Tobacco Science and the Thimerosal Scandal

Mounting evidence suggests that thimerosal, a preservative in many children's vaccines that breaks down to release neurotoxic ethyl mercury, may be responsible for the exponential growth of autism, attention deficit disorder (ADD), hyperactivity (ADHD), speech and language delays, and other childhood neurological disorders now epidemic in the United States.[1] It is undisputed that exposure to mercury in infancy reduces a child's intelligence, with boys suffering the most dramatic injury (testosterone tends to amplify mercury's damage, while estrogen seems to moderate it).[2] Some scientists believe that thimerosal in children's inoculations may even be the cause of the 100-point loss in scholastic aptitude scores among children born in the "Thimerosal Generation" (between 1989 and 2003). Critics also fret about a possible link between thimerosal-laced vaccines and the new epidemic of sudden infant death syndrome[3], asthma, and juvenile diabetes[4].

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[1] Immunization Safety Review, Thimerosal-Containing Vaccines and Neurodevelopmental Disorder, IOM 2001, pp. 31-37 viewed at: http://www.nap.edu/books/0309076366/html/ and Autism A.L.A.R.M. by the AAP and CDC http://www.medicalhomeinfo.org/screening/Autism%20downloads/AutismAlarm.pdf.

[2] Robert F. Kennedy, Jr. Telephone Interview with Boyd Haley, April 9, 2005. *See also* Leo Trasande, Public health and economic consequences of methyl mercury toxicity to the developing brain, Environ Health Perspect 113:590-596 (2005) (*The research found the IQ losses linked to mercury range from one-fifth of an IQ point to as much as 24 points. The study showed about 4 percent of babies, or about 180,000, are born each year with blood mercury levels between 7.13 and 15 micrograms per liter. That level of mercury, the researchers concluded, causes a loss of 1.6 IQ points. The study found that between 316,588 and 637,233 children each year have cord blood mercury levels > 5.8 µg/L, a level associated with loss of IQ. The resulting loss of intelligence causes diminished economic productivity that persists over the entire lifetime of these children. This lost productivity amounts to $8.7 billion annually (range, $2.2-43.8 billion; all costs are in 2000 US$*). *See also* Grandjean P, Cognitive deficit in 7-year-old children with prenatal exposure to methylmercury, Neurotoxicol Teratol. 19(6):417-28 (1997) (*"[m]ercury-related neuropsychological dysfunctions were most pronounced in the domains of language, attention, and memory, and to a lesser extent in visuospatial and motor functions. The effects on brain function associated with prenatal methylmercury exposure therefore appear widespread, and early dysfunction is detectable at exposure levels currently considered safe"*). S*ee also,* CBS News, *Study: IQ Loss From Mercury Costly*, March 1, 2005. Accessed online June 15, 2005 at http://www.cbsnews.com/stories/2005/03/01/health/main677206.shtml.

[3] John Hanchette and Sunny Kaplan, "Vaccination Nation: Children On The Frontline," Gannet News Service, 1998. (Hundreds of infant deaths originally diagnosed as SIDS have been determined by federal vaccine courts to be vaccine related.)

[4] Mark Benjamin, UPI, "The Vaccine Conflict," Washington Free Press, #67 Jan/Feb 2004. Accessed online June 15, 2005 at http://www.washingtonfreepress.org/67/theVaccineConflict.htm.

Thimerosal: History

Thimerosal has been used in vaccines since the 1930s, and internal company documents indicate that the pharmaceutical industry was always aware of the chemical's potential danger.[5] The Eli Lilly Company, which first developed and manufactured thimerosal and owned the patent, knew from the start that thimerosal was unsafe—its testing consisted of administering the serum to 22 terminal meningitis patients, all of whom died within weeks of being injected—a fact not reported in Lilly's study. For decades, Lilly portrayed this incident as proof of thimerosal's safety.[6]

As early as July 1935, Lilly was warned by the Director of Biological Laboratories at the Pitman-Moore Company that Lilly's claims about thimerosal's safety "did not check with ours." Pitman warned that half the dogs it had injected with thimerosal-containing vaccines became

[5] *See* Interoffice Memo from Charles J. Lynn of Eli Lilly, to Mr. Rhodehamel, Director of Lilly's Research Department, April 24, 1930. (*In this internal memo Mr. Lynn warns that Lilly's new thimerosal (merthiolate) jellies and ointments were too strong and that an existing thimerosal solution that contained 2 to 4 times LESS mercury was already causing complaints. Mr. Lynn states "Our experience with the solution ought to serve as a warning and certainly in the face of that warning we ought not to advocate the use of the stronger products without some pretty definite evidence that we will not repeat our solution experience."*)

[6] Smithburn KC, Kempf GF, Serfas, Gilman LH. Meningococcic meningitis – a clinical study of one hundred and forty-four epidemic cases. JAMA 1930;95:776-80. Powell HM, Jamieson WA. Merthiolate as a germicide. Am J Hyg 1931;13:296-310. Lilly's study concluded: "These large doses did not produce any anaphylactoid or shock symptoms. Neither did these quantities in the repeated doses bring about any demonstrable later toxic effects. The toleration of such intravenous doses indicates a very low order of toxicity of [thimerosal] for man."

It is important to keep in mind the following factors that were not even mentioned or considered in Lilly's study: (1) The 22 patients that were administered thimerosal (merthiolate) were all sick with meningitis at the time, so that it is not clear whether any adverse effects induced by the administration of thimerosal were the result of the ongoing infection or the treatment; (2) Approximately 1/3rd of the 22 patients reported on were only followed-up for one day following treatment, and among all 22 patients examined the maximum numbers of days of follow-up was only 62 days, so it would have been difficult to discern the acute adverse effects of thimerosal, let alone chronic conditions that developed over several months.

sick and concluded, "[T]himerosal is unsatisfactory as a serum intended for use on dogs."[7] When thimerosal was used by the army in the 1940s and 1950s (in vaccines), Lilly was required by the Defense Department to label the preservative "Poison."[8] It was well established by the 1940s in peer-reviewed scientific and medical literature that injecting thimerosal into sensitive individuals could cause serious injury.[9]

In May of 1967, a study published in Applied Microbiology found that Lilly's thimerosal killed mice when it was added to injectable vaccines.[10] Four years later, in 1971, Lilly's own tests found that thimerosal was "toxic to tissue cells" in concentrations of less than 1 in 1,000,000.[11] Typical vaccine concentrations are 1 in 10,000, one hundred times the levels that Lilly knew to be dangerous. Yet Lilly continued to promote thimerosal in vaccines as "non-toxic when injected."[12]

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[7] Letter of July 22, 1935 from Director, Biological Laboratories of Pitman-Moore Company to W.A. Jamieson, Director, Biological Division, Eli Lilly & Company. Subcommittee on Human Rights and Wellness, Government Reform Committee. Mercury in Medicine Report, Washington, D.C. Congressional Record, May 21, 2003: E1011-30.

[8] *See* Internal Lilly Memo from J. F. Crooks, September 24, 1942, on file with author.

[9] *See* Ellis FA. The sensitizing factor in merthiolate. J Allergy 1947;18:212-13. (*"…it may be dangerous to inject a serum containing merthiolate into a patient sensitive to merthiolate."*) *See also* Warkany J, Hubbard DM. Acrodynia and Mercury. J Pediatr 1953;42:365-386. (*Thimerosal-containing vaccines cause acrodynia [mercury poisoning] in infants and young children.) See also* Engley FB. Mercurials as disinfectants. Soap and Chemical Specialties 1956;200-5, 223-5. *(Thimerosal was more toxic than other mercurials in medical/scientific use such as mercurochrome, phenylmercuric nitrate, mercuric chloride, mercresin, and mercuric cyanide.)*; *See also* Davisson EO, Powell HM, MacFarlane JO, Godgson R, Stone RL, Culberston CG. The preservation of poliomyelitis vaccine with stabilized merthiolate. J Lab Clin Med 1956;47:8-19. *(Thimerosal broke down into toxic ethyl mercury.) See also* Davisson et al. from Lilly Research Laboratories, Indianapolis, Indiana published (1956) *(Thimerosal broke down into toxic ethyl mercury.)*

[10] E. A. Nelson and R. Y. Gottshall, "Enhanced Toxicity for Mice of Pertussis Vaccines When Preserved with Merthiolate," Applied Microbiology, May 1967, p. 590-593 *("Pertussis vaccines preserved with 0.01% Merthiolate are more toxic for mice than unpreserved vaccines prepared from the same parent concentrate and containing the same number of organisms. An increase in mortality was observed when Merthiolate was injected separately, before or after an unpreserved saline suspension of pertussis vaccine.")*

[11] *See* Eli Lilly memo from J.W. Smith to Dr. M. Michael Sigel. September 7, 1971. Document on file with author. *(J.W. Smith, Ph.D., the head of the Biological Regulatory Requirements Department, stated that "merthiolate must be in the concentration of less than 1/1,000,000 in order not to be toxic to the tissue cells.")*

[12] *See e.g.* Dental Information/Alt Corp.,"Eli Lilly Documents Reveal Dangers of Thimerosal." Accessed online June 15, 2005 at: http://www.altcorp.com/DentalInformation/thimelililly.htm#Waters%20&%20Kraus. *(A 1964 label from a bottle of Thimerosal First Aid Treatment, reads "First Aid Treatment, Merthiolate (Thimerosal), Helps*

When on April 27, 1976, Rexall, which sold thimerosal under license from Lilly, asked Lilly's permission to add a toxicity warning to thimerosal labels, Lilly ordered Rexall not to add the warning and purposely misstated the potential hazards of a product it knew to be toxic: "the mercury in the product is organically bound ethyl mercury and has a completely non-toxic nature."

The first known cases of autism were diagnosed in 1943 in children born in the first months after Eli Lilly began adding mercury to baby vaccines in 1931. Leo Kanner, who first described and named the disease based upon his encounters with 11 autistic children, was one of the fathers of American psychiatry. He described the disease as "a behavior pattern not known to me or anyone else heretofore."[13]

In 1982, the FDA proposed a ban on over-the-counter products that contained thimerosal (like mercurochrome and merthiolate) because of the chemicals' demonstrated toxicity to animal fetuses and humans.[14] (The ban did not go into effect until October 19, 1998.)[15] In 1977, five years earlier, topical thimerosal killed 10 babies at a Toronto hospital when it was dabbed on

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to keep minor cuts wounds free from infection, keep a bottle handy at Home, and at Work, in your Car, and with Camping Equipment, provides all these essential antiseptic qualities: nonirritating to body tissues, compatible with body tissues and fluids, and Nontoxic.")

[13] "Autistic Disturbances of Affective Contact," Nervous Child 2 (1943): 217-250. Reprinted in Childhood Psychosis: Initial Studies and New Insights, ed. Leo Kanner (Washington, D.C.: V. H. Winston, 1973). *See also* Dan Olmsted, "The Age of Autism: The Amish anomaly," April 18, 2005. Accessed online June 15, 2005 at: http://www.washtimes.com/upi-breaking/20050321-115921-9566r.htm.

[14] Department of Health and Human Services, Proposed Rules, CFR Part 333 Docket No. 75N-0183, "Mercury-Containing Drug Products for Topical Antimicrobial Over-the-Counter Human Use; Establishment of a Monograph," Jan. 5, 1982. *(The summary for the proposed rule reads: "The Food and Drug Administration (FDA) is issuing an advance notice of a proposed rulemaking that would classify over-the-counter (OTC) mercury-containing drugs for topical antimicrobial use as not generally recognized as safe and effective and as being misbranded.")*

[15] Federal Register/Vol. 63, No. 77, pgs. 19799-19802, at http://www.fda.gov/ohrms/dockets/98fr/042298a.pdf.

their umbilical cords as a disinfectant.[16] In 1991, thimerosal was banned for use in injections for animals.[17] By then, the peer-reviewed studies demonstrating thimerosal's devastating toxicity to children, adults and animals could have filled a small library.[18] Astonishingly, that same year, America's public health authorities, in consultation with the pharmaceutical companies, mandated that infants be injected with a series of thimerosal-laced vaccines beginning on the day of birth.[19]

New Innoculations for American Children

[16] Fagan DG, Pritchard JS, Clarkson TW, Greenwood MR, "Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic," *Arch Dis Child*. 1977 Dec;52(12):962-4.

[17] Andrea Rock, "Toxic Tipping Point: Are the CDC, the FDA, and other health agencies covering up evidence that a mercury preservative in children's vaccines caused a rise in autism?," March/April, 2004. Accessed online June 15, 2005 at http://www.motherjones.com/news/feature/2004/03/02_354.html

[18] In 1974, an FDA panel found that Thimerosal was unsafe for human use. The panel cited a number of studies demonstrating the highly allergenic nature of Thimerosal and related organic mercury products. For instance, they cited a Swedish study that showed that 26 percent of medical students had hypersensitivity to Thimerosal. Interestingly, the study also found Thimerosal to be an ineffective disinfectant. "The Panel concludes that Thimerosal is not safe for over-the-counter topical use because of its potential for cell damage of applied to broken skin, and its allergy potential. It is not effective as a topical antimicrobial because its bacteriostatic action can be reversed." Subcommittee on Human Rights and Wellness, Government Reform Committee. Mercury in Medicine Report. Washington, DC: Congressional Record, May 21, 2003:E1011-30. *See also* Forstrom L, et al, Merthiolate Hypersensitivity and Vaccination. Contact Dermatitis 1980;6:241-245. *("…reactions can be expected in such a high percentage of Merthiolate (Thimerosal)-sensitive persons that Merthiolate in vaccines should be replaced by another antibacterial agent.") See also* Kravchenko AT, et al, Evaluation of the Toxic Action of Prophylactic and Therapeutic Preparations on Cell Cultures Paper III: The Detection of Toxic Properties in Medical Biological Preparations by the Degree of Cell Damage in the L-132 Continuous Cell-Line. Zh Mikrobiol Epidemiol Immunobiol 1983;3:87-92. (*"Thus Thimerosal, commonly used as a preservative, has been found not only to render its primary toxic effect, but also is capable of changing the properties of cells. This fact suggests that the use of Thimerosal for the preservation of medical biological preparations, especially those intended for children, is inadmissible.") See also* Mercury poisoning in child treated with aqueous merthiolate. MD State Med J 1983;32:523. *("Administration of aqueous Merthiolate (Thimerosal) resulted in a child dying from mercury toxicity.") See also* Winship KA. Organic Mercury Compounds and Their Toxicity. Adv Drug React Ac Pois Rev 1986;3:141-180. *("Thimerosal may present problems occasionally in practice. It is, therefore, now accepted that multi-dose injection preparations are undesirable and that preservatives should not be present in unit-dose preparations.")* Cox NH, Forsyth A. Thiomersal Allergy and Vaccination Reactions. Contact Dermatitis 1988;18:229-233. *(Severe reactions to Thimerosal demonstrate a need for vaccines with an alternative preservative.)* Nascimento LO, Lorenzi Filho G, Rocha Ados S. Lethal mercury poisoning due to ingestion of merthiolate. Rev Hosp Clin Fac Med Sao Paulo 1990;45:216-8. (*"A case of mercurial poisoning caused by ingestion of Thimerosal found in local antiseptic solutions. The clinical picture consisted of grave neurological symptoms which could not be reversed.")*

[19] *Vaccines Timeline*, Centers for Disease Control and Prevention, National Immunization Program (2005). Accessed online June 15, 2005 at http://www.cdc.gov/nip/vaccine/vacc-timeline.htm

Prior to 1989, American preschoolers generally received only three vaccinations, given in up to eleven injections: diphtheria, polio, and MMR (mumps/measles/rubella). In the early 1990's, public health officials dramatically increased the number of thimerosal-containing vaccinations, including hepatitis B, DTaP (diphtheria, tetanus, pertussis) and Hib (Haemophilus b), without considering the cumulative impact of the mercury load on developing brains.[20] Federal officials instituted a requirement for a hepatitis B vaccination within 24 hours of birth when a child's brain is most susceptible to toxic effects.[21] According to Professor Dr. Boyd Haley, the chair of the Department of Chemistry at the University of Kentucky and one of the world's leading authorities on mercury toxicity, an infant receiving the hepatitis B inoculation would have to weigh 275 pounds to bear its mercury loading at EPA's safety standards. (Haley argues that the Hep B vaccine in particular is completely unnecessary at that age since the disease is spread primarily by dirty needles and unsafe sex.)[22] Prior to 2004, babies, even premature low-birth weight ones, received thimerosal within hours of birth.[23] Altogether, before the age of two,

[20] Lyn Redwood, "Poison In Our Vaccines: Investigating Mercury, Thimerosal, and Neurodevelopmental Delay," Mothering Magazine, Novermer/December 2002, Issue 115. Accessed online June 15, 2005 at http://www.mothering.com/articles/growing_child/vaccines/poison.html

[21] Recommended Childhood and Adolescent Immunization Schedule United States 2005, Centers for Disease Control and Prevention, National Immunization Program (2005). Accessed online June 15, 2005 at http://www.cdc.gov/nip/recs/child-schedule.PDF. *See also* Past Childhood Immunization Schedules available at http://www.cdc.gov/nip/publications/MMWRPubs.htm#Book%203.

