

# Alliance for Biosecurity

The Honorable Bernie Sanders  
Chairman  
Senate Committee on Health, Education,  
Labor, and Pensions  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Bill Cassidy  
Ranking Member  
Senate Committee on Health, Education,  
Labor, and Pensions  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Bob Casey  
Member  
Senate Committee on Health, Education,  
Labor, and Pensions  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Mitt Romney  
Member  
Senate Committee on Health, Education,  
Labor, and Pensions  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

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

The Alliance for Biosecurity (Alliance) appreciates the opportunity to submit comments in response to your request for information on policies the Committee should consider during the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

The Alliance is a coalition of biopharmaceutical companies and laboratory/academic partners that promotes a strong public-private partnership to ensure medical countermeasures (MCMs) are available to protect public health and enhance national health security. The Alliance advocates for public policies and funding to support the rapid development, production, stockpiling, and distribution of critically needed MCMs.

Please find below the Alliance's comments for your consideration. We thank you for your ongoing leadership and work to improve the nation's public health infrastructure and medical preparedness and response programs and capabilities, and we look forward to continuing to work with you and stand ready to serve as a resource however we can as the Committee moves forward with PAHPA reauthorization.

Sincerely,



The Honorable Jack Kingston  
Squire Patton Boggs  
Secretariat, Alliance for Biosecurity

### Program Effectiveness

*What specific changes could Congress make to improve the efficiency and effectiveness of current HHS programs and activities? Specifically:*

*Public Health Emergency Coordination and Policy*

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

The Alliance is supportive of the consolidation of decision-making, planning, procurement, and life cycle management of medical countermeasures (MCMs) within the Administration for Preparedness and Response (ASPR). This consolidation has resulted in greater efficiencies and supports efforts to ensure appropriate funding of the stockpiling, replenishment, and addition of new products to the Strategic National Stockpile (SNS).

#### A. Sustained and Sufficient Funding

As evidenced by the newly released Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget, our national security requires a significant investment in preparedness and response capabilities, including increased support for advanced research and development, pandemic influenza preparedness, and the Project BioShield Special Reserve Fund, a more robust SNS, and other critical biopreparedness and biosecurity initiatives. Of particular interest to the Alliance as a group of ASPR's private sector partners, it is important that ASPR/BARDA have sufficient resources (*i.e.*, adequate contracting staff) to undertake expedited contract reviews. Without sufficient contracting staff and systems in place, there will likely be a delay in issuing contracts needed for rapid development of MCMs necessary to keep American safe during a public health crisis.

To that end – and while the Alliance appreciates that Congress must make funding allocations based on a finite number of resources – to ensure minimum adequate funding, authorization levels should take into consideration the FY 2024 funding levels in the PHEMCE Multiyear Budget Report (FY 2022-2026). We would also encourage out-year inflationary and program increases based on technical advice from the program officials to ensure authorizations levels are adequate to support the MCM enterprise.

#### B. Annual Threats-Based Review and Requirement Setting Process

Additionally, while ASPR is currently required to provide an annual threats-based review of the SNS, the Alliance believes there should be more transparency surrounding the requirement-setting process to allow for more congressional oversight and private sector planning. Regular visibility would not only assist Congress in better evaluating funding levels based on identified threats – whether naturally occurring, deliberate, or accidental – but it would also ensure Congress can perform its oversight role with an improved understanding of these threats.

Specifically, the Alliance recommends mandating that: (1) PHEMCE engage in a formal requirement-setting process for all material threat determinations that is based on the most up-to-date assessment of risks to the U.S. public and to national security and is not influenced by budgetary decisions; (2) requirements are periodically updated on a scheduled basis (*i.e.*, every three years, or within six months if informed by U.S. Government intelligence sources of a

material change to the threat landscape); (3) requirements are shared with the congressional committees of jurisdiction; and (4) requirements are shared with private sector partners in a manner that does not compromise national security.

