AMERICAN SOCIETY FOR MICROBIOLOGY

December 23, 2021

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

On behalf of the American Society for Microbiology (ASM), we appreciate the opportunity to submit this response on H.R. 6000, the Cures 2.0 Act, as introduced. We commend you for your steadfast commitment to supporting science, medical research, and public health. ASM is one of the largest life science societies in the world, with a membership of over 30,000 researchers, educators, and health professionals across 109 countries. Our mission is to promote and advance the microbial sciences by deploying our resources and expertise to laboratories and health care settings around the world, advocating for robust funding and collaborative multi-disciplinary scientific research, and fostering a deeper public understanding of microbiology and its role in daily life.

We are pleased to see that Cures 2.0 includes several provisions that reflect ASM priorities, from support for the scientific workforce, to pandemic preparedness, to strategies for addressing major public health challenges including vaccine uptake and addressing antimicrobial resistance. In response to your request for feedback on the legislation, ASM offers the following comments for your consideration as you continue to advance this legislation.

Support for the Research Community

ASM supports the inclusion of Section 502, the Research Investment to Spark the Economy (RISE) Act provisions, including the authorization of $25 billion in "research relief" for independent research institutions, public laboratories, and universities throughout the country to continue work on thousands of federally-backed projects that were interrupted by the COVID-19 pandemic. Appropriating the funds envisioned in the RISE Act will provide much-needed supplemental funding for federally funded research. Microbial science is a cross-cutting endeavor, and our members' federally funded research is fundamental to advances in human health, agriculture, energy, and the environment. ASM has been deeply concerned about the serious consequences of the disruptions to the broader research enterprise, and this funding is critical to mitigating the negative scientific and economic impacts of the COVID-19-related laboratory closures and disruptions on research already in progress.

Establishment of a National Testing and Response Strategy for Future Pandemics

ASM supports the inclusion of Section 102 in Cures 2.0 to prepare for the inevitable outbreaks in the future. Many of our members, including those in hospital and state public health clinical laboratories, have been on the front lines helping our nation address the unprecedented challenges the COVID-19 pandemic presented to our society, our health care system, and our economy. They understand first-hand the supply chain challenges and regulatory hurdles that might have been addressed through a more effective national testing strategy. Our continued recovery from COVID-19 and our response to

future pandemics depends on a multifaceted, coordinated effort at the federal, state, and local levels and across many sectors of society. ASM shares and appreciates your recognition of the essential role that the federal government plays in this effort, given that it has the resources, coordinating ability, and public platform to lead our nation through times of crisis. However, this section could be strengthened by including more specifics on the components of the national plan. There are four key pieces of a national strategy that ASM believes are missing from the current legislation, including:

- Support for diagnostic development and deployment
- Support for a strong clinical microbiology laboratory workforce
- Support for disease surveillance and genomic surveillance
- Alleviating testing supply shortages

Additional information on each of these topics is included below.

Support Diagnostic Development and Deployment

Diagnostics enable and inform all aspects of infectious disease management, from surveillance and detection, to response, containment, and recovery. Testing not only serves to diagnose acute illness, but also plays an integral role in understanding how an infectious disease is being transmitted through communities and determining vaccine effectiveness against the primary pathogen and its variants. A national testing strategy must include support for the development and deployment of diagnostics.

Regulatory barriers need to be removed and technological advances supported if we are to fully harness the power of testing in a public health emergency. Clinical microbiologists must have flexibility to develop and use laboratory-developed tests by CLIA-certified, high complexity laboratories in a public health emergency. Emergency Use Authorization (EUA) regulations should be updated to ensure timely responses in critical situations.

Advances in diagnostic technologies, such as next generation sequencing made possible through the Centers for Disease Control and Prevention (CDC) Advanced Molecular Detection (AMD) program, will continue to be essential in our fight against both emerging and persistent infectious disease threats. We encourage you to consider ways to build on funding and authorizing provisions included in the American Rescue Plan that provided multi-year supplemental funding for the AMD program to transform the way we track pathogens in the U.S.

