

July 16, 2018

TO: Members, Committee on Energy and Commerce

FROM: Committee Majority Staff

RE: Full Committee Markup

I. INTRODUCTION

The Committee on Energy and Commerce will meet in open markup session on Wednesday, July 18, 2018, at 1:00 p.m. in 2123 Rayburn House Office Building to consider the following:

- H.R. 6351, Advancing U.S. Civil Nuclear Competitiveness and Jobs Act; and
- H.R. 6378, Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018.

In keeping with Chairman Walden's announced policy, Members must submit any amendments they may have two hours before they are offered during this markup. Members may submit amendments by email to peter.kielty@mail.house.gov. Any information with respect to an amendment's parliamentary standing (e.g., its germaneness) should be submitted at this time as well.

II. EXPLANATION OF LEGISLATION

A. H.R. 6351, Advancing U.S. Civil Nuclear Competitiveness and Jobs Act

H.R.6351, the Advancing U.S. Civil Nuclear Competitiveness and Jobs Act, addresses issues relating to the competitiveness of civilian nuclear commerce. Section 2 of the legislation requires the Secretary of Energy, in consultation with the Secretary of State, the Nuclear Regulatory Commission, Secretary of Commerce, and Administrator of the Environmental Protection Agency, to identify regulatory, policy, legal, and commercial practices impacting civil nuclear commerce, compare those practices to foreign governments, and make recommendations to improve the competitiveness of the U.S. civil nuclear industry.

Section 3 amends section 57b of the Atomic Energy Act (AEA), which governs the transfer of certain nuclear technologies to foreign countries. The legislation amends the AEA requirement restricting the Secretary from delegating the authorization of export authorizations, with the exception of uranium and reprocessing technologies. The legislation directs the Secretary of Energy to establish procedures for authorizations of low-proliferation risk reactor activities. The procedures only apply to activities that (1) are described in section 810.2 of title 10, Code of Federal Regulations, except activities that require a specific

authorization; and (2) that the Secretary determines the transfer or retransfer will not result in a significant increase of proliferation risk. The procedures may not apply to authorizations to transfer technology to China or Russia, and a transfer of a technology under the procedures to a country will not be inimical to the interest of the United States. The procedures must be developed with the concurrence of the Department of State, and in consultation with the Department of Defense (DOD), Department of Commerce, and NRC.

Section 4 of the legislation also requires the Comptroller General to study the Secretary's development of a retrospective risk formula to meet the requirements under the Convention on Supplementary Compensation for Nuclear Damage as required by the Energy Independence and Security Act of 2007.

B. H.R. 6378, Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018

The Subcommittee held a hearing on June 6, 2018, to review a discussion draft entitled "Pandemic and All-Hazards Preparedness Reauthorization Act of 2018," authored by Reps. Susan Brooks (R-IN) and Anna Eshoo (D-CA). On June 27, 2018, the Subcommittee on Health forwarded the discussion draft, as amended, by voice vote.

H.R. 6378, Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 was introduced on July 16, 2018 by Reps. Susan Brooks (R-IN), Anna Eshoo (D-CA), Greg Walden (R-OR), and Frank Pallone (D-NJ). The legislation will reauthorize key preparedness and response programs such as the Hospital Preparedness Program/ Healthcare Preparedness and Response Program, Temporary Reassignment of Federally Funded Personnel, the National Advisory Committee on Children and Disasters, and the Emergency System for Advanced Registration of Volunteer Health Professionals. It clarifies the use of the Public Health Emergency Fund and codifies the Public Health Emergency Medical Countermeasures Enterprise. It improves the ability of the Secretary of the Department of Health and Human Services (HHS) to fill intermittent Federal employee vacancies in National Disaster Medical System (NDMS) personnel to support preparedness for and response to threats and provides Public Safety Officer Benefit Act coverage for NDMS Employees. In addition, the legislation provides resources for the development of medical countermeasures for pandemic influenza and emerging infectious diseases within Biomedical Advanced Research and Development Authority (BARDA).

Section by Section

Sec. 1. Short title.

This section provides that the Act may be cited as the "Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018".

Sec. 2. Table of contents.

This section lists the table of contents.

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.

