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OSC Calls for Further Review of Whistleblower Disclosures on Zika Testing

FOR IMMEDIATE RELEASE

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Today, the U.S. Office of Special Counsel (OSC) [reported](#) to the White House and Congress on an investigation by the Centers for Disease Control and Prevention (CDC) into the whistleblower disclosures of Dr. Robert Lanciotti, a CDC microbiologist. Dr. Lanciotti is the chief of the CDC's Diagnostics and Reference Laboratory within the agency's Arbovirus Diseases Branch. His lab is based in Fort Collins, Colorado. Dr. Lanciotti raised concerns about the CDC's decision to recommend a test for the Zika virus that Dr. Lanciotti alleges is substantially less sensitive in detecting Zika than another established test. According to Dr. Lanciotti, the CDC-recommended test is nearly 40% less effective in detecting the active Zika virus than the alternative approach utilized by the Fort Collins lab.

OSC referred Dr. Lanciotti's disclosures to the Department of Health and Human Services for investigation on July 1, 2016. CDC's [investigation](#) did not substantiate Dr. Lanciotti's disclosures. CDC investigators stated they were unable to reach a "statistically-valid conclusion about the relative performance of the" tests. The two tests are known as the Trioplex assay—which tests for Zika, dengue, and chikungunya—and the Singleplex assay, which only tests for Zika. Dr. Lanciotti's study found that the Trioplex test missed 39 percent of Zika infections detected by Singleplex. The CDC report pointed to a study by another CDC lab in Puerto Rico that "found no difference in sensitivity."

Dr. Lanciotti also raised concerns that the CDC's Emergency Operations Center withheld information about the sensitivity differences between the tests from public health laboratories. The CDC found that this decision was reasonable given the inconclusive data.

Additionally, Dr. Lanciotti disclosed his belief that the CDC may have given public laboratories the mistaken impression that the Trioplex was a better test, despite contradictory findings that the Trioplex has inferior sensitivity. The CDC did not substantiate this, on the basis that data on the relative performance of the tests is inconclusive.

In his [comments](#) on the CDC's [report](#), Dr. Lanciotti disagreed, stating that "there was clearly enough data to warrant a 'pause' in the recommendation of the Trioplex until an extensive comparison could be performed." He also references summary data compiled by an independent research institution from multiple laboratories, which demonstrated the Trioplex's lower sensitivity. Dr. Lanciotti additionally stated that the method used by this institution to assess the tests is "the most accurate method to evaluate the clinical sensitivity . . . of individual assays."

Prior to disclosing these concerns to OSC, Dr. Lanciotti raised the issues internally and in an email to state public health officials in April 2016. In May, he was reassigned to a non-supervisory position within his lab. After the reassignment, Dr. Lanciotti filed a whistleblower retaliation claim alleging that his diminished duties, from lab chief to a non-supervisory position, was in reprisal for his disclosures. After an investigation, OSC secured an agreement from CDC to reinstate Dr. Lanciotti as chief of his lab.

"As the agency contemplates additional improvements or changes to the Zika testing protocol, I encourage CDC to review Dr. Lanciotti's comments, respond to each of his concerns, and utilize his expertise as the agency works to ensure it is implementing the most effective testing methods in response to this public health emergency," said Special Counsel Carolyn Lerner. "I also encourage the CDC to promote scientific debate within its labs. Whistleblowers should be encouraged to speak out on matters of public concern."

The U.S. Office of Special Counsel (OSC) is an independent federal investigative and prosecutorial agency. Our basic authorities come from four federal statutes: The Civil Service Reform Act, the Whistleblower Protection Act, the Hatch

Act, and the Uniformed Services Employment & Reemployment Rights Act (USERRA). OSC's primary mission is to safeguard the merit system by protecting federal employees and applicants from prohibited personnel practices, especially reprisal for whistleblowing, and to serve as a safe channel for allegations of wrongdoing. For more information, please visit our website at www.osc.gov.