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The Honorable Patty Murray
Chair
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, DC 20510

March 25, 2022

Dear Chair Murray and Ranking Member Burr:

The Infectious Diseases Society of America (IDSA) strongly supports the PREVENT Pandemics Act, especially the Bio-Preparedness Workforce Pilot Program included in Sec. 221. Your legislation represents an important first step in applying lessons learned from the COVID-19 pandemic to strengthen our nation's preparedness for future threats, and we are grateful for your steadfast leadership. As infectious diseases clinicians, scientists and public health experts on the frontlines of the COVID-19 response, IDSA members know firsthand how important your legislation is, and we are eager to work with you toward enactment.

The infectious diseases (ID) and emergency preparedness workforce is the backbone of our medical response infrastructure, and the Bio-Preparedness Workforce Pilot Program included in the PREVENT Pandemics Act is crucial to overcome significant current challenges to recruitment. Nearly 80% of counties in the United States do not have a single ID physician, leaving more than 200 million Americans vulnerable to outbreaks with little to no access to expert care. Significant student debt drives many health care professionals away from ID in favor of more lucrative areas of medicine. The successful implementation of many important provisions of the PREVENT Pandemics Act – addressing critical areas such as public health communications, testing capacity, data modernization, clinical trials and health disparities – hinge upon the availability of the ID and preparedness workforce. Similar shortages of clinical laboratory personnel, infection preventionists, infectious diseases pharmacists and other health care professionals specializing in ID further weaken our communities' resilience.

IDSA also appreciates the Committee's recognition that antimicrobial resistance (AMR) presents a serious threat to our preparedness, and we support the PREVENT Pandemics Act provision to strengthen laboratory capacity and international collaboration to combat AMR. We are also pleased that the Committee agreed to Smith amendment #1, to provide for increased manufacturing capacity for critical generic antibiotic drugs, as persistent shortages of generic antibiotics harm patient care and drive overuse of broader spectrum antibiotics that increase the development of resistance. However, we note that additional policies are necessary to revitalize the research and development of novel antibiotics to address the most difficult-to-treat

infections, and we look forward to working with the Committee to advance the bipartisan PASTEUR Act (S. 2076).

IDSA is pleased to support many additional provisions in the PREVENT Pandemics Act that will review the COVID-19 response, strengthen public health communication, address health disparities, improve surveillance and data collection, expand the public health workforce, apply a One Health framework to preparedness, accelerate medical countermeasure research and development and strengthen the medical product supply chain. More comprehensive comments on the importance of these provisions are attached.

Once again, thank you for your leadership on the PREVENT Pandemics Act. We look forward to working with you to advance this important legislation.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. McQuillen', with a long horizontal flourish extending to the right.

Daniel P. McQuillen, MD, FIDSA
President, IDSA

Attached: Section-by-Section support for the PREVENT Pandemics Act

SECTION-BY-SECTION SUPPORT FOR THE PREVENT PANDEMICS ACT

Title I – Strengthening Federal and State Preparedness

Subtitle A – Federal Leadership and Accountability

Sec. 101. Comprehensive review of the COVID-19 response. IDSA supports this provision and believes that such a review of the COVID-19 response will allow us to better apply lessons learned from the current pandemic to improve our preparedness and response to future events. We appreciate that the task force created by this section would include individuals with expertise in medicine, public health and research, as these disciplines are on the frontlines of the COVID-19 response and will be able to provide candid, direct perspectives and expertise to this review.

Sec. 105. Public health and medical preparedness and response coordination. IDSA supports this section. Increasing coordination across federal agencies should help streamline response activities and reduce the potential for confusion. Regular preparedness exercises and congressional hearings on preparedness will help ensure this important issue remains at the forefront of our national agenda, strengthening our vigilance against future threats.

Sec. 106. Strengthening public health communication. IDSA supports this section to establish a Public Health Information and Communication Advisory Committee. Confusing messages, misinformation and disinformation pose significant challenges to pandemic preparedness and response and have fueled vaccine hesitancy and lack of public cooperation with public health guidelines, such as masking. IDSA appreciates that individuals with expertise in public health and medicine would be included in the advisory committee.

Subtitle B – State and Local Readiness

Sec. 111. Improving state and local public health security. IDSA supports this section to strengthen coordination on public health emergency preparedness, particularly with school systems. Over the course of the COVID-19 pandemic, we learned effective strategies to facilitate in-person learning while preventing transmission of COVID-19, and we saw the negative effects on children when in-person learning was halted. We further saw the important roles schools can play as community hubs to facilitate vaccination. All of these experiences underscore the importance of including school systems in public health emergency planning.

