The Honorable Cathy McMorris Rodgers

1. HHS's leadership and coordination of public health emergencies has been placed on GAO's high-risk list. What are ASPR's specific priorities and planned actionable items to address the concerns raised by GAO to ensure our nation is more prepared for future public health emergencies than we were for the COVID-19 pandemic and prior threats?

   Response: ASPR has taken several steps over the last two years to strengthen HHS's coordination of public health emergencies, including adding the operational and logistics components of Operation Warp Speed to ASPR in the form of the HHS Coordination Operations and Response Element (H-CORE); becoming a stand-alone agency within the Department, which gives ASPR the independence to build out the human resources and acquisitions functions a resilient response organization requires; and relaunching the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), an interagency coordination body that advises HHS on research, development, procurement, and stockpiling priorities needed to better protect the nation from future public health emergencies. Along with these important steps already taken, ASPR continues to focus on activities that address recommendations issued by GAO. ASPR has engaged with GAO to implement many of the recommendations issued under this high-risk area. As noted in the recently released 2023 High-Risk Series report, GAO has already closed around 40 percent of their recommendations made in this area based on the efforts made by HHS. ASPR will continue to coordinate with the HHS Assistant Secretary for Legislation and other HHS agencies to implement crosscutting GAO recommendations within this high-risk area to improve collaboration and coordination for future public health emergencies.

2. Please explain the process by which Biomedical Advanced Research and Development Authority (BARDA) engages with stakeholders through its TechWatch program, including answering the below questions.

   Response: BARDA's TechWatch meetings provide an opportunity for external organizations, including companies, academia, and non-profits, to meet with the federal government and present data related to their medical countermeasures (MCMs) in development, technology platforms, or manufacturing capabilities relevant to BARDA's public health security mission space. TechWatch meetings aim to help "accelerate success" and to better inform next steps for both the organization's product development program and for BARDA's benefit to clearly define the utility of the technology in addressing our mission priorities. TechWatch meetings include representatives from across federal government agencies, allowing organizations to get insight on how their solution could fit within the Government, provide access to other funding agencies if not a fit under BARDA priorities, and better prepare them for a formal proposal submission.

   Stakeholders can visit BARDA's website, https://medicalcountermeasures.gov/Request-BARDA-TechWatch-Meeting/, to request a TechWatch meeting. The website also includes information on the presentation requirements, the areas for which BARDA is actively assessing meeting requests, and more detailed information on the submission process. In short, meeting requests are submitted through our Stakeholder Portal, which are

then evaluated and prioritized based on their relevance to the areas BARDA is actively assessing for TechWatch meetings, and a notification is then sent on whether a meeting is granted.

a. What specific improvements has BARDA initiated to ensure TechWatch works as it was intended, particularly after the initial influx and resulting backlog in submissions and meeting requests?

Response: Significant TechWatch Program enhancements have occurred over the last decade to improve the request process. Most notably, a new TechWatch portal was launched in 2022 that simplified the meeting request process, provides enhanced and more detailed instructions on Product Description, Threat Readiness Level (TRL) determinations, and includes guidance on what to prepare for related to the slide presentation.

As of the hearing date, all TechWatch meeting requests submitted to the portal have been reviewed and a TechWatch meeting was held or scheduled, is in the scheduling queue, or was declined with an official email to the requestor indicating it was not selected for a TechWatch meeting.

b. What mechanisms and practices are currently in place for stakeholders and constituents to follow-up or monitor the status of an individual submission or initial meeting?

Response: The new TechWatch portal described above and launched in 2022 provides contact information for the individuals overseeing the TechWatch Program. These individuals are easily accessible and available to respond to questions regarding meeting requests. Additionally, stakeholders selected for a TechWatch meeting are sent an email that provides contact information to connect directly with TechWatch. This gives the opportunity for stakeholders to follow up on any matter related to the meeting request or preparations for the meeting.

c. What accountability measures currently exist to ensure TechWatch is operating as intended both during and outside a public health emergency?

Response: The launch of the new portal in 2022 along with the reorganization of TechWatch into a new Division of Management Operations within the Office of the Director of BARDA has ensured that the TechWatch Program is monitored on a more frequent basis. As noted above, all requests received as of the date of the hearing through the portal have received a response.

d. How does TechWatch prioritize the research and development of medical countermeasures (MCMs), including vaccines, therapeutics, diagnostics, and devices?

Response: The TechWatch meeting request review process assesses if an organization has a technology, platform, MCM candidate, or capability responsive to an open Area of Interest within the BARDA Broad Agency Announcement (BAA) or DRIVe EZ-BAA, if it aligns with the BARDA Strategic Plan, and if it is at a stage of development that aligns with the BARDA advanced development mandate.

TechWatch reviews meeting requests in the order they arrive and if a company is selected for a meeting it moves into the scheduling queue. BARDA does not prioritize one MCM (i.e., vaccine vs. therapeutic) over another.

For effective industry engagement, TechWatch is intentionally kept in a non-overlapping lane separate from the acquisition process to allow for an open and robust technical and strategic discussion between the organization and the U.S. government. As such, prioritization of MCM development is outside the scope of the TechWatch Program.

e. Please provide the following data:
   i. The number of submissions TechWatch has received since it started, broken down by fiscal year.

Response:

FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23
169	158	205	198	198	185	245	242	161	179	244	3931	718	250	131

   ii. The number of meetings TechWatch has taken since it started, broken down by fiscal year.

Response:

FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23
48	108	82	128	89	103	104	43	89	108	183	624	191	208	162

   iii. The average time between a stakeholder or constituent's initial submission, response from TechWatch, and the scheduling of an initial meeting.

Response: Typically, TechWatch meeting submissions are reviewed within 30 days of submission. During the process, BARDA contacts the submitters to set up a TechWatch meeting within an additional 30-60 days if the product, technology, or capability aligns with mission priorities.

3. Under the Consolidated Appropriations Act, 2023, Congress directed the creation of the White House Office of Pandemic Preparedness and Response Policy. This position will

be appointed by the President and serve as the principal advisor to the President on all issues related to pandemic and preparedness policy, including making recommendations and coordinating federal activities. The Director will also serve as Co-Chair of Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), alongside the current Chair, Assistant Secretary for Preparedness and Response (ASPR).

a. How do you see your role as ASPR interfacing and coordinating with the new Director, both as leads in our nation's pandemic preparedness and response efforts and as Co-Chairs of PHEMCE?

Response: As of the date of this hearing, the White House had yet to implement the new Office of Pandemic Preparedness and Response Policy. ASPR will continue coordination functions within HHS and among other parts of the U.S. government (USG). We look forward to having a strong partner in the White House to continue enhancing the USG's preparedness posture and to further facilitate implementation of national level strategies, including the National Biodefense Strategy and medical countermeasure coordination.

b. Currently, in the case of disagreement among PHEMCE members regarding recommendations, the HHS Secretary has final decision-making authority. Please explain any changes in this current chain of command, taking into account the Director is intended to have a direct line of communication to the President on issues related to pandemic and preparedness policy.

Response: Congress designated the ASPR and Office of Preparedness and Response Director as co-chairs of the PHEMCE, while preserving HHS's responsibility for resolving disagreements regarding recommendations. The PHEMCE will continue to identify national health security needs and assist the Secretary in developing strategies related to medical countermeasure preparedness and the Strategic National Stockpile. Likewise, the Secretary will continue to consider the PHEMCE's recommendations while exercising their independent statutory authority on these matters.

