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Introduction

Good morning Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. Thank you for the opportunity to testify before you today on the Centers for Disease Control and Prevention's (CDC's) ongoing efforts to prepare for and respond to the Zika virus outbreak, which continues to threaten the United States and the rest of the Americas. CDC is the nation's health protection agency, working 24-7 to save lives and protect people.

It has been about 17 months since CDC first activated its Emergency Operations Center to protect the nation and U.S. territories against the threat of Zika. As the director for the Division for Vector-Borne Diseases for CDC's National Center for Emerging and Zoonotic Infectious Diseases, I had the opportunity to serve as the incident manager for the Zika response for most of 2016. This response has been the most complex emergency response to date. It has required expertise from across the agency, including experts in pregnancy and birth defects, mosquito control, laboratory science, travelers' health, virology, transfusion medicine, sexually transmitted diseases, and communication science. We have learned a great deal very rapidly about a surprising infectious disease. For the very first time, we have found that a virus transmitted through the bite from a mosquito can cause birth defects. However, we still have much to learn and Zika remains a significant threat, particularly to pregnant women and their infants.

Thanks in significant part to the Zika supplemental funding provided by Congress, CDC has taken important steps forward. First, we established a causal link between Zika virus infection during

pregnancy and microcephaly, including serious brain abnormalities. In early 2016, CDC established Zika pregnancy registries in collaboration with state, tribal, territorial, and local health departments to rapidly gather information about risks posed by Zika virus infection, including whether there are certain times during pregnancy when the risk of birth defects from exposure to Zika is greatest. These registries capture information about pregnant women with Zika and their babies. While the Zika pregnancy registries contain information on women who have been tested for Zika and are known to be infected, we know that not all pregnant women exposed to Zika will be tested during the relatively narrow time period when we can identify Zika infections. Therefore, CDC also established rapid birth defects surveillance to identify the same Zika-associated birth defects in babies whose mothers might not have been tested for Zika in the time period when maternal infection could be identified. The combination of the pregnancy registries and rapid birth defects surveillance are providing critical data for public health officials and clinicians, and these combined systems are the only way to identify all the babies affected by congenital Zika virus infection.

We also determined that Zika infection can cause a form of paralysis known as Guillain-Barré Syndrome, which can also lead to respiratory failure and death if not treated aggressively. We found that in addition to being transmitted through the bite of a mosquito, Zika can also be sexually transmitted. CDC has been rapidly developing both molecular and serologic tests for Zika and received Emergency Use Authorizations (EUA) from the Food and Drug Administration (FDA) for their clinical use. At the beginning of 2016, no state had the capacity to test for Zika. Today, 49 states, D.C., and Puerto Rico have this testing capacity. Together with CDC's Laboratory Response Network, CDC has conducted over 160,000 Zika tests. CDC has also issued over 60 travel notices to inform the public, especially pregnant women, about international destinations and U.S. territories and states where Zika virus is circulating.

Partnerships with and support for state and local health departments has been essential to help address the threat of Zika. To date, CDC has provided $251 million in Zika-specific funding directly to state, local, and territorial health departments through grants. In addition to direct funding, CDC has awarded funding that directly supports state, local, and territorial efforts, including support to partner organizations, vector-borne disease regional centers of excellence, and the Puerto Rico Vector Control Unit. All of CDC's supplemental funds will be obligated by September 30, 2017. These financial resources are coupled with technical support to states and territories through rapid response teams, as well as laboratory, epidemiologic, entomologic, field investigation, and data management support. In addition, CDC is providing on-going, in-depth support to Florida, Texas, and U.S. territories, where public health officials have found themselves battling local transmission of mosquito-borne Zika.

Collaboration with our sister agencies has also been critical throughout this response. CDC has been working closely with multiple agencies within the Department of Health and Human Services, including the Office of the Assistant Secretary for Preparedness and Response (ASPR) and its Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health (NIH), and the FDA who are all here today. CDC is also working with partners across the U.S. Government, including the Department of State, the United States Agency for International Development (USAID), the Department of Homeland Security (DHS), the Department of Veterans Affairs (VA), and the Environmental Protection Agency (EPA) to communicate with travelers and health care providers, update travel alerts and clinical guidance, further our understanding of the Zika virus, and develop improved mosquito-control methods. Finally, CDC has collaborated with a range of private sector and non-profit partners, including organizations ranging from the March of Dimes to public health associations, like the Association of State and Territorial Health Officials.

