

Congress of the United States
Washington, DC 20515

April 28, 2016

The Honorable Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

We have closely followed the developments surrounding the emergence of the Zika virus and we are committed to making sure that Americans are protected from the full range of threats we may face, whether naturally-occurring or man-made. We will continue to partner with the Administration to ensure that we are as prepared as possible to combat these threats. However, we write to express our significant concerns with the legislative proposal included in the Administration's emergency spending request for Zika. This proposal represents a substantial statutory change to remove the requirement for countermeasures procured under the BioShield Special Reserve Fund (SRF) to be linked to a Material Threat Determination by the Department of Homeland Security (DHS), and, if enacted, would result in our nation being less prepared against serious threats.

The bipartisan Project BioShield Act of 2004 was enacted to encourage and facilitate the development of medical countermeasures (vaccines, drugs, etc.) against chemical, biological, radiological, and nuclear (CBRN) terrorism agents. BioShield serves as an affirmation of the federal government's commitment to purchasing these countermeasures if companies invest the capital and embark on years of long and often difficult development programs to bring them forward. The Pandemic and All-Hazards Preparedness Act further affirmed the urgency and necessity of advancing these medical countermeasures by creating the Biomedical Advanced Research and Development Authority (BARDA) to help manufacturers bridge the "valley of death" to be considered for such procurement. Project BioShield contracts are only available for products that meet specific requirements designed for use against CBRN agents that the DHS has determined pose "a material threat against the United States population sufficient to affect national security."¹

However, in its emergency spending request for Zika, the Administration proposes that BioShield countermeasure procurement would not be required to be associated with a Material Threat Determination by DHS, and could be allowed for any countermeasures the Health and Human Services (HHS) Secretary determines to be necessary to diagnose, mitigate, prevent, or treat any infectious disease that may pose a threat to the public health.

¹ 42 U.S.C. §247d-6B(c)(2).

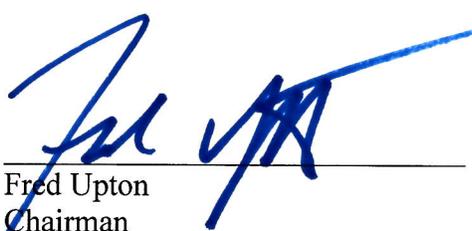
We are deeply concerned about this proposal. The proposal risks further damaging fragile public-private partnerships by eroding confidence in the federal government's commitment to procure medical countermeasures, one of the critical roles the BioShield SRF plays in attracting and sustaining the private sector's research and development of medical countermeasures against very serious identified CBRN threats, such as hemorrhagic fever, typhus, and small pox. The President's Fiscal Year 2017 Budget proposed decreasing funding for the SRF by \$160 million. Just weeks later, the Administration then proposed expanding what would be eligible for these targeted resources. These actions do not instill confidence that the federal government is the committed partner needed in these public-private partnerships.

The proposal also blurs the distinction between public health and national security threats. The latter is the threshold for CBRN threats that are eligible for the SRF under current law—a material threat sufficient to affect national security. Any effort to change how the SRF (and other BARDA resources) are used must be thoughtfully considered in the context of the level of preparedness being lost against established, prioritized threats and the short and long term effects on our national security.

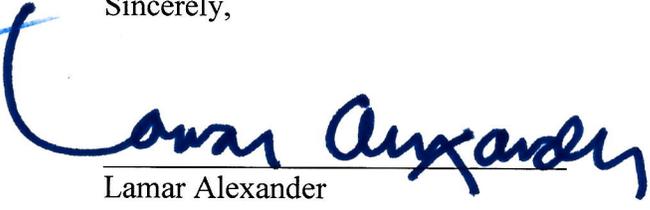
The Blue Ribbon Study Panel (BRSP) on Biodefense has recommended requiring the Department of Health and Human Services to develop a means for prioritizing emerging infectious diseases, and to use this prioritization to inform funding requests, instead of scrambling during emergencies to take resources from existing programs. The Administration's BioShield proposal to rewrite current law is at odds with this recommendation. The BRSP has also expressed concerns about the proposed change to BioShield included in the Administration's emergency spending request for Zika.

We would respectfully request that the Administration remove this legislative proposal from the emergency spending request, and discuss this separately with the House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions Committee. We want to work with you and the Administration to improve the nation's biodefense preparedness and response, especially with regard to emerging infectious diseases, but we believe this proposal will dilute a critical focus and result in our nation being less prepared for identified threats, as well as novel and emerging infectious diseases. It is by making progress against these serious CBRN threats that we will be better prepared to respond to emerging infectious diseases that threaten the health and security of the American people. We would appreciate a prompt response to our request and concerns.

Sincerely,



Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives



Lamar Alexander
Chairman
Committee on Health, Education,
Labor and Pensions
U.S. Senate



Susan Brooks
Member
Committee on Energy and Commerce
U.S. House of Representatives



Richard Burr
Chairman
Select Committee on Intelligence
U.S. Senate