

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

August 11, 2016

The Honorable Nancy Pelosi Minority Leader U.S. House of Representatives Washington, D.C. 20515

Dear Madam Leader:

This letter continues the Administration's efforts to keep you updated on Zika. As of today, there have been more than 7,300 cases of Zika virus infection, 972 pregnant women with any laboratory evidence of Zika virus infection, and 15 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 22 cases of local transmission.

Last week, I updated the Chair and Ranking Members of the Senate and House Appropriations Committees, in addition to the relevant Subcommittee Chairs and Ranking Members, that the Department of Health and Human Services (HHS) is moving aggressively and prudently to use the resources that were repurposed from our efforts to fight Ebola. As you know, we made the decision to repurpose the Ebola funding in April as Congress had not yet appropriated any funding for the Zika response and the Department needed resources to respond to the growing threat of Zika. This decision was made despite the fact that Ebola remains a global health threat and, at the time, we were tracking new Ebola cases re-emerging in West Africa.

Last week's letter also noted that the latest estimates from both the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) showed that they would exhaust their Zika resources by the end of this month. Without any additional resources, NIH and BARDA would be forced to delay critical Zika vaccine development activities. The letter also said we would evaluate all options to prevent the American people, and in particular women of childbearing age, from waiting unnecessarily to access a Zika vaccine.

The failure to pass a Zika emergency supplemental has forced the Administration to choose between delaying critical vaccine development work and raiding other worthy government programs to temporarily avoid these delays.

In order to avoid any Zika vaccine development delays, I have notified Congressional Appropriation leaders that I will use my Secretarial authority to transfer \$34 million in additional resources within NIH and \$47 million to BARDA in order to ensure that neither is forced to delay their Zika vaccine work as the fiscal year closes.

These additional resources that are being made available for NIH 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 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 clean, bipartisan Zika funding bill has left me no choice but to move forward with this action at this time. Similarly, 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, 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.

Even with an additional \$34 million in reallocated funding, the NIH estimates that it will need approximately \$196 million in additional resources in FY 2017 to continue its vaccine and diagnostic development, and research work as it relates to Zika. The funding being transferred will allow NIH to begin the process of setting up a Phase II trial for the DNA-based vaccine that entered a Phase I trial on August 2, 2016. However, there are no additional resources for the other three lead vaccine candidates that NIH is working to develop. Moreover, NIH currently lacks sufficient funds to support diagnostics, and other activities critical to the Zika research response.

Similarly, BARDA will use the \$47 million in additional resources to enter into contracts with key private sector partners to initiate the development of Zika vaccines. 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. The NIH and BARDA FY 2017 funding needs represent only a portion of the total amount that the Administration needs to properly respond to the Zika virus. In February, nearly six months ago, the Administration requested \$1.9 billion in emergency supplemental funding and we will continue to work with Congress to secure this level of funding.

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 Centers for Disease Control and Prevention (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 Puerto Rico, Florida, Texas, and potentially other areas 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. 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.

Sincerely,

Sylvia M. Burwell
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Identical letter sent to:

The Honorable Mitch McConnell

The Honorable Harry Reid The Honorable Paul Ryan

cc: The Honorable Kevin McCarthy

The Honorable Steny Hoyer

The Honorable John Cornyn

The Honorable Richard Durbin

The Honorable Harold Rogers

The Honorable Nita Lowey

The Honorable Thad Cochran

The Honorable Barbara Mikulski

The Honorable Fred Upton

The Honorable Frank Pallone

The Honorable Lamar Alexander

The Honorable Patty Murray

The Honorable Tom Cole

The Honorable Rosa DeLauro

The Honorable Roy Blunt