



SECRETARY OF THE ARMY
WASHINGTON

MAY 04 2017

The Honorable Bernard Sanders
United States Senate
Washington, DC 20515

Dear Senator Sanders:

Thank you for your March 10, 2017 letter regarding the Department of the Army's intent to grant an exclusive, royalty-bearing, revocable license to Sanofi Pasteur, Inc., for the commercialization of two pending U.S. provisional patent applications for Zika Virus Vaccine and Methods of Preparation. These provisional patent applications were filed to protect the patent rights to an early stage technology invented by the Walter Reed Army Institute of Research (WRAIR) that may potentially lead to an effective Zika virus vaccine.

The U.S. Army also received your office's December 2016 request, along with several Freedom of Information Act (FOIA) requests, pertaining to the U.S. Army's intent to grant an exclusive license of WRAIR's potential Zika vaccine to Sanofi Pasteur, Inc. Under Federal law, we are prohibited from releasing trade secrets or proprietary information. Accordingly, we are appropriately redacting the many documents requested. We hope to complete these requests by June 1, 2017.

The U.S. Army lacks the necessary funding and physical capability to develop, manufacture, and distribute a U.S. Food and Drug Administration (FDA)—licensed Zika vaccine based on WRAIR's early stage technology. In order to continue development of a Zika vaccine candidate, the U.S. Army requires a non-Federal partner with sufficient research and production capabilities, as well as the willingness to invest its own substantial capital to obtain FDA licensure. To date, Sanofi Pasteur, Inc., is the only known commercial pharmaceutical company willing to license WRAIR's Zika purified inactivated virus invention for possible FDA approval, manufacturing, and distribution.

Although Sanofi Pasteur, Inc., submitted an application for exclusive license for the U.S. Army's Zika vaccine technology, the decision to grant an exclusive license to Sanofi Pasteur, Inc., is not final. The final terms of the license agreement are being negotiated both to ensure they are in the best interests of the U.S. Government and the public, and to comply with relevant law and regulation.

In deciding whether to ultimately grant a license, the U.S. Army will consider a number of factors including: (1) the number of competing vaccine development efforts currently underway around the world; (2) the substantial cost required to fully develop,

produce, and distribute a FDA-approved vaccine, which necessitates commercial investment; (3) the potential risks assumed by the vaccine developer in moving a vaccine through the regulatory process; and (4) the willingness and capability of other vaccine developers to license, develop, and commercialize our nascent invention.

In summary, after considering all the facts surrounding these particular inventions and the applicable law and regulations, the U.S. Army will choose the best course of action to provide a publicly available, timely, and effective Zika vaccine. A final decision on granting a license is still several months away, but I promise to keep you apprised of our decision.

Thank you for your continued interest in pushing for effective means to control the Zika virus and for your support of the U.S. Army.

Sincerely,

A handwritten signature in cursive script that reads "Robert M. Speer". The signature is written in black ink and is positioned above the printed name.

Robert M. Speer
Acting