

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

February 10, 2015

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Outbreaks, Attacks, and Accidents: Combatting Biological Threats”

On Friday, February 12, 2016, at 9:00 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing titled “Outbreaks, Attacks, and Accidents: Combatting Biological Threats.” The hearing will focus on an October 2015 report from the Blue Ribbon Study Panel on Biodefense, which finds that the United States is underprepared for biological threats. In its report, the Panel recommends a new leadership structure and major reforms to improve the government’s response.

I. BACKGROUND

Efforts to protect against emerging infectious diseases and acts of terror executed with biological weapons, referred to as “biodefense,” encompass a wide range of interventions, including medical research, biosurveillance, and emergency preparedness.

Following the September 11, 2001, terrorist attacks and the subsequent anthrax mailings, Congress passed legislation to address the threat of bioterrorism, and it increased investments in research and preparedness to defend against biological weapons.¹ Significant legislation included the Homeland Security Act of 2002 and the Pandemic and All-Hazards Preparedness Act of 2006, which established new departments and agencies to address preparedness and bioterrorism response.²

Both President Bush and President Obama took action to develop national strategies and provide guidance to agencies involved in homeland security and biodefense. In April 2004, President Bush issued Homeland Security Presidential Directive 10 (HSPD-10), which set forth

¹ Congressional Research Service, *Federal Efforts to Address the Threat of Bioterrorism: Selected Issues and Options for Congress* (Feb. 8, 2011) (R41123).

² *Id.*

four pillars of biodefense: threat awareness, prevention and protection, surveillance and detection, and response and recovery. HSPD-10 emphasized the importance of preparedness, coordination of biodefense roles both domestically and internationally, and mitigation of bioterrorism's potentially damaging effects.³

When President Obama took office in 2009, his Administration quickly developed a national strategy for dealing with biological threats. The Administration's national strategy is aimed at reducing the risk that biological agents will be misused, placing "increased priority on actions to further reduce the likelihood that such an attack might occur."⁴

Currently, the federal government's biodefense initiatives span across an assortment of agencies, each of which varies in terms of its resources, scope, and approach. The Department of Homeland Security (DHS) was created in 2002 and tasked as the primary federal agency with preventing and responding to terrorist attacks within the United States.⁵ DHS's mission includes preventing terrorism, enhancing security, and "ensuring resilience to disasters."⁶

The Department of Health and Human Services (HHS) plays a key role in response planning and has the primary responsibility for public health preparedness.⁷ HHS operates the Biomedical Advanced Research and Development Authority (BARDA), whose goals include advancing the Department's capability to develop, manufacture, and facilitate distribution of medical countermeasures, such as vaccines, during public health emergencies.⁸

Within HHS, the Centers for Disease Control and Prevention (CDC) is responsible for foreign disease outbreak detection and protecting Americans from natural and bioterrorism threats.⁹ Improving the health community's ability to detect and diagnose illnesses that may be related to a bioterror threat and to develop contingency plans to respond effectively are essential

³ Homeland Security Presidential Directive-10, *Biodefense for the 21st Century* (Apr. 28, 2004).

⁴ The White House, National Security Council, *National Strategy for Countering Biological Threats* (Nov. 2009) (online at www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf).

⁵ Homeland Security Act of 2002, Pub. L. 107-296.

⁶ Department of Homeland Security, *Our Mission* (accessed Feb. 1, 2016) (online at www.dhs.gov/our-mission).

⁷ *Id.*

⁸ U.S. Department of Health and Human Services, Biomedical Advanced Research and Development Authority, *BARDA Strategic Plan 2011-2016* (accessed Feb. 1, 2016) (online at www.phe.gov/about/barda/Documents/barda-strategic-plan.pdf).

⁹ Congressional Research Service, *Federal Efforts to Address the Threat of Bioterrorism: Selected Issues and Options for Congress* (Feb. 8, 2011) (R41123).

to its execution of these responsibilities and its mission.¹⁰ Along these lines, the CDC is currently attempting to build a centralized web-based reference laboratory for state health departments that would help accelerate the detection and identification of possible pathogens.¹¹

II. BLUE RIBBON STUDY PANEL ON BIODEFENSE REPORT

Numerous high-level commissions have examined biodefense preparedness and made policy recommendations to Congress and the President. In 2007, Congress formed the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism to assess the nation's overall protection capabilities. The Commission concluded in 2009 that although biological weapons are generally cheaper and easier to acquire than nuclear weapons, U.S. preparedness for bioterrorism is much lower than it is for nuclear threats.¹²

In 2014, experts at the Hudson Institute and the Inter-University Center for Terrorism Studies established a Blue Ribbon Study Panel on Biodefense (“the Panel”) in an effort to provide a holistic assessment of U.S. preparedness and ability to effectively manage biological threats. Led by former Senator Joseph Lieberman and former Secretary of Homeland Security and Governor of Pennsylvania Tom Ridge, the Panel was charged with examining the strength of U.S. biodefense capabilities across a broad range of categories, including threats to public health and safety from emerging and reemerging infectious diseases and potential acts of bioterror. The Panel convened a series of meetings with experts from industry, academia, government, and advocacy organizations to address the four pillars of HSPD-10 and make positive recommendations for improvement of U.S. biodefense policy and preparedness.

