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IDSA
Infectious Diseases Society of America

March 29, 2023

Chairman Bernie Sanders
U.S. Senate
Health, Education, Labor & Pensions Committee
Washington, DC 20510

Ranking Member Bill Cassidy, MD
U.S. Senate
Health, Education, Labor & Pensions Committee
Washington, DC 20510

Sen. Bob Casey
U.S. Senate
Washington, DC 20510

Sen. Mitt Romney
U.S. Senate
Washington, DC 20510

Dear Chairman Sanders and Senators Cassidy, Casey and Romney:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA). **IDSA's top priority for PAHPA reauthorization is enactment of the PASTEUR Act to address antimicrobial resistance**. Additional priorities for PAHPA reauthorization include investing in public health – particularly data collection capabilities, protecting the ability to conduct research into emerging infectious diseases and enhancing laboratory safety. **IDSA also urges Congress to invest in the infectious diseases workforce by addressing barriers to recruitment – including high medical student debt and inadequate reimbursement.** We recognize some of the necessary workforce solutions may fall outside the scope of PAHPA reauthorization, though an ID workforce is central to our preparedness, and we hope to work with the Health, Education, Labor & Pensions Committee and other relevant committees to address critical gaps.

Antimicrobial Resistance

The growing crisis of antimicrobial resistance (AMR) 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. The soon-to-be reintroduced 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.

There are fewer than 50 new antibiotics in development, and only a handful address the most urgent threats. Most large pharmaceutical companies have exited antibiotic R&D, and small biotechs in this space are struggling to stay afloat. Because new antibiotics

must be used very judiciously to protect their effectiveness from the development of resistance, there is very little opportunity for innovators to earn a return on investment in novel antibiotics.

The PASTEUR Act's subscription model is an innovative way to pay for novel antimicrobials that will revitalize the pipeline and support appropriate use. Under PASTEUR, the federal government contracts with innovators to pay for a reliable supply of novel antimicrobials with payments that are decoupled from the volume of antimicrobials used. This approach is modeled after the successful Project BioShield to similarly support development of medical products that are crucial for preparedness but have a limited commercial market. Importantly, the federal government only pays once – the subscription payment is all-inclusive, and PASTEUR only pays for success. Furthermore, PASTEUR will only pay for FDA-approved treatments that are available to patients and address unmet AMR needs – those that will have a big impact for patients and public health.

PASTEUR would also 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. Stewardship programs have demonstrated success in improving patient outcomes and reducing inappropriate antibiotic use, but many facilities do not have the resources necessary to fully implement these programs. During public health emergencies, stewardship programs are often called upon to manage equitable administration of novel therapeutics, which requires additional resources.

In addition, IDSA commends Congress for the creation and support of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), a key resource to address AMR, which causes nearly 3 million antimicrobial-resistant infections and more than 35,000 deaths in the U.S. each year.

We also recommend adequate funding for efforts to support the interoperability of data systems that track AMR and antibiotic use, including the National Healthcare Safety Network (NHSN), particularly in order to facilitate health care facilities' ability to report AMR data. It is impossible to fully understand and track the full scope of AMR over time and to evaluate the impact of interventions without these data.

Infectious Diseases Workforce

A strong nationwide health care and public health workforce to address infectious diseases is critical for future outbreak and pandemic response. Nearly 80% of counties in the U.S. do not have a single ID physician. In the 2022 Match, through which medical residents selected specialty fellowship training programs, only 56% of ID fellowship programs filled their slots, compared to 90% or more of other specialty programs, which reinforces the urgency to build a stronger ID workforce pipeline. ID is one of the lowest paid medical specialties because the codes they primarily bill – inpatient evaluation and management (E/M) codes – are undervalued. High medical student debt drives many physicians to higher paid specialties.

IDSA applauds the enactment in 2022 of the Bio-Preparedness Workforce Pilot Program as part of the PREVENT Pandemics Act and calls on Congress to ensure that the program is funded without delay.

In addition, **reimbursement for ID physicians needs to reflect the high complexity and critical nature of their work to the health care ecosystem and to emergency preparedness and response**. Improved reimbursement will strengthen recruitment and retention of ID specialists, ensuring that patients in all communities have access to ID care. IDSA has urged CMS to increase reimbursement for the services ID physicians provide, starting by maintaining the historic relativity between inpatient and office/outpatient E/M RVUs, which would boost the values of inpatient E/M codes to keep pace with the increases provided for office/outpatient E/M codes in 2021. Unfortunately, CMS rejected this recommendation in its 2023 Medicare Physician Fee Schedule Final Rule without much rationale.

