

INFORMAL COALITION ON BIODEFENSE AND PUBLIC HEALTH PREPAREDNESS

March 18, 2015

The Honorable Roy Blunt
U.S. Senate
260 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Blunt,

On behalf of the undersigned organizations, who have joined together as an informal coalition on biosecurity and public health preparedness, we write today in support of funding for programs critical to the nation's preparedness against threats both naturally occurring - like Ebola and pandemic influenza - and deliberate, such as a chemical, biological, radiological, or nuclear (CBRN) event.

As witnessed by the recent Ebola outbreak, our nation's vulnerability to threats remains high, and the consequences of being unprepared are severe. Funding for the programs that protect Americans and the global community from health security threats must be robust and consistent. It is simply too late to respond after an outbreak or attack.

A strong public health infrastructure is essential to biodefense and public health preparedness and serves as our first line of defense. The Public Health Emergency Preparedness (PHEP) Cooperative Agreements program at the Centers for Disease Control and Prevention (CDC) is the only federal program that supports the work of health departments to prepare for and respond to all types of disasters, including bioterror attacks, natural disasters, and infectious disease outbreaks. Most recently, PHEP investments have enabled rapid local responses to emergencies such as MERS-CoV, Chikungunya, the West Virginia chemical spill, and the multi-state fungal meningitis outbreak. Robust Fiscal Year (FY) 2016 funding would help states and localities restore some of the core capabilities lost due to significant cuts to the program over the past decade.

Annual appropriations to the Hospital Preparedness Programs have been cut dramatically in recent years, leaving capability gaps in our healthcare system's ability to prevent, detect, and respond to infectious disease and other threats. The impact of cuts to this program was illustrated in 2014, as hospitals scrambled to prepare for an unfamiliar Ebola virus absent resources to train frontline staff. FY 2016 funds will help build enhanced system planning and response, increase integration of public and private sector medical planning and assets, and improve grantee infrastructure to help healthcare coalitions prepare for public health emergencies.

We also support robust funding for medical countermeasure (MCM) development and procurement through the Biomedical Advanced Research and Development Authority (BARDA) and the Project BioShield Special Reserve Fund (SRF). In 2004, Congress created the ten-year SRF to support MCM development and stockpiling. This funding has been integral to producing important medical countermeasures to protect the public and cultivating a development pipeline containing over 160 candidate products. However, those funds expired at the end of 2013 and

the continued development of these national security products, and new ones, is now dependent on the annual appropriations process and continued bipartisan and bicameral support for the medical countermeasure enterprise.

The current Ebola outbreak demonstrates the need to plan ahead, be constantly vigilant, and sustain research and development of vaccines and drugs for responding to disease threats including smallpox, anthrax, and pandemic influenza. A consistent, well-funded public-private partnership is our best hope for successfully developing these needed products for all populations.

In order to advance the core purposes of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA, P.L. 113-5), combat bioterrorism, and foster preparedness to protect our nation from man-made and natural disasters, the organizations signed below support the inclusion of the following funding levels in any final version of the FY 2016 Labor, Health and Human Services Appropriations bill:

- \$300 million for ASPR's Hospital Preparedness Program Grants for FY 2016. (*\$255 million was included in the President's Budget.*)
- \$675 million for CDC's Public Health Emergency Preparedness Grants for FY 2016. (*\$644 million was included in the President's Budget.*)
- \$763 million for the Special Reserve Fund for MCM procurement to remain available until expended. (\$255 million was appropriated in FY 2015. \$763 million is required each year for the next three fiscal years to achieve the \$2.8 billion over five years (FY 2014-2018) authorized in PAHPRA.) (*\$646 million was included in the President's Budget.*)
- \$522 million for the Biomedical Advanced Research Development Authority (BARDA) for advanced development for FY 2016. (*\$522 million was included in the President's Budget.*)
- \$571 million for the Strategic National Stockpile for FY 2016. (*\$571 million was included in the President's Budget.*)
- Robust funding for Pandemic Influenza for FY 2016. (*\$170 million was included in the President's Budget.*)

Thank you for consideration of these requests. If you should have any questions please contact any of the following individuals:

- Dara Lieberman, Trust for America's Health (202-864-5942, dlieberman@tfah.org)
- Rebecca McGrath, Alliance for Biosecurity (202-230-5679, rebecca.mcgrath@dbr.com)
- Tamar Magarik Haro, American Academy of Pediatrics (202-347-8600, tharo@aap.org)
- Tracey LaTurner, Biotechnology Industry Organization (202-962-6696 tlaturner@bio.org)

Signed,

*Alliance for Biosecurity
American Academy of Pediatrics
American College of Preventive Medicine*

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American Public Health Association

American Society for Microbiology

American Veterinary Medical Association

Association of State and Territorial Health Officials

Biotechnology Industry Organization

California Healthcare Institute

Infectious Diseases Society of America

International Association of Emergency Managers

National Association of County and City Health Officials

Save the Children

Trust for America's Health

UPMC Center for Health Security

INTRODUCTION:

The informal coalition on biodefense and public health preparedness is committed to the long term success of the US government's biodefense and public health preparedness enterprise. The involved stakeholders promote a sustainable enterprise by protecting and securing funding for key programs, which are essential to combat bioterrorism and to foster public health preparedness to protect our nation from deliberate and natural disasters.