### *Medical Countermeasures Development and Deployment*

#### *1. The Strategic National Stockpile (SNS)*

The SNS is the nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. Unfortunately, the COVID-19 pandemic put a significant strain on the SNS, forcing the federal government to tap into these critical reserves. This serves to underscore that further support – including significant and consistent funding – for the SNS would benefit our preparedness and response capabilities during future public health emergencies. For example, the Alliance has previously expressed support for legislation intended to “streamline the response to the current pandemic and pave the way for more efficiency in the future,” offering additional flexibility and resources to the SNS – including providing incentives to manufacturers to work with the federal government to stock the SNS.

Additionally, the Alliance believes that additional oversight of the SNS is necessary to ensure that procurement, maintenance, and replenishment activities are sufficient. To that end, as noted above, the Alliance suggests that Congress be provided with more visibility into the threat assessment process so that it can ensure the annual threat-based review is aligned with the requested funding levels.

To ensure the best use of taxpayer dollars, the Alliance recommends the prioritization of chemical, biological, radiological, and nuclear (CBRN) MCMs, as they have no commercial market and the U.S. Government is the only purchaser.

#### *2. The Biomedical Advanced Research and Development Authority (BARDA)*

The Biomedical Advanced Research and Development Authority (BARDA) plays a critical role in partnering with biopharmaceutical companies to support advanced research and development of lifesaving MCMs. BARDA's pipeline currently includes over 200 candidate MCMs, such as broad-spectrum antimicrobials, rapid diagnostics, and next-generation products to address CBRN threats. A lack of adequate support for BARDA's programs risks squandering resources invested in the earlier stages of research and decreases the nation's level of preparedness to protect our citizens, thus significant and consistent funding is needed.

#### *3. Project BioShield*

Project BioShield was established to allow HHS to conduct and support research, development, and procurement activities for MCMs “to treat, identify, or prevent harm from any CBRN agent that may cause a public health emergency affecting national security.” The program effectively creates a guaranteed market incentive for pharmaceutical companies to produce CBRN MCMs for which there is no commercial market, such as those against anthrax, smallpox, botulinum toxin, etc. To that end, the Alliance believes it is important that a distinction be made between the approach to stockpiling these bespoke MCMs and those off-the-shelf MCMs for which there is a commercial market.

When Project BioShield was enacted in 2004, Congress provided a 10-year advanced appropriation of \$5.6 billion to create a guaranteed market for the procurement of these critical MCMs and encourage private sector investment in MCM research and development where no commercial market exists. For example, the U.S. Government is the only significant purchaser of vaccines and treatments to protect Americans against anthrax or smallpox. This advanced appropriation expired in 2013. The 2013 and 2018 PAHPA reauthorizations did not provide an advanced appropriation, but rather extended the authorization – most recently, for another ten-year period. Since then, Congress has continued to fund Project BioShield on an annual basis. PAHPA reauthorization is an opportunity to reauthorize and increase the funding authorization and reconsider the original advanced appropriation construct – including extending Project BioShield’s authorization for another five years to mirror the original ten-year authorization.

4. *The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and related strategy, implementation plan, and budget plan*

The Alliance believes that effective public-private partnerships are the best way to support our nation’s preparedness and response capabilities, as private sector partners are the sole developers of critical MCMs such as diagnostics, therapeutics, and vaccines which have no commercial market. Congress should clearly define the PHEMCE’s function under ASPR or another centralized power structure. This would enable the PHEMCE to deliver on its mission to advance preparedness and effectively provide MCMs in a sustainable manner.

Indeed, a November 2021 National Academies of Sciences, Engineering, and Medicine (NASEM) report titled *Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise* detailed four priority areas for improvement of the MCM enterprise, one of which was collaborating more effectively with external public and private partners.

In line with these recommendations, the Alliance believes that PHEMCE should establish an advisory committee incorporating private sector and non-federal partners and stakeholders to enhance transparency and communication, identify and close gaps, and build collaborative solutions. This advisory committee should include a balance of external partners to ensure the expertise of a variety of threats are addressed and considered for the holistic preparedness of the country.

