



# What was mercury doing in vaccines in the first place?

*A group of parents and their supporters say the mercury is responsible for their children's autism. Government agencies say no such connection can be made.*

Sunday, October 9, 2005

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Last year, a panel at the National Academy of Sciences tried to finally settle a gut-wrenching debate: Could a mercury-based preservative used in vaccines until a few years ago be linked to soaring autism rates?

The academy's Institute of Medicine concluded: "The evidence favors rejection of a causal relationship" between the preservative thimerosal and autism.

Furthermore, the panel said, the government should stop pursuing the thimerosal theory and channel autism research into more "promising areas."

Many parents of autistic children don't buy that conclusion. And they have forged a national parents' movement that is working Congress, funding research, buying billboard space and storming Washington. Wendy Fournier, of Portsmouth, president of the National Autism Association and mother of an autistic child says: "Our kids have literally been stolen, stolen, from us! And Damn it, we won't stop until the government comes clean about what they did!"

On Friday and yesterday, Fournier and 150 leaders of other parent groups from around the country held a "Power of Parents" rally on Capitol Hill and lobbied doctors inside a convention of pediatricians. Fournier said some parents were told to leave.

Depending upon whom you talk to, the parents are either looking to blame someone or looking for the truth.

"Clinging to the notion that mercury is somehow related to autism, it's my belief and the belief of the American Academy of Pediatrics that they're barking up the wrong tree," said Dr. Julia McMillan, a professor of pediatrics at Johns Hopkins University in Baltimore.

But said Boyd Haley, chemistry professor and a heavy-metals expert at the University of Kentucky, "The parents are correct on this. The parents are the heroes.

"The people who say there is no causal link are going to be humiliated," he said.

THE CONTROVERSY began in 1997 when Congress, concerned about mercury in the environment, ordered the U.S. Food and Drug Administration to evaluate mercury in food and drugs.

Environmental accidents and studies of island populations that eat predatory fish had shown that unsafe levels of mercury could damage brains, kidneys and developing fetuses.

The preservative thimerosal (also known as Merthiolate) was already in use in 1938 when the FDA first started requiring pharmaceutical companies to prove their products were safe. There had never been a study on thimerosal's effect on developing infant brains.

It was in over-the-counter products and vaccines.

The pharmaceutical companies used the preservative to kill germs in vials that contain 10 doses. A nurse or doctor could put a needle in and out of the vial without picking up bacteria.

The companies could always make vaccines in single-dose vials, which don't require thimerosal, but the process is costlier: about \$4 more per vial.

Thimerosal, the parents of autistic children claim, became dangerous when the government expanded its list of mandated vaccines in the early '90s. Apparently, the U.S. Centers for Disease Control and Prevention and its advisory bodies, which coordinate vaccine schedules, had not tallied the total amount of mercury infants were getting from the vaccines.

When the Maryland-based FDA did in 1999 -- on Congress' orders -- it found the levels of mercury exceeded at least one guideline, the one set by the Environmental Protection Agency.

(The standards are based on methyl mercury, the type of mercury found in fish and emissions; thimerosal contains ethyl mercury. They are the two most toxic forms of mercury, though there is a debate over which is worse.)

How much mercury were infants getting?

Infants who got routine shots at two months were also getting 62.5 micrograms of mercury. At an average weight, that worked out to 118 times the EPA standard for daily consumption.

Health officials prepared to tell the public in the summer of 1999 that thimerosal was going to be phased out of vaccines over theoretical concerns about mercury; vaccine companies voluntarily agreed to transition to thimerosal-free vaccines.

Internal e-mails obtained by Congress show health agencies feared shaking public trust in vaccines, which have been so successful in preventing diseases such as diphtheria, which once killed thousands.

Officials also worried about public perception.

In one e-mail, Peter Patriarca, a former FDA scientist, wrote to the CDC, predicting that the public announcement: "Will raise questions about FDA 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.

"We must keep in mind that the dose of ethyl mercury was not generated by 'rocket science;' conversion of the % of Thimerosal to actual ug (micrograms) of mercury involves 9th grade calculations? Why didn't the CDC and the advisory bodies do these calculations while rapidly expanding the childhood immunization schedule."

Asked why the CDC did not add up the mercury, Glen Nowak, CDC spokesman, said in a phone interview: "I think that was something, looking back, that we wish more attention would have been paid to."

Coincidentally or not, the diagnosis of autism skyrocketed in the last decade as the list of mandated immunizations increased. A neurological disorder that can profoundly affect a person's ability to communicate and form social relationships, autism was once considered rare, about 4 in 10,000. While scientists debate the reason for the rising numbers, the CDC says rates are now as high as 1 in 166. In Rhode Island, the number of autistic children in special education jumped from 30 in 1992 to 605 in 2002.