BACKGROUND:

After the 2001 terrorist attacks, the US government began a dedicated effort to develop and stockpile drugs and vaccines needed to protect the American people from chemical, biological, radiological, and nuclear (CBRN) threats. The government has strategically invested in a diverse set of products to treat a range of pathogens and toxins identified as significant threats, including smallpox and anthrax, but numerous threats have not yet been addressed and our nation remains vulnerable to CBRN attacks and public health emergencies.

Comprehensive public health preparedness relies on the resourcing of myriad health-related programs. Many of these programs have been underfunded or faced declining allocations, resulting in a public health infrastructure that is not at a complete state of readiness. Biodefense, as a component of national health security, is a public health mission area that requires a sustained federal commitment. Key programs developed after 2001, such as the Biomedical Advanced Research and Development Authority (BARDA) and the BioShield Special Reserve Fund (SRF), remain critical to facilitating industry partnerships that will lead to the development of medical countermeasure (MCM) solutions.

FISCAL YEAR 2016 FUNDING REQUESTS:

In order to advance the core purposes of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA, P.L. 113-5), combat bioterrorism, and foster preparedness to protect our nation from man-made and natural disasters, the informal coalition supports the inclusion of the following funding levels in any final version of the Fiscal Year (FY) 2016 Labor, Health and Human Services, and Education Appropriations bill:

Special Reserve Fund (SRF) - \$763 M (\$646 M was included in President's Budget)

A public-private partnership to develop MCMs is required to successfully prepare and defend the nation against these threats. Recognizing that there is little or no commercial market for MCMs, and that such assets can take a decade to develop, Congress established the Project BioShield SRF to provide a visible commitment to the MCM enterprise and adequate long-term funding for the advanced development and procurement of MCMs. Those funds expired in 2013, leaving the

future of the medical countermeasure enterprise uncertain and subject to the annual appropriations process.

\$255 million was appropriated in both FY 2014 and FY 2015 for the SRF. \$763 million is required each year for the next three fiscal years to achieve the \$2.8 billion over five years (FY 2014-2018) authorized in PAHPRA.

CDC's Public Health Emergency Preparedness Cooperative Agreements (PHEP) - \$675 M (\$644 M was included in the President's Budget)

PHEP is the primary source of public health preparedness funding for state and local public health departments to maintain the capacity and capability to effectively respond to public health emergencies resulting from terrorist threats, infectious disease and foodborne outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies. PHEP grants support 15 core public health capabilities identified by CDC, including in the areas of public health laboratory testing, health surveillance and epidemiology, community resilience, countermeasures and mitigation, incident management, information management, and surge management. The grants fund nearly 4,000 state and local public health preparedness staff positions.

BARDA - \$522 M (\$522 M was included in President's Budget)

As a result of BARDA's support and the biopharmaceutical industry's efforts, more than 160 products are now in the advanced development pipeline. This is an impressive accomplishment in less than a decade. Even more importantly, several life-saving products have been procured by the US Government and placed into the Strategic National Stockpile (SNS) and are available to be used in the event of an emergency. The informal coalition supports the President's FY 2016 request for funding for BARDA.

Strategic National Stockpile (SNS) - \$571 M (\$571 M was included in the President's Budget)

Congress established the SNS at the Centers for Disease Control and Prevention (CDC) to provide a supply of large quantities of essential medicines and other medical supplies to states and communities during an emergency within 12 hours of the federal decision to deploy. The informal coalition supports the President's request for the SNS.

Pandemic Influenza – Robust funding (\$170 M was included in the President's Budget)

The Coalition also supports an increased investment in pandemic influenza preparedness to support advanced research and development, pre-pandemic rapid response and the replenishment of pre-pandemic vaccine stockpiles. *“Because the FY 2015 Enacted level for pandemic influenza is inadequate, BARDA will not be able to fund activities on newly-awarded stockpile contracts that are required to maintain the existing stockpile program critical for a swift and*

nimble pandemic response.” [FY2016](#) Public Health and Social Services Emergency Fund Congressional Justification (p.113-114).

Hospital Preparedness Program (HPP) Grants - \$300 M (\$255 M was included in President’s Budget)

The HPP, administered by the Assistant Secretary for Preparedness and Response (ASPR), was recently reauthorized by PAHPRA and provides funding to state and local health departments to build capabilities in the areas of health system preparedness, health system recovery, medical surge, emergency operations coordination, fatality management, information sharing, responder safety and health and volunteer management.

The impact of recent cuts to this program was illustrated in 2014, as hospitals scrambled to prepare for an unfamiliar Ebola virus without ongoing resources available to train frontline staff. Deploying emergency appropriations, HPP will implement a national strategy to prepare hospitals for Ebola through a network of treatment and assessment hospitals. However, a strong and steady baseline of preparedness would be better than waiting for a new threat to appear before ramping up our defenses. FY2016 funding will help build enhanced system planning and response, increased integration of public and private sector medical planning and assets, and improved grantee infrastructure to help healthcare coalitions prepare for public health emergencies.

FOR MORE INFORMATION, PLEASE CONTACT:

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