4. This past October, the Government Accountability Office (GAO) released a report titled "HHS Should Address Strategic National Stockpile Requirements and Inventory Risks." Among other findings, GAO found the Strategic National Stockpile (SNS) often did not have the recommended quantities of products in the SNS, and highlighted the failure to communicate this risk to partners, including Congress. A separate National Academies of Sciences, Engineering, and Medicine (NASEM) report, "Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise," also highlighted the need for increased and more effective collaboration with external public and private partners to improve our greater preparedness and response capabilities, and concluded that Congress should establish a mechanism for industry partner participation in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to solicit, inform and consider industry partner views. PHEMCE was originally codified under the 2019 PAHPA reauthorization to provide a forum and process by which federal entities could

provide input and recommendations to the HHS Secretary regarding the strategic national stockpile. Currently, there is no requirement for PHEMCE to solicit and consider input from industry partners, though there is one for state, local, tribal, and territorial public health departments.

a. Please explain specifically what ASPR is doing to address the concerns raised around the lack of communication with private partners and Congress to ensure that public-private partnerships continue to succeed and provide necessary medication, vaccines, therapeutics, and PPE for the nation.

Response: The PHEMCE is a collaboration of federal partners that have expertise in the different MCM functions that are necessary to ensure countermeasure availability to protect people during public health emergencies. PHEMCE members include the Director of the Centers for Disease Control and Prevention (CDC), Director of the National Institutes of Health (NIH), Commissioner of Food and Drugs, Secretary of Defense, Secretary of Homeland Security, Secretary of Agriculture, Secretary of Veterans Affairs, and the Director of National Intelligence. Members work together to advise the Secretary of HHS regarding MCM research and development, procurement, stockpiling, distribution, and utilization; identifying national health security needs; and developing strategies for logistics, deployment, distribution, and dispensing of countermeasures, particularly as it relates to the Strategic National Stockpile (SNS).

PHEMCE agencies continue to collaborate closely with industry partners. PHEMCE agencies have many channels that already exist to solicit information from industry partners. Industry, therefore, should contact those department/agencies specifically. For example, ASPR can be engaged in the following ways:

- Emailing: ASPRStakeholder@hhs.gov
- Reaching out to BARDA's Tech Watch Program: https://medicalcountermeasures.gov/request-barda-techwatch-meeting/
- Signing up for BARDA's collaboration portal here: https://bdr.hhs.gov/
- Participating in BARDA and/or SNS's industry days. 2022 websites found here: https://www.medicalcountermeasures.gov/barda/barda-industry-day-2022/ and https://access2success.hhs.gov/2022-sns-industry-day/. 2023 dates will be announced in the coming months.
- And for domestic manufacturing topics, ASPR created their newest stakeholder program – IBMSC's IBX Connect. More found here: https://aspr.hhs.gov/IBxConnect/Pages/default.aspx

The PHEMCE body itself is working with industry partners to determine the best cadence and topics for discussion. Much of the PHEMCE's work is classified and ASPR is working with key industry partners to determine best paths forward that will satisfy industry desires to know more about PHEMCE work while still adhering to all national security laws.

b. Please explain how ASPR currently engages and communicates with individual medical countermeasure product sponsors, stakeholders, and Congress.

Response: As noted above, ASPR engages with industry and private sector partners in a number of ways and encourages any partner wishing to communicate more broadly to utilize one or more of the following:

- Emailing: ASPRStakeholder@hhs.gov
- Reaching out to BARDA's Tech Watch Program: https://medicalcountermeasures.gov/request-barda-techwatch-meeting/
- Signing up for BARDA's collaboration portal here: https://bdr.hhs.gov/
- Participating in BARDA and/or SNS's industry days. 2022 websites found here: https://www.medicalcountermeasures.gov/barda/barda-industry-day-2022/ and https://access2success.hhs.gov/2022-sns-industry-day/. 2023 dates will be announced in the coming months.
- And for domestic manufacturing topics, ASPR created their newest stakeholder program – IBMSC's IBX Connect. More found here: https://aspr.hhs.gov/IBxConnect/Pages/default.aspx

The PHEMCE body itself is working with industry partners to determine the best cadence and topics for discussion. Much of the PHEMCE's work is classified and ASPR is working with key industry partners to determine best paths forward that will satisfy industry desires to know more about PHEMCE work while still adhering to all national security laws.

5. Under the Consolidated Appropriations Act, 2023, Congress created a new pilot program to support state stockpiles.
    a. Please explain ASPR's efforts to work towards implementation of the state stockpile pilot program.

Response: Section 2409, "Grants for State strategic stockpiles," included in the PREVENT Pandemics Act language in the Consolidated Appropriations Act, 2023, was authorized, but did not provide appropriations for, grants for state strategic stockpiles. We will continue to look for ways to leverage Strategic National Stockpile's (SNS) funds in a way that furthers the intent of the language.

    b. Please explain how ASPR is ensuring appropriate coordination and alignment with the current federal Strategic National Stockpile, including coordinating on inventory.

Response: Section 2409, "Grants for State strategic stockpiles," included in the PREVENT Pandemics Act language in the Consolidated Appropriations Act, 2023, was authorized, but did not provide appropriations for, grants for state strategic stockpiles. We will continue to look for ways to leverage SNS funds in a way that furthers the intent of the language.

    c. Please explain to what extent ASPR is working with jurisdictions to include these assets as part of any national strategy for responding to future public health

emergencies.

Response: Section 2409, "Grants for State strategic stockpiles," included in the PREVENT Pandemics Act language in the Consolidated Appropriations Act, 2023, was authorized, but did not provide appropriations for, grants for state strategic stockpiles. We will continue to look for ways to leverage SNS funds in a way that furthers the intent of the language.

6. ASPR is in the process of phasing out the Centers for Innovation in Advanced Development and Manufacturing (CIADM) program and has announced plans for several new programs that appear to be alternative replacements – the National Biopharmaceutical Manufacturing Partnership, or BioMaP, as well as the Industrial Base

Expansion Connect, or IBX. In February 2023, GAO noted the CIADM program was unprepared to rapidly produce countermeasures at the scale needed for a response.

a. Please provide a detailed explanation for each of the new programs, including the background and rationale for creation.
b. Please explain the similarities and differences between each of the new programs and the previous CIADM program.
c. Please explain how ASPR plans to rectify the challenges faced under the CIADM program with these new programs.
d. Please provide all actions, timelines, and plans for implementation of the BioMaP and IBX programs.

Response: BARDA's Biopharmaceutical Manufacturing Preparedness (BioMaP) Program will build and sustain manufacturing capacities capable of producing vaccine and therapeutics products to respond to public health emergencies. BioMaP's mission is similar to the CIADM's in that it is focused on providing manufacturing "core services" to vaccine development, preparing for domestic large-scale manufacturing of vaccines and therapeutics in the event of a public health emergency, and building the Nation's biopharmaceutical manufacturing workforce. BARDA leveraged lessons learned from the CIADMs, as well as recent COVID-19 and mpox responses, and designed BioMap to be a consortium, bringing together a much larger group of industry partners in this space (the CIADM program awarded three contracts to industry partners for all three of these areas).

BARDA anticipates establishing the BioMaP consortium in the later part of fiscal year 2023, subject to the availability of funding. The Fiscal Year (FY) 2023 and 2024 President's Budgets requested mandatory funding to support pandemic preparedness and biodefense, including support for ASPR's efforts to build and sustain domestic manufacturing capacities.

ASPR established the Office of Industrial Base Management and Supply Chain (IBMSC) to reestablish and maintain a domestic public health supply chain and coordinate the activities related to medical industrial base expansion and sustainment through the use of Defense Production Act (DPA) and Emergency Support Function (ESF) 8 authorities. This office supported over $17 billion in activities and contracts during the COVID-19 pandemic and requires annualized funding to continue to support the domestic industrial base. The FY 2024 President's Budget also includes a $400 million Pandemic Preparedness and Biodefense request in discretionary funding. The $400 million requested will ensure we are able to maintain some of the capabilities built and used extensively during the COVID-19 pandemic to strengthen the domestic manufacturing base.

7. Under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, HHS was required to develop a strategy for public health preparedness and response to address cybersecurity threats. Just earlier this year, ASPR, working in coordination with the Health Sector Coordinating Council (HSCC) Cybersecurity Working Group, released a Cybersecurity Framework Implementation Guide to help the

public and private health care sectors prevent cybersecurity incidents.

a. Please explain ASPR's role, function, and responsibilities as it relates to cybersecurity.

