



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

AUG - 3 2016

The Honorable Marco Rubio
United States Senate
Washington, DC 20510

Dear Senator Rubio:

Thank you for your letter to President Obama regarding our shared desire to ensure that we are doing everything that we can to combat the Zika virus. I am responding on his behalf.

To date, there have been more than 6,400 Zika cases, 855 pregnant women with any laboratory evidence of Zika virus infection, and 13 babies born with Zika-related birth defects in the United States. Our fight against Zika has taken on added urgency in light of Governor Scott's announcement on July 29 that there is local Zika transmission in Florida. While the arrival of Zika in the continental United States is a development that we expected and planned for, it underscores the urgency that we must do everything possible to minimize the impact that Zika will have on Americans both here in the continental U.S. and in Puerto Rico where there has been a dramatic increase in the number of Zika infections. In particular, pregnant women and their babies are at greatest risk because Zika virus can cause microcephaly and other significant birth defects.

As you know, the Department of Health and Human Services (HHS) is constrained in what it can do since Congress has not yet passed an emergency supplemental bill to provide additional resources. We have, however, moved aggressively to repurpose existing resources, such as funds intended to combat Ebola virus. These limited resources are being used to support states, like Florida, and territories in their efforts to prepare for and respond to Zika virus. This is in addition to a broad range of other efforts that the Department is undertaking to respond to Zika virus, including developing a vaccine and better diagnostic tests, enhancing laboratory capacity, and educating the public about the health risks of Zika virus.

HHS Assistance to Florida

Despite resource constraints that have resulted from a lack of congressional funding, the Centers for Disease Control and Prevention (CDC) has dedicated substantial resources to supporting Florida. Over the course of this year, CDC has provided Florida with more than \$8 million in Zika-specific funding and \$27 million in Public Health Emergency Preparedness (PHEP) funding that can be used to support Zika response efforts. Additionally, CDC has provided laboratories in Florida with enough Zika test kits to assess over 6,000 patient samples.

In June, CDC awarded \$700,000 to Florida through the emergency Epidemiology and Laboratory Capacity (ELC) cooperative agreement for epidemiology work; laboratory staff, equipment, and supplies; and Zika laboratory test kits. This funding award included \$500,000 for seven Florida counties to enhance mosquito control efforts to combat Zika virus. In July, CDC awarded \$1.38 million to Florida in Public Health Preparedness and Response (PHPR) funding to support efforts to protect Americans from Zika virus infection and associated adverse health outcomes, including microcephaly and other serious birth defects, and \$5.6 million in funding through an additional ELC award to build laboratory capacity, enhance epidemiological surveillance and investigation, improve mosquito control and monitoring, and contribute data to the U.S. Zika Pregnancy Registry.

Yesterday, CDC announced that Florida will soon receive an additional \$720,000 in funding to establish, enhance, and maintain information-gathering systems to rapidly detect microcephaly and other adverse outcomes caused by Zika virus infection; ensure that affected infants and their families are referred to appropriate health and social services; and monitor the health and developmental outcomes of children affected by Zika.

By awarding Florida more than \$8 million to support Zika response efforts, CDC has met Florida's requests for Zika-specific assistance. At Florida's request, CDC is also sending a full CDC Emergency Response Team (CERT) with experts in Zika virus, pregnancy and birth defects, mosquito control, laboratory science, and risk communications to assist in the response. If Florida has additional funding or personnel needs, please let us know so we can begin to assess options to provide additional assistance.

Speed and Urgency of HHS Response to Zika

In your letter, you expressed concern about the speed and urgency that the Department was applying to the use of funds that have been repurposed to combat Zika. The Department is committed to using scarce federal dollars aggressively and prudently, especially in light of Congress's inaction to provide any additional resources and the uncertainty around whether Congress will provide resources in the future.

As you know, the Department repurposed \$374 million that could be used for domestic response efforts. These funds were almost entirely split between the CDC, NIH, and BARDA. Since CDC is on the front lines of providing assistance to states, territories, and localities to fight Zika, it received \$222 million.¹ As of the beginning of August, CDC has obligated \$123 million of this total and just yesterday announced \$16 million in additional state awards. CDC plans to obligate virtually the entire remainder of these domestic funds by the end of the fiscal year.

CDC's remaining domestic funds will be used for the following activities:

- Providing technical assistance and deploying additional CDC Emergency Response Teams (CERTs), where requested, to states and localities that are responding to local transmission or travel-related cases of Zika infection.

¹ CDC also received \$78 million in repurposed funding that can only be used for international response efforts.

- Working with states to test Zika specimens. (Since January 1, CDC has tested over 30,000 specimens.)
- Providing grants to states and non-profit organizations to improve mosquito control and surveillance methods and add laboratory capacity.
- Continued funding of critical research efforts that will help us understand the adverse health effects of Zika.
- Continued funding to develop systems to track mothers and babies who are impacted by Zika.
- Continued funding to finance an additional 120 CDC staff who are supplementing the hundreds of existing CDC staff working on the Zika response in the field and at CDC offices in Atlanta, Puerto Rico, and Colorado.