This section amends the duties and functions of the Assistant Secretary for Preparedness and Response (ASPR) to include carrying out drill and operational exercises related to pandemic influenza and the emerging infection disease program. Under current law, ASPR is required to develop a coordinated 5-year budget plan with respect to chemical, biological, radiological, and nuclear agents. This section amends current law to also require that budget to include research and development activities related to the BARDA pandemic influenza and the emerging infectious disease programs established in Sec. 302. This section also requires the ASPR to coordinate with the federal intelligence community to maintain a current assessment of national security threats and inform preparedness and response capabilities based on the range of the threats that have the potential to result in a public health emergency.

Sec. 102. Public health emergency medical countermeasures enterprise.

This section codifies the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). It designates the ASPR as the Chair and identifies the members and outlines the functions of the PHEMCE.

Sec. 103. National Health Security Strategy.

This section clarifies that the National Health Security Strategy should describe potential public health threats facing the nation and identify the processes to prepare to respond to such threats, consistent with other specified plans. The Strategy must include a description of the current public health workforce and its capabilities to improve medical surge capacity; considerations for zoonotic disease and disease outbreaks related to food and agriculture; and global health security and environmental hazards as they relate to domestic public health preparedness and response capabilities.

Sec. 104. Improving emergency preparedness and response considerations for children.

This section codifies and continues the work of the Children's Preparedness Unit at the Centers for Disease Control and Prevention (CDC) to ensure the needs of children are taken into consideration when preparing for and responding to public health emergencies.

Sec. 105. Reauthorizing the National Advisory Committee on Children and Disasters.

This section reauthorizes the National Advisory Committee on Children and Disasters — due to sunset September 30, 2018—to sunset on that date in 2023.

Sec. 106. National Disaster Medical System.

This section provides for direct hire authority, to sunset on September 30, 2021, in order to give the Secretary of Health and Human Services (HHS) more flexibility in hiring for the National Disaster Medical System (NDMS). It also includes greater flexibility in pre-positioning response teams in advance of a public health emergency. This section makes deployed NDMS personnel or their families eligible for Public Safety Officers Benefits (PSOB) for line-of-duty death or serious disability and reauthorizes the NDMS through 2023 at \$57,400,000 per year. Finally, this section requires a joint review of the NDMS and an assessment of medical surge capacity relating to the availability of public health workforce for both widespread and multiple public health emergencies at one time.

Sec. 107. Volunteer Medical Reserve Corps.

This section eliminates the provision in current law requiring the HHS Secretary to appoint a Director to oversee the Volunteer Medical Reserve Corps and reauthorizes the Corps through 2023 at \$6,000,000 per year.

Sec. 108. Continuing the role of the Department of Veterans Affairs.

Current law requires the VA to ensure that VA medical centers are ready to protect patients and staff from a public health emergency, participate in NDMS, develop and maintain a centralized system for tracking the current location and availability of pharmaceuticals, medical supplies, and medical equipment throughout the Department health care system in order to permit the ready identification and utilization of such pharmaceuticals, supplies, and equipment for response to a public health emergency. This section authorizes \$126,800,000 per year through fiscal year 2023 to carry out these provisions.

Sec. 109. Authorizing the National Advisory Committee on Seniors and Disasters.

This section establishes a National Advisory Committee on Seniors and Disasters to provide advice a regarding State emergency preparedness and response activities for seniors and provide input with respect to the medical and public health needs of seniors related to all-hazards emergencies.

Sec. 110. National Advisory Committee on Individuals with Disabilities in All-Hazards Emergencies.

This section establishes a National Advisory Committee on Individuals with Disabilities to provide advice a regarding State emergency preparedness and response activities for disabled individuals and provide input with respect to the medical and public health needs of the disabled community related to all-hazards emergencies.

Sec. 111. Consideration for at-risk individuals.

This section updates and aligns the term “at-risk individual” across the PAHPA framework to improve considerations, ensure consistency in considerations, and provide clarity throughout the framework.

Sec. 112. Public health surveillance.

This section incorporates public health surveillance into the National Health Security Strategy and requires that the surveillance capacity include emerging threats to pregnant and postpartum women and infants, including through monitoring birth defects, developmental disabilities, and other short-term and long-term adverse outcomes.

Sec. 113. GAO study and report on disaster medical assistance teams.

This section requires the Government Accountability Office (GAO) to assess the current mission readiness of ASPR’s disaster medical assistance teams (DMAT) to ensure sustained effective emergency response to current and emerging threats – natural and manmade.

