

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

June 13, 2018

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “The State of the U.S. Public Health Biopreparedness: Responding to Biological Attacks, Pandemics, and Emerging Infectious Disease Outbreaks”

On **Friday, June 15, 2018, 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, “The State of the U.S. Public Health Biopreparedness: Responding to Biological Attacks, Pandemics, and Emerging Infectious Disease Outbreaks.” The hearing will broadly examine the state of the nation’s preparedness for and ability to respond to biological threats, accidents, and naturally occurring infectious disease outbreaks.

I. ROLE OF FEDERAL AGENCIES IN BIOPREPAREDNESS EFFORTS

Four entities within the U.S. Department of Health and Human Services (HHS) play a key role in the framework that serves to address public health-related emergency response planning: the Centers for Disease Control and Prevention (CDC); the National Institutes of Health (NIH); the U.S. Food and Drug Administration (FDA); and the HHS Assistant Secretary for Preparedness and Response (ASPR).¹

CDC is responsible for helping communities prepare for, detect, and respond to public health consequences of all hazards.² For example, CDC is responsible for detecting outbreaks of

¹ U.S. Department of Health and Human Services, Emergency Preparedness & Response (www.hhs.gov/programs/emergency-preparedness/index.html).

² House Committee on Energy and Commerce, Testimony of Rear Admiral Upper Half Stephen C. Redd, M.D., Director, Centers for Disease Control and Prevention, *Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act* (June 6, 2018).

infectious disease, and for developing contingency plans to respond effectively to such outbreaks and to other public health emergencies.³ In addition, CDC currently maintains the Strategic National Stockpile (SNS), which houses the nation’s largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to deplete local supplies.⁴ The Administration announced it would move the SNS under the authority of ASPR as part of the fiscal year 2019 Budget Request.⁵

Created under the 2006 Pandemic All-Hazards Preparedness Act, ASPR serves as the coordinating body for federal governmental health agencies and “hospitals, healthcare coalitions, biotech firms, community members, state, local, tribal, and territorial governments, and other partners across the country to improve readiness and response capabilities.”⁶ ASPR also serves as the principal advisor to the HHS Secretary on “all matters related to Federal public health and medical preparedness and response for public health emergencies.”⁷ In addition, ASPR 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

FDA is responsible for ensuring that medical countermeasures – including drugs, biologics (such as vaccines and blood products), and devices (such as diagnostic tests and personal protective equipment) – are safe, effective, and secure in the case of a biological threat.⁹ FDA is also responsible for the intra-agency and inter-agency coordination of crisis response activities involving regulated products.¹⁰

(<https://docs.house.gov/meetings/IF/IF14/20180606/108389/HHRG-115-IF14-Wstate-ReddS-20180606.pdf>).

³ Centers for Disease Control and Prevention, Bioterrorism Agents/Diseases (Apr. 4, 2018) (www.emergency.cdc.gov/agent/agentlist-category.asp) (accessed June 11, 2018).

⁴ Centers for Disease Control and Prevention, Strategic National Stockpile (www.cdc.gov/phpr/stockpile/index.htm) (accessed June 11, 2018).

⁵ U.S. Department of Health and Human Services, The President’s 2019 Budget (www.gpo.gov/fdsys/pkg/BUDGET-2019-BUD/pdf/BUDGET-2019-BUD-10.pdf) (accessed June 12, 2018).

⁶ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Saving Lives And Protecting Americans From 21st Century Health Security Threats (www.phe.gov/about/aspr/pages/default.aspx) (accessed June 11, 2018).

⁷ Pub. L. No. 109-417.

⁸ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (www.phe.gov/about/BARDA/Pages/default.aspx).

⁹ U.S. Food and Drug Administration, Counterterrorism and Emerging Threats (Mar. 19, 2018) (www.fda.gov/EmergencyPreparedness/Counterterrorism/default.htm).

¹⁰ U.S. Food and Drug Administration, Emergency Management (Mar. 28, 2018) (www.fda.gov/EmergencyPreparedness/CrisisManagement/default.htm).

Within NIH, the National Institute of Allergy and Infectious Diseases (NIAID) conducts research to better understand infectious agents, which “provides the foundation for developing medical products and strategies to diagnose, treat, and prevent a wide range of infectious diseases.”¹¹

II. PREVIOUS WORK IN BIOPREPAREDNESS

Over the past several years, the Subcommittee has held a number of hearings related to biopreparedness. For example, in June 2016, the Subcommittee held a hearing on efforts to combat the growing threat of antibiotic resistance. That hearing examined the threat of newly emerging drug-resistant bacteria, and the need for new diagnostic tests and therapeutics to help better combat this threat. The Subcommittee has also held three hearings on influenza since 2015, and multiple hearings on concerns related to emerging infectious diseases such as Ebola and Zika over this same period.

The Subcommittee has also examined the recommendations made by the Blue Ribbon Study Panel on Biodefense’s October 2015 report, “A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts.” That report provided a holistic assessment of U.S. preparedness and ability to effectively manage biological threats. It also proposed 33 recommendations to facilitate effective biodefense leadership and improve biopreparedness.¹²

IV. WITNESSES

Dr. Anne Schuchat

Director
Centers for Disease Control and Prevention

Dr. Anthony Fauci

Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Dr. Rick Bright

Deputy Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Rear Admiral Denise Hinton

Chief Scientist

¹¹ National Institute of Allergy and Infectious Disease, Biodefense and Emerging Infectious Diseases (www.niaid.nih.gov/research/biodefense-emerging-infectious-diseases) (accessed June 11, 2018).

¹² Blue Ribbon Study Panel on Biodefense, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* (Oct. 2015).

U.S. Food and Drug Administration