MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Health Subcommittee Hearing on June 13, 2023

The Subcommittee on Health will hold a hearing on June 13, 2023, at 10:30 a.m. (ET) in 2322 Rayburn House Office Building. The hearing is entitled "Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security Threats."

I. Witnesses

Panel I

- **Dr. Gerald Parker, DVM, PhD,** Associate Dean for Global One Health and Director for the Pandemic and Biosecurity Policy Program, Texas A&M University
- **Dr. Raynard Washington, PhD, MPH,** Director, Public Health Department, Mecklenburg, County Health and Human Services Agency Mecklenburg County, North Carolina
- **Ms. Phyllis Arthur, MBA,** Senior Vice President, Infectious Disease and Emerging Science Policy, Biotechnology Innovation Organization (BIO)
- **Dr. Julie R. Gralow, MD, FACP, FASCO,** Chief Medical Officer and Executive Vice President, American Society of Clinical Oncology
- **Mr. Ted Okon, MBA,** Executive Director, Community Oncology Alliance

II. Background

On May 11, 2023, the Subcommittee on Health held a bipartisan hearing titled "Preparing for and Responding to Future Public Health Security Threats." Witnesses, including Dawn O'Connell, Assistant Secretary for Preparedness and Response (ASPR), Director Rochelle P. Walensky, Centers for Disease Control and Prevention (CDC), and Robert M. Califf, Commissioner, Food and Drug Administration (FDA), as well as advocates, stakeholders, and other experts discussed the background, history, and current state of our nation's preparedness and response infrastructure, lessons learned based on prior public health emergencies and threats, and recommendations for how to improve our preparedness and response against all-hazards moving forward.

The Pandemic and All-Hazards Preparedness Act (PAHPA)[1] was first signed into law in 2006 to improve the nation's health security and advance U.S. public health and medical

[1] P.L. 109-417.

preparedness and immediate response capabilities for a range of public health security threats, whether deliberate, accidental, or natural. With the backdrop of the 9/11 terrorist attacks, anthrax threats, avian influenza, H5N1, and Hurricanes Katrina and Rita, Congress advanced PAHPA with the intent to protect the nation from chemical, biological, radiological, and nuclear (CBRN) threats. Under this framework, PAHPA authorized many of the federal government's biodefense and pandemic preparedness programs, including the ASPR, the National Health Security Strategy (NHSS), and the Biomedical Advanced Research and Development Authority (BARDA).

PAHPA was reauthorized in 2013[2] and 2019[3] with bipartisan support. Each reauthorization incorporated lessons learned from prior public health emergency responses, including the H1N1 pandemic, Ebola virus outbreak, and Zika virus epidemic. Both reauthorizations continued to advance an all-hazards approach to the medical and public health preparedness and response framework. These reauthorizations established and enhanced many other federal emergency response programs, including the Strategic National Stockpile (SNS), the Project BioShield Special Reserve Fund (SRF), Public Health Emergency Preparedness (PHEP) cooperative agreements, and the Hospital Preparedness Program (HPP), as well as codified the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

The Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT) was signed into law as part of the Consolidated Appropriations Act, 2023.[4] While it did not reauthorize PAHPA authorities, it did take important steps forward to address and update the all-hazards preparedness and response framework based on lessons learned from the COVID-19 response.

A number of authorities and grant programs provided in PAHPA are set to expire at the end of September 2023.

III. Legislation

H.R. __, To reauthorize certain programs under the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes. (Rep. Richard Hudson)

This discussion draft would reauthorize current programs to support public health security and all-hazards response, including the SNS, BARDA, and PHEMCE. Generally, programs are reauthorized for five years at fiscal year (FY) 2023 appropriated levels. The discussion draft also includes revisions to the National Advisory Committees on Disasters, including the National Advisory Committee on Children and Disasters, National Advisory Committee on Seniors and Disasters, and the National Advisory Committee on Individuals with Disabilities and Disasters to streamline the reauthorization process and incorporate increased expert stakeholder perspectives.

[2] Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), P.L. 113-5.
[3] Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA), P.L. 116-22.

[4] P.L. 117-328.

