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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

February 29, 2015

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining the U.S. Public Health Response to the Zika Virus"

On **Wednesday, March 2, 2016, at 10:15 a.m. in room 2322 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing titled "Examining the U.S. Public Health Response to the Zika Virus." The hearing will focus on the outbreak of the Zika virus in Latin America and the U.S. and how the federal government has prepared for and responded to the outbreak.

I. THE ZIKA VIRUS

A. Transmission of the Zika Virus

The Zika virus is primarily transmitted by the *Aedes aegypti* mosquito, but may also be transmitted by the *Aedes albopictus* mosquito.[1] Both types of mosquitos also spread yellow fever, dengue, and chikungunya (all mosquito-borne flaviviruses). The mosquitos are aggressive daytime biters that live inside and outdoors and require very little water to reproduce. The *Aedes aegypti* mosquito is common in the U.S., including in Florida and along the Gulf Coast, as well as in Puerto Rico and Hawaii.[2] The *Aedes albopictus* mosquito can range as far north as New York City and Chicago in the summer.

Zika may also be transmitted sexually, which is of particular concern during pregnancy.[3] On February 16, 2016, the Centers for Disease Control and Prevention (CDC) issued interim

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[1] Centers for Disease Control and Prevention, *Zika Virus: Questions and Answers* (Feb. 12, 2016).

[2] *Short Answers to Hard Questions about Zika Virus*, New York Times (Feb. 24, 2016).

[3] Centers for Disease Control and Prevention, *Interim Guidelines for Prevention of Sexual Transmission of Zika Virus — United States, 2016* (Feb. 12, 2016).

guidelines to prevent sexual transmission of the Zika virus.[4] As of February 23, 2016, the CDC and state health departments were investigating 14 possible reports of sexual transmission of Zika.[5]

The Food and Drug Administration (FDA) recently issued guidelines to reduce the risk of Zika blood transmission.[6] In areas without active Zika transmission, FDA recommends that those at risk for Zika infection defer donation for four weeks. In areas with active Zika transmission, FDA recommends that blood banks import blood from areas without an outbreak.

B. Zika-Related Complications

Most people infected with Zika do not experience symptoms.[7] Only 20 percent of those infected do experience symptoms – including fever, rash, joint pain, and conjunctivitis – that last several days to a week. Zika is usually not severe enough to send those infected to the hospital, and individuals rarely die of the disease. The virus tends to stay in the blood of an infected person for approximately a week.[8]

However, there is emerging evidence to support an association between Zika and more serious health complications, such as microcephaly in infants born to mothers who contracted the Zika virus during pregnancy.[9] Microcephaly is a severe birth defect of the brain, resulting in a baby's head being smaller than average compared to other babies of the same sex and age.[10] Microcephaly has been linked to a number of serious issues, including seizures, developmental delays, intellectual disabilities, problems with movement and balance, and hearing and vision problems.[11] While the scientific understanding of the link between Zika and microcephaly is still evolving, there have been many reports of microcephaly in babies of mothers who were infected with Zika while pregnant. On February 1, 2016, the World Health Organization (WHO)

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[4] *Id.*

[5] Centers for Disease Control and Prevention, *CDC encourages following guidance to prevent sexual transmission of Zika virus* (Feb. 23, 2016).

[6] Food and Drug Administration, *FDA issues recommendations to reduce the risk for Zika virus blood transmission in the United States* (Feb. 16, 2016).

[7] National Institute for Allergy and Infectious Diseases, *Zika Virus* (Feb. 23, 2016).

[8] Centers for Disease Control and Prevention, *Symptoms, Diagnosis, & Treatment* (Feb. Feb. 23, 2016).

[9] Centers for Disease Control and Prevention, *Questions and Answers: Zika virus infection (Zika) and pregnancy* (Feb. 22, 2016).

[10] Centers for Disease Control and Prevention, *Zika Virus: Questions and Answers* (Feb. 12, 2016).

