

MEDICAL EXAMINER

Where's My Lyme Vaccine?

The complex downfall of LYMErix—and what's coming next.

BY REBECCA ONION

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Here's a fun game I've played with fellow woodsgoing types over the years: How much would you pay to get vaccinated against Lyme disease? I generally settle on a number in the three or even low four figures. That's a lot for my budget—a good chunk of a month's mortgage payment—but would be worth it to eliminate the twinges of anxiety I feel about being outside, an activity that is otherwise No. 1 in my book. Without a Lyme vaccine on the market, this question is purely hypothetical, of course. But I'm not alone in the moderate-but-still-painful lengths I'd go to get one—a colleague recently confessed to trying to convince a vet acquaintance to give her a canine Lyme shot. (Yes, dogs can get Lyme vaccines, while humans cannot.) I *think* she was kidding!

I've been playing the what-would-you-do-for-a-Lyme-vax game more frequently this year, as my friends and I have spent most of our social time bushwhacking along the sides of overgrown creeks while our kids run wild. This was also the year we made unlikely folk heroes of giant pharmaceutical companies, proudly bragging about having Pfizer or Moderna or J&J coursing through our veins. A little subculture of vax positivity rose up to celebrate Americans' collective quasi-liberation from COVID, because the COVID vaccine,

like no other vaccine we've ever taken, *directly* fixed a big problem in our lives.

That's different from the way we typically experience vaccines: as preventives for diseases that feel controlled or even obsolete. Sure, I'm hypothetically happy that my young child had access to the DTaP shot—I definitely don't want her to get D, P, or, God forbid, T—but I'm not actively worried about those things because the vaccines against them have done their job and pushed them out of mind. But the COVID shot was a ticket, a Get Out of Jail Free card that took most of the fear out of going to Kroger or seeing vaccinated friends inside of their houses. If science could give us that kind of liberation from a virus, I have heightened interest in it doing the same for the bacteria that lurk in questing ticks on tall grass. As I'm about to leave for my Fourth of July vacation—headed straight into the New Hampshire forest, at the epicenter of Lyme—I'm thinking, again: *Where is my Lyme vaccine?*

We had one, once. The Food and Drug Administration approved LYMERix, manufactured by SmithKline Beecham (now GlaxoSmithKline), for use in 1998. LYMERix worked by inducing antibodies into human blood, which would then go into any ticks that attached to your body. There, they would neutralize the bacteria that cause Lyme, *Borrelia burgdorferi*, before the bacteria could go from the tick into you. In clinical trials, the shot showed about 78 percent effectiveness after the required three doses (hey, I'd take it). But some patients who got the shot after it went on the market testified that they developed arthritis after vaccination. The FDA investigated, but decided the evidence that the vaccine was linked to patients' arthritis wasn't strong enough to withdraw its approval for LYMERix. Sales fell nonetheless, and the company pulled the vaccine in 2002.

The story of LYMERix's downfall has become a case study in the history of vaccines, in part because of its complexity. In his book on the Cutter Incident—a disastrous episode in the mass distribution of the Salk polio vaccine—and its impact on vaccine production, vaccine historian Paul Offit described what happened with LYMERix as a story about liability. The Lyme vaccine was an optional shot, so it wasn't covered by the National Vaccine Injury Compensation Program. (The program was set up in the 1980s to encourage pharmaceutical companies to continue production of vaccines by reducing the fear of liability.) Because of that exemption from the federal program, writes Offit, there was no cushion between the manufacturers of LYMERix and anyone who might claim it caused their arthritis. The vaccine “was left to survive the abuses of personal injury lawyers and the inaccurate media reports that inevitably follow.”

This is how I have seen it explained, in shorthand form: *We don't have a Lyme vaccine because of anti-vaxxers*. Retelling the LYMERix story in 2018, Vox's Brian Resnick described it as “a stark reminder of how anti-vaccine mania of the past few decades is leaving us all more susceptible to disease.” Brittany Flaherty pointed out in a 2019 STAT piece about the Lyme vaccine that LYMERix hit the market at a bad time for vaccine hesitancy and anti-vax activism. The infamous Lancet report claiming that the MMR shot was linked to autism was published in 1998 (it does not; the paper has been widely debunked and retracted), and the rotavirus vaccination RotaShield was withdrawn from the market in 1999, after a number of infants who received it suffered intussusception, or bowel obstruction. There was an unease in the public climate around *any* new shot, especially an optional one.



