PAHPA Reauthorization: Better Preparing For Future Threats

EMERGENT

Originally passed in 2006, the Pandemic All-Hazards Preparedness Act (PAHPA) remains a key part of the United States' preparation and response to bio-threats, disasters and other national emergencies.

PAHPA is the legislative vehicle to shape future US pandemic preparedness.

Additionally, it provides an opportunity to share lessons learned from the COVID and Mpox responses to ensure the US is better prepared for future threats.

Cost of Complacency

Experts from Harvard and Johns Hopkins have estimated that the cost of COVID to the US, when combining economic damages and monetized health and life loss, was about $16 trillion. Experts generally agree that some of this life loss and economic damage could have been avoided, had the US been better prepared for a pandemic. Modeling from the Center for Global Development shows a 47-57 percent chance of another global pandemic as deadly as COVID-19 occurring in the next 25 years, underscoring the critical importance of immediate and continued investment in preparedness. Researchers from the Imperial College London estimate that if a COVID-like pandemic struck the US in the next decade, for every dollar spent on pandemic preparedness, the expected health gain would be $1,703, and the expected economic gain would be $1,102.

Funding

A recent Organization for Economic Cooperation and Development (OECD) study found that, in OECD countries, funding for "pandemic preparedness was generally insufficient, particularly in light of the major human and financial costs associated with global health crises similar to the COVID-19 pandemic."

This finding is not new; to address this, the US needs a bipartisan, comprehensive, and sustained effort around pandemic preparedness, and a comprehensive, unified biodefense budget. Adequate USG funding for pandemic preparedness is critically important to: 1) research and develop new treatments and countermeasures, 2) maintain and exercise sufficient manufacturing capacity, and 3) ensure the integrity of the supply chain, including appropriately managing the Strategic National Stockpile (SNS). Additionally, Congress should provide direction to ASPR/BARDA on the allocation of funds to quickly bring in contracting staff from other federal agencies or implement other near-term solutions to expedite contract reviews.

Overall funding for preparedness and response follows a cycle of panic and neglect, where funds are appropriated during emergencies, but not continued once the crisis abates. As a result, capabilities gained and lessons learned are often lost, resulting in the need for more emergency spending when the next crisis arises. The Mpox response highlighted the importance of maintaining and replenishing the SNS. The SNS allowed much of its smallpox vaccine stockpile to expire without any plan to replenish. The SNS has been chronically underfunded, and to be prepared for all potential threats, the US needs the SNS to have the capabilities for which it was designed, stockpile new countermeasures, maintain the products already stockpiled, and replenish expiring product.

Streamlining Federal Agency Roles and Industry Coordination

The Administration for Strategic Preparedness and Response (ASPR), within the Department of Health and Human Services (HHS), is statutorily tasked with leading the MCM enterprise. Since the ASPR is intended to be the leader of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), other relevant agencies should work in collaboration and coordination with the ASPR. However, the role currently lacks the gravitas and authority to

direct the actions of the PHEMCE. Coordinating directives under a single, top-down source would eliminate confusion and streamline future response processes.

The PHEMCE, which provides input on SNS stockpiling decisions among many other roles, would also greatly benefit from further assessment and reform, including: 1) Increasing Congressional access to the threat assessments. These threat assessments drive PHEMCE's medical countermeasure requirements and decisions; 2) Creating an advisory committee. This advisory committee should incorporate PHEMCE's private sector and non-federal partners and stakeholders, among other public-private partnership coordination improvements; 3) Clearly defining PHEMCE's function. Clearly identifying the function under ASPR or another centralized power structure would aid in its ability to be successful.

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The PHEMCE should include a balance of external partners to ensure there is expertise to address a variety of threats and support a holistic view of national preparedness. Additionally, PHEMCE's strategic planning and decision-making around stockpile needs, requirements, and interactions with other government agencies and the communication of such decisions should be made in concert with the advisory committee, and consider industry partner perspectives, to ensure the capability and capacity to manufacture MCMs is retained. The decisions made by PHEMCE should be communicated to Congress within 120 days.

