In Our Vaccines

INVESTIGATING MERCURY, THIMEROSAL, AND NEURODEVELOPMENTAL DELAY

BY LYN REDWOOD

More than 60 years ago, the Food and Drug Administration (FDA) approved a little-known product, thimerosal, to be used as a preservative. Today, many parents question whether this product is responsible for the current epidemic of children diagnosed with learning disabilities and autism.

Thimerosal

Current thinking suggests that exposure to mercury comes primarily from environmental and dietary sources, dental amalgams, and rare catastrophic events. Recently, however, another common and pervasive source of mercury exposure has been identified. Called thimerosal, it was first approved as an additive by the FDA in the 1930s and has been utilized as a preservative to prevent bacterial contamination in a number of blood and biological products, including vaccines, immune globulins, and over-the-counter eye and nose drops.

The danger thimerosal presents is that it contains 49.5 percent ethyl mercury by weight. Mercury is a potent human toxicant and has long been the source of numerous serious health problems. It is especially toxic to the rapidly developing fetal and infant brain. Federal agencies have published acceptable levels for exposure; but in actual fact, mercury is a poison at any level.

Chemically, thimerosal is a water-soluble, cream-colored crystalline powder. In the human body it is metabolized to ethyl mercury and thiosalicylate. The literature on thimerosal metabolism and excretion is old, and toxicological information is limited. In the past there have been case reports of toxicity and death following inadvertent massive exposures to thimerosal.