Sec. 114. Military and civilian partnership for trauma readiness grant program.

This section establishes a grant program for military-civilian partnerships in trauma care that will allow both sectors to benefit from the others’ expertise and experience. The grants will help develop integrated, permanent joint civilian and military trauma system training platforms to create and sustain an expert trauma workforce between periods of active combat.

Sec. 115. Improvement of loan repayment program for prevention activities.

This section reinstates loan repayment authority for the Centers of Disease Control and Prevention (CDC) to improve postdoctoral programs that train public health responders and leaders, such as the Epidemic Intelligence Service (EIS). These public health leaders are needed to mount successful responses to bioterror attacks, infectious diseases outbreaks and other public health emergencies.

Sec. 116. Report on adequate national blood supply.

This section requires the HHS Secretary to submit to Congress a report containing recommendations related to maintaining an adequate national blood supply, including challenges associated with continuous recruitment of blood donors, ensuring adequacy of blood supply in the case of public health emergencies, and implementation of safety measures and innovation.

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

Sec. 201. Public health emergencies.

This section improves the existing Public Health Emergency Fund (PHEF) by identifying key authorities for which PHEF dollars may be used in the context of immediate support for the response activities for a public health emergency or prior to a potential public health emergency. This section requires the HHS Secretary and the GAO to conduct a review of the PHEF, including policies that may be needed to improve the PHEF and the resources available in such fund and the ability to use such resources during a public health emergency. This section also extends the authorization for the temporary reassignment of personnel during a public health emergency through 2023.

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

This section reauthorizes the CDC Public Health Emergency Preparedness (PHEP) cooperative agreement through 2023 at \$670,000,000 per year. This section also requires states to prioritize nursing homes in All-Hazards Public Health Emergency Preparedness and Response Plans, and to include in those plans information on how utilities plan to ensure that nursing homes return to functioning as soon as practicable following a disaster.

Sec. 203. Strengthening the hospital preparedness program.

Changes the title of “Hospital Preparedness Program” to the “Healthcare Preparedness and Response Program” and in order to better support preparedness efforts and capabilities at the local level, this section amends current law to add coalitions, state hospital associations, and health systems as eligible entities for partnership awards, allows grantees to use funds for healthcare surge capacity response activities, and expands the withholding period for failure to reach benchmarks from one year to two years to allow time to repurpose funds.

Sec. 204. Improving benchmarks and standards for preparedness and response.

This section requires an evaluation of existing performance measures, benchmarks and standards for the Public Health Emergency Preparedness cooperative agreement program and the Healthcare Preparedness and Response Program. The evaluation is to be submitted to the congressional committees of jurisdiction together with the National Health Security Strategy.

Sec. 205. Authorization of appropriations for revitalizing the Centers for Disease Control and Prevention.

This section reauthorizes the biosurveillance and other preparedness capabilities of the CDC at \$161,800,000 per year through 2023.

Sec. 206. Authorization of appropriations for Emergency System for Advanced Registration of Volunteer Health Professionals.

This section extends the authorization of Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP) at \$5,000,000 per year through 2023.

Sec. 207. Regional health care emergency preparedness and response systems.

This section requires the ASPR to develop guidelines to inform regional systems of hospitals, health care facilities, and public health facilities of varying levels of capabilities to treat patients affected by chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, and improve medical surge capabilities and capacity. This section also permits the ASPR to establish a demonstration program to improve medical surge capacity, build and integrate regional medical response capabilities, improve specialty care expertise for all-hazards response, and coordinate medical preparedness and response across State, local, tribal, territorial, and regional jurisdictions. Finally, this section requires the GAO to report within two years on the progress made towards the implementation of the guidelines by health care facilities and hospitals and requires subsequent recommendations to address challenges faced during implementation.

Sec. 208. National Academy of Medicine evaluation and report on the preparedness of hospitals, long-term care facilities, dialysis centers, and other medical facilities for public health emergencies.

This section requires the HHS Secretary to enter into an arrangement with the National Academy of Medicine to evaluate the preparedness of hospitals, long-term care facilities, dialysis centers, and other medical facilities nationwide for public health emergencies, including natural disasters.

Sec. 209. Limitation on liability for volunteer health care professionals.

This section protects a health care professional from liability for harm caused by any act or omission if: (1) the professional is serving as a volunteer in response to a disaster and (2) the act or omission occurs during the period of the disaster, in the professional's capacity as a volunteer, and in a good faith belief that the individual being treated is in need of health care services.

