TESTIMONY

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ADDRESSING NEW VARIANTS: A FEDERAL PERSPECTIVE ON THE COVID-19 RESPONSE

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Chair Murray, Ranking Member Burr, and distinguished members of the Committee, it is an honor to appear before you today to discuss the Centers for Disease Control and Prevention's (CDC) ongoing response to the COVID-19 pandemic. It is my privilege to represent CDC, America's health protection agency. Since launching an agency-wide response to the COVID-19 pandemic nearly 2 years ago, CDC has learned more every day about this novel pathogen, how it spreads, and how it affects people and communities. We are committed to continuing to work to provide science-based guidance about how we can best protect ourselves and our communities as the virus and the pandemic evolves.

Update on Omicron

On November 24, 2021, South Africa reported the identification of a new SARS-CoV-2 variant, B.1.1.529 (Omicron), to the World Health Organization (WHO). Omicron was first detected in specimens collected on November 11, 2021, in Botswana and on November 14, 2021, in South Africa. South Africa has since also detected Omicron in specimens collected on November 8, 2021. As of January 4, 2022, Omicron has been detected in 144 countries around the world, including the U.S., where cases have been confirmed in most states and territories. CDC estimates that for the week ending January 8th, the national proportion of lineages designated as Omicron to be 98.3% with a 95% prediction interval of 96.9-99.1%. The national proportion of lineages designated as Delta is predicted to be 1.7%% with a 95% prediction interval of 0.9-3%.

Data are emerging on how easily Omicron may spread, the severity of illness it causes, and how well available vaccines and therapeutics work against it. The variant has many concerning spike protein substitutions, some of which are known from other SARS-CoV-2 variants to be associated with reduced effectiveness of available countermeasures, including vaccines and therapeutics. The rapid growth rate in Omicron infections is believed to result from a combination of increased transmissibility and the ability to evade immunity conferred by past infection or vaccination (i.e., immune evasion).

At present, early data suggest Omicron infection might be less severe than infection with prior variants; however, reliable data on clinical severity remain limited. Even if the proportion of infections associated with severe outcomes is lower than with previous variants, given the increase in number of infections, the absolute number of people with severe outcomes could be substantial. In addition, demand for ambulatory care, supportive care for treatment of mild cases,

and infection control requirements, including quarantining/isolation of exposed/infected workforce could also stress the healthcare system. These stresses likely will be in addition to the ongoing Delta variant infections and a rising burden of illness caused by other respiratory pathogens, such as influenza, which have begun circulating at greater frequencies.

CDC is working hard with domestic and international partners to better understand how easily Omicron might be transmitted and the effectiveness of currently authorized, cleared, or approved medical countermeasures, such as vaccines and therapeutics, against this variant. In addition, we are working, together with FDA, to ensure that diagnostic tests and variant genomic sequencing accurately measure the spread of Omicron. We continue to monitor and evaluate vaccine effectiveness data from the U.S. Initial data from international partners suggest vaccine effectiveness against infection is significantly reduced; those data also suggest that a booster does provide increased protection against infection, and importantly further decreases the risk of severe disease, including hospitalization, and death from COVID-19. CDC continues to strongly encourage COVID-19 vaccination for everyone 5 years of age and older and boosters for everyone 12 years of age and older. In January 2022, CDC updated its recommendation for when many people can receive a booster shot, shortening the interval from 6 months to 5 months for people who received a Pfizer-BioNTech or Moderna COVID-19 vaccines as their primary series. In addition, CDC recommended that moderately or severely immunocompromised 5–11-year-olds receive an additional primary dose of vaccine 28 days after their second shot. Scientists are also working to determine how well existing treatments for COVID-19 work for Omicron infections. Based on the changed genetic make-up of Omicron, some treatments are likely to remain effective, while others may be less effective.

