DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

MRMC ORTA, MCMR-JA 21 April 2017

Mr. James Love
Knowledge Ecology International (KEI)
1621 Connecticut Ave Suite 500
Washington DC 2009

Dear Mr. Love,

This reply is in response to your letters of 21 December 2016, 12 January 2017 (along with AFSCME, PFAM, PC, SSW, UAEM, and Mr. Dean Baker), and 10 March 2017 objecting to the grant of an exclusive license to Sanofi Pasteur for the Zika vaccine developed by the U.S. Army Medical Research and Materiel Command (MRMC), as published in the Federal Register Notice of Intent to Grant an Exclusive License December 9, 2016.

Our singular goal is to find the best way to provide a quick, safe, and effective Zika vaccine for our U.S. soldiers and the public while complying with all U.S. laws and regulations. Your objection has been read and considered. Your summarized objections include:

1. Reasonable pricing language should be included in the licenses agreement.

2. Exclusivity should be limited to a period less than the life of the patent. You propose 5 years. Additionally you object that exclusivity is not reasonably necessary.

3. Transparency of the costs of research and development should be required. Disclosure of financial details on sales should also be required.

4. The license should require availability and affordability of the vaccine in developing countries.

In response:

1. Any executed patent license will be in accordance with federal laws and regulations, the proposed scope of exclusivity will be in the best interest of the U.S. government and the public, and it will be a reasonable and necessary incentive to call forth the substantial investment capital, expertise, and capabilities required to bring our nascent and unproven technology through FDA licensure to practical application for public use. The U.S. Army lacks the means, expertise, and authority to define, implement, and enforce "affordable prices" or to set price controls for a potential vaccine that will require great investment and face high risk of failure, so we believe market competition among the Zika solutions can more fairly drive the availability and market for products. Nonetheless, granting an exclusive license, under our existing technology transfer statutory framework, places restrictions and requirements upon the licensee that are designed to protect the public interest.

2. MRMC entered into myriad discussions with potential partners and Sanofi Pasteur, Inc. was the only one to move forward with executing a CRADA and to submit a license application. The MRMC vaccine is not the only Zika vaccine or solution being supported by the U.S. Government, and there are numerous other companies pursuing recombinant, subunit, live attenuated, nucleic acid and viral vector vaccines. In our view, exclusivity is needed to incentivize a company to enter a crowded and competitive preclinical marketplace, especially when the cost of clinical trials is substantial (and may even be higher due to competition for clinical trial sites with high Zika incidence). As we discovered in our negotiations, an exclusive license limited to 5 years is not sufficient incentive to attract quality partners with the resources necessary for successfully fielding a Zika vaccine based on our untested invention.

3. Sanofi Pasteur, Inc.'s ultimate decision whether to sign a license agreement with WRAIR is a business decision based on potential return for their shareholders' capital investment versus alternate business opportunities. Considering the high risk and high cost involved in advanced vaccine development, granting an exclusive license for a federally developed technology is often the only

incentive significant enough to attract a competent and willing commercial partner.

4. In deciding whether to ultimately grant an exclusive license to Sanofi Pasteur, Inc., the U.S. Army will consider a number of factors, including (1) the number of other competing vaccine development efforts currently underway around the world; (2) the substantial cost required to fully develop, produce, and distribute an 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) willingness of other vaccine developers to license, develop, and commercialize our nascent invention.

5. The financial provisions and the development plan are considered confidential and treated as business proprietary in accordance with federal law. No business would want the specifics of its development costs and license payment terms to be shared with its competitors. The government does require details of development costs and product sales for license compliance and monitoring, but even after a license agreement is final, we are prohibited by Federal criminal law from disclosing trade secrets or proprietary information.

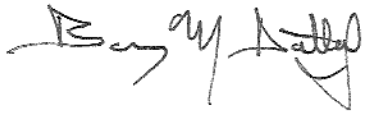
6. While we share your concern regarding affordability of future Zika vaccines in developing nations, the U.S. Army lacks the means, expertise, and authority to define, implement, and enforce international vaccine prices as part of our license agreement for a speculative technology that might or might not develop into an effective vaccine, since every country in the world has different private/public market forces and demands.

We appreciate your comments, concerns, objections, and suggested license provisions. Although the license agreement is not final, we intend to grant an exclusive patent license to Sanofi Pasteur, Inc. as authorized and in accordance with U.S. laws and regulations provided we determine the terms to be in the best interest of the U.S. Government and the public.

Should you believe that my response does not adequately address your concerns and that you have grounds for appeal, you may submit an appeal within 30 calendar days of receiving actual or constructive knowledge of the basis for

the appeal. If the thirtieth calendar day falls on a weekend or Federal holiday, then the appeal will be due the next working day. The procedures for an appeal are found in 37 CFR 404.11 and Appendix B of Army Regulation 70-57.

Sincerely,



Barry M. Datlof
Chief, ORTA