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But there's another reason LYMERix had trouble: It had what I think of as a "New England problem." The perception was that people got Lyme disease from their beautiful lawns in Connecticut. "For many individuals in Lyme-endemic areas, it is precisely the environmental privilege of being able to live in or close to 'nature' that makes possible the environmental risk of Lyme disease," wrote Abigail Dumes, an anthropologist who has published a book about Lyme. Lyme does not stand to affect everyone; it is dependent on the range of the deer tick and cannot be transmitted between people, so it has a unique status among infectious diseases. The LYMERix shot was not like the MMR vaccine, a key tool of public health that would be recommended for all children so that transmissible diseases would stop spreading; it was seen as a choice, one made by privileged adults who wanted to live free of fear. Chinh Le, a member of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices, called the shot a "yuppie vaccine" for people who "will pay a lot of money for their Nikes and their Esprit and shop at L.L.Bean's" and who "will have no consideration for cost-effectiveness when they want a vaccine because they're going to travel to Cape Cod." (I'm in this picture, and I don't like it!) Historian Robert Aronowitz cites Le's testimony in a retrospective of LYMERix as evidence that regulators were lukewarm about the shot. Aronowitz notes that the lack of enthusiasm showed up in their recommendations for who should get it: The government issued a "should consider" recommendation for people at high risk for tick bites in areas where Lyme was present, and a "may consider" for people sometimes exposed to tick habitats. Some experts Aronowitz interviewed thought these designations may have made it hard to encourage uptake.

There are other oddities to the LYMERix saga. Trying to drum up enthusiasm, the pharmaceutical company had aggressively promoted the vaccine through direct-to-consumer advertising emphasizing tick-related anxiety, to a public that wasn't necessarily afraid of Lyme. The end result may have been suspicion of the company, which looked like it was trying to profit from creating a new fear. Then there's the fact that the vaccine intersected with the complicated, decadeslong conflict between some Lyme patients and mainstream doctors (a clash so singular and complex that Dumes wrote a whole book about it). A faction of Lyme patient advocates, who had initially been supportive, ended up not wholly on board with the vaccine. They "were not, of course, against preventing the disease per se but were against the way the vaccine might reinforce the idea that [Lyme disease] was an acute, unproblematic, and clinical entity," explains Aronowitz. That is, the vaccine to them was a falsely simple solution to a problem that was much more complicated and not well understood by current medicine.

Seen from 2021, this history gives me some hope that the next round of Lyme preventive shots will succeed in making it to market and into my family's arms. The failure of LYMERix was not just about "anti-vaxxers," broadly painted, but about a very specific brew of hesitancy—which, at least in part, was fueled by a general unawareness of Lyme. It's also true that there was just less need for the vaccine. In the years since LYMERix was pulled from the market, Lyme has become much more common and geographically widespread in the United States. Cases have tripled—at least. Climate change and human expansion into wooded areas amp up the numbers every year. And public health and government officials are increasingly aware of the cost burden of Lyme.

The increased market for a Lyme preventive has prompted action from pharmaceutical companies. There are two options for preventing Lyme in the works: one vaccine that works the same way LYMERix did; and one shot that would be taken annually, in advance of tick season (technically a preexposure prophylaxis, or PrEP, shot). The vaccine is a collaboration

between Valneva (a French biotech company) and Pfizer and has already shown promising results in Phase 2 trials. In March, the companies announced that their candidate was going into an additional Phase 2 study that would include a pediatric population of kids over age 5. (LYMErix was never approved for kids under 15—another factor in the low demand for the shot.) Pfizer and Valneva hope for their vaccine to be available by 2025.

Meanwhile, MassBiologics is developing a PrEP shot for Lyme. This is a shot that would be immediately effective, unlike a true vaccine, where you have to wait a while to build antibodies before you're covered. Mark Klempner, executive vice chancellor for MassBiologics and a professor of medicine, said over email that MassBiologics' Lyme PrEP shot was almost through its Phase 1 clinical trial, with the next phase anticipated to be completed in 2022; Klempner added that if all continues to go well, the company hopes for FDA approval by 2024.

It's not clear whether these shots will be expensive—as they are in my fantasy about shoving piles of cash at a needle-wielding doctor—or covered by insurance. That will be determined by the designation they receive from the government this time around (it's probably too much of a fantasy to think that they'll just be free, like COVID shots). But I can hope that there will be enough enthusiasm and support for these vaccines when they finally make it to market. I know I'll be more than ready to get my shot and take to the woods. 🍷

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