July 15, 2017

The Honorable Richard Blumenthal
706 Hart Senate Office Building
Washington, DC 20510

Dear Senator Blumenthal:

I am writing in response to your letter to Olivier Brandicourt dated June 27, 2017 regarding the potential license of the Zika vaccine candidate developed by the Walter Reed Army Institute of Research (WRAIR) to Sanofi Pasteur, the vaccines division of Sanofi. As a research-based organization focused on human health, Sanofi Pasteur's commitment in partnering with WRAIR is to ensure that this vaccine, if it can be developed and proves effective and safe, is ultimately priced to make it accessible and available to anyone who needs it, no matter where in the world they live. Any reports to the contrary are simply false and misinformed.

Background on Sanofi Pasteur's and Our Engagement with WRAIR

As you may know, Sanofi Pasteur was the only entity to submit a license application for WRAIR's Zika vaccine candidate. Following our application, the intention to grant the exclusive license to Sanofi Pasteur was published[1] in the Federal Register on December 9, 2016 as required by statute, in order to allow any other parties the opportunity to object within 15 days from the date of the announcement. The Notice Period was subsequently extended, yet still no other entities stepped forward to express interest in licensing the WRAIR IP.

Despite no interest shown by other parties, we at Sanofi Pasteur continue to believe that the Army's inactivated Zika vaccine is a strong candidate (among the 30+ known Zika vaccines in development, several with federal funding) for public use. To determine whether the WRAIR inactivated Zika virus vaccine candidate will ultimately prove to be safe and effective, we plan to:

- conduct a case definition study to validate diagnostic assays and define end points for Phase 3
- better understand the epidemiology through our follow-up of Dengvaxia® trials, where we are also collecting data on Zika cases
- develop an integrated evidence generation plan (with key stakeholders)
- execute Phase 1/2 clinical trials (using existing investment in clinical sites for Dengvaxia® that can be leveraged for Zika trials)
- execute Phase 3 clinical trials and post-licensure trials, if appropriate, feasible, and required.

[1] United States Department of Defense, Department of the Army; Intent To Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg. 89,086 (Dec. 9, 2016)

Additionally, Sanofi Pasteur is using its proprietary serum-free Vero cells and process, including technologies and know-how that are utilized in some of our marketed vaccines, as well as our expertise in diagnostic assays to further evaluate clinically the WRAIR Zika virus vaccine candidate.

Recent media reports have suggested that during the course of our ongoing confidential negotiations to license intellectual property from WRAIR related to this Zika vaccine-candidate, we rejected a "fair pricing" proposal from the US Army. While it is unclear what or who is the source of this information, Sanofi Pasteur did not reject a specific fair-pricing term proposed by WRAIR as part of the licensing negotiations. While we discussed pricing in general, both parties recognized it is premature to set pricing terms at this stage for a technology that will require substantial financial and intellectual capital with no guarantee of a marketable vaccine. Instead, together we are pursuing terms that would provide compensation to the Army based on realized returns from a successful product, which could be significant for the Army.

As we have stated publicly several times, Sanofi Pasteur is committed to leveraging its flavivirus vaccine development and manufacturing expertise to deliver and ultimately price a Zika vaccine in a responsible way, as has been our business practice over our 120 year heritage. Evidence of our commitment to safe, affordable, and accessible vaccines is demonstrated by our industry-leading ranking on the Access to Vaccines Index (https://accesstovaccinesindex.org/report-cards/sanofi/) and the publically available pricing of our products both in the United States and abroad.

Additional Issues Raised in Your Letter

As you note in your letter, Sanofi announced new Pricing Principles for the U.S. on May 9, 2017. These principles express our intent to set our future price increases in the U.S. at or below an independent standard measure of health care inflation, the national health expenditures (NHE) growth projection as determined by the Department of Health and Human Services, and also provide greater transparency around how we set our prices at launch based on clinical, economic and social value, as well as affordability. This policy applies to all of our medicines, including a future Zika vaccine. We have also committed to greater transparency to help stakeholders better understand our pricing decisions. In 2016, the average list price for all of our medicines, including vaccines, increased 4 percent while our total net price declined by 2.1 percent.

Sanofi fully understands that the price and affordability of our medicines is critical for patients and society. In response to your questions regarding insulin pricing practices, we note that Sanofi has not increased the list price of Lantus®, the world's top selling insulin, since November 2014. Additionally, the net price of Lantus over the last five years has decreased as we continue to increase rebates to PBMs and payers to remain included on formularies at a favorable tier, which helps to reduce out of pocket costs to patients.

Your letter also referenced a Sanofi Pasteur settlement with the DOJ, which stemmed from a programming error related to the federal ceiling price. The error resulted in both overpayments and underpayments by the Department of Veteran's Affairs to Sanofi Pasteur from 2002-2011. Importantly, the error was discovered, investigated, and disclosed *by* Sanofi Pasteur, and the decision

to settle – despite the settlement being well in excess of the aggregate overpayments – was to avoid protracted and costly litigation. As a result of our actions, no lawsuit was filed in this matter and there has been no determination of liability by Sanofi Pasteur.

Challenges of Vaccine Development

Successful development, manufacture and distribution of any vaccine require the input and resources of many organizations. Sanofi Pasteur remains focused on bringing to bear our experience in flavivirus R&D, as well as our expertise in all relevant vaccine development fields, to the fight against Zika. Our areas of expertise include product scale-up and manufacturing, clinical and assay development, clinical immunology, quality control/assurance, health economics/epidemiology, cGMP production, product testing and release, and clinical immunology laboratory facilities. Sanofi Pasteur has engaged in this endeavor in the face of opportunity costs through the redeployment of 60 full time scientists, which has resulted in the postponement of other R&D programs in order to advance this vaccine candidate at an unprecedented pace.

The development of any vaccine is a high-risk endeavor, particularly for emerging infectious diseases marked by changes in epidemiology and trajectories that are still evolving. In fact, in November of 2016, the World Health Organization indicated the Zika outbreak is no longer a public health emergency. That announcement was followed by the governments of Brazil (May 12, 2017) and Puerto Rico (June 5, 2017) declaring an end to their respective Zika public health emergencies. Each of these examples underscores the unpredictability of seasonal endemic diseases. To effectively address these types of public health challenges, it is essential for vaccine manufacturers to collaborate with governmental scientific organizations to effectively leverage our complementary resources, expertise, and strengths. Although we continue to negotiate the terms of a licensing agreement with WRAIR, it is important to note that our potential license would not cover all vaccine technologies and thus would not prevent other companies from pursuing vaccine candidates based on alternative technologies in order to create a robust and competitive Zika vaccine marketplace.

Thank you for your interest in these issues and please do not hesitate to contact me with any additional questions.

Sincerely,

David Loew
Executive Vice President and General Manager, Sanofi Pasteur