U.S. House of Representatives
Select Subcommittee on the Coronavirus Crisis
"Moving Beyond the Coronavirus Crisis: The Biden Administration's Progress in Combating the Pandemic and Plan for the Next Phase"

March 30, 2022
Questions for the Record

Dawn O'Connell
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
Washington, DC

Question from Rep. Nydia M Velázquez

1. **How has the American Rescue Plan helped the nation prevent and protect against the coronavirus, and do you think we would be in the same position we are today without the resources it provided?**

   Response: HHS is grateful for the bipartisan Congressional support for funding for the COVID-19 response. The funds that Congress has provided through various COVID-19 supplemental appropriation bills, including the American Rescue Plan, have supported critical COVID-19 response efforts. Without these funds, we would have been unable to mitigate the effects and impact of the COVID-19 virus to date. However, our work is not finished, and funds that Congress has provided for tests, treatments, and vaccines have been exhausted. Without additional funding, we jeopardize all that we have accomplished over the past two years and risk more Americans becoming severely ill and hospitalized, and more disruptions to schools, businesses, and our daily lives.

2. **Please explain why it is important for the country to proactively plan and prepare for any future coronavirus variant or case increases, and how the Biden Administration's National COVID-19 Preparedness Plan will help ensure that we are prepared moving forward.**

   Response: On March 2, 2022, the Biden-Harris Administration released a National COVID Preparedness Plan, created to help America move forward safely, and get us back to our more normal routines. The plan focuses on four key goals: protect against COVID-19; prepare for new variants; prevent economic and educational shutdowns; and continue to lead the effort to vaccinate the world and save lives. The National COVID Preparedness Plan builds on the tremendous progress we've made throughout the COVID-19 response to ensure we're preparing for new variants. Today, we have better monitoring for hotspots and variants of concern. If a new variant emerges, we are able to identify it faster and with greater precision, allowing us to respond more effectively. We also have plans and processes in place to ensure we are able to more quickly develop, authorize, produce, and deliver new vaccines. We are also supporting efforts to stockpile tests, therapeutics, and masks and other personal protective equipment, and we are

standing by to support deployment of those assets as needed. It is important to note that executing this plan will require additional Congressional funding.

Questions from Rep. Mariannette Miller-Meeks

1. **Throughout the COVID-19 pandemic, there has been a focus on vaccines and mitigation strategies such as masks, social distancing, and lockdowns. However, we also know that therapies and treatments are equally as important. How is ASPR ensuring that oral antivirals are acquired and ensure that they are evaluating complications for all different types of patient groups?**

   Response: Over the past 14 months, we have invested in a range of therapeutics – not relying on one product or manufacturer. As the virus has changed and evolved, we have needed to change and evolve with it, modifying our pandemic medicine along the way. Today, we offer the monoclonal antibody treatment bebtelovimab and the oral antivirals Paxlovid and molnupiravir to states and territories on a weekly basis for free. We also allocate the pre-exposure prophylaxis Evusheld on a monthly basis.

   However, without additional Congressional funding, ASPR does not have the ability to:
   - Purchase additional oral antiviral pills beyond the 20 million we have already negotiated.
   - Pre-purchase promising new antivirals. The reason why the Administration has been able to secure more oral antiviral pills than any other country is because we committed to purchasing them early, even prior to their receiving an Emergency Use Authorization (EUA). As more effective pills become available, the federal government will no longer be able to make advance purchase commitments to ensure America is one of the first countries in line.

2. **The way we have and are still responding to COVID-19 has been a burden on our healthcare infrastructure. This needs to be constantly evaluated. Since we know this will not be the last pandemic or viral threat and since COVID-19 is clearly not going away, a dual threat such as a bad flu season could put our public health system in a deeper crisis. How is ASPR ensuring there are enough diagnostic and treatment options to deal with dual threats from COVID-19 and influenza?**

   Response: On March 2, 2022, the Biden-Harris Administration released a National COVID Preparedness Plan to help America move forward safely and get us back to our more normal routines. The plan focuses on four key goals: protect against COVID-19; prepare for new variants; prevent economic and educational shutdowns; and continue to lead the effort to vaccinate the world and save lives.

   The pandemic severely strained our public health and medical supply chains. The medical supply chain ecosystem is complex, with different private sector players and market dynamics across multiple domains of medical equipment and supplies. ASPR is focused on efforts to revitalize and rebuild the nation's domestic manufacturing capacity for critical public health supplies.

   ASPR has established an Industrial Base Management and Supply Chain Office with a focus on building the nation's capacity to manufacture PPE, essential

medicines/chemicals, and diagnostic tests and vaccines, and bringing these critical activities back to American shores. These efforts will ensure we have access and production capacity to support quick and effective production of supplies for whatever pandemic comes next.

However, the funds that Congress has provided for tests, treatments, and vaccines have been exhausted. To maintain and sustain preparedness activities, additional Congressional funding is needed.

We share your concern regarding the additional stress a dual threat from both influenza and COVID could have on our treatment and diagnostic manufacturing infrastructure. Fortunately, when it comes to influenza treatments, there are four FDA-approved antivirals recommended by CDC for use against recently circulating influenza viruses: oseltamivir, baloxavir-marboxil, peramivir and zanamivir. Oseltamivir is the most widely used oral antiviral for the treatment of influenza and is also widely available in generic form with at least 10 different manufacturers approved by FDA to provide drug on the U.S. market. This broad manufacturing capacity ensures that even large waves of influenza infections can be sufficiently covered by the commercial market. In the event that demand for influenza antivirals exceeds commercial capacity, HHS could activate influenza antivirals that are stored in the Strategic National Stockpile (SNS). Due to sound influenza pandemic planning, the nation is well prepared to deal with a large seasonal outbreak of influenza.

As for influenza diagnostics, early in the COVID-19 outbreak, ASPR/BARDA recognized the strain that widespread influenza testing would have on national COVID-19 testing capacity during Flu season. As such, we began supporting the development of multiplexed panels to test for both diseases in one testing platform. BARDA is supporting the development and regulatory approval for 17 test panels for use in laboratory and limited testing resource settings such as homes, nursing facilities, tribal clinics, doctors' offices, and temporary testing centers. Four of these panels have received FDA EUA so far, with the remaining thirteen awaiting FDA review of their submissions or finalizing test development. BARDA is supporting most of these test panel developments through filing of a notice to the FDA under section 510(k) of the Food, Drug, and Cosmetic Act, in preparation for extended circulation of SARS-CoV-2 beyond the end of the public health emergency.