

INFORMAL COALITION ON BIODEFENSE AND PUBLIC HEALTH PREPAREDNESS

April 10, 2018

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 Chairmen Blunt and Cole and Ranking Members Murray 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 Ebola and Zika outbreaks and major natural disasters in 2017, 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 fundamental job of the federal government is to secure the safety of its citizens at home and abroad. But America's day-to-day security requires more than military might. The recently adopted Bipartisan Budget Act of 2018 recognizes that defense and nondefense programs both contribute to the American way of life and to our security.

The organizations signed below support the robust funding for the following programs, which are key to the nation's health security, in any final version of the FY 2019 Labor, Health and Human Services and Education Appropriations bill:

- **At least \$824 million** for Centers for Disease Control and Prevention (CDC)'s **Public Health Emergency Preparedness Grants** to improve preparedness at state and local public health departments. (*\$660 million was included in the President's Budget.*)
- **At least \$610 million** for the **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.*)
- **At least \$474 million** for Assistant Secretary for Preparedness and Response (ASPR)'s **Hospital Preparedness Program** grants to improve preparedness of the healthcare

system. (*\$255 million was included in the President's Budget.*)

- **At least \$710 million** for ASPR's **Project BioShield Special Reserve Fund** for procurement of MCMs for emergency use. (*\$512 million was included in the President's Budget.*)
- **At least \$700 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.*)
- **At least \$632 million** ASPR's **Pandemic Influenza** program to enhance preparedness for pandemic flu. (*\$250 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 hurricanes in Florida, Texas, Puerto Rico, and the Virgin Islands, California wildfires, MERS-CoV, Zika, measles and other infectious diseases, and mass shootings. The response systems and infrastructure that states require to respond to these and other public health emergencies would not exist, in most instances, without PHEP funding. Robust Fiscal Year (FY) 2019 funding would allow states and localities to restore some of the core capabilities lost due to significant cuts to the program over the past decade.

Annual appropriations to the **Hospital Preparedness Program**, administered by the ASPR, have been cut in half in recent years, leaving capability gaps in our healthcare system's ability to prevent, detect, and respond to infectious diseases and other threats. ASPR supports coalitions and their members to develop preparedness and response capabilities in four key domains: foundation for healthcare and medical readiness; healthcare and medical response coordination; continuity of healthcare services delivery; and medical surge. 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. HPP ensures the healthcare system is prepared to save lives, continue operations, and reopen as soon as possible after an emergency. FY 2019 funds will help rebuild the program from years of underfunding.

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 **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 **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 2019 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

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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 \$511.7 million provided by Congress in FY 2017, there remains a substantial shortfall of \$1.27 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.

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. BARDA should receive consistent support for MCM advanced R&D plus additional funding for newer Antimicrobial Resistance investments; required to ensure preparedness and to prevent squandering resources invested the in earlier stages of research and development.

Similarly, since the expiration of emergency supplemental funding, the ASPR's **Pandemic Influenza** program has been woefully underfunded, with \$72 million in FY 2017. 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.

The President's FY 2019 Budget Request also proposes a federal emergency response fund. An emergency fund would be helpful to jumpstart the response to an emergency, including ~~initial~~ R&D and public health and healthcare response. However, an emergency fund *cannot* come at the expense of ongoing investments in preparedness as described above. A community's resilience in the face of a disaster depends greatly on the years of investment, training, planning, research and development in preparedness and response capacity of that community before disaster strikes, something an emergency response fund cannot provide. In addition, an emergency response fund does not preclude the need for supplemental funding in a future public health emergency. For example, the Zika response required \$1.1 billion in emergency supplemental funding from Congress. An emergency fund could therefore serve as a bridge between the initial response and a determination by Congress to appropriate additional emergency funding.

Should Congress move forward with an emergency response fund, we would urge that the following criteria be met: 1) Congress maintains stable, adequate funding for all preparedness programs; 2) the emergency response fund be sufficiently resourced to meet the immediate needs of the response; 3) the entire biodefense enterprise – including MCM development and public health response at the state and local level – is eligible for funding; and 4) appropriate oversight and clear parameters are in place to guide the federal agencies' use and allocation of the money.

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

Informal Coalition on Biodefense and Public Health Preparedness

- Meg Gilley, Alliance for Biosecurity (202-457-6148, meg.gilley@squirepb.com)
- Tamar Magarik Haro, American Academy of Pediatrics (202-347-8600, tharo@aap.org)
- Phyllis Arthur, Biotechnology Innovation Organization (202-962-6664, parthur@bio.org)
- Dara Lieberman, Trust for America's Health (202-864-5942, dlieberman@tfah.org)
- Laura Hanen, National Association of County and City Health Officials (202-507-4255, lhanen@naccho.org)

Signed,

AABB

Alliance for Biosecurity

American Academy of Pediatrics

American Clinical Laboratory Association

American Public Health Association

American Red Cross

America's Blood Centers

Association of State and Territorial Health Officials

Biotechnology Innovation Organization

California Life Sciences Association (CLSA)

Council of State and Territorial Epidemiologists

Healthcare Ready

Health Industry Distributors Association (HIDA)

Infectious Diseases Society of America

Johns Hopkins Center for Health Security

March of Dimes

National Association of County and City Health Officials

National Association of State Emergency Medical Services Officials

National Environmental Health Association

Save the Children

Trust for America's Health