H.R. __, the Public Health Guidance Transparency and Accountability Act (Rep. Cathy McMorris Rodgers)
This discussion draft would establish public participation requirements prior to finalization or implementation of guidance developed, issued, disseminated, and utilized by the CDC. It would ensure CDC guidance does not create, restrict, or revoke any person's rights, responsibilities, or liabilities. Additionally, the text clarifies that CDC guidance is nonbinding and does not have the force or effect of the law.

H.R. __, the PHEMCE Advisory Committee Act (Rep. Richard Hudson)
This discussion draft would establish a PHEMCE Advisory Committee to provide a forum for external private sector partners and stakeholders with expertise in divergent threat portfolios to facilitate increased communication and transparency among stakeholders, the public, and other PHEMCE members, as well as provide input into the existing PHEMCE planning and decision-making processes regarding medical countermeasures development, procurement, and distribution of and against chemical, radiological, biological, and nuclear threats.

H.R. __, the PHE Congressional Review Act of 2023 (Reps. Greg Murphy and Brett Guthrie)
This discussion draft would establish a Congressional review process, similar to that established under the National Emergency Act, in which, not later than six months after a declared Public Health Emergency (PHE), Congress may meet and vote on whether or not to terminate the public health emergency.

H.R. __, the Improving Contract Transparency for the SNS Act (Rep. Morgan Griffith)
This discussion draft provides a 90-day notice requirement to both Congress and the impacted vendor for any modifications, renewals, extensions, or terminations of a procurement contract for products, devices, and supplies for the Strategic National Stockpile. The text also provides a base timeline for such procurement contracts.

H.R. __, the Improving Contract Transparency at BARDA Act (Rep. Morgan Griffith)
This discussion draft requires a 90-day notice requirement to the impacted vendor for any modifications, renewals, extensions, or terminations of contracts, grants, cooperative agreements, or other transactions entered into with BARDA. The text also provides a base timeline for such contracts.

H.R. __, the Biosecurity Infrastructure for Operational (BIO) Early Warning Act (Reps. Dan Crenshaw and Scott Peters)
This discussion draft would provide additional responsibilities and duties to the ASPR regarding disease detection, including requiring the ASPR to develop an annual Early Warning and Disease Detection Strategy and Implementation Plan, as well as a new grant program to implement the plan. It also requires the National Health Security Strategy (NHSS) to include a biological attribution strategy and requires the U.S. Department of Health and Human Services (HHS) to

ensure availability of certain products and technologies related to the safe collection, storage, and transportation of biological hazards.

H.R. 3813, the CDC Leadership Accountability Act (Rep. Brett Guthrie)
H.R. 3813 would require any Director of the Centers for Disease Control and Prevention appointed by the President on or after June 1, 2023, to be confirmed by the Senate.

H.R. 3631, the State Strategic Stockpile Act of 2023 (Reps. Buddy Carter and Chrissy Houlahan)
H.R. 3631 would extend the authorization of appropriations for grants for State Strategic Stockpiles from FY 2024 to FY 2028.

H.R. 3577, the Medical and Health Stockpile Accountability Act of 2023 (Reps. Richard Hudson and Josh Gottheimer)
H.R. 3577 would establish an automated supply chain tracking application to provide near real-time insight into the amount of medical and health supplies available in the Strategic National Stockpile and related entities during a public health emergency.

H.R. 3837, the Improving Public Health Preparedness Act (Rep. Mariannette Miller-Meeks)
H.R. 3837 would require the Secretary of HHS to delegate primary responsibility for administering and maintaining the SNS to ASPR, further codifying the principal responsibilities ASPR has today.

H.R. 3832, the Disease X Act of 2023 (Reps. Lori Trahan, Michael Burgess, Dan Crenshaw, and Susie Lee)
H.R. 3832 would allow BARDA to support advanced research and development of certain countermeasures related to emerging viral pathogens and viral families with significant pandemic potential ("Disease X" threats).

H.R. 3613, the Doctors at the Ready Act (Reps. Kim Schrier and Bill Johnson)
H.R. 3613 would eliminate the sunset on direct hiring authority for the HHS Secretary to appoint personnel to the National Disaster Medical System during a public health emergency.

