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# Health: Risk and the dengue vaccine – Sanofi Pasteur, Dengvaxia, and Philippine Government

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Department of Health officials went on television the other night to announce the suspension of the government's antidengue vaccination program. This move was prompted by the admission of Sanofi Pasteur, the pharmaceutical company behind the vaccine, that the administration of "Dengvaxia" could lead to more severe symptoms for people who have not been previously infected.

The Philippine government first approved the vaccine's use in December 2015, along with Mexico and Brazil. Eight other countries followed suit in 2016, namely, El Salvador, Costa Rica, Paraguay, Guatemala, Peru, Indonesia, Thailand and Singapore. By October 2017, the vaccine had been approved in 19 countries.

Health Secretary Francisco Duque III was very careful in choosing his words. He was concerned not to cause panic among parents who had agreed to have their children vaccinated against dengue. The key word he used was "track" — i.e., to diligently monitor the condition of all those who have received the vaccine. He was also tactful, avoiding any hint of who is to blame for the program. But the issue is unavoidable in a season of unceasing political recrimination. Politicians won't let pass an opportunity to go after those who made the decision in the past administration.

More than 700,000 schoolchildren, nine years old and above, in Metro Manila, Central Luzon and Calabarzon, have received at least the first of three injections of this first-ever licensed dengue vaccine. It is natural for parents to worry. In all likelihood, the parents won't allow their children to get the next injections. More importantly, they will want to know what recourse they have in the event of a dengue infection.

This is a very complex issue — one that involves longstanding debates in medical research, public health policy, corporate profitability and responsibility, and politics. It is extremely important for us to fully understand the terms of this latest clinical finding before we start getting panicky, passing judgment, and exacting accountability.

We might begin with the carefully worded Nov. 29 update from Sanofi. It starts with the wish to update patients, physicians, and drug regulatory agencies on the latest results of the ongoing clinical trials concerning the efficacy and safety of the vaccine. The latest findings are from clinical trials that compare the effects of the vaccine on two groups: individuals who had been infected with dengue prior to vaccination, and those who had not.

"The analysis confirmed that Dengvaxia provides persistent protective benefit against dengue fever in those who had prior infection. For those not previously infected by dengue virus, however, the analysis found that in the longer term, more cases of severe disease could occur following vaccination upon a subsequent dengue infection."

In plain language, the vaccine is effective against subsequent dengue infection for those who have had a prior infection. It does not, however, offer the same benefits to those who have not had any previous dengue infection. On the contrary, in the latter cases, the vaccine appears to cause more severe symptoms in an actual dengue infection. This phenomenon has spooked antidengue researchers for quite some time. They call it “ADE, or antibody-dependent enhancement.”

Sanofi is not withdrawing its billion-dollar product from the market. It proposes rather to insert the following advice in the vaccine’s pharmaceutical label: “Vaccination should only be recommended when the potential benefits outweigh the potential risks (in countries with high burden of dengue disease). For individuals who have not been previously infected by dengue virus, vaccination should not be recommended.” It’s obviously a defense against future class action suits against the company.

The main message leaves no doubt about the future of the vaccine in the market. As one scrolls down the rest of the announcement, this arresting paragraph (meant for the shareholders) greets the reader: “Taking this information into account and expected future sales, Sanofi will record a charge reflecting depreciation of inventories as well as accelerated depreciation of some tangible and intangible assets in its fourth quarter results.” Translation: Expect huge losses from a drastic drop in sales.

I don’t know how much is left of the DOH’s inventory of this vaccine. I doubt if Sanofi would offer to take back the unused vials and reimburse us. After all, the company isn’t saying that the vaccine does not work, only that it is not recommended for those who have not had previous exposure to dengue infection. This crucial piece of information is enough to discourage its further use in a publicly funded vaccination program such as ours. Clearly, a lot of public health money is about to go down the drain.

This is the nature of risk calculation. We bet against what the future may bring, and we are all wiser in retrospect. At about the time the vaccine came out, our hospitals were filling up with dengue patients. Not to buy it after seeing that an increasing number of countries were in the market for the limited supply would have been no less a risky decision to make.

Perhaps, other factors should have entered the calculation. The clinical trials were continuing, the vaccine was expensive, and a decision to adopt it entailed a commitment to use it for an indefinite period. It would have been important to debate what priority the program should take relative to the other pressing health needs of the Filipino people.

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* “Risk and the dengue vaccin”. Philippine Daily Inquirer / 05:10 AM December 03, 2017: http://opinion.inquirer.net/109184/risk-dengue-vaccine#ixzz5LMxC3cXq