Response: HHS serves as the sector risk management agency (SRMA) for the Healthcare and Public Health (HPH) Sector when it comes to cybersecurity and ASPR serves as the lead within HHS to coordinate the Department's SRMA activities. HHS—jointly with our interagency and private sector partners—creates detailed resources and materials for the sector providing best practices and recommendations for building and maintaining cyber resilience and preparedness.

b. Please outline what specific actions ASPR is taking to address cybersecurity threats, including any specific proposals or plans to improve our nation's cybersecurity preparedness and response.

Response: ASPR, through its SRMA role, coupled with active involvement from other stakeholders across the Department, is undertaking numerous proactive measures to support and address cyber threats as well as strengthen the HPH sector's cybersecurity posture. It is important to note that, because of cross-cutting roles and responsibilities, while ASPR is involved, many activities rely on expertise from multiple agencies and programs. Activities specific to ASPR include:

- Developing Resources and Supporting Risk Mitigation Activities.
  - ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE) offers access to free cybersecurity training and resources.
  - The HHS Office of National Security, HC3, and ASPR work together, along with our interagency partners, on identifying, collating, and analyzing threat intelligence. For example, over the past three years, HC3 has released over 190 products to support the HPH sector, including alerts, threat actor profiles, and threat briefings.
- Facilitating Sector Coordination.
  - Collectively, OCR, FDA, OCIO, ONC, ASPR, and other HHS divisions work closely with the HPH sector through the Healthcare Sector Coordinating Council (HSCC) by collaborating with peers in the private sector to develop and publish resources and best practices on protecting the HPH sector, including documents on securing legacy devices and implementing a cybersecurity framework.
  - Internal to HHS, ASPR manages the HPH SRMA Cyber Working Group, which brings together cyber experts from across HHS each week to coordinate HHS activities related to private sector coordination and to address critical information

requests and policy issues identified internally or by HHS leadership, CISA, the National Security Council, and the Office of the National Cyber Director. These efforts are part of the larger HPH sector efforts, supporting and being supported by the broader all-hazards Sector Coordinating Council and Government Coordinating Council.

- Supporting Incident Response.
    - From January 1, 2023, to May 8, 2023, ASPR triaged 69 cybersecurity incidents, working closely with CISA and the Federal Bureau of Investigation (FBI) and conducting outreach to multiple organizations for information and data analyses to determine potential impacts to patient care and safety.
    - ASPR and HHS works closely with FBI and CISA colleagues to identify technical information that can be shared with the private sector and providing actionable intelligence to them so they can evaluate their systems to eliminate or mitigate related vulnerabilities.

c. Please explain the development process for both the statutorily required HHS strategy, as well as the more recent Cybersecurity Framework Implementation Guide, including any opportunities for engagement and feedback from other federal agencies or external stakeholders.

Response: As noted in the previous response, ASPR, through its SRMA role, coupled with active involvement from other stakeholders across the Department, supports efforts to strengthen the HPH sector's cybersecurity posture. It is important to note that, because of cross-cutting roles and responsibilities, while ASPR is involved, many activities rely on expertise from multiple agencies and programs.

- Collectively, OCR, FDA, OCIO, ONC, ASPR, and other HHS divisions work closely with the HPH sector through the Healthcare Sector Coordinating Council (HSCC) by collaborating with peers in the private sector to develop and publish resources and best practices on protecting the HPH sector, including documents on securing legacy devices and implementing a cybersecurity framework.
- Internal to HHS, ASPR manages the HPH SRMA Cyber Working Group, which brings together cyber experts from across HHS each week to coordinate HHS activities related to private sector coordination and to address critical information requests and policy issues identified internally or by HHS leadership, CISA, the National Security Council, and the Office of the National Cyber Director. These efforts are part of the larger HPH sector efforts, supporting and being supported by the broader all-hazards Sector Coordinating Council and

Government Coordinating Council.

d. Please outline any specific actions ASPR is taking to engage with the private sector to ensure proper coordination and communication to counter cybersecurity threats.

Response: HHS now offers free cybersecurity training and resources on its website through an education platform called "405(d)'s Knowledge on Demand" and ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE), which provides online technical resources on health care cybersecurity. These resources are widely distributed and utilized; for example, in the first week of release, the 2023 version of the HICP had over 7,600 downloads and the Hospital Resiliency Landscape Analysis had over 6,800 downloads. HHS also collaborates with federal partners to provide actionable, credible threat intelligence to the HPH Sector to help it better strengthen the security posture of the HPH infrastructure. The HHS Office of National Security, HC3, and ASPR work together, along with our interagency partners, on identifying, collating, and analyzing threat intelligence.

The Honorable Robert E. Latta

1) Under current law, has the authority and direction from Congress to ensure that in the SNS are supplies essential to mounting a robust response, including diagnostic testing supplies. However, I have not heard from you today any commitment on how ASPR will ensure there are key testing supplies drawn into the SNS. While we won't have at the ready a test for a brand new pathogen, we do know these are essential supplies I would consider pathogen-agnostic, and therefore critical to our clinical laboratory community's readiness. These are things like extraction reagents to draw the pathogen out of a patient sample, precision plastics like pipette tips and trays, diagnostics instrumentation, etc. – all testing supplies that were often in short supply during the first year of the COVID PHE.
    - Does ASPR plan on employing a Vendor Managed Inventory (VMI) process to ensure you are responsibly pulling in such materials and supplies?

      Response: ASPR recognizes the importance of testing supplies and how critical it is to have a robust domestic supply chain so these products are available when needed. The SNS has and utilizes authority for Vendor Managed Inventory for some of the current holdings. VMI relies on a partnership with the manufacturer and, in most cases, is used when there is financial benefit to both parties. In practice, VMI works well for products that have short shelf life and is continually replenished. VMI is not a solution for those products where the USG is the primary buyer (e.g. some products for chemical, biological, radiological, and nuclear threats). For COVID tests, ASPR is focused on domestic manufacturing vs. procuring and holding large amounts of tests in the SNS (or using VMI to hold inventory). ASPR does not have sufficient annual funding to maintain a large inventory in this space and is instead focused on enhancing domestic manufacturing.

To support domestic manufacturing generally, including diagnostics and testing supplies, ASPR has invested over $17 billion of COVID-19 supplemental funds in 87 different projects. These projects include sustainment and expansion of the only domestic pipette tip manufacturer, onshoring manufacturing of personal protective equipment (PPE) and its components, and investing in raw materials such as medical grade rubber. As COVID-19 supplemental funds wind down, ASPR will need additional annual funds to continue these investments. The FY 2024 President's Budget includes a $400 million Pandemic Preparedness and Biodefense request. The $400 million requested will ensure we are able to maintain the capabilities built and used extensively during the COVID-19 pandemic to strengthen the domestic manufacturing base.

The Honorable Richard Hudson

1) What is ASPR doing to ensure that small to medium size businesses have access to government funding and provide assistance in the strategic national stockpile and other relevant agencies goal of increasing manufacturing/utilization of American made PPE.

Response: Supporting small to medium sized businesses is critical as ASPR works to reestablish and maintain a domestic public health supply chain. All ASPR contract actions adhere to and follow federal contracting regulations. In addition, all procurements above $10,000 are reviewed by the HHS Office of Small and Disadvantaged Business Utilization and the Small Business Administration to ensure compliance with small business requirements. Lastly, related to PPE, any contract for PPE follows an internal review process that includes legal review as well as the HHS Senior Procurement Executive's Office (above $150 million) for compliance with the Infrastructure Investment and Jobs Act and the Make PPE in America Act.

2) As we know, the strategic national stockpile is essential for supplying healthcare workers and facilities with PPE, however, does ASPR have plans to allocate a certain amount PPE in the strategic national stockpile such as masks for civilian use?