There is currently no mechanism to reimburse for many of the additional services ID clinicians perform during public health emergencies associated with outbreaks or pandemics, such as developing and updating clinical guidelines, training health care staff, scaling up testing and vaccination, managing supplies and collaborating with public health. Leaving these crucial tasks under-resourced promotes burnout among health care personnel and gaps in care. **IDSA calls for the creation of a payment modifier that could be attached to existing billing codes to provide increased reimbursement for care and services directly related to outbreak response during a public health emergency.** This approach could utilize guardrails to ensure the modifier is used as intended, such as clearly defining the circumstances, patients and services that could be eligible for increased reimbursement.

Failure to invest in the ID workforce jeopardizes our nation's preparedness for a wide array of threats, as ID specialists are needed to respond to outbreaks of commonplace as well as emerging infectious diseases. IDSA urges you to collaborate with colleagues on the Appropriations Committee and the Finance Committee on this important preparedness issue.

Additional PAHPA Recommendations

Health Equity

When feasible and relevant, we recommend all preparedness programs incorporate an equity framework that informs and guides program planning and development. Such a framework should identify populations at higher risk of adverse outcomes during a public health emergency and tactics for how to support those communities during preparedness, response and recovery phases.

Public Health Emergency Coordination and Policy

The authorities, duties and functions of the Assistant Secretary for Preparedness and Response (ASPR)

After the elevation of ASPR and reorganization, we hope that these efforts can strengthen coordination pathways among federal agencies and between state and local health departments, health care partners and other stakeholders. We need a truly coordinated federal system that includes not just HHS but also other departments that interface with jurisdictions and specialty organizations on areas key to preparedness. It is essential that federal agencies have clear preparedness and response roles, and that these roles can be understood at state and local levels for improved coordination and information sharing and faster responses.

For example, during this past winter's flu surge, it was difficult to get insurance companies to cover the brand name (Tamiflu) over generics, which had become scarce. It would be helpful in the future to have FDA, CMS, ASPR and CDC all working together to help understand and rapidly solve problems that jurisdictions are reporting.

Congress should provide construction authority for ASPR and CDC as necessary, in line with other federal agencies like NIH, to ensure federal assets are available in a public health emergency.

Strategic National Stockpile (SNS)

In a pandemic or other public health emergency, it is crucially important that the needs of health care and public health workers are appropriately prioritized to ensure access to supplies that are vital to emergency medical response. Over the course of the COVID-19 pandemic, health care facilities and laboratories experienced critical shortages of supplies, including personal protective equipment, nasal swabs, viral transport media and PCR reagents, which slowed down identification of patients who had contracted the virus. It is critical to identify medical product supply chain and logistical bottlenecks. The PREVENT Pandemics Act took some important first steps to strengthen the SNS and medical product supply chains, including establishment of warm base domestic

manufacturing, assessments of supply chains, guidance to states on accessing SNS supplies, authorization of contracts for surge capacity and grants for state stockpiles. There are opportunities for PAHPA reauthorization to build on this progress, with more detailed recommendations below.

- Develop a federally guided supply chain and distribution plan involving all manufacturers of products relevant to diagnostics and pandemic response.
- Require manufacturers to validate diagnostic products on at least two alternative devices so that laboratories that lack the budget and space to purchase additional instruments or platforms are able to run tests on existing devices. Vendors have an incentive not to do this currently, and laboratory use of unvalidated alternatives can void the device warranty.
- 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.
- Expand access to general-purpose Nucleic Acid Amplification and Nucleic Acid Sequencing devices in clinical settings for ordinary use so that they will be ready and available when the next new pathogen emerges. The early deployment of these technologies could feed data directly into the appropriate CDC database for real-time analysis.
- Designate pandemic assessment centers – i.e., institutions partnered with state health departments – to coordinate activities to improve responses and alleviate supply chain issues. These partnerships can work strategically to maximize utilization of existing resources and decrease turnaround times on testing. There is already existing infrastructure for this in the Regional Treatment Network for Ebola and Other Special Pathogens built around the ability of providers and facilities to safely identify, isolate, transport and care for patients with Ebola and other highly infectious diseases. The network was deprioritized and funding expired. Only 10 of the original 55 Regional Ebola and Other Special Pathogen Treatment Centers (RESPTCs) remain funded. These centers should be funded to incorporate into the national special pathogen system (NSPS).

Biomedical Advanced Research and Development Authority (BARDA)

Last Congress, IDSA joined a stakeholder letter urging Congress to include the Disease X Act (Baldwin, S.2640) in the PREVENT Pandemics Act (with Alliance for Biosecurity, Big Cities Health Coalition, BioOhio, Biotechnology Innovation Organization (BIO), Coalition for Epidemic Preparedness Innovations (CEPI), Coherus BioSciences, FluGen Inc., Ginkgo Bioworks, Helix, Institute for Progress, Johns Hopkins Center for Health Security, Securing America's Medicines and Supply, The Gerontological Society of America, Tonix Pharma, US Biologic Inc., and Vir Biotechnology.) We expect the Disease X Act will have a bipartisan, bicameral reintroduction in the coming weeks and recommend its inclusion in PAHPA.

