Additional Questions for the Record
The Honorable Dawn O'Connell, Assistant Secretary for Preparedness and Response,
U.S. Department of Health and Human Services

The Honorable Cathy McMorris Rodgers

1. The U.S. government paid $10.6 billion for 20 million doses of Pfizer's oral antiviral pill, Paxlovid, in early 2022. It is understood these doses were promptly delivered. Pfizer announced in December 2022 the U.S. government committed to purchasing an additional 3.7 million doses, planned for delivery by early 2023, for another $2 billion.

   Response: Responses to the specific questions related to the purchase of additional Pfizer therapeutic products are below. It is important to note that this purchase was made in December 2022 to ensure that Americans had access to these lifesaving products. The 3.7 million purchase occurred when the previous DoD/State Department-USAID/HHS contract previously executed for international vaccine purchase—and no longer needed on the same terms, as international vaccine demand had diminished precipitously—was descoped. Rather than lose the critical taxpayer dollars already attached to the contract, HHS worked with Pfizer to use a portion of the descoped funds for a limited purchase of Paxlovid in anticipation of a winter surge. HHS did not put new money into this purchase.

   A. Please provide details on the state of supply when the additional 3.7 million doses were purchased, including how many Paxlovid doses the U.S. government had on hand.

   Response: In mid-December 2022, HHS reported 10,009,552 Paxlovid doses on hand.

   B. Were any of these doses set to expire?

   Response: The first expiration date for doses on hand at that time was April 2023.

   C. How much money is still owed to Pfizer for this purchase?

   Response: All funds were fully obligated at the time of initial award, final product acceptance and invoicing was completed in March 2023.

   D. What funding was used for the December 2022 purchase?

   Response: The purchase was funded with Coronavirus Response and Relief Supplemental Appropriations [appropriated to HHS] previously obligated in support of the United States Government's global COVID-19 vaccine donations , administered by the United States Agency for International Development.

2. In February 2023, the U.S. government purchased 1.5 million doses of the Novavax vaccine, which is available under Emergency Use Authorization. Information on the purchase price is not publicly available.

A. Please provide details on the state of supply when the additional 1.5 million doses were purchased, including how many Novavax vaccines the U.S. government had on hand.

Response: As of February 2023, 2,143,800 doses of the Novavax vaccine were on hand.

B. How much did the additional 1.5 million doses cost to purchase?

Response: The purchase cost of the 1.5 million doses was $8 million upon delivery of the product.

C. Were any of these doses set to expire?

Response: Original product purchased under the first contract were set to expire by February 28, 2023.

D. How much money is still owed to Novavax for this purchase?

Response: Novavax will be paid $8 million upon delivery of the full 1.5 million doses. As of February 2023, the USG has received 250,000 doses under this order.

E. What funding was used for the February 2023 purchase?

Response: HHS utilized funds from the Coronavirus Response and Relief Supplemental Appropriations Act (P.L. 116-260) for this purchase.

3. There have been several concerning reports regarding the use of taxpayer funding – both federal and state – during the COVID-19 pandemic. Just recently, a new report showed New York City spent $12 million for 3,000 ventilators, most, if not all, of which were then resold to a "junk dealer" less than three years later. This effort was intended to "shore up the New York City Strategic Reserve, a stockpile of medical devices that will be ready for any future crisis."

A. Particularly in light of the state stockpile grant pilot program included in the FY 2023 Consolidated Appropriations Act, please explain any and all current guidance provided to states on developing, maintaining, and managing inventory of current state stockpiles.

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 any and all current guidance provided to states on the Shelf Life Extension Program, and their ability to utilize this program to avoid waste of this magnitude.

Response: The Shelf-Life Extension Program is jointly managed by the Food and Drug Administration (FDA) and the Department of Defense (DoD). Certain drug products that are federally owned assets are eligible for testing through this program to potentially extend the shelf-life of the product. The FDA is the best resource for further information on this program.

4. Last year, the U.S. government agreed to spend over $6 billion to mail millions of at-home COVID-19 tests. Since January 2022, the Department of Health and Human Services (HHS) has allegedly delivered 737 million tests to homes via mail. However, the Administration has thus far provided no accounting to Congress of the number of tests sent, where the tests were sent, or the price of the tests. According to recent news reports, Administration officials, including White House staff, the U.S. Postal Service, and other agencies declined multiple requests for information for nearly a year.

A. Please provide a full accounting of the following by March 24, 2023. Information should include any and all activity that occurred between December 1, 2021 and March 1, 2023.

Response: ASPR has invested over $8 billion in domestic test manufacturers to accelerate production of rapid tests, expand manufacturing capacity, and support a skilled manufacturing workforce here in the United States. HHS facilitated the execution of two primary programs to ensure access of over-the-counter antigen tests through the At Home Delivery Program, also referred to as COVIDTests.gov. The second program is ASPR's Testing and Diagnostics Work Group (TDWG) Delivery to ensure broad access to COVID-19 tests for vulnerable populations. In January 2022, President Biden announced a plan to make one billion free at-home tests available to the American people that included mailing them directly to homes via the At Home Delivery Program in direct partnership with the U.S. Postal Service (USPS). Since this effort began in January 2022, ASPR, in partnership with the U.S. Postal Service (USPS), has delivered more than 753 million at-home tests to homes across the country.

- **A list of all COVID-19 tests contracted or purchased, including the country of origin of the tests:**

Response (CUI – Controlled Unclassified Information): All awards were made to U.S.-based subsidiaries of the following companies. They were all U.S.-incorporated. When the President first made his commitment of 1 billion tests, he promised not to disrupt the supply going to pharmacies, retail outlets, schools, and other key places that U.S.-manufactured tests were being delivered. As a result, we had to widen the aperture to include tests manufactured outside of the United States so as not to disrupt the current supply. Since those initial purchases, we have only purchased tests manufactured outside of the United States when all U.S.-manufactured tests have been purchased (with one exception). The exception to this was AccessBio. The following list represents the origin of manufacture:

  - Quidel – USA

- Access Bio – USA
- iHealth – USA and China
- Orasure – USA
- Abbott – USA
- Roche – South Korea
- Siemens – China
- MaximBio – USA
- InBios – USA
- Osang – South Korea
- Celltrion - South Korea
- Ellume – USA
- BD - USA

- **A list of all manufacturers who sold tests to the government**

  Response: See above

- **A list of all distributors who contracted with the government to deliver tests**

  Response:
  - Goldbelt
  - Atlantic
  - Medea

- **Total number of COVID-19 tests contracted, including a separate delineation of the total number of tests purchased from each manufacturer**

