July 24, 2017

Commander
U.S. Army Medical Research and Materiel Command
ATTN: Command Judge Advocate
MCMR-JA, 504 Scott Street
Fort Detrick, MD 21702-5012
Via Fax: +1 (301) 619-5034
Via Email: barry.m.datlof.civ@mail.mil

Dear Command Judge Advocate:

On July 12, 2017 Gavin Zealy, Senior Director of Business Development for Sanofi Pasteur, sent a letter to six Senators and another to you regarding the proposed exclusive license of a federally-funded Zika vaccine that would give the company a monopoly until 2036.[1]

In his letter, Zealy writes, "...Sanofi Pasteur did not reject a **specific fair-pricing term** proposed by WRAIR as part of the licensing negotiations" (emphasis added).

The letter does not deny that the Army approached Sanofi about reasonable pricing but was rebuffed, as has been reported elsewhere, but instead only denies that the conversation proceeded to the discussion of specific text.

Contrary to Sanofi's stated position, it is not too early to discuss pricing; it is imperative to do so now. If the Army waits until the license is executed, it will have ceded its most important negotiating leverage.

In the absence of any agreement on pricing and supply, Sanofi will be able to price their product to maximize profits, thereby limiting access, particularly in developing countries, to the birth defect preventing vaccine developed with the taxpayer's money, and charge the United States more than anyone else, as they do now for drugs like Aubagio.[2]

[1] http://www.news.sanofi.us/press-statements?item=984
[2] https://www.keionline.org/node/2759

Sanofi has an established track record of charging high prices and interrupting the supply of essential drugs and vaccines that should give the Army added pause about proceeding with an exclusive license that contains no conditions. In the U.S. and Europe, Sanofi has been fined or paid to settle numerous allegations pertaining to pricing abuses, as recently as Spring 2017.[3] Elsewhere, Sanofi has demonstrated that it has had difficulty with vaccine supply, and it has set prices for vaccines that are unaffordable for many and limit access. Examples include:

- Discontinuing the supply of a needed snake antivenom because of a perceived lack of a lucrative market[4];
- Utilizing a tiered pricing model for an inactivated polio vaccine[5] that excluded the PAHO region;
- Unexplained shortages of the inactivated polio vaccine[6];
- Discontinuing production of a measles vaccine thereby leaving the world with only one WHO-prequalified producer of Measles and Measles-Rubella vaccines.[7]

We recommend that you propose the following two specific contractual terms as preconditions to any license that would be executed; the first is designed to protect countries from pricing abuses and supply interruption, providing assurances that will be particularly important in addressing developing country access, and the second is designed to protect the U.S from being charged more than seven other countries with large economies and high per capita incomes:

1) Sanofi agrees to disclose the steps it will take to enable the registration and availability of the vaccine at an affordable price in every county with a demonstrated need, according to the CDC/WHO, either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so; and

2) Sanofi agrees to make the vaccine available to the public in the U.S. at publicly disclosed prices no higher than the median price charged in the seven countries with the largest GDP, which have per capita incomes of at least half that of the U.S.

There is no compelling reason to proceed with a license before the outcome of at least the Phase II trial, at which point the Army can better judge the interests of other companies in a license. Even more fundamentally, the case has not been made to grant anyone an exclusive license, and certainly not Sanofi, giving the non-patent incentives that exist for simply registering

[3] http://www.keionline.org/sanofi-fines
[4] https://www.msfaccess.org/sites/default/files/NTDs_Brief_FavAfrique_ENG_2015.pdf
[5] https://www.msfaccess.org/content/msf-responds-inactivated-polio-vaccine-price-announcement
[6] http://www.newsweek.com/2017/01/06/critical-vaccine-shortage-threatens-polio-eradication-efforts-536844.html
[7] http://www.sanofipasteur.com/en/Documents/PDF/Company_Information_about_measles-containing_vaccines.pdf

a vaccine, including being the first and for a significant time the only company in the market, getting the valuable FDA priority review voucher, and possibly exclusive rights in test data.

A non-exclusive license now would be the prudent approach. But to the extent the Army is committed to proceeding with Sanofi under conditions of exclusivity, the license should not be executed until these common sense public health protections are agreed to.

Sincerely,

James Love
Director
Knowledge Ecology International
james.love@keionline.org

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
Knowledge Ecology International
+1.202.332.2670
andrew.goldman@keionline.org

Jason Cone
Executive Director, USA
Médecins Sans Frontières/Doctors Without Borders

Judit Rius Sanjuan
Access Campaign U.S. Manager and Legal Policy Advisor
Médecins Sans Frontières/Doctors Without Borders