[22] Robert F. Kennedy Jr. Telephone Interview with Boyd Haley, April 9, 2005.

[23] Centers for Disease Control and Prevention, National Immunization Program, "Implementation Guidance for Immunization Grantees during the Transition Period to Vaccines without Thimerosal," July 14, 1999 ("*…infants should continue to receive hepatitis B immunoprophylaxis as currently recommended and should receive hepatitis B vaccines as indicated. Currently, no Thimerosal-free hepatitis B vaccines are licensed for use at birth.*") http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/thimerosal-guidance.htm *See also* Patti White, Registered Nurse, Testimony To the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the Committee on Government Reform, U.S. House of Representatives, Hepatitis B Vaccine Hearings, School Nurse Perspective, May 17, 1999. *And See* Mark Sircus, "Multiple Causes of Autism Spectrum Disorders," Accessed online June 15, 2005 at http://www.mercuryexposure.org/index.php?article_id=165. *("Until recently this injection, given within the first 24 hours of life, contained 25 micrograms of Thimerosal, and still does in most parts of the world.")*

American children receive at least 20 vaccine injections to protect against twelve infectious diseases. By the time they reach first grade, they will have had at least 24 vaccinations.[24]

In a 1991 memo, recently obtained by plaintiffs' lawyers in lawsuits against the pharmaceutical industry, Dr. Maurice Hilleman, one of the fathers of Merck's vaccination programs, warned Dr. Gordon Douglas, President of the company's vaccination division, that six-month-old children administered the shots on schedule would suffer mercury exposures 87 times the existing safety standards. He recommended that thimerosal use be discontinued, "especially where use in infants and young children is anticipated."[25] Hilleman commented that the U.S. Food and Drug Administration, which has a notoriously close relationship with the pharmaceutical industry, could not be counted on to take appropriate action as its European counterpart had. (Europe and Japan were moving quickly to ban thimerosal—Russia banned it 20 years ago.)[26] Hilleman also noted that the drug industry knew of non-toxic alternatives to thimerosal and that "it is worthy of consideration to find another acceptable preservative." While this was the best solution, Hilleman noted that "the costs…may be prohibitive."[27] Apparently, due to the primacy of this cost consideration, Merck ignored Hilleman's warning and for eight years government officials added seven additional shots for children containing thimerosal, bringing the total to 24.

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[24] Centers for Disease Control and Prevention, "Recommended Childhood and Adolescent Immunization Schedule United States, 2005." Accessed online June 15, 2005 at http://www.cdc.gov/nip/recs/child-schedule.PDF.

[25] Merck Memo from Dr. Maurice Hilleman to Dr. Gordon Douglas, "Vaccine Task Force Assignment Thimerosal (Merthiolate) Preservative – Problems, Analysis, Suggestions for Resolution." March 27, 1991. *Los Angeles Times*, February 8, 2005. Accessed online June 15, 2005 at http://www.nomercury.org/science/documents/LATimes-Merck_Memo_2-8-05.pdf.

[26] According to http://nomercury.org/science.htm, Russia, Japan, Switzerland, Sweden, Denmark and Norway have banned thimerosal. Also, as of September 2004, the UK has stopped using thimerosal-containing vaccines.

[27] Merck Memo from Dr. Maurice Hilleman to Dr. Gordon Douglas, "Vaccine Task Force Assignment Thimerosal (Merthiolate) Preservative – Problems, Analysis, Suggestions for Resolution." March 27, 1991. *Los Angeles Times*, February 8, 2005. Accessed online June 15, 2005 at http://www.nomercury.org/science/documents/LATimes-Merck_Memo_2-8-05.pdf.

The ethyl mercury released from thimerosal is a known brain poison and autism rates began rising dramatically in children who were administered the new vaccine regimens. A decade ago, the American Academy of Pediatrics (AAP) estimated the autism rate among American children to be 1 in 2,500. Today, both AAP and the Centers for Disease Control and Prevention (CDC) place the autism rate at an astonishing 1 in 166, or one in 80 boys! Additionally, one in every six children is now diagnosed with a related neurological disorder.[28]

In May of 1999, Patti White, R.N., submitted her testimony to the Government Reform Committee, giving the school nurse's perspective on the growing epidemic. "The elementary grades are overwhelmed with children who have symptoms of neurological and/or immune system damage: epilepsy, seizure disorders, various kinds of palsies, autism, mental retardation, learning disabilities, juvenile-onset diabetes, asthma, vision/hearing loss, and a multitude of new conduct/behavior disorders. We (school nurses) have come to believe the hepatitis B vaccine is an assault on a newborn's developing neurological and immune system. Vaccines are supposed to be making us healthier; however, in twenty-five years of nursing I have never seen so many damaged, sick kids. Something very, very wrong is happening to our children."[29]

There are now 1.5 million autistics in the United States with 40,000 new cases each year. The cost of caring for an autistic child is estimated conservatively at $40,000 to $70,000 annually.[30] Families with children with autism and other neurological diseases have filed over 6,900 claims

[28] American Academy of Pediatrics & CDC's National Center on Birth Defects and Developmental Disabilities. 2004. Autism A.L.A.R.M. Accessed online June 15, 2005 at http://www.nomercury.org/science/documents/autism_alarm.pdf.
[29] Patti White, Registered Nurse, Testimony To the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the Committee on Government Reform, U.S. House of Representatives, Hepatitis B Vaccine Hearings, School Nurse Perspective, May 17, 1999.
[30] John Morgan, "Amber Tamblyn's Divine Intervention for Autism," USA Today, July 25, 2004.

since 1988 in the special federal "Vaccine Court," where the defendant is the federal government.[31] Some plaintiffs have also filed in trial courts. Thimerosal defendants in those cases include Merck, GlaxoSmithKline, Aventis, Wyeth, and Eli Lilly.

Drug makers wary of liability began reducing thimerosal in children's vaccines in 1999,[32] but it wasn't removed from most until late 2002 and early 2003. Many vaccines still contain thimerosal, including Chiron's and Aventis' pediatric flu vaccines as well as meningitis, diphtheria and tetanus given as boosters at age 11.[33] Thimerosal is still present in over 200 FDA-approved drugs, including, interestingly, steroids and collagen injections.[34] The industry now claims to have removed thimerosal, but there is no independent checking and parents and pediatricians must take the word of the same companies that have behaved deceitfully on this subject in the past.

For example, drug maker Merck & Co. announced in September 1999 that it had eliminated the toxin from children's vaccines. "Now, Merck's infant vaccine line," the company's press release

[31] National Vaccine Injury Compensation Program as of March 1, 2005. Accessed online June 15, 2005 at http://www.hrsa.gov/osp/vicp/monthly_stats_post.htm.
[32] CDC, "Joint Statement (concerning Thimerosal) of the American Academy of Pediatrics (AAP) and the U.S. Public Health Service (PHS)," July 7, 1999. Accessed online June 15, 2005 at http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/thimerosal-AAP&PHS.htm. *See also* Sarah Bridges, "The Rise Against Mercury," SEED Magazine, June 2004, at 80.
[33] Institute for Vaccine Safety, "Thimerosal Content in Some US Licensed Vaccines," May 2005. Accessed online June 15, 2005 at http://www.vaccinesafety.edu/thi-table.htm
[34] FDA. August 5, 2003. "Mercury in Drug and Biologic Products," available at http://www.fda.gov/cder/fdama/mercury300.htm (last updated Sept. 14, 2004). *See also* NEWMOA Mercury in Products Database, available at http://www.newmoa.org/Newmoa/htdocs/prevention/mercury/imerc/notification/ and FDA Tables, available at http://web.wxyz.com/investigations/thimerosal_charts.html. *See also* Department Of Health And Human Services, Food and Drug Administration,[Docket No. 98N-1109], "Mercury Compounds in Drugs and Food; Request for Data and Information," April 29, 1999, available at http://www.fda.gov/ohrms/dockets/98fr/042999b.txt

said, "is free of all preservatives."[35] But this March, the *Los Angeles Times* revealed that Merck had continued selling old mercury-laced vaccine stocks at least into 2002.[36] Earlier this month, the *Times* reported that Wyeth removed thimerosal from its popular nasal decongestant back in 1994, yet continued to use the mercury preservative in two of its pediatric vaccines until 2000 when the government asked manufacturers to voluntarily remove it from children's shots.[37] Worst of all, the pharmaceutical companies have made no effort to eliminate thimerosal in vaccines given to developing countries. Each year, tens of millions of children in the world's poorest nations are injected with this brain-killing poison.[38]

Conspiracy

During the 1990s, there were a significant number of reports filed into VAERS (The Vaccine Adverse Event Reporting System) from doctors, public health regulators, and parents of children whose autism seemed directly linked to the vaccines. In response, in the autumn of 1999, the CDC asked its employee Thomas Verstraeten to perform the first large study of over 100,000 American kids whose vaccine and medical records were stored in CDC's Vaccine Safety Datalink (VSD). Verstraeten provoked alarm within the vaccine industry community when his data showed clear causative links between thimerosal and neurological damage, including autism. "The harm," Verstraeten observed, "is done in the first month of life by thimerosal in vaccines." He wrote in a December 17, 1999 e-mail to Robert Davis, a leading pharmaceutical

[35] Merck, Press Release, September 9, 1999. Accessed online June 15, 2005 at http://www.nomercury.org/science/documents/Merck_Press_Release_9-9-99.pdf.
[36] Myron Levin, "Merck Misled on Vaccines," *Los Angeles Times*, March 7, 2005.
[37] Myron Levin, "Firm Removed Mercury from Nasal Spray, Not Infant Shots," *Los Angeles Times*, June 7, 2005.
[38] For U.S. pharmaceuticals the global market for vaccines containing Thimerosal is a goldmine. UNICEF, the World Health Organization's (WHO) 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. *See* Annette Fuentes, "Autism in a Needle?," Nov. 11, 2003, at http://www.inthesetimes.com/site/main/article/648/P40/

industry consultant, that despite "running, rethinking, rerunning, and rethinking" the damaging effect of thimerosal persisted. He titled his 1999 e-mail, "It just won't go away."[39]

When Thomas Saari, a spokesperson for American Academy of Pediatrics reviewed Verstraeten's data, he panicked. "What if the lawyers get hold of this?" he wrote in an e-mail to his colleagues, "There's not a scientist in the world that can refute these findings."[40]

As word of Verstraeten's findings spread, panicked public health agencies who had green-lighted thimerosal began warning each other of the study's implications. In a June 1999 e-mail memo to CDC's Jose Cordero and Robert Bernier, Peter Patriarca, the director of FDA's Division of Viral Products and an American Association of Pediatrics Infectious Disease Committee member (both AAP and FDA had strongly supported the vaccine regimen), worried that "the greatest point of vulnerability on this issue is that the systematic review of thimerosal in vaccines by the FDA could have been done years ago. The calculations done by FDA are not complex."[41] (By then, the FDA had calculated that a birth dose of the hepatitis B vaccine would result in mercury exposure nearly 38 times the EPA safety guideline. Referring to huge cumulative doses of thimerosal that children were now receiving in the multiple vaccinations, Patriarca observed, "We must keep in mind that the dose of ethyl mercury was not generated by 'rocket science … [It] involves ninth grade algebra. What took the FDA so long to do the calculations? Why didn't CDC and the advisory bodies do these calculations when they rapidly expanded the childhood immunization schedule?" He added, "I'm not sure if there will be an easy way out of

[39] Dr. Thomas Verstraeten, e-mail to Robert Davis and Frank DeStefano, December 17, 1999.
[40] Dr. Tom Saari, e-mail to Committee on Infectious Diseases, American Academy of Pediatrics, liaisons, and ex-officios, June 13, 2000.
[41] Dr. Peter Patriarca, e-mail to Lawrence Bachorik, July 2, 1999.

the potential perception that the FDA, CDC and immunization policy bodies may have been 'asleep at the switch' re: thimerosal until now."[42]

Compromised Agencies

Then Patriarca pointed out the seminal problem that helped provoke this public health crisis in the first place, and that would steer government officials into a shameful conspiracy to cover up the greatest public health scandal in American history; the ubiquitous conflicts of interest—financial and otherwise—that infect relationships between the pharmaceutical industry and the public health authorities. "It will also raise questions," he cautioned, "about various advisory bodies regarding aggressive recommendations for use [of thimerosal in child vaccines]." Many members on the advisory bodies who review vaccine science have financial ties to industry. The agencies tainted by these conflicts include the Centers for Disease Control and Prevention ("CDC"), the agency charged with investigating medical issues; the Food and Drug Administration ("FDA"), the agency charged with regulating vaccines; the Institute of Medicine ("IOM"), which examines policy issues for the National Academies; and the American Academy of Pediatrics (AAP).