  Response (CUI – Controlled Unclassified Information): The total procured across all programs, including those that supported the USPS and TDWG programs were as follows:

  - Quantities purchased from manufacturers:
    - Quidel (USA) – 165,899,576
    - Access Bio (USA) – 89,000,000
    - iHealth (USA) – 72,000,000
    - iHealth (China) - 357,986,272
    - Orasure (USA) – 110,600,000
    - Abbott (USA) – 792,330,768
    - Roche (South Korea) – 158,000,000
    - Siemens (China) – 134,000,000
    - MaximBio (USA) – 8,900,000
    - InBios (USA) – 10,880,000
    - Osang (South Korea) – 100,000,000
    - Celltrion (South Korea) – 31,359,250
    - Ellume (USA) – 8,400,000
    - BD (USA) - 8,656,200

  - Quantities purchased from distributors:

        - Goldbelt - 8,000,000
        - Atlantic - 1,000,000
        - Medea - 9,152,480

- **Total number of COVID-19 tests purchased, including a separate delineation of the total number of tests purchased from each manufacturer**

    - **Response:** In aggregate, 2,066,164,546 tests have been purchased. The total number of tests purchased from each manufacturer is listed above.

- **Total number of COVID-19 tests distributed, including a separate delineation of the total number of tests distributed by each distributor**

    - **Response:** Through both programs, including the USPS distribution and TDWG distribution programs, more than 1.169 billion tests have been distributed. The distributor by channel is listed below.

- **Total number of COVID-19 tests delivered, including a separate delineation of the total number of tests delivered by each distributor**

    - **Response:** USPS has delivered 753 million tests through the At Home Delivery Program and the TDWG Program has delivered over 417 million tests.

- **Exact cost of each COVID-19 test contracted**

    - **Response:** The sum weighted average cost of each COVID-19 test kit contracted was $4.54. The weighted average cost across all DoD and HHS contracts by company follows below.

- **Exact cost of each COVID-19 test purchased**

    - **Response (CUI – Controlled Unclassified Information):** Weighted average test kit cost by company follows:

        - Quidel (USA) – $4.63
        - Access Bio (USA) – $2.93
        - iHealth (USA) – $2.65
        - iHealth (China) - $4.96
        - Orasure (USA) – $4.61
        - Abbott (USA) – $4.91
        - Roche (South Korea) – $4.18
        - Siemens (China) – $4.45
        - MaximBio (USA) – $6.44
        - InBios (USA) – $5.16
        - Osang (South Korea) – $2.37
        - Celltrion (South Korea) – $1.98

        - Ellume (USA) – $15.94 (please note: the additional cost accounts for their accessibility to those with visual impairments.)
        - BD (USA) - $8.66
    - Cost of Tests from Distributors:
        - Goldbelt - $6.45
        - Atlantic - $6.83
        - Medea - $6.82

- **Total cost of all COVID-19 tests contracted**
    - **Response:** The total cost of all COVID-19 tests contracted and purchased was approximately $9.325 billion.

- **Total cost of COVID-19 tests purchased, including a separate delineation of the total costs of tests purchased from each manufacturer**
    - **Response:** The total cost of all COVID-19 tests contracted and purchased was approximately $9.325 billion. The total by manufacturer is listed above.

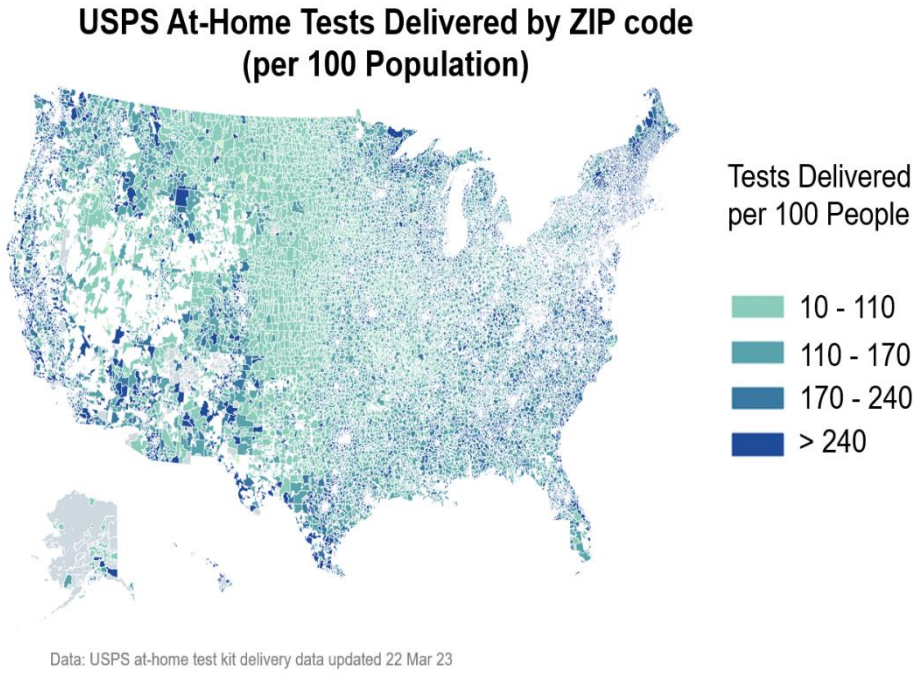
- **Total cost of shipping for the COVID-19 tests**

    - **Response (CUI – Controlled Unclassified Information):** ASPR cannot speak to the costs associated with USPS shipping and would defer to the Postmaster General; however, the TDWG mission has spent $37.1 million in shipping as of February 2023 with an average cost of $0.15 per test shipped.

- **Total cost of any termination fees on contracts in the case of cancelled or delayed orders**

    - **Response:** ASPR conducted no cost terminations for non-deliveries and funds were not spent on tests the U.S. government (USG) did not receive.

- **Exact location, identified by state, Congressional District, and zip code, where the tests were sent**
    - **Response:** The program allows anyone with a valid U.S. postal address to place an order. This includes persons in U.S. territories as well as U.S. government and military employees with a valid APO or FPO address. The below map represents the distribution of At Home delivered tests per capita by ZIP Code. Specific ZIP code level delivery data for the At Home Test kit mission remains proprietary to USPS; I respectfully request the Committee Chair seek this information directly from USPS. Since this effort began in January 2022, ASPR, in partnership with the U.S. Postal Service (USPS), has delivered more than 753 million at-home tests to homes across the country.



