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

August 11, 2016

The Honorable Andrew Slavitt
Acting Administrator
Centers of Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphry Building
Washington, D.C. 20201
Re: Reimbursements for blood units tested for Zika

Dear Acting Administrator Slavitt,

As you know, following the active transmission of the Zika virus in Miami, Florida, the Food and Drug Administration recommended testing blood donations for the Zika virus in both Miami-Dade County and Broward County.

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. Both of the available tests are individual nucleic acid tests (NATs), and cannot be used to test a multi-donor pools, raising the costs per donor. The current cost of testing blood donations for Zika is estimated at $7 to $10 per donor; a cost incurred by blood centers and then passed along to hospitals. We urge the Centers for Medicare and Medicaid Services (CMS) to create a code for hospitals to use to get reimbursed for the additional cost of blood that has been tested for the Zika virus, in order to protect our blood supply and protect the financial security of our hospitals and blood donation centers.

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 to secure their blood supply against the Zika virus, and to protect their supply from being contaminated, quarantined, or destroyed in the event of active Zika transmission in their region. In the past three to five years, many blood centers have been struggling financially, and many operate on margins of less than two to three percent.

PRINTED ON RECYCLED PAPER

Blood centers that are voluntarily testing donations for the Zika virus are currently at an additional competitive disadvantage, as are hospitals that are purchasing tested blood to keep their patients safe. CMS needs to address this by allowing hospitals to be properly reimbursed for blood that has been tested for Zika, so that blood centers can be paid in full for the costs of administering these tests.

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. The Zika virus has only been actively transmitted in a single ZIP code, but the FDA recommended that blood donations be tested in a region that encompasses almost 4.5 million people. We request that CMS work to allow blood centers to fulfill their obligation to the FDA and to the American public, and that a new reimbursement code for tested blood is implemented.

We look forward to hearing your reply.

Sincerely,

Lloyd Doggett

Patrick Murphy

Rosa DeLauro

Ted Deutch

Ileana Ros-Lehtinen

Frederica S. Wilson

Eddie Bernice Johnson

David Jolly