Of these, CDC is particularly compromised. CDC has the extraordinary power to guarantee a market and profits to vaccine makers. But the people who make these decisions often have a financial stake in their outcomes. According to a February 2004 report by UPI investigative

[42] E-mail from Peter Patriarca to Martin G. Meyers, June 29, 1999. *See also* Subcommittee on Human Rights and Wellness, Government Reform Committee. Mercury in Medicine Report. Washington, DC: Congressional Record, May 21, 2003:E1011-30.

journalist Mark Benjamin, members of CDC's vaccine advisory committees often share vaccine patents, own stock in vaccine companies, receive payment for research or to monitor vaccine trials, and funding for academic departments. Furthermore, CDC itself each year receives money from vaccine makers from licensing agreements and for work on collaborative projects and CDC scientists regularly leave the agency to work for vaccine manufacturers.[43]

For example, officials on the committee that mandated the thimerosal-laden hepatitis B vaccination for infants in 1991 were closely tied to industry. The advisory committee chair, Sam Katz, helped develop a measles vaccine manufactured by Merck, which also manufactures the hepatitis B vaccine. When he chaired the committee, he was also a paid consultant for Merck, Wyeth and most of the other vaccine makers. Another member of that committee was Dr. Neal Halsey, Director of the Division of Disease Control at Johns Hopkins University and former CDC employee. Halsey has worked as a consultant and researcher for most of the vaccine companies. His Institute for Vaccine Safety at Johns Hopkins is funded by vaccine manufacturers including Merck and Wyeth.[44]

An August 2001 report by the House Government Reform Committee found that "four out of eight CDC advisory committee members who voted to approve guidelines for the rotavirus vaccine in June 1998 had financial ties to the pharmaceutical companies that were developing

[43] Mark Benjamin, "UPI Investigates: The vaccine conflict." UPI, July 21, 2003. Accessed online May 29, 2005 at http://www.upi.com/view.cfm?StoryID=20030718-012134-4422r.

[44] Halsey's Financial Disclosure: The Institute for Vaccine Safety has received research grant support from the Food and Drug Administration, the World Health Organization, and SmithKline Beecham; educational grant support from Merck & Co, SmithKline Beecham, North American Vaccine, and Pasteur Mérieux Connaught. Dr Halsey has received honoraria for a manuscript on hepatitis B vaccine from Ross Products Division, Abbott Laboratories Inc, Abbott Park, Ill. See, for example, http://www.whale.to/v/halsey.html and http://www.whale.to/vaccines/classen3.html (last viewed June 16, 2005). *See also* Nicholas Regush, "The Vaccine Machine - Is it a Follow-The-Money Operation?" ABCNews.com, June 25, 2000.

different versions of the vaccine."[45] One of them was Dr. Paul Offit, who shared a patent for one of the rotavirus vaccines and acknowledged he would make money if the vaccines were approved. Merck had bought copies of Offit's book (perhaps thousands), What Every Parent Should Know About Vaccines. Offit has been a principal proponent of thimerosal-laced vaccines and recently told me that he believed it had been a mistake to precipitously remove thimerosal from vaccines. He also said he was "offended" by my suggestion that a scientist's direct financial stake in CDC approval might bias his judgment. "It's offensive to say that physicians and public health people are in the pocket of industry and thus are making decisions that they know are unsafe for children, Bobby. It's just not the way it works. It isn't. It couldn't, because when people are given the kind of responsibility that happens at CDC, they can't do that. That's why they don't do that."[46]

Indiana's Republican Congressman Dan Burton, who has an autistic grandson, has investigated the relationship between vaccine makers and the CDC. He told the UPI, "CDC routinely allows scientists with blatant conflicts of interest to serve on intellectual advisory committees that make recommendations on new vaccines, … while these same scientists have financial ties, academic

[45] Mark Benjamin, "UPI Investigates: The vaccine conflict." UPI, July 21, 2003. Accessed online May 29, 2005 at http://www.upi.com/view.cfm?StoryID=20030718-012134-4422r.

[46] Robert F. Kennedy, Jr. Telephone Interview with Dr. Paul Offit, May 4, 2005. When I raised the possibility with Offit that personal financial entanglements with for-profit vaccine makers might cloud the judgment of some panel members, he told me, "If that vaccine (the rotavirus vaccine to which he shares a patent) ever was a vaccine, I would get, personally get money. To what extent does that provide for me, conflict? It provides no conflict. I have simply been informed by the process, not corrupted by it. When I sat around that table—my sole intent is trying to make recommendations that best benefited the children in this country. The notion that people think that provides for me anything other than enlightenment, it's just a little offensive. You should, Bobby, feel happy that people like me who've devoted their lives to try to make vaccines or understand viruses are part of this system."

affiliations and other ... interests in the products and companies for which they are supposed to be providing unbiased oversight."[47]

Now, Verstraeten was giving this agency and its pharmaceutical industry partners bad news about a toxic chemical in all the vaccines that had been approved through this tainted process. It was a message no one wanted to hear.

Verstraeten Provokes Panic

Despite his professed efforts to manipulate the data to reduce the effect, Verstraeten's confidential report of February 2000 concluded that there was a ten-fold increased risk of autism and related neurodevelopmental problems, resulting from the mercury in the vaccines.

By June 2000, Verstraeten had prepared his study for publication showing thimerosal's causative relationship to neurodevelopmental disorders, including autism.[48] Instead of publishing the article, however, he shared his findings that month at a secret meeting with sixty pharmaceutical industry representatives and public health officials at the Simpsonwood Retreat center in Norcross, Georgia. The meeting was held with no public notice and apparently convened at Simpsonwood to avoid the reach of the Freedom of Information laws which public health officials interpreted to cover only meetings at government offices. Attendees included numerous

[47] Mark Benjamin, "UPI Investigates: The vaccine conflict." UPI, July 21, 2003. Accessed online May 29, 2005 at http://www.upi.com/view.cfm?StoryID=20030718-012134-4422r.

[48] Thomas Verstraeten, Robert Davis, and Frank DeStefano, "Risk of neurologic and renal impairment associated with thimerosal-containing vaccines," June 1, 2000 on file with author. This study was never published, but it's finding were presented a week later at the Simpsonwood meetings in Georgia. The study examined cumulative mercury exposure at 1, 2, 3 and 6 months of age for more than 109,000 children born between 1992 and 1997 and found that the risks of language and speech delays, and developmental delays in general are increased by exposures to mercury from Thimerosal containing vaccines during the first six months of life.

high ranking CDC and FDA representatives, vaccine officials from WHO (World Health Organization), and representatives of vaccine makers GlaxoSmithKline, Merck, Wyeth, and Aventis, all of whom are named defendants in lawsuits by the parents of autistic children.[49]

Transcripts of those discussions were first obtained by a Congressional committee investigating thimerosal and more recently by Safe Minds, a group of anti-thimerosal advocates. Those transcripts paint an unsavory picture of frantic scrambling by vaccine makers and CDC reps who had seen Verstraeten's unpublished study. We see leaders at the highest level of America's medical community charged with protecting public health, hatching a plan with pharmaceuticals to hide the dangers of thimerosal from the public, protect the pharmaceutical manufacturers of the chemical and the regulatory agency bureaucrats who had approved its use from liability.

Dr. Verstraeten, who shortly after that meeting announced that he had accepted a job working for thimerosal vaccine maker GlaxoSmithKline, introduced his research as "the study that nobody thought we should do," and summarized his findings[50]: "we have found statistically significant relationships between" thimerosal exposure and neurological disorders.[51] He noted that "the bottom line is … our signal [linking thimerosal to neurological disorders] will simply not go away."[52] He warned that even this thoroughly damning data actually understates the true problem, because many of the children considered in the study were "just not old enough to be

[49] One of the most interesting participants was Vito Caserta, Chief Medical Officer for the National Vaccine Injury Compensation Program (NVICP). His appearance at this meeting leads one to suspect they knew Thimerosal was a problem that would have a major impact on NVICP.
[50] Transcript, "Scientific Review of Vaccine Safety Datalink Information," Simpsonwood Retreat Center, Norcross, Georgia, June 7-8, 2000, at 31. Accessed online June 15, 2005 at http://www.nomercury.org/science/documents/Simpsonwood_Transcript.pdf
[51] Ibid. at 40.
[52] Ibid. at 153.

diagnosed,"[53] (autism is typically not diagnosed until age three or four) and predicted that the problem in this cohort would certainly get worse.

Dr. Verstraeten recounted that the clear relationship between thimerosal and autism and other neurological disorders reflected in the VSD data had prompted him to review the large body of research studies linking thimerosal to brain damage. "When I saw this, and I went back through the literature, I was actually stunned by what I saw."[54]

[53] Ibid. at 43.
[54] Ibid. at 162.

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Indeed, the link between ethyl mercury and neurological disorders is as well-documented in medical and scientific literature as the link between tobacco and cancer.[55] And the totality of the evidence is overwhelming. Scores of animal, DNA, epidemiological, clinical, cadaver and other studies point to mercury as a prime culprit in America's epidemic of neurological disorders.[56]

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[55] In August of 1998, the FDA reviewed the existing literature on Thimerosal in an internal "Point Paper" prepared for the Maternal Immunization Working Group. This document recommended [emphasis added]: *For investigational vaccines indicated for maternal immunization, the use of single dose vials should be required to avoid the need of preservative in multi-dose vials…Of concern here is the potential neurotoxic effect of mercury especially when considering cumulative doses of this component in early infancy.* Subcommittee on Human Rights and Wellness, Government Reform Committee. Mercury in Medicine Report. Washington, DC: Congressional Record, May 21, 2003:E1011-30. The EMEA, which is responsible for establishing guidelines for the use of drugs and biologics in the European Union, issued a report on June 29, 1999, following an initial meeting in London on April 19, 1999 encouraging the removal of Thimerosal from childhood vaccines [emphasis added]: *The toxicity profile of ethylmercury would appear to be similar to that of methylmercury. "In view of the demonstrated risks of Thimerosal and other mercurial containing preservatives, for vaccination in infants and toddlers, the use of vaccines without Thimerosal and other mercurial preservatives should be encouraged."* Subcommittee on Human Rights and Wellness, Government Reform Committee. Mercury in Medicine Report. Washington, DC: Congressional Record, May 21, 2003:E1011-30. In a July 2, 1999, email, Dr. Ruth Etzel of the USDA noted [emphasis added]: *"We must follow three basic rules: (1) act quickly to inform pediatricians that the products have more mercury than we realized; (2) be open with consumers about why we didn't catch this earlier; (3) show contrition. If the public loses faith in the Public Health Services recommendations, then the immunization battle will falter. To keep faith, we must be open and honest and move forward quickly to replace these products." See also* Jalili MA, Abbasi AH. Poisoning by ethyl mercury toluene sulphonanilide. Br J Ind Med 1961;18:303-8. (*Mass poisoning of Iraqi farmers by ethyl mercury*) *See also* Samluji S. Granosan M Mercurial poisoning with fungicide. J Fac Med Baghdad 1962;4:83-103. *See also* Dahhan SS, Orfaly H., Electrocardiographic Changes In Mercury Poisoning. Am J Cardiol. 1964 Aug;14:178-83. *(Ethyl mercury poisoning causes heart and tissue injury.) See also* Al-Kassab S, Saigh N. Mercury and calcium excretion in chronic poisoning with organic mercury compounds. J Fac Med Baghdad 1962;4:118-123. *See also* Spann JW, Heath RG, Kreitzer JF, Locke LN. Ethyl mercury p-toluene sulfonanilide: Lethal and reproductive effects on pheasants. Science 1972;175:328-31. (*Water birds die or suffer reproductive effects from ethyl mercury exposure*).

[56] Baskin DS, et al., Thimerosal induces DNA breaks, caspase-3 activation, membrane damage, and cell death in cultured human neurons and fibroblasts, Toxicological Sciences 74(2):361-8 (2003) (*Study demonstrates that thimerosal in micromolar concentrations rapidly induces membrane and DNA damage and initiates programmed cell death in human nervous system cells and muscles.)* and Costa M, et al, DNA Damage by Mercury Compounds: An Overview, Advances in Mercury Toxicology, Suzuki T, et al,(Eds.), Rochester Series on Environmental Toxicity, Plenum Press, New York, pages 255-273 (1991) (*Review of mercury and DNA damage. Most abundant DNA lesions induced by mercury were DNA strand breaks. As breaks are not repaired, the authors suggest these may be of significance in producing cell death. Mercury was found to bind tightly to DNA and no agent was found that could dissociate the two*.) and Ariza ME, et al, Mutagenic effect of mercury in eukaryotic cells, In Vivo 1994

Toxicological studies show mercury, in all forms, is a potent neurotoxin,[57] and many studies support a relationship between thimerosal exposure and neurodevelopmental disorders.[58] Animal studies and experimental studies clearly document biological and molecular abnormalities in brains exposed to thimerosal.[59] Among them, multiple *in vitro* experiments

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Jul-Aug;8(4):559-63, (*Acute exposure to low concentrations of mercury in Chinese hamster ovary cells results in a dose dependent binding of mercury to DNA. Study showed that even low doses (0.1 to 0.4 microM) of mercury that were non-toxic to cells caused mutations in genes when compared to non-treated controls)*

[57] A quick search at the National Library of Medicine's PUBMED and TOXNET sites netted hundreds and even thousands of studies on search terms such as: mercury neurotoxicity, mercury and development and mercury and brain. (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed) and (http://toxnet.nlm.nih.gov/cgi-bin/sis/search). NoMercury.org has a page dedicated to such studies: The Science, "Is Mercury in Vaccines Dangerous?" (2005) at: http://www.nomercury.org/science.htm (last visited June 15, 2005).

