



February 4, 2022

The Honorable Patty Murray, Chair  
Health, Education, Labor and Pensions  
Committee  
U. S. Senate  
Washington, DC 20510

The Honorable Richard Burr, Ranking Member  
Health, Education, Labor and Pensions  
Committee  
U. S. Senate  
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr:

On behalf of the American Society for Microbiology (ASM), one of the largest life science societies comprised of more than 30,000 researchers and health professionals, we thank you for your leadership on preparing the United States for future public health emergencies. We appreciate the opportunity to provide comments on the discussion draft of the PREVENT Pandemics Act. We are committed to working with the Committee members and you to bolster the systems and programs needed to handle both pressing health threats and the inevitable outbreaks of the future.

Many of our members, including those in clinical laboratories, have been on the front lines of the COVID-19 pandemic. While ASM members in clinical laboratories played a critical role in the crisis, our members in research areas also played an invaluable role in responding to the pandemic and providing important information valuable to our long-term strategy for responding to future pandemics, including basic biomedical research and vaccine and therapeutic development.

Our recovery from COVID-19 and readiness for future pandemics depends on a multi-faceted, coordinated effort at the federal, state, and local levels and across many sectors of society. The federal government plays an indispensable role in this effort, given that it has the resources, coordinating ability, and public platform to lead our nation through times of crisis. The government also needs the capacity and expertise of the private sector, including academic and commercial laboratories, in times of crisis.

Below are our comments on specific areas of the discussion draft, in order that they appear in the discussion draft.

**Sec. 212: Genomic sequencing, analytics, and public health surveillance of pathogens**

We applaud the inclusion of the text of the Tracking Pathogens Act in this section of the bill. Significantly boosting U.S. genetic surveillance and viral sequencing is key to moving beyond the COVID-19 pandemic and effectively responding to future challenges not only associated with novel and evolving infectious diseases, but also seasonal threats, antimicrobial resistance and food and waterborne pathogens. This language builds on the work initiated under the American Rescue Plan by supporting and enhancing existing genomic sequencing and surveillance activities, supporting continued partnerships between public health entities and the broader academic research and clinical laboratory ecosystem, and codifying the Centers for Disease Control and Prevention (CDC) Centers of Excellence in Genomic Sequencing and Molecular Epidemiology. The bill also ensures this

work can be sustained by setting forth a strong, multi-year funding authorization level of \$175 million for the Advanced Molecular Detection (AMD) program at the CDC.

Since 2014, the AMD program has employed next generation sequencing (NGS) to bring the concept of precision medicine to bear for “precision public health.” AMD has given us new tools to detect disease faster, identify outbreaks sooner, and protect people and the food supply from emerging and evolving disease threats. Including the Tracking Pathogens Act in this section will ensure that this critical work can continue now and into the future.

### **Sec. 221: Improving recruitment and retention of the frontline public health workforce**

We thank the Committee for including provisions to support the public health workforce by reauthorizing the Public Health Workforce Loan Repayment program. The public health workforce is just one part of the health and laboratory ecosystem that needs support. **We urge you to include the text of S. 3244, the Bolstering Infectious Outbreaks (BIO) Preparedness Workforce Act of 2021 in this legislation.**

Although ASM and its members have understood it for some time, the COVID-19 pandemic has brought the critical need for both sustained funding for fundamental research and a strong clinical laboratory workforce into the spotlight. These highly trained professionals have served on the front lines of the COVID-19 response, and the clinical microbiologist’s role of developing, validating and deploying timely, accurate and reliable diagnostics, has taken on even greater significance. Diagnostics enable and inform all aspects of infectious disease outbreak management—from surveillance and detection, to response, containment, and recovery.

But accurate and reliable diagnostic tests are useless without skilled personnel to staff the labs and oversee and perform the tests. In 2016, the Bureau of Labor Statistics predicted we needed 12,000 new clinical laboratory professionals each year to meet rising demand.<sup>1</sup> That includes clinical microbiologists—highly trained scientists with PhDs or medical degrees. Results of a survey published in the *American Journal of Clinical Pathology* in 2019 showed a total vacancy rate of 10.14%, with a staff vacancy rate of 10.56% and a supervisor vacancy rate of nearly 7%. Results also revealed that 17.38% of clinical microbiology department employees are expected to retire in the next five years.<sup>2</sup>

The pandemic only exacerbated the existing shortage in clinical laboratory scientists and infectious disease laboratory professionals. Unless this problem is addressed, we will experience another testing crisis in the future as already-stretched labs will be unable to process the workload. The federal government can provide incentives and support, such as loan forgiveness provided in S. 3244, for these professionals, some of whom (e.g., clinical microbiologists) do not benefit from federal program support.

