THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE

Testimony before the
House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

Hearing on the FY 2024 Budget Request for the National Institutes of Health, Centers for Disease Control and Prevention, and the Administration for Strategic Preparedness and Response

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Chair Aderholt, Ranking Member DeLauro, and distinguished members of the Subcommittee, it is an honor to testify before you today on the Fiscal Year (FY) 2024 President's Budget request submitted by the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR).

ASPR is working on more high-consequence, no-fail missions than ever before. We are living in an increasingly interconnected world where diseases and other threats can travel quickly, unnoticed for days. With infectious disease outbreaks becoming more frequent, we are also experiencing an increase in the frequency and intensity of natural disasters. To keep up with the evolving threat landscape, ASPR must remain nimble and ever vigilant while learning from each response it leads. I am grateful for the strong Congressional support we receive for the work that we do, but there are three key problems I am trying to solve through our budget request.

The first is how ASPR can maintain the capabilities built and used extensively during the COVID-19 pandemic as supplemental COVID-19 funds are exhausted. We know some capabilities—like ASPR's industrial base management and supply chain work—will be important to prevent shortages of critical supplies during our next response. With significant supplemental investments provided during the COVID-19 response, ASPR has built a program to ensure we have COVID-related personal protective equipment (PPE) and critical supplies manufactured in the United States moving forward. We have also invested in capabilities to ensure we have visibility into the supply chain for those supplies. These efforts, however, are funded with COVID-19 dollars. In FY24, we are seeking funding to move this important capability to annual funds, which will allow us to use them in future responses and apply them to supplies other than those needed to respond to COVID-19. We have asked for funding to sustain this work as part of our $400 million request for Pandemic Preparedness and Biodefense.

A second problem I am trying to solve through our FY24 request is how we can be more prepared for the next pandemic. We were able to move out so quickly with countermeasures against COVID-19 because of past investments in coronavirus research and development due to prior outbreaks of SARS and MERS. We know the seven viral families most likely to cause a pandemic. While we have time, it is important to get the same head start on these viruses as we had on coronaviruses. With enough funding, we can develop vaccine, therapeutic, and diagnostic prototypes that can be pulled off the shelf whenever one of these viruses with high pandemic potential emerges. The Department's FY24 request includes $20 billion to support pandemic preparedness, of which about $10.5 billion would come to ASPR to begin work against these viral families. Also, the $400 million Pandemic Preparedness and Biodefense request will also ensure we have ready resources to immediately scale up manufacture of those prototypes when we have the first indication of an outbreak.

The third problem that I am trying to solve with our FY24 budget request is how to ensure that we have the increased funding needed to support ASPR as its overall responsibilities and programs continue to grow. As many of you are aware, in the summer of 2022, ASPR was designated an Operating Division—or agency—within HHS. ASPR now has the independence to build human resources, contracting, and finance capabilities to meet our unique mission and respond to whatever public health emergency or disaster is at hand. The FY24 budget requests an

additional $35 million in Operations to start building out our acquisitions and IT workforce—two functions critically important to our success as a response organization.

While I have focused specifically on three of the problems our FY24 request is trying to solve, our overall request directly supports ASPR's mission to help the country prepare for, respond to, and recover from public health emergencies and disasters.

Overview of ASPR's FY24 Funding Request

ASPR is responsible for many aspects of our country's preparedness and response infrastructure. ASPR leads the development, acquisition, and stockpiling of medical countermeasures (MCMs), such as vaccines, therapeutics, PPE, medical devices, and other resources needed during public health emergencies, and is working to prepare for future emergencies by expanding and sustaining the requisite industrial base. ASPR also deploys National Disaster Medical System (NDMS) response teams to states and territories during or following disasters to bolster the local response. ASPR helps prepare the health care sector for emergency events through the Health Care Readiness and Recovery (HCRR) program and safeguards it against cyber threats through its role as the Sector Risk Management Agency. Also, through the Medical Reserve Corps (MRC), ASPR supports the mobilization of volunteer units to assist in communities' public health needs, such as vaccination clinics, blood donations, and more.

Given the significant work for which ASPR is responsible, I am pleased to present the discretionary FY 2024 President's Budget request for ASPR is **$4,271,913,000**, which is $642,236,000 above FY 2023 enacted. The President's Budget also proposes $20 billion in HHS-wide mandatory pandemic preparedness funding, of which $10.5 billion would support ASPR activities. Today, I will take a few minutes to highlight a few of the key requests and provide details on how funds would be used to strengthen operational capabilities.

Biomedical Advanced Research and Development Authority
Having MCMs ready in a public health crisis requires long-range investment in the research and development of highly specialized products. ASPR, through the Biomedical Advanced Research and Development Authority (BARDA), works with both public and private sector partners to support the advanced research, development, regulatory authorization, and procurement of life-saving medical products—drugs, vaccines, therapeutics, diagnostics, and medical devices.