- **The data and/or formula on which the Administration relied in determining the location to send the COVID-19 tests**
    - **Response:** COVIDtests.gov relied on users to order tests. Tests were not distributed without a user-initiated order. Everyone living in the United States and U.S. territories, as well as U.S. government and military employees with a valid APO or FPO address, were eligible to order tests. People were able to order tests through the online COVIDTests.gov website or through a 1-800 toll-free call center. Households were only allowed to place one order during each of the four ordering rounds. Since this effort began in January 2022, ASPR, in partnership with the U.S. Postal Service (USPS), has delivered more than 753 million at-home tests to homes across the country.

- **Number of unique households that received a COVID-19 test**
    - **Response:** The program did not manage delivery of tests to unique households but rather operated via unique mailing addresses; considerations were made for multidomain and multifamily addresses. Since this effort began in January 2022, ASPR, in partnership with the U.S. Postal Service (USPS), has delivered more than 753 million at-home tests to homes across the country.

- **Number of households that received multiple COVID-19 tests**
    - **Response:** All households were allowed to place one order each round. That order provided four tests. Since this effort began in January 2022, ASPR, in partnership

with the U.S. Postal Service (USPS), has delivered more than 753 million at-home tests to homes across the country.

- **Number of COVID-19 tests currently in the Strategic National Stockpile**
  - **Response:** As of February 8, 2023, there were 532 million COVID-19 tests in the Strategic National Stockpile.

- **Number of individuals who requested free at-home COVID-19 tests through https://www.covid.gov/tests**
  - **Response:** To date, the program has purchased approximately 2.066 billion tests. This is inclusive of purchases throughout FY21-FY23. Since this effort began in January 2022, ASPR, in partnership with the U.S. Postal Service (USPS), has delivered more than 753 million at-home tests to homes across the country.

5. Originally created in the first Pandemic and All-Hazards Preparedness Act, the Assistant Secretary for Preparedness and Response is "the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies." For over a decade, the Government Accountability Office (GAO) has recognized HHS's leadership deficiencies it its ability to properly perform its lead role in coordinating and responding to public health emergencies. These coordination failures hindered the response to COVID-19.

   A. Please explain specific efforts the Administration for Strategic Preparedness and Response (ASPR), as the designated lead on federal preparedness and response issues, is making to ensure formal, defined, and effective coordination among entities within HHS and agencies across the federal government during public health emergencies.

   Response: ASPR's mission is to assist the country in preparing for, responding to, and recovering from public health emergencies and disasters. ASPR accomplishes our mission in several ways, including: developing, stockpiling, and distributing response tools against multiple threats; sending clinical response teams to places in times of crisis; and ensuring our health care and public health partners have the knowledge and tools they need to navigate today's challenges and confront whatever challenges lay ahead. ASPR utilizes authorities in the Public Health Service Act and responsibilities outlined in Emergency Support Function 8 (ESF-8, Public Health and Medical Services) and various Federal Interagency Operational Plans (FIOPs) under the National Response Framework (NRF) in order to coordinate within HHS and across the federal government.

   Additionally, ASPR coordinates the HHS Disaster Leadership Group (DLG), which serves as a forum for HHS senior leaders to deliberate and address specific policy and operational response issues that require guidance, decision-making, or concurrence from multiple HHS components, provides the HHS Secretary with unified policy recommendations or options, and identifies the full spectrum of HHS resources, funding, and subject-matter expertise that can be leveraged to mitigate gaps and challenges

effecting national health security. This body works closely with our interagency and White House colleagues as we coordinate responses to public health emergencies.

The recently released 2023-2036 ASPR Strategic Plan sets the direction for the organization, prioritizes agency actions, and facilitates coordination and collaboration with partners. The Strategic Plan reflects ASPR's continuing commitment to strengthen our ability to prepare, respond, and recover quickly from multiple health threats. All the factors and actions are considered in the development of other federal plans, such as the Federal Interagency Operational Plan and related Incident Annexes that are currently in development.

6. In the FY 2023 Consolidated Appropriations Act, a new Office of Pandemic Preparedness and Response Policy was created within the Executive Office of the President, led by a Director appointed by the President.

   A. Please explain ASPR's anticipated engagement and coordination with this new office, including how specific and defined roles, duties and responsibilities will be divided, duplicated, or enhanced.

   Response: As the White House works to implement the office, ASPR will continue coordination functions within HHS and among other parts of the U.S. government. We look forward to having a strong partner in the White House.

   B. Please explain how ASPR and the new office plan to coordinate and engage with other agencies involved in our nation's preparedness and response, including how roles and responsibilities will be clearly and fully defined.

   Response: This office has yet to be implemented. As the White House works to implement the office, ASPR will continue coordination functions within HHS and among other parts of the U.S. government. We look forward to having a strong partner in the White House.

7. ASPR is currently in the process of re-constituting the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). As of the creation of the new Office of Pandemic Preparedness and Response Policy in the FY 2023 Consolidated Appropriations Act, the PHEMCE is co-led by the Assistant Secretary for Preparedness and Response and the Office Director, and is tasked with developing requirements for medical countermeasure (MCM) stockpiling and procurement.

   A. Please explain, in detail and including any timelines, the vision and plan for PHEMCE moving forward, including any efforts to prevent future bureaucratic delays in the stockpile and procurement decision-making process.

Response: The 2022 PHEMCE Strategy and Implementation Plan[1] outlines the strategic vision, goals and objectives, and associated timelines for completing the outlined goals and objectives.

B. Please explain the revised leadership structure of PHEMCE, including reporting structures and how the current federal partners will engage.

Response: As part of the revised structure, the PHEMCE engages with federal partners at all levels to inform decisions about medical countermeasure preparedness, including technical work groups and leadership decisions. The PHEMCE is led by ASPR and includes the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Food and Drug Administration (FDA), Department of Defense (DoD), Department of Homeland of Security (DHS), Department of Agriculture (USDA), Department of Veterans Affairs (VA), and Office of the Director of National Intelligence (ODNI). Representatives from each agency meet regularly at the work group and leadership levels to develop and evaluate polices that inform decisions throughout the medical countermeasure enterprise. The agency heads meet every two months to review and approve recommendations from the work groups.

C. Please explain the engagement, coordination, and regular interaction PHEMCE currently has with industry and private stakeholders, and any plans to improve the engagement and increase the regular cadence.

Response: The PHEMCE continues to work on classified, market-moving, and commercial-confidential missions, which limit its ability to hold open meetings. PHEMCE members are continuously engaging with both federal and non-federal partners in their routine duties and continue to seek out opportunities to discuss the work of the PHEMCE with outside partners whenever feasible. Our medical countermeasure enterprise is built on the public-private partnerships established by BARDA. These relationships remain critical to the success of our work.

