

# United States Senate

WASHINGTON, DC 20510

June 26, 2017

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

Dear Acting Secretary Speer:

The United States, along with much of the developing world, remains concerned about the Zika virus and possible outbreaks in the coming summer months. Congress has appropriated millions of dollars toward Zika vaccine development and we are more than eager to see a vaccine come to market in the near future. However, it is imperative that any forthcoming vaccine is accessible and affordable for all, especially given the significant taxpayer investment to date. In order to discuss these issues in an open and transparent way, we urge the Army to convene a public hearing regarding its Zika vaccine candidate licensing plans.

Last year, more than 40,000 people in U.S. states and territories contracted the Zika virus. According to a recent Centers for Disease Control and Prevention (CDC) report, five percent of pregnant women with Zika had a baby born with a birth defect, such as microcephaly. In addition to the severe emotional trauma for families dealing with Zika-related birth defects, the lifetime financial costs to care for a child with microcephaly or other severe developmental disabilities are estimated to be as high as \$10 million. With more than 70 countries around the world reporting Zika infections, Army personnel are at elevated risk for Zika exposure. Last year, the Department of Defense reported that more than 70 service members and spouses had been diagnosed with Zika.

Recognizing the threat this virus posed to families and children worldwide, the U.S. Army—in collaboration with the National Institutes of Health (NIH)—spearheaded efforts to research and develop a Zika vaccine. Last year—after conducting nearly \$10 million in federally funded basic medical research, development, and pre-clinical studies at these agencies—the Army launched a process to partner with Sanofi in order to complete clinical trials, manufacture, and ultimately bring a Zika vaccine to market. Sanofi received \$43 million for phase II trials, with the possibility of an additional \$130 million for phase III trials.

Considering the taxpayer funds already invested in research and development of a Zika vaccine—not to mention the millions more that may be spent—we remain concerned by reports that the Army is considering an exclusive license with Sanofi, which would provide the company with monopoly rights through 2036, without any parameters to ensure reasonable pricing of the eventual product.

We have many important questions about this license and believe that U.S. taxpayers deserve answers before a final license is granted. As such, we request that the Army convene a

public hearing as soon as possible on the proposed exclusive license of this vaccine to Sanofi. We would recommend that the hearing include discussion of the following topics:

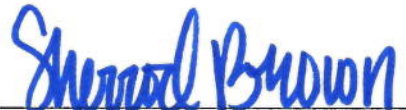
- The role that federal funding has played, and will continue to play, in the research and development of the Zika vaccine, and the extent of financial investment by Sanofi;
- Why an exclusive license is preferable to a non-exclusive license in this case, how the Army makes determinations under 35 U.S.C. § 209(a) of the Bayh-Dole Act when deciding to proceed with an exclusive license, and relevant lessons from the NIH's technology transfer experience;
- Issues regarding the pricing, affordability, and government purchasing of the resulting vaccine;
- An assessment of interest among pharmaceutical companies in partnering on a Zika vaccine; and
- Issues regarding the timing of the proposed license.

We would recommend that the hearing include a diverse witness panel, including representatives from Sanofi, the Army technology transfer division, health officials such as Dr. Rebekah Gee of the Louisiana Department of Health, public interest groups including Doctors without Borders and Knowledge Ecology International, and independent academic economists. Thank you for your consideration of this request and we look forward to your prompt reply.

Sincerely,



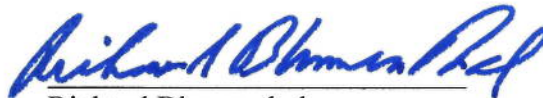
Richard J. Durbin  
United States Senator



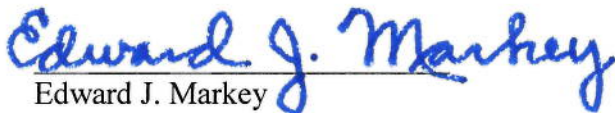
Sherrod Brown  
United States Senator



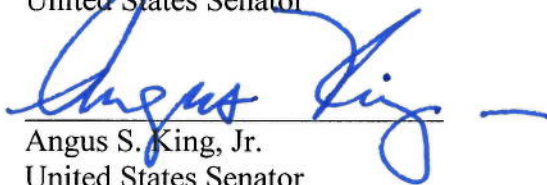
Bernard Sanders  
United States Senator



Richard Blumenthal  
United States Senator



Edward J. Markey  
United States Senator



Angus S. King, Jr.  
United States Senator

CC: Lt. Gen. Nadja West, Army Surgeon General, U.S. Army Medical Command