Sec. 114. Assessment of containment and mitigation of infectious diseases. IDSA supports this section, which represents another important opportunity to assess lessons learned from the COVID-19 pandemic, including specifically on isolation and quarantine. Early in the pandemic, state and local public health departments had very little warning to prepare to receive and manage quarantined travelers. Isolation and quarantine preparedness is one of the most challenging aspects of public health emergency response planning. It is highly resource-intensive and complex, requiring coordination of overlapping authorities across various levels of government, and complicated and resource-intensive public health and health care system activities. There are major logistical challenges and costs associated with finding suitable isolation and quarantine facilities, meeting the needs of the population under isolation or quarantine, monitoring their health and ensuring timely medical evaluation and testing when necessary, including safe and secure transport from isolation or quarantine locations to and from health care facilities.

Title II – Improving Public Health Preparedness and Response Capacity

Subtitle A – Addressing Disparities and Improving Public Health Emergency Responses

IDSAs support this subtitle and recognize the significant role of social determinants of health in determining health outcomes. The COVID-19 pandemic starkly highlighted longstanding health inequities, and the federal government must provide leadership and resources for efforts to reduce health disparities. We appreciate that in addition to authorizing new grants in this area, the subtitle also calls for a report from the Department of Health and Human Services to Congress and a Government Accountability Office study on social determinants of health, as well as a National Academies of Sciences report on health disparities, all of which should help drive a long-term federal commitment to these issues.

Subtitle B – Improving Public Health Data

IDSAs support this subtitle to improve the availability of infectious diseases data (particularly demographic data to aid in the identification of at-risk populations and potential health disparities) and to strengthen and expand activities related to advanced molecular detection and genomic sequencing of pathogens. We appreciate the particular attention to the need to support rapid and accurate reporting of laboratory test results during a public health emergency. Better deploying novel diagnostic techniques and genomic sequencing capabilities for routine use in our communities will also help ensure the readiness of these technologies and public health and health care personnel in future emergencies.

Subtitle C – Revitalizing the Public Health Workforce

IDSAs strongly support this subtitle, particularly the Bio-Preparedness Workforce Pilot Program, which is crucial to support recruitment and address serious shortages in the infectious diseases and emergency preparedness workforce. In addition, IDSAs note the importance of provisions to improve recruitment and retention of the public health workforce. Infectious diseases clinicians in hospitals and clinics frequently work hand-in-hand with public health professionals in state and local health departments in crucial areas including policy development, vaccination campaigns, public communications, screening and diagnostic testing, surveillance and data collection. It is essential to ensure that both clinical and public health settings are sufficiently staffed with appropriate experts.

Subtitle D – Improving Public Health Responses

Sec. 231. Centers for public health preparedness and response. IDSAs support this section, acknowledging the importance of translational research and dissemination of findings to support ongoing improvements to preparedness. IDSAs note that many of the activities described in this section are examples of activities that are best performed by partnerships across public health and health care. Ensuring a health care workforce trained in biopreparedness and infectious diseases will allow these centers to maximize their potential.

Sec. 232. Vaccine distribution plans. IDSAs support this section, as tracking vaccine distribution helps identify challenges and best practices to facilitate rapid, efficient and equitable distribution of vaccines during pandemics.

Sec. 234. Supporting laboratory capacity and international collaboration to address antimicrobial resistance. IDSAs strongly support this section to improve our capacity to identify and track resistance threats across international borders. A study published in 2022 found that in

2019, 1.27 million deaths globally were directly caused by antimicrobial-resistant infections, making AMR a leading cause of death, higher than HIV/AIDS or malaria.

Sec. 235. One Health framework. IDSA supports this provision to strengthen federal collaboration across multiple agencies related to the prevention, detection, control and response for zoonotic diseases. Many of the most serious infectious diseases threats with outbreak or pandemic potential are zoonotic in nature, and a well-integrated One Health approach to preparedness is essential.

Title III – Accelerating Research and Countermeasure Discovery

Subtitle A – Fostering Research and Development and Improving Collaboration

Sec. 301. Research and activities related to long-term health effects of SARS-CoV-2 infection. IDSA supports this section and agrees that there is still a great deal to learn about the long-term health impacts of COVID-19 and a significant need for more research to inform optimal management of patients experiencing long-term health impacts of COVID-19.

