

It's time to develop a vaccine for Lyme disease, doctor says

By Ilene Raymond Rush
FOR THE INQUIRER

Stanley Plotkin, 81, creator of the rubella vaccine, hopes another vaccine can be made to vanquish Lyme disease.

Plotkin's call for a new Lyme disease vaccine is also personal. In an op-ed piece for the New York Times this summer, Plotkin, a Doylestown resident and professor of pediatrics at the University of Pennsylvania, described how in 2005, his son, Alec, was felled with a heart ailment caused by Lyme.

Although Alec has since recovered, Plotkin urged patients and physicians to contact the Centers for Disease Control and Prevention and encourage the agency to make a Lyme vaccine a top priority. The need is particularly urgent in Chester, Montgomery and Bucks Counties, national hot spots for Lyme.

It wouldn't be the first time a Lyme vaccine has been developed. In 1998, the Food and Drug Administration approved a vaccine called LYMERix. Due to negative media coverage, poor marketing, and tepid endorsement by federal officials, who recommended that the vaccine be given only to "high risk" patients, it was pulled off the market in 2002.

Key to LYMERix's demise was the opposition of activists, who argued that the vaccine produced undesirable symptoms, chiefly arthritis. Their objections led to a 1999 class-action suit filed by the Philadelphia law firm Sheller, Ludwig & Bailey, on behalf of 121 individuals who claimed side effects from the vaccine and accused the manufacturer of concealing knowledge of them.

Although tests later revealed no indication that the Lyme vaccine produced any long-term adverse reactions, the drug's maker, GlaxoSmithKline, axed the drug, citing poor market performance.

In 2003, the legal claims were settled. GlaxoSmith-

Kline paid \$1 million in legal fees to the Sheller firm and some smaller ones, although no claimants received restitution.

Now, in light of the 300,000 cases of Lyme forecast this year by the CDC, there is again wide interest in developing a Lyme vaccine. Several candidates are in the works.

Researchers from Stony Brook University, Brookhaven National Laboratory, and drug manufacturer Baxter International have developed a promising vaccine. Like LYMERix, this bioengineered vaccine kills the *Borrelia* bacteria in the gut of the tick before it can be transmitted to humans, but it protects against a broader array of species than the earlier vaccine and against American and European strains of the disease.

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Stanley Plotkin, University of Pennsylvania professor of pediatrics

According to Benjamin Luft at Stony Brook, one of the vaccine's developers, the new effort averts side effects, such as arthritis, by cutting out possible cross-reactivity with certain human proteins. "When we developed this vaccine," he says, "those regions were removed."

Another possible vaccine, from researchers at Yale and Howard Hughes Medical Institute, aims to neutralize the bacteria in a tick's saliva before it infects humans, an idea Plotkin applauds.

"It's important to note that when the tick bites, it doesn't transmit the organism immediately," Plotkin says. "It takes about 24 hours for the organism in the tick to become infectious for humans. Neutralizing a tick is a great idea, but it's not yet at the point

where we can trust it."

Neither vaccine is ready for prime time, and "it will certainly not be in two years," he says. "People have to appreciate that the process takes at least 15 years from beginning to end and can cost up to \$500 million."

Plotkin hopes firms learn from LYMERix.

"People don't decide on their own that they're going to take a vaccine," he says. "You have to convince the medical profession... Once you've done that, people will take the advice of their physicians."

Plotkin is well aware of a certain resistance to vaccines, particularly in the Lyme community. But he notes that while some parents resist allowing their children to receive MMR vaccines, there are "no measles left and no rubella

left. Lyme disease is still very much with us."

Plotkin is also alert to disputes about treating Lyme, particularly the so-called chronic kind. While not ruling out the possibility that such lingering symptoms exist, Plotkin is blunt. "If you don't get the disease in the first place, you're not going to get chronic symptoms. Whether or not there are chronic symptoms — and I wouldn't rule out that possibility, despite lack of current evidence — that issue should not affect whether a vaccine is used."

"Or maybe," he says, "it's an additional reason to use a vaccine."

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