MILKEN INSTITUTE

March 29, 2023

The Honorable Bernie Sanders
Chairman
HELP Committee
United States Senate
Washington, DC 20510

The Honorable Bill Cassidy, MD
Ranking Member
HELP Committee
United States Senate
Washington, DC 20510

The Honorable Robert Casey, Jr.
HELP Committee
United States Senate
Washington, DC 20510

The Honorable Mitt Romney
HELP Committee
United States Senate
Washington, DC 20510

Re: Request for Information for the Pandemic and All-Hazards Preparedness Act (PAHPA Act) Reauthorization

Dear Chairman Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney,

Thank you for the opportunity to provide comments in preparation for the Pandemic and All-Hazards Preparedness Act (PAHPA Act) reauthorization. We commend the bipartisan leadership of the Senate Health, Education, Labor, and Pensions (HELP) in providing an opportunity to add our perspective ahead of the reauthorization. We look forward to collaborating with the Committee on policies that will improve and strengthen the nation's biosecurity and preparedness infrastructure.

FasterCures and the Center for Public Health are centers of the Milken Institute, a nonprofit, nonpartisan think tank focused on accelerating measurable progress on the path to a meaningful life. As part of the Milken Institute, FasterCures and the Center for Public Health work to catalyze practical, scalable solutions to address the challenges of our biomedical and public health systems, respectively. Guided by a conviction that the best ideas, when under-resourced, cannot succeed, we conduct research and analysis and convene top experts, innovators, and influencers from different backgrounds and competing viewpoints. We leverage this expertise and insight to construct programs and policy initiatives.

In this letter, we present our comments on programs and activities in the order listed in the request for comments. However, we would emphasize that our priorities are in the following areas: establishing robust early warning capabilities as a core component of biosurveillance activities; the long-term commitments for public-private partnerships (such as the Strategic National Stockpile and Supply Chain Control Tower (SCCT) with enhanced coordination to support pharmaceutical supply-chain resilience; and the enactment of the PASTEUR Act to encourage antibiotic development.

Program Effectiveness

To improve the efficiency and effectiveness of current HHS programs and activities, we recommend improvements in the following areas:

Public Health Emergency (PHE) Coordination and Policy

Responsibilities and Authorities of the Secretary of Health and Human Services (HHS) Prior to or During a PHE

In the reauthorization of PAHPA, we recommend HHS revisit the patchwork of data sharing agreements and invest in the system upgrades necessary for accurate and equitable public health surveillance. Revisiting data sharing and infrastructure needs moves us toward more interoperable public health data systems that share health information appropriately, in the right format. We need sustainable systems that can receive timely, exchangeable data from various sources, like laboratories and hospitals, and exchange these data with HHS in an efficient manner. In order to address how our current data sharing system leads to slow outbreak detection and response, Congress should provide the Centers for Disease Control and Prevention (CDC) with the authority to set public health data standards and require reporting of more complete public health data. The Improving DATA in Public Health Act provides an opportunity to reduce the burden on data providers while building more complete surveillance of outbreaks and other threats. Now is the time for Congress to fund and HHS to pilot studies to understand real-world needs and potential use in different communities. These pilots should include efforts to improve the completeness of demographic and other equity-related data.

These data surveillance limitations are critical as the end of the Public Health Emergency (PHE) declaration nears. Outside of a public health emergency, the CDC has limited authority to collect public health surveillance data from state and local health agencies. With the unwinding of the PHE on May 11, 2023, reporting of COVID-19 lab results and immunization data to CDC will change, as HHS will no longer have authority to require lab test reporting for COVID-19. This may affect the reporting of negative test results and impact the ability to calculate percent positivity for COVID-19 tests in some jurisdictions, further complicated by changes in overall test availability.

CDC has been working to sign voluntary Data Use Agreements (DUAs), encouraging states and jurisdictions to continue sharing vaccine administration data beyond the PHE. Additionally, hospital data reporting will continue as required by the conditions of participation stipulated by the Centers for Medicare & Medicaid Services (CMS) through April 30, 2024; reporting, however, may be reduced from the current daily standard to a lesser frequency. Having to rely more on targeted passive surveillance systems and compiling data from a sample of health-care facilities is suboptimal and may lead to incomplete data sets that miss communities disproportionately affected by COVID-19.

National Health Security Strategy (NHSS)

The NHSS outlines a vision to strengthen our nation's ability to prevent, detect, prepare for, and respond to new health threats. In the reauthorization of PAHPA, we recommend the NHSS continue to emphasize a whole-of-society approach and to consider the following:

1. *Establish robust early warning capabilities as a core component of biosurveillance efforts.* In the future, many new pathogens are expected to be zoonotic in origin due to land-use changes, food-production practices, and population growth—both at home and abroad. As zoonotic outbreaks become more frequent, biosurveillance systems will need to monitor the effects of these changes on animal health and their potential spillover to humans. Biosurveillance efforts must integrate early warning capabilities that can detect emerging threats at their source. Early warning systems should also integrate into efforts to surveille and predict AMR (antimicrobial resistance). Relatedly, the NHSS 2019–2022 acknowledged the importance of promoting a One Health approach to early warning detection and diagnosis. However, actions to carry out such an approach were absent from the accompanying implementation plan. In the reauthorization, we encourage a stronger focus on how a One Health approach can be implemented within the US.