Workforce

Government and industry need to invest in jobs and training to prepare for the next pandemic. Sustainable preparedness requires investment in the people that power the public health and manufacturing sectors. Industry needs a qualified manufacturing workforce now and "bench strength" to meet surge requirements during a future PHE. The Senate Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) seeks to revitalize the public health workforce by allowing the HHS Secretary to directly appoint new individuals to preparedness and response positions within HHS. Congress should also include additional funding for this initiative for it to be successful. HHS should also collaborate with industry to help determine which federal and state workforce needs are more critical.

Office of Global Affairs

The Office of Global Affairs (OGA) is the diplomatic voice of the U.S. Department of Health and Human Services. The OGA global strategy includes mitigating the impact of infectious diseases and preparedness to respond to public health emergencies. However, it should be expanded, and more emphasis should be placed on creating an international market for domestically produced medical countermeasures to support the goals outlined in the Global Strategy. Facilitating a broader market for medical countermeasures will provide more incentive for medical countermeasure manufacturing, will support domestic investment made to expand the industrial base during the COVID pandemic, and provide the United States the opportunity to retain its global competitive advantage in vaccine and therapeutic development. The OGA should develop policy frameworks, agreements, and operational plans to facilitate HHS decision-making in response to both single and multiple international requests for emergency assistance, including for the deployment of medical countermeasures and medical or public health personnel.

Oversight

Regular visibility into the threat assessment process would assist Congress in better evaluating appropriate levels of funding to ensure the PHEMCE fulfills its statutory requirements, and Congress would be better able to perform its oversight role with an improved understanding of all biological threats, whether naturally occurring, deliberate, or accidental. As noted in a recent Government Accountability Office (GAO) Report, the "SNS contained most medical countermeasure types recommended, but often not in the recommended quantities." Thus, Congress should consider appropriate actions going forward to ensure the HHS Secretary, in consultation with PHEMCE, submits this annual threat-based review, as required by statute, and that it is aligned to the funding requested.

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ASPR and BARDA must also engage directly with OMB and Congress on their annual budgeting process and align on funding realities. ASPR Dawn O'Connell noted in her recent blog post that the "SNS has been chronically underfunded and unable to purchase all of the countermeasures in the quantities recommended by the PHEMCE." Lastly, continued reporting from ASPR on the use of both yearly and supplemental funding and its intended goals is needed.

Equity

Congress should consider requiring the CDC, in coordination with HHS, to collect and distribute data on racial and ethnic health disparities related to Public Health Emergencies (PHE) and localized outbreaks of emerging infectious diseases (EIDs). Congress should ensure that the comprehensive racial data on cases, hospitalizations and fatalities collected is then shared with the public.

Food and Drug Administration (FDA) MCM Initiatives

The MCM Priority Review Voucher program should continue - Congress could either eliminate the sunset of the program, or extend the sunset of the program. The current program, which will expire on October 1, 2023, is an important incentive for the pharmaceutical industry to address the need for medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) threats. A recent Congressional Budget Office (CBO) report cites estimates of average company research and development expenditures for a new medicine at more than $2 billion. Because there is no commercial market for MCMs, MCM development is particularly risky, as well as time-consuming and costly for companies. That is why there are only a very small number of companies in the private sector engaged in MCM development. The current sunset, October 1, 2023, for the PRV program creates a disincentive for companies to develop countermeasures for these threats, leaving the American people more vulnerable to a biological attack.

Congress should also consider narrowly expanding the scope of the MCM PRV to include Department of Defense (DoD)- identified CBRN threats to the Warfighter. An expanded program would better align the incentive with CBRN threats that are unique to the Warfighter/DoD. Extending and enhancing this powerful market incentive for companies will encourage much needed investment in CBRN medical countermeasure research and development to address all security threats.