[58] Ball LK, Ball R, Pratt RD. An assessment of thimerosal use in childhood vaccines. Pediatrics. 2001 May;107(5):1147-54. PMID: 11331700. *(High-dose exposure to thimerosal causes acute neurotoxicity and nephrotoxicity. Limited data on toxicity from low-dose exposures to ethylmercury are available, but toxicity may be similar to that of methylmercury … Exposure of infants to mercury in vaccines can be reduced or eliminated by using products formulated without thimerosal as a preservative."*).Gasset AR, et al., Teratogenicities of ophthalmic drugs. II, Arch Ophthalmol 1975;93:52-55. *(The ethyl mercury from Thimerosal readily crosses the blood/brain and placenta barriers when administered to rabbits and their offspring.)* and Murata K, et al, Delayed brainstem auditory evoked potential latencies in 14-year-old children exposed to methylmercury, J Pediatr. 2004 Feb;144(2): 177-83, *(Study looked at possible exposure-associated delays in auditory brainstem as objective measure of neurobehavioral toxicity in 14-year-old children with developmental exposure to mercury from seafood. Study found that some neurotoxic effects from exposure to mercury in the womb are irreversible.)* and Crump KS, et al, Influence of prenatal mercury exposure upon scholastic and psychological test performance: benchmark analysis of a New Zealand cohort, Risk Anal. 1998 Dec;18(6):701-13, *(Decreased scholastic and psychological test performance significantly associated with the level of mercury in mothers' hair.)* and Derban LK. Outbreak of food poisoning due to alkyl-mercury fungicide on southern Ghana state farm. Arch Environ Health 1974;28:49-52. *(Mass poisoning by ethyl-mercury fungicide on southern Ghana state farm kills 20 and leads to autistic-like symptoms in children.)* and Waly M, Olteanu H, Banerjee R, Choi SW, Mason JB, Parker BS, Sukumar S, Shim S, Sharma A, Benzecry JM, Power-Charnitsky VA, Deth RC. Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal. Mol Psychiatry. 2004 Apr;9(4):358-70. PMID: 14745455. (*Study found that thimerosal inhibited growth factor signaling pathways that regulate the body's ability to excrete heavy metals.*) and Makani S, Gollapudi S, Yel L, Chiplunkar S, Gupta S. Biochemical and molecular basis of thimerosal-induced apoptosis in T cells: a major role of mitochondrial pathway. Genes Immun. 2002 Aug;3(5):270-8. PMID: 12140745. *(Thimerosal causes important immune system cells to self-destruct by disrupting the energy pathway causing an imbalance in the cell's chemistry to the point of overloading the cell's defense system (glutathione). See also*

[59] Baskin DS, et al, Thimerosal induces DNA breaks, caspase-3 activation, membrane damage, and cell death in cultured human neurons and fibroblasts. Toxicological Sciences 74(2):361-8 (2003). *(Study demonstrates that thimerosal in micromolar concentrations rapidly induces membrane and DNA damage and initiate programmed cell death in human muscle and nerve tissues.)* Ueha-Ishibashi T, Oyama Y, Nakao H, Umebayashi C, Nishizaki Y, Tatsuishi T, Iwase K, Murao K, Seo H. Effect of thimerosal, a preservative in vaccines, on intracellular Ca2+ concentration of rat cerebellar neurons. Toxicology. 2004 Jan 15;195(1):77-84. *(Thimerosal caused brain damage and cell mutation in 2-week-old rats and its potency is almost similar to that of methylmercury.")* Limke TL, Heidemann SF, Atchison WD. 2004. Disruption of intraneuronal divalent cation regulation by methylmercury: are specific targets involved in altered neuronal development and cytotoxicity in methylmercury poisoning? NeruroToxicology. (25):741-60. *(Organic mercury crossing the blood-brain barrier accumulates in the highest concentrations in the cerebellum, especially the neuronal cells. The cerebellum controls movement and cognition.)* Oliver WT, Platonow N. *Studies on the pharmacology of N-(ethylmercuri)-p-toluenesulfonanilide*, Am J Vet Res.

with cells from the brains of animals prove that thimerosal causes membrane damage and cell death.[60] Pharmacokinetic studies show that mercury tends to accumulate (and remain for

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1960 Sep;21:906-16. *(Ethylmercury caused progressive degenerative changes in the heart, moderate hypoalbuminemia [an abnormally low blood level of albumin], and reduced blood A/G ratio. It produced diffuse lesions in the cord, cerebellum, cerebrum and caused glomerulonephhritis [a type of kidney disease caused by inflammation of the internal kidney structures (glomeruli)].)* Mukai N., An experimental study of alkylmercurial encephalopathy, Acta Neuropathol, Acta Neuropathol (Berl). 1972;22(2):102-9. (*Mice injected with ethyl mercury suffer brain damage*.) Tryphonas L, Nielsen NO., Pathology of chronic alkylmercury poisoning in swine. Am J Vet Res 1973;34:379-392. (*Pigs fed methylmercury suffer severe brain and kidney damage*.) Miller MW, Clarkson TW (Eds*)* et al., Mercury, Mercurials and Mercaptans, Chapter 12. Metabolic fate of ethyl mercury salts in man and animal. Springfield, IL: Charles C. Thomas Publisher, 1973, pgs. 209-32. (*Ethylmercury accumulates in brains of mice, causing damage similar to methylmercury*.) Wright FC, Palmer JS, Riner JC. Retention of mercury in tissues of cattle and sheep given oral doses of a mercurial fungicide, Ceresan M. J Agric Food Chem 1973;21:614-5. (*Mercury accumulates in brain, organs and tissues of sheep and cattle*.) *See also* Cinca I, et al., Accidental ethyl mercury poisoning with nervous system, skeletal muscle, and myocardium injury, J Neurol Neurosurg Psychiatry. 1980 Feb;43(2):143-9. ("*The clinical, electrophysiological, and toxicological, and in two of the patients the pathological data, showed that this organic mercury compound has a very high toxicity not only for the brain, but also for the spinal motoneurones, peripheral nerves, skeletal muscles, and myocardium.*")

[60] Humphrey ML, Cole MP, Pendergrass JC, Kiningham KK. Mitochondrial Mediated Thimerosal-Induced Apoptosis in a Human Neuroblastoma Cell Line (SK-N-SH). Neurotoxicology. 2005 Apr 30; [Epub ahead of print] PMID: 15869795. *(Study tracked thimerosal's chemical pathway in cells, found it killed neurons, caused morphological changes, including membrane alterations and cell shrinkage. Findings suggest thimerosal causes deleterious effects on the cellular architecture and initiates cell disintegration.)* Parran DK, Barker A, Ehrich M. Effects Of Thimerosal On Ngf Signal Transduction And Cell Death In Neuroblastoma Cells. Toxicol Sci. 2005 Apr 20; [Epub ahead of print] PMID: 15843506. *(Human tissue cells exposed to increasing concentrations of Thimerosal experienced cell death and fragmented DNA. Thimerosal interfered with cell function at very low levels, less than 1ppb. At 4.35 nM Thimerosal, 50 percent of neurons were killed in 48 hours, meaning that less than 1ppb of mercury from Thimerosal could kill neurons, nearly 20 times less than Burbacher et al (2005) found building up in the neurons of monkeys (16ppb) after Thimerosal injection. Parran et al concluded that "[t]hese data demonstrate that thimerosal could alter NGF induced signaling in neurotrophin-treated cells at concentrations lower than those responsible for cell death.")* Shanker G, Aschner M. Methylmercury-induced reactive oxygen species formation in neonatal cerebral astrocytic cultures is attenuated by antioxidants. Brain Res Mol Brain Res. 2003 Jan 31;110(1):85-91. *(Shanker et al show methylmercury causes oxidative stress and kills brain cells, and that antioxidants protect these cells from damages. Dr. Jill James' work suggests that autistic children have abnormal levels of antioxidants which would make them more vulnerable to the damages caused by mercury in vaccines.). See also* Sebe and Itsuno Organomercury compounds and Minamata disease. Subtle changes within the organism. Nisshin Igaku Jpn J Med Prog. 1962 Sep;49:607-31. Japanese. No abstract available. PMID: 13987554 [PubMed - OLDMEDLINE for Pre1966] *(Demonstrated neurotoxicity of ethyl mercury, found signs of poisoning in rats, consisting of weight loss, ataxia [inability to coordinate muscular movements], and closing of the hindlegs.)* Saito et al. [Studies on Minamata disease. I. Establishment of the criterion for etiological reserch in mice.] Jpn J Exp Med. 1961 Aug;31:277-90, PMID: 14496123 [PubMed - OLDMEDLINE for Pre1966] (*Ethyl mercury causes dolphin kick convulsion and Minamata disease in mice*.) Yonaha M, Ishikura S, Uchiyama M. Toxicity of organic compounds. III. Uptake and retention of mercury in several organs of mice by long term exposure of alkoxethylmercury compounds. Chem Pharm Bull 1975;23:1718-25. Nelson EA, Gottshall RY. Enhanced Toxicity for Mice of Pertussis Vaccines When Preserved with Merthiolate. Appl Microbiol 1967;15:590-593. *(Thimerosal-containing vaccines are more toxic for mice than unpreserved vaccines prepared from the same parent concentrate and containing the same number of organisms…An increase in mortality was observed.)* Fagan DG, Pritchard JS, Clarkson TW, Greenwood MR. Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic. Arch Dis Child. 1977 Dec;52(12):962-4. PMID: 606172 *(Analyses of tissues from 10 patients dead from Thimerosal poisoning deduce that Thimerosal can induce blood and organ levels of organic mercury which are well in excess of the minimum toxic levels in adults and fetuses…Although Thiomersal is an ethyl mercury compound, it*

considerable periods of time) in the brains of monkeys and other animals after injection of thimerosal-containing vaccines.[61] Truckloads of studies show that developing infant brains are particularly susceptible to low doses of mercury.[62] Reams of medical evidence from Europe, Russia, Japan and the United States link thimerosal (ethylmercury) to developmental and other neurological disorders, including autism.[63] "You couldn't construct a study that shows thimerosal is safe," Dr. Boyd Haley told me. "It's just too darn toxic. If you inject thimerosal into an animal, its brain will sicken," he continued. "If you apply it to living tissue, the cells die. If you put it in a Petri dish, the culture dies. Knowing these things, it would be shocking if one

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has similar toxicological properties to methyl mercury and the long-term neurological consequences produced by the ingestion of either methyl or ethyl mercury-based fungicides are indistinguishable.)

[61] Yonaha M, Ishikura S, Uchiyama M. Toxicity of organic compounds. III. Uptake and retention of mercury in several organs of mice by long term exposure of alkoxethylmercury compounds. Chem Pharm Bull 1975;23:1718-25. (*Rats poisoned by ethyl mercury suffer weight loss, loss of muscle control, and closing of the hindlegs.*) Saito et al. reported the dolphin kick convulsion as a criterion for experimental Minamata disease in mice. Blair AMJN, Clark B, Clarke AJ, Wood P. Brain and tissue concentrations of mercury after chronic dosing of squirrel monkeys with thiomersal. Toxicology 1975;3:171-6. (*Ethyl mercury from Thimerosal found to lodge in brain tissue of monkeys. Authors concluded "accumulation of mercury from chronic use of thiomersal-preserved medicines is viewed as a potential health hazard for man."*) See also Harry GJ, Harris MW, Burka LT. Mercury concentrations in brain and kidney following ethylmercury, methylmercury and Thimerosal administration to neonatal mice. Toxicol Lett. 2004 Dec 30;154(3):183-9. *(Mice injected with Thimerosal accumulate mercury in the brain and kidney. "By 7 days, mercury levels decreased in the blood but were unchanged in the brain.")* and Burbacher T, Shen DD, Liberato N, Grant KS, Cernichiari E, and Clarkson T. "Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal," The National Institute of Environmental Health Sciences, April 21, 2005. Accessed online June 15, 2005 at http://ehp.niehs.nih.gov/members/2005/7712/7712.pdf. *(Monkeys were exposed to vaccines containing thimerosal (via i.m. injection) at birth and 1, 2, and 3 weeks of age. Burbacher's study confirmed the earlier results of other scientists showing that mercury from Thimerosal clears from the blood by going into the organs of the body, not by being excreted.)* and Magos L, Brown AW, Sparrow S, Bailey E, Snowden RT, Skipp WR. The comparative toxicology of ethyl- and methylmercury. Arch Toxicol. 1985 Sep;57(4):260-7. PMID: 4091651. *(Neurotoxicity of ethyl- and methyl- mercury were similar, though higher levels of inorganic mercury were found in brains of ethylmercury-treated rats.)*

[62] National Research Council. (2003). Toxicological Effects of Methylmercury. Committee on the Toxicological Effects of Methylmercury, Board on Environmental Studies and Toxicology, Commission on Life Sciences. National Academy Press, Washington, DC. (See Chapter 5.) Mahaffey KR. (1999). Methylmercury: A new look at the risks. Public Health Reports. 114(5):402-13. *(Pre-natal and infant mercury exposures cause multiple impacts to basic brain development by disrupting the division and migration of neuronal cells.) See also* IOM, NTP, NIEHS PowerPoint presentation: Comparative Toxicity of Ethyl and Methyl Mercury viewed at http://www.iom.edu/includes/DBFile.asp?id=7504. *("Ethylmercury is a potent neurotoxin … Infants may be more susceptible than adults … Ethylmercury exposure from vaccines (added to dietary exposures to methylmercury) probably caused neurotoxic responses (likely subtle) in some children.")*

[63] Axton JHM. Six cases of poisoning after a parenteral organic mercurial compound (Merthiolate). Postgrad Med J 1972;48:417-21. (*Four children and two adults who were accidentally injected with toxic amounts of Thimerosal…Five out of the six patients died*).

could inject it into an infant without causing damage."[64] Indeed, no clinical study has ever demonstrated the safety (or the efficacy)[65] of Thimerosal, and its dangers have long been assumed by the pharmaceutical industry and within governmental regulatory agencies and in the scientific community.

The damaging effect of thimerosal, for example, is uncontested in Eli Lilly's own Material Safety Data Sheet, a disclosure document required by federal law. Lilly acknowledges that thimerosal is "toxic;" has "Nervous System and Reproductive Effects" and "alters genetic material." The company also warns that exposure to the mercury in their product "in utero and in children can cause mild to severe mental retardation and mild to severe motor coordination impairment."[66]

In 1977, a well-known published Russian study by Dr. N.D. Mukhtarova found that the majority of adults who were exposed to much lower concentrations of ethyl mercury than those given to American children in vaccines were still suffering neurological injury and neuropathology several years after the exposure.[67]

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[64] Robert F. Kennedy, Jr. Telephone Interview with Boyd Haley, April 9, 2005.

[65] Stetler HC, Garbe PL, Dwyer DM, Facklam RR, Orenstein WA, West GR, Dudley KJ, Bloch AB. Outbreaks of group A streptococcal abscesses following diphtheria-tetanus toxoid-pertussis vaccination. Pediatrics. 1985 Feb;75(2):299-303. PMID: 3881728. *(Study showed thimerosal was ineffective at preventing bacterial contamination. "The only feasible and cost-effective preventive measure now available is careful attention to sterile technique when administering vaccine from multidose vials.")* Notably, one of the co-authors of this study, Dr. Walter Orenstein, served as Director of the National Immunization Program at the CDC from 1993-2002 and promoted continued use of Thimerosal.

[66] Eli Lilly, MSDS, (1991). Accessed online June 15, 2005 at http://www.nomercury.org/science/documents/MSDS-Eli_Lilly-1991.pdf.

[67] Mukhtarova ND. Late sequelae of nervous system pathology caused by the action of low concentrations of ethyl mercury chloride. Gig Tr Prof Zabol 1977 Mar(3):4-7.

As far back as January 5, 1982, the FDA published its notice of proposed rule making regarding thimerosal in over-the-counter medications.[68] FDA's scientific panel's opinions and recommendations were the culmination of five years of research concerning the potential hazards and safety of thimerosal and other mercury products. The FDA scientific panel's conclusions were clear and unequivocal. Thimerosal was deadly to human cells in vitro. The FDA determined that thimerosal was significantly more toxic for living animal tissue than it was for bacteria, concluding that "[i]t was found to be 35.3 times more toxic for embryonic chick heart tissue than for staphylococcus areus."[69] As a result of these studies, FDA banned thimerosal in non-prescription medications. How could FDA ban the topical application of thimerosal as too dangerous, while allowing the same chemical to be injected in large doses into newborn babies during the most vulnerable stage of brain development? According to FDA insiders, there was little communication between the FDA division charged with safety in over-the-counter medications and the division that regulated vaccines.[70]

The scientific literature had even persuaded the Institute of Medicine (IOM) that thimerosal might be linked to autism. IOM would subsequently backpedal away from these findings under pressure from CDC, but in 2001, based upon an extensive review of the scientific evidence, the Immunization Safety Review Committee of the IOM concluded that although the scientific proof of causation was yet incomplete, it was "biologically plausible" that thimerosal exposures from

[68] Department of Health and Human Services, Proposed Rules, CFR Part 333 Docket No. 75N-0183, Mercury-Containing Drug Products for Topical Antimicrobial Over-the-Counter Human Use; Establishment of a Monograph, Jan. 5, 1982. The summary for the proposed rule reads: "The Food and Drug Administration (FDA) is issuing an advance notice of a proposed rulemaking that would classify over-the-counter (OTC) mercury-containing drugs for topical antimicrobial use as not generally recognized as safe and effective and as being misbranded." Ibid at 1.
[69] Ibid. at 17.
[70] Robert F. Kennedy Jr., Telephone Interview with Sarah Bridges, May 20, 2005. A current scientist at FDA told Bridges on the condition of anonymity that, due to turf issues, the FDA division that banned OTC thimerosal never coordinated with the FDA division that oversaw vaccine safety.

the recommended childhood immunization schedule could be associated with autism, ADHD, and speech or language delay, and urged that no more children should be exposed to mercury in vaccines.[71] With all this evidence, it's no wonder that Verstraeten found himself "stunned" when confronted by the wave of scientific literature confirming the findings in his epidemiological study.