IT DIDN'T TAKE long for parents to start connecting thimerosal and autism rates.

And it didn't take long for people to ask: What was mercury, a poison, doing in vaccines?

"It [would be] sort of like Gerber grinding up glass and putting it in baby food. Even if it's a little tiny amount, what would you want that in there for," says Sallie Bernard, of Aspen, Colo., who has an autistic son.

In 1999, shortly after the public announcement about thimerosal, Bernard and another mother, a nurse in Atlanta, started pulling the scientific literature on mercury poisoning and concluded that the symptoms of mercury poisoning resembled autism.

The mercury theories started going around the Internet. Mercury poisoning, they began to think, was why their children were speechless, spinning, rocking, flapping their arms, staring at Elmo with faces pressed right on the TV.

In Boston, the mercury argument made sense to Mark Blaxill, father to an autistic daughter, Michaela. "We played by the rules and were taking our kids to doctor," he says. "We look up and say holy crap -- there's a lot of sick kids around and we're not alone. Something is going on and no one is facing up to it."

The CDC had also started looking into the possible connection.

Autism is thought to be partly genetic. Some scientists believe it also has an environmental trigger.

According to documents filed with the House Committee on Government Reform, the CDC directed one of its scientists to analyze the CDC's Vaccine Safety Datalink, a database that tracks reports of adverse reactions to vaccines by keeping 6 million records from four HMOs.

The CDC's goal was to see if thimerosal was linked to neurological or kidney damage.

From 1999 to 2000, the scientist, Dr. Thomas Verstraeten, culled records of 110,000 children.

He reported results of Phase I in 2000, saying he had found a "statistically-significant association" between exposure to thimerosal during the first six months of life and attention deficit disorder, tics, language and speech delays, and general neurodevelopmental delays.

For autism, the study found a "slight, but not significant increase for highest exposure," he told public health officials gathered at a meeting near the CDC's Atlanta headquarters in June of 2000.

Asked for his opinion of his findings, Verstraeten said: "When I saw this, and I went back through the literature, I was actually stunned by what I saw because I thought it is plausible.

He also said, at a different point in the meeting: "Personally, I have three hypotheses. My first parental hypothesis is parental bias. The children that are more likely to be vaccinated are more likely to be picked up and diagnosed. Second hypothesis. I don't know. There is a bias that I have not yet recognized and nobody had told me yet.'

"Third hypothesis. It's true, it's thimerosal. Those are my hypotheses."

The majority of attendees, including Verstraeten, said the results were preliminary; more analysis needed to be done.

Dr. Richard Johnston, a pediatrician at the University of Colorado School of Medicine, said he'd support a recommendation that infants of up to 2 not be given thimerosal-containing vaccines, if there was a choice.

"My gut feeling? It worries me enough. Forgive this personal comment," he told his colleagues, "but I got called out at eight o' clock for an emergency call and my daughter-in-law delivered a son by C-section. Our first male in the line of the next generation, and I do not want that grandson to get a thimerosal-containing vaccine until we know better what is going on. . . . I think I want that grandson to be only given thimerosal-free vaccines."

Nowak, the CDC spokesman, said the agency didn't make that recommendation to the public because the research on thimerosal was preliminary and because there weren't enough thimerosal-free vaccines on the market.

The government's public health agencies allowed the vaccine industry to sell its stock of thimerosal-containing vaccines. Merck & Co., for one, would continue to ship vaccines with mercury in them for another year.

The House Committee on Government Reform said the agencies acted too slow.

"They could have, but did not require vaccine manufacturers to remove thimerosal from vaccines by a specific date," stated the House report, in an investigation led by U.S. Rep. Dan Burton, an Indiana Republican. "They could have, but did not, urge pediatricians to choose thimerosal-free vaccines when both were available."

The House committee blamed "institutional malfeasance" and said the government was protecting the pharmaceutical industry.

In the summer of 2000, as the CDC was studying thimerosal, Aly Fournier, of Portsmouth, was getting her shots, which contained thimerosal.

"For them to have this information. . ." said Wendy Fournier, Aly's mother, "they should have said, 'Whoa, whoa, we have a potential problem, we need to stop using thimerosal until we find out for sure what its effects are in these doses.' They didn't do it, they swept it under the rug."

THE CDC contracted with the Institute of Medicine to study the issue in 2001 and then again last year.

In the first study, the panel convened by the IOM considered a broad hypothesis: Was thimerosal linked to autism or any other neurologic disorders?

The IOM concluded it didn't have enough evidence to accept or reject the theory, but said a link was "biologically plausible," and called for more research.

