Select Subcommittee on the Coronavirus Pandemic
U.S. House Committee on Oversight and Accountability

Examining the White House's Role in Pandemic Preparedness and Response
March 6, 2024

Office of Pandemic Preparedness & Response Policy
Answers to Questions for the Record

Questions from Chairman Brad Wenstrup, D.P.M.

1. **Has the Office of Pandemic Preparedness and Response Policy (OPPR) been involved in National Science Advisory Board for Biosecurity (NSABB) discussions or deliberations concerning U.S. policy regarding gain of function research or dual use research of concern? If not, do you anticipate OPPR engaging with the NSABB on these issues? If not, why?**

On January 6, 2023, the National Science Advisory Board for Biosecurity (NSABB), a federal advisory committee to the Department of Health and Human Services (HHS), delivered a draft report regarding "Proposed Biosecurity Oversight Framework for the Future of Science." The National Institutes of Health (NIH) released the final version of the NSABB report on March 6, 2023. On August 7, 2023, I was appointed the inaugural Director of the Office of Pandemic Preparedness and Response Policy (OPPR). OPPR is responsible for coordinating federal policy and activities to prepare for, and respond to, pandemic and other biological threats. Accordingly, OPPR shares its perspective and advice to agencies as appropriate.

2. **Has OPPR provided any policy advice or other counsel to the White House or federal departments and agencies concerning the U.S. position or approach concerning the proposed Pandemic Accords in the World Health Organization? If not, do you expect OPPR will be involved?**

Pandemics can start anywhere and are, by definition, global events: They not only create health risks, but also create national security and economic risks for U.S. citizens and people around the world. The Pandemic Accord negotiations are intended to improve global health security by enhancing the global ability to detect emerging infectious disease incidents as early as possible and by improving the ability to mitigate these biological incidents. OPPR, consistent with its authorizing statute, advises on international cooperation in preparing for, and responding to, pandemics and biological threats to national security.

3. Monoclonal antibody (mAb) treatments were an important tool during COVID-19 for patients with compromised immune systems. Those with HIV/AIDS, organ transplants, and autoimmune diseases often couldn't rely on vaccines for protection. But mAbs became less effective over time as COVID strains changed. However, these patients are still at great risk for COVID, suffering from higher disease burden and mortality, and need new options in the future.

- **As co-chair of the Public Health and Emergency Medical Countermeasures Enterprise (PHEMCE), how is your office coordinating with HHS to develop new mAbs that can be used to prevent COVID-19 for immune-compromised patients?**

- **Does the Administration plan to support new "plug and play" platform technologies, which would allow quick changes to mAbs to keep up with COVID strain changes? If so, how does HHS plan to speed their development?**

In response to Question 3:

The Biden-Harris administration has made significant investments in the development of therapeutics for COVID-19, funding basic research, early-stage innovation, and more advanced technologies since January 2021. Project NextGen has also allocated $1.25 billion to advanced development of new COVID-19 therapeutics, with additional amounts allocated to support earlier stage development of new platform approaches, as well as technologies that support improvements in vaccines and therapeutics, including monoclonal antibodies—whether faster development, less expensive manufacturing, or better access. Since June 2023, HHS, through Project NextGen has carried out the following:

- Provided $100 million in funding for an investment portfolio to expand investments in early-stage vaccine and therapeutic technologies.
- Invested $326 million in Regeneron's monoclonal antibody pre-exposure prophylaxis candidate to neutralize SARS-CoV-2 variants. It is designed to prevent infection in individuals who are immune compromised or who are not protected adequately by vaccination. The Chemical and Biological Defense Program at the Department of Defense has also had success using high performance computer and artificial intelligence to quickly retarget mAbs to keep up with SARS-CoV-2 variants.
- Invested in two early-stage candidates utilizing new platform approaches that, if successful, will be able to better adapt to the emergence of new emerging variants.