[11] Centers for Disease Control and Prevention, *Facts about Microcephaly* (Feb. 12, 2016).

declared a Public Health Emergency of International Concern (PHEIC) for the recent clusters of microcephaly and other neurological disorders in Brazil.[12]

Brazil has confirmed more than 580 cases of microcephaly and is investigating more than 4,100 additional cases.[13] Colombia, which has seen over 20,000 cases of Zika, including more than 2,100 cases in pregnant women, has projected that it may see 500 to 600 cases of Zika-related microcephaly.[14] There are not yet confirmed cases of Zika-related microcephaly in Colombia, likely because Zika did not emerge in Colombia until five months after it was detected in Brazil.[15]

CDC has issued guidelines for pregnant women travelling to areas where Zika virus transmission is ongoing, as well as guidelines for the screening, testing, and management of returning pregnant travelers.[16] CDC recommends that pregnant women consider postponing travel to any area where there is local transmission of Zika.[17]

Additionally, scientists believe that there may also be a link between Zika and Guillain-Barré Syndrome (GBS), a rare disorder where an infected person's own immune system damages nerve cells, causing muscle weakness and paralysis.[18] The symptoms can last several weeks or months, but most people experience a full recovery. However, GBS can result in permanent damage or even death.[19]

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[12] World Health Organization, *Zika Strategic Response Framework & Joint Operations Plan: January-June 2016* (Feb. 2016).

[13] *Colombia reports 'probable' case of microcephaly in aborted fetus*, Reuters (Feb. 24, 2016).

[14] *Colombia reports 'probable' case of microcephaly in aborted fetus*, Reuters (Feb. 24, 2016); *More Than 2,100 Pregnant Colombian Women Infected With Zika Virus*, Reuters (Feb. 1, 2016).

[15] *Why isn't Zika causing birth defects in Colombia? It may only be a matter of time*, Washington Post (Feb. 2, 2016).

[16] Centers for Disease Control and Prevention, *Update: Interim Guidelines for Health Care Providers Caring for Pregnant Women and Women of Reproductive Age with Possible Zika Virus Exposure — United States, 2016* (Feb. 12, 2016).

[17] Centers for Disease Control and Prevention, *Question and Answers: Zika virus infection (Zika) and pregnancy* (Feb. 22, 2016).

[18] Centers for Disease Control and Prevention, *Zika Virus: Questions and Answers* (Feb. 12, 2016).

[19] *Id.*

Some South American communities are reporting a dramatic increase in the number of GBS cases after the arrival of Zika.[20] However, the connection between GBS and Zika is still unknown.[21] The CDC and the Brazilian Ministry of Health are collaborating to determine if having Zika makes an individual more likely to contract GBS.[22]

II. THE ONGOING ZIKA OUTBREAK

A. Latin America

The current Zika outbreak originated in Brazil; cases of fever and rash were first identified in February 2015, and the Pan American Health Organization (PAHO) issued an alert for the first confirmed Zika virus infection there in May 2015.[23] Brazil estimates that they have seen between 500,000 and 1,500,000 cases of Zika.[24] Due to the magnitude of the outbreak, Brazilian authorities have stopped counting cases of the virus.

There is now active local transmission in 28 countries and territories in South and Central America.[25] PAHO predicts that the virus will eventually spread locally to every country in the Americas except Canada and Chile.[26]

On February 22, 2016, CDC officials arrived in Brazil to launch a case control study with Brazilian health officials on the link between Zika and microcephaly.[27] The 16-member CDC team will collect blood samples from mothers and babies, both those born with and without microcephaly, to try to determine what may be causing the defect.[28] They hope to have results of the study in April of this year.

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[20] *Zika has been linked to birth defects. Now it may be causing paralysis*, Washington Post (Feb. 21, 2016).

[21] Centers for Disease Control and Prevention, *Guillian-Barre syndrome Q & A* (Feb. 8, 2016).

[22] Centers for Disease Control and Prevention, *Zika Virus: Questions and Answers* (Feb. 12, 2016).

[23] *Id.*

[24] World Health Organization, *Zika Strategic Response Framework & Joint Operations Plan: January-June 2016* (Feb. 2016).

[25] Pan American Health Organization, *Zika Epidemiological Update - 17 February 2016* (online at www.paho.org/hq/index.php?option=com_content&view=article&id=11599&Itemid=41691&lang=en).

[26] *Short Answers to Hard Questions about Zika Virus*, New York Times (Feb. 24, 2016).

[27] *CDC Arrives In Brazil To Investigate Spread of Zika Virus*, NPR (Feb. 22, 2016).

