

IN THESE TIMES

Please consider subscribing to the print edition and supporting independent media:

<http://www.inthesetimes.com/subscribe/>

This article is permanently archived at: [http://www.inthesetimes.com/comments.php?id=434\\_0\\_1\\_0\\_C](http://www.inthesetimes.com/comments.php?id=434_0_1_0_C)

BY ANNETTE FUENTES | 11.11.03

# Autism in a Needle?

## The toxic tale of vaccinations and mercury poisoning

Lyn Redwood's son Will was a healthy, happy baby who met all the normal developmental standards—he was walking and talking by one year. About three months later, however, he began to regress, losing speech, avoiding eye contact and appearing miserable. “He didn’t seem happy anymore,” Redwood said in a recent interview. “He just wanted to sit in his infant seat and watch videos over and over again.”

Doctors initially blamed hearing problems for Will's decline. Neurologists told the parents that their son had global and receptive speech delay. At age 5, the boy was diagnosed as autistic by his school.

Seeking answers to her son's condition, Redwood turned to the Internet in 1999 and began a search that led to startling discoveries about thimerosal. This vaccine preservative is composed of nearly 50 percent mercury, which is a known neurotoxin especially harmful to fetuses, infants and children. What's more, it has been linked to a range of symptoms collectively known as Autism Spectrum Disorders. At one end is severe autism, in which children are socially withdrawn, do not speak and exhibit bizarre, repetitive, sometimes aggressive behaviors. At the other end are Asperger's Syndrome, a high-functioning form of autism, Pervasive Developmental Disorder (PDD), Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD).

Thimerosal was widely used since the '40s in over-the-counter medicines until that use was banned in 1998. It's still found in some vaccines for adults and infants. Its medical, political, economic and international implications represent a chilling chapter in the history of public health, in which regulatory agencies were negligent, if not guilty, in covering up health hazards, by failing to act quickly to protect millions of children. Said Redwood, a nurse practitioner and a board of health member in her Georgia county, where vaccination is a major public health program: “If someone had told me prior to 1999 that vaccines were responsible for my son's disabilities, I would have thought they were crazy.”

Regulators 'asleep at the switch'

Before 1980, autism was diagnosed in 1 in 10,000 children; in 2002, the National Institutes of Health raised that figure to 1 in 250 children. The Autism Society of America now estimates that autism disorders are growing by 10 percent or more annually. Some scientists believe boys are afflicted by the neurological disorders of autism at a rate three to six times that of girls because the female hormone estrogen protects against mercury toxicity.

In a sad twist, scientists increasingly believe that the mercury-laced vaccines meant to protect children from illness are at the root of this spike. In 1985, four of the shots recommended for infants in their first 18 months contained thimerosal. By 1991, the Centers for Disease Control and Prevention (CDC) added three Hepatitis B shots (each containing 12.5 micrograms of thimerosal) and four Hib shots (each with 25 micrograms of mercury). As a result, the number of vaccines containing thimerosal jumped to 11, and the amount of mercury exposure mushroomed to 237.5 micrograms, an amount that exceeded all federal limits.

Neither the Food and Drug Administration (FDA) nor the CDC, the nation's chief regulatory agencies for pharmaceutical products and the watchdogs of public health, added up the micrograms. The regulatory spotlight was finally fixed on thimerosal in 1997 when Congress passed the FDA Modernization Act. Part of the act required the FDA to investigate all drugs that contained mercury and determine their effects on humans. Within a year, the FDA had called for the removal of all thimerosal-containing products from over-the-counter products. Thimerosal remained in more than 50 vaccines, however, until the Public Health Service (which includes the FDA, the CDC and the National Institutes of Health) and the American Academy of Pediatrics issued a statement in July 1999 "urging" vaccine makers to reduce or eliminate thimerosal because of "theoretical potential for neurotoxicity."

Last year, the staff for Rep. Dan Burton (R-Ind.) obtained an internal e-mail written June 29, 1999, by former FDA scientist Peter Patriarca. In that e-mail Patriarca offered his colleagues a "pros and cons" assessment of the thimerosal statement shortly before its release:

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. Will also raise questions about various advisory bodies about aggressive recommendations for use. 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 algebra. What took the FDA so long to do the calculations? Why didn't CDC and the advisory bodies do these calculations while rapidly expanding the childhood immunization schedule?

Roger Bernier, of the CDC's national immunization program, received the e-mail. In a recent interview he explained why the cumulative amount of mercury was never figured. "Vaccines tend to be evaluated on an individual basis, the requirements for safety and efficacy on an individual basis," Bernier said. "This holistic view of safety was not part of

the review.” Bernier said the health agencies did not order vaccine makers to stop using thimerosal and to recall existing vaccines containing it because “this was a theoretical concern, it was conceived as precautionary measure, not because evidence showed a risk. There wasn’t a sense of urgency. It was viewed as something to be done—not because we had to, but because it should be done.”