Additionally, the Alliance believes that PHEMCE’s strategic planning and decision-making around stockpile needs and requirements should be more transparent, current, and based on up-to-date risk assessments, and made in concert with this advisory committee, as this will help ensure the capability and capacity to manufacture MCMs is retained. To that end, it would be helpful to clearly identify and streamline PHEMCE’s functions and processes going forward, especially as they relate to its coordination with private sector partners.

The traditional budget formulation process for the annual President's Budget often makes political tradeoffs that may result in agencies like ASPR requesting less funding for biosecurity preparedness than is required to protect the country from pandemics or intentional health security threats. The Alliance recommends codifying a process wherein ASPR submits the required Countermeasure Budget Plan based on its professional judgment without modification from the Office of Management and Budget to ensure actual needs are reflected in the submission. This

will provide the insight and transparency needed for Congress to understand the actual resource requirements for our biodefense enterprise.

#### *5. The Material Threat Medical Countermeasures Priority Review Voucher Program*

The Alliance suggests eliminating the statutory sunset or, at a minimum, extending the MCM Priority Review Voucher (PRV) Program, which is expected to sunset on October 1, 2023. The MCM PRV Program promotes innovation and efficiency in the development of new MCMs and is essential for future MCM development for which there is no commercial market. Allowing this important program to sunset creates a disincentive for companies to develop these critical CBRN MCMs, as it can take most drugs and vaccines up to 10-15 years from early-stage development to FDA approval.

#### Gaps in Current Activities & Capabilities

- 1. What gaps do you see in the PAHPA framework, or how it has been implemented to date? (These gaps could be related to any of the programs noted above, or other aspects of the public health and medical preparedness and response ecosystem that are otherwise currently unaddressed.)*

#### Pandemic Influenza

The Alliance is mindful of the importance of addressing an ongoing public health threat facing our nation: pandemic influenza. While pandemic influenza has been identified as a top national security threat by the U.S. government, there remain unaddressed challenges facing the domestic influenza vaccine enterprise. One way to address these challenges is through strong and consistent federal funding to support the development and manufacturing of influenza vaccines, therapeutics, and diagnostics, as there is no commercial market for many of these products. Supporting these pandemic influenza activities will go a long way to ensuring that we are better prepared and able to respond to future influenza outbreaks.

- 2. Additionally, aside from currently authorized programs and activities, what gaps exist in HHS' capabilities, and what types of activities or authorities are necessary for HHS to fulfill the intent of PAHPA and related laws?*

#### Emerging Infectious Diseases

With emerging infectious diseases (EIDs) continuing to emerge at a rapid rate, the Alliance believes ASPR should regularly evaluate the EID landscape and generate a robust research and development pipeline of MCM candidates to be stockpiled and deployed during an EID emergency.

#### Partnerships

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

- 1. How can these entities be better supported in appropriately engaging with the federal government to understand available resources, capabilities, and expectations prior to, during, and following a public health emergency?*

#### ASPR Engagement with Private Sector Partners

The Alliance believes it would be beneficial to explore ways to encourage ASPR, along with BARDA and SNS, to engage more frequently with private sector partners in the Broad Agency Announcement process to speed the development of new MCMs and stockpiling of existing MCMs against CBRN threats.

Furthermore, to improve transparency with private sector-partners, the Alliance recommends requiring the ASPR to conduct an annual meeting with each private sector partner with an existing countermeasures contract to discuss additions, modifications, and replenishments of all countermeasures, consistent with the requirements above.

#### PHEMCE Advisory Committee

As noted above, the Alliance believes that PHEMCE should establish an advisory committee in accordance with NASEM's 2021 recommendations that would incorporate private sector and non-federal partners and stakeholders to enhance transparency and communication, identify and close gaps, and build collaborative solutions. This advisory committee should include a balance of external partners to ensure the expertise of a variety of threats are addressed and considered for the holistic preparedness of the country.