

Glaxo withdraws its Lyme disease vaccine

Treatment is still safe, but demand too low

Tuesday, February 26, 2002

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The Lyme disease vaccine, dogged by safety questions since it became available three years ago, was discontinued yesterday by its manufacturer.

GlaxoSmithKline Plc cited insufficient demand for its decision to yank Lymerix, which was initially hailed by doctors and public-health officials as a breakthrough in combating a notorious bacteria that claims up to 16,000 victims each year.

Instead, Lymerix was blamed for causing the kind of arthritic symptoms it was supposed to prevent. In its first two years on the market, the vaccine prompted 905 adverse-event reports, such as swelled joints and aching muscles. Dozens of lawsuits are pending.

A Glaxo spokeswoman said the controversy didn't play a role in the company's decision. Neither, she said, was the move made in response to pressure from regulators, which a Food and Drug Administration spokeswoman confirmed.

"Safety wasn't a factor in our decision," said Ramona Dubois, a spokeswoman for Glaxo, which inherited Lymerix last year after buying the vaccine's original manufacturer, SmithKline Beecham.

"Despite our best efforts, demand hasn't reached a sustainable level. The market just wasn't there," she said.

Glaxo also is withdrawing an application with regulators to market a pediatric version, she said. The company has halted all research into Lyme disease.

At the time the FDA approved Lymerix in late 1998, SmithKline touted the vaccine as a driver of growth. But 1999 sales were a disappointing \$40 million and the ensuing negative publicity caused sales to plummet, although more recent figures aren't available.

The controversy also engulfed the FDA, which was criticized for approving the product, given that a protein used to make the vaccine may produce an untreatable form of severe arthritis in people with a commonly held gene.

The decision was a victory for consumer advocates, who have been lobbying the FDA to force Glaxo to withdraw Lymerix.

"It should have never been approved in the first place," said Karen Forschner of the Lyme Disease Foundation, a nonprofit that recently obtained clinical-trial data that she said raised questions about the extent to which side effects were recorded properly.

"It was based on bad science. It's a crummy vaccine that's probably caused significant injury to people, but information wasn't shared with the FDA or the public," she said. "This decision will probably save thousands of people from having similar problems."

Barbara Fisher, who sits on the FDA advisory panel that last year heard testimony from people claiming injury from Lymerix, agreed that Glaxo's decision to discontinue the vaccine was overdue.

"The evidence has been compelling for some time," said Fisher, who also heads the nonprofit National Vaccine Information Center. "The science says that certain people are vulnerable to this product."

The Glaxo spokeswoman said doctors can contact the drug maker for instructions on returning unused doses. She noted, however, that doctors aren't being told not to vaccinate patients.

Stephen Sheller, an attorney who represents about 350 people claiming harm from Lymerix, said the lawsuits will proceed.

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