#### Toxicity and plausibility

While the FDA and CDC moved glacially slow on mercury, the EPA had been since the early '70s aggressively educating the public about ingesting mercury in food, especially fish, and setting standards for exposure. The inconsistent approach to mercury is reflected in the standards agencies set for maximum daily consumption. Set in micrograms per kilogram of body weight, the EPA’s standard is lowest, at .1 micrograms, the FDA’s is .4 micrograms. Those guidelines are for methylmercury, the toxic cousin of ethylmercury, which is in thimerosal. While some government scientists defending the use of thimerosal have argued that ethyl is less toxic than methyl, both forms will harm living tissue, according to Boyd Haley, chair of the department of chemistry at the University of Kentucky and an expert on toxic metals. “Some parents of autistic children called me and asked me to look at thimerosal. We did some experiments with human brain tissue and it was dramatic,” Haley said. “It penetrates the proteins in the brain. It is toxic to neurons and enzymes.” Haley co-authored an August 2003 study that showed autistic children retained more mercury in their bodies than normal children, evidenced by higher levels of the toxin in their hair. That means the ethylmercury from thimerosal had been absorbed into their brain and other body tissue, likely causing neurological damage.

The July 1999 statement on thimerosal hardly put the issue to rest. For Redwood, it was the catalyst that led to the creation of SAFE MINDS, a parents’ group that has conducted research on the thimerosal-autism disorders link. With several other parents of autistic children, in 2001 Redwood published “Autism: A Novel Form of Mercury Poisoning” in the journal *Medical Hypotheses*. Their study showed that the symptoms of mercury poisoning mirrored those of autism and concluded that early exposure to mercury from thimerosal had caused many cases of autism, while genetic and environmental factors made some children more vulnerable than others. “Once we got the paper together, we contacted the NIH, CDC and FDA,” Redwood said. “We got mixed responses. We petitioned the FDA on three occasions to take thimerosal off the market. They turned us down.”

The CDC launched its own study of thimerosal safety in vaccines in fall 1999, tasking Dr. Thomas Verstraeten to analyze the agency’s Vaccine Safety Datalink, which gathers information on vaccine safety from several health maintenance organizations. Verstraeten’s first report in February 2000 found a statistically significant risk for neurological developmental disorders at age 3 months as the amount of thimerosal that babies received increased. And he found a risk of autism 2.48 times greater for infants getting higher amounts of thimerosal in vaccines, compared to infants who received thimerosal-free vaccines. A June 2000 analysis by Verstraeten found a link between thimerosal and language, speech and developmental delays during the child’s first 6 months. Verstraeten’s initial findings were never publicly released, and SAFE MINDS

obtained copies of his reports only through Freedom of Information Act filings in 2001. For Robert Krakow, whose son is autistic, Verstraeten's findings were a bittersweet discovery. "If the Verstraeten report had been publicized, my wife would have read about it because she was up on these things and our son wouldn't have had thimerosal-containing vaccines," he said. "Why is the public not told? To protect the vaccine makers." Verstraeten left the CDC shortly after his presentation to work for vaccine maker GlaxoSmithKline in Belgium. He declined to comment for this article, citing "ongoing litigation in the U.S. regarding thimerosal."

The thimerosal issue continues to reverberate in the scientific and public health community. The Institute of Medicine (IOM), an advisory body created by the National Academies of Science, convened in fall 2001 to assess thimerosal's potential to cause autism and other neurological problems in children. The IOM's statement, after assessing Verstraeten's research and hearing testimony of scientists such as Haley and others linking autism and thimerosal, walked a fine line. It said in part: "Although the hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders is not established ... the hypothesis is biologically plausible."

In the past year, further studies of thimerosal's connection to autism have been churned out in scientific journals, primarily denying any link. A December 2002 study funded by the National Institutes of Health and published in *The Lancet* claimed thimerosal was safe for babies. An October 2003 study from Denmark also purported to disprove the thimerosal-autism link. The most recent study, published November 1 in *Pediatrics* by Thomas Verstraeten and a CDC colleague, uses the same CDC database but this time erases any connection between thimerosal and neurological damage to children.

If the CDC and FDA seemed to acknowledge the risks of thimerosal four years ago and the need to get mercury out of medical products, today the official stance is to circle the wagons against mounting public and scientific criticism about its handling of the thimerosal issue. "Rational people can think differently, but to resolve this issue they must be honest to the American people," Haley said of the regulators. "They could come out and say we've cleaned it up, we'll keep it out. But what they do is come up with cockamamie articles and fight back."

