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ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

June 4, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act"

On **Wednesday, June 6th, 2018 at 10:00 a.m. in room 2123 of the Rayburn House Office Building**, the Subcommittee will hold a hearing titled "Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act."

I. BACKGROUND

The Pandemic All-Hazards Preparedness Act (PAHPA) was enacted in 2006, to improve public health and medical emergency preparedness and response activities.[1] The Act established the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS) and provided new authorities for preparing and responding to public health emergencies, including the development and acquisition of medical countermeasures (MCMs). The law was reauthorized in 2013 for an additional five years (through fiscal year (FY) 2018) and currently supports key preparedness and response programs at ASPR and the Centers for Disease Control and Prevention (CDC). [2]

ASPR is primarily responsible for managing the Hospital Preparedness Program (HPP), the Biomedical Advanced Research and Development Authority (BARDA), Project BioShield, and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). BARDA supports the advanced development and procurement of MCMs such as drugs and vaccines that

[1] P.L. 109-417.

[2] P.L. 113-5.

are determined to be priorities for national security.[3] Products receiving Food and Drug Administration (FDA) approval can be considered for inclusion in the Strategic National Stockpile (SNS). The PHEMCE, which is led by ASPR and includes partners from other federal agencies, establishes requirements for products that are included in the SNS.[4] Historically, CDC has been responsible for the procurement of FDA approved products for the SNS, the maintenance of the SNS, and the expertise and logistics involved with deploying SNS products to communities in the case of a public health emergency. However, the President's FY 2019 Budget announced the Secretary's decision to transfer control of the SNS from CDC to ASPR; this transfer is currently ongoing.[5]

Within CDC's core public health mission, they play an essential role in defending and combatting public health threats. Authorities within PAHPA bolster CDC's role, as CDC is responsible for managing the Public Health Emergency Preparedness (PHEP) cooperative agreement as well as authorities related to public health alert communications and public health situational awareness and biosurveillance. The PHEP provides funding to state, local and territorial public health departments to assist in building preparedness and response capabilities to public health threats. Through PHEP funding, CDC funds the Cities Readiness Initiative, which is designed to enhance preparedness in the nation's largest population centers to effectively respond to large-scale public health emergencies that require the distribution of life-saving medications and medical supplies.

FDA is responsible for evaluating the safety and effectiveness of medical products (including MCMs) before a product is approved, licensed, or cleared for marketing. FDA also can issue an emergency use authorization (EUA) to help facilitate MCM access during public health emergencies. During an emergency, FDA can issue an EUA that allows for (1) use of an unapproved medical product; or, (2) unapproved use of an approved medical product if certain statutory criteria are met. For example, FDA must find that, based on all available evidence, the known and potential benefits of the product outweigh the known and potential risks. FDA also has the authority to extend the expiration date of medical products in certain emergency situations if there is scientific evidence to do so and can take a number of actions to help address shortages including working to bring new manufacturers into the product area and allowing temporarily for the importation of products from registered facilities overseas.

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[3] Office of the Assistant Secretary for Preparedness and Response, *Biomedical Advanced Research and Development Authority* (https://www.phe.gov/about/BARDA/Pages/default.aspx).

[4] Office of the Assistant Secretary for Preparedness and Response, *Public Health Emergency Medical Countermeasures Enterprise* (https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx).

[5] Department of Health and Human Services, *Fiscal Year 2019, Public Health and Social Services Emergency Fund, Justification of Estimates for Appropriations Committee* (https://www.hhs.gov/sites/default/files/fy-2019-phssef-cj.pdf).

II. LEGISLATION

The hearing will examine H.R. ___, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2018 authored by Reps. Brooks (R-IN) and Eshoo (D-CA). Below is a summary of the bill's provisions.

TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND RESPONSE FOR PUBLIC HEALTH EMERGENCIES

Sec. 101. Coordination of preparedness for and response to all-hazards public health emergencies.

Currently, ASPR is required to carry out drills and operational exercises to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness and response. This section would amend that requirement to include the pandemic influenza and emerging infectious disease program established under this bill.