BARDA's advanced research and development program bridges gaps in national preparedness that no other federal agency does. BARDA supports and invests in the late stages of development that are necessary to reach authorization of medical products to address chemical, biological, radiological, and nuclear (CBRN) threats, emerging infectious diseases, pandemic influenza, and the growing public health threat of antimicrobial resistance.

To date, BARDA's efforts have led to 70 FDA licensures, approvals, and clearances of MCMs. Through investments in innovation, future products developed by BARDA have the potential to revolutionize emergency response and basic health care for all Americans.

The FY 2024 President's Budget requests over $1 billion for BARDA, or $65 million above FY 2023 enacted, to develop innovative vaccines and therapeutics, as well as non-

pharmaceutical interventions that protect Americans from health security threats. With the requested funding, BARDA will continue to invest in MCMs to prepare and respond to CBRN threats through the development of vaccines and therapeutics.

In addition to funding CBRN investments, the FY 2024 President's Budget provides $375 million for the Pandemic Influenza program at ASPR, which BARDA will use to implement an end-to-end strategy to prepare for the next influenza pandemic by supporting the development, authorization, and manufacturing of better diagnostics and treatments to prevent and respond to seasonal and pandemic influenza. The influenza MCM program supports the formulation and development of alternative vaccine delivery methods for flu vaccines that do not rely on an egg supply, as well as faster platforms, more sustainable approaches for vaccine and therapeutic development, and the expansion of national flu vaccine manufacturing capacity.

Pandemic Preparedness and Biodefense
The $400 million requested in FY24 for Pandemic Preparedness and Biodefense will ensure we are able to quickly respond to emergent pathogens with pandemic potential. The request would enable ASPR to rapidly close critical gaps identified during the acute phase of response and accelerate progress within long-term programs while mitigating impacts to other programs. The requested funding would accelerate advanced development and additional manufacturing of medical countermeasures for clinical trials and, when appropriate, patient care as part of an emergency response. During the recent Ebola Sudan outbreak in Uganda and ongoing Marburg outbreaks in Equatorial Guinea and Tanzania, ASPR had to reallocate funding planned for the advanced development of antimicrobials as well as chemical, radiological, and nuclear MCMs to quickly ramp up manufacturing of investigational vaccines and therapeutics. Similarly, during the mpox response, ASPR delayed Rad/Nuc investments to accelerate the fill-finish of the JYNNEOS vaccine. With the $400 million requested, ASPR would be able to accelerate delivery of medical countermeasures in response to an outbreak without delay and with minimal impact to other priory threat areas. In addition, these funds will ensure that we are able to continue supporting our industrial base management and supply chain work and continue to onshore key components of the medical countermeasure supply chain.

Strategic National Stockpile
The Strategic National Stockpile (SNS) manages and delivers lifesaving MCMs when and as needed during public health emergencies and disasters. The SNS is the largest federally owned repository of pharmaceuticals, critical medical supplies, federal medical stations (FMS), and medical equipment available for rapid delivery to support federal, state, and local responses to health security threats.

In the past few years, the SNS has supported several important response efforts. Throughout the COVID-19 response, the SNS has been on the front lines of distributing PPE and other critical supplies to states that need them. During the first six weeks of the COVID-19 pandemic, the SNS deployed 90 percent of its PPE to help frontline health care workers across the United States. In addition to PPE, the SNS deployed thousands of ventilators to help treat critically ill patients and all 32 of the SNS's federal medical stations to provide surge capacity when hospitals ran out of beds. In the summer and fall of 2021, the United States saw a surge of COVID-19 cases and hospitalizations related to the Delta variant. Using medical material procured during the

pandemic, the SNS responded to this uptick in cases by deploying 2,919 ventilators and 1,279 high flow nasal cannulas. The SNS also supported the national COVID-19 vaccination efforts, including the vaccine distribution process through procuring PPE, supporting testing, and distributing ancillary supplies for vaccination.

In addition to supporting the ongoing COVID-19 response, the SNS provided critical vaccines and therapeutics to help stem the mpox outbreak that began last year and deployed Tamiflu to states that needed additional courses to treat flu during the surge of RSV and flu cases this winter. The SNS also provided FMS capabilities to support deployed deployed NDMS teams as they responded to hurricanes and other natural disasters throughout 2022.

The FY 2024 President's Budget requests $995 million for the SNS, an increase of $30 million above FY 2023 enacted. These funds will ensure the SNS's assets are available and ready to protect America from 21st century health threats in FY 2024. The increased funding will be used to sustain current product lines and to procure targeted countermeasures previously supported by BARDA that lack a significant commercial market.

