



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

Dear Chairman Alexander:

The Alliance for Biosecurity (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.

The Alliance appreciates the opportunity to submit comments in response to your “Preparing for the Next Pandemic: A White Paper” (White Paper). The Alliance agrees that it is imperative that Congress act on needed changes this year in order to better prepare for the next pandemic, and submits the following comments in response to select questions posed in the White Paper for which the Alliance is uniquely positioned to respond.

### **1. Tests, Treatments, and Vaccines – Accelerate Research and Development**

*RECOMMENDATION 1.1: Congress and the administration should identify and implement public-private manufacturing models to improve and maintain sustainable domestic vaccine manufacturing capacity and capabilities. One approach has been the advanced development manufacturing program.*

The chemical, biological, radiological, and nuclear (CBRN) threat is real and growing. It is critical that the country continue ongoing efforts to develop, procure, and stockpile medical countermeasures (MCMs) to both deter an attack and protect our citizens against emerging infectious disease (EID) 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. Generally, the Alliance is supportive of public-private partnerships that provide incentives and support for the manufacturing of these critical MCMs.

*RECOMMENDATION 1.4: Engage and partner with the private sector early to develop diagnostic tests, ensure flexibility to develop and use laboratory-developed tests in a public health emergency, and ensure that the stockpile is better prepared to address diagnostic needs.*

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 noted in the White Paper, the diagnostics



developed for CBRN threats are guided by the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) implementation plan. Given PHEMCE's charge with coordinating Federal efforts to enhance CBRN and EID preparedness from a MCM perspective, 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.

### **3. Stockpiles, Distribution, and Surges – Rebuild and Maintain Federal and State Stockpiles and Improve Medical Supply Surge Capacity and Distribution**

*RECOMMENDATION 3.1: Utilize existing authorities to build public-private partnerships, such as vendor managed inventory contracts with manufacturers and distributors, to create excess medical supplies managed by private sector partners that could be needed for the next pandemic or public health emergency. Additionally, the Strategic National Stockpile could contract with manufacturers to maintain manufacturing capability for certain products, such as N95 masks or other personal protective equipment, to rapidly manufacture supplies needed for a future pandemic.*

The Alliance believes that public-private partnerships for the development and availability of MCMs are a core element of global health security. Alliance member companies contribute significantly to preparedness and response capabilities against a variety of CBRN threats, as well as naturally occurring threats such as pandemic influenza and various other EIDs. By leveraging our collective knowledge and expertise, the Alliance is committed to building and strengthening these critical partnerships between government and the biopharmaceutical industry, and to help identify and provide solutions to the threats facing our nation. These partnerships support the essential mission of the SNS in ensuring the availability of needed MCMs during times of crisis, and should be leveraged in creating excess supply of MCMs so that we are positioned to appropriately respond to future pandemics.

*RECOMMENDATION 3.3: Require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished, both at the federal and state level. Additionally, stockpiled supplies and countermeasures should more frequently and consistently utilize the shelf-life extension program to extend the life of a product in reserve or better identify the expiration of such products and plan to use those products before expiration.*

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. Its role in supplementing state and local supplies during such public health emergencies cannot be overstated. The Alliance supports efforts to restock and revamp the SNS, and to improve SNS inventory management and distribution.

However, efforts to restock and revamp the SNS must take into account the unique considerations associated with those countermeasures 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 biological, chemical, radiological or nuclear (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. The Alliance urges 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.

*RECOMMENDATION 3.5: Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.*

See response to Recommendation 3.3.

*RECOMMENDATION 3.6: Better leverage the support provided by FEMA and their emergency management experience and assets by improving a coordinated process between HHS and FEMA to more rapidly distribute supplies to states, health care providers, and other entities on the front lines, while utilizing HHS expertise with respect to public health and medical care and medical supplies.*

The Alliance is supportive of the recent 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 also believe that any “coordinated processes” should be designed so as not to impede HHS/ASPR’s role in overseeing the SNS. HHS/ASPR are the federal entities that possess the requisite expertise with respect to public health and medical care and supplies.

#### **4. Public Health Capabilities – Improve State and Local Capacity to Respond**

Future health and economic security can best be achieved by a sustainable funding for programs, projects, and activities that are critical to preventing, detecting, and responding to infectious disease threats. The Alliance encourages Congress to create a Health Defense Operations (HDO) budget designation that would permanently exempt critical health programs, projects, and activities at agencies like BARDA,



CDC, and NIH from the Budget Control Act and 302(b) spending caps. Congress should decide the specific programs, projects, and activities exempted, and would have oversight and transparency as part of the annual discretionary appropriations process. To ensure Congressional appropriators have the best information on which to base decisions, we suggest that all programs excepted as part of an HDO designation be required to submit a professional judgment bypass budget to Congress. The NIH submits three bypass budgets to Congress every year that explain the true resource needs for cancer, HIV/AIDS and Alzheimer's research.

## **5. Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency**

*RECOMMENDATION 5.1: Congress must clarify who is in charge and has the ability and authority to keep a continued focus on preparedness for pandemics and other major public health threats when other priorities may seem more pressing, and improve how federal agencies will coordinate during a pandemic. These roles and responsibilities must also be clearly communicated to states and local governments so they can include this information in their own preparedness planning.*

See response to Recommendation 3.6.

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In conclusion, the Alliance very much appreciates your interest in, and support for, prudent policies that ensure we are able to efficiently and effectively respond to public health emergencies. Though beyond the scope of your White Paper, the Alliance recognizes that many of the key priorities discussed above have traditionally been underfunded when compared to the funding levels proposed in the PHEMCE multiyear budget. With finite resources available to deal with an ever-expanding set of issues, the Alliance believes that the funding levels proposed and validated by the PHEMCE – the entity charged with coordinating Federal efforts to enhance CBRN and EID preparedness from a MCM perspective – should be requested by the Administration and appropriated by Congress. As such, the Alliance has attached to these comments its FY 2021 appropriations requests, as we believe funding these programs appropriately is equally as important as developing policies to ensure that we are better prepared for the next pandemic.

We look forward to working with you to advance these critical priorities for our nation.

Sincerely,

A handwritten signature in black ink that reads "Jack Kingston".

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