Alliance for Biosecurity

The Honorable Richard Hudson
Member of Congress
9th Congressional District of North Carolina
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Member of Congress
16th Congressional District of California
272 Cannon House Office Building
Washington, DC 20515

Dear Congressman Hudson and Congresswoman Eshoo:

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

1. Suggestions on how to reauthorize and revise existing PAHPA programs.

- **Assistant Secretary for Preparedness and Response**

The Alliance is supportive of the consolidation of decision-making, planning, procurement, and life cycle management of MCMs within the Assistant Secretary 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).

Nevertheless, the Alliance believe that we must make a significant investment now in America's 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 Public Health Emergency Medical Countermeasures Enterprise (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.

The Alliance also 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 chemical, biological, radiological, and nuclear (CBRN) threats.

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.

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.

- **Public Health Emergency Medical Countermeasures Enterprises**

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.

- **Strategic National Stockpile**

As you are aware, one critical preparedness tool is the ability of the Secretary of Health and Human Services (HHS) to declare public health emergencies and maintain the SNS – 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, 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 CBRN MCMs, as they have no commercial market and the U.S. Government is the only purchaser.

- **Biomedical Advanced Research and Development Authority**

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.

Furthermore, with emerging infectious diseases (EIDs) continuing to emerge at a rapid rate it, 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.

- **BioShield Special Reserve Fund**

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 of funding over a five-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.

- **Medical Countermeasure Budget Plan**

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.

2. Additional policy suggestions

<u>Pandemic Influenza</u>

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.

<u>MCM Priority Review Voucher Program</u>

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.

<u>Domestic Manufacturing Requirements</u>

The Alliance appreciates ongoing efforts to increase U.S. manufacturing of “essential drugs,” MCMs, and other medical supplies. However, the Alliance is concerned about the impact that an approach requiring solely domestic manufacturing for specialized MCMs might have on U.S. preparedness and innovation. Such an approach would have an outsized impact on smaller biotech companies. For example, one Alliance member has expressed concerns about they would

face in establishing a domestic manufacturing and supply chain for a certain antibiotic, which is formulated into its final drug product. Currently, the company does not have the capacity to produce the antibiotic, nor can the antibiotic be sourced in the United States. This threatens to limit innovation in the antibiotics space, which is currently being driven by small biotech companies, and puts potentially devastating constraints on U.S. preparedness efforts.

Without the domestic capacity, there are in some instances no viable options for product developers to make this change. As such, we request that as the Committee considers how to best move forward with expanding manufacturing infrastructure and capacity in the United States, it provide sufficient flexibility for specialized MCMs. Moreover, the Committee should consider providing an exemption process specifically for MCMs to be developed and implemented by ASPR/BARDA that considers various factors, including whether: (1) the MCM is produced in the United States and there are reasonably available commercial quantities a satisfactory quality; (2) the cost of procurement would be significantly increased; and (3) the amount of the MCM held in the SNS is sufficient. Additionally, the Committee should provide financial assistance/incentives for companies to transition their manufacturing capacity to the United States, such as the reestablishment of tax incentives that spur domestic manufacturing and plant construction and avoid unintended consequences including significant costs to U.S. taxpayers.

Intellectual Property

Finally, the Alliance hopes policymakers will use this opportunity to focus on removing trade barriers and shoring up global supply chains to safely and efficiently speed up MCM manufacturing and distribution. However, as the Committee contemplates how best to do so, the Alliance urges that you consider the importance of protecting American intellectual property to avoid putting at risk the public-private partnerships that are critical to the success of the MCM enterprise.

3. Top three priorities (in no particular order):

- Provide authorizations consistent with the fiscal year funding levels provided in the current PHEMCE Multiyear Budget Report.
- Establish a PHEMCE Advisory Committee.
- Ensure that PHEMCE's strategic planning and decision-making around stockpile needs and requirements is more transparent, current and based on up-to-date risk assessments, and made in concert with the PHEMCE Advisory Committee.