

Office of the Governor
State of Louisiana

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GOVERNOR



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May 10, 2017

Robert M. Speer
Acting Secretary of the Army
101 Army Pentagon
Washington, DC 20310-0101

Dear Mr. Speer,

As Governor of the State of Louisiana, I write to express my serious concern about the Department of Defense's proposed exclusive license of patents on a Zika vaccine to Sanofi, particularly if the license does not address the pricing of the vaccine to U.S. residents.

Louisiana remains one of the Gulf states most likely to be affected in the event that the Zika virus continues to spread. A decision to give one company, Sanofi, a monopoly, without any constraints on the price for the vaccine, could cripple state budgets and threaten public health in the event of local Zika transmission. As many as 540,000 Louisiana residents on Medicaid alone could benefit from an effective Zika vaccine, but all my constituents deserve access in the event of local transmission. I am concerned that an unaffordable Zika vaccine will unnecessarily expose our state's most vulnerable citizens, our babies, to risk for serious lifelong complications of preventable Zika infection.

It is my understanding that considerable federal support has gone into creating the vaccine, including federally-funded clinical trials, a \$43 million BARDA grant to Sanofi for Phase II trials, with the option for an additional \$130 million in funding for the later trials if needed for the vaccine's approval by the FDA. Sanofi would also be eligible for a valuable priority review voucher, worth millions of dollars, and possibly benefit from several years of exclusive rights on the data from the clinical trials the U.S. government has funded. The extent of public investment in the development of the vaccine calls into question the need for an exclusive license, and it certainly provides a compelling reason to ask questions about the price of the vaccine now, before a license is signed, rather than after a monopoly has been granted.

Furthermore, because the vaccine in question is the Zika Purified Inactivated Virus (ZPIV) and makes use of the inactivated virus to produce an immune response, it may have added benefits and value as a booster vaccination to DNA Zika vaccines. Preliminary studies by NIAID found that the ZPIV induced antibodies that neutralized the virus and protected animals from disease when they were challenged with Zika.

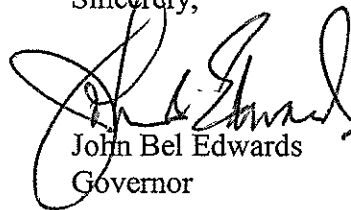
Robert M. Speer
May 10, 2017
Page 2

I am concerned that the Department of Defense has yet to address concerns about pricing and affordability for the vaccine, despite requests from nearly a dozen non-governmental organizations representing patient interests. In April 2017 the Department of Justice ordered Sanofi to repay nearly \$20 million in overcharges to the Department of Veterans Affairs. Sanofi is known to charge U.S. residents far more than residents of other industrialized countries for other medications, such as Sanofi's multiple sclerosis drug Aubagio (teriflunomide).

We believe our interests would be better served by avoiding the grant of an exclusive license on the Army's Zika patents. Barring that, U.S. residents, particularly those that I represent in Louisiana, deserve assurances that the vaccine will be affordable to people who have already paid for most of the research and development costs.

No one should have to worry about their child being born with microcephaly or other birth defects, and certainly no one should have to face that frightening prospect simply because the vaccine is unaffordable. Louisiana taxpayers have already paid once for this invention, and it is reasonable to expect that the Department of Defense at minimum ensure that our residents pay reasonable prices on the other end.

Sincerely,



John Bel Edwards
Governor

cc: Barry Datlof