



U.S. HOUSE OF REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE

February 29, 2016

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Examining the U.S. Public Health Response to the Zika Virus”

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, March 2, 2016, at 10:15 a.m. in 2322 Rayburn House Office Building, entitled “Examining the U.S. Public Health Response to the Zika Virus.” The Subcommittee will hear testimony on the spread of the Zika virus across the Americas, the potential link between Zika and other illnesses, including microcephaly and Guillain-Barré Syndrome (GBS), and the public health plan to respond to the virus both in the United States and internationally.

**I. WITNESSES**

Panel One:

- Nicole Lurie, M.D., Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services;
- Thomas Frieden, M.D., Director, Centers for Disease Control and Prevention;
- Anthony Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health;
- Luciana Borio, M.D., Assistant Commissioner, Counterterrorism Policy, U.S. Food and Drug Administration; and,
- Timothy Persons, Ph.D., Chief Scientist, U.S. Government Accountability Office.

Panel Two:

- Peter Hotez, M.D., Ph.D., Dean, National School of Tropical Medicine, Baylor College of Medicine, President, Sabin Vaccine Institute, and Texas Children’s Hospital Endowed Chair in Tropical Pediatrics;
- Lawrence O. Gostin, J.D., Linda D. and Timothy J. O’Neill Professor of Global Health Law, Georgetown University Law Center;

- Joseph Conlon, M.S., Technical Advisor, American Mosquito Control Association; and
- Jeanne Sheffield, M.D., Director, Division of Maternal-Fetal Medicine, Johns Hopkins School of Medicine.

## II. BACKGROUND

### a. History and Spread of the Virus

In the last year, the Zika virus has captured the attention of public health officials across the Western Hemisphere. Scientists first identified the Zika virus in 1947 among monkeys living in the Zika forest of Uganda. The first human cases of Zika were detected in Africa in 1952. The first outbreaks were reported on Yap Island in Micronesia in 2007, and French Polynesia in 2013.

The ongoing outbreak in Latin America began in Brazil in February 2015, and was identified as Zika virus in May 2015.<sup>1</sup> Due to the magnitude of the outbreak, Brazil has stopped counting Zika cases, but estimates 500,000 to 1,000,000 cases.<sup>2</sup> As of February 19, the World Health Organization (WHO) reports local transmission of Zika in 48 countries and territories.<sup>3</sup> Further, imported (travel-related) cases have been reported in the United States, Europe, and non-endemic countries in Asia and the Pacific.<sup>4</sup> Health experts predict that the virus will likely spread to all countries in the Western Hemisphere except Canada and Chile, the only countries in the region without *Aedes* mosquitoes.

The Zika virus is primarily spread through the bite of an infected mosquito. The virus is predominantly carried by the *Aedes aegypti* mosquito, and possibly by the *Aedes albopictus* mosquito, also known as the Asian tiger mosquito. These mosquitoes also carry yellow fever, dengue, and chikungunya. In addition to mosquito bites, the virus can spread through sexual transmission, blood transfusion, and from mother to child during pregnancy.

According to the Centers for Disease Control and Prevention (CDC), the most common symptoms of a Zika infection are fever, rash, joint pain, and conjunctivitis (red eyes). The illness is usually mild with symptoms beginning 2 to 7 days after being bitten by an infected mosquito and lasting for several days to a week. Only about 1 in 5 people infected with Zika will become sick; the remainder are asymptomatic.<sup>5</sup>

More concerning, there are numerous reports of microcephaly, a serious birth defect in which a baby is born with a head smaller than expected, exhibits improper brain development,

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<sup>1</sup> World Health Organization, *Zika: Strategic Response Framework & Joint Operations Plan*, Feb. 2016 [hereinafter WHO Framework].

<sup>2</sup> *Id.*

<sup>3</sup> World Health Organization, *Zika Virus, Microcephaly, and Guillain-Barre Syndrome Situation Report*, Feb. 19, 2016, available at [http://apps.who.int/iris/bitstream/10665/204454/1/zikasitrep\\_19Feb2016\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/204454/1/zikasitrep_19Feb2016_eng.pdf?ua=1)

<sup>4</sup> WHO Framework, supra note 1.

<sup>5</sup> Centers for Disease Control and Prevention, *Zika Virus: Questions and Answers*, page last updated Feb. 12, 2016, available at <http://www.cdc.gov/zika/disease-qa.html> (last accessed Feb. 25, 2016).

and other poor health outcomes in babies of mothers infected with Zika while pregnant. Health officials are investigating possible links between Zika infection and birth defects, as well as other neurological and congenital disorders, including Guillain-Barré Syndrome (GBS), an immune disorder characterized by muscle weakness and sometimes paralysis. While medical research has not determined if there is a causal link between Zika and birth defects or GBS, there does appear to be a correlation.

