

The Dengvaxia Disaster Was Twenty Years in the Making—What Will Happen with a Rushed COVID-19 Vaccine?

By [Children's Health Defense](#)

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*For several weeks, **Dr. Anthony Fauci** and **Bill Gates** have been beating the drum about a COVID-19 vaccine, seeking to keep the world's coronavirus optics focused on a medical intervention that Gates acknowledges to be risky enough to require [indemnification against lawsuits](#). The two are casting a COVID-19 vaccine—which they speculate could be ready in as little as 18 months—as the passport for a return to “normalcy.” The two opinion leaders' gambit seems to be backfiring among people savvy enough to understand that [Fauci's](#) and [Gates'](#) organizations, pocketbooks and agendas are driving the rush for an indemnified vaccine. Other Americans may be too distracted by the historically unprecedented lockdown, however, to think through the safety issues raised by a potential COVID-19 vaccine.*

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Americans would be well advised to revisit a virus-and-vaccine cautionary tale that briefly captured front-page attention a year ago. In April 2019, the U.S. Food and Drug Administration (FDA) approved Sanofi Pasteur's [Dengvaxia vaccine](#), joining [19 other countries](#) in granting regulatory approval to the world's first dengue vaccine. The FDA gave its green light not long after the Philippines—the first country to roll out the vaccine widely—witnessed hundreds of distressing hospitalizations and deaths in 9-16 year-olds, representing a clear [safety signal](#).

Dengvaxia's fallout was so dramatic that it even overrode the U.S. media's customary whiteout of vaccine safety problems. As summarized by National Public Radio (NPR), the Philippines' mass dengue vaccination program—[implemented with “undue haste”](#)—not only killed children but provoked protests, criminal investigations, indictments, revocation of the vaccine's license in that country and a plummeting of parental confidence in vaccine safety from 82% to 21%.

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Viral vaccines and “disease enhancement”

Given that an estimated [40%](#) of the world's population is at risk of mosquito-borne dengue

infection, it is not surprising that the vaccine industry has had a dengue vaccine on its list for decades. There are [four types](#) of dengue virus that can trigger infection, albeit with a highly variable [trajectory](#) that ranges from asymptomatic infection or “mild and non-specific febrile illness” (together representing about [75%](#) of cases) to “classic dengue fever” and, in an “occasional” subset, more severe outcomes such as plasma leakage, bleeding, shock or death. In children, experts believe the majority of dengue infections are [subclinical](#). Researchers note that [environmental and host immune factors](#) play a significant role in shaping both susceptibility and outcomes.

Natural infection with one type of dengue virus provides long-lasting protection against the same type but only short-term protection against the other three varieties. The vexing result is that, in some individuals, subsequent infection with a different dengue virus can [increase the risk](#) of severe outcomes—a phenomenon known as “disease enhancement.” In a [2018 review](#), researchers listed Zika reports of “enhanced illness” resulting from influenza, respiratory syncytial virus (RSV), Zika, West Nile virus, dengue and coronavirus—and emphasized that either infection *or vaccination* could produce this response.

In 2018, the WHO’s Global Advisory Committee on Vaccine Safety reviewed some of the deaths associated with Dengvaxia but stated that it could not determine whether the vaccine was [causally related](#) to the “vaccine-related immune enhancement.” This disingenuous conclusion flies in the face of decades of evidence showing some viral vaccines to be capable of “subverting” the immune system and provoking “[exacerbated illness](#).” It is doubtful that WHO or Sanofi are unaware of this phenomenon, which numerous publications [acknowledge](#) as a “[major obstacle](#)” for the development of safe dengue and other viral vaccines. After the problems in the Philippines, however, Sanofi’s global medical director [asserted](#) that “In hindsight . . . Sanofi wouldn’t do anything differently.”

A dengue expert who develops vaccines for the U.S. military issued [warnings](#) about Dengvaxia’s risks ahead of time—vainly cautioning that vaccinating 9-16 year-olds who were “seronegative” or “dengue-naive” at baseline (that is, had never before been exposed to dengue) was likely to significantly augment their lifetime risk of severe disease when later exposed to dengue. (About [21%](#) of vaccinees were seronegative.) Why did this industry [insider](#)—who has been a paid dengue vaccine consultant to Takeda, Merck, Sanofi Pasteur and SmithKlineBeecham—voice these concerns and condemn international health institutions for [unethical, unscientific and “contorted explanations”](#) that “fail[ed] to identify breakthrough dengue disease in vaccinated subjects as serious adverse events”? As he pointed out in numerous letters and articles, the potential for vaccine-enhanced dengue disease was readily apparent in Dengvaxia’s clinical trials, but both Sanofi and WHO chose to [ignore the evidence](#).