Response: Generally, the contents of the SNS may be deployed at the discretion of the Secretary within statutory authorities, for whatever national security/emergency purpose the Secretary determines to be appropriate. It is important to note that SNS's PPE requirements are based on usage by healthcare workers during a pandemic response, rather than the needs of the general public. This means that while PPE may be deployed for use by the general public whenever the Secretary deems it necessary, doing so impacts the availability of PPE in the SNS for healthcare workers. It is important to note that the mission of the SNS is much larger than providing PPE. The SNS is part of the federal medical response infrastructure and can supplement medical countermeasures needed by states, tribal nations, territories, and the largest metropolitan areas during public health emergencies. The supplies, medicines, and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient. These services are usually provided when supplies are not commercially available in other ways.

Finally, it's important to note that ASPR does not have annualized funding for PPE purchases. Historically, PPE has been purchased with supplemental funding from Pandemic Influenza, Ebola, and COVID-19 funding packages. SNS's current base funding levels are not sufficient to support additional PPE procurements.

3) Does ASPR plan on providing funding for companies that are researching next Gen PPE, for example, PPE that has an extended shelf life or is washable/reusable.

Response: Next generation PPE will be critical in the prevention, mitigation, and response

for the next public health emergency and disaster. As Congress considered FY 2025 levels, ASPR notes that a portion of the $20 billion requested in Mandatory funding be considered to support the continued investment in these critical products.

The Honorable Early L. "Buddy" Carter

1) Stakeholders are aligned that we must ensure the sustainability of medical countermeasures, including in our response capabilities and capacities. Confronted with increasing threats, a unique marketplace, and the challenges posed by in the pandemic response, securing the domestic supply chain is critical to confronting 21st Century biosecurity. Could you explain how ASPR, using existing authorities and requirements, is working (including through BARDA, the SNS, PHEMCE, and other mechanisms) to ensure that investments, acquisitions, or related contract incentives are flexibly designed to enhance U.S. domestic health security infrastructure? Similarly, how is ASPR planning to utilize existing resources and authorities to address critical sustainment of this industrial and research base?

Response: ASPR concurs with the assessment that ensuring the sustainability of medical countermeasures is critical. In May 2023, ASPR delivered to Congress the 2022 Medical Countermeasure Preparedness Report (MCMPR) (i.e., the annual threat-based review of the SNS report). This document is not publicly released due to procurement sensitivities but was finalized and delivered to Congress as required. We would be pleased to follow up and ensure you have a copy.

Generally, this report shows that ASPR's requirements for MCMs are flexibly designed to enhance domestic health security infrastructure. For example, ASPR's requirements are not for particular drugs manufactured by particular companies; they are for categories of countermeasures pertaining to particular threats. This approach allows manufacturers complete visibility into what the USG needs to procure against a threat and affords them the opportunity to come into a given space.

2) As you know, emerging infectious diseases (EID) often become material threat determinations and can have significant consequences on America's economy, defense, and population. While BARDA has often been drawn into the EID space following public health emergencies (Ebola, Zika, and Covid-19), how will you as ASPR empower BARDA and the broad Public Health Emergency Medical Countermeasures Enterprise to address the threat of EID, and subsequent potential weaponization?

Response: Material threat determinations (MTDs) are issued by the Department of Homeland Security (DHS) and are typically based on the threat posed by weaponized chemical, biological, radiological, or nuclear agents. Project Bioshield funding can be used to develop medical countermeasures to respond to a threat with an MTD. Especially in the wake of COVID-19, ASPR recognizes EID threats as national security threats. ASPR is taking important steps now through the requirements process to identify and characterize the pandemic potential of a number of EID pathogens and establish requirements for platform technologies as well as MCMs needed to address these risks.

DHS evaluates pathogens for weaponization potential, and should they be a concern, issues MTDs accordingly. With current authorities, BARDA is supporting the development of broad-spectrum antivirals, host-directed therapeutics that are pathogen agnostic, and platform technologies against existing threats.
Separate authorities and appropriations are needed to ensure ASPR and BARDA are well-positioned to research and develop next generation technologies for EIDs.

3) With the upcoming expiration of several authorities and grant programs provided in the Pandemic and All-Hazards Preparedness Act (PAHPA), what adjustments should we consider in order to better encourage and support domestic pharmaceutical and medical product manufacturing within the U.S. to ensure a reliable and sustainable supply chain?

Response: First, ensuring a reliable supply chain is a critical ASPR mission. ASPR's Office of Industrial Base Management and Supply Chain (IBMSC) has been created to reestablish and maintain a domestic public health supply chain and coordinate the activities related to medical industrial base expansion and sustainment through the use of Defense Production Act (DPA) and Emergency Support Function (ESF) 8 authorities. This office and its critical functions were initiated with COVID-19 supplemental funding and require annualized base funding to continue this key work.

Second, ASPR is seeking domestic construction authority in the PAHPA reauthorization to support construction and alteration of non-federally owned facilities, as needed, to support medical countermeasure requirements. This request was included in the FY 2024 President's Budget request. This authority was provided to ASPR as part of the COVID-19 supplemental funds but expires upon depletion of these funds.

Third, as you know, ASPR worked closely with the Department of Defense (DoD) during the COVID-19 pandemic, including entering into an agreement to have DoD provide acquisitions support throughout much of the response. DoD used its acquisitions authorities on behalf of HHS to quickly and efficiently invest in the research, development, and procurement of the vaccines, therapeutics, tests, and PPE needed throughout the COVID-19 response. The Memorandum of Understanding between ASPR and DoD will expire at the end of FY 2023. ASPR has requested that the PAHPA reauthorization provide the same acquisitions authorities as used by DoD for ASPR to accelerate work both in steady state, and in any future response scenarios, without relying on DoD. Thus far, neither the House nor the Senate PAHPA bills include these authorities in their base text.

4) The COVID-19 pandemic underscored vulnerabilities in our domestic public health supply chains, particularly for essential medical supplies and pharmaceuticals. What can we learn from the challenges faced during the pandemic and how might Buy American policies be used or modified to better support U.S.-based manufacturers and consequently improve our resilience to future health security threats? What incentives do you

recommend is needed to strengthen and support domestic manufacturing of pharmaceuticals and essential medical supplies?

Response: Throughout the acute phase of the pandemic response, solving critical public health supply chain issues has been a focus of our work at ASPR.

ASPR's industrial base management and supply chain work was borne out of these initial supply chain pinches the country experienced in March 2020 when the whole world needed the exact same supplies at the exact same time and they were all manufactured elsewhere. ASPR views addressing the challenge of ensuring that a resilient domestic PPE supply chain is available when needed as a two-prong process: first, we must invest in the domestic manufacturing of products; and second, we must create a market for those products.

To address the first prong, using emergency supplemental appropriations, ASPR is building a program to ensure that we have personal protective equipment and critical supplies manufactured in the United States moving forward. ASPR's Office of Industrial Base Management and Supply Chain (IBMSC) has spent over $17 billion on approximately 87 contracts to support the manufacturing of these supplies in the United States. There is currently no annual funding for ASPR's domestic manufacturing work. This work was funded by COVID-19 supplemental funding. ASPR has included a $400 million request in the FY 2024 President's Budget for Pandemic Preparedness and Biodefense. Part of this funding would be used to support continued investments in the domestic industrial base. We are hopeful that this funding will be included by Congress for this and future budgets to support this important work.

In addition to the sustained funding that is needed to continue this work, ASPR also needs construction authority, which was requested as part of the FY 2024 President's Budget. COVID-19 supplemental legislation included language that allowed ASPR to support the physical construction of domestic manufacturing facilities. Once the COVID-19 funds run out or are rescinded, no new projects can be initiated using this authority. Authority for acquisition, construction, or alteration of non-federally owned facilities would allow ASPR to sustain the work to onshore and build domestic manufacturing capacity. We have asked Congress to consider granting us this authority as part of the Pandemic and All-Hazards Preparedness Act reauthorization.