Support a Strong Clinical Microbiology Laboratory Workforce

A national testing strategy that incudes accurate and reliable diagnostic tests, a steady supply of testing materials, and a connected network of labs is 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.[1] That includes clinical microbiologists—highly trained scientists with PhDs or medical degrees. Prior to the COVID-19 pandemic, a mere 5,000 laboratory professionals entered the workforce annually, and clinical

[1] https://ascls.org/workforce/

microbiology laboratories had more than 10 percent vacancies.[2] The pandemic only made this situation worse.

Congress should consider measures to boost recruitment to fill workforce shortages and measures to ensure that we do not lose key personnel amidst a crisis. One example is H.R. 5602, the BIO Preparedness Workforce Act, which establishes a bio-preparedness and infectious diseases workforce loan repayment program. We could rapidly scale-up testing by enacting a biomedical version of the National Guard to mobilize scientists, as ASM leaders proposed in an opinion piece in the New York Times last year.[3] Furthermore, any new proposals aimed at shoring up health-related emergency responders should include clinical microbiologists.

Unless we address the clinical laboratory staffing shortages, we will experience another testing crisis in the future as already-stretched labs will be unable to process the workload. In addition to the exponential increase in workload for laboratories during a pandemic, understaffed labs will be pulled away from other essential testing functions. The federal government can provide the incentives, and educational and training support for this profession, which currently does not benefit from federal program support.

Support Disease Surveillance and Genomic Sequencing

A national strategy must include robust surveillance, timely reporting, and communication, which are key to understanding when, where and how a pandemic may be disproportionately affecting specific demographic groups in the population, as we have seen with COVID-19. The inclusion of basic demographic data with test results like race, ethnicity, age, and sex is essential to ensuring public health has the information needed to guide decision making. We need a modern public health data infrastructure in place to ensure more accurate and complete reporting, and to ensure that the system is "usable" and interoperable between independent and academic-based laboratories and public health departments. It is essential that this infrastructure buttresses the integration of hospital clinical microbiology labs -often the bellwethers of an emerging crisis- with public health laboratories. Such infrastructure should also be geared toward ensuring that groups have equitable access to testing and that testing and other resources are targeted appropriately.

To adequately address data modernization needs, sustained funding to CDC is needed to develop uniform data standards, provide grants to states to implement the surveillance plans, and to bolster existing infrastructure such as the national influenza monitoring system. We believe the most efficient way to build a surveillance system now and in the future is to scale up existing programs as part of a robust, effective national surveillance plan.

The CDC AMD program noted above has been identified by CDC leadership as a "core capability," and has become an increasingly indispensable part of the agency's infrastructure and laboratory capacity as it relates to outbreak response and surveillance. AMD uses next generation sequencing (NGS), giving CDC and state public health labs in all 50 states new tools to detect disease faster, identify outbreaks sooner and protect people from emerging and evolving disease threats like SARS-CoV-2. Through AMD, labs have been able to apply sequencing to the novel virus and then make the data available through a

[2] https://academic.oup.com/ajcp/article/152/2/155/5499263?login=true
[3] https://www.nytimes.com/2020/04/27/opinion/biomedical-national-guard-covid.html

global database. In the case of COVID-19, the increased capacity for microbial genomics, as well as a greater openness about sharing that data, is essential to the response by providing a clear picture of how the virus is emerging so that our response can be quicker, more effective, and more accurate. By using NGS, AMD technology brings the concept of precision medicine to bear for "precision public health," and funding for this program should be significantly increased as part of a larger commitment to disease surveillance.

Alleviating Testing and Laboratory Supply Shortages

Testing supply shortages were a persistent challenge throughout the COVID-19 pandemic, and a national strategy is needed to ensure that shortages of the magnitude experienced over the past year can be avoided in the future. The clinical laboratory supply shortages have now extended to research laboratories, which also are experiencing delays in critical materials. Addressing laboratory shortages must be done in a coordinated way and in a manner that allows clinical lab directors and researchers to plan accordingly for the future. The federal government has a key role to play in addressing these challenges, including assisting states and stakeholders to track, communicate, and help resolve laboratory testing and research supply issues. ASM has called for a large scale and coordinated system to connect the public, clinical, commercial, and industry sectors to ensure sufficiently robust supply lines, transparency about when and where shortages exist and for what materials, transparency around supply allocations so laboratories can plan ahead (minimizing the need for real time decision-making), and cross-sector communication about supply levels. To carry out this important mission, clinical labs should have the supplies (e.g. reagents, swabs, buffers) and testing kits they need to meet the demands in their area. Likewise, lifesaving research projects will be stymied and potentially lost without a steady and predictable supply chain.

