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July 10, 2023

Chairman Bernie Sanders
U.S. Senate
HELP Committee
Washington, DC 20510

Sen. Bob Casey
Member
HELP Committee
Washington, DC 20510

Ranking Member Bill Cassidy
U.S. Senate
HELP Committee
Washington, DC 20510

Sen. Mitt Romney
Member
HELP Committee
Washington, DC 20510

Dear Chairman Sanders and Senators Cassidy, Casey and Romney:

The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to provide comments on the draft legislation to reauthorize the Pandemic and All Hazards Preparedness Act (PAHPA). IDSAs represents over 12,000 clinicians, scientists and public health professionals dedicated to prevention, diagnosis and treatment of patients with infectious diseases (ID) who are on the frontlines of ID outbreak response.

IDSAs's top priority for PAHPA reauthorization is enactment of the PASTEUR Act (S. 1355) to address antimicrobial resistance (AMR). Additional priorities for PAHPA reauthorization include investing in public health – particularly data collection capabilities, appropriate tracking and distribution of medical countermeasures and laboratory safety and diagnostic capabilities. **IDSAs also urges Congress to invest in the infectious diseases workforce by addressing barriers to recruitment – including high medical student debt and inadequate reimbursement.** A strong ID workforce is central to our preparedness, and we realize some of the necessary workforce solutions may fall outside the scope of PAHPA reauthorization. We hope to work with the Health, Education, Labor & Pensions Committee and other relevant committees to address critical gaps in ID workforce.

Response to the Discussion Draft

Overall, IDSAs urges the Committee to provide funding levels that meet the demonstrated need for existing programs and are not lower than current authorization levels. In addition, the following comments are related to specific sections of the draft legislation.

Section 101 – Public Health Emergency Preparedness Program

Given the known threat of pandemic influenza and the potential of other reemerging respiratory viruses such as new coronaviruses, we urge the Committee to ensure that the proposed changes do not diminish preparedness against the most likely pandemic threats. In accordance with the Coalition to Stop Flu, of which IDSAs is a member, we suggest the following changes:

- Page 3, lines 8-10 – We are concerned that the proposed amendment removes specific references to preparedness for pandemics, as opposed to preparedness for CBRN threats in the paragraph prior. We suggest amending these lines as follows:

- (A) in subparagraph A(ii), by striking “influenza” and inserting “pathogens causing a pandemic, including pandemic influenza.”
- Page 5, lines 1-3 – To ensure continued focus on pandemic influenza, we suggest amending to:
 - (iv) in subparagraph (B), by striking “pandemic influenza” and inserting “pathogens causing a pandemic, including pandemic influenza.”

Section 102 – Improving and Enhancing Participation of EMS Organizations in the Hospital Preparedness Program

IDSAs recommend sustained funding within the Hospital Preparedness Program for local and state first responders as part of the National Special Pathogen System (NSPS). NSPS supports the urgent preparedness and response needs of hospitals, health systems, and health care providers related to treating patients with special pathogens and is an integral part of preparedness and detection of special pathogens.

Section 104 – Pilot Program to Support State Medical Stockpiles

We appreciate dedicated support for state medical stockpiles, which alleviates some of the burden on states in an emergency and allows states to be better prepared to respond in an ID outbreak or pandemic. We also welcome the Committee’s recognition of the need to share best practices among states to allow quality improvement in state stockpiles.

Section 105 – Enhancing Domestic Wastewater Surveillance for Pathogen Detection

We appreciate the authorization of funding for health departments or a partnership between a health department and other public and private entities to engage in wastewater surveillance and research, and to maintain this infrastructure for readiness purposes. This is a good opportunity for partnership with ID clinicians in health care settings to provide data about their patient populations that can be compared to surveillance data. The program should include an accessible database utilizing a common platform and standards for monitoring (e.g., frequency, seasonality.) It is also important to coordinate with animal health partners as many zoonotic diseases provide early warning signs for diseases in humans.

Section 106 – Reauthorization of Mosquito Abatement for Safety and Health Program

We appreciate the reauthorization of the Mosquito Abatement for Safety and Health program in PAHPA, providing support for preventing the spread of vector borne diseases that pose serious risks. We greatly appreciate the inclusion of text that clarifies that the use of novel technologies is encouraged as part of this program. We also appreciate the reinforced support for training and education as part of the program, to help support a response ready workforce as new vector borne threats emerge, as seen recently with local transmission of malaria.

