



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

SEP 01 2016

The Honorable Charles Grassley
United States Senate
Washington, D.C. 20510

Dear Senator Grassley:

Thank you for your August 26th letter regarding our shared desire to ensure that we are doing everything that we can to combat the Zika virus in the United States.

As of today, there have been 16,832 cases of Zika virus infection reported, 1,595 pregnant women with laboratory evidence of Zika virus infection, and 17 babies born with Zika-related birth defects in the United States. Our fight against Zika has taken on added urgency in light of Florida Governor Rick Scott's announcement on July 29 that there is local transmission of Zika infection in Florida. Since that time, Florida has announced that there are 47 cases of local transmission. 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. 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 provided any funding to help HHS fight Zika. In the absence of any congressional funding, we have prioritized responding to Zika by moving aggressively to repurpose existing resources, such as funds intended to combat Ebola virus, which remains a public health challenge. These limited resources are being used to support states 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 vaccines and better diagnostic tests, enhancing laboratory capacity, and educating the public about the health risks and steps that can be taken to minimize the chance of being exposed to Zika virus.

Steps Taken to Fight Zika without Congressional Funding

The Department is committed to using scarce federal dollars aggressively and prudently, especially in light of Congress's inaction to provide any additional resources to date. As you know, in April, the Department repurposed \$374 million from accounts primarily intended to help fight Ebola to support domestic Zika response efforts.

These funds were almost entirely split between the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA).

Centers for Disease Control and Prevention

Since CDC is on the front lines of providing assistance to states, territories, and localities to fight Zika, it received \$222 million. As of August 26th, CDC has obligated \$194 million of this total. CDC plans to obligate virtually the entire remainder of these domestic funds by the end of the fiscal year on 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.
- Working with states to test Zika specimens. (Since January 1, CDC has tested over 30,000 specimens.)
- 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 and labs in Atlanta, Puerto Rico, and Colorado.

CDC has distributed more than half of its domestic Zika funds to provide assistance to states, cities, and territories. To date, CDC has awarded approximately \$108 million to support these local jurisdictions in the fight against Zika, including:

- On July 21, CDC announced that it would award nearly \$60 million in Epidemiology and Laboratory Capacity (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.
- On July 1, CDC awarded \$25 million in Public Health Emergency Preparedness (PHEP) grants to cities, states, and territories to help them strengthen their preparedness and response plans.
- On August 2, CDC awarded \$16.4 million to help states establish birth registries for babies born to mothers who had Zika.
- On August 24, CDC awarded \$6.8 million to national public health partners to assist state, tribal, local, and territorial jurisdictions with their Zika responses in a wide range of activities, including surveillance and epidemiology, vector control, communication and outreach to pregnant women and vulnerable populations, and planning with key stakeholders.

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

Without additional resources, CDC will have a severely limited capacity to support mosquito control and surveillance efforts in the continental U.S. or other U.S. 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 in cases of local transmission and testing specimens to determine the presence of Zika virus in communities.

National Institutes of Health

The NIH is leading the Department's efforts to develop safe and effective Zika vaccines. Importantly, the NIH Vaccine Research Center (VRC) announced on August 3, 2016, that it has begun Phase I trials on a DNA-based vaccine ahead of schedule. In addition, NIH is working to support efforts to improve Zika diagnostics, to develop therapeutics, and to conduct other critical research activities that will assist the Zika response. The NIH received \$47 million in repurposed Ebola dollars to conduct this work, and as I wrote to the Congressional leadership in an August 11th letter, this funding will be exhausted by the end of August.

In order to avoid a delay in the development of a Zika vaccine, I transferred an additional \$34 million in funding to help provide short-term financing to NIH's Zika efforts.¹ This funding will allow the NIH to conduct preparatory activities associated with the Phase IIB study of the VRC DNA vaccine candidate mentioned above. These additional resources that are being made available for NIH's Zika activities are coming exclusively from other NIH accounts. As you know, there has been bipartisan support for providing additional support to NIH as it is on the front lines of finding effective treatments and cures for many of our nation's most devastating illnesses, including cancer, heart disease, stroke, diabetes, Alzheimer's disease and others. Reallocating these NIH resources is not consistent with a strategy to provide maximum support to the important work that our nation's leading scientists are performing, but the lack of a bipartisan Zika funding bill left me no choice but to provide resources through this action.

