July 17, 2017

The Honorable Richard J. Durbin
711 Hart Senate Office Building
Washington D.C. 20510

The Honorable Bernard Sanders
332 Dirksen Senate Office Building
Washington DC 20510

The Honorable Edward J. Markey
225 Dirksen Senate Office Building
Washington DC 20510

The Honorable Sherrod Brown
713 Hart Senate Office Building
Washington D.C. 20510

The Honorable Richard Blumenthal
706 Hart Senate Office Building
Washington D.C. 20510

The Honorable Angus King, Jr.
113 Hart Senate Office Building
Washington D.C. 20510

Dear Senators:

We write to you regarding the letter of July 12, 2017 sent to you by Gavin Zealy, Senior Director of Business Development for Sanofi Pasteur, on the proposed exclusive license of a federally-funded Zika vaccine to the company.[1]

Mr. Zealy's letter makes a nuanced objection to recent reports that Sanofi rejected the Army's request for fair pricing considerations in the license of the Zika vaccine, albeit in a way that seems designed to mislead the public.

[1] http://www.news.sanofi.us/press-statements?item=984

Zealy writes, "...Sanofi Pasteur did not reject a **specific fair-pricing term** proposed by WRAIR as part of the licensing negotiations" (emphasis added). At the same time, the letter does acknowledge that price was discussed "in general."

It is our understanding that the Army raised the issue of having language in the license wherein Sanofi would ensure that the price in the United States was fair and reasonable, but that Sanofi was opposed to having *any* language in the license on the pricing.

Sanofi's letter illustrates the lack of clarity and indeed candor as regards the effort by Sanofi to obtain the greatest freedom to charge whatever the market will bear in the United States for a federally-funded vaccine. A public hearing can clear up much confusion as regards the actual efforts (or lack thereof) by the Army to protect the public from high prices for the Zika vaccine, and can also address two other questions. First, is there a sufficiently compelling policy need and legal basis to give Sanofi a legal monopoly on the vaccine until 2036, under the restrictions on exclusive licenses found in 35 U.S.C § 209? Second, what is the willingness of Sanofi to make commitments on the vaccine pricing before the license is signed?

We also note the recent directive from the Senate Armed Services Committee, which calls upon the Department of Defense to ensure that U.S. residents do not pay more for DoD-funded drugs or vaccines than the median price of the seven largest economies with a per capita income of at least half that of the United States.

> 115th Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, page 173.
>
> **Licensing of federally owned medical inventions**
> The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.

It should also be mentioned that there is no reason to rush the decision, and we do not understand why the Army feels it must act now. BARDA has already funded a Phase 2 trial for the vaccine, with an option to fund a Phase 3 trial if needed. These trials will take time, and positive outcomes may yield better leverage for licensing.

We encourage the Senators to insist that the Army hold a public hearing on this proposed license, so that Sanofi and others can present evidence regarding the need for an exclusive license, and explore the commitments Sanofi will or should make on pricing issues, before any license is executed, and not after when there will be more limited recourse.

Sincerely,

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