'91 Memo Warned of Mercury in Shots

By Myron Levin, Times Staff Writer

A memo from Merck & Co. shows that, nearly a decade before the first public disclosure, senior executives were concerned that infants were getting an elevated dose of mercury in vaccinations containing a widely used sterilizing agent.

The March 1991 memo, obtained by The Times, said that 6-month-old children who received their shots on schedule would get a mercury dose up to 87 times higher than guidelines for the maximum daily consumption of mercury from fish.

"When viewed in this way, the mercury load appears rather large," said the memo from Dr. Maurice R. Hilleman, an internationally renowned vaccinologist. It was written to the president of Merck's vaccine division.

The memo was prepared at a time when U.S. health authorities were aggressively expanding their immunization schedule by adding five new shots for children in their first six months. Many of these shots, as well as some previously included on the vaccine schedule, contained thimerosal, an antibacterial compound that is nearly 50% ethyl mercury, a neurotoxin.

Federal health officials disclosed for the first time in 1999 that many infants were being exposed to mercury above health guidelines through routine vaccinations. The announcement followed a review by the U.S. Food and Drug Administration that was described at the time as a first effort to assess the cumulative mercury dose.

But the Merck memo shows that at least one major manufacturer was aware of the concern much earlier.

"The key issue is whether thimerosal, in the amount given with the vaccine, does or does not constitute a safety hazard," the memo said. "However, perception of hazard may be equally important."

Merck officials would not discuss the contents of the

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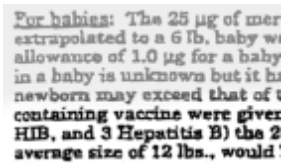
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Mercury memo
February 8, 2005

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memo, citing pending litigation.

Separately, the drug giant is trying to fend off a legal onslaught over Vioxx, the popular painkiller it introduced in 1999. The company, based in Whitehouse Station, N.J., faces hundreds of lawsuits claiming that the drug caused heart problems and that Merck concealed the risks. Merck, which in September pulled Vioxx off the market, has denied the allegations.

The legacy of thimerosal, meanwhile, also is causing problems for Merck and other drug companies.

More than 4,200 claims have been filed in a special federal tribunal, the Vaccine Injury Compensation Program, by parents asserting that their children suffered autism or other neurodevelopmental disorders from mercury in vaccines. A handful of similar claims are awaiting trial in civil courts. The plaintiffs cite various scientific studies that they say prove the dangers of thimerosal, including at the levels found in vaccines.

Thimerosal has been largely removed from pediatric vaccines in recent years in what health officials have described as a precautionary measure. (This has been accomplished as drug makers have voluntarily switched from multi-dose vials of vaccine, which require a chemical preservative like thimerosal, to single-dose containers.)

In September, Gov. Arnold Schwarzenegger signed legislation prohibiting vaccines with more than trace amounts of thimerosal from being given to babies and pregnant women. Iowa has a similar ban.

For their part, Merck and other vaccine makers, along with many government health officials and scientists, say there is no credible evidence of harm from the amounts of mercury once widely present in kids' shots. They cite a report in May by a committee of the national Institute of Medicine concluding that the evidence "favors rejection of a causal relationship" between vaccines and autism.

The seven-page Merck memo was provided to The Times by James A. Moody, a Washington lawyer who works with parent groups on vaccine safety issues. He said he obtained it from a whistle-blower whom he would not name.

The memo provides the "first hard evidence that the companies knew — or at least Merck knew — that the children were getting significantly more mercury" than the generally accepted dose, the lawyer said.

He also provided a copy to attorneys for Vera Easter, a Texas woman who blames thimerosal for the condition of her 7-year-old son, Jordan, who is autistic and mentally retarded. The Easter lawsuit is pending in U.S. District Court for the Eastern District of Texas. The defendants include Merck; rival vaccine makers GlaxoSmithKline, Aventis Pasteur Inc. and Wyeth; and thimerosal developer Eli Lilly & Co.