To address the second prong of establishing a strong domestic manufacturing base for PPE and critical supplies, ASPR is also committed to supporting the fledging market by purchasing what it can from domestic manufacturers. ASPR has been able to leverage purchases by the Strategic National Stockpile for this purpose. In fact, ASPR is proud to report compliance with all Infrastructure Investment and Jobs Act provisions requiring that PPE in the SNS be domestically manufactured. However, domestically procured product is, on average, 20-30 percent more expensive than internationally sourced product. Now that much of the COVID-19 supplemental dollars have been rescinded, any future purchases of PPE and critical medical supplies will have to come out of annual funding and the SNS currently receives no annual funding for these purchases. Given the continued

bipartisan interest in investing in domestic PPE manufacturing, we are hopeful Congress might provide the SNS with increased funding as requested in the FY 2024 budget.

Finally, early in the COVID-19 response, it became clear that HHS could not procure the domestic products our country needed at the speed in which it needed them. As a result, we entered into a Memorandum of Understanding with the Department of Defense (DoD) in which they agreed to provide assisted acquisitions support on our behalf. DoD executed more than $90 billion in contracts for us over the three years of the acute response. DoD's unique authorities allowed it to save critical time when investing in early-stage vaccines, therapies, and tests. DoD could fund promising prototypes and then move the successful ones through the advanced research pipeline, without having to recompete the contracts. These authorities were used by DoD in support of Operation Warp Speed to procure five of the six COVID-19 vaccines on behalf of HHS. ASPR's current authorities, on the other hand, require it to stop and recompete the contracts when they move into the next phase of development. This is challenging for domestic manufacturers as it slows down momentum and creates uncertainty that a company will be funded to complete the work. The authority to award follow-on production contracts from prototypes without recompeting the requirements would allow ASPR to move more quickly and predictably in the future. In addition, ASPR was lucky that DoD was willing to take on this work for us during the COVID-19 pandemic. We know that DoD has its own set of critical national security responsibilities across this complex threat landscape and may not always be in a position to assist ASPR in contracting efforts.

We hope that domestic manufacturing authority, sustainable funding for the SNS, and additional acquisitions authorities will be considered as part of your legislative process.

The Honorable Gus Bilirakis

1) Last Congress the leaders of BARDA and H-CORE briefed congressional staff on the Administration's COVID-19 vaccine distribution efforts. At that briefing the head of H-CORE stated that 60% of COVID-19 vaccine dosages went unused and had to be thrown away. Not counting the cost of Operation Warp Speed, we've spent more than $25 billion buying COVID-19 vaccines. The Administration decided to waste about $15 billion, while simultaneously telling Congress you lacked funding.
    - As the government winds down its vaccine distribution program, are we still wasting 60% or more of all the shots that we have bought? What percentage of COVID-19 vaccines dosages distributed by the government are lost due to spoilage?

      Response: The federal government entered into contracts and supported procurement to ensure that every person who wanted a vaccine had access. In some cases, multi-dose vials were opened and not every dose was administered. To reduce the instances of this happening, the U.S. government ordered single dose vials as soon as the manufacturers made them available.

While every effort was made to reduce wastage safely and effectively, administering some of the doses in a vial to willing patients became paramount. Estimated COVID-19 vaccine wastage is less than 15 percent of what has been distributed.

2) The recent Mpox response highlighted the issue of expired products in the Strategic National Stockpile (SNS), which hindered a prompt wide-scale federal response. Efficiently cycling stockpiled products into public use can accelerate product deployment, minimize taxpayer waste, and encourage continued private sector research and development of medical countermeasures and capabilities. The 2023 Omnibus PREVENT Pandemics provision has granted the SNS the authority to cycle products nearing their expiration dates.
    - What are ASPR's plans for implementing the SNS product cycling provisions outlined in the PREVENT Pandemics Act?

      Response: ASPR is not aware of any challenges related to expired SNS products during the mpox response. In ASPR's 16-year history, ASPR has invested in a range of efforts to prepare for threats identified by the Department of Homeland Security (DHS). One of the key identified threats – by DHS, ASPR, and Congress – is smallpox. ASPR and other federal partners have invested in preparing for the threat of smallpox for over a decade. We have a number of countermeasures within the SNS to aid in a response, should this country experience any sort of smallpox attack. Certain medical countermeasures we procured and stockpiled for smallpox also protect against and treat the symptoms of mpox. We were grateful to be in a position where our existing smallpox medical countermeasure portfolio could be leveraged against mpox. A more complete mpox timeline can be found from my September 14, 2022, Senate HELP testimony here: https://www.help.senate.gov/imo/media/doc/OConnell.pdf

      Further, SNS appreciates work done by Congress to expand SNS's authority to cycle MCM product for use before expiry. The provision referenced and included in the PREVENT Pandemics Act language in the Consolidated Appropriations Act, 2023, requires product to meet several criteria before they are eligible for sale, including that product be "excess." At the time of this hearing, SNS continues to evaluate what activities can be done within the parameters of the enacted legislation.

3) Ensuring access to critical medicines, especially during an emergency, is vital. There are concerns around the availability of certain drugs and supplies, and in some cases the over-reliance on some countries (China, in particular) for some of these goods. At the same time, the drug manufacturing process is incredibly complex, with many steps and inputs performed in highly specialized facilities; thoughtfully designed and diversified global supply chains are critical to our business and our patients. The United States needs

a comprehensive strategy that tackles raw material sourcing dependencies, incentivizes US production, strengthens coordination among key trading partners to maintain free movement of goods, and builds and maintains robust national reserves. Bearing in mind that not all supply chains are the same, and not all drugs carry the same sourcing risk. Still, the pharmaceutical industry may be over-reliant on China for chemicals, secondary agents, and other base industries that left the US due to cost, environmental, and other factors.

What is ASPR doing to incentivize US production for Medical Countermeasures and to strengthen and diversify these base industries to bolster domestic production and improve supply chain resilience and US independence from China?

Response: ASPR's Office of Industrial Base Management and Supply Chain (IBMSC) was started to reestablish and maintain a domestic public health supply chain and coordinate the activities related to medical industrial base expansion and sustainment through the use of Defense Production Act (DPA) and Emergency Support Function (ESF) 8 authorities. This office supported over $17 billion in activities and contracts during the COVID-19 pandemic and has requested annual funding to be able to provide appropriate oversight and support to those contracts. ASPR has included a $400 million request in the FY 2024 President's Budget for Pandemic Preparedness and Biodefense. Part of this funding would be used to support continued investments in the domestic industrial base. We are hopeful that this funding will be included by Congress for this and future budgets to support this important work.

4) BARDA is often constrained by Material Threat Assessments or specific Areas of Interest that are strictly defined. Given that we don't always know what threats may emerge, there is a need for more flexibility and the ability to rapidly shift between threats. It would appear that a platform-based approach would provide such flexibility. Indeed, BARDA was directed in the last appropriations law to assess the role platforms can play and report back to the Congress.
    - How are you addressing this need to allow BARDA to work outside the box?

      Response: In November 2022, BARDA created the FASTx (Flexible and Strategic Therapeutics) Program, which is establishing platform capabilities to rapidly and nimbly pivot to discover, develop, and deliver novel therapeutics against newly emerged and previously unknown threats. Current investments will primarily support nucleic acid-based countermeasures, including siRNA, and mRNA-expressed monoclonal antibodies. These technologies allow the promise to use such platforms to develop safe and effective therapeutics against novel threats with knowledge of just the genomic sequence of the new threat. In addition, BARDA is investing in host-directed therapies that address the pathophysiological and medical consequences of exposure to an emerging and novel threat without a priori knowledge of the threat itself. In the vaccine space, BARDA is also investing in new platforms to rapidly discover, develop, and deliver novel vaccines against emerging threats. Together, investing in platform technologies will provide for the capability to develop and deliver new vaccines and therapeutics against emerging variants of threats for which MTDs are established as well as for truly novel, unknown emerging threats. BARDA is also supporting the development of threat-agnostic diagnostics that can detect a

previously unknown threat, as well as detect emergence of resistance of current viruses/strains to available MCMs.

5) The SNS has clear gaps both in operational capability and needed updates to Information Technology. What is being done to modernize the SNS?

