

Alliance for Biosecurity



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The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear President Trump & All Members of Congress,

The member companies of the Alliance for Biosecurity commend the President's quick action in submitting its significant supplemental funding request and the quick bipartisan response by Congress by providing more than \$15 billion in disaster recovery aid for communities affected by the recent natural disasters.

The member companies of the Alliance for Biosecurity work every day to develop new vaccines and treatments to respond to an array of disease threats from global pandemics to deliberate biological attacks. To accomplish our mission and be prepared for the next health threat, it is critical to have a robust public-private partnership with the Federal Government and adequate, consistent resources for the Department of Health and Human Services (HHS).

In the wake of the recent natural disasters, we want to highlight a few of the critical programs within HHS that keep Americans safe in the event of a natural disaster or deliberate attacks on the homeland. It is critically important for these programs to receive adequate funding in the fall budget negotiations and any future supplemental appropriations to backfill transferred resources. These programs include:

- Office of the Assistant Secretary for Preparedness and Response (ASPR): ASPR was created in the wake of Hurricane Katrina to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters. ASPR focuses on preparedness planning and response; building federal emergency medical operational capabilities; countermeasures research, advance development, and procurement; and grants to strengthen the capabilities of hospitals and health care systems in public health emergencies and medical disasters. The office provides federal support, including medical professionals through ASPR's National Disaster Medical System, to augment state and local capabilities during an emergency or disaster.
- Biomedical Advanced Research and Development Authority (BARDA): BARDA plays a critical role in partnering with biopharmaceutical companies to support advanced research and development of life-saving Medical Counter Measures (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,

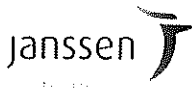
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radiological and nuclear (CBRN) threats. It typically requires 10 years and significant long-term financial investment to develop a new drug or vaccine, and MCMs are often riskier to develop than other products due to scientific and regulatory complexities.

- Pandemic Influenza:**
 Pandemic influenza is a threat that we know with certainty will strike again in the future. The development and manufacturing of influenza vaccines, therapeutics, and diagnostics by industry is dependent on Federal funding to support the scale and scope of USG requirements. There is no commercial market for these products. Increased investments are needed in order to adequately prepare through R&D for next generation flu products, testing and evaluation of existing products, and sustaining and replenishing stockpiles.
- Project BioShield Special Reserve Fund (SRF):** The SRF represents the only market for many MCMs that are not yet approved by the FDA. The SRF has been critical to our nation's biodefense for over a decade by advancing the development of more than 50 million doses of drugs against anthrax, smallpox, botulinum toxin and radiological threats. There is no commercial market for these products. Without robust, stable, and consistent funding to fill our preparedness gaps, this public-private partnership to create life-saving countermeasures against our nation's most pressing CBRN threats will be in jeopardy.
- Hospital Preparedness Program (HPP):** HPP enables health care systems to save lives during emergencies that exceed day-to-day capacity of health and emergency response systems. Annual appropriations to the Hospital Preparedness Program, 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. HPP 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.
- Strategic National Stockpile (SNS):** The SNS is responsible for strategic procurement and stockpiling of 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, the

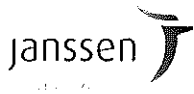
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CDC's SNS is the only federal resource readily available to respond once state and local supplies are depleted. The SNS is the procurement mechanism for many FDA-approved MCMs, some of which have no commercial market, such as licensed vaccines and drugs against smallpox and anthrax. The SNS also holds supplies of biopharmaceutical products. The SNS is organized for scalable response to a variety of naturally occurring or manmade public health threats, as the repositories contain enough supplies to respond to multiple large-scale emergencies simultaneously like we are currently seeing with Hurricanes Harvey and Irma.

- Public Health Emergency Preparedness (PHEP): PHEP is a critical source of funding for state, local, tribal, and territorial public health departments to help health departments to build and strengthen their abilities to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events. Preparedness activities funded are targeted specifically for the development of emergency-ready public health departments that are flexible and adaptable.

We urge you to increase support for a more complete suite of capabilities in biosecurity to protect our homeland. It will take a sustained and robust public and private sector investment to analyze and respond to looming biological and public health threats – whether natural or intentional.

We cannot predict exactly when or where the next threat will appear, but we know it will. By investing in advanced medical countermeasure development and procurement now, we will better prepared for future events.

Again, we commend the quick bipartisan response to provide much needed initial funding to communities impacted by Hurricane Harvey. We encourage the Administration's follow-on request and Congress to provide significant supplemental funds to rebuild the base public health infrastructure and enhance the development of biosecurity response capacities to protect the American citizens for future natural or intentional biological and public health threats.

Best,

Chris Frech & Brent MacGregor
Alliance for Biosecurity Co-Chairs

Copy: Assistant Secretary Robert Kadlec, M.D.
CDC Director Brenda Fitzgerald, M.D.

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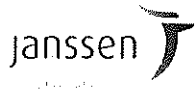
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Acting Secretary Eric Hargan



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The Alliance for Biosecurity is a coalition of biopharmaceutical companies and laboratory/academic partners that promotes a strong public-private partnership to ensure medical countermeasures 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 medical countermeasures. For more information on the Alliance for Biosecurity please visit allianceforbiosecurity.com

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