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- *From:* chronichell70@xxxxxxxxx
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On May 26, 11:55 am, lipanz <lipanzmari...@xxxxxxxx> wrote:

Concerns (and Lawsuits) Grow Over Reactions to Lyme Vaccine

Federal health authorities are currently investigating whether the Lyme disease vaccine, Lymerix, caused severe cases of arthritis and even Lyme disease itself in some people, according to a recent report in the New York Times.

Until now, the government was actively investigating illnesses that broke out after vaccination only if they were officially classified as serious defined as life–threatening, persistent and long–term or requiring hospitalization. Lyme disease and arthritis were not generally regarded as meeting those criteria.

Researchers from both the FDA and the disease–control centers will now investigate all cases of arthritis and all symptoms of Lyme disease reported to have developed after a patient has been vaccinated, Dr. Susan S. Ellenberg, director of biostatistics and epidemiology at the FDA said.

The FDA had approved the vaccine made by SmithKline Beecham Biologicals, about two years ago, and about 440,000 Americans have received it so far. The company maintains that the shot is safe.

Dr. Ellenberg, said the FDA, working with the CDC, would investigate the reports "to find out what the cases really are, to get more information." Dr. Ellenberg and Dr. Walter A. Orenstein, assistant surgeon general and director of the centers' national immunization program, said it remained to be determined whether the vaccine was the cause of the reported illnesses.

When the FDA's vaccine advisory committee recommended that the vaccine be approved for marketing, several members expressed concern that the

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vaccine could set off an autoimmune condition that, in turn, would result in arthritis.

Some also said they feared it could cause flare-ups of Lyme disease among people previously infected with the Lyme bacteria, *Borrelia burgdorferi*.

Physician Opposition

The New York Times report claims that in interviews, "more than a dozen doctors in areas where Lyme disease is common say they have treated 170 people with arthritis and Lyme disease that they attribute to the vaccine."

Some doctors say the drug agency should never have approved the Lyme vaccine or should have responded more quickly to adverse reports. Dr. Andrea Gaito, a New Jersey rheumatologist and president of the International Lyme and Associated Disorders Society, said she had told the agency that 21 patients developed severe arthritis soon after being given the vaccine by other doctors, according to the Times report.

Dr. Gaito, who does not give the vaccine, said she believed that the vaccine caused arthritis and Lyme disease itself but that the problems were not always linked to it because the vaccine took effect only after three shots given over the course of a year. "The FDA had just better withdraw this vaccine now," Dr. Gaito said.

Dr. Charlene C. Demarco of Egg Harbor, N.J., an internist and family doctor, said 50 of her patients had developed autoimmune arthritis after receiving Lyme vaccine from other doctors and 30 others appeared to have flare-ups of previous Lyme infections. She maintains that the FDA did not move quickly enough after initial reports of adverse effects.

Dr. Ellenberg from the FDA conceded that they had at times acted too slowly. "We wish that some of these cases had been brought to our attention sooner," she said. "They should have been given a higher priority."

Despite the fact that the FDA's vaccine advisory committee eventually recommended approval of Lymerix, the panel's chairwoman, Dr. Patricia L. Ferrieri of the University of Minnesota Medical School, said it had taken the action with unusual "ambivalence" because of concerns about the possibility of severe reactions.

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Autoimmune Reaction

Dr. Allen C. Steere, who directed SmithKline Beecham's trials of the vaccine, told the committee that it was hypothetically possible that the vaccine could set off an autoimmune reaction in which the body's immune system attacks its own tissue, and that this could cause treatment-resistant arthritis.

In addition, Dr. Steere had expressed the concern as early as 1995, shortly after the start of the clinical trials, when he said that some patients were already developing joint pain after getting the vaccine.

"A small percentage of patients have developed joint pain and arthritis following vaccination," Dr. Steere said in a letter to the National Institutes of Health.

In July 1998, two months after Dr. Steere recommended the vaccine's approval, he and colleagues reported in the journal *Science* that they believed they had found the cause of the adverse effects. They discovered that a piece of protein on the outer surface of the Lyme bacteria was strikingly similar, to a natural human protein in blood and other cells. This raised the theoretical possibility that when an infected tick bites a human, the person's immune system T-cells, the soldiers on the front line of the body's defense against disease, could destroy not only the foreign invader but also some of the body's own protein.

Legal Action

About 60 patients who believe they were made ill by the Lyme vaccine are suing SmithKline Beecham for monetary damages, said Stephen A. Sheller, a lawyer with Sheller, Ludwig & Badey, of Philadelphia, which is handling the suits. And class-action suits have been filed by the firm in New York, New Jersey and Pennsylvania seeking to require the company to warn doctors and patients that it poses possible risks for those who are genetically predisposed to autoimmune arthritis or who have been previously infected with Lyme bacteria.

To see the complete text of the Lymerix complaint filed against SmithKline Beecham go to <http://www.sheller.com/complaint.htm>.

New York Times November 21, 2000

That's interesting, I'm more interested in that angle of the controversy. First and foremost, I can't believe any Dr. would even think that the vaccine could actually cause Lyme. The obvious reason is that the vaccine is developed with a protein of the bacteria,

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meaning a piece of it, so its impossible to get infected with Lyme through this vaccine. This sort of arguments with no basis is what makes many scientists, Dr, etc to roll their eyes and dismiss possible relevant information.

Steere talks about a possible autoimmune response, and I'm sure he suspects a lot of people did develop Lyme like syndrome due to the vaccine. Ironically, that will go in turn to validate the hypothesis that people will develop severe illness even after the infection has been cleared up, and hence long term use of antibiotics has very little therapeutic. Hopefully this will result in more research put into understanding this phenomenon.