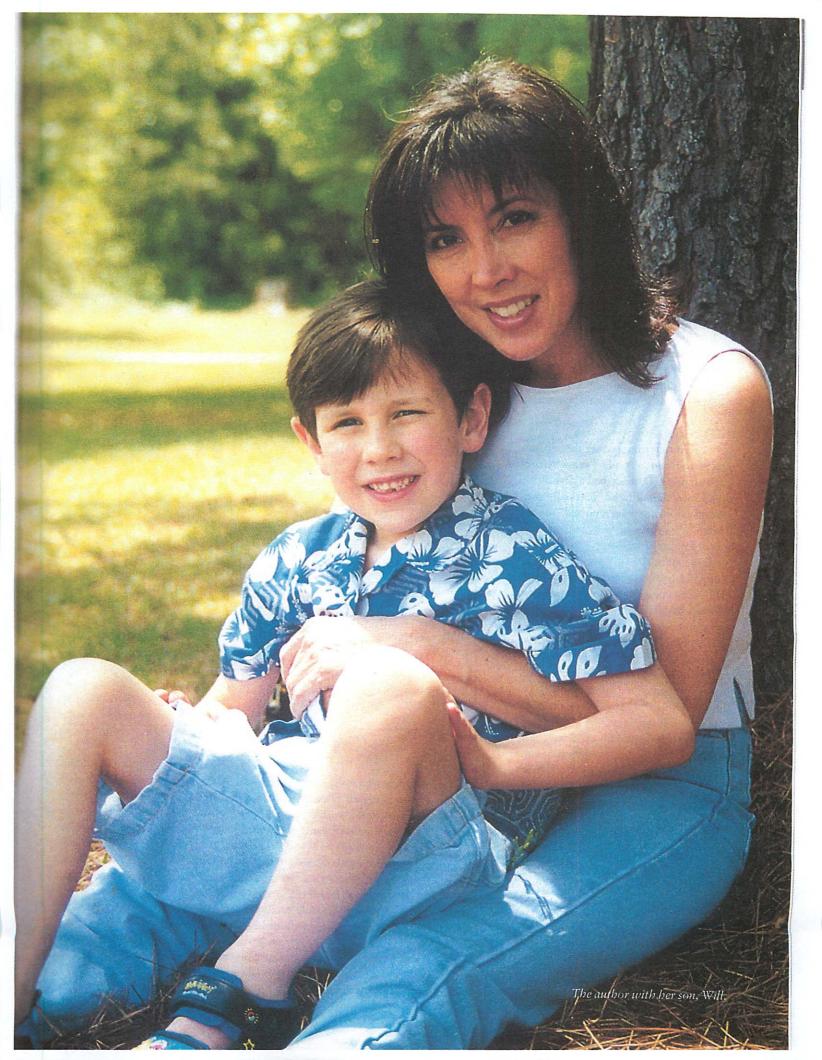
The FDA's Discovery

The FDA Modernization Act, signed into law in 1997, included an amendment requiring the agency to compile a list of drugs and foods that contain intentionally introduced mercury compounds and to provide a quantitative and qualitative analysis of the mercury compounds on the list. One may ask why the FDA did not routinely perform this task. The FDA's mission is to

ensure purity, safety, potency, and efficacy of individual products, yet such analyses have never been a required part of the permitting process. In its review, which took two years to complete, the FDA discovered that infants who receive vaccines containing thimerosal may be exposed to more mercury than recommended by federal guidelines for total mercury exposure.

Infant vaccines that routinely contained thimerosal were DPT (diphtheria-pertussis-tetanus), hepatitis B, and Hib (*Hemophilus influenzae* type b). Following the vaccination schedule recommended by the Centers for Disease Control (CDC), infants were exposed to anywhere from 0.0 to 187.5 mcg of ethyl mercury, depending on the vaccine manufacturer, and total exposure over 18 months could be as high as 237.5 mcg. The dose the Environmental Protection Agency (EPA) deems allowable is 0.1 mcg per kilogram per day. If an average five-kilogram (11-pound) infant received all thimerosal-containing vaccines at a two-month visit, his or her exposure that day would be 62.5 mcg ethyl mercury —125 times the EPA guideline.

In its analysis, the FDA multiplied EPA's daily exposure levels of 0.1 mcg per kilogram by 180 days, even though the exposures had occurred on only four days during this time period. It is perplexing that the FDA chose to average an infant's total exposure to mercury over the first six months of life, as though children were being exposed on a daily basis, and reported that amounts were only slightly above one of the federal guidelines. According to toxicologists, because of the inherent pharmacokinetics of mercury and its long half-life in the body, the effect of a large injected dose cannot be calculated as though it were ingested in small amounts over a longer period of time. This method of analysis inaccurately minimizes the levels of exposure. If one were to look at the mercury in thimerosal from a



daily dose perspective, no one vaccine containing thimerosal would meet the EPA's safety guidelines. A simple analogy can be made that since one may safely consume four Tylenol a day in six-hour intervals for a month, consuming 120 Tylenol in one day would be equally safe. (In fact, it would be a fatal dose.)

At the same time the FDA findings were released, the American Academy of Pediatrics (AAP) published an interim report to physicians on thimerosal in vaccines. In the report, the AAP and Public Health Service agreed that the use of thimerosal-containing vaccines should be reduced or eliminated, stating that any potential risk was of concern.¹ While this report discussed much of the uncertainty regarding the potential effect of mercury exposure in vaccines, it clearly stated that there was no evidence of harm having occurred from such exposure. The report also said, "Infants and children who have received thimerosal-containing vaccines do not need to have blood, urine, or hair tested for mercury since the concentrations would be quite low and would not require treatment." Without such tests, of course, it was impossible to know that there was no "evidence of harm."

exposed populations suggests that intermittent large exposures may pose more risk than daily small exposures. One study investigated children who had suffered prenatal exposure to intermittent bolus doses of methyl mercury (found in fish) via the mothers' diets. The exposure level was thought to be safe at the time. However, when evaluated years later, the children were found to have lower scores on memory, attention, language, and motor function tests.³

In a recent investigation, mercury levels were obtained before and after exposure to 12.5 mcg of ethyl mercury in hepatitis B vaccine in 15 preterm and 5 term infants. There were no differences between the two groups with respect to mean prevaccination levels, although postvaccination mercury levels were significantly increased in both groups of infants. Postvaccination levels in preterm infants were three times higher than those of term infants, a difference that was statistically significant. One preterm infant developed a postvaccinal mercury level of 23.6 mcg per liter, which falls within the range known to result in neurodevelopmental dysfunction.

