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Merck Misled on Vaccines, Some Say

The firm supplied shots containing a mercury compound after saying it had halted its use.

By Myron Levin
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Drug maker **Merck** & Co. continued to supply infant vaccine containing a mercury-based preservative for two years after declaring that it had eliminated the chemical.

In September 1999, amid rising concern about the risks of mercury in childhood vaccines, Merck announced that the Food and Drug Administration had approved a preservative-free version of its hepatitis B vaccine.

"Now, Merck's infant vaccine line," the company's press release said, "is free of all preservatives."

But Merck continued to distribute vaccine containing the chemical known as thimerosal, along with the new product, until October 2001, according to an FDA letter sent in response to a congressional inquiry.

The thimerosal-containing supplies had expiration dates in 2002.

Merck executives confirmed the details in the FDA letter but defended the accuracy of Merck's announcement in 1999, saying the company had indeed begun to produce preservative-free vaccine.

Merck continued to supply the preservative-containing version "during the transition period to ensure an adequate supply of vaccine to help protect the nation's children," said spokeswoman Mary Elizabeth Blake. She said package labels disclosed which lots of vaccine were preservative-free.

Parent groups and a congressional critic of U.S. vaccine policy are crying foul.

"As far as the world knew, the product coming out of Merck had no thimerosal in it," said Sallie Bernard, executive director of Safe Minds, a group concerned about childhood exposure to mercury, a neurotoxin. Parents and doctors who wanted a thimerosal-free product "would be totally confused," she said.

Rep. Dave Weldon, a Florida Republican and a physician, said what Merck did was "misleading."

"You had people literally into 2002 getting shots with mercury, having been told it was all taken out in 1999," he said. "There should have been a much more cautious announcement that we're going to eliminate the mercury over time." The FDA letter was sent to Weldon in June 2003 in response to his questions about progress in removing mercury from vaccines.

Thimerosal, which is nearly 50% ethyl mercury, has largely been eliminated from most routine childhood vaccines, though it still is present in most flu shots. It had been widely used as a sterilizing agent to prevent bacterial contamination from repeated insertion of needles into multi-dose vials of vaccine.

More than 4,200 claims have been filed in the federal Vaccine Injury Compensation Program by parents alleging that their children suffered autism or other neurological disorders from mercury in their shots.

Last year California banned thimerosal in childhood vaccines as of 2006.

Vaccine makers and many health officials say there is no credible evidence of harm from the small doses of mercury once widely present in kids' shots. They cite a report last May by the prestigious Institute of Medicine of the National Academy of Sciences, which concluded that available evidence "favors rejection of a causal relationship" between vaccines and autism.

Parents have cited contrary findings and say the studies cited by the institute's panel were flawed.

Though they said there was no proof of harm, the U.S. Public Health Service and the American Academy of Pediatrics in July 1999 acknowledged that mercury exposures from a multitude of shots exceeded federal health guidelines, and they called on manufacturers to voluntarily eliminate thimerosal from kids' vaccines.

Last month The Times disclosed a leaked Merck memo from 1991 showing that the company was aware at that time of concerns about thimerosal. In the memo, a former Merck scientist calculated that 6-month-old children who received their shots on schedule could receive a mercury dose up to 87 times higher than the guideline for the maximum daily consumption of mercury from fish.

"When viewed in this way, the mercury load appears rather large," said the memo by Dr. Maurice R. Hilleman, an internationally renowned vaccinologist and a former senior vice president of Merck. "The key issue is whether thimerosal, in the amount given with the vaccine, does or does not constitute a safety hazard."

Hilleman and Merck executives have declined to discuss the memo.

Merck's announcement of the new thimerosal-free vaccine figured strongly in a shift in federal immunization policy.

In issuing their 1999 appeal, federal authorities also recommended that the first hepatitis B shot, typically given to newborns in their first 12 hours of life, be postponed except for at-risk infants — those whose mothers had tested positive or whose hepatitis B status was unknown.

But that caveat was lost in confusion over the new policy, and some hospitals delayed the birth dose even for at-risk children. Fearing that these babies could contract the serious disease, the Centers for Disease Control and Prevention reinstated the birth dose for all newborn babies, citing the availability of the new Merck vaccine.

The Merck release was issued Sept. 9, 1999, and the CDC announced the revised policy the next day.

The CDC notice cited the introduction of the Merck vaccine and the expectation that a preservative-free version from a second manufacturer would be available soon. It called on hospitals and doctors to assure

that they had enough of the new product for newborns before giving it to older babies.

"There was a belief there was enough thimerosal-free hepatitis vaccine, so they went back to the birth dose," said Glen Nowak, a spokesman for the CDC.

Dr. Eric Mast, chief of the prevention branch in the CDC's division of viral hepatitis, said the agency had not conducted surveys to determine the percentage of newborns who got mercury-free shots. But he said the CDC had not received reports "from state health departments or providers that there was a problem with access" to preservative-free vaccine.

Weldon, however, said that with the old product continuing to flow into the market, he was "fairly confident that newborns continued to get mercury-containing vaccines."

"It would have to be a very well-informed and diligent pediatrician to make sure all of the stock he supplied contained no mercury," he said.

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