What We Expect in 2017

It is impossible to predict with certainty what we will see in the way of local transmission of Zika, but here is what CDC's scientists anticipate:

- Zika virus will continue to circulate in most regions in the Americas where it has been introduced.
- Over the past year, an average of 30 to 40 pregnancies per week with laboratory evidence of possible Zika virus infection have been reported from the 50 states, and a much higher number from the U.S. territories. Dozens of new cases in pregnant women continue to be reported each week.
- We expect fewer Zika cases in 2017 in some areas outside of the continental U.S., such as Puerto Rico, because a significant proportion of the population was infected in 2016 and is no longer susceptible to infection.
- Within the continental U.S., local outbreaks remain possible, such as those seen this past year in Florida and Texas. Zika outbreaks in the U.S. mainland may be localized due to protective factors like air conditioning, window screens, and less dense living conditions; however, we must be prepared for local outbreaks and different scenarios -- including more extensive transmission.
- There are about 40 million people traveling between the continental U.S. and Zika-affected areas each year. Therefore, all U.S. jurisdictions must continue to be prepared to evaluate, test, and manage patients with potential Zika virus infection, particularly pregnant women.

With these expectations in mind, CDC continues to recommend that those living in areas of local Zika transmission and those traveling to areas of local Zika transmission take steps to prevent mosquito bites and prevent sexual transmission. At the request of state and local public health officials, CDC will

continue to send emergency response teams to states and territories with Zika outbreaks. CDC will also continue to provide reference and surge laboratory capacity for the nation; continue registries to track Zika-affected pregnancies and births; help states deploy and target effective mosquito control; and support timely, accurate, and effective communications to the public and health care providers. In order to cultivate capacity and innovation in the area of vector control, CDC will work with our newly awarded vector-borne disease regional centers of excellence to generate the research, knowledge, and capacity needed to prepare the nation for ongoing vector threats, such as Zika. We will also collectively work with our commercial partners on diagnostic and vector control innovation. Finally, to help facilitate access to the specialty care that is needed by infants affected by Zika, CDC has established a provider referral network called Zika Care Connect that includes a hotline to help families find specialists and a website launched last month. Even when a vaccine becomes available and deployed, these CDC investments will remain critical to protect U.S. states and territories against Zika and other mosquito-borne threats.

Zika Virus Diagnostic Testing

The Zika virus has presented multiple diagnostic challenges, and while we have overcome some of these, several key challenges remain.

One of our first challenges was that while Zika infection typically causes a mild illness or no symptoms at all, the impact of Zika on pregnancies can nonetheless be significant. Therefore, CDC currently recommends testing for all pregnant women who live in or travel to an area with risk of Zika that has a CDC Zika travel notice. At the beginning of the emergency response in January 2016, women did not have access to even one Zika test that was approved for clinical use. However, within three months of initiating the emergency response CDC received EUAs for both a molecular test (Zika nucleic acid test) to detect Zika in the first two weeks after infection and a serological test (IgM) to detect

infection for weeks to months after an infection. Once FDA authorized emergency use of these tests, CDC worked to distribute them rapidly to state laboratories and ensured state laboratories were proficient in their use, while also sharing information about test performance with manufacturers that were developing their own tests. This allowed others to benchmark their tests against the first FDA-authorized Zika tests. Today there are 12 Zika nucleic acid tests with emergency use authorizations and 49 state public health laboratories have Zika nucleic acid testing capacity. Forty-six states have the capacity to conduct CDC's IgM test, known as MAC-ELISA, and two more IgM tests have since received EUAs. To further increase testing capacity at the height of demand in 2016, CDC arranged for referral labs to provide MAC-ELISA testing. These labs continue to provide Zika testing support, and now have the option of either using the MAC-ELISA or using commercially available tests now available under EUA.

CDC remains committed to making ongoing improvements to Zika diagnostics and will continue to share information with public health and commercial laboratories about test performance for tests that are approved for clinical use. Fortunately, FDA's EUA process allows for updates to be made to diagnostic tests as the scientific community makes discoveries that can be used to improve test performance. This ensures that clinicians have the best possible information to counsel their patients. As CDC has made these improvements, the Agency has worked to quickly update laboratory guidelines and notify public health partners and manufacturers of these changes. This includes updating the information on CDC diagnostic test inserts, the information posted on our website for CDC-developed tests that are FDA-authorized for distribution, and published and posted testing guidance.

CDC also works with states to ensure that they have sufficient proficiency to perform CDC's tests. Additionally, CDC provided laboratory surge support to states and territories during periods of high testing volume, so that patients received information about their health status as quickly as

possible. This process has been a major challenge, but CDC remains committed to ongoing communication with and support of our public health partners in preventing the spread of Zika.

