

**Answer to Post-Hearing Question for the Record
Submitted to the Honorable Donna E. Shalala
from Representative Michael C. Burgess, MD, Subcommittee on Oversight and Investigations,
House Committee on Energy and Commerce**

“Outbreaks, Attacks, and Accidents: Combating Biological Threats”

February 12, 2016

The Honorable Michael C. Burgess, MD

- 1. As a physician, I understand that the development and validation of precise diagnostics for emerging outbreaks is crucial to combating biological threats such as Zika virus. We need to quickly develop diagnostics for these purposes and work to ensure that public health laboratories and hospital laboratories throughout the country are able to screen people for the disease and that patients have access to these tests. I'm concerned that the CDC is creating barriers for laboratories to quickly disseminate the test and by not enabling competing tests, there's no way to assess whether or not the CDC test is adequate. Please describe the process CDC engages in for sharing necessary information, test reagents, and reference materials to laboratories develop tests for emerging infectious diseases. I've also heard that despite the lack of cooperation from the CDC, some physicians have already developed tests for Zika virus at Texas Children's Hospital and Stanford University. Have you considered collaborating with these academic medical centers on developing diagnostics?**

While our Study Panel is aware of the CDC process for sharing information, test reagents, and reference materials with laboratories for the purposes of developing tests for emerging infectious diseases, we do not possess sufficient information with which to describe this process in detail for you. We recommend that you obtain this information directly from the CDC.

Our Study Panel does not engage in the development of diagnostics. We do highly recommend government collaboration with academia and the private sector toward this end. The CDC and other government agencies should inform their activities with the existing expertise and progress within the U.S. biomedical enterprise. It would be better for the CDC to collaborate with academic medical centers and foster such innovation than for the CDC to operate in a vacuum, or worse, engage in unhealthy competition with the private sector.