2. *Advance a framework for private-sector engagement in preparing for and responding to emergencies.* The NHSS recognizes the private sector's critical role in confronting new vulnerabilities, particularly in the development and availability of medical countermeasures. However, to avoid transactional relationships with the private sector, we urge the NHSS to articulate a framework for private-sector engagement with the US government at the time of strategy or program formulation. To the extent feasible, the US government should look to co-construct preparedness and response strategies alongside representatives of the private sector so that the capabilities and resources of the private sector can be built into scenario planning and tabletop exercises. We also encourage a broader view of the private sector beyond the health and medical product sector to include organizations in data, technology, agriculture, and finance, which can bring to bear nontraditional data systems, advanced analytics, and cutting-edge technologies.

The comments above are further detailed in a letter that we submitted to ASPR to inform the 2023–2026 NHSS on March 11, 2022.

Medical Countermeasures Development and Deployment

Strategic National Stockpile

Public health responses to the COVID-19 pandemic demonstrated the strength of public-private partnerships (PPPs) in bolstering the resiliency of the pharmaceutical supply chain in support of public health nationally, regionally, and locally. Our research determined that well-designed PPPs—linking the public and private sectors—fostered a more comprehensive "last-inch delivery" of medications to enable increased access to health-care products and services to communities, especially those that have been historically marginalized and under-resourced. The federal government should consult successful PPPs enacted before and during the COVID-19 pandemic to evaluate those most useful to continue and how future partnerships may be best used.

Examples include the Public Health Emergency Medical Countermeasures Enterprise, the SCCT, Operation Warp Speed, and the Strategic National Stockpile (SNS).

In the reauthorization of PAHPA, we encourage enacting policies that sustain long-term opportunities and commitments for PPPs specific to the SNS to enhance coordination of the production, distribution, and delivery of critical medicine and supplies. Biomedical manufacturers and health supply-chain distributors have crucial expertise and resources that should be leveraged during emergencies, while supporting public health goals broadly. These stakeholders must be regarded as essential partners and therefore be included in planning considerations for appropriate distribution capabilities, capacity, and utilization for the SNS to understand what is readily available in the market.

To further equip the SNS, we recommend the inclusion of HR 405, the Essential Medicines Strategic Stockpile Act, as part of the PAHPA reauthorization to require that HHS establish a list of 50 generic drugs that are essential to a public health emergency and subsequent response. To go a step further, Congress may want to create a mechanism that enables enhanced visibility and early notification of potential drug shortages, particularly around essential medicines.

Additionally, we encourage the consideration of public- and private-sector collaboration to develop shared metrics that reward partner quality, reliability, and sustained engagement. Despite the demonstrated strengths of PPPs in response to the COVID-19 pandemic, partnership strains were observed among stakeholders who were less willing to leverage their regular business model to form unique partnerships supporting the production of much-needed supplies, resulting in offered solutions that were less likely to succeed. Therefore, recording partnerships in a comprehensive registry of private-sector supply-chain health partners that profiles their expertise, capacity to engage, geographic reach, and other core competencies will streamline efficiency to bolster preparedness and response.

The Public Readiness and Emergency Preparedness (PREP) Act

Leveraging PREP Act authorities, we recommend further efforts to enable nimble health workforce reassignment in health agencies. We support efforts to reexamine the role of pharmacists as agents of public health both in times of emergency and for ongoing public health response. Pharmacies located within five miles of 90 percent of Americans serve as key community health-care access points for the public. Pharmacists were granted additional powers through the PREP Act, an emergency waiver linked to but not dependent upon the PHE for COVID-19 declared under Section 319 of the Public Health Service (PHS) Act. Under PREP authorities, HHS granted pharmacists and pharmacy technicians the ability to order and administer COVID-19 tests, vaccines, and therapeutics for patients as young as three years old. Those authorities run through October 1, 2024, but because pharmacists operate largely under state laws, the intersection of federal and state policies will be unclear once the emergency expires on May 11, 2023.

We urge the Senate to consider legislative action to permanently expand Medicare coverage to include services provided by a pharmacist including testing, drug regimens, and vaccines for COVID-19, influenza, and certain other illnesses. For example, HR 7213, the Equitable Community Access to Pharmacist Services Act, would expand coverage for these services and for pharmacist services during a public health emergency or to address health equity.

Support for Jurisdictional Preparedness and Response Capacity

Hospital Preparedness Program (HPP) Cooperative Agreements

At the onset of the COVID-19 pandemic, the United States quickly realized the government struggled to collect real-time, accurate, and integrated data on infections, hospitalizations, deaths, and more. There was no standardization in data infrastructure, with existing systems lacking interoperability and functioning in fragmented silos. Beginning in April 2020, the Federal Emergency Management Agency (FEMA) at the National Response Coordination Center, the HHS, and private-sector distributors were in coordination with jurisdictional partners and hospitals to create the SCCT, a new public-private partnership that began in an informatics storage and processing application. It grew throughout the pandemic to include pharmaceutical distribution, COVID-19 testing equipment, and hospital inventory.

