

Statement from the American Society for Microbiology

In Response to the House Energy & Commerce Subcommittee on Health Hearing:

“Preparing for and Responding to Future Public Health Security Threats:

May 11, 2023

The American Society for Microbiology (ASM), on behalf of its 30,000 members in the United States and around the world, thanks full Committee Chair McMorris Rodgers, full Committee Ranking Member Frank Pallone, Subcommittee Chairman Brett Guthrie, Subcommittee Ranking Member Anna Eshoo and members of the House Energy & Commerce Subcommittee on Health for holding this hearing on preparing for and responding to future public health security threats as Congress prepares to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). The United States must be prepared to rapidly respond to declared and potential public health emergencies, including novel infectious disease pandemics such as COVID-19. We have learned a great deal over the past three years, and PAHPA reauthorization is an important opportunity to improve our nation’s ability to respond in a timely and coordinated manner to public health threats. ASM responded to the Request for Information from Representatives Hudson and Eshoo earlier this spring, and we offer the following points below:

Our experience with COVID-19 demonstrates the need to respond quickly and effectively.

This means early disease detection and surveillance through the use of cutting-edge genomics technology deployed through the Centers for Disease Control and Prevention (CDC). We also need to ensure resilient supply chains, including for diagnostics and ancillary supplies, through the Administration for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA), including use of the Strategic National Stockpile (SNS).

The Advanced Molecular Detection (AMD) program within the CDC National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), which brings cutting edge, next generation sequencing of pathogens to the front lines of public health. This innovative program, established in 2014, was significantly underfunded and undervalued until the COVID-19 pandemic shone a spotlight on the enormous need for rapid, accurate detection and genomic characterization of the novel pathogen, especially as variants emerged and evolved. Had this program been more fully supported at a level closer to \$175 million per year, the “surge” required during the pandemic would have been easier to deploy.

Beyond the technology it brings to public health laboratories in all 50 states and the District of Columbia, the AMD program funds bioinformatics training programs and has established important partnerships with academic institutions, most notably in the newly established Pathogen Genomics Centers of Excellence. The program also partnered with private sector and commercial entities to accomplish the task of sequencing during COVID, setting an example for how these connections can be sustained to address new threats and those that are seasonal, foodborne and epidemic to the U.S., including antimicrobial resistance. We strongly encourage the Committee to ensure that the AMD program and others that are essential to readiness are authorized at the necessary funding levels and are more fully integrated into response policies and plans as you reauthorize PAHPA.

ASM calls for support for the new Supply Chain Control Tower and the Food and Drug Administration's (FDA) Resilient Supply Chain and Shortages Prevention Program as administered in a partnership between ASPR and FDA. The program could be strengthened with funding authorization and with additional authorities, including ensuring that the statutory authorities relating to device shortages are equal to those available when there are drug shortages. In particular, the time limitation and tie to public health emergencies (PHE) for manufacturers to submit device shortage notifications puts the FDA behind in responding to early signs of supply constraints or a potential shortage.

We also urge the Committee to ensure that the SNS includes diagnostics and ancillary supplies among medical countermeasures. Diagnostic tests and ancillary supplies (swabs, pipette tips and reagents to name a few) should 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 to administer 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. The nature of these shortages even negatively affected diagnostics for non-infectious diseases like cancer, which require some of the same supplies. 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.

Clinical laboratories play an essential role in a public health emergency

Qualified academic, hospital-based, and independent laboratories should play an essential role 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 the CDC —a

decision that cost us critical time in our testing response. 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. It is important that clinical laboratories be able to develop laboratory-developed tests without pre-market approval when a public health emergency (PHE) is underway, with follow up requirements that are important to ensure that high complexity lab testing close to the patient is not stymied.

To ensure better partnerships between academic and other clinical laboratories in emergencies and provide a trained, “surge” workforce for the short-term, ASM calls for a “national guard” structure, or a rapid response force of microbiologists and other scientists who could help reinforce the health care system in the event of a major crisis or pandemic.¹ This would allow hospital laboratories to serve as the backbone for medical diagnoses in a pandemic. The success of this structure, however, is dependent on addressing the significant personnel shortages that persist in clinical laboratories. The federal government can recognize and incentivize people to pursue medical microbiology careers through loan forgiveness and training programs.

Biosafety and biosecurity policies should be grounded in science

The United States has a strong track record of safely conducting life-saving research and adhering to the most stringent biosafety and biosecurity standards. This has enabled us to lead the world in science and innovation, and we have saved countless lives through the development of diagnostics, vaccines and therapeutics to target infectious disease threats. When considering biosafety and biosecurity policies, it is important that they be evidence-based and draw from scientific expertise both inside and outside of governmental agencies to address the security implications of existing, emerging and reemerging infectious disease threats. ASM appreciates the recent recommendations and revisions put forth by the National Science Advisory Board for Biosecurity (NSABB) following a thorough review of policies governing ePPP and DURC that seek to balance benefits with risks. The NSABB appropriately leverages scientific and bioethical expertise to inform these policies. We urge the federal government to take up these recommendations and implement a robust oversight plan for ePPP and DURC.

ASM and its members look forward to working with the Committee as it works in a bipartisan manner to reauthorize PAHPA. We stand ready to assist you in this effort.

###

¹ <https://www.nytimes.com/2020/04/27/opinion/biomedical-national-guard-covid.html>

The American Society for Microbiology is one of the largest professional societies dedicated to the life sciences and is composed of 30,000 scientists and health practitioners. ASM's mission is to promote and advance the microbial sciences.

ASM advances the microbial sciences through conferences, publications, certifications and educational opportunities. It enhances laboratory capacity around the globe through training and resources. It provides a network for scientists in academia, industry and clinical settings. Additionally, ASM promotes a deeper understanding of the microbial sciences to diverse audiences.