Easter's lawyer, Andy Waters, described the memo as "incredibly damning and incredibly significant." After receiving it in the fall, he confronted Merck lawyers about why he hadn't seen it earlier.

In a letter to Waters in October, Merck attorneys said they had in fact made available 32 boxes of records, but that the copying service hired by the plaintiffs for some reason had failed to copy several of the boxes — including the one with the Hilleman memo.

"The memo," said company spokeswoman Mary Elizabeth Blake, "was produced voluntarily by Merck in the ordinary course of discovery proceedings."

Hilleman is a former senior vice president of Merck who developed numerous vaccines for the company. A 1999 profile in the Philadelphia Inquirer said that "it is no exaggeration to assert, as many scientists do, that Maurice Hilleman has saved more lives than any other living scientist."

Hilleman, 85, currently director of the Merck Institute for Vaccinology, had officially retired and was a consultant to Merck when he wrote the '91 memo. He declined to be interviewed.

The memo was sent to Dr. Gordon Douglas, then head of Merck's vaccine division and now a consultant for the Vaccine Research Center at the National Institutes of Health. Douglas also declined to comment.

The memo stated that regulators in several countries had raised concerns about thimerosal, including in Sweden, where the chemical was being removed from vaccines.

"The public awareness has been raised by the sequential wave of experiences in Sweden including mercury exposure from additives, fish, contaminated air, bird deaths from eating mercury-treated seed grains, dental amalgam leakage, mercury allergy, etc.," the memo said.

It noted that Sweden had set a daily maximum allowance of mercury from fish of 30 micrograms for a 160-pound adult, roughly the same guideline used by the FDA. Adjusting for the body weight of infants, Hilleman calculated that babies who received their shots on schedule could get 87 times the mercury allowance.

The Swedish and FDA guidelines work out to about four-tenths of a microgram of mercury per kilogram of body weight. A stricter standard of one-tenth of a microgram per kilogram has been adopted by the Environmental Protection Agency and endorsed by the National Research Council.

These standards are based on methyl mercury, the type found in fish and airborne emissions from power plants. Though toxic, the ethyl mercury in thimerosal may be less hazardous than methyl mercury, some scientists say, because it is more quickly purged from the body.

"It appears essentially impossible, based on current information, to ascertain whether thimerosal in vaccines constitutes or does not constitute a significant addition to the normal daily input of mercury from diverse sources," the memo said.

"It is reasonable to conclude" that it should be eliminated where possible, he said, "especially where use in infants and young children is anticipated."

In the U.S., however, thimerosal continued to be added throughout the '90s to a number of widely used pediatric vaccines for hepatitis B, bacterial meningitis, diphtheria, whooping cough and tetanus.

It was added to multi-dose vials of vaccine to prevent contamination from repeated insertion of needles to extract the medicine. It was not needed in single-dose vials, but most doctors and clinics preferred to order vaccine in multi-dose containers because of the lower cost and easier storage.

The Hilleman memo said that unlike regulators in Sweden and some other countries, "the U.S. Food and Drug Administration … does not have this concern for thimerosal."

A turning point came in 1997 when Congress passed a bill ordering an FDA review

of mercury ingredients in food and drugs.

Completed in 1999, the review revealed the high level of mercury exposure from pediatric vaccines and raised a furor. In e-mails later released at a congressional hearing, an FDA official said health authorities could be criticized for "being 'asleep at the switch' for decades by allowing a potentially hazardous compound to remain in many childhood vaccines, and not forcing manufacturers to exclude it from new products."

It would not have taken "rocket science" to add up the amount of exposure as the prescribed number of shots was increasing, one of the e-mails said.

While asserting that there was no proof of harm, the U.S. Public Health Service in July 1999 called on manufacturers to go mercury-free by switching to single-dose vials. Soon after, Merck introduced a mercury-free version of its hepatitis B vaccine, replacing the only thimerosal-containing vaccine it was still marketing at the time, a company spokesman said.

By 2002, thimerosal had been eliminated or reduced to trace levels in nearly all childhood vaccines. One exception is the pediatric flu vaccine made by Aventis and still sold mainly in multi-dose vials.