Sec. 302. Research centers for pathogens of pandemic concern. IDSA supports this section to advance the development of medical products for viruses with pandemic potential. This provision will help speed the availability of new life-saving tools for future pandemics.

Sec. 303. Improving medical countermeasure research coordination. IDSA supports this provision, which will help ensure that the best surveillance and epidemiological data are regularly informing medical countermeasure research to help strengthen our preparedness for emerging threats.

Sec. 304. Accessing specimen samples and diagnostic tests. IDSA supports this section, recognizing that increasing access to specimen samples will expand capacity for developing and validating new diagnostic tests. IDSA also supports allowing HHS to contract with public and private entities to improve the rapid development and availability of diagnostic tests to support public health responses.

Title IV – Modernizing and Strengthening the Supply Chain for Vital Medical Products

IDSA supports Title IV to strengthen the Strategic National Stockpile (SNS), domestic manufacturing surge capacity for medical countermeasures and the supply chain for medical products. Limited supplies of COVID-19 treatments and diagnostic tests have presented ongoing challenges throughout the pandemic. Significant health care resources are expended to optimally manage limited supplies to ensure they are directed to the patients with the greatest need while leaving many other patients without access. We agree with the need to identify manufacturing vulnerabilities and build in redundancies to prevent shortages of key products. Shortages of personal protective equipment and testing supplies significantly hampered our response to COVID-19, risking the safety of our health care personnel and limiting our ability to diagnose and track infections.

Throughout the COVID-19 pandemic, IDSA has repeatedly heard from members working in state and local health departments and hospitals regarding confusion about how to access medical

products from the SNS and other medical countermeasures. Improving communication and transparency will greatly benefit frontline responders and allow them to better serve their patients and communities. Grants to support state stockpiles are very important, as most states do not have the resources to maintain their own stockpiles without federal support.

Title V – Enhancing Development and Combating Shortages of Medical Products

Subtitle A – Development and Review

Sec. 501. Advancing qualified infectious disease product innovation. IDSA greatly appreciates the inclusion of a provision aimed at combating antibiotic resistance. IDSA supports this section to expand QIDP eligibility to include biologics, recognizing that biologics may play a helpful role in treating antibiotic-resistant infections. QIDP status, while helpful, has proven to be insufficient alone to sustain antibiotic research and development. Most large pharmaceuticals have left the space, and since 2019, two small biotech companies focused on antibiotic R&D filed for bankruptcy. Factors unique to antibiotics – namely, short duration of use and the need to use them judiciously to prevent the development of resistance – make it extremely difficult for companies to earn a return on investments in antibiotic innovation. To address these significant challenges, IDSA looks forward to working with the Committee to advance the bipartisan PASTEUR Act.

Sec. 502. Modernizing clinical trials. IDSA supports this section, particularly the focus on decentralized clinical trials, which we agree will help foster more diverse participation in clinical trials and expand access to clinical trials to patients who do not live close to a large academic medical center. IDSA notes that the successful inclusion of broader patient populations in clinical trials will require health care professionals in all communities to identify and enroll patients in trials. Additional policies are needed to address workforce shortages and ensure providers are located in communities with the greatest need.

Sec. 503. Accelerating countermeasure development and review. IDSA supports this provision to help ensure that safe and effective therapeutics are appropriately reviewed and made available to patients as rapidly as possible.

Sec. 504. Third-party test evaluation during emergencies. IDSA supports this provision, recognizing that consultation by the U.S. Food and Drug Administration (FDA) with third parties can allow diagnostic tests to be much more rapidly evaluated and made available for use during public health emergencies.

Sec. 507. Increasing EUA decision transparency. IDSA supports this section to help ensure FDA shares more safety and effectiveness information with the public about products authorized for emergency use. We greatly appreciate the heroic efforts of FDA to rapidly and thoroughly review products during the COVID-19 pandemic to speed patient access to life-saving tools. However, limited public availability of safety and efficacy data contributed to delayed uptake and uneven use of some COVID-19 therapeutics and hampered the ability of professional societies to develop clinical guidelines. Increased access to data will greatly improve patient care.

Sec. 509. GAO study and report on hiring challenges at FDA. IDSA supports this section to help ensure sufficient staffing at FDA to carry out its mission.

