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May 13, 2016

The Honorable Sylvia M. Burwell
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

I write to gain a better understanding about the U.S. health care system's capacity to prepare and respond to active Zika virus transmission on American soil, and inquire about the systemic and infrastructure changes that will be necessary to combat the Zika epidemic.

The Zika virus, first identified in humans in Africa in 1952, re-emerged in Brazil in 2015, and since then has spread rapidly throughout South and Central America and the Caribbean. According to the Centers for Disease Control and Prevention (CDC), 42 countries and territories have active local transmission of the virus, 38 of which are in Latin America and the Caribbean. As of May 5, 2016, the Pan-American Health Organization (PAHO) confirmed 8,672 cases of Zika in the western hemisphere, along with another 289,233 suspected cases.¹

As of May 4, 2016 there are 472 cases of Zika in the U.S., which were acquired after travel to an area with active Zika transmission or through sexual transmission by a partner who has traveled to a high burden Zika country.² To date, individuals in 43 states and the District of Columbia have been diagnosed with Zika; 10 of these cases are in Massachusetts. Local transmission among U.S. territories is currently limited to Puerto Rico, American Samoa, and the U.S. Virgin Islands. Experts expect that Zika infected mosquitoes will appear along the Gulf Coast of the U.S. as the warmer summer approaches. Already at the forefront of this health emergency, residents in the four Border States with Mexico have been provided by the federal government with information on how to prepare for and protect against an influx of the virus.³

Transmission of Zika typically occurs from the bite of an infected mosquito. However, recent evidence also confirmed the disease can be transmitted through sexual contact. Although Zika is historically considered a benign virus resulting in mild flu like symptoms, recent investigations have discovered the alarming connection between the virus and the development of

¹ http://ais.paho.org/hip/viz/ed_zika_cases.asp

² <http://www.cdc.gov/zika/geo/united-states.html>

³ <https://www.epa.gov/border2020/zika-informational-resources-us-mx-border-residents>

microcephaly, in which an infant is born with a much smaller head size and an underdeveloped brain. Children who suffer from microcephaly will undoubtedly need lifelong access to special health, education and other social services.

Additionally, Zika infection has been connected to the autoimmune disorder, Guillian-Barré Syndrome (GBS) and other neurological effects in patients of all ages. GBS, which can cause partial or full paralysis, is found to be more severe in Zika-related cases. Recovery of mobility, when possible, is expected to take much longer than traditional GBS, requiring intensive care and structured rehabilitation for extended periods of time. Combined, health outcomes from microcephaly and GBS could put an enormous strain on the health care system in the United States as well as on education and social services throughout the nation.

The main species of mosquito involved in the transmission of Zika virus is *Aedes aegypti*. The same mosquito is also responsible for spreading dengue, chikungunya and yellow fever. *Aedes aegypti* mosquitoes are endemic to all tropical and subtropical regions around the world. Another species, *Aedes albopictus*, is also thought to be a potential vector for Zika, and this species has a much larger population endemic throughout the U.S.⁴

Some countries combating Zika, like El Salvador, have responded to the appearance of microcephaly by encouraging women to avoid pregnancy until 2018.⁵ Unfortunately, many women in Latin America, the Caribbean and even in the U.S. have limited access to reproductive health services including family planning and contraception. This is an untenable situation for women and families around the world.

The threat of Zika is a somber reality, but having a health care system with the necessary infrastructure to plan for and respond to the disease will be crucial to our success in combating this threat. In light of the impending surge of Zika infections here in the United States, I respectfully ask that you respond to the following questions by June 13, 2016.

1. A large geographic area of the U.S. will be at risk of Zika infection given the estimated range of the *Aedes aegypti* and *Aedes albopictus* mosquitoes.⁶ Please identify how the emergency supplemental appropriation request of \$1.9 billion will be used toward detecting, diagnosing, and providing care for individuals infected with Zika.
2. What is being done to prepare the U.S. health care system, including the health care workforce, and individual state health departments for an increased incidence and severity of microcephaly, Guillian-Barré syndrome, and other neurological disorders associated with Zika? Does the Department of Health and Human Services (HHS) anticipate that the U.S. health care infrastructure will need additional funding or specialized facilities?