On February 1, 2016, the WHO determined that the rapid spread of Zika infections and the suspected link to microcephaly, a serious birth defect, constituted a “Public Health Emergency of International Concern” under the International Health Regulations.<sup>6</sup> Colombia, Dominican Republic, Ecuador, El Salvador, and Jamaica have all advised women to postpone getting pregnant,<sup>7</sup> and the CDC has issued a level 2 travel warning, including recommendations that pregnant women in particular postpone travel to all countries with local transmission of the Zika virus.<sup>8</sup>

No instances of local transmission of Zika from mosquitoes have been reported in the continental United States, but cases have been reported among travelers who visited Central and South America. Transmission is ongoing in Puerto Rico, the U.S. Virgin Islands, and American Samoa. One child was born in Hawaii with microcephaly; the mother became infected with the virus while living in Brazil early in the pregnancy. Further, the CDC is currently investigating sexual transmission of the virus and, as of February 23, is investigating 14 additional reports of possible sexual transmission of the virus in the United States, including possible transmission to pregnant women.<sup>9</sup> While there have not been any confirmed cases of infection by blood transfusion in the United States, there have been multiple reports of blood transfusion transmission cases in Brazil.<sup>10</sup>

#### **b. Current Status of Diagnostics, Vaccines, and Other Treatments for Zika**

Currently, there are no commercially available diagnostic tests for Zika virus. Zika virus testing is performed at the CDC and a few State health departments.

During the first week after onset of symptoms, Zika can be diagnosed by performing a reverse transcriptase-polymerase chain reaction (RT-PCR) test on serum.<sup>11</sup> This test can accurately determine whether a person has been infected with Zika, but is only effective while the virus is still present in the blood or other fluid. The CDC reported to committee staff that

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<sup>6</sup> WHO statement on the first meeting of the International Health Regulations Emergency Committee on Zika virus and observed increase in neurological disorders and neonatal malformations, Feb. 1, 2016, <http://www.who.int/mediacentre/news/statements/2016/1st-emergency-committee-zika/en/>.

<sup>7</sup> WHO Framework, *supra* note 1.

<sup>8</sup> Centers for Disease Control and Prevention, *Zika Travel Information*, page last updated Feb. 23, 2016, available at <http://wwwnc.cdc.gov/travel/page/zika-information> (last accessed Feb. 25, 2016).

<sup>9</sup> Centers for Disease Control and Prevention, *Update: Interim Guidelines for Prevention of Sexual Transmission of Zika Virus-United States, 2016*, Feb. 23, 2016, <http://emergency.cdc.gov/han/han00388.asp>.

<sup>10</sup> Centers for Disease Control and Prevention, *Transmission & Risks*, page last updated Feb. 24, 2016, available at <http://www.cdc.gov/zika/transmission/index.html> (last accessed Feb. 25, 2016).

<sup>11</sup> Centers for Disease Control and Prevention, *Diagnostic Testing*, page last updated Feb. 11, 2016, available at <http://www.cdc.gov/zika/hc-providers/diagnostic.html> (last accessed Feb. 25, 2016).

health departments in 9 jurisdictions have validated the RT-PCR assay and thus have the capacity to test for Zika virus.<sup>12</sup>

After this initial period, tests to examine the presence of antibodies must be used. These antibodies can persist for several weeks after an infection—currently, an Enzyme-Linked Immunosorbent Assay (ELISA) test is used 2 to 12 weeks after infection. However, the presence of similar antibodies from dengue, chikungunya, or even a yellow fever vaccine will cross-react and give a positive result. As a result, a plaque-reduction neutralization testing (PRNT) may be needed to measure virus-specific antibodies and discriminate between cross-reacting antibodies.<sup>13</sup> The PRNT test is described as a specialized and lengthy test and currently, is only performed by the CDC.

No specific therapy or vaccine for Zika is approved by the U.S. Food and Drug Administration (FDA) for use in the United States, nor is one available outside the United States. While scientists are working toward a vaccine and building on related work, it is not likely that a vaccine will be available in the near future.

#### **c. Need for Additional Research on Zika**

While medical researchers have not concluded definitively that Zika causes microcephaly, GBS, or other disorders, increasing evidence indicates a correlation. At this point in time, we do not know the risk of Zika to an individual pregnancy, nor do we know the risk of Zika in causing additional disorders such as GBS. Some researchers have speculated that, in the future, we may see cases where a child presents as normal, but has mental or physical disabilities after becoming infected with Zika *in utero*. In addition, we do not know whether individuals who contract Zika but are asymptomatic will have any negative effects for themselves or their children, nor do we know if previous infection from a related virus, such as dengue or yellow fever, has an impact on the effects of Zika on an individual.

#### **d. Vector Control**

According to the CDC, the best way to prevent diseases spread by mosquitoes is to avoid mosquito bites. Official recommendations include wearing protective clothing and repellants, staying indoors with windows closed or screened, and, for pregnant women, delaying travel to affected areas.<sup>14</sup>

Currently, the most effective way to prevent or reduce the spread of Zika is through vector control of the mosquito population. The *Aedes aegypti* mosquito breeds in small containers of fresh water, including in roadside trash, discarded tires, flower pots, and even bottle

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<sup>12</sup> The nine states/territories with this testing capacity include: Arkansas, California, Florida (in Tampa/Hillsborough County), Hawaii, Maryland, New Hampshire, New York State, Puerto Rico and Texas (in Dallas County). Email from CDC Washington office to committee staff, February 10, 2016.