Belatedly—a year and a half after the launch of the Philippines’ disastrous vaccination campaign—Sanofi announced that “[new information](#)” was prompting the company to declare that “vaccination should not be recommended” for seronegative individuals of any age. Repackaging Dengvaxia as a vaccine solely for individuals who have had at least one laboratory-confirmed bout of dengue is easier said than done, however, because many mild dengue infections go [undiagnosed and undocumented](#).

The dengue vaccine pipeline

Sanofi reluctantly revised its recommendation to provide Dengvaxia only to individuals with

evidence of past infection, which “leaves a [substantial unmet need](#)” that other dengue vaccine developers appear only too eager to exploit. Although Sanofi’s formulation—which took two decades and two billion dollars to develop—is the first dengue vaccine ever to make it out of the pipeline and into the marketplace, two other vaccines (TAK-003 and Butantan-DV) are currently undergoing late-stage [clinical trials](#) in Asia/Latin America and Brazil, respectively.

Dengue vaccine development has been marked by strong for-profit [industry involvement](#). In addition, there has been “[wide participation and co-ownership](#)” by U.S. government institutions in dengue vaccine research and development, even though dengue disease poses little threat on the U.S. mainland. With dengue-endemic areas limited to Puerto Rico and a few offshore territories and protectorates, HHS—the umbrella agency for the National Institutes of Health (NIH), Fauci’s National Institute of Allergy and Infectious Diseases (NIAID), the CDC and the FDA—owns [65 dengue-vaccine-related patents](#), dwarfing the 19 owned by Sanofi and the 12 and 4 owned by GlaxoSmithKline and Merck, respectively. All of the private companies involved in dengue vaccine development share patents with U.S. government agencies; meanwhile, [very few](#) patent applications have been filed in developing countries.

CDC scientists [designed and constructed](#) the TAK-003 vaccine and then licensed it to Japan’s Takeda Pharmaceutical Company, Asia’s largest pharmaceutical conglomerate. However, preliminary analyses of the clinical trial results suggest that TAK-003 may suffer from similar problems as Dengvaxia, providing “[unbalanced protection](#) among the four types of dengue” that could “increase the risk of severe disease after exposure to a second type of the virus.” Takeda plans to apply for approval in dengue-endemic countries anyway.

Some experts are placing their bets on the third finalist, Butantan-DV, developed by none other than [NIAID](#). NIAID has sponsored Butantan-DV clinical trials in Brazil since 2013, [licensing its vaccine technology](#) to Brazil’s Butantan Institute and launching the most recent trials in 2016. Not content to lurk in the background, NIH and NIAID have taken pains to call attention to their role in the vaccine’s development; publications presenting clinical trial results have titles referring to the “[National Institute of Allergy and Infectious Diseases tetravalent dengue vaccine](#)” and the “[National Institutes of Health dengue vaccine](#).” In studies published to date, investigators only monitored adverse reactions for [21 days](#).

Mosquito versus needle

The Dengvaxia experience—involving a skewed immune response and enhanced risks—raises questions “applicable to [all dengue vaccine candidates](#)” and a number of other viral vaccines. One not-often-discussed consideration pertains to the “considerable differences between a wild-type [dengue virus] delivered by a mosquito versus needle administration of a vaccine,” which have the potential to elicit different immune responses. Instead of acknowledging these vaccines’ potentially unconquerable risks, why not focus on training health care workers in the provision of the supportive care known to be “[very effective](#) when delivered by experienced practitioners”? Even in severe cases of dengue characterized by vascular permeability and fluid loss, practitioners who “accurately and rapidly” replace fluids can stabilize patients’ condition—“and rather quickly”—with the result that “the vascular permeability phenomenon [abruptly disappears](#).” In addition, fruitful avenues of research could include studying the environmental and immune system factors associated with the minority of cases that involve more severe dengue outcomes.

With vaccine damage occurring in association with many different vaccines, it is unclear why so many individuals and organizations jumped on the anti-Dengvaxia bandwagon last year, but—with a rushed COVID-19 vaccine in the works—their words of warning are worth heeding. As NPR [noted](#), “the debacle in the Philippines offers a key lesson for governments and manufacturers when it comes to approving and selling new vaccines: Slow down.” The dengue expert who presciently warned about Dengvaxia’s dangers [put it this way](#):

Dengvaxia-enhanced disease has created a major ethical dilemma for the vaccine community, an enduring public health management crisis, and legal nightmare. Vaccines should not harm recipients, directly or indirectly. WHO and the manufacturer owe the customer a safe product.

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