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U.S. House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations hearing on Friday, February 12, 2016 entitled "Outbreaks, Attacks, and Accidents: Combatting Biological Threats."

The Honorable Michael C. Burgess, M.D. (TX – 26)
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 to 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?

Response to the Additional Question for the Record

The importance of near-real time biosurveillance, laboratory capacity and accurate point of need diagnostics for emerging and reemerging infectious diseases, as well as biodefense cannot be overstated. Development efforts for rapid detection/diagnostics, whether from natural outbreaks or deliberate attacks have not been given sufficient long-term attention and programmatic priority.

I hope you can see from this statement that I share your understanding and concern that we urgently need more development programs now for accurate and rapid Zika point of care diagnostics for patients in the health care setting. But we also need long-term, sustainable and focused rapid detection/diagnostic programs for emerging infectious diseases not only for patients, but also in a broader one health context that encompasses the human/animal nexus because most emerging infectious diseases that we have experienced, and can expect to see in the future are zoonotic. The gaps and funding shortfalls in veterinary diagnostic laboratory capabilities and capacities are much worse compared to the gaps in the CDC laboratory response network and need to be addressed too.

The unfolding Zika outbreak is serious, and once again highlights the importance of rapid and accurate diagnostics. There are no FDA approved Zika diagnostics available, but the CDC is gearing up and working hard to respond to this serious crisis to support state and local public health authorities. I cannot speak on behalf of the CDC regarding their laboratory testing procedures, so it is recommended that the committee ask the CDC directly how they are making information, testing materials and test results

available to laboratories and health care providers. But, I will summarize what I understand from publically available information, personal experiences and interaction with public health colleagues on how CDC is supporting local and state health authorities, as well as clinicians and their patients regarding Zika diagnostics.

Zika virus is a nationally notifiable disease. State, local and territorial health departments are encouraged to report laboratory-confirmed cases of any arbovirus, such as Zika, to CDC through ArboNET, the national surveillance system for arborviral diseases. Healthcare providers should report suspected Zika cases to their local, state or territorial health department according to laws or regulations for reportable diseases in their jurisdiction. Clinicians should consult with, and obtain information for submitting clinical samples for Zika testing from their health department of jurisdiction.

The CDC has developed two diagnostic tools; 1) the CDC Zika IgM Capture Enzyme-Linked Immunosorbent Assay (ZIKA MAC-ELISA) to detect antibodies the body makes in response to an infection that may indicate a recent Zika and/or related arbovirus infection such as Dengue, and 2) the Trioplex Real-time Reverse Transcription Polymerase Chain Reaction (Trioplex rRT-PCR) assay to detect the presence of Zika, Chikungunya or Dengue genetic material to determine which infection a patient may have.

The CDC requested, and the FDA recently issued an Emergency Use Authorization (EUA) for these two CDC diagnostic tests. The CDC will distribute these tools and reagents to qualified laboratories in the laboratory response network, but only those labs certified by the CDC to perform high-complexity tests. Test results require careful interpretation, and CDC provides laboratories, health care providers and tested individuals with information regarding these Zika laboratory diagnostics, to include limitations of the tests and guidance for interpretation of test results in the context of a patient's travel history, clinical history and other epidemiologic criteria. There is no indication that CDC plans to distribute these diagnostic tools to hospitals or other health care settings, but rather limit their availability to a relatively few specialized CDC approved public health laboratories.

Clinicians must submit samples for testing to their local or state public health department of jurisdiction, and not to CDC directly. Test results will be reported back to the state or local health departments of jurisdiction, not directly to clinicians. CDC's website indicates laboratory results are currently taking at least 3 weeks to report after receipt of a sample, and that health departments, clinicians and patients should expect longer reporting delays as summer approaches.

Clinicians and patients alike urgently need point of care Zika diagnostics that provide rapid, accurate results. Advanced diagnostics being developed by hospitals, academia and industry, such as the Texas Children's and Houston Methodist Hospital collaborative in Texas are very encouraging. My colleagues and I at Texas A&M University will promote and collaborate with Texas Children's and Houston Methodist Hospital, as well as other institutions in Texas and globally on emerging infectious disease diagnostics and biosurveillance systems, to include Zika diagnostics. I have been in direct contact with the Texas Children's Hospital collaborative as well as a similar effort at UTMB through Governor Abbot's Texas Task Force on Emerging Infectious Disease Preparedness. It is clear that Zika testing demands will outpace CDC approved laboratory capacity, if it has not done so already as CDC laboratory reporting already requires at least 3 weeks. Hospital-based diagnostics offer the potential to provide test results in hours, not weeks; and to overcome a public health laboratory capacity bottleneck. Hospital-

based local testing also enables rapid, direct and local clinician to clinical laboratory pathology consulation further improving patient outcomes. However, with any new diagnostic technology that is not yet FDA approved, use in a clinical setting must be done in strict compliance with clinical laboratory standards and regulations.