

February 3, 2016

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

Dear Secretary Burwell,

We are concerned about news of the rapidly spreading Zika virus, which appears to represent a serious public health threat to pregnant women and their unborn children. Its explosive spread in the Americas, where Brazil has tragically experienced the most cases thus far, is alarming, and one recent analysis makes the troubling suggestion that Zika virus could reach parts of the United States in which 60 percent of the population resides. This week, the World Health Organization announced that suspected Zika-linked conditions constitute a public health emergency of international concern. Jointly, as chairman of the Senate health committee and as author of the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA), we are interested in working together with you to ensure that our nation is as prepared as possible for this and other emerging public health threats.

Over the past decade, Congress has worked with the Department of Health and Human Services to bolster our medical and public health preparedness and response capabilities. The bipartisan PAHPA, and its reauthorization in 2013, put in place key programs to advance medical countermeasures to protect the American people. PAHPA recognized that pregnant women and children represent vulnerable populations with unique considerations both when it comes to public health emergencies and with the development of therapeutics and vaccines to protect them against novel and emerging threats.

These unique considerations for women and children are highlighted in the case of Zika virus. Much remains unknown about the link between Zika virus infection and microcephaly, as well as reports of Guillain-Barré syndrome and other central nervous system malformations. We request that you keep us apprised of the Department's research to better understand the Zika virus and the full range of health threats it may pose to Americans, as well as the steps the Department is taking to rapidly advance a real-time diagnostic for the Zika virus, actions to speed the development of a vaccine to prevent transmission of this virus, and therapeutics to treat it and timelines associated with these efforts.

¹ Anticipating the international spread of Zika virus from Brazil. Bogoch II, Brady OJ, Kraemer MU, German M, Creatore MI, Kulkarni MA, Brownstein JS, Mekaru SR, Hay SI, Groot E, Watts A, Khan K. Lancet. 2016 Jan 14. pii: S0140-6736(16)00080-5.

http://directorsblog.nih.gov/2016/01/26/zika-virus-an-emerging-health-threat/

As we saw with the Ebola outbreak in 2014, it is critical that clinicians and travelers have timely and accurate information in the face of an emerging threat. This is all the more important because of the unique threat that infection with the Zika virus appears to present to pregnant women and their unborn children. Reports by the Brazil Ministry of Health of increased cases of Guillain-Barré syndrome are similarly concerning, as health officials work to determine whether Zika virus infection and these cases are related.³

Each public health emergency our nation has endured has informed preparedness efforts for the next threat we may face. As the Department engages with the global health community to combat the Zika virus and takes steps to help protect our citizens against it, we strongly encourage you and your colleagues to apply the lessons learned from previous experiences. This includes fully leveraging the tools the Department has at its disposal to rapidly advance the research and development of Zika diagnostics, vaccines, and therapeutics. For example, as part of the response to the Ebola outbreak in 2014, Congress gave the Secretary of Health and Human Services the ability to add conditions to the neglected tropical disease priority review voucher program in order to incentivize the development of therapies for threats such as the Zika virus. We look forward to hearing from you regarding whether you plan to add Zika to the list of conditions eligible for such vouchers in order to incentivize the timely development of a vaccine to protect families across our nation and the world.

Thank you again for your commitment to and partnership in combatting this and other emerging public health threats.

Sincerely,

Lamar Alexander United States Senator Richard Burr United States Senator

CC: Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response

Dr. Robin Robinson, Director, Biomedical Advanced Research and Development Authority

Dr. Tom Frieden, Director, Centers for Disease Control and Prevention

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

Dr. Francis Collins, Director, National Institutes of Health

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases

³ http://www.cdc.gov/zika/disease-qa.html