

# United States Senate

WASHINGTON, DC 20510

February 5, 2016

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

Dear Secretary Burwell:

We request that you expeditiously consider the addition of the Zika virus to the list of tropical diseases eligible for the Priority Review Voucher (PRV) program.

This week, the World Health Organization declared the Zika-linked cluster of birth defects an international public health emergency. Thousands of people have been affected by the Zika virus. Zika is actively spreading in 26 countries and three U.S. territories and the first locally transmitted case has been reported in the continental United States. Currently, there is no vaccine or treatment for the virus. Although the most common symptoms of the Zika virus are mild, the disease may cause more serious health concerns for pregnant women. Some reports suggest a correlation between Zika virus and serious birth defects of the brain, including microcephaly, which has been linked with developmental delays, seizures, and other potentially life-threatening problems. Given the breadth of the Zika virus outbreak, and the potential associated risks to pregnant women, the time to act is now.

In 2007, Congress established a PRV program to encourage the development of treatments for neglected tropical diseases. Companies that develop a product that can be used for the prevention or treatment of an eligible tropical disease may receive a PRV from the Food and Drug Administration (FDA), which can then be used to obtain FDA priority review of a new drug application for a second product, or sold to another company for use on one of its products. The statute identifies a list of eligible infectious diseases, which includes Tuberculosis, Malaria, and Dengue fever. Congress added Ebola virus to this list in 2014, and granted the Secretary of the Department of Health and Human Services the authority to add new diseases to this list by order. You exercised this authority for the first time last summer when you added two new conditions, Chagas and neurocysticercosis, to the voucher program. We ask that in the face of this public health emergency, you do the same for the Zika virus – to encourage development of products to treat or prevent infection with the Zika virus.

Families affected by the Zika virus need prevention and treatment options. Including Zika virus in the Priority Review Voucher program could help catalyze the development of these important tools. We ask that you consider this request in the near term, and that you continue to use all authorities available to the agency to help combat this disease.

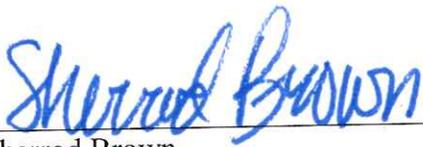
Sincerely,

Handwritten signature of Al Franken in blue ink, written over a horizontal line.

Al Franken  
United States Senator

Handwritten signature of Bill Nelson in blue ink, written over a horizontal line.

Bill Nelson  
United States Senator

Handwritten signature of Sherrod Brown in blue ink, written over a horizontal line.

Sherrod Brown  
United States Senator

CC: Dr. Stephen Ostroff, Acting Commissioner, Food and Drug Administration