Additionally, on November 30, 2023, the Biomedical Advanced Research and Development Authority (BARDA) announced a request for project proposals from product developers for the advanced clinical development and assessment of Next-Generation pre-exposure prophylaxis therapeutics for COVID-19. In light of the ongoing capability gap for therapeutics that provide protection through pre-exposure prophylaxis and treatment against new SARS-CoV-2 variants,

BARDA is looking to partner with developers and other organizations to advance the clinical development of the next generation of therapeutics for COVID-19. To be considered for an award, applicants must provide epitope mapping and data demonstrating that their product has a high barrier to resistance, including demonstration that multiple mutations are required to generate a resistance variant that is as fit as other circulating variants.

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Questions from Rep. Debbie Dingell

1. What steps did OPPR take to ensure that our whole-of-government response stayed on top of the threat posed by this recent respiratory virus season?

The respiratory disease season affects millions of people each year, and OPPR has worked closely with departments and agencies to coordinate a robust response to the fall/winter respiratory disease season. Prior to OPPR's creation, a combination of industry and government efforts ensured that, for the first time in history, vaccines or immunizations were available to help protect against severe illness caused by COVID-19, influenza, and respiratory syncytial virus (RSV). There is now a Food and Drug Administration (FDA)-approved and Centers for Disease Control and Prevention (CDC)-recommended RSV vaccine for individuals between 32 and 36 weeks of pregnancy to prevent lower respiratory tract disease in infants from birth through 6 months of age. Additionally, an RSV immunization (preventive antibody) for infants was recently approved, and there are two RSV vaccines approved for use in individuals aged 60 years and older. The immunization for infants has been shown to reduce the risk of RSV-related hospitalizations and healthcare visits by nearly 80 percent. To meet demand for dose availability of the RSV immunization for infants, the Administration held several meetings with the manufacturers, eventually resulting in the accelerated release of hundreds of thousands of additional doses.

The Administration also convened two summits with leaders and stakeholders from the long-term care facility industry to discuss opportunities to better protect elder Americans, who are at increased risk of severe illness if they become infected with respiratory pathogens. OPPR is leveraging the lessons learned from this season to convene stakeholders from across the interagency and industry to help integrate planning efforts for the 2024-25 fall-winter respiratory disease season.

Overall, COVID-19 deaths were 69% lower in 2023 than 2022, but COVID-19 remains the tenth leading cause of death among Americans and many of these deaths could be prevented using widely available vaccine and therapeutics. OPPR remains committed to learning from past and current experiences to integrate and synchronize efforts to better prepare for future predictable biological events, like the fall-winter respiratory disease season, as well as future unpredictable biological events from new naturally-occurring pathogens, or as a result of accidental or deliberate releases of pathogens.

2. Last year, updated Influenza and COVID vaccines were approved by FDA in July and September respectively. As a result, there was a five-week gap between both vaccines being available at the same time in pharmacies, clinics and doctor's offices. Data indicate that the COVID vaccine uptake rate was around 10% higher for those who also received the Influenza vaccine when both vaccines were available as compared with the first five-week period when only the Influenza vaccine was available.

a. What role is OPPR playing this year in coordinating with FDA and CDC for influenza and COVID vaccines for 2024?

b. What actions could OPPR, FDA and CDC take this year to reduce or eliminate the gap between Influenza and COVID vaccines approval and recommendation dates?

c. What support, if any, do Federal agencies need to achieve closer alignment of Influenza and COVID vaccines approval and recommendation dates?

In response to Question 2:

The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) can meet at any stage of FDA's evaluation of a medical product, as well as after a product has been approved and marketed. Typically, a VRBPAC meeting is held to advise FDA and provide recommendations related to clinical trial data for vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which the FDA has regulatory responsibility. It met on March 5, 2024, to discuss and make recommendations on strain selection for 2024-2025 influenza vaccines. It recommended switching from a quadrivalent to trivalent influenza vaccine for the next influenza season. FDA generally follows the VRBPAC's recommendations when selecting influenza strains. Following the March 5 VRBPAC meeting, FDA informed the public that the United States would move from quadrivalent to trivalent influenza vaccines for the 2024-2025 influenza season. FDA anticipates that there will be an adequate and diverse supply of approved trivalent seasonal influenza vaccines for the United States in the coming season. On May 16, 2024, VRBPAC will meet to discuss and make recommendations on strain selection for 2024-2025 COVID-19 vaccines.

