

# Alliance for Biosecurity

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The Alliance for Biosecurity, a consortium of innovative companies committed to the development of products to respond to national security threats, including bioterrorism pathogens and emerging infectious diseases, appreciates the opportunity to submit written public witness testimony regarding the government response to the ongoing Ebola outbreak. Alliance members recognize the significant needs and challenges of finding timely solutions to these rare, but lethal diseases. As such, we are dedicated to promoting strong, effective partnerships among government, industry, and other stakeholders in order to advance our shared goal of developing critically needed medicines for the American public.

The Ebola outbreak has raised important questions about our nation's preparedness for all health threats, whether from infectious diseases, chemical weapons or radiological and nuclear agents. Moreover, it serves as a warning for the malevolent use of dangerous pathogens, chemicals or radiological weapons. As we witness the devastating impact that Ebola is having in West Africa and the larger global public health and economic concerns the outbreak has produced, it is clear that programs to protect Americans at home and abroad from health security threats with significant health, social, and economic impact must be enabled and funded *in advance* of disasters and outbreaks.

Unwavering vigilance and a sense of urgency at all times, even in the absence of a current crisis, are the only way to ensure meaningful preparedness. As the Ebola outbreak appears to worsen despite massive effort, it is clear that it is simply too late to mount an effective response after a crisis begins.

Almost a decade ago, the Department of Homeland Security (DHS) determined that Ebola and Marburg viruses are "material threats" to U.S. national security. The Department of Defense (DoD) has a separate threat list that also includes these viruses. Yet, as you know, there is currently no licensed vaccine or therapeutic available to prevent and treat Ebola. This capability vacuum presents a significant challenge to managing and ultimately stemming the outbreak.

No commercial market exists for vaccines and therapeutics for Ebola and other serious disease threats, including smallpox, anthrax, MERS, and pandemic flu. The only "customers" to support preparedness are government bodies, and these drugs and vaccines are a significant investment often taking 8-12 years and nearly \$1 billion to develop. Therefore, a consistent, well-funded public-private partnership is our best hope for successfully developing these necessary products to protect Americans and to assist the international community.

Emergency supplemental requests at the time of crisis are inadequate to the challenge. BARDA and the Project BioShield Special Reserve Fund (SRF), when adequately funded, provide the resources to research, develop, and procure a diverse portfolio of medicines to control epidemics and save lives. The SRF in particular was designed to provide a way for the government to

procure countermeasures when they are needed and ready, without resorting to emergency requests. As BARDA is supporting an expanding number of important programs, funding for advanced development, manufacturing and SRF procurement also needs to increase to successfully complete these programs. Without a long-term funding commitment for these critical health security assets and the entire medical countermeasure enterprise, our nation is at risk in the face of the next public health emergency.

Furthermore, it is critical to ensure that emergency programs for Ebola products be funded without jeopardizing our preparation for other dangerous threats. The U.S. Government and the myriad federal agencies involved in preparedness and public health must have the ability to plan ahead, be constantly vigilant, and sustain research and development of vaccines and drugs. Investing in developing, procuring, and stockpiling medicines to respond to the range of known threats, and having the ability to react to emerging diseases, is prudent. Preparedness is an appropriate and essential investment of our nation's resources. It will protect lives and minimize future emergency expenditures.

It is essential that the federal government continues to demonstrate to biopharmaceutical companies (and their investors) the federal government's commitment to this space. The Alliance for Biosecurity remains concerned that the coordinated five year MCM budget plan required under the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA; Pub. Law 113-5, 42 U.S.C. § 300hh-10), which became law on March 2013, has still not been delivered to Congress. The purpose of this provision is to produce a plan that would inform priorities, create a metric of success for reaching those priorities, and ultimately allow for an understanding of anticipated needs. The first annual plan was statutorily required to be prepared within one year of PAHPRA's passage. The delivery of this report is essential as it would be a critical signal to the biopharmaceutical industry that the U.S. Government remains committed to the medical countermeasure (MCM) enterprise.

The existing U.S. government infrastructure responsible for developing and stockpiling the vaccines and drugs essential to any effective preparedness and response plan encompasses numerous government stakeholders. Responsible agencies include Office of the Assistant Secretary for Preparedness and Response (ASPR), BARDA, National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), DoD, DHS, and White House National Security Council (NSC). These departments and agencies have greatly aided programs in key biosecurity areas, but they must coordinate effectively and eliminate any barriers that may slow or complicate development and distribution of vaccines and drugs.

Congress and the White House must continue to provide sustained, transparent, and substantial funding for the development of drugs and vaccines against all health security threats, effectively enhancing capabilities achieved to date. Resolute focus on all health security threats is imperative in the midst of responding to this unprecedented Ebola outbreak. The continued cooperation of government agencies well beyond the current crisis will be critical for ensuring that the U.S. response to future outbreaks is strong.