[71] Institute of Medicine, Immunization Safety Review Committee, Thimerosal-containing vaccines and Neurodevelopmental Disorders, Oct. 1, 2001.

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After two days of reviewing his study, there emerged a general agreement among the scientists and regulators at Simpsonwood that Verstraeten's epidemiological data was dispositive. Dr. Bill Weil, a consultant to the American Academy of Pediatrics told the group, "You can play with (the results) all you want … they are statistically significant."[72]

Dr. Richard Johnston, an immunologist and pediatrician from the University of Colorado, who has done paid research for thimerosal distributor SmithKline Beecham, was concerned enough to worry about his own family members. "My gut feeling?" he said. "Forgive this personal comment, but I … do not want [my] grandson to get a Thimerosal-containing vaccine until we know better what is going on…In the meantime … I think I want that grandson to only be given Thimerosal-free vaccines."[73]

Robert Brent, a pediatrician at the Alfred I. duPont Hospital for Children in Deleware, also considered the data dispositive and vocalized the fear that evidently gripped the room: with this strong science against us, how do we defend the lawsuits? "[Y]ou could readily find a junk scientist who would support the claim with a 'reasonable degree of certainty'," said Brent. "But you will not find a scientist with any integrity who would say the [reverse] with the data

[72] Transcript, "Scientific Review of Vaccine Safety Datalink Information," Simpsonwood Retreat Center, Norcross, Georgia, June 7-8, 2000, at 207. Accessed online June 15, 2005 at http://www.nomercury.org/science/documents/Simpsonwood_Transcript.pdf

[73] Ibid. at 199-200.

available … [W]e are in a bad position from the standpoint of defending any lawsuits … I am concerned."[74]

Dr. John Clements, an advisor to the Vaccines and Biologics division of the World Health Organization, and an aggressive advocate of thimerosal-laced vaccines in Third World nations, also tipped his hat to the wide body of existing studies linking thimerosal and neurological disorders while remonstrating those members of the group who had allowed Verstraeten's research to proceed, flatly declaring "this study should not have been done at all, because the outcome of it could have, to some extent, been predicted." No matter what steps the committee takes now to mitigate Verstraeten's inescapable conclusions, he warned that "through freedom of information [laws, Verstraeten's work] will be taken by others and will be used in other ways beyond the control of this group." And he urged that "now…the research results have to be *handled*."[75]

The meeting closed with a discussion about how to keep the information from the public. "We have been privileged so far, that given the sensitivity of information, we have been able to manage to keep it out of, let's say, less responsible hands," said Bob Chen,[76] head of CDC's Vaccine Safety and Development unit. "[C]onsider this embargoed information," Dr. Roger Bernier, the associate director for Science at the CDC's National Immunization Program (NIP),

[74] Ibid. at 229.
[75] Ibid. at 247-48.
[76] Ibid. at 256.

announced at the meeting's close. "We have asked you to keep this information confidential … [while we] … consider these data in a certain protected environment."[77]

Verstraeten's initial study was never published and the CDC scrambled to block public access to his original data and the Vaccine Safety Datalink (VSD) files in general. In 2002, CDC turned its VSD data files over to an outside agency, the American Association of Health Plans, with a $190 million contract[78] that purports to shield the data from Sunshine Laws like the Freedom of Information Act (FOIA) or even subpoena, by characterizing the data as proprietary to the HMO's that helped generate it. CDC has told independent researchers that Verstraeten's original data has been lost, and that there is no way to replicate his original study.[79] This despite the fact that iron-clad ethical standards dictate that agencies like CDC retain scientific research data so that it can be replicated.

The Cover-Up

CDC then commissioned the Institute of Medicine (IOM) to develop its own assessment of the link between thimerosal and neurological disorders. CDC and NIH funded the review with over $2 million[80] and worked in collaboration with IOM to develop its conclusions. Since CDC, as

[77] Ibid. at 113. *See also* Bernier quote at 256 "I think the fact that we were able to hold this meeting the last two days is a direct result of the fact that this information has been held fairly tightly… consider this embargoed information…and very highly protected information."
[78] Centers for Disease Control and Prevention, Procurements and Grants Office, "Public Notification of Award of Contract 200-2002-00732, American Association of Health Plans," September 20, 2002.
[79] Robert F. Kennedy, Jr. interview with David Geier. *See also* IOM, "Vaccine Safety Research, Data Access, and Public Trust," Feb. 2005, at 63-64.
[80] Department of Health and Human Services, Centers for Disease Control and Prevention. Inter/Intra-Agency Agreement (IAA), Project Title: Vaccine Safety Review Panel, IIA#: 00FED17358. Sept. 2000.

the primary advocate for thimerosal-containing vaccines and the expanded vaccine schedule, was neck-deep in this tragedy, its involvement in the study presented a clear conflict of interest.

CDC's directives to the IOM from the start were transparent; the new studies should not find a link between thimerosal and neurological disorders and, regardless of the facts, should reassure the public about vaccine safety.

IOM's Immunization Safety Review Committee met for an organizational meeting in January 2001 to discuss its charge.[81] Before any research was evaluated the committee members and IOM staff fortified each other with not so subtle reminders that their job was to toe the line and produce no bad news about vaccine safety—whatever the facts might be. One committee member, Dr. Michael Kaback, stated (according to transcripts gained through FOIA), "We have got a dragon by the tail here. At the end of the line, what we know is—and I agree—that the more negative that presentation [the IOM report] is, the less likely people are to use vaccination, immunization, and we know what the results of that will be. We are kind of caught in a trap. How we work our way out of the trap, I think is the charge."[82]

Dr. Marie McCormick, chair of the Immunization Review Committee, was even more frank, noting that the CDC, which had funded the $2 million study, "wants us to declare, well, these things are pretty safe…." Before her committee reviewed a single study or a shred of data she expressed her confidence that, "we are not ever going to come down that [autism] is a true side

[81] Transcript of closed meeting - IOM Immunization Safety Review Committee, held at National Academy of Sciences, Washington DC, Jan. 12, 2001. Accessed online June 15, 2005 at http://www.nomercury.org/iom/iom.pdf
[82] Ibid. at 32-33.

effect of [vaccine exposure.]"[83] Dr. McCormick told me emphatically that she receives no money from the pharmaceutical companies but records show that the Harvard School of Public Health, where she works as a chairperson, receives millions from pharmaceutical companies.[84]

Dr. Kathleen Stratton, a member of IOM staff and study director of the Immunization Safety Review Committee, reiterated McCormick's message, "We said this before you got here, and I think we said this yesterday, the point of no return, the line we will not cross in public policy is to pull the vaccine, change the schedule … We wouldn't say compensate, we wouldn't say pull the vaccine, we wouldn't say stop the program."[85]

Despite not having heard any of the evidence, she predicted that the probable conclusion was going to be that the "evidence was inadequate to accept or reject a causal relation [between vaccines and neurological disorders]." She said that this result was "what Walt said" he wanted.[86] Dr. Stratton told me she was referring to Walter A. Orenstein, M.D., the former Director of the National Immunization Program at the Centers for Disease Control and

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[83] Ibid. at 97. Furthermore, Dr. McCormick stated "I think autism is one of these – there is going to be slim, if any, association but people panic about the disease. … Let's not prolong this discussion because this is my hobby horse." (Ibid. pgs. 102-103).

[84] Dr. McCormick is the Chairperson of the Maternal and Child Health program at Harvard University School of Public Health. She also is the head of the Harvard Center for Children's Health, which, "aims to foster a series of partnerships between researchers and between policymakers, the business community, the media and children and their families." Among those in the business community are numerous pharmaceutical companies who in 1997 helped to contribute over $97 million to the Harvard School of Public Health in the way of research grants and other funding methods. *See* "Wrong Message From the Wrong Person: The Truth Behind the IOM Report on Autism and Vaccines," About.com, May 21, 2001. Accessed online May 29, 2005 at http://autism.about.com/library/weekly/aa052901a.htm.

[85] Transcript of closed meeting - IOM Immunization Safety Review Committee, held at National Academy of Sciences, Washington DC, January 12, 2001, at 74. Accessed online June 15, 2005 at http://www.nomercury.org/iom/iom.pdf

[86] Ibid. at 123. Stratton, whose agency would later feed the panel a series of pre-cooked studies to review, was so confident of the outcome that she was willing to wager—even before a single study had been completed. She told the panel, "[w]e will never have it here. I think that actually you don't have to agonize over it. Not to prejudge your decisions over the next three years, but I will bet you a hundred bucks you will never come up with a category five [unequivocally established causality]. It won't even cross your mind" (Ibid. at 130).

Prevention (CDC) in Atlanta, Georgia. "Even recommending research is recommendation for policy," she added, signaling IOM's apparent intent to derail further research on the links between Thimerosal and neurological disorders. When I recently asked Stratton, and then pressed her repeatedly, whether she would give thimerosal to her own children, she refused to answer the question.[87]

It was an open secret among high-ranking public health officials that the CDC studies were not intended to explore, study or assess the link between thimerosal and neurological disorders, but to "rule out" any links, and to give cover to official statements that thimerosal was safe. In May 2001, Dr. Gordon Douglas, M.D., Director of Strategic Planning for the Vaccine Research Center at the National Institutes of Health (NIH), assured a Princeton University gathering that, "Four current studies are taking place at the CDC in collaboration with NIH to rule out the proposed link between autism and thimerosal." (Emphasis added) In addition to his federal duties as a leading public health official, Dr. Douglas also works for the thimerosal vaccine producer Aventis and formerly served as president of Merck's vaccination program. In that capacity in 1991, he had received Dr. Hilleman's urgent warning about thimerosal and chose to ignore it. With extraordinary candor he told his listeners, "In order to undo the harmful effects of research claiming to link … vaccine[s] to an elevated risk of autism, we need to conduct and publicize additional studies … to assure parents of [vaccine] safety."[88]

CDC's Ginned-up Health Studies

[87] Robert F. Kennedy Telephone Interview with Kathleen Stratton, April 28, 2005.
[88] Princeton University, Class 11, May 2, 2001. Accessed online June 15, 2005 at http://www.nomercury.org/science/documents/Lecture_11_Dr_Douglas_at_Princeton.PDF

In May 2004, IOM issued its pre-ordained conclusion that there was no proven link between autism and thimerosal in vaccines and strongly recommended that no further studies should address the issue.[89] In reaching its conclusion, the IOM flatly refused to credit the many clinical studies that clearly show that thimerosal is toxic and that a small subset of kids are differentially injured by it. The panel also refused to hear or give weight to pharmacological, clinical, or toxicological research from prestigious doctors at universities across the country who were anxious to share their studies linking thimerosal to the wide range of neurological disorders.[90] Instead, the IOM relied on five badly flawed epidemiological studies. Four of them were from European countries whose populations were exposed to a fraction of the thimerosal given to American kids, and not initially exposed on the day of birth, but five weeks later.

Unlike other scientific studies, epidemiological studies can be easily manipulated by eliminating vulnerable subgroups that are particularly susceptible to injury. At Simpsonwood, Dr. Philip Rhodes, a statistician with the National Immunization Program, had suggested excluding from the Verstraeten study children who had unusually high exposures and high incidence of neurological injuries including autism. Data from this subgroup would, of course, support the autism signal; eliminating them would dampen thimerosal's links to autism.[91]

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[89] Final Report, Immunization Safety Review: Vaccines And Autism, Immunization Safety Review Committee Board on Health Promotion and Disease Prevention, IOM, May 2004. Accessed online June 15, 2005 at http://www.iom.edu/report.asp?id=20155

[90] They refused, for example, to allow Dr. Richard Deth, Northeastern University, to speak to the committee even though he had just published startling new evidence regarding Thimerosal in a respected journal the week prior to the meeting of Feb. 9, 2004.

[91] Transcript, "Scientific Review of Vaccine Safety Datalink Information," Simpsonwood Retreat Center, Norcross, Georgia, June 7-8, 2000, pg. 107. Viewed at: http://www.nomercury.org/science/documents/Simpsonwood_Transcript.pdf

When the panel gathered again in February 2004 to review the thimerosal issue, its focus had subtly changed; the issue that CDC now wanted to address was whether thimerosal-containing vaccines might trigger autism, not neurodevelopmental injuries.[92] Neurodevelopmental disorders are a broad family of behavioral abnormalities, including autism, attention deficit/hyperactivity disorders, speech and language delays. Each of these conditions encompasses their own universe of disorders. Autism, for example, is a complex constellation of symptoms that includes impeded communication, behavior and social interactions. Autism manifests differently among different patients and distinct collections of autistic symptoms are oftentimes referred to by their own name. Narrowing the question allowed IOM and CDC to focus on disproving the purported causal nexus between vaccines and autism, completely ignoring the significant body of literature establishing a causal association between mercury exposure and the broad range of neurological disorders. Focusing on autism alone and then narrowly defining the ailment, was the trick used by IOM to escape the "trap" described by Dr. Kaback at the January 2001 meeting. When I asked Kathleen Stratton why the committee had focused on autism, she admitted that the pending autism lawsuits, not public health, were the committee's driving motivation. At that time, the government was defending 4,500 lawsuits in vaccine courts alleging that thimerosal had caused autism. "Because that was sort of ... what the court cases were about, and this would obviously be used ultimately ... [t]he government needed an answer on autism, so that's what we looked at." When I asked whether that narrow focus wasn't CDC's way of dodging the more central question of whether thimerosal should be allowed in vaccines, Stratton elaborated, "Clearly, mercury is very toxic. Clearly, ethyl mercury is neurotoxic. Clearly, ethylmercury affects cell systems—animals, human cells—all those sorts

[92] Transcript, Immunization Safety Review Committee, Vaccines and Autism, February 9, 2004, National Academy of Sciences, Washington DC. Accessed online June 15, 2005 at http://www.iom.edu/file.asp?id=19140

of things, and clearly, when it was injected into newborn mice they had weird behavior. The point is, mercury is not good for you. Granted, thimerosal…I mean it can't be good for you right? And certainly, at some doses it's very bad for you. But the question [we were charged with answering] is whether any of those animal or in-vitro studies make a connection to autism."[93] The narrow focus on autism also allowed the committee to take advantage of CDC's hastily-created European epidemiologic studies that had concluded that thimerosal did not cause autism, and to tap dance around the overwhelming science linking thimerosal to the wider spectrum of neurodevelopmental injuries.