<sup>13</sup> *Id.*

<sup>14</sup> Centers for Disease Control and Prevention, *Zika Virus: Questions and Answers*, page last updated Feb. 12, 2016, available at <http://www.cdc.gov/zika/disease-qa.html> (last accessed Feb. 25, 2016).

caps. The mosquito is known as a “daytime biter”—meaning that it bites during the day in addition to the early morning and evening—and favors biting humans over other animals.

Reduction of the breeding sites is an effective means to control the mosquito population, but depends heavily on broad public participation and education. The mosquito population can also be controlled through pesticides. Other emerging technologies are being explored, including the release of genetically modified mosquitoes, biological control, and auto-dissemination traps which spread larvicide.

In the United States, vector control is handled at the State and local level. Many states create mosquito control districts funded by the State, locality, or both. The level of services varies greatly—some local jurisdictions provide services directly, others contract for services with private companies. While the Federal government does not appear to specifically provide funds for mosquito abatement, grants provided by the CDC to States through Epidemiology and Laboratory Capacity (ELC) grants allow for funds to be used to detect, monitor, and control mosquito- and tick-borne diseases in the United States.<sup>15</sup>

#### **e. Supplemental Budget Request**

On February 8, 2016, President Obama announced that he would ask Congress for more than \$1.8 billion in emergency funding to prepare for and respond to the Zika virus. The Administration submitted the formal request on February 22, 2016.<sup>16</sup> The request includes additional funding for the Departments of Health and Human Services and State, and for the U.S. Agency for International Development (USAID). The majority of the money—\$1.509 billion—is designated for various HHS agencies. The HHS request includes:

- *Centers for Disease Control and Prevention - \$828 million.*
  - Grants and technical assistance to Puerto Rico and U.S. Territories - \$225 million. The funding would expand vector control programs to reduce transmission by *Aedes aegypti* mosquitoes, enhance lab capacity for Zika virus and other infectious disease testing, and expand surveillance and response, among other activities.
  - Domestic response - \$453 million. This funding would, in part, provide grants to the 13 States with known *Aedes aegypti* populations to improve vector prevention and control and support CDC emergency response teams, enhance epidemiology, laboratory, and surveillance capacity to track Zika virus in people and mosquitoes, provide education strategies for

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<sup>15</sup> Centers for Disease Control and Prevention, *Epidemiology and Laboratory Capacity for Infectious Diseases*, page last updated July 27, 2015, [http://www.cdc.gov/nceid/dpei/epidemiology-laboratory-capacity.html#\\_blank](http://www.cdc.gov/nceid/dpei/epidemiology-laboratory-capacity.html#_blank); American Mosquito Control Association, *Funding for National Disease Surveillance Network through Epidemiology and Laboratory Capacity (ELC) Grants from the Centers for Disease Control*, available at <http://www.mosquito.org/cdc-funding-position-paper>.

<sup>16</sup> Emergency Supplemental Appropriations Request to respond to the Zika virus, Feb. 22, 2016.

key populations, improve diagnostics for Zika virus, and research the potential link between Zika and microcephaly.

- CDC International Response Activities - \$150 million. This funding would, in part, expand the Field Epidemiology Training Program, infectious disease surveillance, and emergency response activities in Zika-affected countries.
- *National Institutes of Health Research, Including Vaccines - \$130 million.*
  - This funding supports the development of a vaccine for Zika and chikungunya by building upon existing resources. The funds would also support basic research on Zika, including the natural history of the virus.
- *Food and Drug Administration Vaccine and Diagnostics Development and Review - \$10 million.*
  - This funding supports, in part, highly targeted regulatory science research for the development and regulatory review of medical products and blood screening assays for the Zika virus.
- The request for additional HHS funding also includes \$246 million to the CDC for a one-year increase in Puerto Rico's Medicaid Federal Medical Assistance Percentage from 55 to 65 percent to support health services for pregnant women at risk of infection or diagnosed with Zika virus and for children with birth defects, and other health care costs, and an additional \$295 million to support other HHS needs related to the virus, including rapid advanced development and commercialization of new vaccines, diagnostic tests, and vector control methods.

### III. ISSUES

The following issues will be examined at the hearing:

- The potential spread of Zika in the continental United States, and our preparedness for such an event;
- Ways to control the spread of Zika, both domestically and internationally;
- The current state of research into (a) the link between Zika and other health conditions, including microcephaly and GBS; (b) rapid diagnostic testing for Zika; and (c) a vaccine or other therapeutics for Zika;
- The President's emergency supplemental appropriations request; and
- U.S. preparedness for future outbreaks.

#### **IV. STAFF CONTACTS**

If you have any questions regarding the hearing, please contact Alan Slobodin, Sam Spector, Jen Barblan, or Brittany Havens at (202) 225-2927.