Response: The PHEMCE Multiyear Budget for Fiscal Years 2022-2026 projected an overall funding need of $2.6 billion over the 5-year period for SNS procurement of products approved or soon to be approved. This figure does not include sustainment of products purchased throughout the COVID-19 pandemic. This need is in stark contrast to the $965 million SNS was appropriated in FY 2023. This document is publicly available via ASPR's website and is used to promote general gaps in resources across the entire medical countermeasure spectrum (available online: https://aspr.hhs.gov/PHEMCE/Documents/2022-2026-PHEMCE-Budget.pdf). ASPR will continue to advocate for increased funding for the SNS.

The SNS continues to find ways to clarify capabilities for state, local, tribal, and territorial (SLTT) partners, but this continues to be challenging when the mission continues to expand. ASPR hopes to be able to work with Congress on ensuring funding commensurate with the mission. The SNS is continuing to evaluate strategies to support the implementation of the National Strategy for a Resilient Public Health Supply Chain (National Strategy), developed in response to Section 4 of Executive Order (EO) 14001: Sustainable Public Health Supply Chain. Among the plan's implementation tasks include formalized and expanded SLTT and private-sector engagement; discussion of best practices and new approaches for stockpiling, storage, and distribution; and providing expanded training, technical assistance, and information sharing for Federal, SLTT, and private-sector partners on SNS capabilities and capacity to support and sustain coordinated response to pandemics, natural disasters, and man-made threats.

6) ASPR must continue to prepare for biological agents that are known to present national security risks as potential bioweapons, namely through Project BioShield. Smallpox is identified by the USG as a "Category A" agent, meaning it has been given high priority due to its potential threat to national security. Given revelations that our stockpile of smallpox vaccine for immunocompromised patients dwindled to almost zero in recent years, and that the PREVENT Pandemics Act required ASPR to report on stockpile depletion after a deployment:

- Has ASPR completed the depletion report for smallpox post the deployment for Mpox?

  Response: At the time of this hearing, the report was in the review process. We look forward to providing the report to Congress as soon as possible.

- Should this provision be further expanded or amended in the PAHPA reauthorization legislation?

Response: At the time of this hearing, the report was in the review process. We look forward to providing the report to Congress as soon as possible.

- What is the current state of the smallpox vaccine stockpile for the US?

Response: SNS inventory amounts are sensitive due to national security implications. Information on current holdings, and specifically smallpox vaccine amounts, are included in the Medical Countermeasures Preparedness Review that was delivered to Congress in May 2023. It is important to note that the SNS plans to maintain its quantity of smallpox vaccine to meet the needs of the immunocompromised population, based on available resources.

- Why did the stockpile have so little vaccines for immunocompromised patients at the start of the Mpox outbreak, when over 20 million doses had been stockpiled previously?

Response:

Since the first reported case of mpox in the United States on May 18, 2022, ASPR worked tirelessly to accelerate the acquisition and delivery of vaccines and therapeutics to jurisdictions. This important work first started with an examination of our holdings within the SNS. As reported publicly, the SNS contains both ACAM2000 – our first line of defense to vaccinate Americans in the event of accidental or intentional release of smallpox – and JYNNEOS, for which we keep a small stockpile, and never 20 million doses, to routinely vaccinate laboratory workers at risk of exposure to smallpox and other orthopoxviruses such as mpox. In addition to the 2,400 doses the SNS kept on-hand for rapid deployment, ASPR kept an additional 1.4 million vials of JYNNEOS in -50 degree storage at Bavarian Nordic (BN), to be available if needed for response to a larger outbreak. Those doses are now being deployed for use in the current outbreak. ASPR also had an additional 16.5 million vial equivalents in bulk drug substance to be lyophilized (or "freeze dried") in the coming years for easier storage and longer shelf-life. 5.5 million vial equivalents of that bulk drug substance are being filled and finished now and in the coming months to respond to the current outbreak. ACAM2000, which is not approved or authorized by the Food and Drug Administration (FDA) for emergency use to prevent mpox, contains live, replicating virus and may not be advisable for those who are immune compromised. Given the potential of mpox cases in persons who may also have HIV or other immune compromising conditions, ASPR worked with other HHS agencies and offices to determine the JYNNEOS vaccine was our best line of defense against this mpox outbreak.

ASPR has made over a million vials of JYNNEOS available to jurisdictions for use against the current outbreak – the largest JYNNEOS mpox vaccine program in the world.

A more complete mpox timeline can be found from my September 14, 2022, Senate HELP testimony here: https://www.help.senate.gov/imo/media/doc/OConnell.pdf

- Have the stockpile requirements changed given the most recent Mpox outbreak and its impact on the smallpox vaccine supply?

Response: There are no requirements for mpox. However, the PHEMCE did make a recommendation that HHS should continue stockpiling for the most deadly threat (in this case, smallpox) and prioritize products that are versatile and could be used for other less deadly threats (in this case, mpox).

The Honorable Debbie Dingell

Health workers depend on a readily available supply of gloves, makes, and gowns to keep them and their patients safe. In the early days of COVID-19, we believed we had an adequate stockpile of Personal Protective Equipment (PPE). But unfortunately, we quickly realized the Strategic National Stockpile was woefully unprepared to meet the escalating needs of the health care

perform in accordance with NIOSH performance standards and should provide the expected level of protection to the wearer when used in conjunction with an Occupational Safety and Health Administration (OSHA)-compliant respiratory protection program, including training and fit testing.

This information was communicated in a letter sent to all jurisdictions receiving PPE from the SNS and was explained on a phone call with each jurisdiction. In addition, the US Food and Drug Administration issued an Emergency Use Authorization allowing the use of expired N95 respirators, as well as allowing the use of non-FDA cleared, NIOSH-approved N95 respirators to be used in health care settings.

workforce in early. And on top of this, several shipments from the SNS in early 2020 contained provide the expected level of protection to the wearer when used in conjunction with an Occupational Safety and Health Administration (OSHA)-compliant respiratory protection program, including training and fit testing.

This information was communicated in a letter sent to all jurisdictions receiving PPE from the SNS and was explained on a phone call with each jurisdiction. In addition, the US Food and Drug Administration issued an Emergency Use Authorization allowing the use of expired N95 respirators, as well as allowing the use of non-FDA cleared, NIOSH-approved N95 respirators to be used in health care settings.

PPE that exceeded their manufacturer-designated expiration date, with some reports showing PPE had expired as early as 2010.

Ms. O'Connell, as we prepare to strengthen our response to the next health crisis, can you explain how ASPR is ensuring products are not expiring in the SNS and what more Congress can do to keep a reliable reserve of PPE in the stockpile?

Response: Historically SNS was authorized to respond primarily to chemical, biological, radiological, nuclear, and explosive (CBRNE) threats. While the threats that SNS is expected to respond to have grown to include natural disasters, pandemic influenza, and emerging infectious diseases, SNS's annual funding has not grown sufficiently to allow SNS to be sufficiently prepared to meet these threats. This means that outside of supplemental appropriations for Pandemic Influenza, Ebola, and COVID-19 SNS has not been funded to procure PPE.

In the absence of funding to replace PPE procured with previous supplemental funding and in order to get the best value for the American people, in the years prior to the pandemic rather than disposing of expired product that might still be useful, SNS supported NIOSH to evaluate the N95 respirators. This supplemental testing on the expired N95 respirators indicated that select models of N95 respirators had been found to continue to perform in accordance with NIOSH performance standards and should provide the expected level of protection to the wearer when used in conjunction with an Occupational Safety and Health Administration (OSHA)-compliant respiratory protection program, including training and fit testing. Only the select SNS held models identified by NIOSH as suitable for use were sent to jurisdictions.

All jurisdictions receiving PPE from the SNS bearing expired dating received a letter communicating this information and the same information was explained on a phone call with each jurisdiction. In addition, the US Food and Drug Administration issued an Emergency Use Authorization allowing the use of expired N95 respirators, as well as allowing the use of non-FDA cleared, NIOSH-approved N95 respirators to be used in health care settings.