TITLE III—ACCELERATING MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

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

This section codifies ASPR's role in coordinating the operation of the Strategic National Stockpile (SNS) with the CDC and authorizes funding for the SNS at \$610,000,000 per

year through fiscal year 2023. It authorizes \$7,100,000,000 in funding for the Bioshield Special Reserve Fund for fiscal years 2019 through 2028 and allows for funds to be provided by advance appropriations at a rate of not less than \$710,000,000 per year. This section also requires the Secretaries of HHS and Department of Homeland Security (DHS) to notify the Health, Education, Labor and Pensions Committee of the Senate, the Security and Government Affairs Committee of the Senate, and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives of the material threat list on an annual basis, and promptly notify Congress each time there is a change to the threats on the list.

Sec. 302. Biomedical advanced research and development authority.

This section provides authorities for the Director of the Biomedical Advanced Research and Development Authority (BARDA) to develop strategic initiatives for threats that pose a significant level of risk to national security, including antimicrobial resistant pathogens. This section grants BARDA other transactional authority (that is, authority to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects) similar to the Department of Defense and authorizes \$536,700,000 in funding per year for BARDA through fiscal year 2023. In addition, this section establishes a Pandemic Influenza Program at BARDA to support research and development activities to enhance a rapid response to pandemic influenza at \$250,000,000 in funding per year through fiscal year 2023. Finally, this section establishes an Emerging Infectious Disease Program at BARDA to support research and development activities with respect to an emerging infectious diseases at \$250,000,000 per year through fiscal year 2023.

Sec. 303. Report on the development of vaccines to prevent future epidemics.

This section requires the HHS Secretary to submit to Congress a report detailing the activities carried out by the Department to support the development of vaccines to prevent future epidemics, including work carried out through domestic and global public-private partnerships and other collaborations intended to spur the development of such vaccines.

TITLE IV—MISCELLANEOUS PROVISIONS

Sec. 401. Cybersecurity.

This section amends a provision in current law to require that the next version of the National Health Security Strategy address cybersecurity threats. This section also designates the ASPR as the lead role in HHS for ensuring the ability of the health care sector to provide continuity of care during a cybersecurity incident.

Sec. 402. Miscellaneous FDA amendments.

This section makes technical corrections and provides that when publishing information about qualified drug development tools—such as biomarkers and animal models—as

required by law, the Food and Drug Administration (FDA) shall not disclose information that would compromise national security.

Sec. 403. Formal strategy relating to children separated from parents and guardians as a result of zero tolerance policy.

This section requires the ASPR to submit to the House Energy and Commerce Committee a formal strategy to reunify children who, as a result of the “zero tolerance” policy, were separated from their parent or guardian and placed into a facility funded by HHS, and to address deficiencies identified by the previous work of the Committee, which began in 2014, regarding the oversight of, and care for, unaccompanied alien children in the custody of the Department.

Sec. 404. Biological threat detection.

This section codifies the joint HHS-Department of Homeland Security biosurveillance program known as Biowatch. It allows for the exchange of information and technology between agencies and authorizes the two departments to make recommendations regarding research, development, and procurement biological threat detection systems. In addition, this section requires the development of guidelines for biological threat detection systems at the local level.

Sec. 405. Strengthening Mosquito Abatement for Safety and Health.

This section authorizes grants for mosquito control programs and reauthorizes CDC’s Epidemiology-Laboratory Capacity Grants at \$40,000,000 per year through fiscal year 2023.

Sec. 406. Additional strategies for combating antibiotic resistance.

This section codifies the Advisory Council on Combating Antibiotic-Resistant Bacteria, originally established by Executive Order 13676 in 2014, which will provide advice, information, and recommendations to the HHS Secretary regarding programs and policies intended to combat antibiotic-resistant bacteria.

Sec. 407. Additional purposes for grants for certain trauma centers.

This section updates previously authorized trauma center federal grant programs and furthers the core missions of trauma centers by permitting funding to be used to support essential personnel, costs associated with patient stabilization and transfer, coordination with local and regional trauma systems, surge capacity, and trauma education and outreach.

III. STAFF CONTACTS

If you have any questions regarding this markup, please contact Karen Christian of the Committee staff at (202) 225-2927.