Currently, ASPR is required to develop, and update each year, a five-year budget plan for medical countermeasures based on the priorities established by the public health emergency medical countermeasures enterprise strategy and implementation plan. This section would require that the five-year budget plan include consideration of the research and development activities of the pandemic influenza and emerging infectious disease program established by this bill.

Sec. 102. Public health emergency medical countermeasures enterprise.

This section would require the Secretary to codify an existing interagency panel of advisors known as the PHEMCE. The ASPR would serve as the Chair of the PHEMCE and the panel must include representatives from: BARDA, CDC, National Institutes of Health (NIH), FDA, the Department of Defense (DOD), the Department of Homeland Security (DHS), the Department of Agriculture (USDA), the Department of Veterans Affairs (VA), and representatives of any other federal agencies, as the ASPR determines appropriate. The function of the PHEMCE would be to advise ASPR on the research, development, and procurement of security countermeasures and assist ASPR in the identification of gaps in public health preparedness and response.

Sec. 103. National Advisory Committee on Children and Disasters.

This section would reauthorize the National Advisory Committee on Children and Disasters (NACCD) through 2023. The NACCD was established to provide expert advice and consultation to the HHS Secretary on the medical and public health needs of children in disasters and public health emergencies.

Sec. 104. National Disaster Medical System Personnel.

This section would provide ASPR with direct hire authority for National Disaster Medical System (NDMS) personnel. NDMS personnel are health professionals deployed by ASPR in emergency situations to fill in gaps in care, supplement a health systems' response capabilities, or provide support at large-scale public events.

This section would also provide death benefits for NDMS personnel by defining them as public safety officers under the Public Safety Officers' Benefits (PSOB) program administered by the U.S. Department of Justice. Under PSOB, a death benefit is provided to eligible survivors of public safety officers whose deaths are the result of certain injuries in the line of duty.

This section would reauthorize the NDMS at $57.4 million for each of fiscal year 2019 through 2023.

Sec. 105. Volunteer Medical Reserve Corps.

This section would reauthorize the Medical Reserve Corps at $6 million for each of fiscal years 2019 through 2023.

Sec. 106. Continuing the role of the Department of Veterans Affairs.

This section would reauthorize funding for VA medical facilities emergency preparedness at $126.8 million for each of fiscal years 2019 through 2023. Under these authorities the VA is required to provide for the readiness of VA medical centers to protect patients and staff from a public health emergency as well as fulfill their obligations as part of the federal response to such emergencies; secure Department medical centers and research facilities; track pharmaceuticals, medical supplies, and equipment in order to permit the ready use of such items for a variety of purposes, including response to a public health emergency; train VA health care personnel in medical matters to respond to public health emergencies or attacks from incendiary weapons or other explosive weapons; and participate in the NDMS.

TITLE II—OPTIMIZING STATE AND LOCAL ALL-HAZARDS PREPAREDNESS AND RESPONSE

Sec. 201. Public health emergencies.

This section would amend the authorities of the Public Health Emergency Fund (Fund). It would rename the Fund to the Public Health Emergency Response Fund and specify uses for the Fund. This section would permit the Secretary to transfer to the Public Health Emergency Response Fund not more than one percent from any discretionary appropriations. The Secretary would be required to submit a report to the committees of jurisdiction not later than 90 days after the end of each fiscal year describing expenditures made from the Fund, the emergencies for which the expenditures were made and those activities undertaken, any unobligated balances, and all obligations incurred in that fiscal year. This section would also reauthorize temporary reassignment authority through 2023.

Sec. 202. Improving State and local public health security.

This section would reauthorize the PHEP cooperative agreement at $670 million for each of fiscal years 2019 through 2023.

Sec. 203. Partnerships for State and regional hospital preparedness to improve surge capacity.

This section would reauthorize the Hospital Preparedness Program (HPP) at $264.6 million for each of fiscal years 2019 through 2023. It would also add to the list of potential partners an entity may have to be eligible for an award to include a health coalition, state hospital association, or a health system.

Sec. 204. Revitalizing the Centers for Disease Control and Prevention.

This section would reauthorize public health alert communications, biosurveillance, and situational awareness programs at CDC at $161.8 million for each of fiscal years 2019 through 2023.

