

# Mercury in vaccines leads to wave of suits

Stephen Van Drake

When Alexander Stewart of Aventura says a new word, his family becomes elated, the boy's mother Linda said.

Two years ago, Alex, now 8, stopped speaking, lost his appetite and emotionally withdrew from his parents, Linda and Dennis, and older brother, David, 10.

Doctors broke the bad news that Alex was autistic. Even worse was the fear that childhood vaccinations may have caused this tragedy.

At birth and for the first three years of his life, Alex was normal in every way, Linda Stewart said.

"His speech was perfect, and he used to speak French, too, but that's gone now."

Like millions of infants, Alex received vaccinations from vials containing the preservative Thimerosal, used since the 1930s and discontinued in the United States in October.

The youngster mastered all developmental milestones by age 3. Then, over the following three years, his speech, emotional state and appetite gradually eroded, his mother said.

The mystery behind Alex's slide into autism may ride on a tsunami of lawsuits that may soon wash against 10 of the world's largest drug companies and others in the distribution chain of Thimerosal, which plaintiffs say has more than the trace amounts of mercury allowed by federal law.

Hundreds of children and their parents in scores of lawsuits filed in South Florida and elsewhere claim Thimerosal's toxic mercury caused autism or similar symptoms. Lawyers say the cases will soon rival asbestos and tobacco suits in prominence before the public.

Drug giants deny culpability. They contend there's no reliable scientific data linking Thimerosal to autism or any adverse reactions.

Autism is a developmental disorder of the brain affecting social interaction and communication skills.

The Thimerosal-autism debate takes center stage July 16 in Cambridge, Mass., as the U.S. National Academy of Sciences Institute of Medicine meets publicly.

The stakes are high. Plaintiffs' lawyers say the victims and the damages number in the millions of kids and billions of dollars.

## Perfect litigation storm?

On May 31 in Miami-Dade Circuit Court, the Stewarts sued major pharmaceutical companies, Florida Thimerosal-vaccine distributors and the Miami physician who vaccinated Alex, said their Miami lawyer James L. Ferraro.

Ferraro said his firm has filed four such suits in Florida, including one each in Broward and Palm Beach circuit courts.

"I wouldn't be surprised that there are tens of thousands of cases out there," he said.

The torrent of suits against drug titans promises litigation equal to the assault against Big Tobacco, said Miami mass tort lawyer Roberto Villasante of Robles Law Center.

In September, Villasante filed the first Florida Thimerosal suit in Miami-Dade Circuit Court for 5-year-old Steven Demos and his parents, Nick and Linda.

Court documents show Steven's scenario closely resembles Alex's. Villasante said he studied Thimerosal for a year before filing this suit.

"I met with scientists and doctors all over the country, many national experts, and I'm absolutely certain the science is there that supports our theory of mechanism of injury," he said.

Villasante's legal theories include negligence, failure to warn and failure to test Thimerosal, making and selling an inherently dangerous drug (strict liability), civil battery, breach of warranties and violation of Florida's Deceptive Trade Practice Act.

He's also the only lawyer demanding that drug companies withdraw and destroy stockpiles of vaccines with Thimerosal made and distributed before October.

Villasante said he has filed Thimerosal actions in New York and North Carolina and will file 20 more Thimerosal cases in 15 states within three weeks.

The Robles firm leads a national coalition of 25 trial lawyers in 15 states sharing resources that is poised to launch a second wave of lawsuits against pharmaceutical companies.

Waters & Kraus of Dallas spearheads a second group of 17 firms, including Ferraro's. Waters filed the first Thimerosal suit, said Tanja K. Martini, a Waters associate.

"We have already filed 60 such cases in federal and state courts," she said. Forty more will be filed soon by members of the Waters consortium, Martini said. Waters lawyers will try the first Thimerosal case in February in Texas.

The litigation continues to gain momentum.

This week, Villasante requested the presiding judge in the Demos case to certify as a class all alleged Thimerosal victims in the nation to force pharmaceutical companies to fund research to medically monitor Thimerosal-affected children. Villasante said disorders from Thimerosal emerge months or years after vaccinations.

"I want the drug companies to help monitor and, where possible, identify early symptoms so children and parents can be helped."