Combating Antimicrobial Resistance

ASM is pleased that the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act is included in Sec. 105 of the Cures 2.0 legislative text. ASM has endorsed this legislation, which would establish a subscription program that provides a predictable return on investments for critically needed new antibiotics through federal payments delinked from antibiotic sales and use. It will also incentivize the development of antibiotic and diagnostic stewardship guidelines to encourage appropriate use of antibiotics and includes critical transition measures to stabilize the fragile antibiotic ecosystem in the near-term.

Antimicrobial resistance (AMR) is one of the most daunting challenges in safeguarding public health in the U.S. and globally. Every year, approximately 700,000 people die from drug-resistant infections. Infectious disease experts predict that by 2050, this number will dramatically increase to as many as 10 million people worldwide. The problem is particularly serious in developing countries in which, for example, drug resistant strains of tuberculosis cause 200,000 deaths every year. To date, the U.S. and global response has not sufficiently dealt with the breadth and complexity of this threat—it is now considered a global crisis by the World Health Organization, the G20, and the United Nations (UN).

Antibiotic stewardship programs have proven effective in improving patient outcomes, reducing inappropriate antibiotic use, limiting antibiotic resistance and lowering health care costs. During the COVID-19 pandemic, stewardship programs were critical in efforts to successfully launch novel therapies for patients with COVID-19. However, many stewardship programs lacked sufficient resources to sustain

stewardship activities during the pandemic. Even prior to the pandemic, many hospitals lacked adequate resources to implement evidence-based stewardship practices fully. The PASTEUR Act would provide support for hospitals to strengthen their stewardship programs and encourage hospitals to report data on antibiotic use and resistance to the CDC National Healthcare Safety Network to enhance our national understanding of antibiotic resistance and evaluate our interventions.

Beyond the PASTEUR Act provisions, we encourage you to consider additional ways to promote the concept of "One Health" to combat antimicrobial resistance, since at its root, AMR is ultimately an environment problem, where the health manifestation is its sequelae. Surveillance is one way to accomplish this, because considering all areas—human health, animal health, and environmental health—and tracking resistance across multiple vectors will ensure a complete picture of where resistant organisms are developing and how they are transmitted. ASM is also supportive of government providing pull and push incentives to help overcome the economic market failure problem that is at the core of the knotty AMR menace.

Support for Vaccine and Immunization Programs

ASM strongly supports the universal application of vaccines to prevent illness and death caused by infectious diseases. Thanks to federal investments in basic and clinical research, there is a sound evidence-based foundation for U.S. immunization strategies. There is no doubt that the development and effective use of vaccines for a broad range of life-threatening illnesses has saved countless lives in our nation and around the world. The recent reemergence of vaccine preventable diseases is alarming since outbreaks of once nearly eradicated diseases not only harm the patient, but put the local populations at risk, especially the most vulnerable members of these communities.

ASM is pleased that Cures 2.0 authorizes additional funding in Sec. 104 for the CDC to carry out an awareness campaign about the safety and importance of vaccines, as well as funding to strengthen immunization information systems. We encourage you to include the following language from the VACCINES Act of 2019 (H.R. 2862) that would allow CDC to develop and deploy a national system for surveillance of vaccination rates that would allow for data to be collected and used to improve access to vaccines across the country.

(a) IN GENERAL.—Section 317 of the Public Health Service Act (42 U.S.C. 247b) is amended by adding at the end the following new subsection:

"(n) VACCINE SURVEILLANCE AND RESEARCH.—

"(1) SURVEILLANCE.—

"(A) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with the National Vaccine Advisory Committee and the Director of the National Vaccine Program, shall develop and deploy a national system for surveillance of vaccination rates.

