Autism in a Needle?

The Toxic Tale of Vaccinations and Mercury Poisoning

By Annette Fuentes

Lyn Redwood and her son Will.

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.

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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 At one end is severe autism, in which children are socially withdrawn, do not speak and exhibit bizarre, repetitive, sometimes aggressive behaviors.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."

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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-Ill.) 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

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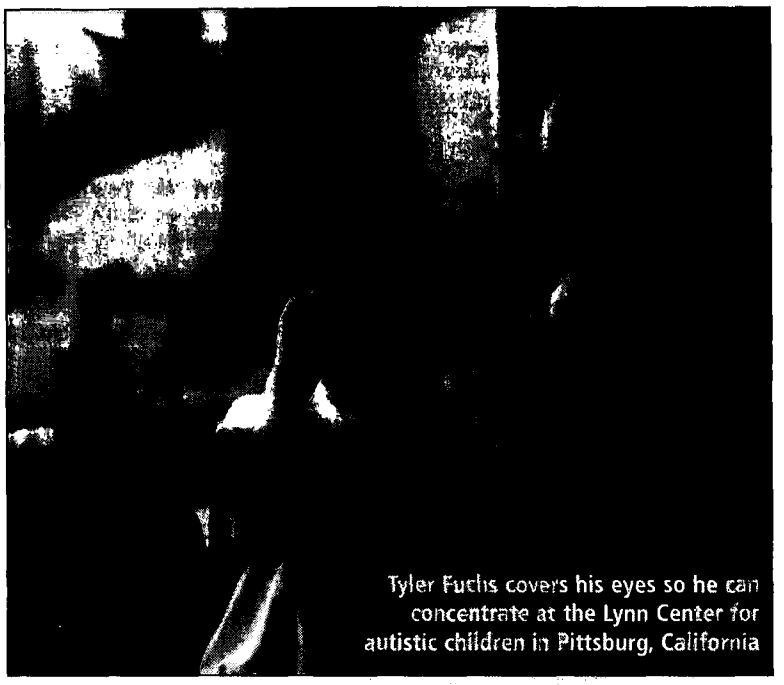
metals. "Some parents of autistic children called me and asked me to look at thimerosal. We did some experiments with human brain tissue and it was dramatic," Haley said. "It penetrates the proteins in the brain. It is toxic to neurons and enzymes." Haley co-authored an August 2003 study that showed autistic children retained more mercury in their bodies than normal children,



DAN ROSENSTRAUCH / KRT

Tyler Fuchs covers his eyes so he can concentrate at the Lynn Center for autistic children in Pittsburg, California

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."

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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

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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 Pediatrix, 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

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Eli Lilly and Thimerosal

Thimerosal is an organic compound that is 49.6 percent ethylmercury. Eli Lilly and Co., the Indianapolis-based drug giant, developed and registered thimerosal under its trade name Merthiolate in 1929 and began marketing it as an antibacterial and fungal product. It became the most widely used preservative in vaccines. Thimerosal cannot be used with live cell vaccines such as MMR (measles, mumps, rubella) or polio because it would kill the vaccine. The only research looking into the safety of thimerosal was done in 1930 by Eli Lilly-sponsored doctors who injected it into 22 patients with meningitis. The human experiments failed to prove that thimerosal was not toxic. Nonetheless, researchers H.M. Powell and W.A. Jamieson published a study in September 1931 in the *American Journal of Hygiene* that stated thimerosal had a "low order of toxicity" for humans, without mentioning that the human subjects were ill and subsequently died. Internal Lilly documents from the time, however, revealed that the company's researchers were worried about Merthiolate's burning qualities when used on the skin. By 1933, Eli Lilly's Jamieson had "the new sense of thimerosal's toxicity when he received a letter from a researcher who had injected it into dogs and saw severe local reactions, leading him to state Merthiolate is unsatisfactory as a preservative for serums intended for use on dogs."

In the 70 years since thimerosal/Merthiolate was developed, the FDA never required Eli Lilly to conduct clinical studies of its safety, despite ample evidence of its toxicity and its high allergic properties. In fact, the FDA today still refers to the 1931 Powell and Jamieson study on its web site as indication of the "safety and effectiveness" of thimerosal as a preservative. Thimerosal/Merthiolate was widely used in over-the-counter products including ointments, eye drops, nasal sprays and contact lens solutions. In 1998, the FDA finally banned thimerosal for use in OTC products—16 years after it began a safety review of mercury-containing products. It took another year before the CDC and the FDA would ask manufacturers to remove thimerosal from childhood vaccines. Eli Lilly stopped making Merthiolate-containing products in the mid-'80s but still profits from licensing agreements with pharmaceutical companies around the world.