[28] *Disease detectives hunt Zika virus-microcephaly connection in Brazil*, CNN (Feb. 24, 2016).

B. United States

In late January 2016, CDC activated its Incident Management System to centralize its response to the Zika outbreak and the possible linkages to microcephaly and GBS.[29] On February 8, 2016, CDC elevated its response to Level 1 activation, the highest response level at the agency.[30] This status reflects "the agency's assessment of the need for an accelerated preparedness to bring together experts to focus intently and work efficiently" in anticipation of local Zika transmission in the continental U.S.

As of February 24, 2016, there have been no locally transmitted mosquito-borne cases of Zika in the contiguous U.S.[31] There have been 107 travel-associated cases. There have been 39 locally acquired cases in two U.S. territories: Puerto Rico and the U.S. Virgin Islands.[32] Puerto Rico is expected to be hit hard by the Zika virus, with the potential for tens of thousands of cases.[33]

The CDC predicts an increasing number of Zika cases among travelers and those returning to the U.S. from countries with widespread outbreaks.[34] The agency also believes it is likely that we will see local transmission in the continental U.S., although it believes that outbreaks of Zika will be limited, as with previous outbreaks of dengue and chikungunya.[35]

III. DIAGNOSIS, TREATMENT, AND RESPONSE

A. Availability and Development of Diagnostics

There are currently several types of tests available to diagnose Zika, but none are commercially available.[36] They are available at CDC and at a few state and local health departments. A DNA test (known as an RT-PCR) can detect Zika when administered during the

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[29] Centers for Disease Control and Prevention, *CDC Emergency Operations Center moves to highest level of activation for Zika response* (Feb. 3, 2016).

[30] *Id.*

[31] Centers for Disease Control and Prevention, *Zika virus disease in the United States, 2015–2016* (Feb. 25, 2016).

[32] *Id.*

[33] *CDC: Puerto Rico Could be Hit Hard by Zika,* USA Today (Feb. 17, 2016).

[34] Centers for Disease Control and Prevention, *Countries and Territories in the Americas with Active Zika Virus Transmission* (Feb. 23, 2016).

[35] Centers for Disease Control and Prevention, *Transcript for CDC Telebriefing: Zika Virus Travel Alert* (Jan. 28, 2016).

[36] Centers for Disease Control and Prevention, *Diagnostic Testing* (Feb. 11, 2016).

first week after onset of symptoms.[37] It cannot detect Zika once the virus has left an infected person's bloodstream. A second test, which detects Zika antibodies, may be effective for longer than a week after the onset of symptoms. The test does, however, cross-react with dengue, chikungunya, and other flaviviruses, so it may result in false positives. Finally, CDC has a second antibody test (known as a PRNT), which can measure virus-specific antibodies and may be able to determine the primary flavivirus infection.

CDC and FDA are working together to expand availability of diagnostic testing at public health labs.[38] FDA is also reaching out to potential commercial product manufacturers to encourage them to develop and submit applications for diagnostic tests for Zika.

B. Development of Treatments and Vaccines

There are currently no treatments or vaccines for Zika.[39] The National Institute of Allergy and Infectious Disease (NIAID) within the National Institutes of Health (NIH) is currently researching potential Zika virus treatments.[40] They are examining several approaches that have been successful with related flaviviruses and with hepatitis C, which is not a flavivirus but is closely related. NIAID's goal is to develop a broad-spectrum antiviral drug that could be used to treat a variety of flaviviruses, including Zika.

NIAID is actively working to develop Zika vaccine candidates.[41] NIAID is using existing vaccine platforms for other flaviviruses as a starting point for a Zika vaccine. An investigational Zika vaccine could be ready to enter early stage human trials in 2016.[42]

C. Vector Control Efforts

One strategy to prevent or reduce transmission of Zika, as well as the other mosquito-borne diseases, is to control mosquito vectors and limit person-to-mosquito contact.[43] Mosquito control in the U.S. is generally managed at the state and local level by mosquito control districts.[44]

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[37] Memorandum from CDC Division of Vector-Borne Diseases re: Revised diagnostic testing for Zika, chikungunya, and dengue viruses in US Public Health Laboratories (Feb. 7, 2016).

[38] Food and Drug Administration, *Zika Virus Response Updates from FDA* (Feb. 23, 2016).