⁴ <http://www.cdc.gov/zika/vector/index.html>

⁵ http://www.nytimes.com/2016/01/26/world/americas/el-salvadors-advice-on-zika-dont-have-babies.html?_r=0

⁶ <http://www.cdc.gov/zika/vector/range.html>

3. Please describe the ways in which HHS has encouraged adjustments to the delivery of reproductive health care in the U.S. in response to the Zika crisis. Please also identify the resources, materials, and educational tools that health centers and medical personnel will need in communities affected by Zika.
4. The National Institute of Allergy and Infectious Diseases (NIAID) has led research on the infection, replication, pathogenesis, and transmission of Zika and the vectors carrying the disease. I understand that NIAID is accelerating efforts to develop vaccine candidates. Please share the status of Zika virus vaccine development, whether clinical trials of the vaccine candidates would happen in the U.S., and the timeline for vaccine introduction.
5. CDC has a nationwide network of 150 labs,⁷ which are charged with responding to public health emergencies. A small number of these labs are currently able to conduct diagnostic tests that can either identify if an individual has ever been infected with the Zika virus, or if an active Zika infection is present. Does the CDC have plans to expand diagnostic testing to more of the labs in its Laboratory Response Network? Quest Diagnostics has recently received permission from the Food and Drug Administration to market the first commercially available diagnostic test for active Zika infection.⁸ Is Quest Diagnostic's manufacturing capacity capable of handling the demand for testing nationwide or are other diagnostic tests currently under development to meet the anticipated demand by patients and their physicians? What is the potential impact of the new rapid, low cost, RNA-based Zika assay just published on May 6, 2016?⁹ Please describe funding that would be necessary to optimize these technologies.
6. The U.S. is currently considering a field trial that would use genetically modified mosquitoes to reduce the population of *Aedes aegypti* mosquitoes transmitting the Zika virus.¹⁰ The mosquito population would be reduced because the progeny of the genetically modified mosquitoes would contain a lethality trait that ensures they will not survive. In other studies using a different modification approach, mosquito species that carry malaria have been genetically modified to prevent transmission to humans by impeding the parasite from entering the mosquito's saliva.¹¹ While the particular genetic modification for malaria is still in the early stages of development, has a similar technique been studied or considered as another vector control strategy to address the transmission of Zika?
7. CDC is currently distributing Zika kits in parts of Puerto Rico containing educational materials, insect repellent, condoms, a thermometer to detect fever, bed nets and mosquito "dunks" (which are tablets placed in standing water to kill mosquito larvae).¹² How is HHS

⁷ <http://emergency.cdc.gov/lrn/factsheet.asp>

⁸ <http://www.reuters.com/article/us-health-zika-questdiagnostics-idUSKCN0XP35W>

⁹ [http://www.cell.com/cell/abstract/S0092-8674\(16\)30505-0](http://www.cell.com/cell/abstract/S0092-8674(16)30505-0)

¹⁰ <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM487377.pdf>

¹¹ <http://www.pnas.org/content/112/49/E6736.full>

¹² <http://www.cdcfoundation.org/pr/2016/cdc-foundation-partners-and-cdc-to-provide-zika-prevention-kits-pregnant-women>

currently engaging and educating the U.S. public about the Zika emergency? Will Zika kits be similarly distributed throughout U.S. areas that are the most susceptible to vector-borne transmission?

8. The effect of climate change could bring the mosquitoes carrying the Zika virus to a larger geographic area and to higher altitudes. Please describe how climate conditions have been factored into the agency's assessment of disease burden and impact on the health care system.
9. PAHO has recently identified Zika virus in non-human primates in Brazil.¹³ There is a now a concern that primates will become a "reservoir" for the virus, allowing it to circulate among the animal population via mosquito bites while the human infection rates actually decrease due to increased immunity from previous infection. However, the virus circulating in the animal reservoir could be the source of new human infection when the animals encounter individuals either in different locations or if travelers visit the area who have not been previously exposed. The importance of a viral reservoir has been illustrated in a number of mosquito borne diseases, including yellow fever. Primates also serve as the reservoir for yellow fever, and the virus is perpetuated in nature through a mosquito-primate-mosquito transmission cycle.¹⁴ A similar situation is possible with Zika virus, providing a way to continually reintroduce the disease to humans. Cycling infection by the Zika virus is arguably more devastating even than yellow fever and other related viruses due to the tragic side effects of microcephaly, GBS and other neurological abnormalities only seen after Zika infection. How will the discovery of Zika in South American primates impact both the short-term and long-term health care strategies in the U.S. to prepare and educate the public about the virus?

Thank you for addressing these concerns. If you have any questions, please have a member of your staff contact Elyssa Malin or Jeanette Roberts at 202-224-2742.

Sincerely,



Edward J. Markey
United States Senator

¹³ <http://biorxiv.org/content/biorxiv/early/2016/04/20/049395.full.pdf>

¹⁴ <http://www.cdc.gov/yellowfever/transmission/index.html>