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Good morning Chairwoman Johnson, Ranking Member Lucas, and distinguished members of the committee. I am Dr. Dan Jernigan, the director of the Influenza Division at the Centers for Disease Control and Prevention. I want to thank the committee for the opportunity to discuss innovations in influenza vaccine technology and for bringing attention to influenza as an ongoing and very serious public health threat.

Each year, influenza (also commonly known as "flu") causes a significant health burden in this country with many millions of Americans becoming ill, hundreds of thousands requiring hospitalization, and tens of thousands dying. The recent 2017-2018 influenza season was particularly severe, causing thousands of flu-related deaths, including 186 children. The 2018-2019 season, while less severe, was record breaking in length at 21 weeks of elevated influenza activity. Influenza pandemics occur less frequently than seasonal epidemics, but their impacts can be even more devastating and result in millions of deaths around the globe.

Influenza vaccination remains the single best way for Americans to protect themselves. Current influenza vaccines are the best protection available, however, there is more work to be done to increase the effectiveness at preventing influenza-related illness, healthcare visits, and death. CDC, and other components of the Department of Health and Humans Services (HHS), including the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Biomedical Advanced Research and Development Authority (BARDA), are working together other Federal partners to use cutting edge science to make influenza vaccines better. But this is a complicated, multi-year process that must be

both stepwise and iterative. In order to improve the prevention and control of influenza, we need to increase both vaccine effectiveness and the number of Americans receiving their influenza vaccinations.

CDC has a central role in every part of the seasonal influenza vaccine development and administration cycle including: virologic surveillance and tracking, strain selection, production of candidate vaccine viruses (which are influenza viruses that are prepared by CDC or another public health partner to be used by vaccine manufacturers to produce a flu vaccine) vaccine distribution, public education, determining vaccine effectiveness and monitoring safety. The resulting data are used to provide feedback and inform policy and recommendations for new and better vaccines. CDC is the global leader in tracking and studying influenza disease and flu viruses. We have some of the world's very best scientists working on flu 24/7, and have used innovative surveillance, diagnostic, and sequencing approaches to dramatically advance what we know. However, influenza viruses are incredibly difficult to track because they constantly change. These changes are why we select new vaccine components every year and they are also why new flu strains can emerge and lead to devastating pandemics.

CDC believes that long-lasting, broadly protective "universal" vaccines are the ultimate goal for flu prevention. We are still years away from having a universal vaccine. The good news is that we think in the much-nearer future, we can save millions of Americans from the flu by making incremental improvements to vaccines that can be produced using already available production platforms and by improving the immunization infrastructure necessary to get more Americans vaccinated each flu season. In the Executive Order on Modernizing flu vaccines recently signed by the president, CDC is called upon to focus on these nearer-term gains. Today I will talk about some innovative things we have already implemented in influenza prevention, as well as areas where we would like to implement further improvements.

Influenza viruses travel around the world with great speed and require innovative approaches to detection and tracking. Our surveillance systems provide the scientific basis for vaccine virus selection – for each year's seasonal flu vaccine, as well as for pandemic vaccine stockpiling. We diligently monitor for genetic changes in the flu virus around the world and identify how those genetic changes affect disease transmission and severity. CDC continues to work to enhance and expand its data systems to provide vital information for public and private sector decisions about new vaccine innovation and immunization recommendations. We are working to modernize our data systems to not only track disease and viruses in near-real time, but also to obtain greater depth and precision of data.

Over the last decade, CDC has significantly improved worldwide surveillance and characterization of influenza viruses in support of more effective vaccines. Globally coordinated epidemiologic and virologic surveillance is the foundation of the influenza vaccine virus selection and development process. CDC serves as one of six World Health Organization (WHO) Collaborating Centers that receive and characterize thousands of influenza viruses each year and support core influenza staff at the WHO. CDC contributes a large amount of virus characterization and genomic sequencing data for both the U.S. and global viruses and is an innovator in new methods for the strain selection process. This process involves working across the United States and with countries all around the world to characterize many thousands of influenza viruses, which are used to inform vaccine strain selection and to develop the vaccines. CDC partnerships with more than 50 Ministries of Health and other health agencies have strengthened global influenza surveillance and created the capacities to analyze and characterize flu viruses more quickly and to increase the number of candidate vaccine viruses CDC produces to expand options for suitable vaccine development.

We develop diagnostic assays for public health laboratories in the United States and globally, and through our International Reagent Resource, we ship them around the world to help stop the spread of flu at its source. CDC continues to increase our ability to sequence viruses around the world –

we use next generation sequencing to gather and analyze genomic data and share those data with other stakeholders. Genomic data help us make better decisions about what goes in each year's flu vaccine, and also help us evaluate viruses for their pandemic potential. We would like to be able to move completely to a domestic and global flu surveillance model that is "sequence-first," a method that uses Next Generation Sequencing (NGS) for all specimens sent to CDC for virologic surveillance. Next Generation Sequencing reveals the genetic variation among different virus particles in a single specimen and allows public health laboratorians to confirm the genetic identity of circulating viruses. These sequence data are also now a vital component of the twice-yearly WHO influenza vaccine virus selection process and are used in molecular modeling and forecasting. As the cost of Next Generation Sequencing drops and the availability of more rapid sequencing platforms increases, this technique may begin to serve as a routine approach for influenza virologic surveillance.

