Congress of the United States
House of Representatives
Washington, DC 20515

July 20, 2016

The Honorable Dr. Robert M. Califf, MD
Commissioner, Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993
Re: Testing the United States' Blood Supply for the Zika Virus

Dear Commissioner Califf,

We write regarding our concern on the spread of the Zika virus in the United States and the safety of our national blood supply. We urge the Food and Drug Administration (FDA) to institute a policy of mandatory testing of blood donations in high-risk areas.

A universal testing requirement could be introduced on a prioritized basis, beginning with states 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. The Roche test is currently being used by South Texas Blood & Tissue Center and Gulf Coast Regional Blood Center, the only two facilities performing universal blood screening in the continental US. Other blood centers could use the cobas or Procleix Zika virus blood screening assays for universal testing as well. 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

If we wait for the first confirmed locally transmitted Zika case to begin testing, we risk serious harm to the stability of our blood supply. Current guidelines indicate that if two unrelated cases of locally transmitted Zika are diagnosed within 14 days of one another, blood collected within the "area of active transmission" must be tested, put through pathogen reduction technology, or discarded. Currently, the Centers for Disease Control and Prevention (CDC) define the "area of active transmission" on a statewide basis, and the FDA says discussions regarding more localized regions are ongoing; however, as of today, no consistent method of determining area of active transmission other than at the state level is in place.

As a result, if two unrelated mosquito-borne cases of Zika were discovered in Texas within two weeks, the whole state may be required to undertake blood safety interventions. We must implement universal screening now to prevent contamination of the blood supply before it occurs.

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

Rosa DeLauro