

March 1, 2022

The Honorable Patty Murray, Chair Health, Education, Labor and Pensions Committee US Senate Washington, DC 20510 The Honorable Richard Burr Ranking Member Health, Education, Labor and Pensions Committee US Senate Washington, DC 20510

Dear Chair Murray and Ranking Member Burr,

The American Association for Clinical Chemistry (AACC) offers the following comments on the draft, "Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, which would rebuild and strengthen our nation's public health infrastructure. We are pleased that the Senate Health, Education, Labor & Pensions (HELP) Committee is taking the necessary steps to ensure that we are better prepared to address a similar situation 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.

Since the onset of the pandemic, AACC has surveyed clinical laboratories performing COVID-19 testing to gain insight into the problems they were encountering. We recently reached out to the laboratory community to learn what challenges they are continuing to face. To date, we have received responses from 43 laboratories, which cumulatively perform more than 100,000 COVID tests daily. Among our findings are:

Supply Issues

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

Staffing Issues

- 90% of labs are struggling with personnel shortages
- 82% of labs are struggling with staff burnout

March 1, 2022 Page Two

These findings mimic what we found throughout the pandemic, namely that supplies were in short supply and that there are insufficient trained laboratory personnel to meet the increasing testing demands of the public.

Section 212 Genomic sequencing, analytics, and public health surveillance of pathogens We back the committee's decision to incorporate the Tracking Pathogens Act in the draft legislation. We believe it is essential that the federal government invest additional resources into new, innovative technologies, such as next generation sequencing, that can more readily identify harmful pathogens and prevent a future pandemic. In addition, we support additional funding for improving the skills of our laboratory personnel performing NGS testing.

Section 221 Improving recruitment and retention of the frontline public health 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 nearly one in four staff since 2008 and it is expected to get worse in the ensuing years. We believe a loan repayment program may increase the number of personnel needed to carry out our nation's public health needs.

We suggest that additional language be included to address the broader staffing issue facing the United States. Most COVID 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.

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.

March 1, 2022 Page Three

There are several options available to Congress:

- provide Title VII funding for allied health training programs to expand their MLS training programs
- expand the public health workforce loan forgiveness program to include all laboratory
 professionals who work in underserved areas or create a similar program for the broader
 healthcare community.

Title IV Modernizing and Strengthening the Supply Chain for Vital Medical Products (Sections 401, 408, 409. 410)

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 support allocating additional federal funding to the states so that they can purchase and stockpile supplies for a future pandemic. 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.

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, 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.

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.