H.R. 2416, To amend the Public Health Service Act to reauthorize a military and civilian partnership for trauma readiness grant program. (Reps. Michael Burgess and Kathy Castor)
H.R. 2416 would reauthorize the "Military Injury Surgical Systems Integrated Operationally Nationwide to Achieve ZERO Preventable Deaths Act, or "Mission ZERO" Act, a military and civilian partnership for trauma readiness grant program, for fiscal years 2024 through 2028. The program provides grants for eligible trauma systems and centers to incorporate full military trauma teams or individual military trauma providers into their hospitals.

H.R. 3840, the Ensuring Sufficient Supply of Testing Act (Reps. Neal Dunn and Debbie Dingell)
H.R. 3840 would authorize clinical laboratories to enter into certain contracts and cooperative agreements related to vendor-managed inventory and warm-based surge capacity to meet the needs of the SNS.

H.R. 3795, To amend the Public Health Service Act to require the development of a diagnostic testing preparedness plan to be used during public health emergencies, and for other purposes. (Reps. Greg Pence, Kim Schrier, Larry Bucshon, and Andre Carson)
H.R. 3795 would require ASPR to develop a public plan for rapid development, authorization, scaling, procurement, and distribution of diagnostics and clinical diagnostic laboratory testing capacity during a public health emergency, including opportunities to facilitate coordination and collaboration between government agencies and private sector partners. ASPR would be required to submit a report to Congress on the effectiveness of activities implemented under the plan within one year after implementation.

H.R. 3703, the Helping Evaluate Appropriate Logistical Infrastructure for National Government (HEALING) Response Act of 2023 (Reps. Bob Latta and Robin Kelly)
H.R. 3703 would require the U.S. Comptroller General to review and issue recommendations regarding the current status of existing efforts and programs rapidly to produce medical countermeasures domestically, including the Centers for Innovation and Advanced Drug Manufacturing, the National Biopharmaceutical Manufacturing Partnership, and Industrial Base Expansion Connect.

H.R. 3742, To direct the Comptroller General of the United States to evaluate the Federal Government's collection and sharing of public health data to respond to public health emergencies. (Reps. Scott Peters and Brett Guthrie)
H.R. 3742 would direct the U.S. Comptroller General to review the current authorities, policies, and operational tools used by the Secretary of HHS to collect and share public health data, including how these authorities were used during the COVID-19 public health emergency; how federal funds were expended for such purposes; any challenges posed by redundant and duplicative data reporting requirements, systems, and tools and any publicly available resources to track how this data is collected, shared, and utilized.

H.R. 3820, To amend the Public Health Service Act to strike the requirement that the Director of the Centers for Disease Control and Prevention be appointed by and with the advice and consent of the Senate (Rep. Frank Pallone, Jr.)
H.R. 3820 would remove the requirement for a Director of CDC to be appointed by the President to be confirmed by the Senate. Under current law, this requirement would take effect January 1, 2025.

H.R. 3794, the Fast-Track Logistics for Acquiring Supplies in a Hurry (FLASH) Act of 2023 (Rep. Robert Garcia)
H.R. 3794 would authorize certain contracting and transaction authorities for HHS to purchase, procure, and acquire medical countermeasures, designs, products, services, processes, methods, and other supplies.

H.R. 3791, the Improving Data Accessibility Through Advancements (DATA) in Public Health Act (Reps. Lauren Underwood, Ami Bera, Kathy Castor, and Rosa DeLauro)
H.R. 3791 would authorize the CDC to require reporting of public health and health care data and information from health care providers and facilities, including pharmacies; public health, clinical, and other laboratories and diagnostic testing entities; state, local, and tribal health departments; and other entities. It would also require CDC to designate certain standards and implementation requirements for the exchange of electronic health information and electronic reporting. Additionally, this bill creates a Public Health Information Sharing and Availability Advisory Committee to make recommendations on effective health care data and information reporting and sharing, and establishes a grant program to develop and facilitate best practices for the collection and use of public health data and standards.

IV. Staff Contacts

If you have questions regarding this hearing, please contact Molly (Brimmer) Lolli of the Committee staff at 202-225-3641.