8. During the COVID-19 pandemic, Congress provided HHS over $70 billion to develop and procure vaccines, drugs, devices, tests, PPE and other emergency supplies. This funding was appropriated through supplementals funds in 2020 and 2021 and allocated to support providers and vulnerable populations. This is in addition to the funds provided in the FY 2023 Consolidated Appropriations Act.

A. Please provide a detailed accounting and summary of the unspent COVID-19 emergency supplemental balances that remain available to ASPR and HHS.

Response: Thank you for this question. All remaining unobligated HHS balances are being executed or already allocated for execution. ASPR's remaining funds are being put to research into next-generation vaccines and therapies, restocking the SNS, supporting

[1] https://aspr.hhs.gov/PHEMCE/2022-SIP/Documents/PHEMCE-SIP-2022-508.pdf

domestic manufacturing of critical medical supplies, and distributing vaccines and therapies until they move to the commercial market in the fall.

B. If applicable, please provide a detailed plan as to how ASPR plans to allocate any unspent funds in 2023 across ASPR's key programs, including Biomedical Advanced Research and Development Authority (BARDA), Strategic National Stockpile (SNS), and Project BioShield.

Response: Thank you for this question. All remaining unobligated HHS balances are being executed or already allocated for execution.

9. It is well recognized the COVID-19 pandemic stretched the Strategic National Stockpile (SNS) almost to its breaking point. As a result, many products previously stockpiled by the SNS have been fully exhausted or expired. These include therapeutics and vaccines to protect the American people against COVID-19, influenza, smallpox, and many other threats. This was confirmed by a recent report by the Government Accountability Office (GAO), which found the SNS did not contain the recommended quantities of most medical countermeasures required. In the FY 2023 Consolidated Appropriations Act, the SNS received $965 million. It is imperative these funds are deployed strategically and quickly to ensure the American people are protected from public health security threats.

A. Please explain, in detail, ASPR's plan, including a timeline, to ensure the SNS replenishes key products in the stockpile that have been expended or expired, particularly those products that have been previously recognized previously as noted gaps.

Response: A key priority of mine is increasing the funding to the Strategic National Stockpile, as requested in the FY 2024 President's Budget. This report highlighted what we have known to be true for many years: the SNS does not receive adequate funding to purchase all of the products necessary to fully prepare the country for whatever public health threat lies ahead. For FY 2023, Congress has appropriated $965 million to the SNS, $10 million below the amount requested in the FY 2023 President's Budget but $120 million above FY 2022 appropriated levels. ASPR anticipates using the funds to support procurement of several products previously supported by BARDA that lack a significant commercial market. These items include procurement of sufficient quantities of a domestically manufactured, FDA-approved, smallpox antiviral to treat an estimated 350,000 people during a smallpox incident, meeting the stockpiling requirement for this product. Additionally, SNS anticipates procurement of medical countermeasures (MCMs) to enhance response to a radiological/nuclear incident. Lastly, with any remaining funding, SNS may procure limited quantities of anthrax therapeutics. Congress should note that spend plans are still in development at the time of this hearing.

It is also important to note that with the re-launch of the PHEMCE in 2022, ASPR has finalized the PHEMCE Multiyear Budget for the first time since before the COVID-19 response. This report found that the SNS needs approximately $2 billion to fully fund its mission in FY 2024 and procure and sustain necessary products to prepare for and protect

against chemical, biological, radiological, and nuclear (CBRN) threats and infectious disease threats.

B. Please explain, in detail, ASPR's plan for any organizational or structural changes to the SNS contracting, procurement, and maintenance process to ensure the SNS is better prepared for future public health security threats.

Response: In July 2022, HHS Secretary Becerra designated ASPR as an operating division (or agency) within HHS. I deliberately requested this change to give ASPR more control, ownership, and visibility over contracting actions and procurement, among other key functions.

In February 2023, ASPR announced an internal reorganization to account for our growth and expanding mission space coming out of the acute pandemic response, and to incorporate many of the lessons we learned along the way. As part of this reorganization, I made the SNS a stand-alone office reporting directly to me. Previously, SNS was three levels down in the Office of Response. This new structure creates increased accountability and visibility into the work the SNS is doing, particularly as it endures increased scrutiny emerging out of the acute COVID-19 response.

10. Historically, ASPR's primary mission has been to prepare for and protect Americans from threats posed by intentional attacks with chemical, biological, radiological, and nuclear (CBRN) weapons. ASPR's mission has now expanded to emerging infectious disease outbreaks, natural disasters, and other public health security threats.

A. Please explain, in specific detail, what efforts ASPR is taking to ensure we are best prepared against CBRN threats, both from domestic and international adversaries.

Response: ASPR has long led the nation's preparedness for, response to, and recovery from all types of threats and disasters, including CBRN threats. ASPR partners closely with the intelligence community to understand the full range of CBRN threats, from domestic to international adversaries. ASPR also leverages quantitative risk modeling tools, including those supported by the Department of Homeland Security and internally within ASPR, to help ensure ASPR is addressing the most significant CBRN threats to national security and implementing the most impactful and cost-effective solutions.

Specifically, ASPR leads the PHEMCE, an interagency body that advises the HHS Secretary—and ASPR by delegation—regarding research and development plans and stockpiling actions to ensure the right balance of medical countermeasures (MCMs) for CBRN threats and emerging infectious diseases and to improve the availability and use of those countermeasures during disasters and emergencies. ASPR also supports the implementation of the 2022 National Biodefense Strategy and Implementation Plan, which outlines how the U.S. government should prepare for and respond to a wide range of bioincidents.

In partnership with industry, BARDA has built a robust and formidable pipeline of MCMs that are currently in advanced development. These efforts focus on countering the medical

consequences of 18 CBRN threats identified by the Department of Homeland Security. As of the date of the hearing, these advanced development programs have supported 36 products that have transitioned to support under Project Bioshield (PBS), 26 of which have been procured for the SNS. BARDA's efforts have led to 69 FDA licensures, approvals, or clearances of MCMs since 2008. Thirty-one of these (listed below) were developed to counter CBRN threats, eight of which received the Breakthrough Designation and 14 of which were approved under the FDA's Animal Rule.