CDC has distributed the majority of obligated funds to provide direct assistance to states, cities, and territories. To date, CDC has awarded approximately \$101 million to these local jurisdictions to fight Zika, including:

- \$25 million in PHEP grants to cities, states, and territories to help them strengthen their preparedness and response plans.
- \$60 million in ELC grants to states, cities, and territories to strengthen lab capacity, mosquito control and surveillance efforts, and help states purchase additional equipment and supplies that can be used to fight Zika.
- \$16.4 million to help states establish birth registries for babies born to mothers who had Zika.

CDC has also used repurposed funding to support education and communications outreach, staffing, and other technical support for laboratory capacity, mosquito control, research, and innovation.

Need for Congressional Funding

Now that the United States is in the height of mosquito season and with the progress in developing a Zika vaccine, the need for additional resources is critical. Without additional funding as requested in the President's request for an emergency supplemental, our nation's ability to effectively respond to Zika will be impaired. Below are some of the potential impacts that the lack of funding will have on our response efforts:

- **The National Institutes of Health's (NIH)** latest estimates are that they will exhaust the \$47 million that they received in repurposed funding to combat Zika by the end of the month. Today, the NIH announced that it began Phase I trials for a DNA-based Zika vaccine. Without additional funding, the second phase of clinical trials that NIH is planning to conduct for this vaccine and others will be delayed. A delay in this stage of development will delay when a safe and effective Zika vaccine is available to the American public. In addition, research and development of other vaccine candidates, diagnostics, therapeutics and vector control technologies may be constrained.

- **Biomedical Advanced Research and Development Authority (BARDA)**, the component within HHS that provides funding to private sector partners to develop medicines and vaccines, estimates that it will exhaust the \$85 million that it received in repurposed funding to combat Zika by the end of the month. Without additional short term funding, BARDA will be unable to provide financing to private sector partners that could be instrumental in developing a Zika vaccine. In addition, funding is needed to support the development of innovative Zika vaccines, vaccine platform technologies, further development of better diagnostic tests, and additional work on important pathogen reduction technologies to protect the blood supply from Zika.
- **The NIH's Zika in Infants and Pregnancy (ZIP) study will be delayed.** The ZIP study aims to improve our understanding of the health effects of Zika virus infection on pregnant women and their developing fetuses and infants by following 10,000 pregnant women for the duration of their pregnancies and their infants for at least one year after birth. Additional funding is needed to accelerate and expand enrollment in ZIP, and continue following the infants through their first year to provide critical answers regarding the range and true risk of congenital anomalies caused by the virus.
- **Without additional resources, the CDC will have a severely limited capacity to support mosquito control and surveillance** efforts in the continental U.S. or other territories and to further improve diagnostic testing for Zika. In addition, CDC will be severely constrained in its ability to provide any additional funding to states and localities, and in its ability to help manage additional local Zika outbreaks, including sending emergency teams to be on-site and testing specimens to determine the presence of Zika virus in communities.
- **The Health Resources and Service Administration (HRSA) will be unable to expand maternal and child health services** or place additional National Health Service Corps clinicians in Puerto Rico.
- **The Centers for Medicare and Medicaid Services (CMS) will not have the authority to provide additional federal matching funds to Puerto Rico and other territories** to support costs related to the screening and treatment of pregnant women and care of infants born with microcephaly.

These examples demonstrate the urgent need for the Administration's request for \$1.9 billion in emergency supplemental funding, which is the most effective way to enhance our ongoing efforts to respond to this challenge in Florida, in other states, and in U.S. territories. In regards to the immediate needs that NIH and BARDA face, I am evaluating all options in order to avoid delaying the development of a Zika vaccine. At the same time, I want to urge you to work with your leadership to develop a bipartisan bill that will allow us to mount the full and timely response to the Zika virus that the American people deserve.

Thank you for your continued support of the Administration's emergency supplemental proposal and your ongoing engagement on this important issue. I hope that we will be able to work

together to find a bipartisan path forward when Congress reconvenes. My team will continue to work closely with state and local health officials in Florida to respond to this public health challenge. We will continue to work closely with our partners and communicate the most up-to-date information to Members of Congress and other stakeholders. If you have any questions or concerns, please do not hesitate to contact Jim Esquea, Assistant Secretary for Legislation at (202) 690-7627.

Sincerely,

A handwritten signature in black ink, reading "Sylvia M. Burwell". The signature is written in a cursive, flowing style. The first name "Sylvia" is written with a large, prominent "S". The middle initial "M." is written in a smaller, more compact cursive. The last name "Burwell" is written with a large, prominent "B".

Sylvia M. Burwell