Despite these efforts to provide resources to NIH to finance their immediate needs, there are no additional resources to ensure the execution and completion of the Phase IIB trial for the VRC DNA vaccine candidate, to support the development of other lead vaccine candidates that NIH is working to develop, and no resources to support its work on diagnostics and research activities. In addition, without additional resources, 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 infants by following 10,000 pregnant women for the duration of their pregnancies and their infants at several intervals 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 abnormalities caused by the virus. The NIH estimates that it will need approximately \$196 million in additional resources in FY 2017 to continue its vaccine, diagnostic and therapeutics development, and research work as it relates to Zika.

¹ In your letter, you asked if there is a legal impediment to using unobligated balances to respond to Zika. Funds can only be obligated for the purposes appropriated by Congress, with the exception of limited Secretarial transfer authority. This authority was used to transfer funding to prevent stalling vaccine development supported by NIH and BARDA.

Biomedical Advanced Research and Development Authority

BARDA is leading our efforts to partner with the private sector to develop vaccines and innovative Zika diagnostic tests, and blood screening tests and pathogen reduction technologies to protect the blood supply. Earlier this year, the Department repurposed \$85 million in Ebola funding to help BARDA begin this critical work. At the beginning of August, BARDA estimated that it would exhaust these resources by the end of August and would be forced to limit the number of vaccine candidates supported and delay critical vaccine development activities. To avoid any delays in our critical vaccine development work, I made the decision to transfer an additional \$47 million to BARDA. This additional funding will enable BARDA to move forward and enter into contracts with key private sector partners to initiate the development of Zika vaccines. Resources that are being provided to BARDA are being transferred from HHS agencies such as the Administration for Children and Families, which is on the front lines of fighting poverty, the Centers for Medicare and Medicaid Services (CMS), which is responsible for administering some of our most important health care programs, and the Substance Abuse and Mental Health Services Administration, which is leading our fight against opioid addiction and mental health issues. After these resources are exhausted, however, BARDA estimates that it will need \$342 million in additional funding in FY 2017 to continue its vaccine, diagnostic development, and pathogen reduction work with these and other partners.

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. With the actions described above, we have exhausted our ability to even provide short-term financing to help fight Zika. Our nation's ability to mount the type of Zika response that the American people deserve sits squarely with Congress. Our latest estimates are that domestic response funds that are being used by the CDC, NIH, and BARDA will be virtually exhausted by the end of the fiscal year.

When Congress returns in September, there will be less than one month to provide resources to avoid a scenario where agencies on the front lines of the Zika response have to severely curtail many of their critical efforts. For CDC, this could involve reducing the number of staff and related activities that comprise our Zika efforts in states and territories that are trying to control the spread of Zika. For NIH, this could involve delaying or possibly halting research work on vaccines. And for BARDA, this could result in companies that have partnered with the U.S. government to develop a Zika vaccine not having access to additional funding needed to continue their work. The Health Resources and Services Administration will be unable to expand maternal and child health services or place additional National Health Service Corps clinicians in Puerto Rico. Finally, without Congressional action, CMS will not have the authority to provide additional federal matching funds to Puerto Rico and other U.S. territories to support costs related to the screening and treatment of pregnant women and care of infants born with microcephaly. In short, allowing any of these scenarios to come to pass puts the American people needlessly at risk and will result in more Zika infections and potentially more babies being born with microcephaly and other birth defects.

I urge you to work to develop a bipartisan bill that will allow us to mount a comprehensive and timely response to the Zika virus. I stand ready to work with you to accomplish this goal. If you have any questions or concerns, please do not hesitate to contact Jim Esquea, Assistant Secretary for Legislation at (202) 690-7627.

I will also share this response with Senator Lankford who co-signed your letter.

Sincerely,

A handwritten signature in black ink that reads "Sylvia M. Burwell". The signature is written in a cursive style with a large, sweeping initial 'S'.

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