Indeed, the only American epidemiological study that IOM reviewed was Verstraeten's study, which had since been completely revised to substantially dilute the causal link between thimerosal and autism; with help and guidance from a vaccine industry consultant, Verstraeten had finally achieved the result that had defied his earlier efforts.

Verstraeten's Revisions

After the 2001 IOM meeting, it took Verstraeten three years to rework the numbers to make thimerosal's dramatic links to autism go away. Verstraeten's co-author was his former pen-pal, the vaccine industry consultant, Robert Davis (who co-authored the original study along with Frank DeStefano of CDC).[94] They presented their "latest" data, which reduced the significant risk for autism that had so discomforted the public health community in Verstraeten's earlier study. Now, Verstraeten and Davis concluded that they could neither support nor refute the idea

[93] Robert F. Kennedy Telephone Interview with Kathleen Stratton, April 28, 2005.
[94] CDC Thimerosal VSD Study, February 29, 2000, by Thomas Verstraeten, Robert Davis, Frank DeStefano.

that thimerosal was causing autism. Verstraeten declined to present the report himself, allowing Davis to carry the ball. He has since refused to comment on the study, except in a letter to the Journal of Pediatrics, where his revised study was published, in which he clarified that the study in no way rules out the possibility that vaccines cause autism. Verstraeten explained that the "article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended, which is the conclusion to which a neutral study must come."[95] When Republican Congressman Dan Burton subpoenaed Verstraeten to testify about his knowledge of the thimerosal conspiracy, he refused to come back to the US to testify. He was in Belgium working for a vaccine maker. He continues to do research for the CDC.

It is unclear why CDC and IOM allowed Robert Davis, whose prolonged and substantial industry ties were well-known, to be involved with the study, where he no doubt influenced the younger and less experienced Verstraeten, a CDC researcher. Davis had previously done work for Merck, GlaxoSmithKline, and Wyeth, three of the thimerosal Defendants.

As they worked toward a more industry-friendly conclusion, Davis and Verstraeten culled through the files and figured out which kids they would include/count and which would be dropped out of the study. Their first analysis showed alarming correlations between mercury exposure and increased autism risk (over ten times higher risk). Davis, the more senior scientist, helped Verstraeten to "rerun" data, adding and subtracting population groups, revising diagnostic categories and reducing statistical power. The one consistent result of Davis's involvement was

[95] Letter to Editor from Thomas Verstraeten, M.D., Pediatrics Vol. 113 No. 4 April 2004, pp. 932. Accessed online June 20, 2005 at http://pediatrics.aappublications.org/cgi/content/full/113/4/932.

the steady reduction of the risk found to be associated with thimerosal in vaccines. In the final study, Verstraeten and Davis ended up excluding older children (already past the common age of diagnosis) and including very young children (who hadn't reached the common age of diagnosis). Since autism does not normally manifest until age 3 or 4, that choice would have the effect of severely dampening the autism signal. Even all this tinkering could not make the autism signal disappear. Verstraeten and Davis added patient data that had been provided to the VSD database by a notoriously sloppy and financially unstable HMO that did not show a strong link between brain damage and thimerosal. Since the data set from the first HMO showed a strong signal and data from the second did not, Verstraeten and Davis were asked to claim that their study was "neutral" and further research was needed. According to Congressman Dave Weldon, the HMO "was in receivership [bankruptcy] by the state of Mass., its computer records had been in shambles for years, it had multiple computer systems that could not communicate with one another (Journal of Law, Ethics and Medicine Sept. 22, 2000), and it used a health care coding system totally different from the one used across the VSD."[96] Referring to Weldon's criticism of the revised conclusions, Davis said, "Of course the data changed from one phase of the VSD study to another. It evolved. If Congressmen [sic]Weldon questions that, then he doesn't fully understand the proper approach to scientific research." He added, "Science is best left to scientists."[97]

When independent researchers Dr. Mark Geier and his son, David Geier tried to replicate Verstraeten's research, CDC told them that Verstraeten's data was lost. Of course, a hallmark of

[96] Letter from Congressman Weldon to CDC Director Julie L. Gerberding (Oct. 31, 2003).
[97] Sarah Bridges, "The Rise Against Mercury," SEED Magazine, June 2004, at 109.

science is to retain data sets to allow corroboration. But mysteriously much of CDC data on many vaccine studies has disappeared.[98]

Verstraeten is an interesting figure and appears to have had at least something of a conscience. When, at the outset, he encountered pressure from CDC and the pharmaceutical industry warning him that his research efforts were opening a Pandora's box, Verstraeten initially pushed back. In an e-mail to Davis he argued, "We should use sound scientific argumentations and not let our standards be distorted by our desire to disprove an unpleasant theory."[99] In 2004, he refused to appear at IOM to defend his revised study, perhaps because he didn't believe in it, and, later on, when IOM, CDC and vaccine manufacturers were publicly distorting the results of that study in support of the position that thimerosal had "no effect" on autism rates, Verstraeten responded, on his own accord, with a letter to the American Journal of Pediatrics, firmly affirming that his study was neutral on this issue and that more study on the autism link was needed.[100]

Verstraeten's study, which does not pretend to compare children who received thimerosal to unexposed children, is the only one that examines the U.S. population among the five studies relied upon by the IOM. The rest are even weaker studies from Europe.

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[98] Ibid.
[99] E-mail from Verstraeten to Dr. Robert Chen.
[100] Letter to Editor from Thomas Verstraeten, M.D., Pediatrics Vol. 113 No. 4 April 2004, at 932. Accessed online June 15 at http://pediatrics.aappublications.org/cgi/content/full/113/4/932. *(Verstraeten explains that the first study indicated a positive association between thimerosal exposure and neurodevelopmental effects, but that they weren't able to confirm it in the second phase follow-up study, so therefore it was considered neutral, but he felt compelled to reiterate that was not to be meant to be interpreted as a negative association, rather, more study was recommended. Verstraeten wrote "The article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended, which is the conclusion to which a neutral study must come.")*

European Studies

At the Simpsonwood meeting Dr. Robert Brent had urged investigators "to get other populations to study," arguing that "I do not think that reanalysis of this [American] data is going to be as helpful as we would hope."[101]

"What we care most about," says a note from one participant, "is a consistent body of epi[demiological] evid[ence] that consist[ently] shows no assoc[iation]."[102] Notes from at least one other committee member indicate that CDC was already planning to use epidemiology from Europe to disprove causation.[103]

In response to Dr. Brent's call for studies of "other populations" a number of researchers, almost all financially allied with CDC and the drug industry, collected data on cases of autism in Sweden, Denmark, and the U.K. The most oft-cited of these are three studies of Danish children by Paul Stehr-Green (2003), Andres Hviid (2003) and KM Madsen (2003).[104]

Denmark was an ideal population for the CDC's purposes. First, the Danes used less than half the dose of thimerosal on their children, so the adverse impacts were less pronounced (Denmark

[101] Transcript, "Scientific Review of Vaccine Safety Datalink Information," Simpsonwood Retreat Center, Norcross, Georgia, (Jun. 7-8, 2000) pg. 249. Accessed online June 20, 2005 at http://www.nomercury.org/science/documents/Simpsonwood_Transcript.pdf

[102] Plaintiff's Response in Opposition to Defendants' *Daubert* Motion, 56, *Easter v. Aventis Pastuer, Inc.*, No. 5:03-CV-141 (E.D. Tex. 2005). 153 Id. at 01848

[103] One participant wrote, "other countries – looked at issue because of nature of other countries? CDC-project with Denmark on autism." Id. at 01905

[104] Madsen et al. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. Pediatrics, 2003; 112: 604-606.176 and Hviid et al. Association between thimerosal–containing vaccine and autism. JAMA, 2003; 290: 1763-1766. and Stehr-Green, Autism and Thimerosal-Containing Vaccines, Lack of Consistent Evidence for an Association, Am J Prev Med 25(2):101-106 (2003).

experienced 1/70th of the U.S. autism rates). "It's as if a researcher trying to study the involvement of mosquitos on malaria conducted his research in Minnesota instead of Panama," Dr. Boyd Haley told me in disgust.[105] Secondly, an anomaly in Danish statistics collection created a deceptive blip that was of great advantage to CDC in its campaign to deceive the American public.

In 1992 Denmark banned thimerosal. Prior to that date, Danish public health authorities only counted autism in patients that had been hospitalized due to the illness—a small fraction (16% to 25%) of the total.[106] In 1995, the national registry began registering all autistics—including outpatients—quadrupling the national count. At the same time, Denmark began using a far more inclusive definition of autism and dramatically expanded treatment opportunities for autistics, further increasing the number of reported cases. The raw data therefore made it appear that removing thimerosal actually increased the rates of autism!

Stehr-Green took advantage of the autism spike that resulted from Denmark's skewed data gathering methodologies to argue that autism rates in Denmark, when thimerosal was being used, were exceedingly low and then began to rise following thimerosal's removal.

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[105] Robert F. Kennedy, Jr., Telephone Interview with Boyd Haley, Apr. 9, 2005.

[106] Hooker BS, Trelka JA. "More on Madsen's Analysis." J Am Phys Surg 9(4):101 (2004). *(In criticizing the 2003 study by Madsen et al., Hooker and Trelka point out that "Madsen's collection of inpatient treatment data since 1971 was tainted by adding outpatient activities in 1994." Furthermore, as pointed out in Stehr-Green's 2003 study, prior to 1992, the data in the Danish registry excluded cases diagnosed in one of Copenhagen's largest clinics, which accounted for approximately 20% of all Danish autism cases. This evidence suggests "the 2003 Madsen analysis is at best indeterminate regarding the effect of discontinuing the use of thimerosal-containing vaccines on autism incidence." Dr. Hooker corrected for the inaccuracies of the Madsen team and calculated that autism incidence actually decreased significantly after 1993, "including a dramatic 75% reduction within the 2 to 4-year-old cohort." Hooker concludes that the Madsen et al. errors "could have been easily avoided through proper accounting of the existing data in the Danish registry.")*

KM Madsen, the author of the most intellectually honest of the three Danish studies, grudgingly acknowledges that several external events "may" have spuriously increased the apparent number of autism cases after thimerosal was removed from vaccines and concedes that "[o]ur data cannot, of course, exclude the possibility that thimerosal at doses larger than used in Denmark may lead to neurodevelopmental damage."[107]

The Swedish portion of the study by Stehr-Green had many of the same limitations. The authors only collected data on children hospitalized for autism, no outpatient data was ever included. Moreover, Swedish children received only one-third the dose of that in the United States.[108]

During the only federal trial of an autism case, Easter v. Aventis, et al, in the Texas Federal District Court, the plaintiff's attorney Dana Fox got the pharmaceutical industry's own expert witness to concede that the Danish studies were fatally flawed. Dr. Philip Wang acknowledged that the "dramatic" rise in autism reported in Sweden and Denmark after thimerosal was removed from vaccines "most likely reflect[ed] changes in diagnostic practices and the availability of services for autism."[109] That admission pulled the rug from beneath IOM's studies, breaking the slender reeds upon which the panel principally based its 2004 pronouncement about thimerosal's safety.[110]

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[107] Madsen et al. "Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data," Pediatrics, 112(3):604-606 (2003).

[108] Paul Stehr-Green, "Autism and Thimerosal-Containing Vaccines, Lack of Consistent Evidence for an Association," 25(2) Am J Prev Med, 25(2):101-106 (2003).

[109] Wang R. at ¶ 90 (Ex. B-6 from Defendants' brief).

[110] Plaintiff's Response in Opposition to Defendants' *Daubert* Motion, 56, *Easter v. Aventis Pastuer, Inc.*, No. 5:03-CV-141 (E.D. Tex. 2005). 153 Id. at 01848 at ¶89. In his report, Dr. Wang correctly states that the "dramatic" rise in autism reported in Sweden and Denmark after thimerosal was removed from vaccines "mostly likely reflect[ed] changes in diagnostic practices and the availability of services for autism."

When I spoke to the IOM panel chair Marie McCormick she seemed to still be unaware of this mortal defect in the European study methodologies. "They stopped thimerosal," she insisted, referring to the Scandinavian experience, "and the incidence of autism continued to increase."[111] When I next asked her if the Danish studies lacked relevancy since they examined thimerosal doses that were less than half those given American kids, she dodged the question by arguing that children examined in the U.K. study had doses comparable to those received by American children. This is flat-out untrue. The children who were subjects of the U.K. study (another ginned-up study done at the prompting of and in cahoots with the CDC),[112] received 75 micrograms of thimerosal during their first 6 months compared to 187.5 micrograms given to U.S. kids during the same period.[113] Furthermore, American children got a giant dose of 62.5 micrograms on a single day, whereas the maximum one-day dose for British kids was 25 micrograms. Dr. Neal Halsey, Director, Institute of Vaccine Safety at Johns Hopkins University and Chairman of the Committee on Infectious Diseases of the American Academy of Pediatrics told me that it was this giant so-called "bolus dose" that most shocked and frightened him due to its potential to damage a child's brain.

When I asked Kathleen Stratton how the committee could have acted on European studies that were so badly flawed and ignored the mountains of solid clinical and biological and

[111] Robert F. Kennedy, Jr., Telephone Interview with Dr. Marie McCormick, April 27, 2005.
[112] See e-mails between Robert Chen, CDC and Elizabeth Miller of the Communicable Disease Surveillance Centre at United Kingdom's Health Protection Agency. Jun. 26, 2001 through Nov. 8, 2001.
[113] Andrews and Miller et al. Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association. Pediatrics, 114(3):584-591 (2004).

epidemiological studies that contradicts them[114], she told me, "The committee didn't think they were badly flawed."[115]

The Pichichero Study

In addition to the four epidemiological studies, IOM relied heavily on one non-epidemiological report—a clinical study by Michael Pichichero, published in Lancet in 2002.[116] Pichichero's report is also seriously flawed. Pichichero examined the blood of healthy infants who had recently received thimerosal-containing vaccines and found that the mercury quickly disappeared from their blood.[117] He concluded that the rapid elimination of mercury from the blood indicated that it did not remain in their bodies long enough to cause serious damage. But Pichichero's assumption that an absence of mercury in the infants' blood indicated that the mercury had left their bodies is not necessarily true. Dr. Boyd Haley has shown, using Pichichero's own data, that Pichichero could account for only a small portion of the eliminated mercury by measuring its concentration in the children's fecal material. It was highly likely, therefore, that the mercury had lodged instead in the children's brains or organs. Furthermore, Pichichero studied only 33 normal kids and never indicates whether any had low glutathione levels. This is the category of

[114] The European studies have many other defects not mentioned here. One particularly glaring problem with the Danish studies is that they all compare children with low level exposures to those with higher level exposures. The study authors did not find a cohort group who did not get any Thimerosal exposures. The study results are further confused since the children with low exposures were most likely the ones who got vaccinated on the day of birth when they were most susceptible to mercury toxicity, fatally skewing the authors' attempts to hypothesize a dose-related response.
[115] Robert F. Kennedy Jr., Telephone Interview with Dr. Kathleen Stratton, April 28, 2005.
[116] Michael E Pichichero, Elsa Cernichiari, Joseph Lopreiato, John Treanor, "Mercury concentrations and metabolism in infants receiving vaccines containing thiomersal: a descriptive study," The Lancet, 360:9347, (Nov. 30, 2002.); *See also* Donald G. McNeil Jr., "Study Suggests Mercury in Vaccine Was Not Harmful," *The New York Times*, Section A; Column 3; National Desk; Pg. 22, Dec. 4, 2002.
[117] Michael Pichichero, "Mercury Concentrations and Metabolism in Infants Receiving Vaccines Containing Thimerosal: A Descriptive Study," Lancet, 2002; 360: 1737-41.

children that has trouble clearing mercury and seems to be particularly susceptible to neurological damage from mercury exposure.[118]

Undisclosed Conflicts

All of the key studies relied upon by IOM not only have disastrously flawed methodologies, but most of their authors are burdened with serious conflicts of interest and bias that cast doubt on the integrity of their reports. Most of the conflicts arise from financial ties with the very vaccine makers who are defendants in thimerosal lawsuits. Pichichero, for example, had previously done paid research and consulting work for Eli Lilly and virtually all the other thimerosal vaccine companies. He works at University of Rochester where the Health Science building is funded by a patent on the thimerosal-laced HIB vaccine.[119] As I mentioned above, Verstraeten and Davis both have strong financial ties to vaccine makers.