- Raxibacumab anthrax antitoxin (2012)
- HBAT botulinum antitoxin (2013)
- Anthrasil anthrax antitoxin (2015)
- Neupogen to treat myelosuppressive radiation exposure (2015)
- Neulasta to treat myelosuppressive radiation exposure (2015)
- BioThrax vaccine for post-exposure prophylaxis of anthrax (2015)
- ANTHIM anthrax antitoxin (2016)
- Roche Cobas Liat *C. difficile* diagnostic (2017)
- VABOMERE to treat complicated urinary tract infections (2017)
- Leukine to treat myelosuppressive radiation exposure (2018)
- TPOXX oral formulation to treat smallpox disease (2018)
- ZEMDRI to treat complicated urinary tract infections (2018)
- XERAVA to treat complicated intra-abdominal infections (2018)
- RECELL to treat thermal burn wounds (2018)
- Seizalam to treat status epilepticus (2018)
- QMS Plazomicin Assay diagnostic to aid in plazomicin (ZEMDRI) therapy (2018)
- Silverlon dressing to manage mustard-induced vesicant injuries (2019)
- Applied Biosystems anthrax detection kit (2019)
- OraQuick Ebola rapid diagnostic test (2019)
- JYNNEOS smallpox and mpox vaccine (2019)
- ERVEBO Ebola vaccine (2019)
- INMAZEB to treat Ebola Virus Disease (2020)
- EBANGA to treat Ebola Virus Disease (2020)
- Quick Ebola Rapid Antigen Test to detect Ebola Zaire (2020)
- StrataGraft to treat deep-partial thickness burns (2021)
- NPLATE to treat thrombocytopenia from radiation exposure (2021)
- Lumify Ultrasound (2021)
- TEMBEXA to treat smallpox disease (2021)
- TPOXX intravenous formulation to treat smallpox (2022)
- Sliverlon for cutaneous radiation injury and radiation dermatitis (2023)
- Nexobrid for debridement of burn injuries (2023)

B. Please explain, in specific detail, how ASPR is prioritizing America's stockpile of critical CBRN vaccines, treatments, and PPE and ensuring they are well-maintained.

Response: The threat-based review of the contents of the SNS, required by section 319F–2 of the Public Health Service Act (42 U.S.C. 247d-6b), determines product acquisition

plans and stockpile targets. The threat-based review is an annual process that leverages PHEMCE expertise to inform ASPR prioritization of MCM investment, development, procurement, and stockpiling efforts against a limited budget. The threat-based review enables ASPR to identify gaps and prioritize MCMs for procurement or maintenance in upcoming budget cycles. The 2023 threat-based review (report name: The Medical Countermeasure Preparedness Review) is in final rounds of PHEMCE clearance and will be delivered to Congress in short order.

Ultimately, the procurement and maintenance of the materiel in the SNS is dependent on the availability of appropriations. An initial procurement begins the very expensive cycle of maintenance and sustainment. Products expire, degrade, require maintenance, and ultimately need to be repurchased. ASPR uses all methods available to us to extend the life of products, rotate products as part of vendor-managed inventory, and sell products to other parts of the USG where opportunities exist. However, ensuring America's stockpile of critical CBRN vaccines, treatments, and personal protective equipment (PPE) are well-maintained is an expensive mission. ASPR stands ready to provide additional information to the Committee about this work.

C. Please explain, in specific detail, how BARDA is engaging with industry private sector partners to ensure there is no disruption in the availability of these supplies.

Response: While BARDA has some minimal engagement with private sector partners in domestic manufacturing, ASPR's Office of Industrial Base Management and Supply Chain (IBMSC), added as a permanent office in ASPR's recently announced reorganization, supports the most direct engagement with private sector partners and is focused on expanding, securing, and building resiliency in the nation's capacity to manufacture PPE, essential medicines/chemicals, diagnostic tests, and vaccines, and bring these critical activities back to American shores. The office will continue to build on the investments made during the COVID-19 response to build and strengthen domestic manufacturing capacity for PPE and other public health and medical supplies. To reduce any possible disruptions in the availability of these supplies, it is important that we maintain and strengthen the capabilities we have built during the COVID-19 public health emergency and apply them to prevent shortages or supply chain challenges in the next outbreak or disaster we face.

11. From the early days of the COVID-19 public health emergency, private sector companies and experts engaged with the federal government to partner and provide best-in-class expertise. Productive public-private partnerships provide a means by which the very best science, technology, innovations and infrastructure can be brought to address the threat at hand, which was evidenced during the COVID-19 success stories. Unfortunately, there were also examples of how these partnerships can prove unsuccessful, including inflated contract prices for faulty products, failure to execute and fulfill contracts, and lack of transparency, reliability, and communication from the federal government.

A. Please explain specific actions ASPR is taking to improve the contracting and procurement process to ensure we can rapidly convene and contract with private

sector industry partners and experts in a productive manner, while providing necessary certainty and flexibility for our partners.

Response: I agree that public-private partnerships were critical to our early response efforts and is a model that BARDA uses in its daily advanced research and development work. The FY 2024 President's Budget seeks additional authorities, discussed below, to allow ASPR to execute acquisitions and contracting actions as quickly as some of our interagency colleagues.

Early in the pandemic, because HHS was unable to move contracts as fast as was needed, ASPR entered into an assisted acquisitions agreement with the Department of Defense (DoD) to execute contracts on our behalf. This agreement ends at the end of FY 2023, and it is imperative that ASPR be given similar authorities moving forward.,

Specifically, ASPR does not have the authority to award follow-on production contracts from prototypes without recompeting the requirements; this authority was used to procure certain COVID-19 vaccines. ASPR also does not have the broad authority afforded to DoD to procure experimental supplies, including diagnostic reagents and ancillary supplies like needles and syringes to be used in the development of the best solutions. ASPR lacks contracting mechanisms, like DoD's commercial solutions opening authority, that can facilitate rapid and efficient acquisition of technology and services in a response.

For the COVID-19 response, HHS had to partner with DoD to get the supplies and services it needed at the speed required for response. To support procurement of these products and critical supplies, as well as the tools and services to distribute them, ASPR proposes that Congress provide broader other transaction authority (OTA) for the organization to enter into arrangements other than contracts, grants, and cooperative agreements for additional specific circumstances when other mechanisms are not likely to achieve the best result or provide the best value to the government. Note that this proposal was included in the FY24 President's Budget request. If authorized, this authority would improve the speed and efficiency of developing a novel vaccine, therapeutic, or diagnostic and moving directly into large-scale manufacturing, reducing timelines to begin production by months.

