ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States House of Representatives

COMMITTEE ON ENERGY AND COMMERCE 2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

> Majority (202) 225-2927 Minority (202) 225-3641

MEMORANDUM

May 19, 2017

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

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

On <u>Tuesday, May 23, 2017, at 10:00 a.m. in 2123 Rayburn House Office Building</u>, the Subcommittee on Oversight and Investigations will hold a hearing titled "U.S. Public Health Response to the Zika Virus: Continuing Challenges." The hearing will examine challenges confronting the U.S. public health response to the Zika virus outbreak, including whether key agencies have sufficient resources to address the threat, general preparedness issues, and the status of ongoing vaccine development efforts.

I. THE ZIKA VIRUS

The 2016 Zika virus outbreak resulted in 5,102 symptomatic Zika virus diseases cases reported in the U.S. states and the District of Columbia, and 36,079 cases reported in the U.S. territories.¹ The Zika virus is primarily transmitted by the *Aedes aegypti* mosquito, and it can also be transmitted by the *Aedes albopictus* mosquito.² These mosquitos are aggressive daytime biters that live indoors and outdoors and require very little water to reproduce. The *Aedes aegypti* mosquito is common in the United States, including states along the Gulf Coast, Puerto Rico, and Hawaii.³ The *Aedes albopictus* mosquito also ranges as far north as New York City and Chicago in the summer.⁴ Furthermore, Zika virus can also be transmitted sexually.⁵

¹ Centers for Disease Control and Prevention (CDC), 2016 Case Counts in the US (May 12, 2017).

² CDC, Potential Range in US (Jan. 19, 2017).

 $^{^3}$ *Id*.

⁴ *Id*.

⁵ CDC, Sexual Transmission & Prevention (May 2, 2017).

Only 20 percent of those infected with Zika virus experience symptoms, including fever, rash, joint pain, and conjunctivitis, which last several days to a week. Zika virus is usually not severe enough to send those infected to the hospital, and infection rarely results in death. There is scientific consensus that Zika virus infection in mothers during pregnancy can cause microcephaly in newborns. Microcephaly is a severe birth defect of the brain, resulting in a baby's head being smaller than average. Microcephaly is linked to a number of serious health issues, including seizures, developmental disabilities, problems with movement and balance, and hearing and vision problems.

As of April 25, 2017, 1,793 pregnant women in the U.S. states and the District of Columbia, and 3,700 pregnant women in the U.S. territories have laboratory evidence of possible Zika virus infection. Additionally, scientists believe there may also be a link between Zika and Guillain-Barré Syndrome, a rare disorder that causes muscle weakness and paralysis and can result in permanent damage or even death. 11

II. 2016 FEDERAL FUNDING FOR ZIKA RESPONSE AND ONGOING VACCINE DEVELOPMENT

On February 22, 2016, the Obama Administration requested \$1.89 billion in emergency supplemental funding from Congress to support domestic and international efforts to prevent, detect, and respond to the Zika virus. The request included \$1.509 billion for the Department of Health and Human Services (HHS)—largely for prevention and response activities in the continental U.S. and U.S. territories—\$335 million for the U.S. Agency for International Development, and \$41 million for the Department of State. On April 6, 2016, the White House Office of Management and Budget and the Secretary of HHS announced that they had identified \$589 million—largely from existing Ebola funds—that could be reprogrammed and spent on immediate Zika response efforts. On September 28, 2016, the Senate and House passed legislation that appropriated \$1.1 billion in supplemental funding for ongoing Zika response efforts. Former President Obama signed the legislation on September 29, 2016.

⁶ National Institute of Allergy and Infectious Diseases, *Zika Virus* (online at https://www.niaid.nih.gov/diseasesconditions/zika-virus) (accessed May 17, 2017).

⁷ CDC, Symptoms (May 1, 2017).

⁸ CDC, Congenital Zika Syndrome & Other Birth Defects (Apr. 28, 2017).

⁹ *Id.*; Boston Children's Hospital, *Microcephaly: Symptoms and Causes* (online at http://www.childrenshospital.org/conditions-and-treatments/conditions/microcephaly/symptoms-and-causes) (accessed May 17, 2017).

¹⁰ CDC, Pregnant Women with Any Laboratory Evidence of Possible Zika Virus Infection in the United States and Territories (May 4, 2017).

¹¹ CDC, Zika and Guillain-Barré Syndrome (Aug. 9, 2016).

¹² Congressional Research Service (CRS), *Zika Response Funding: Request and Congressional Action* (Sept. 30, 2016).

¹³ *Id*.

A key issue at the hearing will be to assess whether federal and state agencies have sufficient resources to address Zika outbreaks in the 2017 summer season. For instance, CDC reported that as of February 28, 2017, it had obligated 72 percent of the funding that Congress appropriated through September 30, 2017, for the agency's Zika efforts. ¹⁴

A number of vaccines are currently underway to address the Zika threat. To date there are 32 vaccine candidates in development, with six currently in human clinical trials. Five candidates are in Phase I trials, which study a small group of healthy persons without the disease. One vaccine, developed by the National Institutes of Health (NIH), has reached Phase II trials which are studying several hundred people affected by the disease. Because a vaccine candidate would still need to go through Phase III trials before being approved, it is estimated that no FDA-approved vaccine will be available to the public before 2020. ¹⁶

III. GAO AUDIT FINDS CHALLENGES FOR AGENCIES CONFRONTING ZIKA THREAT

The Government Accountability Office (GAO) is expected to release a report at the hearing that examined federal and state efforts to confront the Zika virus.¹⁷ GAO's audit found that predicting the spread of the Zika virus remains difficult because of the inability to develop reliable statistical models. The audit also determined that while a number of diagnostic tests have been developed to test for Zika infection, these tests are limited in their detection ability due to issues with sensitivity of the tests, cross-reactivity with related viruses, and the window of time for detection. Problems with diagnostic testing have likely affected the accuracy of Zika virus case counts. Lastly, GAO found limitations in mosquito control efforts at the state and local level, and identified challenges in developing accurate mapping of mosquito distribution. GAO made five recommendations to CDC and FDA to improve processes regarding diagnostic tests and mosquito distribution maps.¹⁸

IV. WITNESSES

The following witnesses have been invited to testify:

Dr. Timothy Persons

Chief Scientist U.S. Government Accountability Office

¹⁴ CDC, Fighting Zika 24/7: CDC's Response to Zika (Mar. 29, 2017).

¹⁵ WHO Vaccine Pipeline Tracker. World Health Organization. http://www.who.int/immunization/research/vaccine_pipeline_tracker_spreadsheet/en/.

¹⁶ Briefing by CRS staff to House Committee on Energy and Commerce Staff (May 8, 2017).

¹⁷ GAO, Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks (May 2017) (GAO-17-445).

¹⁸ *Id*.

Dr. Lyle R. Petersen

Director
Division of Vector-Borne Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Luciana Borio

Acting Chief Scientist U.S. Food and Drug Administration

Dr. Anthony Fauci

Director National Institute of Allergy and Infectious Diseases National Institutes of Health

Dr. Rick A. Bright

Director

Biomedical Advanced Research and Development Authority Deputy Assistant Secretary Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services