Last year, the Institute of Medicine narrowed its focus. This time the institute only looked at the connection between thimerosal and autism, not the broader question of all potential brain damage.

"You're narrowing it so much. . . . It sort of eliminated everything that was somewhat supportive that there might be a connection," said Thomas M. Burbacher, director of the National Infant Primate Lab at the University of Washington.

Nowak, the CDC spokesman, said, "The primary concern, what we were hearing from parents was autism. That was the highest priority for people who were concerned about thimerosal."

U.S. Rep. Dave Weldon, a Florida Democrat and a doctor, said the CDC shaped its request for the study in a way that gave little weight to lab studies on thimerosal.

Weldon said they looked at population studies in countries that had also used thimerosal. But, he said, "the bulk were from European children who received anywhere from half to a third of the mercury exposure that U.S. children received."

Dr. Marie C. McCormick, chairwoman of the Institute of Medicine's panel that looked at the thimerosal issue last year, said in an e-mail to The Journal: "He is correct if you look at the total dose up to age 2 years."

But in one study in Denmark, she said, infants had doses in the first year that were comparable to the United States.

McCormick said the Institute of Medicine committee acted independently and decided on its own that population studies were the best way to judge causality. She said the studies were convincing because they consistently showed no association. She said the IOM also looked at lab work, but found it theoretical at best.

The lab work, she said, showed that the mercury in thimerosal could be toxic, but failed to show how that could lead to autism.

"It's just not an evenhanded debate. The evidence is really on the side of no association, and I think it's going to accumulate further," she said.

The IOM did use one U.S. population study. The study turned out to be the final version of Verstraeten's Phase 1 study. This version of the study, which looked at different ages and groups of children, dropped any association between thimerosal and neurological disorders.

Yet Weldon said while the study made no connection, its author, Verstraeten, wrote:

"The bottom line is and has always been the same: an association between thimerosal and neurological outcomes could neither be confirmed nor refuted; and therefore more study is required."

AROUND THE COUNTRY, scientists continue to research thimerosal. Their studies are hailed as proof for or against a link.

Ethyl mercury, the mercury in thimerosal, was eliminated in an infant's stool in days, one study found. That's good news.

But the bad news: The National Primate Research Center at the University of Washington found that infant primates didn't excrete all the ethyl mercury.

Some of it converted to potentially harmful inorganic mercury and lodged in the brain.

"Smart people know there's a lot more questions to ask about thimerosal," said Burbacher, the author. "To say no more research is needed. That's ludicrous. You lose credibility."

Other scientists would like to work with the CDC's original data. But no one can seem to find it.

"They claim it's been destroyed," said Haley, the chemistry professor at the University of Kentucky. "This is by a government agency whose job it is to keep that kind of stuff. It's so symptomatic of someone who's seriously involved in a major coverup."

Nowak, spokesman for the CDC, said it's true, the data sets from Phase I are gone. "They weren't kept," he said.

Those data "were a preliminary analysis and we weren't in the practice of saving data sets for those analyses."

EDWARD SAGEBIEL, spokesman for Eli Lilly, the Indianapolis-based company that developed thimerosal, said Lilly is facing hundreds of lawsuits by "parents who blame thimerosal for their children's autism."

"We believe that science, not politics or a legal system will really find the causes for autism," he said.

Another 4,900 parents have filed thimerosal claims with the federal Vaccine Injury Compensation Program. In an effort to settle cases out of court, vaccine companies pay into the program, which awards an average of \$800,000 to people judged to be harmed by vaccines.

In 2002, some lawmakers slipped a provision to shield vaccine makers from lawsuits into the massive Homeland Security legislation. "At the 11th hour at night, they put a provision in the bill," Congressman Burton, a Republican, testified. The provision was repealed by several Republicans and Democrats after parents rallied.

Many parents have now turned their attention to lobbying lawmakers to ban thimerosal. The preservative is still in one brand of infant flu shot, though thimerosal-free flu shots are available. In July, Nebraska Sen. Chuck Hagel, a Republican, filed a bill to ban mercury in shots for pregnant women and infants, as did Congressman Weldon. Six states have passed similar laws. An anti-thimerosal bill is pending in Rhode Island.

In May, 150 families in California chipped in for full-paged anti-mercury ads in USA Today.

In July, 700 marched at a "Power of Truth" rally in Washington. In August, "Mercury is toxic" billboards popped up around Chattanooga, Tenn., Raleigh, N.C., and Grand Rapids, Mich. There's a book out. And radio talk show host Don Imus is on a rant in support of the parents.

Despite getting booted out of a doctors' convention in Washington yesterday, Wendy Fournier, of Portsmouth, believes the mothers and fathers are "finally getting people to really listen and not think we're a bunch of lunatic parents."

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