supplies to run COVID-19 tests;
- 42% were unable to obtain supplies needed to run non-COVID-19 tests;

Staffing Issues

- 90% were struggling with personnel shortages; and
- 82% were struggling with staff burnout.

These findings mimicked what we found throughout the pandemic, namely that supplies were in short supply and that there were an insufficient number of trained laboratory personnel to meet the testing demands of the public. We will share with you the findings from a survey conducted earlier this year, once the findings are available. Our more specific comments follow:

Strengthening Our Nation's Public Health Infrastructure
AACC recommends that Congress increase funding to improve our public health infrastructure. Past neglect has weakened the Centers for Disease Control and Prevention's (CDC's) ability to carry out its assigned duties. The CDC, working closely with state and local health departments, should oversee pandemic surveillance activities, such as testing capacity and related supply chain issues, the rate of disease transmission across the nation, recognition and reporting about where a virus is spiking or falling, as well as contact tracing data.

Moving forward, given the likelihood that COVID-19 will be a health issue for the foreseeable future, Congress should also provide the funds necessary for CDC to not only rebuild the current public health infrastructure, but also to prepare for future health crises. It takes significant time to identify and acquire necessary technology, to hire and train personnel, to develop and implement response strategies, and to identify and adopt useful reporting measures. Providing CDC with additional funding to carry out these important duties should be central to any pandemic preparation strategy.

Replenishing National Stockpiles
In a public health emergency, the availability of essential supplies such as swabs to collect specimens or reagents and test kits to perform laboratory testing should not determine whether the public has access to testing. We recommend that Congress seek input from federal and state agencies as well as medical service provider groups and medical device manufacturers to determine what amount and types of supplies were in short supply during the most recent pandemic so they can be stockpiled, so that our nation will be better prepared for the future.

Further, for the protection of our essential frontline healthcare workers, the availability of sufficient personal protective equipment (PPE) to ensure the safety of these at-risk public servants and their families, should never be a point of compromise; such essential PPE should be stockpiled. Although coordination with public health stakeholders at the state and local level is essential, management of such critical stockpiles at the national level is anticipated to be the most cost-effective approach.

Improving Coordination of the Supply Chain
While restocking essential supplies is critical, establishing a well-organized and effective means for distributing them is also important. AACC believes the federal government needs to play a larger role in coordinating these supply chain management activities to ensure streamlined coordination between the public and private sectors.

During the recent pandemic, laboratories competed with one another and with state testing facilities to obtain supplies needed to test and care for their patients. This is not acceptable. While we agree that state and local officials must continue to play a central role in coordinating efforts, there are some things that only the federal government can accomplish.

We recommend that Congress work with the healthcare community and public health officials to develop a clearer plan for ensuring that officials at the national level are aware of essential medical supply needs and how these supplies can be more efficiently produced and allocated to facilities in need.

Expanding the Laboratory Workforce
AACC supports efforts to restore the public health workforce that has been decimated by reduced federal funding and retirements. Local and state health departments have lost approximately one in four staff since 2008 and it is expected to get worse in the ensuing years. We believe a loan repayment program may encourage more individuals to pursue a public health vocation, thereby helping reduce this shortage.

We suggest that language be included to address the broader laboratory staffing issue facing the United States. Most COVID-19 testing performed during the pandemic was performed in hospitals and commercial laboratories, which are also experiencing severe personnel shortages. According to the Bureau of Labor Statistics (BLS), 72,100 additional clinical laboratory personnel are needed by 2028 just to meet the growing demand for testing services—and this was prior to COVID-19.

Demand for laboratory testing is likely to continue to increase as the population grows older, point-of-care-testing (POCT) expands, and new tests are developed. Currently, Medical Laboratory Scientists (MLS) programs do not produce enough graduates to fill existing vacancies. Over the next ten years, clinical laboratories need approximately 7,000 laboratory professionals annually, but the MLS programs graduate only 6,000 students a year, leaving a sizeable deficit.

One contributing factor to this shortage is the decline in MLS programs. In 1990, there were 720 MLS training programs. Now there are 608—a reduction of 15 percent. Additionally, MLS students are required to participate in full-time clinical rotations during training, which are becoming more difficult to arrange. Most programs cite insufficient and shrinking numbers of hospital laboratories willing to accept students and provide them with supervised and guided

clinical experiences. This training is essential to providing MLS students with a complete education necessary for ensuring accurate patient results that contribute to positive patient outcomes. There are several actions Congress can take separately or together, such as:

- Providing Title VII funding for allied health training programs to expand their MLS training programs; and
- Expanding the public health workforce loan forgiveness program to include all laboratory professionals.

Ensuring Access to Laboratory Developed Tests

When COVID-19 first emerged, CDC developed and sent to public health laboratories throughout the country a test kit that did not accurately detect the condition. To fill this void, clinical laboratories, regulated under the Clinical Laboratory Improvement Amendments (CLIA), responded by establishing laboratory developed tests (LDTs) in lieu of the CDC test kit. Initially, these efforts were hindered by a Food and Drug Administration (FDA) Emergency Use Authorization (EUA) edict that barred clinical laboratories from utilizing such LDTs without prior agency approval. This additional regulatory burden at a crucial time in the spread of this pandemic delayed the ability of America's clinical laboratories to rapidly respond and provide tests for this highly contagious disease. Fortunately, the agency modified its policy within a few weeks but significant damage had already been done.

AACC recommends that this regulatory barrier to developing LDTs be permanently eliminated, so that clinical laboratories do not encounter a similar problem when a future pandemic occurs. Under CLIA regulation, these medical testing facilities are already subject to stringent personnel, quality control, and proficiency testing requirements and they routinely develop, validate, and perform LDTs for a wide range of serious diseases and public health conditions (e.g., influenza, prescription drug monitoring, newborn screening). Clinical laboratories should not be subjected to duplicative, unnecessary regulation by multiple federal agencies, especially during periods of our nation's greatest need.

We have also heard that supporters of the Verifying Accurate Leading-edge IVCT Development (VALID) Act may seek to attach their measure to this bill. VALID would codify the very regulatory burden we referenced in the previous paragraphs. AACC urges you <u>not</u> to include VALID in this important legislation.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from

around the world. On behalf of AACC, I would like to thank you for the opportunity to provide comments on this legislation. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

Shannon Haymond, PhD, DABCC, FAACC
President, AACC