To better position HHS to rapidly acquire the quantities of supplies needed for experimentation, technical evaluation, and strong operational capabilities in future emergencies, without relying on DoD or other Federal agencies, we also propose providing ASPR the authority for procurement and acquisition of supplies for experimental or test purposes, similar to that of DoD's. These materials and assets would include chemical materials and reagents, medical supplies, PPE, and ancillary supplies (e.g., needles and syringes) for the development of supplies needed for national public health and health security.

Further, providing ASPR the authority to acquire innovative commercial products, services, processes, and methods—like DoD's commercial solutions opening authority—would allow ASPR to acquire products or services such as technology investment

agreements, research and development activities, and other capabilities needed to respond to an outbreak in the future without relying on other federal agencies.

The Honorable Gus Bilirakus

1. **How is ASPR ensuring it has access to the range of real-world evidence capabilities needed by respective HHS agencies to be prepared to answer key questions for disease surveillance, front line treatment, public health planning and accelerated development of effective therapies and vaccines?**

   Response: ASPR partners with numerous HHS agencies, including CDC, NIH, CMS, ONC, and FDA, to facilitate information sharing, provide situational awareness for existing and emerging health threats, and inform decision makers. In early 2023, ASPR, CDC, and CMS created the Hospital Surveillance Data Council to establish governance over health care facility data collection and to streamline inter- and intra-agency data sharing. Additionally, ASPR and CDC continue to partner on HHS Protect and Tiberius. HHS Protect is the Public Health Emergency Common Operating Picture for HHS and Tiberius is the MCM supply, production, and distribution tracking tool for ASPR. Both systems combined data and analytics from hundreds of different data sources across state, local, tribal, and territorial governments, other federal agencies, and the private sector. The data streams include data on testing, hospital admissions, deaths, vaccine and therapeutic utilization, and supply chain, among other details. ASPR, through the Supply Chain Control Tower, is also monitoring the medical supply chain, looking for emerging threats or impacts from public health emergencies. ASPR and CDC are also closely partnered on modeling and forecasting through CDC's Center for Forecasting and Analytics and formal interagency agreement.

2. **In your testimony you reference the role that ASPR continues to play in responding to the COVID-19 pandemic. That this has been ongoing since Operation Warp Speed was initiated, and that ASPR continues to be an integral part in the procurement and distribution of vaccines, therapeutics, and tests. At what point does ASPR intend to entirely transition their role in this process to more appropriate agencies and private sector entities as we navigate a future where COVID-19 is endemic? What is your plan to swiftly maneuver throughout this transition? Please provide a concrete timeline for this process.**

   Response: I agree with you. We are reaching an end to the acute response phase of the COVID-19 pandemic, and it is important that much of the emergency response work ASPR has led during this phase transition to other federal and private partners as we move to steady state. One important function that ASPR will maintain, as we make this transition, is the advanced research and development work that BARDA will lead with NIH on next-generation vaccines, therapeutics, and diagnostics. It is critical that we have new tools in the pipeline that improve upon the ones we currently have. This virus continues to mutate, and our countermeasures must continue to keep up.

   With this in mind, we are making several changes in the coming months to step back from our current role as the procurer and distributor of the current vaccines and therapeutics. Commercialization is necessary to transition COVID-19 countermeasures to established pathways

for distribution and payment. While there are many considerations, and timelines may shift based on the trajectory of the virus, we anticipate that the transition of vaccines to established pathways for distribution and payment will occur in early fall 2023. The transition of therapeutics to the commercial market will vary by product and will likely occur for at least one of the oral antivirals beginning in late fall 2023.

To that end, we have hosted a series of eight webinars and listening sessions with partners from patient and provider groups, advocacy organizations, manufacturers, distributors, and other stakeholders to gather feedback on how we can support a smooth transition to the commercial market. In late February 2023, we convened our most recent webinar that engaged all stakeholder groups with whom we have been working thus far. H-CORE remains actively engaged with our HHS colleagues in coordinating the transition in a thoughtful, well-synchronized manner.

ASPR also is working with our partners, including CDC, IHS, HRSA, ACL, and others, to coordinate actions between federal partners to ensure they have what they need as we move towards commercialization.

The Honorable Neal Dunn, M.D.

1. **Does BARDA have statutory or regulatory authority to approve for use the products it helps advance and develop?**

   Response: Thank you for this question, but no, ASPR is not a regulatory agency.

2. **Is it fair to say that BARDA's success is dependent at least in part on the FDA?**

   Response: Thank you for this question. Medical products developed in the United States, including products developed by ASPR, are subject to FDA premarket authorization requirements.

3. **Why did the administration choose to centralize the control of distribution of monoclonal antibodies and other COVID-19 therapeutics at the federal level?**

   Response: The federal government's priority is to distribute COVID-19 therapeutics in an efficient, equitable, and transparent manner. Under the current system, state and territorial health departments can order COVID-19 therapeutic products seven days a week in a process known as "threshold and replenishment." In this process, the federal government replenishes the available supply, replacing products ordered by sites in the jurisdiction the previous week. This ensures that the total amount of product available to jurisdictions each week is consistent. Requests for additional products can be made by state and territorial health department officials at any time if the current supply is not sufficient to meet demand.

The Honorable Greg Pence

We all remember the testing shortages during the Omicron surge in the winter of 2021 as demand outpaced supplies. Unfortunately, this shortage came during the holiday season as many people were traveling. According to a GAO report released in October 2022, the Strategic National Stockpile, which

is a vital part of our medical response infrastructure, did not contain the appropriate quantities of recommended medical countermeasures.

1. **What is ASPR doing to ensure that we are better prepared with diagnostic testing for future public health emergencies, and what steps are you taking to ensure that the appropriate quantities of diagnostic testing equipment and supplies are included in the Strategic National Stockpile?**

   Response: The Omicron variant hit just as manufacturers of over-the-counter tests—only recently introduced to the broader market at that time—were starting to ramp up manufacturing. The manufacturing timing and overwhelming transmissibility of the Omicron variant left the country well short of the demand at the time for over-the-counter- tests. At the time, ASPR's Office of Industrial Base Management and Supply Chain (IBMSC), which is now a permanent office in ASPR's recently announced reorganization, focused on supporting manufacturers, identifying critical supplies, and procuring and distributing tests as quickly as they came off of the supply line. Fortunately, we have seen demand and supply level out since that initial surge, but to be sure, we have stockpiled 532 million tests in the Strategic National Stockpile to use in case of an unexcepted surge. We now know that it takes about six to eight weeks to ramp up manufacturing; those 532 million tests will provide a stop gap for the country while manufacturing catches up.