It is also worth noting that we are also losing the research workforce, which includes future CDC, FDA, industry, epidemiologists and scientists. This also will result in a brain drain with a negative impact on the US's ability to respond to any threat.

### **Sec. 304 Accessing specimen samples and diagnostic tests**

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<sup>1</sup> <https://ascls.org/workforce/>

<sup>2</sup> <https://academic.oup.com/ajcp/article/152/2/155/5499263?login=true>

We appreciate the inclusion of Sec. 319B in this section of the draft, as clinical microbiology laboratories outside the public health setting such as academic, hospital-based, and independent laboratories play a critical, supporting role in a public health emergency. We have learned over the course of the pandemic that it takes multiple partners to provide the required level of testing, and that we must maximize test development and validation early on and for all purposes, from prevention to patient care, to surveillance and reference. The “surge capacity” that a coordinated and inclusive public-private partnership can provide is crucial in a public health emergency.

#### **Title IV: Modernizing and Strengthening the Supply Chain for Vital Medical Products**

We appreciate the inclusion of provisions and sections (i.e., sections 515 and 516) in this title that would evaluate challenges in maintaining critical supply lines in an emergency and that take into account planning needs in the health care system. We urge you to ensure that diagnostic tests and ancillary supplies (swabs, pipette tips and reagents to name a few) be considered “qualified pandemic or epidemic products.” Clinical testing supply shortages plagued laboratories over the course of the pandemic, with a tremendous impact on our ability to test for COVID-19, and therefore diagnose those with the infection and in need of countermeasures such as therapeutics. The diversion of resources to meet that demand also prevented necessary testing for “routine” infectious diseases such as sexually transmitted infections, strep throat, and urinary tract infections. Diagnostics enable and inform all aspects of infectious disease outbreak management—from surveillance and detection, to response, containment, and recovery. As such, we must ensure that diagnostic supplies and ancillary provisions receive the same attention in our preparedness efforts as medical countermeasures.

A national testing strategy is essential in a crisis so that we can maximize the utilization of testing when it is needed most. We encourage the Committee to formally authorize the creation of a comprehensive national database that will ensure that all partners in an emergency response have transparency into the supply chain at a national level. **The federal government should fund development of a large scale, coordinated system to connect the public, clinical, academic, commercial, and industrial sectors to ensure sufficiently robust supply lines, transparency about when and where shortages exist and for what materials, and transparency around supply allocations.** This will enable public health entities, manufacturers, and clinical laboratories to plan ahead (minimizing the need for real-time decision-making), and more effectively leverage the power of testing to combat an outbreak.



When the demand for testing increased in the spring of 2020, clinical laboratories were unable to fully deploy testing due to unpredictable shortages. A lack of testing supplies coupled with anxiety over the potential to exhaust existing supplies hindered our ability to bring the pandemic under control. Beyond reagents, there were shortages of transport media and plastics, affecting tests developed and offered by independent, hospital, and academic-based laboratories. A comprehensive system with near real time data will give line of sight to all laboratories as to the status of multiple supply chains and allow for effective planning and appropriate resource allocation.

#### **Sec 504: Third party test evaluation during emergencies**

Qualified academic, hospital-based, and independent laboratories played an essential role to play in the early stages of a pandemic in both diagnostic testing and genomic surveillance; yet during the early days of the COVID-19 response, we relied solely on public health labs and CDC—a decision that cost us critical time in our testing response. We are pleased to see this section recognizes the importance of third parties in test development and validation, as many of our members outside public health did over the past year. We are also glad that the bill recognizes the need for funding this work as demonstrated by language that allows for cooperative agreements. Private sector laboratories will need funding to take on these activities, since current laboratory information systems do not universally integrate with public health departments that rely on laboratory data. While there is a cost associated with connecting to these systems, such integration is critical for the type of rapid response required. The upfront costs should not be a hindrance to laboratory participation, so funding will be required. Laboratories (both public and private) are a critical component of any public health response and need to work together to ensure accurate, reliable and safe testing can be deployed as quickly as possible in an emergency.

We deeply appreciate your strong and steadfast leadership, and your pursuit of legislation, including authorization of multi-year funding, that will protect our nation from future pandemics and other health and economic threats. ASM stands ready to work with you to help improve the systems we have in place today, and to develop the solutions that will help address tomorrow's challenges. If you have any questions, you may contact Mary Lee Watts, ASM Director of Federal Affairs, at [mwatts@asmusa.org](mailto:mwatts@asmusa.org).

Sincerely,

Stacey L. Schultz-Cherry, PhD  
Chair, ASM Public and Scientific Affairs Committee



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