Despite the progress CDC has made on the diagnostic landscape, there is still work to do. CDC will continue to work towards diagnostic test improvements that can detect current or recent Zika infection faster and with greater accuracy. This can help decrease the testing burden on the public health system and ensure that patients and their doctors have timely, accurate information. Additionally, sensitive serological tests are needed that can detect recent or previous Zika virus infection without cross-reacting with other flaviviruses, like dengue virus. This cross reactivity makes it difficult to counsel pregnant women about previous exposure to Zika virus. Finally, we need to better understand how long Zika virus can remain in body fluids such as blood and semen, which can inform our laboratory guidance as well as our prevention messaging.

Tracking the Zika Virus

As CDC continues to advance our ability to detect Zika in patients, we also continue to improve our ability to monitor the spread of Zika in communities. Zika virus is a nationally notifiable disease, meaning states and territories report cases of the virus to CDC. CDC conducts multi-faceted surveillance for Zika and other arboviruses through ArboNET, an integrated network that funds 49 states, the Commonwealth of Puerto Rico, and six large municipalities to conduct human case investigations, collect and test mosquitoes, and perform laboratory analysis on arboviruses including Zika, through our Epidemiology and Laboratory Capacity cooperative agreement. Our most recent surveillance data show that we have documented 36,583 cases of Zika virus disease in the U.S. territories and 5,282 in U.S. states and DC. Of these cases, we have identified 224 cases of Zika in Florida and Texas due to local mosquito transmission. CDC has also documented 3,795pregnant women with laboratory evidence of Zika virus infection in U.S. territories and 1,845 in U.S. states and D.C.

Of the nearly 1,000 births in 2016 recorded in the Zika pregnancy registries, 51 had a Zika-associated birth defect, mostly serious brain abnormalities and microcephaly. CDC has found that among pregnant women with confirmed Zika virus infection, about 10 percent of their fetuses and babies were affected by serious Zika-associated birth defects, primarily serious damage to their brains. For those with Zika infections in the first trimester, 15 percent of fetuses and babies had Zika-associated birth defects. The Zika pregnancy registries have also allowed CDC to identify some gaps in care. Based on data reported to the registries, only about one in four babies born to women with Zika virus infection during pregnancy are receiving the recommended brain imaging after birth. Some brain abnormalities are only identified with brain imaging, suggesting that the impact of Zika on babies born to mothers infected with the virus may be underestimated.

In addition to monitoring the impact of Zika, CDC scientists are also monitoring the vector itself in order to better target prevention resources and best support state and local vector control efforts. Documenting the national and local range of mosquito species is an important public health activity because it can inform vector control activities, allowing for the selection of species-appropriate interventions. Zika virus is transmitted primarily by the *Aedes aegypti* mosquito, but also in some circumstances by other species such as the *Aedes albopictus* mosquito. Both of these mosquito species are spreading to new areas within the United States. Using county collection records, CDC has created maps that reflect which counties have documented these species and overlaid the best estimated range of these mosquitoes. However, because we must rely on voluntary county collection records of where mosquito species have been identified, we have been careful to caution the public that these maps reflect our best estimate of where mosquitoes could potentially live. As CDC continues to publish additional information about the range of *Aedes* species mosquitoes, we will continue to communicate the limitations of these reports. Importantly, CDC's investment in the mosquito surveillance system MosquitoNet will allow for more extensive collection of this information, which is intended to improve

the precision of our estimates and provide new information about insecticide resistance in communities across the country.

Conclusion

In closing, the emergence and reemergence of diseases spread by mosquitoes and other insects is exemplified but not limited to the present Zika outbreak. With the spread of the *Aedes aegypti* and other vector mosquito species, mosquito-borne outbreaks will continue and cannot be expected to occur in isolation of one another. The Commonwealth of Puerto Rico and Hawaii were already responding to outbreaks of dengue when Zika virus arose as an urgent public health threat. Alarmingly, the emergence of mosquito-borne diseases appears to be accelerating. Over the past few decades, we have seen a resurgence of dengue and the introduction and spread of West Nile virus, chikungunya virus, and now Zika virus into the Western Hemisphere. Out of the more than 200 known arboviruses in existence, CDC knows of 86 that can cause illness in people. It is very hard to determine which one might next cause an epidemic. However, we know that mosquito-borne diseases will continue to be introduced. Because of this, we need to address the threat of vector-borne diseases systematically, rather than episodically.

Thank you again for the opportunity to appear before you today and for your support of our fight to protect the U.S. and its territories from the threat of Zika virus. I appreciate your attention to this continuing outbreak and I look forward to answering your questions.