   In addition, ASPR's Biomedical Advanced Research and Development Authority (BARDA), Detection Diagnostics and Devices Infrastructure (DDDI) Division is funding development of leading-edge diagnostic products for use in response to future biological incidents across the spectrum of diagnostic needs. Use cases being addressed include home-use molecular tests and point-of-care molecular testing platforms, both to bring testing closer to the patient and enable test-to-treat care scenarios. Also included are pathogen family tests and next-generation sequencing-based threat agnostic testing, to make diagnostic testing available faster. BARDA/DDDI is also working in collaboration with IBMSC to ensure test manufacturing capabilities for these and other critical testing technologies are available domestically and able to produce needed tests quickly during a biological incident.

The Honorable Buddy Carter

1. **When Americans turned to the Strategic National Stockpile (SNS) in 2020, they found its contents depleted and outdated. What steps is ASPR taking to ensure that the SNS is well equipped for the next public health emergency?**

   Response: I agree. A well-stocked Strategic National Stockpile (SNS) is critically important for our preparedness and response posture moving forward. Restocking the SNS after those early COVID-19 days has been an important priority for me. Using supplemental funds appropriated to respond to the COVID-19 pandemic, SNS has significantly increased its inventory of domestically manufactured PPE and ventilators that could be used to respond to a future pandemic or CBRN event. Going forward, maintaining this capacity is important but additional funding will be needed to ensure capacity is sustained. This requirement is reflected in the Mandatory Pandemic Preparedness proposal included in the FY 2024 budget request.

The SNS is tasked with holding more than just PPE and pandemic-related supplies. It must stock critical medical countermeasures (MCMs) necessary to protect the health security of the United States. The MCMs held in the SNS are FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease. MCMs held by SNS are intended to supplement and resupply state and local public health agencies in the event of an emergency. In addition, many of the products within the SNS are not commercially available and the SNS/USG is the only purchaser of the products.

The threat-based review of the contents of the SNS, required under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d-6b), determines product acquisition plans and stockpile targets. The threat-based review is an annual process that leverages PHEMCE expertise to inform ASPR prioritization of MCM investment, development, procurement, and stockpiling efforts against a limited budget. The threat-based review enables ASPR to identify gaps and prioritize MCMs for procurement or maintenance in upcoming budget cycles. Ultimately, the procurement and maintenance of the material are dependent on congressional appropriations.

2. **During the COVID-19 pandemic, we saw the United States experience shortages of large quantities of medications, active pharmaceutical ingredients (APIs), and drug precursors from Communist China. What is the Federal government doing to ensure that Americans are not dependent on our adversaries for critical medicines?**

Response: With funds appropriated though COVID-19 supplementals, ASPR is investing in domestic manufacturing of several important medical supplies, including API. As an example, on May 18, 2020, BARDA awarded Phlow Corp. a contract (75A501200C00092) to address the near-term threat of drug shortages of essential medicines for hospitalized COVID-19 patients, to establish a Strategic Active Pharmaceutical Ingredient (API) Reserve (SAPIR), and to build U.S.-based advanced large scale commercial manufacturing capabilities to supply domestic self-sufficiency for manufacturing of critical APIs and finished essential medicines to prevent future drug shortages. This work is intended to strengthen U.S. national health security interests by enhancing the nation's supply chain resiliency for essential medicines, including those used for COVID-19 patients, and ensuring that the United States has the necessary API reserve and U.S.-based manufacturing capabilities to meet the nation's needs for patient care in national emergency situations. These initial efforts have proven successful and Phlow has met all the contractual milestones; however, additional funds will be required to sustain these efforts going forward.

To build and sustain a domestic advanced pharmaceutical manufacturing ecosystem, additional HHS investments through the ASPR Office of Industrial Base Management and Supply Chain (ASPR-IBMSC) have been directed at developing and deploying innovative manufacturing technologies, as well as establishing new partnerships to improve the responsiveness and resilience of the domestic pharmaceutical supply chain. These investments to address API and KSM supply chain vulnerabilities include domestic direct, biologically derived production of APIs and antibiotics and fine chemicals or catalysts whose use are more prevalent in U.S. pharmaceutical production.

3. **Scientists have described the growing trend of antimicrobial resistance as one of the greatest public health crises facing the world. And yet, the development of novel antibiotics is at an all-time low. What is the Federal government doing to incentivize the development of novel antibiotics and ensure the American public has ready access to effective antimicrobials?**

   Response: I agree. 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. Fortunately, BARDA has long recognized AMR as a threat to our national security as well as our ability to provide a certain standard of care. BARDA's antimicrobials (AM) program is developing MCMs that treat both DHS-identified biothreats (anthrax, plague, tularemia, melioidosis, and glanders) and health care-associated and community-acquired drug-resistant 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 development of three antibiotics to FDA marketing authorization.

   BARDA is actively supporting 18 preclinical and clinical stage antibacterial candidates, including a microbiome-based therapy for recurrent C. difficile, a phage cocktail for recurrent urinary tract infections, and five innovative first-in-class candidates with activity against drug resistant health care-associated and community-acquired infections and biothreat pathogens. Six 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.

4. **The entire nation was caught flat footed when COVID19 hit. That was particularly evident with the SNS program within ASPR. Now that we are on the other side of the pandemic, do you believe you have all the tools necessary should another pandemic hit? Specifically, do you believe there should be a continuous cycle rotation of pharmaceuticals that are part of the SNS? Do you believe additional products, such as generic shortage products, be included in the SNS and/or as part of a new stockpile of essential medicines to help prevent and mitigate shortages?**

   Response: The FY 2024 President's Budget seeks additional funding for the SNS to ensure it is able to meet its mission. In order to fully stock it so we are prepared for the next threat, the recent PHEMCE Multiyear Budget estimates that $2 billion annually is needed to fully stock the SNS—this is over $1 billion more than it received last year.

   In addition to funding, the FY 2024 President's Budget outlines new tools that are needed to better track and manage medical product shortages.

   Specific to the SNS holdings, SNS utilizes vendor-managed inventory (VMI) when practical. When industry and the market can support the volumes relative to shelf-life, VMI is a better

value. Consideration for VMI or VMI with rotation is always done as part of the acquisition strategy and requirement development. SNS's use of VMI with rotation is limited by several factors, including SNS holding of CBRN materiel for which there is limited or no commercial market (thus no means to rotate stock) and large SNS requirements that exceed the rotational capability of vendors.