Section 203 – Medical Countermeasures for Viral Threats with Pandemic Potential

We appreciate the inclusion of language to help produce medical countermeasures that can be used for unknown viruses with pandemic potential. We recommend that the legislative language be amended to make a distinction between threats that consistently exist or continually circulate and have a significant potential to become a pandemic (e.g., pandemic influenza) and those priority virus families and other viral pathogens with a significant potential to cause a pandemic.

Section 205 – Pilot Program for Public Health Data Availability

The inclusion of a Pilot Program for Public Health Data Availability in the draft is an important step to ensuring robust public health data systems that provide an essential function in public health emergencies. We recommend providing adequate funding for this pilot to be effective and orienting this program toward data sharing between local and state health departments and the federal government as well as aggregation of data that is already being collected by the Department of Health and Human Services.

To ensure that this is handled effectively, we recommend that the Centers for Disease Control and Prevention (CDC) lead the National Health Data Board and the legislation provide sufficient clarity for implementation. CDC

should retain access to public health data to ensure this data is managed appropriately and shared with local and state public health departments. The National Health Data Board should include at least one non-federal individual with infectious diseases expertise. In addition, health care facilities should be involved to provide meaningful clinical data to the extent practicable and allowable under existing data privacy laws. To encourage appropriate involvement of all necessary parties in pandemic planning and response, we recommend adding the Director of the Office of Pandemic Preparedness and Response to the National Health Data Board.

Section 202 – Strategic National Stockpile and Material Threats

IDSA appreciates the Committee’s efforts to improve the efficiency and effectiveness of the Strategic National Stockpile (SNS). We strongly urge the Committee to add language addressing the issues of diversification and replenishment, which remain a significant challenge and threat to our preparedness. For example, while the stockpile holds influenza antivirals, most of these products are more than 15 years past the date of manufacture. The age of these products played a role in some states’ deliberation as to whether to accept products from the SNS during spot shortages and increased demand for antivirals in the 2022-23 flu season. We join with the Coalition to Stop Flu in suggesting the following change, using language adapted from H.R. 9476, the Protecting America from Seasonal and Pandemic Influenza Act of 2022 (the “Influenza Act”) for an all-hazards approach:

- Page 23, lines 13 and following, add new subparagraph (I) after new subparagraph (H) and redesignate current subparagraphs (H) through (K) as subparagraphs (J) through (M):
 - *(i) establish a schedule and execute a plan to diversify and replenish products in the stockpile, as appropriate, including through—*
 - *(1) dynamic management of antivirals and other therapeutics;*
 - *(2) vendor-managed inventory of testing equipment and supplies;*
 - *(3) replenishment of aging antivirals and other therapeutics, testing equipment, supplies, and other products; and*
 - *(4) diversification of stockpiled products.*

IDSA recommends the development of data systems and requirements to track recipients of federally distributed medical countermeasures (MCM) to help ensure equitable access and utilization of MCM. In addition, the development and distribution of MCM should be accompanied by a coordinated plan for prioritizing patients at the greatest clinical risk in case of scarcity of MCM supply. Planning should include input from subject matter experts in the fields of medicine, ethics, law, and public health policy, as well as patient and community representatives. During the COVID pandemic, a lack of a comprehensive plan led to preventable disparities in access to care including vaccination and therapeutic treatment.

In addition, diagnostics capacity needs to be strengthened to ensure timely access to testing and accurate identification of pathogens. PAHPA should be a vehicle to ensure a robust, diversified national supply and diagnostic infrastructure that can support public health emergencies. Recommendations to achieve this include:

- Initiate a national inventory of diagnostic equipment. The federal government should identify choke points and establish and fund a plan to address them, including through backup plans and redundancies to avoid breakdowns in access to testing supplies.
 - Include research labs in this inventory, including labs with smaller machines (e.g., thermocyclers).
- Develop a national database, accessible by all laboratories, to identify available equipment and ensure all resources are utilized.
- Authorize BARDA, in collaboration with CDC, NIH and FDA, to fund development of rapid, accurate, easily accessible, self-administrable diagnostic tests that are readable at the point-of-care or at-home. COVID-19 has proven the value and importance of point-of-care and at-home

diagnostics, which free up scarce health care capacity in pandemic situations and increase access to vulnerable and underserved populations.

