Congress of the United States Washington, DC 20515

June 13, 2017

Mr. Robert M. Speer Acting Secretary of the Army 101 Army Pentagon Washington, D.C. 20301-1400

RE: Zika Vaccine Agreement

Dear Secretary Speer:

As Members of Congress representing Florida, we write to you regarding the proposed exclusive license of patents on a Zika vaccine from the U.S. Army to Sanofi Pasteur through the year 2036, without addressing concerns of affordability.

According to the Centers for Disease Control and Prevention (CDC), Florida experienced 1,115 laboratory-confirmed symptomatic cases of the Zika virus in 2016, and 5,102 symptomatic cases of Zika were reported nationwide. With the summer months upon us, we brace for another mosquito season and hope it is better than the last. However, we owe it to our constituents to do more than just hope – we must proactively ensure that our government is taking all necessary steps to protect Americans from the Zika virus.

To that end, we are very concerned about reports that the Army is planning to exclusively license French pharmaceutical company, Sanofi Pasteur, to manufacture a Zika vaccine that has been developed at the Walter Reed Army Institute of Research since March of 2016. As Members representing Florida, we are especially concerned of the potential for monopolistic practices that would effectively keep this lifesaving vaccine out of reach for far too many of our constituents.

Adding insult to injury, this vaccine has been created with millions of dollars of federal funding. Taxpayers, who have endowed the research and development of a Zika vaccine that would keep Americans Zika-free and prevent deadly birth defects in babies, should be protected from high prices; not forced to pay more than anyone else around the globe. Walter Reed and the National Institutes of Health have done all of the pre-clinical research, and are currently doing Phase I clinical trials. Sanofi has also received a Department of Health and Human Services Biomedical Advanced Research and Development Authority grant of \$43 million for Phase II trials with an option for \$130 million for Phase III trials if needed.²

¹ https://www.cdc.gov/zika/reporting/2016-case-counts.html

² https://wayback.archive-it.org/3926/20170127192443/https://www.hhs.gov/about/news/2016/09/26/barda-awards-funding-speed-development-zika-vaccine.html

As the benefactors of this vital scientific research, Americans deserve to know how an exclusive license is either a reasonable or necessary incentive to bring the product to market in this particular instance, as required under 35 U.S.C. § 209; and at a minimum, Americans deserve binding assurances from Sanofi that U.S. residents will not pay more than residents of other high-income nations. Accordingly, we urge you to (1) hold a public hearing on the proposed license so that the public and Sanofi may address concerns over the pricing of the vaccine, and (2) delay the decision regarding the exclusive license on the patent until after such public hearing has been held.

Our constituents know the repercussions of the Zika virus, and stand to suffer physically and financially in the event of an outbreak. For instance, the per-child lifetime medical and indirect Zika costs have been estimated by the CDC to be as high as \$10 million.³ We are eager to see a Zika vaccine come to market, but if the vaccine is unaffordable, the results will be devastating, and in some cases, deadly, for our constituents. We look forward to your prompt response.

Sincerely,

Deblie Wasserman Schultz (FL-23)

Member of Congress

Darren Soto (FL-09) Member of Congress

Lois Frankel (FL-21) Member of Congress

Kathy Castor (FL-14) Member of Congress

Alcee L. Hastings (FL-20) Member of Congress Theodore E. Deutch (FL-22)

Member of Congress

Ileana Ros-Lehtinen (FL-27)

Member of Congress

Al Lawson (FL-05) Member of Congress

I'ha!

Charlie Crist (FL-13) Member of Congress

³ https://www.cdc.gov/media/releases/2016/t0404-zika-summit.html