The threat-based review of the contents of the SNS, required under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d-6b), reviews the status of the SNS holdings against all the needed MCMs required to respond to the array of threats the United States faces. The threat-based review is an annual process that leverages PHEMCE expertise to inform ASPR prioritization of MCM investment, development, procurement, and stockpiling efforts against a limited budget. The threat-based review enables the ASPR to identify gaps and prioritize MCMs for procurement or maintenance in upcoming budget cycles. Ultimately, the procurement and maintenance of the SNS are dependent on the availability of appropriations.

The Honorable Troy Balderson

1. **What is the current rate at which COVID-19 vaccines are wasted? Can you provide the data showing the estimated percent of shots wasted dating back to January 2021? What is the estimated cost of that waste to the taxpayer?**

Response: The USG-required delivery schedule for COVID-19 vaccine product was developed to provide an opportunity to vaccinate all eligible U.S. persons with primary series and booster doses. ASPR projected vaccine distribution requirements based on the population of the United States and the rate of vaccination at any given time to ensure there was adequate supply of vaccines across the country for anyone who wanted it. As the rate of vaccine administration slowed due to declining vaccine acceptance, the likelihood of leaving unused doses in a vial increased, even as providers continued to follow best practices to spare every dose possible. 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. **Can you please outline the similarities and differences between Operation Warp Speed (OWS) and its successor, HCORE? A reason for OWS' speed and success was the balance between the public sector's financial investment and the private sector's freedom to innovate. How will HCORE continue to work with and integrate the private sector?**

Response: The vaccines and therapeutics available to us today are the result of an unprecedented partnership between HHS and the Department of Defense, 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 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.

Partnerships are the foundation of H-CORE. Its work requires close coordination across the federal government; private industry; and state, local and territorial governments. H-CORE leverages the expertise and experience found both inside and outside of government to accelerate solutions to public health threats, and then make those solutions available to the American people. One example is H-CORE's relationship with the major pharmacy chains. As a result of this strong partnership, we have been able to distribute vaccines, therapeutics, and tests to pharmacy locations—where 50 percent of Americans are likely to receive their vaccines. Likewise, H-CORE works with ASPR's Regional Emergency Coordinators and Regional Medical Countermeasures Advisors to conduct outreach and stakeholder engagement with state and territorial health departments. H-CORE uses commercial business practices to approach logistical challenges and integrates, prioritizes, and accelerates end-to-end solutions to combat these threats.

3. **In December, ASPR purchased 3.7 million courses of Paxlovid. Last week, HHS purchased 1.5 million doses of the Novavax COVID-19 vaccine. How many doses of each have you so far received and distributed? Do you expect those doses to be exhausted by the time both products are commercialized? What funding was used for this purchase? When commercialized, how will you ensure no one pays for doses that taxpayers have already purchased?**

Response: Over the last three years, using COVID-19 supplemental funding provided by Congress, the U.S. government has taken the lead to develop, purchase, and distribute countermeasures to combat the unprecedented circumstances of the COVID-19 pandemic. We have been planning for the move away from government-purchased COVID-19 vaccines and treatments for months and are working with industry partners to transition the purchase and distribution of vaccines and therapeutics to more standard pathways where such products would be covered by public and private payors and distributed through traditional channels. Timelines regarding commercialization are different for each product and depend on several factors, including the trajectory of the virus, the products' regulatory status, and the manufacturers' ability to manufacture enough product for nationwide distribution. As we work through these and other issues, our aim is to provide a smooth transition for each product as it enters the commercial market while remaining accessible to those that need it. Commercialization is necessary to transition COVID-19 countermeasures to established pathways for distribution and payment by both public and private payers. For the Paxlovid procurement, HHS utilized funds that were de-obligated from a DoD/State Department-USAID/HHS contract that was descoped. In mid-December 2022, HHS reported 10,009,552 Paxlovid doses on hand. The first expiration date for doses on hand at that time was April 2023. We do not have a specific commercialization timeline for Paxlovid at this time. The date to transition is dependent on, for example, how quickly we draw down the existing USG-purchased supply and the manufacturer's readiness for commercialization.

2,143,800 doses of the Novavax vaccine were on hand when the 1.5 million doses were purchased. Funding under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (P.L. 116-136) supported the contract for the February 2023 Novavax purchase. Providing a non-mRNA vaccine option to Americans, including those who cannot tolerate mRNA, has remained

an important component of our vaccine program. At this time, ASPR does not plan on purchasing additional doses of COVID-19 vaccines. We remain focused on distributing and managing the existing supply of USG-purchased COVID-19 vaccines and continuing to work with commercial partners to transition the development and distribution of vaccines and therapeutics to the private sector. We anticipate that vaccines will transition to the commercial marketplace in the fall of 2023.

4. **We have heard from industry that, up to 18 months ago, ASPR promised a request for proposals regarding the Strategic National Stockpile, emergency distribution centers, and the lessons learned from Operation Warp Speed and COVID-19 in general. They still have not received this solicitation from ASPR. Again, I see PAHPA as a great vehicle to make these needed reforms. Will you commit to issuing a request for proposals from your private sector partners within the next 60 days?**

   Response: I am unaware of this request for proposal solicitation. We remain grateful for our industry partners and continue to seek out their advice and consultation. Since those challenging early days, BARDA has resumed and expanded contacts with industry on a variety of MCM requirements and ASPR has firmly committed to three comprehensive activities that address our supply chain issues from different angles. The Industrial Base and Medical Supply Chain Division, the HHS Coordination Operations Response Element, and the Supply Chain Control Tower all utilize data from and about industry and industry stakeholders, including both national and global supply chain factors. ASPR will continue to maintain an open dialogue with private sector partners, to the extent the law allows, and issue requests for information or proposals, as well as standard funding opportunity announcements, to address specific gaps and challenges as we coordinate across the entire supply chain landscape. We would be very happy to discuss supply chain related proposals in legislation with staff members.

5. **What is our current system for monitoring and testing community-wide wastewater? Are there ways to expand or improve capacity for states and localities to test wastewater to be better prepare for specific strains or increased prevalence of disease?**

   Response: Thank you for this question, but ASPR does not monitor wastewater. CDC leads this work.

6. **Historically, public health response relied on syndromic surveillance. With passive technologies advancing, how is ASPR utilizing wastewater as a data point for pre-syndromic surveillance to inform policy making, response, and medical counter measure development? What insights can be gained from facility level wastewater surveillance as compared to municipal level wastewater surveillance? How is ASPR looking to integrate domestic and international wastewater surveillance into their COP to equip decisionmakers to accelerate medical countermeasures?**

   Response: Thank you for this question, but CDC leads this work.