Sec. 205. Authorization of appropriations for Emergency System for Advanced Registration of Volunteer Health Professionals.

This section would reauthorize the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP) at $5 million for fiscal years 2019 through 2023.

TITLE III—ACCELERATING MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

Sec. 301. Strategic national stockpile and security countermeasure procurement.

This section would codify the assignment of the Strategic National Stockpile to ASPR and reauthorize the SNS at $610 million for each of fiscal years 2019 through 2023. It would prevent disclosure of additional highly sensitive information under the Freedom of Information Act. It would also reauthorize the BioShield Special Reserve Fund at $7.1 billion for fiscal years 2019 through 2028 and allow for such funding to be provided by advance appropriation.

Sec. 302. Biomedical advanced research and development authority.

This section would reauthorize BARDA at $536.7 million for each of fiscal years 2019 through 2023. This section would require the Secretary, acting through BARDA, to establish a Pandemic Influenza Program to support research and readiness related to pandemic influenza and authorize $250 million for each of fiscal years 2019 through 2023 to carry out such program. It would also require the Secretary, acting through BARDA, to establish a program that supports research, development, and manufacturing related to emerging infectious diseases and authorizes $250 million for each of fiscal years 2019 through 2023 to carry out such program. This section would expand the definition of qualified pandemic or epidemic products for purposes of BARDA authorities to include a product manufactured, used, designed, developed, modified,

licensed, or procured to diagnose, mitigate, prevent, treat, or cure an infectious disease. This section would also amend the definition of other transactions authorities.

TITLE IV—MISCELLANEOUS PROVISIONS

Sec. 401. Cybersecurity.

This section would designate ASPR as the lead agency responsible for ensuring healthcare sector capabilities to provide continuity of care during cybersecurity incidents and placing the Healthcare Cybersecurity Communications and Integration Center (HCCIC) under ASPR.

Section 401 would also add cybersecurity to the existing list of biodefense threats, which includes chemical, biological, radiological, and nuclear (CBRN) threats, for various purposes. As part of the National Health Security Strategy, the Secretary would need to include provisions that promote strategic initiatives to advance countermeasures to diagnose, mitigate, prevent, or treat harm from any cybersecurity threat. This section would require ASPR to include with the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan, a plan for medical countermeasures to address cybersecurity threats. The plan must describe cybersecurity agents that may present a threat to the nation and detail corresponding efforts to develop medical countermeasures or products as well as identify and prioritize near-, mid-, and long-term needs with respect to such countermeasures or products.

Section 401 requires PHEP awardees to undertake activities to meet the cybersecurity goals of the National Health Security Strategy. It also requires the Secretary to identify measurable evidence-based benchmarks and objective standards with respect to cybersecurity threats that PHEP awardees must measure progress towards and at least annually test, exercise, and rigorously evaluate preparedness and response capability to such threats. This section would require HPP awardees to use funds for activities that achieve preparedness goals, including with respect to cybersecurity threats. Under this section, cybersecurity threats have been added as an eligible threat for purposes of FDA's emergency use authority (EUA). The "eligible product" definition is also amended for EUA purposes by this section to include products intended for use to prevent, diagnose, or treat a disease or condition involving a cybersecurity threat. The term "qualified pandemic or epidemic product" is amended also to include cybersecurity threats. Finally, FDA review and approval of MCM authority is revised to take into consideration the material threat posed by cybersecurity threats.

Sec. 402. Miscellaneous FDA amendments.

This section would clarify that FDA need not make sensitive information publicly available through its drug development tools program if it compromises national security. It would also make other technical amendments to the Federal, Food, Drug and Cosmetic Act.

III. WITNESSES

Panel I:

Robert Kadlec, MD
Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services

Stephen Redd, MD, RADM
Director
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention (CDC)

Anna Abram
Deputy Commissioner for Policy, Planning, Legislation, and Analysis
Food and Drug Administration (FDA)

Panel II:

Erik Decker
Chief Security and Privacy Officer
University of Chicago Medicine

M. Michelle Berrey, MD, MPH
President and CEO
Chimerix, Inc

Umair Shah, MD, MPH
Executive Director
Harris County Public Health
President
National Association of County and City Health Officials (NACCHO)