- The next fast-moving, novel infectious disease pandemic could be right around the corner. However, there is no sustained funding, program, or strategy dedicated to accelerating the development of medical countermeasures for previously unidentified infectious disease threats, referred to here as 'Disease X.'
- To increase resilience against these 'Disease X' threats, we recommend Congress explicitly require a medical countermeasures strategy and dedicated program at BARDA focused not on single agents, viral and non-viral, but specifically on viral families from which a threat—known or unknown—is most likely to cause a pandemic or major epidemic. Accordingly, BARDA's statutory authority should be augmented and durably

funded in order to undertake these activities proactively, rather than having to wait for specific congressional emergency supplemental funding that often comes late. We recommend that Congress therefore add a specific requirement for accelerated advanced development and manufacture of flexible medical countermeasures for viral families with pandemic potential and previously unknown pathogens at BARDA. These products, and the strategy needed to rapidly develop them, are vital to our country's public health preparedness, our citizens' health, and national security.

Other ASPR activities financed through the general HPP budget, such as the Regional Disaster Health Response System (RDHRS) demonstration projects

- Regional systems in development should align with regional planning for emerging and special pathogens led by the RESPTC network to help build capabilities and capacity across grantees and regions.

Epidemic Intelligence Service (EIS) Loan Repayment Program

- IDSA supports 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.

The Epidemiology and Laboratory Capacity Cooperative Agreement Program and related activities, including mosquito abatement

- The Epidemiology and Laboratory Capacity Grant Program supported many different functions during the COVID-19 pandemic. This program needs the flexibility and adequate funding to provide ongoing capacity for everyday epidemiology and laboratory capacity at the local and state level in addition to responding to episodic outbreaks.
- IDSA supported the creation of the Strengthening Mosquito Abatement for Safety and Health program and urges reauthorization of the program prior to expiration.

Biosurveillance and Public Health Situational Awareness

The following recommendations relate to data reporting and sharing, which is important for health care and public health to provide optimal clinical care, address emerging threats, pinpoint populations that are most at risk and evaluate the impact of interventions.

In the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (2016), Congress required the establishment of a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of, rapid response to and management of potentially catastrophic infectious disease outbreaks, novel emerging threats and other public health emergencies that originate domestically or abroad. However, this capability is still lacking, as demonstrated during the COVID-19 pandemic and 2022 mpox outbreak.

The following additional recommendations would help facilitate data reporting and sharing.

- Automate data collection/sharing to the full extent possible to reduce the burden on providers, health care systems, labs and public health agencies.

- Provide public health agencies with resources to automate their data monitoring and reporting systems and better access to patient-level data and demographic information to ensure equitable response and planning. Information technology systems need to be in place in addition to the regulatory levers to ensure information is shared without barriers such as cumbersome individual data use agreements.

- Standardize data collection and simplify the information needed for case reporting to reduce burdens for clinicians and public health labs.
- Help reduce barriers for public health agencies to access commercial data.
- Provide CDC with the authority, capacity and resources to require the reporting of minimum necessary nationwide data and share it with local communities, including public health departments, in a timely manner to help inform and strengthen local responses.
- Increase necessary infrastructure, research into and resources for surveillance that is not dependent on accessing the health care system, e.g., wastewater surveillance, pharmacy surveillance, school absenteeism, internet searches and animal surveillance.
- Develop and support a One Health approach to surveillance, providing insights into zoonotic diseases that have the potential to impact human health (in addition to the One Health framework and collaboration enacted as part of the FY2023 omnibus appropriations legislation).

Vaccine tracking and distribution

Accurate, complete, actionable data is necessary to address vaccine inequities and ensure populations who are most at risk benefit from public health interventions. Public health officials should collect and use data regarding, and input from, historically marginalized populations in developing guidance and plans for vaccine distribution and administration and make additional recommendations to ensure equitable access for these populations where appropriate. Recommendations above on data collection can help improve data collection variables where necessary, including race and ethnicity data and data on sexual orientation/gender identity, housing status and drug use.

IDSA also recommends that public health officials include equity considerations in communications with providers and the public, including sociodemographic risk factors, to help provide justification when equity interventions are incorporated into local policies and resource allocation decisions, including vaccine distribution plans.

Policies for the inclusion of at-risk individuals in public health emergency preparedness and response activities

As stated above, health officials should use data regarding, and input from, historically marginalized populations in developing guidance and make additional recommendations for these populations where appropriate.

