June 25, 2020

The Honorable Lamar Alexander
Chair, Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20515 Washington, DC 20510

Dear Chairman Alexander:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to provide feedback on the Senate Health, Education, Labor and Pensions (HELP) committee's white paper, "Preparing for the Next Pandemic." The COVID-19 pandemic demonstrates some of the current shortcomings in our healthcare system and the need for near-term changes and long-term reforms. AACC offers the following suggestions.

Strengthening Our Nation's Public Health Infrastructure
AACC recommends that Congress improve funding of our public health infrastructure. Federal expenditures for the Centers for Disease Control and Prevention (CDC), when adjusted for inflation, remain at fiscal year 2008 levels. This flat funding has resulted in the elimination of more than 50,000 local public health services jobs over the past decade. As a result, the CDC does not have the infrastructure or resources it needs to carry out its assigned responsibilities, particularly during a pandemic.

AACC is pleased that the coronavirus relief bills passed by Congress have provided additional interim funding to help CDC to carry out its activities. More information is needed on how this money is being spent and whether it is sufficient for the agency to accomplish its tasks. We believe 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 the 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 rebuild the public health infrastructure not only to address the current situation 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 in order to determine what amount and types of supplies need to be stockpiled based on their current experience, 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, so as to ensure streamlined coordination between the public and private sectors, and especially to help ensure that the private sector is engaged with a single public sector entity rather than with multiple state or regional sectors.

During the current 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.

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.

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.

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 focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

We look forward to working with you on this most important issue. To facilitate these interactions, or if you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

Carmen L. Wiley, PhD, DABCC, FAACC
President, AACC