

## **FDA Issues Lyme Vaccine Warning**

About a dozen people who believe they were severely sickened by the Lyme disease vaccine pleaded with government scientists Wednesday to restrict vaccine sales or at least to insist that doctors disclose all possible side effects.

Vaccine safety experts found no proof that the Lymerix vaccine is dangerous \_ the rare cases of arthritis and other symptoms could be coincidence. But they called the accusations troubling and demanded that Americans be better informed before being inoculated.

The Food and Drug Administration has opened an unusually intense investigation of the Lymerix complaints. Wednesday, the agency's scientific advisers expressed frustration that vaccine manufacturer GlaxoSmithKline has had two years to answer lingering safety questions, but still hasn't.

There must be "some way to at least inform people of these concerns, albeit not proven," FDA adviser Dr. Pamela Diaz of the Chicago Department of Public Health said.

Patients and their relatives said doctors hid possible side effects before administering the vaccine, then often dismissed symptoms when they appeared. One woman in the vaccine's original study charged that researchers refused to record her symptoms, which would be a violation of federal research rules if it occurred.

"Everything that's part of your day-to-day functioning is taken away from you," said Emily Biegel of Blue Point, N.Y., describing her husband's intense pain after vaccination.

"How many of you have had it? How many of you people would give it to your loved ones?" Karen Burk of Bethlehem, Pa., asked panelists. She said her husband "couldn't get out of bed, ... couldn't walk, couldn't peel a banana" after being vaccinated.

Lyme disease, spread by deer ticks in the Northeast and certain other parts of the country, causes fatigue, fevers and joint pain that can persist for weeks. Some patients develop severe arthritis. If untreated with antibiotics, it also can severely damage the heart and nervous systems.

Lyme sufferers begged the FDA to approve Lymerix, the world's first Lyme vaccine, in 1998. It requires two shots given about a month apart and a third a year later to get about 80 percent protection from Lyme disease.

The FDA has received 1,048 reports of Lymerix recipients suffering possible side effects. GlaxoSmithKline, which insists the vaccine is safe, has distributed 1.4 million doses to doctors but can't say how many people have been inoculated.

Many reports are of minor complaints or are not believed to have been caused by the vaccine, but the FDA is studying 133 reports of severe arthritis-like symptoms. That's because of a theory that the vaccine might set off an autoimmune reaction where the body attacks its own tissues, particularly in people who carry a certain gene called HLA-4.