Historical Perspective

It is interesting to note that thimerosal was introduced only a few years before Leo Kanner, MD, described a new mental disorder that differed "markedly and uniquely from anything reported" previously.² In its early history, autism was diagnosed more frequently in affluent families, but by the 1970s it had become more evenly distributed socioeconomically. This apparent widening in demographics paralleled the rising availability of vaccines to all children through federally sponsored programs.

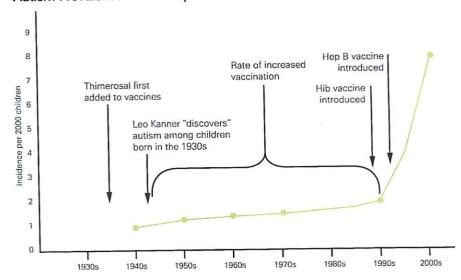
The 1980s and especially the 1990s saw a tremendous rise in the occurrence of autism spectrum disorders (ASD). In the late 1980s and early 1990s, the vaccine schedule was amended to include both hepatitis B and Hib vaccines, each administered to infants three times during the first six months of life. Their addition to the vaccine schedule potentially tripled infants' exposure to mercury, should they receive all thimerosalcontaining vaccines. Another concern is that these vaccine exposures occur on top of prenatal exposures from immune globulin preparations (routinely administered during pregnancy to Rh- mothers) and from dietary, dental, and environmental exposures.

Current Investigations

Recent information from large epidemiological studies conducted in mercury-

Thimerosal in Vaccines Implicated in Autism

Autism Prevalence and the Spread of Thimerosal Vaccines



CITATIONS FOR TIMELINE CHART

- Thimerosal first introduced into vaccines: W. M. Egan, "Thimerosal in Vaccines." Presentation to the FDA, September 14, 1999.
- Leo Kanner "discovers" autism among children born in the 1930s: L. Kanner, "Autistic Disturbances of Affective Contact," The Nervous Child 2, no. 3 (1942–1943): 217–250.
- 3. Average prevalence of autism in studies conducted prior to 1970 is 1 in 2,000; for studies after 1970, the rate is 1 in 1,000: C. Gilberg and L. Wing, "Autism: Not an Extremely Rare Disorder," *Acta Psychiatr Scand* 99, no. 6 (1999): 399–406.
- Rate of autism reported for 1994–1995: M. Bristol, D. Cohen, E. Costello, et al. "State
 of the Science in Autism: Report to the National Institutes of Health," J. Autism Dev.
 Disord. 26, no. 2 (1996): 121–157.
- Rate of autism reported for 1998: Centers for Disease Control and Prevention, "Prevalence of Autism in Brick Township, New Jersey, 1998: Community Report," www.cdc.gov/ncbdd/dd/report.htm.

At the June 21, 2000, meeting of the Advisory Committee for Immunization Practices, held in Atlanta, Thomas Verstraeten of the National Immunization Program presented a review of Vaccine Safety Datalink information on thimerosal-containing vaccines. Over 400,000 children participated in the Vaccine Safety Datalink program. From this database, 100,000 charts were reviewed to determine exposure to thimerosal-containing vaccines and specific neurodevelopmental outcomes. Statistically significant associations were found between cumulative exposure to thimerosal-containing vaccines at two months of age and unspecified developmental delay; three months of age and tics; six months of age and attention deficit disorder; one, three, and six months of age and speech and language delay and neurodevelopmental delays in general.

According to a report in the Weekly Epidemiology Record that reviewed the use of thimerosal as a vaccine preservative, "This safety assessment cannot currently exclude the possibility of subtle neurodevelopmental abnormalities in infants from a cumulative exposure to thimerosal in vaccines."

What Next?