Partnerships

What specific steps could Congress take to improve partnerships with states and localities, community-based organizations and private sector and nongovernment stakeholders, such as hospitals and health care providers, on preparedness and response activities?

When considering partnerships, it is crucial to prioritize health care professionals with infectious diseases expertise. Patients with serious infections have better outcomes, shorter hospital stays and lower health care costs when they receive care from ID physicians. ID physicians are often primary links between hospitals and state and local health departments, partnering on a wide range of preparedness and response activities. In addition, ID physicians are often among the most trusted public messengers, particularly on the state and local level.

In addition to the critical workforce needs outlined above, Congress and HHS should help build partnerships between public health and health care professionals and facilities on a routine basis to ensure strong

relationships are in place before a public health emergency. Ensuring sufficient workforce capacity in both public health and health care is a key first step. In addition, encouraging joint planning groups and trainings, clear and regular bidirectional communication channels and clear roles and responsibilities that include protected time and compensation can all help connect health care and public health and allow more effective and efficient emergency response, including activation of contingency clinical service teams. Once established, such communication channels and teams can also assist in addressing critical issues of antimicrobial resistance and epidemiology in the nonemergent setting.

How can foundational programs, such as the public health emergency preparedness cooperative agreements and the hospital preparedness program, be improved to ensure state, local and health system readiness to mount effective responses?

The Public Health Emergency Preparedness program and the HPP program should be leveraged to build public health and health care coordination, as outlined in the previous question. HPP-supported health care coalitions and regional partnerships are key to ensuring that the required workforce with necessary relationships and arrangements, such as mutual aid agreements, are in place prior to a public health emergency.

Research and Lab Safety

Research on emerging infectious diseases is imperative to detect pandemics as they are developing and prepare populations sufficiently to respond to pandemics. Enhanced potential pandemic pathogens (ePPP) research, a type of gain-of-function (GOF) research, has received particularly renewed attention due to the COVID-19 pandemic. ePPP research is important because it can help us understand potential human-pathogen interactions, assess their likelihood of emerging in a pandemic and inform preparedness efforts, including surveillance and the development of medical countermeasures. While this type of research is inherently risky and requires strict oversight based on biosafety principles, there is also risk of not undertaking this type of research, leaving us unprepared for the next pandemic. Unbiased bodies with appropriate scientific expertise should perform the oversight of this research.

In February 2022, the U.S. government charged the National Science Advisory Board for Biosecurity (NSABB) — which comprises members with significant expertise in science, research methodology, biosecurity and bioethics — with reviewing policies governing ePPP research and dual-use research of concern (DURC). They are to examine and recommend a forward-thinking approach to the funding review process for such studies.

In January 2023, NSABB released its Proposed Biosecurity Oversight Framework for the Future of Science, which includes a comprehensive set of thoughtful recommendations designed to increase the safety of ePPP research and DURC while allowing vital research to continue. The recommendations include the following:

- Develop an integrated approach to oversight of ePPP research and DURC with clear federal, institutional and investigator responsibilities.
- Clarify that federal department-level review is required for research that can be reasonably anticipated to enhance any pathogen's transmissibility and/or virulence (which would likely be broader than our current definition of ePPP).
- Remove blanket exclusions for research associated with surveillance and vaccine development while implementing processes for urgent, rapid review of research critical for public health or national security.
- Develop guidelines to ensure that there is no feasible alternative method to gain the benefits of the research with less risk and eliminate unnecessary risks.
- Increase transparency in the review process for ePPP research.

- Ensure that ePPP research conducted at institutions outside the U.S. is subject to review, evaluation and ongoing oversight procedures equivalent to domestic U.S. policies and procedures.

Additionally, investments in our infectious diseases research capacity and improvements to biosafety are essential. Access to BSL-4 facilities for research purposes can facilitate biosecurity research efforts. Despite the need for BSL-4 labs demonstrated by recent outbreaks, the number of laboratories in the U.S. is limited and unequally distributed across the country. The current facilities are located in Atlanta, GA; Fort Detrick in Frederick, MD; and San Antonio and Galveston, TX. Adding new facilities with BSL-4 capabilities would increase research capacity and strengthen outbreak and pandemic preparedness in the U.S. 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.

The federal government should support empirical research on biosafety efforts. Important research topics include why laboratory accidents happen, the frequency of these types of accidents and other data needed to create and update evidence-based mitigation measures. This type of research informs biosafety practices and mitigates the threat of laboratory accidents.

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. The COVID-19 pandemic provides an illustration of the many gaps in all hazards preparedness, especially related to novel infectious disease outbreaks. Please contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org with any questions.

Sincerely,

Carlos del Rio, MD, FIDSA
President