The Panel reported that the U.S. remains underprepared for a biological attack or emerging infectious disease.¹³ Moreover, the report identified specific challenges to the management of U.S. biodefense—the overarching theme being a need for unifying leadership—and made a number of key recommendations to improve readiness in this area.

The Panel cited as particularly urgent the need to define a single national leader under which preparedness for and response to biological threats can be unified, managed, and directed. The Panel recommended that the responsibility of biodefense be “institutionalized in the Office

¹⁰ Centers for Disease Control and Prevention, *Public Health Emergency Response: The CDC Role* (accessed Feb. 1, 2016) (online at www.bt.cdc.gov/DocumentsAPP/Improving_biodefense.pdf).

¹¹ Centers for Disease Control and Prevention, *Justification of Estimates for Appropriations Committees: Fiscal Year 2016* (accessed Feb. 1, 2016) (online at www.cdc.gov/budget/documents/fy2016/fy-2016-cdc-congressional-justification.pdf).

¹² Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, *The Clock is Ticking: A Progress Report on America's Preparedness to Prevent Weapons of Mass Destruction Proliferation and Terrorism* (Oct. 21, 2009).

¹³ *Blue Ribbon Panel report: United States lacking in biodefense*, Washington Post (Oct. 28, 2015) (online at www.washingtonpost.com/news/checkpoint/wp/2015/10/28/blue-ribbon-panel-report-united-states-lacking-in-biodefense/).

of the Vice President of the United States,” and that doing so would “ensure that biodefense will be addressed by every Administration, at the highest levels, and with adequate access to the President.” The Panel also recommended that the Vice President be empowered with “jurisdiction and authority,” and that he or she take necessary action “to ensure adequate biodefense for the United States, address relevant international issues and requirements, and coordinate the U.S. biodefense enterprise.”¹⁴

The report suggested that the Vice President should be empowered with the budgetary authority to review and advise on all agency biodefense-related budgetary matters for the executive branch and that this be done in close collaboration with the Director of the Office of Management and Budget (OMB).¹⁵

Additionally, the Panel proposed 33 discrete recommendations to facilitate effective biodefense leadership and governance structure.¹⁶ The recommendations fall into the following broad categories:

- The need for leadership in achieving coordination, both in the executive and legislative branches and with the intelligence community;
- Recognizing and institutionalizing an approach to public health preparedness that combines human, animal, and environmental health;
- Development and distribution of medical countermeasures, including coordinating efforts across the private and public sectors;
- Improving biosurveillance and biodetection capabilities, including better coordination between all levels of government and emergency response services;
- Increasing support and incentives for hospital preparedness; and
- Addressing the intersection of biology and cybersecurity.

While many of the recommendations of the Panel involve executive branch actions and activities, the Panel also offered certain recommendations for Congress. Along with any necessary legislation to authorize new or augment existing programs, the Panel provides recommendations for enhanced oversight of a number of key sectors within the executive branch that deal with biodefense activities.¹⁷ For example, recommended hearings and oversight of matters falling within the Energy and Commerce Committee’s jurisdiction include:

- The mission focus and appropriate funding of BARDA;
- Biosurveillance and detection capabilities;
- Global health response;
- Medical countermeasures innovation;

¹⁴ Blue Ribbon Study Panel on Biodefense, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* (Oct. 2015).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.* A list of proposed hearings can be found in Appendix A of the Panel report.

- Identifying potential cyber vulnerabilities present in laboratory and research databases, within and outside the government;
- Investigating the effectiveness of the Select Agent Program (SAP), and determining how SAP requirements can be improved in order to be less burdensome; and
- Exploring food supply protection and response plans, and determining whether these plans have been sufficiently updated, exercised, and funded.

III. WITNESSES

Dr. Donna Shalala

Member, Blue Ribbon Study Panel on Biodefense
Former Secretary of Health and Human Services

Rep. James C. Greenwood

Member, Blue Ribbon Study Panel on Biodefense
President and CEO, Biotechnology Industry Organization (BIO)
Former Chairman, Subcommittee on Oversight and Investigations

Dr. Tara O'Toole

Senior Fellow, IQT
Former Undersecretary of the Science and Technology Directorate, Department of Homeland Security

Dr. Gerald W. Parker

Associate Vice President, Public Health Preparedness and Response
The Texas A&M University System