- Require ASPR, in collaboration with FDA and CDC, to incorporate diagnostics supply chain resiliency into influenza pandemic planning and develop a plan for quickly ramping up public and private testing capacity (including clinical labs, public health labs, at-home). Testing and diagnostics supply chains are distinct from vaccines and treatments. Therefore, specific strategies are needed to ensure a robust diagnostics supply chain and an ability to quickly increase capacity in an outbreak.

Title III – Addressing the Needs of All Americans

IDSA appreciates the attention given to the needs of specific populations including children and people with disabilities. In addition, we recommend the establishment of a funding mechanism for the testing/care/treatment/vaccination for uninsured patients during public health emergencies. This was enormously helpful during the COVID public health emergency to make sure that patients received the preventive measures and treatment that they needed.

In addition, additional funding is needed to support healthcare facilities that care for special pathogens in biocontainment units – this should not be solely limited to response to Ebola Virus Disease. Cost of providing this care is significant and a growing concern as outbreaks of special pathogens are occurring with greater frequency.

Title IV – Strengthening Biosecurity

IDSA appreciates the inclusion of dedicated funding to establish and maintain no less than 12 regional biocontainment laboratories at a BSL-2/3 level to facilitate biosecurity issues. However, we continue to stress the need for increased access to BSL-4 facilities to facilitate biosecurity efforts. Adding new facilities with BSL-4 capabilities would increase research capacity and strengthen outbreak and pandemic preparedness in the U.S. and would work hand in hand with the proposed biocontainment laboratory network. New labs should be positioned strategically throughout the country based on safety assessments and geographic equity to prepare for and respond to novel agents quickly and safely. Biosafety practice considerations should be at the forefront of existing laboratories and for creating new labs.

Section 501 -- Epidemic Intelligence Service (EIS) Loan Repayment Program

IDSA is pleased to see the reauthorization of the EIS Loan Repayment Program in the draft. However, we also continue to support revision of the Tax Code to exclude student loan repayments made for CDC fellows (authorized under 42 U.S.C. 247b-7) from gross income. This will allow funding to support greater capacity for surveillance and outbreak response at CDC and will benefit patients and communities at risk for infectious diseases outbreaks. In addition, we support other efforts to support and strengthen the public health and infectious diseases workforce.

Antimicrobial Resistance

The growing crisis of antimicrobial resistance and our insufficient antimicrobial arsenal undermine U.S. public health preparedness and significantly hamper our nation's ability to respond to a wide range of threats, including pandemics, outbreaks, natural disasters and bioterror attacks. AMR is already a growing pandemic worsened significantly by COVID-19. As we've stressed in previous comments, the PASTEUR Act would increase our nation's resilience by strengthening the antibacterial and antifungal pipeline to ensure clinicians have the innovative products they need to treat patients, and ensuring antimicrobials are used appropriately. This is an essential component of national preparedness to infectious threats.

The PASTEUR Act would strengthen our nation's infrastructure to address AMR and provide much needed resources to antimicrobial stewardship programs in health care facilities, with priority given to rural, safety net and critical access hospitals and long-term care facilities. Further, the PASTEUR Act's subscription model is an innovative way to pay for novel antimicrobials that will revitalize the pipeline and support appropriate use. The federal government would contract with innovators to pay for a reliable supply of novel antimicrobials with

payments that are decoupled from the volume of antimicrobials used, reducing market pressures that can lead to inappropriate use of antimicrobials. **We urge you to include PASTEUR in the final PAHPA reauthorization legislation** to adequately address the threat AMR plays in the country's pandemic and infectious threats preparedness efforts.

Thank you for the opportunity to comment on reauthorization of the Pandemic and All Hazards Preparedness Act at this critical time in our nation's history. Please contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org with any questions.

Sincerely,

A handwritten signature in purple ink, appearing to read 'C. del Rio', is positioned above the typed name.

Carlos del Rio, MD, FIDSA
President