A paucity of data exists on the metabolism, excretion, and toxicity of ethyl mercury; the levels of risk to the fetus from maternal exposures and to the infant from exposure during critical windows of neurological development; and the effect of large intermittent bolus exposures to ethyl mercury compared to daily low-dose oral exposures to methyl mercury. These concerns are being addressed in investigations by governmental and private agencies.

There appears to be no general consensus as to how best to diagnose and treat elevated mercury levels in children. The effectiveness of chelating agents in crossing the blood-brain barrier has become a topic of scrutiny, along with the possibility of treating a long-standing exposure that occurred during a critical time in development. At a recent conference, a number of physicians who specialize in the treatment of autism and developmental disorders reported finding many children with elevated mercury levels who had remarkable improvement in behaviors, speech, and cognition when treated with a program to reduce oxidative stress and metal body burden.⁸

What to Do

Despite this information, the FDA has only "encouraged" vaccine manufacturers to reduce or eliminate thimerosal. Until there is more research assuring its safe use in infants, it would only be prudent to give preference to all thimerosal-free vaccines. Writing about thimerosal, Neal Halsey of the Johns Hopkins University Institute for Vaccine Safety stated, "We can say there is no evidence of harm, but the truth is no one has looked."

Numerous vaccine products containing thimerosal are still on the market. Both the general public and healthcare providers need to be aware of the availability of vaccine products with and without thimerosal. Parents research the safest carseats and toys for their children but don't realize they need to research vaccines as well. Thimerosal has been eliminated from latex paints, Merthiolate, and many other products because of its serious toxic effects on infants. Although the FDA has focused on thimerosal in only infant vaccines at this time, all vaccines that contain this product should come under scrutiny in the near future.

NOTES

- American Academy of Pediatrics, "Thimerosal in Vaccines: An Interim Report to Clinicians," www.aap.org/new/thimpublic.htm, accessed October 18, 1999.
- 2. L. Kanner, "Autistic Disturbances of Affective Contact," *The Nervous Child* 2, no. 3 (1942–1943): 217–250.
- 3. P. Grandjean, et al., "Cognitive Performance of Children Prenatally Exposed to 'Safe' Levels of Methylmercury," *Environ. Res.* 77 (1998): 165–172.
- 4. G. Stajich, et al., "latrogenic Exposure to Mercury after Hepatitis B Vaccination in Preterm Infants," *J. Pediatrics* 136, no. 5 (2000): 679–681.
- 5. P. Grandjean, et al., "Methylmercury: Significance of Intrauterine and Postnatal Exposures," Clin. Chem. 40, no. 7 (1994): 1395–1400.
- 6. P. Stehr-Green, "Review of Vaccine Safety Datalink Information on Thimerosal-Containing Vaccines," presentation to the Advisory Committee on Immunization Practices, June 7–8, 2000.
- 7. "Thimerosal as a Vaccine Preservative," Wkly. Epi. Rec. 75, no. 2 (2000): 12–16.
- Defeat Autism Now conference, Boston, spring 2002.
- 9. "Uproar Over a Little-Known Preservative, Thimerosal, Jostles US Hepatitis B Vaccination Policy," *Hep. Control Rep.* 4, no. 2 (Summer 1999).

FOR MORE INFORMATION

Books

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McCandless, Jaquelyn, MD. Children with Starving Brains: A Medical Treatment Guide for Autism Spectrum Disorder. Bramble Company, 2002.

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Seroussi, Karyn. Unraveling the Mystery of Autism and Pervasive Developmental Disorder: A Mother's Story of Research & Recovery. Simon & Schuster, 2000.

Waites, Junee and Helen Swinbourne. Smiling at Shadows: A Mother's Journey Raising an Autistic Child. Ulysses Press, 2002.

Websites

www.autismresearchinstitute.com www.autism-mercury.com www.canfoundation.org www.safeminds.org www.909shot.com www.vaccinesafety.edu/thi-tale.html

For additional information on autism, see the following articles in past issues of *Mothering:* "Show Us the Science," no. 105, and "Promising Approaches," no. 100.

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