The Advisory Committee on Immunization Practices (ACIP) develops recommendations for U.S. immunizations, including ages when vaccines should be given, number of doses, time between doses, and precautions and contraindications. The ACIP's recommendations are forwarded to the CDC Director and once adopted become official CDC policy. These recommendations are then published in CDC's Morbidity and Mortality Weekly Report. The ACIP holds three regular meetings each year, in addition to emergency sessions, to review scientific data and vote on recommendations for immunizations. The ACIP is next scheduled to meet on June 26 to June 28, 2024, and ACIP plans to make recommendations for the use of 2024-2025 COVID-19 vaccines at that time. In the past, ACIP made recommendations for updated COVID-19 vaccines at

emergency sessions following FDA authorization or approval of updated products, typically in September. A vote at the June ACIP meeting would align COVID-19 vaccine recommendation timelines with influenza vaccine recommendation timelines.

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Questions from Rep. Robert Garcia

1. In your capacity as Director of the White House Office of Pandemic Preparedness and Response (OPPR), can you elaborate on the challenges the COVID-19 pandemic raised with regards to our country's ability to quickly and effectively procure and distribute needed medical supplies like personal protective equipment, tests, and vaccines?

2. Was it a challenge for the federal government to buy these kinds of supplies early in the pandemic?

In response to Questions 1 and 2:

Later this year, OPPR will provide a report to Congress that summarizes observations from the recent pandemic as well as opportunities to enhance our preparedness for future biological events. Independent of that report, it is clear that the COVID-19 pandemic posed significant challenges to our country's ability to procure and distribute personal protective equipment (PPE) and medical countermeasures (MCM) when they were in greatest demand. The pandemic exposed vulnerabilities in the nation's medical supply chain including the lack of access to key ingredients that are only available from foreign sources, manufacturing, distribution, and administration of critical supplies and MCMs. Supply chain disruptions were multifaceted, but included effects from an extended global lockdown, transportation restrictions, congestion at ports and freight delays, crisis driven demand increases and hording, and workforce disruptions. The combination of these issues led to significant distribution challenges. Among other things, the federal government had to compete for PPE and MCM with other countries, state and local authorities, and the domestic and global healthcare industry. Additionally, it became evident the need for PPE and other critical supplies extended beyond healthcare workers to a broader range of critical workers needed to keep our communities and economy going. Our report will provide more details on these issues, along with recommendations for actions Congress can take to mitigate the risks the United States will face during future biological events.

3. Last year, I introduced H.R. 3794, the Fast-track Logistics for Acquiring Supplies in a Hurry (FLASH) Act that would authorize the Biomedical Advanced Research and Development Authority to award follow-on production contracts or transactions, procure supplies for experimental or test purposes, and acquire innovative commercial products and commercial services in the event of an emergency like COVID-19. Would a policy like the FLASH Act make a difference if we were faced with a similar emergency—and is this something that could save lives?

The authority to award follow-on production contracts from prototypes without recompeting requirements would allow the Administration for Strategic Preparedness and Response (ASPR) and BARDA to move faster in the future without having to rely on the support of the Department of Defense (DoD). DoD has its own critical national security responsibilities across a complex threat landscape, and it may not always be able to assist other federal contracting efforts.

Additional legal authority for ASPR would strengthen its ability to execute contracts during a public health event or emergency. During the COVID-19 response, the BARDA and DoD partnership allowed for the use of non-competitive follow-on production agreements and allowed the United States government (USG) to lock in a lower price during the initial agreement since the USG was guaranteeing a procurement if the developer was successful in achieving data to support emergency use authorization. The USG has leverage to negotiate a better price at the beginning of an effort. If a separate contract needs to be negotiated for procurement, the USG could lose that negotiating advantage. Giving BARDA this authority would allow BARDA to use product development contracts awarded prior to a pandemic to rapidly pivot to a response if there is an outbreak—something that cannot occur currently. Increased and streamlined procurement capabilities would likely translate to lives saved.