Initially, FEMA, HHS, and the private-sector partners operated under these parallel, unconnected systems, which led to operational challenges. As the pandemic response evolved, health-care distributors opted into data sharing in the SCCT, recognizing they had essential information to share to ensure communities were supported. The Control Tower multisector collaboration identified inventory movement and supply chain through the centralization and modernization of data, including allocation predictions using public-health data.

Existing and long-standing relations between distributors and the government were instrumental in integrating data across sectors. Currently, the SCCT has eight distributors who voluntarily provide limited data about the supply of five PPE categories, 30+ pharmaceuticals, and other medical products on a near-daily basis. The SCCT has also integrated supply status from around 5,000 hospitals and 15,800 long-term care facilities.

The reauthorization of PAHPA presents an opportunity to standardize health data reporting in the SCCT program. We suggest including language to provide distributors with data analytic parameters to ensure information is recorded and reported using consistent standards and flows bidirectionally across the supply chain. Applied extensions of the SCCT model that leverage existing data platforms to drive decision-making in response to public health crises other than COVID-19 should be examined and prioritized.

National Disaster Medical System (NDMS)

The COVID-19 pandemic elucidated the reality that not all communities have equitable access to the health-care resources and services necessary to respond effectively to a public health emergency. While national and regional efforts to address health-care preparedness challenges, establish best practices, and increase medical surge capacity are much needed, they are futile without considering and involving health-care access points (e.g., pharmacies, Federally Qualified Health Centers, and clinics) serving rural and/or under-resourced communities.

To ensure that communities are represented in future efforts to stand up a more comprehensive public health emergency system capable of responding to health security threats, we suggest the reauthorization of Title III of PAHPA and call for a study from the Government Accountability Office (GAO) that reflects data and information sharing abilities from pharmacies, Federally Qualified Health Centers, clinics, et cetera, and the public sector during the COVID-19 pandemic. Appropriate measures include sharing data and information related to medical surge

capacity, workforce availability and capacity, personal protective equipment, and vaccine distribution.

Gaps in Current Activities and Capabilities

Antimicrobial resistance (AMR) is a significant public health threat often described as a silent pandemic. Many experts believe antibiotic-resistant infections threaten our society more than the COVID-19 pandemic. Over 3 million people in the United States suffer from antibiotic-resistant infections every year, resulting in at least 50,000 deaths. Globally, AMR is a leading cause of death that has been connected to nearly 5 million deaths in 2019. Without any concerted action, it is estimated that the global death toll from AMR could reach as high as 10 million annually by 2050. The COVID-19 pandemic has only worsened AMR, with rates of drug-resistant hospital-onset infections and deaths jumping at least 15 percent in the first year of the pandemic alone. In future emergencies, the rise of AMR could severely hamper our ability to treat patients suffering from bacterial infections, leading to more morbidity and mortality.

We urge you to enact the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act in the reauthorization of PAHPA. The PASTEUR Act creates a new financial mechanism for paying for antibiotics that would help revitalize the development pipeline and bolster our nation's ability to prepare for and respond to threats that include pandemics, natural disasters, and other biological threats.

Despite the substantial need, antibiotics development has received little investment. The development of antibiotics, like all medicines, takes years and significant resources. Yet, when new antibiotics reach the market, they face a far more uncertain market than other medicines due to low prescription volumes and prices. This combination makes it difficult for an antibiotics developer to sustain the manufacturing and operational costs necessary to keep the drug on the market. Our research has found that the PASTEUR Act, which outlines a new payment mechanism for antibiotics that delinks payment from volumes, would open the door to new, much-needed investment in this sector because it provides developers with the possibility of a predictable revenue stream. In addition, it should be noted that most R&D in antibiotics today is conducted by small, single-product companies, not large pharmaceutical companies. With every month and year that passes when we do not solve the AMR crisis, these small companies will shutter their doors, and expertise will continue to dwindle as scientists and researchers leave the field.

Partnerships

States and localities, community-based organizations, and private sector and non-government stakeholders must all come together with the federal government as collaborative partners in order to promote policies, systems, and environments that protect and improve the health of all people in all communities. In a report released last year, *Learning from COVID-19: Reimagining Public-Private Partnerships in Public Health*, we call for an evolution from traditional public-private partnerships toward those that emphasize a shared responsibility of all sectors, industries, and communities as agents of public health and accountability for the public good. The report highlights partnerships and case studies that emerged in response to the COVID-19 crisis and offers lessons to promote and protect public health so that they can be leveraged for the future, both in times of crisis and non-emergencies. The report also offers recommendations for how

public-private partnerships can be strengthened to maximize their impact on public health preparedness and response.

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Thank you for the opportunity to comment on the Pandemic and All-Hazards Preparedness Act reauthorization. The Milken Institute welcomes the chance to provide additional detail on the information above and serve as a resource as you continue to refine the legislation.

Sincerely,

Esther Krofah
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Milken Institute