[39] Centers for Disease Control and Prevention, *Zika Virus: Questions and Answers* (Feb. 12, 2016).

[40] National Institute for Allergy and Infectious Diseases, *Zika Virus* (Feb. 23, 2016).

[41] *Id.*

[42] *Id.*

[43] Centers for Disease Control and Prevention, *Surveillance and Control of Aedes aegypti and Aedes albopictus in the United States* (Jan. 25, 2016).

[44] American Mosquito Control Association, *Frequently Asked Questions* (accessed Feb. 25, 2016).

Local campaigns in the past to remove potential breeding sites and spray larvicide have been ineffective in eliminating *Aedes* mosquitos.[45] Additionally, these mosquitos may have become resistant to some pesticides.

CDC has issued recommendations for vector surveillance and control.[46] Several new methods for controlling mosquitos, such as genetically engineered mosquitos and infecting mosquitos with bacteria to prevent breeding, have been proposed.[47] However, these methods are still being evaluated and have not been widely deployed.

IV. ZIKA SUPPLEMENTAL FUNDING

On February 8, 2016, the Administration indicated its intent to send a $1.8 billion dollar supplemental funding request to Congress in response to the spread of the Zika epidemic to cover both the domestic and global preparedness efforts.[48] On February 18, 2016, before the formal request was transmitted, the Chairman of the House Committee on Appropriations turned down the emergency request, directing the Administration to use $1.4 billion in unobligated Ebola funds to meet the immediate needs of responding to the Zika outbreak.[49] The Administration has indicated that most of the funds set aside for Ebola are committed and that failure to appropriate additional funds would shortchange efforts to address Zika.[50]

On February 22, 2016, the Administration transmitted its $1.9 billion emergency supplemental funding request to Congress, to support response activities to prevent, detect, and respond to the Zika virus, both domestically and internationally. The request includes $1.5 billion for the Department of Health and Human Services, largely for prevention and response activities in the U.S. territories and domestically, including enhanced epidemiology, laboratory, and surveillance capacity; active surveillance for Zika infections in pregnant women; targeted prevention and education strategies for providers as well as the public; vector prevention and control; improved diagnostics; research on the potential link between Zika and microcephaly; vaccine research; and funding for a one-year expanded Federal Medical Assistance Percentages (FMAP) for Puerto Rico and other U.S. territories to support health services for pregnant women

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[45] *Can GMO mosquitoes really help us stop Zika? A closer look*, Vox (Feb. 17, 2016).

[46] Centers for Disease Control and Prevention, *Surveillance and Control of Aedes aegypti and Aedes albopictus in the United States* (Jan. 25, 2016).

[47] *Can GMO mosquitoes really help us stop Zika? A closer look*, Vox (Feb. 17, 2016).

[48] *Obama Asks Congress for $1.8 Billion to Combat Zika Virus*, New York Times (Feb. 8, 2016).

[49] Letter from Hal Rogers, Chairman, House Committee on Appropriations et al., to Shaun Donovan, Director, Office of Management and Budget (Feb. 18, 2016).

[50] *Ebola Funds Too Dry to Fight Zika, Obama's Health Officials Tell Congress*, Washington Times (Feb. 24, 2015).

and for children with microcephaly and other birth defects.[51] The request also includes funding for international response activities in Zika-affected countries: $150 million for CDC, $335 million for the U.S. Agency for International Development, and $41 million for the Department of State.[52]

V. WITNESSES

Panel 1

Dr. Thomas R. Frieden
Director
Centers for Disease Control and Prevention

Dr. Anthony S. Fauci
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Dr. Luciana Borio
Acting Chief Scientist
U.S. Food and Drug Administration

Dr. Nicole Lurie
Assistant Secretary for Preparedness and Response
Department of Health and Human Services

Dr. Timothy Persons
Chief Scientist
Government Accountability Office

Panel 2

Lawrence Gostin
Founding Linda D. & Timothy J. O'Neill Professor of Global Health Law, Georgetown University Law School
Faculty Director, O'Neill Institute for National & Global Health Law

Dr. Peter Jay Hotez
Dean, National School of Tropical Medicine
Baylor School of Medicine

Dr. Jeanne Sheffield

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[51] Letter from Shaun Donovan, Director, Office of Management and Budget, to the President (Feb. 22, 2016).

[52] *Id.*

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