New authorities granted to ASPR via the PREVENT Pandemics Act, as included in the

Consolidated Appropriations Act, 2023, allows for the sale of MCMs to STLT and federal partners. ASPR is evaluating how to implement this new authority without harming domestic manufacturers of PPE.

While these measures are helpful, if Congress wants SNS to maintain a reliable reserve of PPE in the stockpile, sustained funding at a level that allows SNS to procure both CBRNE MCMs and domestically manufactured PPE is required.

The COVID-19 pandemic also exposed vulnerabilities in our heavy dependence on overseas manufacturers for PPE. We must identify ways we can strengthen our domestic industrial base so we have an adequate supply for the SNS, but also so we can quickly scale up manufacturing of important medical supplies here at home when we need them the most. And partnering with private industry could be the key to achieving both these goals.

1) Ms. O'Connell, what steps can Congress take to help the SNS leverage the private sector to strengthen our supply of critical medical supplies?

Response: Throughout the acute phase of the pandemic response, solving critical public health supply chain issues has been a focus of our work at ASPR.

ASPR's industrial base management and supply chain work was borne out of these initial supply chain pinches the country experienced in March 2020 when the whole world needed the exact same supplies at the exact same time and they were all manufactured elsewhere. ASPR views addressing the challenge of ensuring that a resilient domestic PPE supply chain is available when needed as a two-prong process: first, we must invest in the domestic manufacturing of products; and second, we must create a market for those products.

To address the first prong, using emergency supplemental appropriations, ASPR is building a program to ensure that we have personal protective equipment and critical supplies manufactured in the United States moving forward. ASPR's Office of Industrial Base Management and Supply Chain (IBMSC) has spent over $17 billion on approximately 87 contracts to support the manufacturing of these supplies in the United States. There is currently no annual funding for ASPR's domestic manufacturing work. This work was funded by COVID-19 supplemental funding. ASPR has included a $400 million request in the FY 2024 President's Budget for Pandemic Preparedness and Biodefense. Part of this funding would be used to support continued investments in the domestic industrial base. We are hopeful that this funding will be included by Congress for this and future budgets to support this important work.

In addition to the sustained funding that is needed to continue this work, ASPR also needs construction authority as requested in the FY 2024 President's Budget. COVID-19 supplemental legislation included language that allowed ASPR to support the physical construction of domestic manufacturing facilities. Once the COVID-19 funds run out or are rescinded, we will no longer be able to utilize this authority. Codifying the authority for acquisition, construction, or alteration of non-federally owned facilities would allow ASPR to sustain the work to onshore and build domestic manufacturing capacity. We have

asked Congress to consider granting us this authority as part of the Pandemic and All-Hazards Preparedness Act reauthorization.

To address the second prong of establishing a strong domestic manufacturing base for PPE and critical supplies, ASPR is also committed to supporting the fledging market by purchasing what it can from domestic manufacturers. ASPR has been able to leverage purchases by the Strategic National Stockpile for this purpose. In fact, ASPR is proud to report compliance with all Infrastructure Investment and Jobs Act provisions requiring that PPE in the SNS be domestically manufactured. However, domestically procured product is, on average, 20-30 percent more expensive than internationally sourced product. Now that much of the COVID-19 supplemental dollars have been rescinded, any future purchases of PPE and critical medical supplies will have to come out of annual funding and the SNS currently receives no annual funding for these purchases. Given the continued bipartisan interest in investing in domestic PPE manufacturing, we are hopeful Congress might provide the SNS with increased funding as requested in the FY 2024 budget.

Finally, early in the COVID-19 response, it became clear that HHS could not procure the domestic products our country needed at the speed in which it needed them. As a result, we entered into a Memorandum of Understanding with the Department of Defense (DoD) in which they agreed to provide assisted acquisitions support on our behalf. DoD executed more than $90 billion in contracts for us over the three years of the acute response. DoD's unique authorities allowed it to save critical time when investing in early-stage vaccines, therapies, and tests. DoD could fund promising prototypes and then move the successful ones through the advanced research pipeline, without having to recompete the contracts. These authorities were used by DoD in support of Operation Warp Speed to procure five of the six COVID-19 vaccines on behalf of HHS. ASPR's current authorities, on the other hand, require it to stop and recompete the contracts when they move into the next phase of development. This is challenging for domestic manufacturers as it slows down momentum and creates uncertainty that a company will be funded to complete the work. The authority to award follow-on production contracts from prototypes without recompeting the requirements would allow ASPR to move more quickly and predictably in the future. In addition, ASPR was lucky that DoD was willing to take on this work for us during the COVID-19 pandemic. We know that DoD has its own set of critical national security responsibilities across this complex threat landscape and may not always be in a position to assist ASPR in contracting efforts.

We hope that domestic manufacturing authority, sustainable funding for the SNS, and additional acquisitions authorities will be considered as part of your legislative process.

The Honorable Ann Kuster

1) As you know, strong supply chain management is a critical part of the response to any public health event. How are you making sure investments made for COVID, such as the Supply Chain Control Tower, are sustained for other emergencies?

Response: To date, ASPR has utilized COVID-19 supplemental funding to support the Supply Chain Control Tower (SCCT). Specifically, funding was provided to the HHS Protect contract to fund the SCCT module within the system, which is how all distributor

data are submitted, cleaned, analyzed, and visualized. Additionally, ASPR funded a contract with Johns Hopkins Applied Physics Lab for supply chain modeling and data management subject matter expertise. Also, ASPR funded specific supply chain data licenses to procure additional supply chain related data feeds. Going forward, these efforts will be dependent on future appropriation of funding to sustain and enhance efforts. Without additional funding for sustainment, almost all SCCT activities will end in September 2024.

2) During COVID and the recent infant formula crisis, we learned the importance of enabling better data sharing between industry and ASPR. I understand the data sharing agreements put in place during COVID are all voluntarily. To help us better understand our supply chain risks, should we require this type of data sharing going forward?

Response: Currently, voluntary data sharing between federal and industry partners in this space continues to be the most productive way to receive this data. SCCT industry partners have all expressed a desire to continue voluntarily sharing data and most have already signed an updated data use agreement that expands on, and continues, the data sharing post-COVID.

3) During the COVID response, the HHS Coordination Operation and Response Element (H-CORE) took on a critical role to coordinate the public health response across the federal government. Going forward, what is the role of H-CORE? Will H-CORE continue its coordination role for all medical countermeasures?

Response: The vaccines and therapeutics available to us today are the result of an unprecedented partnership between HHS and the Department of Defense (DoD), through the Countermeasures Acceleration Group (CAG), previously known as Operation Warp Speed. Together, this team helped develop and deliver over 750 million doses of vaccine and over 11 million treatment courses to protect the American people from COVID-19. On December 31, 2021, our Memorandum of Understanding with DoD expired, and on January 1, 2022, we successfully completed the planned transition of this work to the recently established HHS Coordination Operations and Response Element, or H-CORE. H-CORE institutionalizes the logistics and operations efforts previously led by the CAG within ASPR. It will allow us to build on the progress to date, retain expertise and skills, and continue providing the necessary tools to the American people to respond to the COVID-19 pandemic and future outbreaks.

4) I understand that there are next generation treatments in the pipeline as part of the Administration's commitment to "Project Next Gen". In addition to supporting the development of vaccines and monoclonal antibodies, is there funding and government support available to help speed the manufacturing of oral antiviral COVID treatments?

Response: Due to the pharmaceutical industry's interest in the development of oral antivirals, with at least three unique drugs in phase 3 clinical trials as of June 2023, Project NextGen funds for therapeutic development are focused on the unmet need of finding monoclonal antibodies that may be more resilient against new variants of SARS-CoV-2. It

is likely that new oral antivirals for the treatment of COVID-19 may become available without government funding, and monoclonal antibody development has lagged behind oral antiviral development. Monoclonal antibodies for pre-exposure prophylaxis are vital for populations that are not protected by the COVID-19 vaccines such as the immune compromised population. In fact, immune compromised patients are one of the few patient populations that are still hospitalized with COVID-19, even when fully vaccinated.