Eli Lilly faces hundreds of lawsuits from parents who blame thimerosal for their autistic children. But the pharmaceutical giant has powerful friends in the White House and Congress. The elder George Bush sat on Lilly's board of directors in the '70s and White House Budget Director Mitch Daniels was a Lilly executive. Lilly CEO Sidney Taurel was named by President George W. Bush to the Homeland Security Advisory Council. In November 2002, Congress passed a provision, tucked into a spending measure for homeland security, to indemnify Eli Lilly from lawsuits and require families to seek compensation through the federally funded Vaccine Injury Compensation Program. It was repealed in February 2003 after public outcry. Senate Majority Leader Bill Frist (R-Tenn.) still hopes to pass a similar bill. Congressional consideration for Eli Lilly makes sense. In the 2002 election cycle, the company gave more than $1.5 million to federal candidates, with three-quarters to Republicans, making it the fourth biggest giver in the pharmaceutical industry, according to the Center for Responsive Politics. In the current election cycle, the company already has given close to $230,000 (67 percent) to Republicans, to federal candidates.

Eli Lilly may be determined to avoid liability for thimerosal, but it does not care what it has aborted children with neurological problems. This year, the FDA approved Strattera, a new Eli Lilly drug for the treatment of Attention Deficit Hyperactivity Disorder, the ailment that Eli Lilly profits from damaged children is not lost on parent Robert Krakow. "What Eli Lilly is providing Strattera for is saying it's up to 30 percent of children can be helped. You realize what we are dealing with."

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the candidates on health care

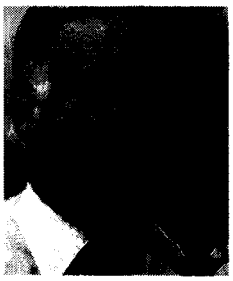
Given the long and sordid history of GOP connections to the pharmaceutical industry, health care and, especially, prescription drugs are issues Democrats usually have in their favor. This makes all the more disturbing recent Republican attempts to co-opt these issues with glossy pronouncements of working for prescription drug coverage while at the same time attaching language to the Homeland Security bill that would absolve drug conglomerates like Eli Lilly from paying damages for thimerosal litigation. Consistent as ever, Bush even awarded a contract to provide "universal health care" to 25 million Iraqis within a year while pushing tax cuts that will add to the already 44 million uninsured Americans. **—Williams Cole**

CAROL MOSELEY BRAUN

She is one of only two candidates to promote a Canada-style single-payer health plan. Moseley Braun points out that the current health-care system accounts for 15 percent of the GDP, a higher rate than any other industrialized nation, while leaving millions without health insurance. She would introduce a health proposition based on the Federal Employee Health Benefits Program that, because not employer based, would allow freelancers, small business owners and the unemployed to receive health insurance and seniors to receive prescription drug coverage. The payment system would be combined with Medicaid and Medicare in order to reduce bureaucracy and would be financed by hikes in income tax. As a senator in 1994 she fought the pharmaceutical industry-supported Product Liability Fairness Act, a bill that granted significant immunity to drug companies.

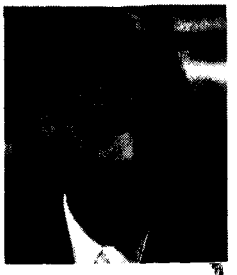
WESLEY CLARK

While encouraging in his power to debate Bush regarding the military and foreign policy, one worries that, because his domestic policies are so undeveloped, this candidate may actually be vulnerable during a debate with Dubya on health care. Nevertheless, he has identified health care as a "crisis" in the country but has invited much criticism, if not outright dismissal, from other Democratic candidates, most of whom have well-developed health-care proposals. Time to enlist some good people, General.



HOWARD DEAN

The Doctor obviously has a lead in credibility regarding health-related issues—and it seems like a record to boot: He signed into Vermont law an insurance program that gave 99 percent of children health coverage and a third of elderly residents state help with prescription drugs. He also is the only candidate to release a comprehensive plan on prescription drugs, including supporting legalizing drug re-importation from Canada; banning direct ads from drug companies, which have climbed from $55 million to $2 billion in the last 12 years; creating a national law that forces physicians to disclose gifts from the pharmaceutical industry; and expanding the list of preferred drug lists that would lead physicians to cheaper yet effective drugs and allow states more flexibility in controlling drug costs. He's also a founder of the Business for Affordable Medicine coalition. But his high profile on medical issues also has invited criticism from other candidates who point out his alignment with Newt Gingrich in 1995 criticizing Medicare and his 2002 attempt to eliminate a prescription drug program in Vermont.



JOHN EDWARDS

The southern senator shines among politicians in his battles with pharmaceutical conglomerates and has called the lobbying power of the drug industry "a scary thing to see up close." His successful record as a trial lawyer winning suits against HMOs and the pharmaceutical industry compelled him to fight Republican efforts to absolve litigation against drug companies like Eli Lilly. He said he wants to make health care coverage a "birthright" and has co-sponsored a Patient's Bill of Rights. In June he unveiled a proposal to reduce prescription drug costs. His crusade even earned him the nickname, at least in the *Irish Times*, the "Erin Brockovich of Capitol Hill." He reported small investments in pharmaceutical and health-care company stocks.

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