

INFORMAL COALITION ON BIODEFENSE AND PUBLIC HEALTH PREPAREDNESS

March 23, 2016

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

The Honorable Patty Murray
U.S. Senate
154 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Tom Cole
U.S. House of Representatives
2467 Rayburn Office Building
Washington, D.C. 20515

The Honorable Rosa DeLauro
U.S. House of Representatives
2413 Rayburn Office Building
Washington, D.C. 20515

Dear Senators Blunt and Murray and Representatives Cole and DeLauro,

On behalf of the undersigned organizations, who have joined together as an informal coalition on biodefense and public health preparedness, we write 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) attack.

As witnessed by the recent Ebola and Zika outbreaks, 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.

The organizations signed below support the inclusion of the following funding levels in any final version of the FY 2017 Labor, Health and Human Services and Education Appropriations bill:

- **\$675 million** for Centers for Disease Control and Prevention (CDC)'s **Public Health Emergency Preparedness Grants** to improve preparedness at public health departments. (*\$660 million was included in the President's Budget.*)
- **\$575 million** for CDC's **Strategic National Stockpile** for purchasing and distributing large quantities of essential FDA-approved medications and other medical supplies to states and communities during an emergency. (*\$575 million was included in the President's Budget.*)
- **\$300 million** for Assistant Secretary for Preparedness and Response (ASPR)'s **Hospital Preparedness Program** grants to improve preparedness among local healthcare coalitions. (*\$255 million was included in the President's Budget.*)
- **\$607 million** for ASPR's **Biomedical Advanced Research Development Authority (BARDA)** for advanced development of medical countermeasures (MCMs). (*\$512 million was included in the President's Budget.*)
- **\$560 million** for the ASPR's **Project BioShield Special Reserve Fund** for procurement of MCMs for emergency use. (*\$350 million was included in the President's Budget.*)

- **\$250 million** for ASPR's **Pandemic Influenza** program to enhance preparedness for pandemic flu. (*\$125 million was included in the President's Budget.*)

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)** program at the 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) 2017 funding would help states and localities restore some of the core capabilities lost due to significant cuts to the program over the past decade.

Strategic procurement and stockpiling of medical countermeasures (MCMs), medical supplies, and equipment for all populations are necessary to protect Americans' health and save lives during an emergency. If a CBRN event were to occur on U.S. soil tomorrow, the CDC's **Strategic National Stockpile (SNS)** is the only federal resource readily available to respond once state and local supplies are depleted. The SNS is the procurement mechanism for many FDA-approved MCMs, some of which have no commercial market, such as licensed vaccines and drugs against smallpox and anthrax. The SNS also holds supplies of biopharmaceutical products that are available commercially but only in limited quantities and stockpiling allows for rapid mass deployment during an emergency. The President's Budget included level funding for the SNS in FY 2017; however, the CDC notes in their Congressional Justification that at this level, they will not be able to replace all SNS countermeasures scheduled to expire in FY 2017 and therefore all current capabilities cannot be maintained.

Annual appropriations to the **Hospital Preparedness Program**, administered by the ASPR, have been cut dramatically in recent years, leaving capability gaps in our healthcare system's ability to prevent, detect, and respond to infectious diseases 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 2017 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.

The **Biomedical Advanced Research and Development Authority (BARDA)** plays a critical role in partnering with biopharmaceutical companies to support advanced research and development of life-saving MCMs. BARDA's pipeline currently includes over 200 candidate MCMs, such as broad-spectrum antimicrobials, rapid diagnostics, and next-generation products to address chemical, biological, radiological and nuclear threats. It typically requires 10 years and significant long-term financial investment to develop a new drug or vaccine, and MCMs are often riskier to develop than other products due to scientific and regulatory complexities. Funding for BARDA in FY 2017 will ensure continuity of funding for candidate MCMs currently in the pipeline; provide funding for new MCMs reaching the critical stages of preclinical and clinical development; and support products to address antimicrobial-resistant threats. As BARDA's mission has expanded over time, we believe there should be a commensurate increase in new funding for the program.

The **Project BioShield Special Reserve Fund (SRF)** represents the only market for many MCMs that are not yet approved by the FDA. Robust funding is needed in FY 2017 to purchase the MCMs needed to fill our preparedness gaps for CBRN threats, and demonstrate the U.S. government's commitment to this public-private partnership. Established by Congress in 2004, the SRF was originally funded through an appropriation of \$5.6 billion over 10 years, which successfully spurred the development and procurement of more than 50 million doses of vaccines and drugs against anthrax, smallpox, botulinum toxin, and radiological threats. However, those funds expired at the end of 2013 and the program is now dependent on the annual appropriations process. In FY 2014 and FY 2015, only \$255 million was appropriated for the SRF. While we were encouraged by the \$510 million provided by Congress in FY 2016, there remains a substantial shortfall of \$600 million to \$1 billion under the level authorized by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA, P.L. 113-5)—\$2.8 billion for FY 2014-2018.

Similarly, since the expiry of emergency supplemental funding, the ASPR's **Pandemic Influenza** program has been woefully underfunded, with \$115 million appropriated in FY 2014 and \$72 million in both FY 2015 and FY 2016. Influenza is a constantly evolving threat that circulates around the globe throughout each year. To ensure our nation can respond immediately to an influenza pandemic of today and to influenza pandemics of the future, this program must be appropriately funded so as to: (1) advance research and development of next-generation influenza technologies, (2) maintain and test critical domestic manufacturing infrastructure to support surge requirements for pandemic flu vaccines, and (3) replenish stockpiles and manage the lifecycle of influenza vaccines and antivirals to address current threats.

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

- Maureen Hardwick, Alliance for Biosecurity (202-230-5133, maureen.hardwick@dbi.com)
- Tamar Magarik Haro, American Academy of Pediatrics (202-347-8600, tharo@aap.org)
- Tracey LaTurner, Biotechnology Innovation Organization (202-962-6696, tlaturner@bio.org)
- Dara Lieberman, Trust for America's Health (202-864-5942, dlieberman@tfah.org)

Signed,

*Alliance for Biosecurity
American Academy of Pediatrics
American College of Preventive Medicine
American Society for Microbiology
American Veterinary Medical Association
American Public Health Association
Association of State & Territorial Health Officials
Trust for America's Health
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International Safety Equipment Association
National Association of County and City Health
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