"(B) AUTHORIZED ACTIVITIES.—The surveillance system under subparagraph (A) may include the following:

"(i) Use of immunization data available to the Centers for Disease Control and Prevention and its contractors.

"(ii) Integration of data from existing systems—

"(I) to measure vaccination confidence over time;

"(II) to understand variations across time and geography; and

"(III) to measure vaccine refusal.

"(C) USE OF DATA.—The Secretary may use data collected pursuant to the surveillance system under subparagraph (A) to predict and identify areas and communities where—

"(i) vaccines are or will be underutilized;

"(ii) vaccine confidence is low or decreasing; or

"(iii) misinformation about the safety of vaccines, not supported by scientific or medical evidence, has been directed in a targeted manner.

"(D) CONSULTATION.—In developing the surveillance system under subparagraph (A), the Secretary shall consult with the National Academies to synthesize existing evidence and develop a standardized measurement of vaccine confidence.

"(E) FUNDING.—There are authorized to be appropriated $15,000,000 for each of fiscal years 2020 through 2024 to carry out this paragraph.

"(2) GRANTS FOR RESEARCH.—The Secretary may award grants for research—

"(A) to improve the understanding of vaccine hesitancy;

"(B) to improve understanding of health care provider attitudes and beliefs toward vaccination; and

"(C) to develop effective strategies for addressing non-adherence to the safe and recommended use of vaccines and encouraging the safe and recommended use of vaccines."

Authorizing an Advanced Research Projects Agency for Health (ARPA-H)

The creation of an Advanced Research Projects Agency for Health (ARPA-H) at the National Institutes of Health (NIH) in Sec. 501 is an intriguing concept intended to boost translating research into urgently needed capabilities for the benefit of human health. Recent initiatives such Operation Warp Speed and RadX demonstrate how focused work on urgent needs, when supported by federal funding and conducted through public-private partnerships, can lead to the development of lifesaving products and capabilities in record time. This model could prove useful in developing more effective and urgently needed solutions to global threats like antimicrobial resistance and seasonal threats like influenza. It is

also important to recognize that these innovative partnerships were successful in the absence of a new, dedicated agency of this nature at the NIH, and there is risk in establishing a permanent entity that will require continued, robust support and staffing indefinitely.

We appreciate that the President's budget proposed and the House and Senate Appropriations Committees' FY 2022 Labor, Health and Human Services, Education and Related Agencies bill include funding for an ARPA-H that is separate and supplemental to base funding for existing NIH Institutes and Centers. If established, the funding for the new entity must be maintained in this way. Sustained, robust support for basic and clinical research at NIH provides the foundation for the discoveries and technologies that lead to products that treat and cure disease or advance health care capabilities. We also know that budget parameters can and do change. We remain concerned that ARPA-H could ultimately result in less investigator-initiated research funded by NIH Institutes and Centers, and reduced paylines.

We recognize this concept is a priority for many and is intended to fill a critical gap in the development of therapies and platforms that is preventing progress against diseases and conditions that affect millions of Americans and people around the globe. We look forward to working with you to find a path forward that can address concerns but also meet the needs of the scientific and patient community and advance innovation.

Support for long COVID, integrative Learning Collaborative

ASM supports the interdisciplinary Learning Collaborative with HHS in Sec. 101. The importance of an integrative approach with experts from multiple sectors is crucial to further the understanding of long COVID. ASM applauds Cures 2.0 for including developers of diagnostics and therapeutics along with clinical laboratories in the Learning Collaborative. Clinical laboratories have a unique position of being both behind the scenes and on the front lines of an infectious disease outbreak. For the last 18 months, clinical laboratories across the country have adapted to supply chain and workforce shortages despite an immensely high demand for COVID-19 test kits. They consistently provide accurate and reliable COVID-19 diagnostic testing and will give a unique perspective to the Learning Collaborative.

Conclusion

Thank you for the opportunity to share our feedback on Cures 2.0. We look forward to working with your offices as you continue to advance this important legislation. Should you have any questions, please reach out to Mary Lee Watts, ASM Director of Federal Affairs, at mwatts@asmusa.org.

Sincerely,

Allen D. Segal
ASM Chief Advocacy Officer