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[118] Burbacher et al. "Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal," The National Institute of Environmental Health Sciences, April 21, 2005. Accessed online June 20, 2005 at http://ehp.niehs.nih.gov/members/2005/7712/7712.pdf. According to Burbacher et all, blood mercury is not a good indicator of risk of adverse effects on the brain, since low blood levels may not mean that the mercury has been excreted but that it has lodged in the brain. "Blood [mercury levels] may not be a good indicator… particularly under conditions of rapidly changing blood levels such as those observed following vaccinations." Ibid. at 17.

This paper is co-authored by Dr. Thomas Clarkson who earlier published a review in the New England Journal of Medicine that downplayed the possibility of thimerosal causing autism. Now he seems to have changed his mind in favor of the link between brain damage and thimerosal. Dr. Boyd Haley has taken Clarkson's earlier study to task for not considering age, genetic susceptibility and synergistic toxicities. Clarkson was among the toxicologists who missed the fact that hair mercury levels are more a measure of ability to excrete mercury than a measure of total exposure.

Another paper by Parran et al. in ToxSci (Toxicological Sciences) April 2005 entitled "Effects of Thimerosal on NGF (nerve growth factor) Signal Transduction and Cell Death in Neuroblastoma Cells" concludes that, "These data demonstrate that Thimerosal could alter NGF-induced signaling in neurotrophin-treated cells at concentrations lower than those responsible for cell death." According to Boyd Haley, this critical conclusion clearly implicates Thimerosal as a culprit in the autism epidemic.

[119] Pichichero has an acknowledged financial tie to Eli Lilly, the developer of thimerosal and the main target of thimerosal litigation. He has also admitted financial ties to a number of thimerosal-laced vaccine manufacturers, including Merck, Eli Lilly, Wyeth, Smith Kline Beecham and others.

The European studies were dogged by even worse conflicts. All were funded by vaccine makers or thimerosal proponents including the CDC and WHO. Paul Stehr-Green's Denmark study was financed in part by the Statens Serum Institut, a thimerosal vaccine manufacturer.[120] Anders Hviid, the principal author of another of the studies, is an employee of the Statens Serum Institut. Elizabeth Miller, author of three United Kingdom studies, regularly works for a host of thimerosal-laced vaccine makers.[121]

CDC in some cases funded and in others aggressively promoted the creation and publication of these deceptive studies before providing them to the IOM, in preparation for its February 2004 meeting.[122] The British study[123] was created at the prompting of, and in cahoots with CDC. [124] On December 10, 2002, for example, Jose Codero, Assistant Surgeon General at CDC, sent a letter to the Journal of Pediatrics, asking the editors to publish Madsen's Danish study two days

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[120] Paul Stehr-Green, Autism and Thimerosal-Containing Vaccines Lack of Consistent Evidence for an Association, Am J Prev Med 25(2):101-106 (2003). Accessed online June 20, 2005 at http://www.pkids.org/AMJPRMED.pdf. *See also* Danish Statens Serum Institut, National Surveillance of Communicable Diseases, "Thimerosal in Vaccines." Accessed online June 20, 2005 at http://www.ssi.dk/sw2901.asp.

[121] Medicines Act 1968 Advisory Bodies Annual Reports 2001 Committee On Safety Of Medicines And Subcommittees Declaration Of Interests (2005), at http://www.mca.gov.uk/aboutagency/regframework/csm/csmdoi01.pdf. Dr. Elizabeth Miller's 2002 conflict of interest statement on file with the UK's Committee on Safety of Medicines lists the following funding sources: North American Vaccine (which has a relationship with Staten Serum Institute {Hviid} to import vaccines into the United States, a representative of North American Vaccine also attended Simpsonwood); Wyeth Lederle Vaccines; Chiron Biocine; Baxter Health Care; Smith Kline Beecham; and Aventis Pasteur.

[122] *See also* F. E. Yazbak, M.D., "The Flu Vaccine Saga: The Latest Twist" (Feb. 25, 2005) viewed at www.redflagsdaily.com ("*The CDC has systematically rejected the findings of small clinical autism studies dealing with the MMR-autism connection; the CDC has always praised and encouraged large epidemiological studies, such as the Peltola Group studies (Finland) that were supported by the vaccine manufacturer; the CDC funded a large epidemiological study in Denmark, though the findings could hardly be relevant to the situation in the United States where we administered more vaccines during the first year of life and added thimerosal to some of them. Danish vaccines were thimerosal-free since 1991; the CDC highly supported and often quoted an epidemiological study by Kaye that was based on a similar concept as that of the NIAID Flu study. Kaye had concluded that the MMR vaccination did not cause autism because the prevalence of autism continued to rise even after a great majority of children had been vaccinated for years*.")

[123] Andrews N, Miller E, Grant A, Stowe J, Osborne V, Taylor B., "Thimerosal exposure in infants and developmental disorders: a retrospective cohort study in the United kingdom does not support a causal association," Pediatrics. 2004 Sep;114(3):584-91.

[124] Emails between Robert Chen, CDC and Elizabeth Miller of the Communicable Disease Surveillance Centre at United Kingdom's Health Protection Agency. Jun. 26, 2001 through Nov. 8, 2001.

before it was even submitted![125] "It's quite unusual to have a CDC official endorse a study in that way," says Dr. Haley, who has published over 130 papers in peer-reviewed journals. "I have never heard of it before."[126] The CDC's unusual decision to aggressively promote the publication of research by asking for its "expedited review" demonstrates the depth of the agency's commitment to protect the vaccine industry and to cover its own tracks on thimerosal.

The authors mostly neglected to disclose their conflicts in violation of the policies of the journals in which they published and of universally-accepted peer review ethics.

Pichichero did not declare any of his conflicts in publishing his article despite the Lancet's iron-clad policy requiring that such conflicts be fully revealed. While Pichichero revealed his vaccine industry ties in prior articles, he neglected to comply only in this instance.[127]

Elizabeth Miller also published her three United Kingdom studies without disclosing that she is a long time consultant to the vaccine industry. When she presented her results to the IOM in February 2004, Miller admitted coyly that "my department does, on occasion, do collaborative work which has commercial sponsorship. . ."[128] She never disclosed when she published her three articles assuring the public of vaccine safety that she was an expert witness for the vaccine companies GlaxoSmithKline, Aventis Pasteur and Merck in thimerosal litigation in the U.K.

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[125] Former NCBDDD (CDC) Director's (Dr. Jose Cordero) Letter to the Editor of Pediatrics (FOIA requested currently) recommending publication of the Madsen et al. 2003 Study. Viewed at http://www.whale.to/a/reb.html.
[126] Robert F. Kennedy, Jr., Telephone Interview with Boyd Haley, April 9, 2005.
[127] For example, in an article in the American Academy of Family Physicians newsletter of April 2000, Dr. Pichichero makes this disclosure statement (3):"The author has received research grants and/or honoraria from the following pharmaceutical companies: Abbott Laboratories, Inc.; Bristol-Myers Squibb Company; Eli Lilly & Company; Merck & Co.; Pasteur Merieux Connaught; Pfizer Labs; Roche Laboratories; Roussel-Uclaf; Schering Corporation; Smith Kline Beecham Pharmaceuticals; Upjohn Company; and Wyeth-Lederle."
[128] Transcript, Immunization Safety Review Committee, Vaccines and Autism, February 9, 2004, National Academy of Sciences, Washington DC, at 101. Accessed online June 15, 2005 at http://www.iom.edu/file.asp?id=19140.

Miller published her reports in the Journal of Pediatrics in violation of that organization's strict conflicts of interest disclosure requirements.[129]

Verstraeten and Davis also published their article in the Journal of Pediatrics in October 2003 without revealing their myriad conflicts, despite the Journal's rules and standard ethical mandates that such conflicts be disclosed. Verstraeten identified himself, incorrectly, as a CDC employee. He was at the time an employee of a thimerosal vaccine maker.[130]

The Journal of Pediatrics is the principal publication of the American Academy of Pediatrics, which has its own heavy conflicts. The AAP has consistently supported the position of the vaccine manufacturers in the thimerosal controversy without telling its readers that it solicits and regularly receives significant funding from the vaccine companies, including Wyeth, GlaxoSmithKline and Merck.[131]

Furthermore, the Journal of Pediatrics itself receives substantial advertising revenue from thimerosal vaccine producers, perhaps explaining why the Journal overlooked its own bias policies and did not require Verstraeten, Davis, Miller and others to reveal their conflicts when publishing articles on thimerosal safety.

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[129] Andrews and Miller et al., Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association. Pediatrics, 114(3):584-591 (2004). The Acknowledgments for this study read "This study was funded by the World Health Organization, grant 18/181/854, and was conducted on behalf of the Global Vaccine Safety Advisory Committee." Miller does not list her Non-Professional interests. See footnote #121.

[130] Verstraeten, Davis, et al., Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases, Pediatrics 112(5):1039-1048 (Nov. 2003). Verstraeten was a CDC employee at the time of the original study in 2001. In the summer of 2001 he took a job with a vaccine maker in Switzerland. This conflict is not mentioned in the Acknowledgments section of the study printed in Pediatrics in 2003.

[131] American Academy of Pediatrics, Friends of Children Fund Corporate Members, (2005). Accessed online June 15 at http://www.aap.org/donate/FCFhonorroll.HTM

Firestorm

Based upon these wretchedly-flawed studies ginned up by CDC from badly compromised authors, IOM, in 2004, dismissed the possibility of a causal relationship between exposure to thimerosal from vaccines and autism and declared that no more federal money should be spent on researching the link.[132] The release of IOM's conclusions triggered a firestorm. Dissent even came from within the panel. One committee member, Dr. Steve Goodman complained that the final report's conclusions were inconsistent with the committee's findings.

"First of all, we didn't dismiss anything. We simply stated the epidemiology evidence [viewed by the committee] favored no relationship, which is true ... What we did say is if you've got a fixed pot, don't spend huge amounts more on epidemiology. What we said was that resources would be better spent on understanding the biology."[133] Dr. Goodman told me, "We didn't say that more research shouldn't be done. We said we should gain a better understanding of autism. We can design better studies. That's what we said."[134]

Numerous government agencies, organizations and public officials also attacked the IOM study as biased and fatally flawed.

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[132] Autism Newsletter, "IOM finds no link between thimerosal and autism," May 24, 2004. Viewed at: http://www.childdevelopmentinstitute.org/autismnwsltrs/2004/05242004.htm *("The overwhelming evidence from several well-designed studies indicates that childhood vaccines are not associated with autism," and "[r]esources would be used most effectively if they were directed toward those avenues of inquiry that offer the greatest promise for answers. Without supporting evidence, the vaccine hypothesis does not hold such promise," committee Chair Marie McCormick stated in an IOM news release.)*

[133] Bob Miller, "Gene flaw may link autism, vaccine additive," Southeast Missourian, December 13, 2004. Accessed online June 15 at http://semissourian.rustcom.net/story/152176.html

[134] Robert F. Kennedy, Jr., Telephone Interview with Steve Goodman, May 4, 2005.

Republican Congressman Dave Weldon, M.D., whose Human Rights and Wellness Sub-Committee had been investigating the links between thimerosal and autism for three years in an exhaustive process that included testimony from numerous scientific experts, immediately attacked the IOM report for its conclusion and the IOM and CDC for their conflicts of interest and bias. Later that month, the Congressional Record published "The Mercury in Medicine Report" on May 21, 2003 by Weldon's committee. The committee report made a specific finding that: "The CDC in general and the National Immunization Program in particular conflicted in their duties to monitor the safety of vaccines, while also charged with the responsibility of purchasing vaccines for resale as well as promoting increased immunization rates."[135]

The report faulted CDC which, it said, was plagued by "bias[es] against theories regarding vaccine-induced autism," had therefore selected researchers "who also worked for vaccine manufacturers to conduct population-based epidemiological studies."[136] The report condemned the IOM studies as "of poor design, under-powered, and fatally flawed."[137]

The report concluded that:

> **"Thimerosal used as a preservative in vaccines is likely related to the autism epidemic.** This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of

[135] Congressional Record, Extensions of Remarks, May 21, 2003, at E1013. Accessed online June 20, 2005 at www.aapsonline.org/vaccines/mercinmed.pdf.
[136] Ibid. at E1029.
[137] Ibid. at E1013.

> safety data regarding injected Thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies' failure to act is indicative of institutional malfeasance for self protection and **misplaced protectionism of the pharmaceutical industry.**"[138] [emphasis added]

Congressman Weldon told me that there is an extremely close relationship between the CDC and vaccine manufacturers and CDC's treasured "partnerships" with the vaccine industry invariably take precedence over vaccine safety. Weldon explained that CDC is not interested in an honest search for truth on the issue because "an association between vaccines and autism would force CDC officials to admit that their policies irreparably damaged thousands of children. Who would want to make that conclusion about themselves?"[139]

The day after the IOM issued its "no link" report, the U.S. Office of Special Counsel (OSC)—an independent investigative and prosecutorial agency that serves as a channel for whistleblowers—forwarded hundreds of specific complaints and its conclusion that there is a "substantial likelihood of a substantial and specific danger to public health caused by the use of thimerosal/mercury in vaccines because of its inherent toxicity and its link to neurological disorders, including autism" to the U.S. Senate and House Committees with oversight authority for HHS, requesting a congressional investigation.

Under this kind of pressure from Congress, the public and its own panel members, convened a second panel to review the findings of the first IOM panel. On February 17, 2005, the second

[138] Ibid. at E1030.
[139] Robert F. Kennedy Jr., Telephone interview with Congressman Dave Weldon, May 5, 2005.

panel, made up of different scientists, criticized the earlier panel for lack of transparency and urged CDC to open up the VSD database to public access.

