Congress of the United States

House of Representatives

Washington, DC 20515

August 11, 2016

The Honorable Dr. Robert M. Califf, MD
Commissioner, Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993
Re: Preserving blood safety and supply after local Zika transmission

Dear Commissioner Califf,

We write to express our continuing concern for the safety of our national blood supply with the Zika virus present in domestic mosquitoes. While we appreciate the Food and Drug Administration's quick response to the emergence of locally transmitted cases in Miami and the recommended cessation of blood donations in Miami-Dade and Broward Counties, we believe it is more critical than ever that the Food and Drug Administration (FDA) recommends a policy of universal testing of blood donations in high-risk areas.

A testing requirement could be introduced on a prioritized basis, beginning with states adjacent to Florida and along the Gulf of Mexico, which are at the highest risk of active transmission. Following this, the FDA should determine which inland areas are the highest priority and phase in blood testing for these locations. The FDA should also phase in testing for domestic destinations that receive large numbers of international travelers from where Zika is endemic. This testing requirement should be implemented in a way that avoids overwhelming the capacity of current testing facilities, with more areas included as testing ability increases. As you are aware, many blood donors would have no way of knowing they carried the Zika virus, since eighty percent of those infected are asymptomatic, and many others have only mild symptoms.

Two tests have been approved under the FDA's Investigational New Drug Application (IND) protocol: cobas, by Roche Diagnostics; and Procleix, by Grifols and Hologic, Inc. There are four testing sites currently using the technology: Qualtex in Atlanta; Gulf Coast Regional Blood Center in Houston; and the American Red Cross and Creative Testing in Tampa. Blood centers have used testing under IND successfully in the past, most recently in testing for West Nile Virus

In addition to the blood centers in Miami-Dade and Broward Counties, more blood and tissue donation centers have begun to voluntarily use these IND tests, but those that fail to test their

donations are leaving the safety of our national blood supply at risk. Donations had to be temporarily halted in those two counties, with recently collected blood quarantined until it can be tested. Additionally, blood centers that had received units of blood from that area have to quarantine those units until further guidance is issued. This is putting a strain on the blood supply, and could have been largely avoided if blood was already being tested in Miami-Dade and Broward Counties.

At a time when the Zika virus was only actively transmitted in a single ZIP code, the FDA recommended that blood donations be blocked for almost 4.5 million people. Many other blood centers around the country are issuing donation bans for anyone who has recently traveled to Miami-Dade or Broward County. While the FDA is assessing blood recommendations on a case-by-case basis, it is our fear that if locally transmitted Zika is found in a larger area, blood donation bans could expand to the state or along the Gulf Coast. We must implement widespread universal screening now to prevent any further contamination of the blood supply before it occurs and to preempt a widespread shortfall in the blood supply.

The cost of testing is less than $10 per blood donor—a small amount, when compared to the millions of dollars required for the lifetime care of a single infant born with microcephaly or the effects of a nationwide blood shortage.

Thank you for your timely response.

Sincerely,

Lloyd Doggett

Patrick Murphy

Rosa DeLauro

Ted Deutch

Ileana Ros-Lehtinen

Frederica S. Wilson

Eddie Bernice Johnson

David Jolly