The stakes are high for the pharmaceutical industry. Eli Lilly, inventor of thimerosal, was granted protection from lawsuits by parents of autistic children under a short-lived provision slipped into the Homeland Security Act in November 2002 (see sidebar). But hundreds of lawsuits now have been filed against it and other companies, including Merck, GlaxoSmithKline, Aventis Pasteur and American Home Products, which have used thimerosal in children's vaccines. An additional 4,000 claims are pending in the federal Vaccine Injury Compensation Program. "These kids are not going to die. They are going to live 50, 60 years and the cost will be monumental," said Krakow, a New York attorney who filed a case with the vaccine compensation program on behalf of his son. "The political hurdles are the bigger problem. This is so big and gets to the heart of lots of issues, like what I call the government-pharmaceutical complex."

Thimerosal is global

Today, vaccine makers have removed thimerosal from almost all childhood vaccines or created thimerosal-free alternatives. But some still have trace amounts, such as GlaxoSmithKline's Pediatix, and its DTaP-Hepatitis B vaccine. Aventis Pasteur manufactures six vaccines for adults using thimerosal, including tetanus and flu, each with 25 micrograms of ethylmercury. Merck's Hepatitis B for adults contains 25 micrograms of ethylmercury. While the health effects of that amount of mercury for adults are unknown, limiting exposure in all forms—in foods and environmentally—should be a priority of the FDA and CDC, according to Kentucky researcher Haley. "They should be working on getting all the mercury out. Thimerosal suppresses the immune system, and if you have some elderly person who has a compromised immune system, a flu shot with thimerosal can pose a risk," Haley said. "They are saying its OK to give to Third World countries where children have compromised immune systems to begin with." (Representatives for Aventis and Merck did not respond to requests for comment on their companies' policies on thimerosal use.) But to date, neither the FDA nor the CDC has issued a clear preference for thimerosal-free vaccines. Many critics believe that is a politically defensive, not a scientifically sound one.

The Third World is the next frontier in the thimerosal debate. Eli Lilly has licensing agreements with drug companies in 40 countries that make thimerosal and market it under the trade name Merthiolate. In countries where sanitary conditions are questionable, vaccine preservatives become crucial. Single-dose vials rather than multi-dose containers have provided one solution in the United States, but in the developing world that strategy poses challenges and costs. The World Health Organization (WHO), which has a vast vaccination program, assessed the thimerosal issue in 1999, prompted by the U.S. health agencies' review. The agency echoed the U.S. position and declared in its weekly newsletter: "With the weight of public opinion against the use of mercury of any sort, WHO and other agencies has begun the process of reducing and removing [thimerosal] from vaccines." The WHO outlined a three-year plan for creating alternative preservatives and new vaccine delivery technologies with the goal of eventually eliminating mercury.

Yet in 2003, WHO abandoned this aggressive plan and issued a revised policy on thimerosal, citing its own vaccine advisory committee's decision that ethylmercury is less harmful than methylmercury, and that "there is no reason on grounds of safety to change immunization practices with [thimerosal]-containing vaccines since the benefit outweighs any risks." What happened over four years, according to Dr. Philippe Duclos, coordinator of WHO's Immunization Safety Project, was a dose of reality. "Taking thimerosal away was more tricky than originally thought," he said. "Taking it away might have created a vaccine with a lower safety profile. And the use of monodose vaccines in many places is difficult because of production capacity. Changing the capacity is a major investment, and you can't just assume things will be done correctly. It takes time."

Duclos insisted that recent research has shown risks associated with thimerosal are more

theoretical than real—and so far alternatives are elusive. “Vaccine distribution in developing countries is a tricky thing. If you use monodose, products will overload the cold chain [the process by which vaccines are maintained at between 2 and 8 degrees Celsius]. Expanding that capacity would take a tremendous amount of time and money and it becomes a matter of priorities.”

For U.S. pharmaceuticals, though, the global market for vaccines containing thimerosal is a goldmine. UNICEF, the WHO’s parent body, purchases 40 percent of all vaccines used in developing countries and Merck is its sole supplier. Merck makes Recombivax HB, a Hepatitis B vaccine that contains thimerosal.

Beyond the issue of thimerosal’s link to autism and developmental disorders lies the larger question of public trust in national vaccination programs—in the United States and the developing world, where global agencies like the WHO and its health programs can be viewed as politically suspect. The thimerosal debacle at the FDA and CDC, with its taint of conflicts of interest with big drug companies and compromised research, does more harm than good, given that the medical community’s primary directive is “First, do no harm.”

“I am a farm boy. I own a farm today. I am a person who knows the value of vaccinations,” [Haley] said. “But if the American people realize how the CDC and the vaccine boards work, they are going to lose faith, and that isn’t my doing. Its their own doing.” ■

**Annette Fuentes** is a New York-based journalist who writes frequently on health and social policy issues. A contributing editor of *In These Times*, she is co-author with Barbara Ehrenreich of *Women in the Global Factory*.

## Oppose the Bush Administration

Most of the world **opposes the administration’s** deadly plans for war, but much of America seemingly supports them. Why? Unlike the international press, American media are for the most part **unwilling to challenge the half-truths** and lies of Bush and the warhawks. Help us **counter the cowardice of the mainstream press**. Support *In These Times* by **subscribing** today.