

As I watched the webcast of the Tick-Borne Disease Working Group's May 10 meeting, I was generally heartened by what I saw. Subcommittees on different subject areas presented their reports. It seemed to embody what the Working Group was supposed to be — stakeholders with a variety of viewpoints examining all relevant information on Lyme and other tick-borne diseases.

Lyme Disease Vaccine Safety Ignored

Alas, my assessment of things changed drastically when it came time for the Lyme disease Vaccine and Therapeutics Subcommittee's report. As presented at the meeting, it appears that this subcommittee paid no attention whatsoever to the Lyme community's valid concerns about past safety problems with the LYMERix vaccine, nor to our fears that such problems would be repeated with any new Lyme disease vaccines that are now in the pipeline.

Questioned about this by Working Group member Patricia Smith, the presenter was very dismissive. He said something along the lines of, "There's no reason to rehash the past. Let's just move forward with the vaccine."

Conversations about vaccines and related issues continued during the meetings on May 15-16, 2018. Again, certain speakers seemed stubbornly oblivious to why this is such a hot-button topic in the Lyme community.



This comes as the French company Valneva SE is preparing for Phase 2 trials of its proposed Lyme vaccine, VLA-15. It has received fast-track designation from the FDA, which is a way of expediting the development of new drugs that are deemed to be especially needed.

In recent months, there has also been a lot of news coverage that seems to frame any discussion of a Lyme vaccine inaccurately. They seem to be saying, “A Lyme vaccine—any Lyme vaccine—is automatically a good thing. Anybody who raises any questions about it is a wicked ‘anti-vaxxer.’ After all, look what those terrible people did to LYMERix.”

Why does raising valid questions about this make somebody “anti-vaccine”?

So, let me clarify a few points for the record.

LymeDisease.org is not anti-vaccine. Rather, we think important questions should be answered about the last Lyme vaccine before a new one is approved.

LYMERix Resulted In A Number of Serious Problems

Plain and simple, we care about safety. LYMERix, introduced in 1998 and withdrawn from the market in 2002, resulted in a number of serious problems. I will name just a few:

1. More than 1,000 adverse events related to LYMERix were reported to the FDA, including death, strokes, musculoskeletal effects, and neurologic effects.
2. More than 400 people who felt they had been injured by the vaccine were preparing a class-action lawsuit against the manufacturer. (It ended up not going forward, after the company took the product off the market).
3. The last vaccine was not very effective; it required three doses given over the span of a year and achieved less than 80% effectiveness. Furthermore, it was unclear whether booster shots would be required.

According to Valneva, VLA15 targets outer surface protein A (OspA) of borrelia, and “the anticipated safety profile is expected to be similar to other vaccines using the same technology.”

Guess what. LYMERix was also based on OspA. And its safety issues have never been appropriately addressed.

Here’s our bottom line: we want these concerns investigated and resolved before any new Lyme vaccine comes on the market.

What About Co-Infections? A False Sense of Security

There's another matter as well. It's becoming ever clearer that tick-borne diseases include many strains of borrelia (not just *Borrelia burgdorferi* — what might be considered “classic” Lyme) along with other pathogens such as babesia, anaplasma/ehrlichia, and Powassan virus. An OspA vaccine will do nothing to prevent co-infections.

Consequently, we're also concerned that a vaccine that only targets classic Lyme will give a false sense of security to those who receive it.



The market for a Lyme vaccine is projected to be between \$800 million to \$900 million a year. I would think a company that stands to make that kind of money would cross their t's and dot their i's, in preparing the way for their product. Yet, the manufacturers have not been forthright about safety issues with the previous vaccine, nor have they reached out to the Lyme community in connection with this new one.

Here's a thought: Valneva, why don't you change your approach, starting right now? Answer our questions. See if you can allay our fears. It's the right thing to do.

Editor's note: Any medical information included is based on a personal experience. For questions or concerns regarding health, please consult a doctor or medical professional.