With the growing number of COVID-19 cases from the Omicron variant, and consistent with current understanding of the disease trajectory, on December 23, 2021, CDC released updated guidance for isolation and quarantine for healthcare workers, decreasing their isolation time after infection with COVID-19. Healthcare workers with COVID-19 who are asymptomatic and not immunocompromised can return to work after 7 days with a negative test. If health care personnel test positive at day 5-7, they can return to work 10 days after their initial test, as long as symptoms have improved and at least 24 hours have passed since last fever without the use of fever-reducing medications. Additionally, CDC released an update to guidance for contingency and crisis management in the setting of significant healthcare worker shortages. Healthcare

workers who have received all recommended COVID-19 vaccine doses, including a booster, do not need to quarantine at home following high-risk exposures, as long as they remain fully compliant with masking requirements. These updates provide healthcare facilities with the strategies to limit the effects of staff shortages caused by COVID-19 on patient care.

On December 27, 2021, CDC updated and shortened the recommended isolation and quarantine time for the general population. It is important to note that this guidance does not supersede the guidance for health care workers or guidance from state or local public health jurisdictions. CDC shortened the recommended time for isolation from 10 days for people with COVID-19 to 5 days, if asymptomatic or improved and fever-free for at least 24 hours, followed by 5 additional days of wearing a well-fitting mask both at home and in public when around others. The change is motivated by science demonstrating that the majority of SARS-CoV-2 transmission occurs early in the course of illness, generally in the 1-2 days prior to onset of symptoms and the 2-3 days after. Additionally, CDC changed the recommended quarantine period for those exposed to COVID-19. For people who are unvaccinated or are more than five months out from their second mRNA dose (or more than 2 months after the J&J vaccine) and not yet boosted, CDC now recommends quarantine for 5 days followed by strict mask use for an additional 5 days. Alternatively, if a 5-day quarantine is not feasible, it is imperative that an exposed person properly wear a well-fitting mask at all times when around others for 10 days after exposure. Individuals who have received their booster shot do not need to quarantine following an exposure, but should properly wear a mask for 10 days after the exposure. For all those exposed, best practice would also include either an antigen test or nucleic acid amplification test (NAAT) for SARS-CoV-2 at day 5 after exposure. If symptoms occur, individuals should immediately quarantine until a negative test confirms symptoms are not attributable to COVID-19.

On January 6, 2022, CDC reduced isolation and quarantine periods in school settings to align with current CDC recommendations for isolation and quarantine. CDC recommends that students, teachers, and staff who are asked to quarantine, including those who are not fully up to date on recommended vaccinations, should not go to school or school events in-person during their quarantine period unless they are participating in a school sponsored “test-to-stay” program. Schools may consider Test to Stay as an option for keeping asymptomatic school-associated close contacts in the classroom as an alternative to traditional quarantine at home. This includes

people who are a school-associated close contact, are not up to date on recommended vaccinations, do not test positive for SARS-CoV-2, and have no symptoms. Test to Stay combines contact tracing and serial testing that is repeated at least twice during the 5-to-7-day period post-exposure to allow asymptomatic school-associated close contacts who are not up to date on recommended vaccinations and do not test positive to continue in-person learning. Outside of the school setting, quarantine recommendations would still apply.

New data about the virologic, epidemiologic, and clinical characteristics of the Omicron variant are rapidly emerging. CDC will continue to actively monitor for and respond to this variant, and we will continue to work diligently with state, local, and global public health officials, and industry partners to learn more, monitor the spread of Omicron, and inform the public.

Testing

On December 2, the White House announced new steps to ensure that Americans have access to no-cost self-testing. CDC is working on multiple fronts to expand access to testing, in support of this aim. CDC has awarded approximately $30 billion to public health departments to support activities, including testing, through the Epidemiology and Laboratory Capacity cooperative agreement. For schools, CDC has provided $10 billion to states to support COVID-19 screening testing (i.e., testing of asymptomatic persons in order to identify unknown cases of the disease and avoid further transmission) for teachers, staff, and students to assist schools in staying safely open for in-person instruction. More than 23.5 million tests were conducted in schools between April 2021 and November 2021.

CDC also supports Operation Expanded Testing, which provides no-cost screening testing for schools, underserved populations, child care settings, and congregate settings. The program is available to all states and territories and can be tailored to each site's testing needs. Three federally funded contractors (coordination hubs) provide testing materials, supplies, and results reporting at no direct cost to recipients through a hub and spoke model.

