The Honorable Patty Murray
Chair
Senate Committee on Health, Education, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510

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

Dear Chair Murray and Ranking Member Burr:

The Alliance for Biosecurity (Alliance) appreciates the opportunity to work with you and the Senate Health, Education, Labor, and Pensions Committee as you work to develop bipartisan legislation to consider lessons learned during the COVID-19 response to improve the nation's public health infrastructure and medical preparedness and response programs and capabilities.

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.

Below please find the Alliance's recommendations in response to those areas of interest that were included in your announcement of this forthcoming legislation earlier this year:

- **Strategies for strengthening and modernizing federal public health and medical preparedness and response systems and programs, including infrastructure, to better support states, localities, and Tribes**

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 SNS. The Biomedical Advanced Research and Development Authority (BARDA) – which sits within ASPR – provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health emergencies. While the Alliance is supportive of close coordination between the Department of Health and Human Services (HHS) and the Federal Emergency Management Agency (FEMA) – as well as other relevant agencies, such as the Centers for Disease Control (CDC), National Institutes of Health (NIH), and Food and Drug Administration (FDA) – we believe the Committee should ensure that

any coordinated processes be designed so as not to impede HHS/ASPR's role in overseeing the SNS, as they are the federal entities that possess the requisite expertise with respect to public health and medical care and supplies.

The Committee should also ensure 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 the current and any future public health crises.

The Alliance also believes that public-private partnerships for the development and availability of MCMs are a core element of global health security and contribute significantly to preparedness and response capabilities against a variety of chemical, biological, radiological, and nuclear (CBRN) threats, as well as naturally occurring threats such as pandemic influenza and various other emerging infectious diseases (EIDs). As such, it is important that the Committee continue to recognize that these partnerships support the essential mission of the SNS in ensuring the availability of needed MCMs during times of crisis and leverage them to create excess supply of MCMs so that we are positioned to appropriately respond to future pandemics.

We are also supportive of the proposal included in the *American Jobs Plan*, which would invest $30 billion over four years to better protect Americans from future pandemics. As we have seen over the past two decades, outbreaks of SARS, Ebola, influenza, Zika, and others have had a devastating impact on America's physical and economic health. In addition to naturally occurring threats, rapid advances in biological sciences have increased the chance that biotechnology could be used to create novel pathogens to potentially start future epidemics or pandemics. As such, in order to protect America from the next public health crisis, it is imperative that we make a significant investment now in America's preparedness and response capabilities, including increased support for advanced research and development, pandemic influenza preparedness, and Project BioShield Special Reserve Fund (SRF); specific funding for EIDs; a more robust SNS; and other critical biopreparedness and biosecurity initiatives.[1]

- **Strengthening readiness within the medical countermeasure enterprise to ensure that countermeasures can be rapidly identified and advanced through clinical development and manufacturing and appropriately deployed and distributed when a new public health threat is identified**

The CBRN threat is real and growing. It is critical that the country continue ongoing efforts to develop, procure, and stockpile MCMs to both deter an attack and protect our citizens against EIDs and bioterrorism. There is a limited commercial market for MCMs; consequently, without advanced development and stockpile funding, companies have neither the incentive nor the ability to invest in these life-saving therapies. The Alliance urges the Committee to continue to

[1] Attached are the Alliance's FY22 Appropriations Requests, which outline specific funding levels we believe should be considered the minimum to support the MCM enterprise.

pursue public-private partnerships that provide incentives and support for the manufacturing of these critical MCMs.

Moreover, as you are aware, one critical preparedness tool is the ability of the HHS Secretary to declare public health emergencies and to 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 for the SNS would benefit our preparedness and response capabilities during future public health emergencies. 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, such as by: (1) allowing the SNS to accept gifts from companies and individuals during a public health emergency; (2) permitting the SNS to sell existing products when they are no longer needed, thus reducing waste and ensuring that the SNS has sufficient financial resources; and (3) allowing for public-private partnerships to maintain and strengthen the SNS, including by providing incentives to manufacturers to work with the federal government to stock the SNS.

Additionally, as Congress prepares to move forward with the FY 2022 budget and appropriations process, it is important to underscore the need for strong support and consistent funding of those programs that are critical to advancing America's preparedness and response efforts, including BARDA, Project BioShield SRF, and SNS, among others. While the Alliance appreciates that Congress must make funding allocations based on a finite amount of resources, we believe that funding allocations for America's biopreparedness and biosecurity initiatives be made based upon the multi-year budget established by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which coordinates federal efforts to enhance CBRN and EID preparedness from a MCM perspective. Current funding levels for these initiatives have traditionally been significantly underfunded by Congress based upon PHEMCE's professional judgement. Furthermore, it is important – and unfortunate – to point out that ASPR currently has no dedicated funding to address EIDs, so MCMs are often not available for immediate response when an EID outbreak occurs. As such, the Alliance urges the Committee to consider creating a separate EID budget line item that would allow the ASPR to regularly evaluate the EID landscape.

Note, too, even the PHEMCE multi-year budget is unable to contemplate all of the potential public health threats that America might face. For example, the current PHEMCE multi-year plan did not contemplate COVID-19 and the associated costs to procure necessary diagnostics, therapeutics, vaccines, and additional MCMs. With regard to diagnostics, specifically, the Alliance appreciates that diagnostic tests are a critical part of the MCM enterprise and are used to inform the appropriate use of MCMs following a CBRN incident. As such, the Alliance believes that fully supporting and implementing PHEMCE's implementation plan with respect to

diagnostics is the best way to ensure we are prepared to address diagnostic needs when the next pandemic arises.

The Alliance also notes that infections caused by drug resistant pathogens are far more difficult and costlier to treat. According to the CDC Antibiotic Resistance Threats in the United States Report, more than 2.8 million antibiotic-resistant infections occur in the United States each year, and at least 35,000 people die as a result. Moreover, as you likely are aware, drug resistant pathogens are also a prime candidate for weaponization by our nation's enemies, both state and non-state actors. Unfortunately, due to market failures in our healthcare system, many of innovative antibiotic companies have stopped producing their critical drugs. It is for this reason that the Alliance believes that there is an urgent need for the Committee to take steps to reinvigorate the antimicrobial pipeline. Consistent with the March 2015 U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria, the Alliance supports an accelerated, coordinated, full government response to antibiotic resistance that increases and incents development of innovative antimicrobial drugs to treat resistant infections. One way to do this is to establish a subscription-style model that provides antibiotic developers an upfront payment in exchange for access to their antibiotics. Another idea is to allow Medicare to provide an add-on payment to qualified inpatient hospitals that use specific antibiotics to treat infections.

Finally, the Alliance urges the Committee to consider ways to address another 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 key way to address these challenges is through strong federal funding, at the level provided in the PHEMCE multi-year budget, 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 to ensuring that we are better prepared and able to respond to future influenza outbreaks.

- **Modernizing the development of medical countermeasures to address public health threats**

Efforts to restock and revamp the SNS must take into account the unique considerations associated with those MCMs for which the SNS is *the* repository. As you know, 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 urges that a distinction made between the approach to stockpiling these bespoke MCMs and those off-the-shelf MCMs for which there is a commercial market.

- **Improving and securing the supply chain for the U.S.'s critical medical supplies needed to swiftly address public health threats**

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.

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.

In conclusion, the Alliance very much appreciates your interest in improving the nation's public health infrastructure and medical preparedness and response programs and capabilities. We look forward to working with you as the Committee develops this important legislation and stand ready to serve as a resource however we can.

Alliance for Biosecurity

Sincerely,

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