#### **The case for causation**

Villasante wrote in the Demos complaint, "In 1982, an expert FDA panel concluded Thimerosal was unsafe and should be removed from all over-the-counter products."

Experts agree that if ingested in more than trace amounts, mercury poses health risks.

In June 1999, the FDA announced that infants receiving Thimerosal-laced vaccines at several visits may be exposed to more mercury than recommended by federal safety guidelines for total exposure to mercury, Martini said.

She also noted that in July 1999, the American Academy of Pediatrics issued a warning that Thimerosal-containing vaccines could be hazardous to infants' health.

Last year, the Institute of Medicine published a book, "Immunization Safety Review." It discussed the "plausibility of a causal relationship between vaccines and the neuro-developmental disorder of autism," according to Martini.

Ferraro associate L.H. Steven Savola said one overriding factor shines through: statistics.

In his March complaint filed in Broward Circuit Court for Mohamed and Juliet Edoe, parents of Justin, Savola wrote that after a typical immunization schedule during the first 18 months of life, American infants were exposed to 237.5 micrograms of mercury from Thimerosal in vaccine products.

This exposure exceeds federal guidelines "by a factor of 30-plus times the permissible limit," he stated.

#### Pharmaceuticals' defense

Pharmaceutical industry representatives say Thimerosal simply killed bacteria and fungi in multivaccination vials. And it worked well, they said.

Doctors could draw up to 10 inoculations from each vial containing Thimerosal. This saved everyone money, according to court documents.

Drug companies concurrently made and sold single vaccine vials without Thimerosal.

Indianapolis-based Eli Lilly (NYSE: LLY) patented Thimerosal in the 1930s and licensed it to GDL International, Dow Chemical (NYSE: DOW), Sigma-Aldrich (Nasdaq: SIAL), American International Chemical and Spectrum Laboratory Products, co-defendants in these suits.

"Eli Lilly knew from the 1930s of the toxic effects of Thimerosal but didn't warn anyone," Martini said. "Instead, it said the drug only contained trace amounts of mercury and said it was non-toxic."

Eli Lilly disagreed.

"There is no causal link established between Thimerosal and any adverse reactions to vaccines," said Eli Lilly spokeswoman Joan Todd, adding that her company discontinued the sale or use of the product about 10 years ago.

"Vaccines containing the preservative have been administered to billions of children and adults worldwide with no data to suggest that the Thimerosal in these vaccines poses a public health risk," said Peter Paris, spokesman for Lyon, France-based co-defendant Aventis-Pasteur.

Since October, drug companies ceased using Thimerosal in vaccines marketed in the United States, said Nancy Pekarek, spokeswoman for co-defendant GlaxoSmithKline (NYSE: GSK), the world's second largest drug company.

Pekarek said the industry's action was totally voluntary. Martini, however, noted that drug companies sell Thimerosal vaccines to developing countries.

GlaxoSmithKline in October also agreed to exchange any domestic inventories of vaccines with Thimerosal for new FDA-approved substitutes, Pekarek said.

Pharmaceutical companies named in the suits also include: Lederle Pharmaceutical, Wyeth Pharmaceuticals (NYSE: WYE), Merck & Co. (NYSE: MRK), Parke-Davis (now part of Pfizer, NYSE: PFE), and Baxter Pharmaceutical Products (part of Baxter Healthcare, NYSE: BAX).

Will federal act give some immunity?

Defendants in court documents argue that such injury claims should be funneled through the fast-track, no-fault Childhood Vaccine Injury Act of 1996 that granted drug companies limited immunity from vaccine-related lawsuits.

Plaintiffs' lawyers, however, counter that Thimerosal is a contaminating "adulterant" that drug companies intentionally added to vaccines.

Vaccines alone don't cause injury, plaintiffs' lawyers say. It's Thimerosal.

As scores of lawyers engage in civil combat, life goes on for Alex, Linda and Dennis Stewart. Day by day.

For two years, Alex has attended a special school for autistic children.

"He's doing very well through speech and occupational therapies and a lot of vitamins," his mother said. "Alex is very positive and does a tremendous amount of work, but it still makes my heart bleed because it's very difficult for a parent to have a special needs child on a daily basis."

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