The Increased Community Access to Testing (ICATT) program is another testing initiative jointly managed by CDC and other agencies with three primary objectives: working with pharmacies to ensure equitable access to COVID-19 diagnostics, establishing surge testing sites to provide infection control to populations at elevated risk for SARS-CoV-2 transmission, and establishing community testing sites to increase access to COVID-19 testing in under-

resourced communities. In October 2021, ICATT reached its goal of establishing 10,000 community testing sites and plans to double that number in 2022 to 20,000 sites.

At the community level, CDC is supporting the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and other agencies with the distribution of tests to Community Health Centers, food banks, and rural clinics that receive grants from the Health Resources and Services Administration (HRSA). Support includes the provision of updated self-testing guidance and materials to accompany test distribution to ensure the public is educated about the use of these tests and how to handle positive results. These materials are publicly available on CDC's website.

Together, these actions will help Americans access the tests they need to help them stop the spread of COVID-19.

Genomic Sequencing and Surveillance

Viruses are constantly changing, and this includes SARS-CoV-2. Currently, the only way to definitively determine if an infection was caused by Omicron is by genomic sequencing. Genomic sequencing allows scientists to identify and monitor how SARS-CoV-2 changes over time, understand how these changes affect the characteristics of the virus, and use this information to better evaluate how it might impact health.

Building on years of investments, CDC has intensified efforts to vastly expand genomic sequencing capacity at both the federal and state levels over the past year. In addition to direct support to public health laboratories, CDC provides support to academic institutions to conduct genomic surveillance research in collaboration with public health agencies and augments sequencing capacity through contracts with commercial diagnostic laboratories to support the national genomic surveillance system. Collectively, CDC's national genomic surveillance efforts can reliably detect very low levels of variants, even variants that account for as little as 0.1% of all COVID-19 cases, circulating in the U.S. with high confidence.

The CDC Advanced Molecular Detection program established the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) to coordinate SARS-CoV-2 sequencing. The SPHERES collaboration includes scientists from clinical and public health laboratories, academic institutions, and the private sector. The SPHERES consortium is led by CDC's Advanced Molecular Detection (AMD) program, which over the past six years has invested in federal, state, and local public health laboratories to

expand the use of pathogen genomics and other advanced laboratory technologies to strengthen infectious disease surveillance and outbreak response.

On November 28, 2021, in partnership with U.S. public health laboratories and the Association of Public Health Laboratories, CDC rapidly activated enhanced surveillance for specimens with specific characteristics indicating a possible case of Omicron. The agency requested that public health laboratories send these specimens to CDC as quickly as possible to accelerate the confirmation of Omicron cases and to enable subsequent virological characterization. This led to the rapid identification of the first cases of Omicron in the U.S. CDC began detecting Omicron through its routine baseline genomic surveillance on December 5, 2021. CDC and other federal agencies continue to work with international partners to learn more about variants circulating globally and will continue to monitor all data sources closely to identify cases of Omicron in the U.S.

The rapid detection of Omicron in the U.S. reflects the work that CDC and partners have done over the course of the pandemic to build local capacity, enhance communication and information exchange, and advance new technologies. CDC continues to accelerate this work, as it is essential to the nation's ability to rapidly detect and respond to emerging threats.

Travel Screening

As of December 6, 2021, all air travelers, regardless of citizenship or vaccination status, are required to show a negative pre-departure COVID-19 viral test administered no more than 1 day before travel, or documentation of having recovered from COVID-19 in the past 90 days, before they board their flight to the U.S. CDC continues to recommend that all travelers get a COVID-19 viral test 3-5 days after arrival, and that unvaccinated travelers quarantine for 5 days after travel. CDC's December 2021 amended air travel order strengthens already robust protocols in place for international travel, including requirements for most foreign travelers to be fully vaccinated before travel to the U.S.

This new one-day testing requirement will help to protect travelers and the health and safety of American communities from COVID-19. In light of concerns and unknowns regarding Omicron, these measures will bring an additional layer of public health security and give us time to ramp up surveillance, continue our messaging about the need for vaccination and boosters, encourage non-pharmaceutical interventions like mask-wearing and distancing, and continue to learn more about this emerging variant and its capabilities. Both the U.S. Government and the

airline industry are committed to making this process as seamless as possible for the traveling public.

