May 22, 2017

The Honorable Tim Murphy
Chairman, House Energy and Commerce
Oversight & Investigations Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Ranking Member, House Energy and Commerce
Oversight & Investigations Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Murphy and Ranking Member DeGette:

Thank you for scheduling a hearing on the U.S. Public Health Response to the Zika Virus: Continuing Challenges. Sanofi Pasteur, the vaccines division of Sanofi, is pleased to participate in this effort by partnering with the Walter Reed Army Institute of Research (WRAIR) and the Biomedical Advanced Research and Development Authority (BARDA) on a Zika vaccine candidate, an important component of Zika response.

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 was followed by the government of Brazil on May 12, 2017, declaring an end to its Zika public health emergency after 95% fewer cases were recorded between January and mid-April, 2017, compared to the same period the prior year. 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.

In advancing this Zika vaccine candidate in collaboration with the U.S. government, we have contributed significant resources, including over 60 full time scientists, proprietary technical manufacturing expertise, and utilization of our robust flavivirus clinical trials network to bring the vaccine candidate through Phase II studies. Sanofi Pasteur has engaged in this endeavor in the face of opportunity costs associated with delaying other R&D programs in order to advance this vaccine at an unprecedented pace. Despite claims to the contrary, we do so not based on projected commercial return, but out of our sense of corporate responsibility to contribute our capabilities to address a potential public health crisis.

Significant attention has been paid to whether our public-private partnership with the WRAIR may constitute a monopoly for Sanofi Pasteur. Questions have also been raised regarding the potential pricing of a future Zika vaccine. In truth, dozens of other companies, many with funding from the U.S. government, are also developing Zika vaccine candidates, some using similar approaches, others using other novel technologies. It is unclear at this time which approach, if any, will ultimately succeed. However, as we continue to negotiate the terms of a licensing agreement with WRAIR for its patents, and whether that agreement ultimately is exclusive or non-exclusive, 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.

Additionally, it is premature to consider or predict Zika vaccine pricing at this early stage of development. As noted earlier, ongoing uncertainty around epidemiology and disease trajectory make any commercial projections theoretical at best. However, if we ultimately reach a licensing agreement with the WRAIR and bring a Zika vaccine to market, Sanofi Pasteur has a history of working with governments and non-governmental organizations around the world to make our vaccines available at affordable prices. 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. It is in the public-health interest to price this and other vaccines in a way that will facilitate access to and usage of a preventive vaccine. We have demonstrated that commitment in the past, and, if we bring a Zika vaccine to market, we intend to do so for Zika as well.

Given the many uncertainties surrounding the future of Zika, we believe the WRAIR and BARDA are to be commended for their approach to partnership with industry. In fact, given the high risk nature of vaccine development and unpredictability for diseases like Zika, if the U.S. government changes its historic approach to licensing terms, it could undermine the intent of these types of collaborations.

Sincerely,

Adam Gluck
Vice President and Head, U.S. Government Relations
Sanofi

Cc:

The Honorable Morgan Griffith
The Honorable Joe Barton
The Honorable Michael Burgess
The Honorable Susan Brooks
The Honorable Chris Collins
The Honorable Tim Walberg
The Honorable Mimi Waters
The Honorable Ryan Costello
The Honorable Buddy Carter
The Honorable Greg Walden
The Honorable Janice Schakowsky
The Honorable Kathy Castor
The Honorable Paul Tonko
The Honorable Yvette Clarke
The Honorable Raul Ruiz
The Honorable Scott Peters
The Honorable Frank Pallone