5) The annual process to guide inventory purchases for the Strategic National Stockpile (SNS) was suspended for fiscal years 2020 through 2022. According to the GAO, when these reviews were renewed recently, they did not meet statutory requirements, and as such, Congress does not have the information it needs to conduct proper oversight of the SNS. As you implement a plan to meet these statutory requirements, will it involve an annual class review to ensure that the treatments and vaccines in the stockpile are the safest, most effective, and least vulnerable to antimicrobial resistance (AMR) that are available?

Response: Congress should be aware that the SNS Annual Review was delivered to Congress for 2020 and 2021. The 2022 Annual Review was delivered to Congress in May 2023. Each has been delivered, as required, to the Committees identified in statute.

6) Also in reference to the SNS - if the next pandemic hits, or we are the victims of a bioweapon, and we find that SNS treatments are ineffective because they have become susceptible to antimicrobial resistance (AMR), or that we ignored other treatments on the

market or in development that better fight certain pathogens, that would not only be a tremendous waste of taxpayers' money, but an even bigger tragedy in the unnecessary loss of lives. Are there any obstacles to your conducting routine class reviews of treatments and vaccines in the stockpile to ensure they are not outdated?

Response: The drugs currently in the SNS are FDA approved or authorized and therefore are determined to meet the relevant standards for safety and efficacy against the pathogens they are intended to treat. Should an AMR strain arise, their safety and efficacy will be reevaluated. NIH and BARDA continue funding multiple products that have activity against emerging AMR strains and, if approved or authorized, could be candidates to add to the stockpile (should funds be available to support them).

7) Antimicrobial resistance (AMR) is contributing to 5 million deaths per year globally and significantly increasing our health care costs. Novel antibiotics will allow us to more rapidly cure patients and discharge them from the hospital—improving their lives and reducing costs. This is why I am a previous cosponsor of the bipartisan PASTEUR Act – legislation – which Representatives Peters and Ferguson recently reintroduced. The PASTEUR proposal would be transformative to the fragile and failing antimicrobial ecosystem, revitalizing antimicrobial R&D and helping ensure American people have the products we need to treat resistant infections. How would you describe the threat of AMR, and how will ASPR help strengthen the antimicrobial pipeline?

Response: Antimicrobial resistance (AMR) represents a significant threat to many of the advancements we have come to take for granted in modern medicine such as complex surgeries and chemotherapy. ASPR has long recognized AMR as a threat to our national health security as well as our ability to provide a certain standard of care. ASPR's antimicrobials program is developing MCMs that treat both DHS-identified biothreats (anthrax, plague, tularemia, melioidosis, and glanders) and antimicrobial resistant health care-associated and community-acquired pathogens. As of March 2023, BARDA has supported the development of 125 antibacterial candidates: 92 under the Combating Antibiotic Resistant Bacterial (CARB-X) partnership, 32 within the Advanced Research and Development portfolio, and two using PBS funding. Through these efforts, BARDA supported the development of three antibiotics that achieved FDA marketing authorization.

BARDA is actively supporting 18 preclinical and clinical stage antibacterial candidates, including a microbiome-based therapy for recurrent *Clostridioides difficile*, a phage cocktail for recurrent urinary tract infections, and four innovative first-in-class candidates with activity against drug resistant health care-associated and community-acquired infections and biothreat pathogens. Five antibacterial candidates are currently in Phase 3 clinical development. BARDA is also supporting the late-stage development and procurement under PBS of NUZYRA for the treatment of both pulmonary anthrax and community-acquired bacterial pneumonia, and cefepime-taniborbactam for the treatment of melioidosis, urinary tract infections, and hospital-acquired bacterial pneumonia. For fiscal year 2023, BARDA is expanding its Advanced Research & Development portfolio to include drugs to treat drug-resistant fungal infections caused by *Candida* and *Aspergillus* species in response to a requirement for medical countermeasures to treat

fungal infections associated with injuries resulting from a nuclear detonation.

The Honorable Angie Craig

1) Assistant Secretary O'Connell, can you describe BARDA's investments into advanced manufacturing technologies? How can we further support the work of ASPR in bringing more of this production back from overseas?

Response: Throughout the acute phase of the pandemic response, solving critical public health supply chain issues has been a focus of our work at ASPR.

ASPR's industrial base management and supply chain work was borne out of these initial supply chain pinches the country experienced in March 2020 when the whole world needed the exact same supplies at the exact same time and they were all manufactured elsewhere. ASPR views addressing the challenge of ensuring that a resilient domestic PPE supply chain is available when needed as a two-prong process: first, we must invest in the domestic manufacturing of products; and second, we must create a market for those products.

To address the first prong, using emergency supplemental appropriations, ASPR is building a program to ensure that we have personal protective equipment and critical supplies manufactured in the United States moving forward. ASPR's Office of Industrial Base Management and Supply Chain (IBMSC) has spent over $17 billion on approximately 87 contracts to support the manufacturing of these supplies in the United States. There is currently no annual funding for ASPR's domestic manufacturing work. This work was funded by COVID-19 supplemental funding. ASPR has included a $400 million request in the FY 2024 President's Budget for Pandemic Preparedness and Biodefense. Part of this funding would be used to support continued investments in the domestic industrial base. We are hopeful that this funding will be included by Congress for this and future budgets to support this important work.

In addition to the sustained funding that is needed to continue this work, ASPR also needs construction authority as requested in the FY 2024 President's Budget. COVID-19 supplemental legislation included language that allowed ASPR to support the physical construction of domestic manufacturing facilities. Once the COVID-19 funds run out or are rescinded, we will no longer be able to utilize this authority. Codifying the authority for acquisition, construction, or alteration of non-federally owned facilities would allow ASPR to sustain the work to onshore and build domestic manufacturing capacity. We have asked Congress to consider granting us this authority as part of the Pandemic and All-Hazards Preparedness Act reauthorization.

To address the second prong of establishing a strong domestic manufacturing base for PPE and critical supplies, ASPR is also committed to supporting the fledging market by purchasing what it can from domestic manufacturers. ASPR has been able to leverage purchases by the Strategic National Stockpile for this purpose. In fact, ASPR is proud to report compliance with all Infrastructure Investment and Jobs Act provisions requiring that PPE in the SNS be domestically manufactured. However, domestically procured product

is, on average, 20-30 percent more expensive than internationally sourced product. Now that much of the COVID-19 supplemental dollars have been rescinded, any future purchases of PPE and critical medical supplies will have to come out of annual funding and the SNS currently receives no annual funding for these purchases. Given the continued bipartisan interest in investing in domestic PPE manufacturing, we are hopeful Congress might provide the SNS with increased funding as requested in the FY 2024 budget.

Finally, early in the COVID-19 response, it became clear that HHS could not procure the domestic products our country needed at the speed in which it needed them. As a result, we entered into a Memorandum of Understanding with the Department of Defense (DoD) in which they agreed to provide assisted acquisitions support on our behalf. DoD executed more than $90 billion in contracts for us over the three years of the acute response. DoD's unique authorities allowed it to save critical time when investing in early-stage vaccines, therapies, and tests. DoD could fund promising prototypes and then move the successful ones through the advanced research pipeline, without having to recompete the contracts. These authorities were used by DoD in support of Operation Warp Speed to procure five of the six COVID-19 vaccines on behalf of HHS. ASPR's current authorities, on the other hand, require it to stop and recompete the contracts when they move into the next phase of development. This is challenging for domestic manufacturers as it slows down momentum and creates uncertainty that a company will be funded to complete the work. The authority to award follow-on production contracts from prototypes without recompeting the requirements would allow ASPR to move more quickly and predictably in the future. In addition, ASPR was lucky that DoD was willing to take on this work for us during COVID. We know that DoD has its own set of critical national security responsibilities across this complex threat landscape and may not always be in a position to assist ASPR in contracting efforts.

We hope that domestic manufacturing authority, sustainable funding for the SNS, and additional acquisitions authorities will be considered as part of your legislative process.