In addition, CDC is collaborating with commercial partners on SARS-CoV-2 surveillance programs that involve voluntary testing of arriving international travelers at some of the busiest airports in the U.S. Arriving international air travelers are offered pooled testing conducted in the airport and offered at-home kits to be used 3-5 days after arrival. Participants and their respective health departments are notified of positive test results. Some positive samples are sequenced, enabling detection of novel SARS-CoV-2 variants among travelers entering the U.S.

Vaccination Efforts

The recent emergence of the Omicron variant further emphasizes the importance of vaccination, boosters, and prevention efforts needed to protect against COVID-19. As of January 6, 2022, nearly66.3% of the U.S. population over the age of 5 have completed a primary vaccination series, and approximately 35.3% of the eligible population has received their booster dose, indicating there is still more work to be done. Even as we learn more about the Omicron variant, vaccination remains the best public health measure to protect from disease, slow the spread of SARS-CoV-2, and reduce the likelihood of new variants emerging. Scientists are currently investigating Omicron, including how well vaccinated people will be protected against infection, hospitalization, and death. CDC recommends that everyone 5 years and older protect themselves from COVID-19 by getting vaccinated.

On November 29, CDC strengthened its recommendation on booster doses for individuals who are 18 years and older. Data from clinical trials showed that a booster shot increased immune response in trial participants. With an increased immune response, people have improved protection against COVID-19. For the Pfizer-BioNTech and J&J/Janssen vaccines, clinical trials also showed that a booster shot helped prevent symptomatic COVID-19. CDC recommends that everyone ages 12 years and older should get a booster shot 5 months after vaccination with an initial Pfizer-BioNTech or Moderna series, or 2 months after the J&J/Janssen vaccine. CDC recommends clinical preference for individuals to receive an mRNA COVID-19 vaccine over Johnson & Johnson's COVID-19 vaccine for primary and booster vaccination due to risk of rare, but serious adverse events. In addition, CDC recommends that moderately or severely immunocompromised 5 years of age and older receive an additional primary dose of vaccine 28 days after their second shot.

Global Efforts

CDC works closely with public health authorities around the world, including Ministries of Health. CDC also supports critical multilateral partners, including WHO, Africa CDC and UNICEF. CDC's support to other nations includes a range of activities to strengthen capacity to prevent, detect, and respond to local COVID-19 cases. These efforts help provide timelier and more accurate data to inform public health decision-making, strengthen the public health workforce globally, mitigate COVID-19 transmission across borders, and minimize disruptions to essential health services. CDC's international collaborations and support for special investigations contribute to the scientific understanding of COVID-19 and address crucial unknowns regarding clinical severity, extent and pathways of transmission, and infection.

In addition, CDC is working with global partners and over 50 low- and middle-income countries to support planning, implementation, and evaluation of COVID-19 vaccination programs, including vaccine safety programs. We are currently developing plans to extend additional support to countries that are unable to effectively manage and distribute donated vaccines. CDC is also supporting countries' development of timely, high-quality data on vaccine delivery and safety and providing technical assistance and personnel to Gavi, COVAX, and WHO to assist with the development and implementation of strategies to distribute vaccines and implement vaccine programs.

Of particular importance related to detection of and response to the Omicron variant and in addition to ongoing efforts, CDC is building on a strong foundation of decades of work to augment laboratory capacity in partnership with ministries of health around the world. CDC also has participated in partnerships to develop sequencing capacity in southern Africa.

Conclusion

Although we are still learning about Omicron, we have been fighting COVID-19 for the last two years, and we know what people can do to protect themselves. Until we know more about the risks of Omicron, it is especially important to use all tools we have available to protect ourselves and our communities. If you are not yet vaccinated – now is the time. If you are eligible, please get your booster. In areas of high and substantial transmission, regardless of vaccination status, wear a mask in indoor public places. Remember, where possible, to stay 6

feet away from people and avoid crowds and poorly ventilated areas. If you are experiencing symptoms or have been exposed to someone with COVID-19, get tested and stay home.

Lastly, we also must continue to focus on how we can better prepare for the future. Recent investments in public health have increased surveillance and sequencing capabilities that have proven effective to quickly identify Omicron here and around the world. We must make investments now to make sure we maintain and address the long-standing vulnerabilities in our public health system. I am committed to working with Congress to find common ground to support our public health system and make meaningful strides toward achieving health security for all Americans now and into the future.