Additionally, CDC has developed and deployed a mobile mini-lab that can be carried on a plane, set up in remote, resource-limited settings to process and test specimens, and send the genomic data up to a cloud platform for further analysis and action. What was once a room full of equipment is now a device that can fit in the palm of your hand. Particularly in an outbreak setting, we can even more rapidly characterize viruses and improve detection of influenza viruses with pandemic potential. CDC can use this technology to detect other pathogens beyond flu, making it a valuable tool in resource challenged outbreak settings.

Over the last few years, CDC has transformed its ability to make influenza vaccine viruses for use in vaccine manufacturing. We have established high-containment laboratories that are dedicated to generating vaccine viruses that adhere to FDA standards of quality. We also now routinely use reverse genetics to very rapidly design and build vaccine viruses. By combining the data from our expansive global flu surveillance, we can quickly detect an emerging influenza virus with pandemic potential, and within hours start the process of synthesizing the vaccine. Most recently, we demonstrated this

approach using the mobile mini-labs to rapidly detect and characterize swine influenza viruses. Within hours, CDC staff pulled the genomic sequence of the swine influenza virus from the cloud platform and using the sequence synthesized a vaccine virus that met all GLP quality standards for use in manufacturing if the emerging swine influenza virus were to pose a higher pandemic threat. Having this capability to rapidly make influenza vaccine viruses could allow the U.S. to respond more quickly in the case of a pandemic. Using these methods, CDC will continue to work to expand the production capability of non-egg-based vaccine candidates by using cell-based and recombinant platforms.

CDC has developed and maintains one of the nation's system for monitoring the effectiveness of influenza vaccines, the U.S. Vaccine Effectiveness Network (U.S. VE Network). The U.S. VE Network currently consists of five study sites across the United States that measure the flu vaccine's effectiveness in reducing outpatient medical visits due to laboratory-confirmed influenza. This system provides critical information for manufacturers and researchers in developing enhanced vaccines by collecting more specific data about how well the vaccine works each season. Data collected through the network are instrumental in making recommendations for vaccine use, selection of new viruses for updating vaccines, and communication to the public on the performance of the vaccines. These data are more specific and are not available through other surveillance systems. Examples include: the type of vaccine received by the patient, the influenza virus subtype, and age group. Sustained increases in our vaccine effectiveness studies are needed to improve our understanding of how well different vaccine products work, and factors that influence how individuals respond to influenza vaccination and infection. Last year, CDC funded a randomized control trial to look at comparative effectiveness of cell-based vaccines. In future years, CDC would like to continue to expand the U.S. VE Network to allow for more enrollees and greater granularity of studies regarding specific vaccine products, and clinical outcomes for subpopulations and age cohorts.

CDC recommends an annual flu vaccine for everyone six months of age and older. However, even with this recommendation, fewer than half of adults in the United States receive their influenza vaccinations. Research indicates that part of the reason people choose not to get the flu vaccine is their perception that flu vaccine isn't effective. While CDC is working to improve vaccine effectiveness of flu vaccines, Americans also need to understand that the current vaccines still avert millions of cases of flu, and thousands of hospitalizations and deaths. We also want to assure Americans that the vaccine is safe. Hundreds of millions of Americans have safely received seasonal flu vaccines over the 50-year history of U.S. flu vaccination. We have been working with our partners, such as pharmacies, to make sure that vaccines are readily available in a variety of healthcare settings. The healthy choice to get vaccinated should also be an easy choice. Also, through health communication campaigns and working with our partners, CDC helps to inform healthcare providers and the general public on the benefits and safety of flu vaccine.

CDC supports the Federal, state and local public health workforce comprising the nation's immunization infrastructure. Through its vaccine contracts and distribution systems, CDC is the largest public purchaser of routinely recommended vaccines, including approximately 10 percent of the seasonal influenza vaccines distributed in the United States each year. In addition, ensuring access to vaccination is a key strategy in improving influenza vaccination coverage rates. Purchase and delivery of vaccines for vulnerable populations, including uninsured adults and pregnant women, will strengthen the safety net for those otherwise unable to access vaccine. In order to improve the prevention and control of influenza through vaccination, CDC will expand its data systems to provide essential information for public and private sector decisions about new vaccine innovation and immunization recommendations. CDC supports states in the development and maintenance of immunization information systems for tracking vaccinations in the United States; however, significant improvements in

interoperability of these systems are needed. CDC will continue to modernize these information systems to achieve greater capabilities for monitoring child and adult vaccination.

In the coming years, CDC will continue its collaboration with FDA, NIH, and BARDA, and other Federal partners to fight influenza through improvements in the vaccine production process, better detection and tracking of influenza illness and viruses, the development of new influenza vaccines and monitoring of vaccine effectiveness, and improvements in influenza treatment and control.

I want to take this opportunity to urge everybody to make sure you and your families are vaccinated and protected from the flu before the holiday season begins. Thank you for the opportunity to talk about CDC's important role of using science and innovation to fight influenza. I am happy to answer any questions you may have.