HHS Coordination Operations and Response Element
Last year, HHS successfully transitioned the operations and logistics capability that the Department of Defense (DoD) brought to Operation Warp Speed (OWS) into ASPR's HHS Coordination Operations and Response Element (H-CORE). With funding provided in the Consolidated Appropriations Act, 2023, H-CORE is now formally established within ASPR as a permanent logistics and operations hub.

H-CORE has incorporated early lessons learned during the COVID-19 response and has been able to quickly pivot to support the distribution of dozens of vaccines and therapeutics, based on new scientific data and an ever-changing virus, to ensure that those who need COVID-19 countermeasures have access to them. With its partners, H-CORE stood up innovative new models for equitably delivering preventative measures like test kits and masks to the American public.

The FY24 President's Budget requests $83 million for H-CORE, an increase of $8 million above FY 2023 enacted. This funding will support critical data collection and management systems, staff with scientific, contracting, operational, and other expertise, and will be used for logistics and operational needs across ASPR and the Department.

National Disaster Medical System
Last year, ASPR successfully executed one of the largest deployments of personnel and equipment of the past five years in support of a hurricane. ASPR deployed ten NDMS teams, with hundreds of additional incident management, logistical, and regional staff, supporting seven free-standing emergency room sites around Florida in the aftermath of Hurricane Ian. Throughout 2022, ASPR's NDMS teams provided care for over 4,000 patients in need across the United States.

The FY 2024 President's Budget requests an increase of $33 million dollars above FY 2023 enacted, for a total of $130 million. This increase in funding will provide expanded personnel

recruitment and training, continue the Pediatric Disaster Care Program, and maintain NDMS equipment prepared for immediate deployment in the event of a disaster.

Health Care Readiness and Recovery
ASPR's Health Care Readiness and Recovery (HCRR) portfolio invests in programs and activities that strengthen health care entities on the local and regional levels to provide innovative, coordinated, and lifesaving care in the face of emergencies and disasters.

Recent events, such as the COVID-19 pandemic, revealed critical gaps in the nation's health care preparedness and response infrastructure, demonstrating the need to support care delivery and improve coordination between different levels of care to improve patient outcomes and eliminate preventable deaths. The HCRR budget line's portfolio focuses on building emergency preparedness capabilities throughout the health care delivery system, and as a result, is uniquely positioned to address many of these challenges.

The FY24 President's Budget requests $312 million for HCRR, an increase of $7 million from FY 2023 enacted. Of those funds, $29 million will be used to support the National Special Pathogen Service Care Strategy, with $21 million dedicated to expanding the Regional Ebola and other Special Pathogen Treatment Centers network to reach 15 total operational sites, and $8 million for the National Emerging Special Pathogens Training and Education Center program. The budget would also provide $240 million in funding for Hospital Preparedness Program (HPP) cooperative agreements with states and territories throughout the United States.

Operations
Our request also supports our transition to an Operating Division while ensuring ASPR can continue to rapidly respond to new and emerging threats going forward. The FY24 President's Budget requests $69.8 million to support these efforts.

Funds will support enhancing and sustaining ASPR's contracting capabilities. Throughout the COVID-19 response, ASPR relied on assisted acquisitions support from DoD. That relationship is set to expire at the end of FY23. ASPR needs to be able to absorb the work that DoD handled for ASPR, as well as continue to perform the standard contracting work ASPR manages on a day-to-day basis. In FY22, for example, ASPR executed over 1,500 contract actions and obligated over $4.1 billion. ASPR accomplished this with a much smaller number of acquisitions specialists than are employed by other similarly situated agencies, such as the Federal Emergency Management Agency (FEMA) and the Defense Logistics Agency. The FY24 budget request will support the building out of ASPR's workforce to continue this work internally.

The requested funding will also ensure ASPR has appropriate financial experts and subject matter experts onboard to support the mission. Additional staff will ensure adequate capacity for formulation, execution, monitoring, and funds control of ASPR's financial resources.

Our FY24 budget request for Operations also includes support for ASPR's information technology infrastructure. Now that ASPR is an Operating Division, it must purchase several tools and applications it used to receive through the Office of the Secretary, as well as hire full-time employees, to support implementation and overall management of such systems. The

requested funding will also ensure ASPR is able to perform cyber risk assessments to ensure compliance with federal and departmental mandates.

Conclusion

I have laid out some of the problems we are trying to solve through ASPR's FY24 budget request. I have also offered examples of why this funding is needed to support our many nationally important programs and staff. Thank you again for inviting me to testify before you on the FY24 President's Budget request for ASPR and how funding will enhance overall operations and preparedness for future public health and medical incidents. I look forward to answering your questions.