States Act to Fill the Federal Vacuum

State officials also reacted negatively to the IOM report. During the three-year period the IOM committee reviewed its carefully selected studies by tame scientists denying the links between vaccines and autism, the Iowa Human Resources Committee reviewed scientific and biological data from independent researchers. "After three years of review, I became convinced there was sufficient credible research to show a link between mercury and the increased incidents in autism," said Iowa's Republican State Senator Ken Veenstra. "The fact that Iowa's 700 percent increase in autism began in the 90s, right after more and more vaccines were added to the children's vaccine schedules, is solid evidence alone. The IOM has not convinced me."[140] In May 2004, Iowa became the first state to ban mercury in vaccines.

California Governor Arnold Schwarzenegger followed, signing his state's mercury ban last year.[141] Sixteen other states are currently considering their own bans. The Frist bill would repeal the current states' bans and prohibit more states from enacting their own bans on mercury.[142]

Counter Arguments

[140] Id. ¶ 77
[141] Id. ¶ 79
[142] Protecting America in the War on Terror of 2005, S. 3, 109th Cong. § 126 (1st Sess, 2005), viewed at http://www.nomercury.org/science/documents/S_3_War_on_Terror_Act_2005.pdf.

In defending its conclusions, industry and CDC have tried to attribute the ten-fold increase in autism and other neurological disease in the last decade as an artifact of the past failure to properly diagnose the disease. Boyd Haley finds this notion laughable. "Missing autism is like missing a train wreck," says Haley. He adds, "The ten-fold increase occurred instantaneously across multiple jurisdictions and in all databases—NIH, 50 state health departments, etc. Not all of them simultaneously adopted some new diagnostic criteria." Finally, he adds, "If the change is just diagnostic, then where are all the 20-year-old autistics?"[143]

Eli Lilly's own researchers—Robert and Julia Gerlai of the company's Neuroscience Discovery Research Division, have confirmed that the increase in prevalence of autism is real and cannot be attributed to diagnostic criteria or misclassification. They suggest that some environmental cause is responsible for the epidemic.[144]

In California, the Department of Developmental Services experienced an increase of 273% in reported cases of autism between 1987 and 1998.[145] The California State Legislature responded by commissioning the University of California's Medical Investigation of Neurodevelopmental Disorder (M.I.N.D.) Institute to conduct an exhaustive study to determine the reason for this increase.[146] That study also concluded that the observed increase was real and could not be

[143] Robert F. Kennedy Jr., Telephone Interview with Dr. Boyd Haley, May 5, 2005.
[144] Gerlai &Gerlai, Autism: a large unmet medical need and a complex research problem, Physiology & Behavior 79:461-470 (2003); Gerlai & Gerlai, Autism: a target of pharmacotherapies? Drugs Discovery Today, Vol 9(8): 366-373 (2004).
[145] Gurney, Analysis of Prevalence Trends of Autism Spectrum Disorder in Minnesota, 157 Arch. Pediatr. Adolesc. 622-627 (2003) *(Autism Spectrum Disorder increased from 3 per 10,000 (1991-92) to 52 per 10,000 (2001-2002);* Blaxill, What's Going On? The Question of Time Trends in Autism, Public Health Reports, 119:536-551 (2004).
[146] Byrd, Report to the Legislature on the Principal Findings from The Epidemiology of Autism in

explained by changing diagnostic criteria, misclassification, or migration of autistic children into California.[147]

Haley adds that if CDC was really interested in uncovering the truth, it would commission epidemiological studies of American cohorts who escaped vaccination, most obviously the children of Jehovah's Witnesses, Christian Scientists or the Amish. But CDC has instead worked furiously to quash such studies by cutting off federal funding and denying independent scientists access to the VSD database. Using that database, scientists could make comparative studies of children receiving zero mercury from vaccines and children that were fully vaccinated. CDC says it made the VSD unavailable to outside researchers due to "potential issues of patient confidentiality." But Haley says that patient confidentiality is routinely safeguarded through a number of well-established techniques in such studies.[148] When I raised the possibility of encouraging such studies to Kathleen Stratton, the chief IOM staffer on the thimerosal panel, she told me, "that's a great idea, no one has ever suggested it before." The statement is incredible; Stratton was the chief scientific organizer of the IOM's vaccine project; the idea of finding an uncontaminated U.S. cohort to study as a "control" group is Science 101. In fact, Dr. Boyd Haley has repeatedly urged IOM and CDC to conduct such a study, including at two public and tape-recorded meetings—one of these attended by Kathleen Stratton.[149]

California: A Comprehensive Pilot Study (October 17, 2002).

[147] Croen, LA et al. The Changing Prevalence of Autism in California, Journal of Autism and Developmental Disorders, 32(3):207-215 (2002); *But See* Commentary: Blaxill, Baskin, and Spitzer on Croen et. al. (2002), The Changing Prevalence of Autism in California, Journal of Autism and Developmental Disorders 33(2):223-226 (2003) (refuting Croen's "diagnostic substitution" postulate) and Croen, Response: A Response to Blaxill, Baskin, and Spitzer on Croen et al. (2002), "The Changing Prevalence of Autism in California" 33(2): 227-229 (2003) (agreeing that the slight degree of diagnostic substitution would not explain the dramatic increase in autism).

[148] Robert F. Kennedy Jr., Telephone Interview with Dr. Boyd Haley, May 5, 2005.

[149] Dr. Boyd Haley has repeatedly called for such studies at public meetings and seminars sponsored by Autism One and Defeat Autism Now (DAN). Stratton was on one DAN conference call, when Dr. Haley made this plea.

In April 2005, UPI reporter Dan Olmsted undertook the task himself. He scoured the Amish of Lancaster, Pennsylvania, who refuse to immunize their infants. Given the national rate of autism, Olmsted calculated that there should be 130 autistics among the Amish. He found only four. One had been exposed to high levels of mercury from a power plant. The other three – including one child adopted from outside the Amish community – had received their vaccines.[150]

Finally, a critical new piece of evidence is now emerging: recent epidemiological studies show that U.S. autism rates are dropping in lockstep with the gradual discontinuance of thimerosal that began in 1999.

Researcher Mark Blaxill has graphically plotted the rising incidence of autism in California alongside rising thimerosal exposures and found the two trends tracking in lockstep. The slow increase in thimerosal dosing beginning in 1989 and its decrease in 1997 correlates directly with California's rise and slight recent decline in autism rates.[151] A soon-to-be published study by Drs. Mark and David Geier shows rates of autism and other neurodevelopmental disorders declining nationally following the elimination of thimerosal from most vaccines.

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[150] Dan Olmsted, "The Age of Autism: Julia," *Washington Times*, April 19, 2005, available at http://washingtontimes.com/upi-breaking/20050417-052541-5549r.htm.

[151] Thimerosal-Containing Vaccines and Neurodevelopmental Outcomes Meeting Agenda, Cambridge, MA, Monday, July 16, 2001 audio file available at: http://www.altcorp.com/DentalInformation/iomthimvacconf.htm After presenting his data regarding the association of the rising incidence of autism in California with thimerosal exposure from vaccines Mr. Blaxill told the meeting "We are seeing an anomaly (the rise in autism) that nobody has a good explanation for, and the reason it hasn't been addressed is that it is uncomfortable, and the reason it is uncomfortable is the hypothesis on the table…the very parties that are investigating the question of the disease are the very parties that are the principles in the decisions that produced the exposure." *See also* A study by Mark Blaxill, which was published in an article by Stehr-Green P, Tull P, Stellfeld M, Mortenson PB, Simpson D. Autism and thimerosal-containing vaccines: lack of consistent evidence for an association. Am J Prev Med. 2003 Aug;25(2):101-6.

Six recent epidemiological studies of American populations by this father-son team, reviewed by world-renowned epidemiologist, Walter Spitzer, show a huge correlation between thimerosal and neurological damage including autism.[152] Dr. Geier and his son, David Geier, are the only independent researchers that have been permitted access to the Vaccine Safety Datalink (VSD) database of the CDC. It took them 14 agonizing months of stubborn persistence, patient combat and, finally, direct Congressional intervention to overcome the extraordinary obstacles erected by the determined CDC bureaucrats intent on keeping the files secret. The Geier's Kaflaesque saga to access the VSD files, which they recounted to me and which is partially retold by Sarah Bridges in the June 2004 SEED magazine[153], reads like the bureaucratic equivalent of an Everest ascent.

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[152] 1.Geier DA, Geier MR, A two-phased population epidemiological study of the safety of thimerosal-containing vaccines: a follow-up analysis. Med Sci Monit. 2005 Mar 24;11(4):CR160-170 (*Exposure to mercury from thimerosal-containing vaccines administered in the US was a consistent significant risk factor for the development of neurological disorders. Showed significantly increased risks for autism, speech disorders, mental retardation, personality disorders, and thinking abnormalities reported to VAERS following thimerosal-containing DTaP vaccines in comparison to thimerosal-free DTaP vaccines. Cumulative exposures to thimerosal associated with tics, attention deficit disorder (ADD), language delay, speech delay, and neurodevelopmental delays in general)* and 2. Geier DA, Geier MR, A comparative evaluation of the effects of MMR immunization and mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism. Med Sci Monit. 2004 Mar;10(3):PI33-9. Epub 2004 Mar 1. (*The results of this study agree with a number of previously published studies showing biological plausibility and epidemiological evidence linking increased doses of mercury from thimerosal-containing vaccines and neurodevelopmental disorders.)* and 3. Geier MR, Geier DA, Neurodevelopmental disorders after thimerosal-containing vaccines: a brief communication. Exp Biol Med (Maywood). 2003 Oct;228(9):991-2; discussion 993-4. ("*This study presents the first epidemiologic evidence, based upon tens of millions of doses of vaccine administered in the United States, that associates increasing thimerosal from vaccines with neurodevelopmental disorders. An analysis of the Vaccine Adverse Events Reporting System (VAERS) database showed statistical increases in the incidence rate of autism, mental retardation, and speech disorders after thimerosal-containing diphtheria, tetanus, and acellular pertussis (DTaP) vaccines in comparison with thimerosal-free DTaP vaccines.*") and 4. Geier DA, Geier MR., An assessment of the impact of thimerosal on childhood neurodevelopmental disorders. Pediatr Rehabil. 2003 Apr-Jun;6(2):97-102. ("*Neurodevelopmental disorder dose-response curves for increasing mercury doses of thimerosal in childhood vaccines were determined based upon examination of the Vaccine Adverse Events Reporting System (VAERS) database and the 2001 US' Department of Education Report. The evidence presented here shows that the occurrence of neurodevelopmental disorders following thimerosal-containing childhood vaccines does not appear to be coincidental*.") and 5. Geier DA, Geier MR., Thimerosal in childhood vaccines, neurodevelopment disorders, and heart disease in the United States. J Am Phys Surg. 2003;8:6-11., *(Showed increasing relative risks for neurodevelopment disorders and heart disease with increasing doses of mercury.)* and 6. Geier DA, Geier MR. Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunizations: A Follow-Up Analysis. Int J Toxicol, 23:369-376, (2004). *(This study supports previous epidemiological, clinical and experimental evidence that administration of thimerosal-containing vaccines in the US resulted in a significant number of children developing neurological disorders.)*

[153] Sarah Bridges, "The Rise Against Mercury," SEED Magazine, June 2004, pg. 107-111.

One product of their efforts was recently published in the peer-reviewed Medical Science Monitor. In this study, the Geiers assessed thimerosal exposure in about 110,000 children and found a statistically significant association between cumulative exposure to thimerosal and neurodevelopmental disasters including tics, attention deficit disorder (ADD/ADHD), speech and language delays, and autism.[154]

When the Geiers discovered that one vaccine manufacturer had used a non-thimerosal preservative in its DTaP vaccines, they compared the medical records of kids who received that vaccine to kids who had received an additional 75 to 100 µg of mercury from thimerosal-containing DTaP vaccines. Dr. Geier found a 2 to 6 fold increase in neurological development disorders among children who had received the additional thimerosal.[155] The Geiers concluded in the American College of Toxicology's journal that their results "demonstrate a connection between mercury exposure via infant vaccinations and the dramatic increase in autism and other neurodevelopmental disorders in the United States."[156] All six of the Geier's articles were subjected to the most rigorous peer-review[157] and have been published.

Indeed, every relevant epidemiological study (those that involve doses of thimerosal comparable to what was given to children in the United States), except Verstraeten's, which was neutral,

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[154] Geier DA and Geier MR. A Two-Phased Population Epidemiological Study of the Safety of Thimerosal-Containing Vaccines: a Follow-Up Analysis. Med. Sci. Monit., 11(4): CR160-170 (2005).
[155] Geier MR, Geier DA., Neurodevelopmental Disorders After Thimerosal-Containing Vaccines: A Brief Communication, Exp Biol Med (Maywood). 2003 Oct;228(9):991-2; discussion 993-4.
[156] Geier DA, Geier MR., Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunizations: A Follow-Up Analysis. Int J Toxicol, 23:369-376, (2004).
[157] Many of Dr. Geier's publications underwent and passed an additional peer review process after publication as part of the Hazardous Substances Data Bank (HSBD) of the United States National Library of Medicine (NLM). The HSDB is a toxicology file on the NLM's Toxicology Data Network. Furthermore, the HSDB is peer-reviewed by the Scientific Review Panel (SRP).

confirm that exposure to thimerosal is a cause of neurological development disorders, including autism. (One of Verstraeten's data sets showed a strong correlation, the other did not.)[158]

Mountains of new evidence confirm the causative link between thimerosal and neurological injury, including autism. Numerous studies show that autistic children have higher mercury loads than non-autistics.[159] There have been many reports of significant improvements in some brain-injured children by removing mercury from their bodies.[160] Most of the 95+ symptoms of autism are identical to the symptoms of mercury poisoning including symptoms like hand-wagging and toe walking, which are unique to autistics and victims of mercury poisoning.[161]

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[158] Critics of Verstraeten's study suggest that the data set that showed no link was generated by a habitually sloppy and financially unstable HMO.

[159] Wecker L, et al. Trace Element Concentrations in Hair from Autistic Children. J Ment Defic Res. 1985 Mar;29 (Pt 1):15-22. ("*Results indicate that the concentrations of trace elements (including mercury) in hair from normal children differ from patterns observed in both autistic and autistic-like children. Furthermore, evidence suggests that hair analysis may have potential use as a diagnostic tool for autism.*") And Holmes AS, et al, Reduced Levels of Mercury in First Baby Haircuts of Autistic Children, Int J Toxicol. 2003 Jul-Aug;22(4):277-85 (*Study shows that the more severe the case of autism, the lower the amount of mercury present in that child's hair. "Hair excretion patterns among autistic infants were significantly reduced relative to control.")* and Bradstreet J et al, A Case-Control Study of Mercury Burden in Children with Autistic Spectrum Disorders, J Am Phys Surg 8(3):76-79. Summer 2003. (Study confirmed earlier epidemiology {see Geier 2001} through DMSA challenge. While cadmium and lead levels were similar in both groups, autistic children had six times more mercury in urine than controls in response to DMSA).

[160] Lowell JA, et al., *Mercury* Poisoning Associated with Hepatitis-B Immunoglobulin. Lancet 1996;347:480. ("*Study encountered mercury toxicity in a patient who received high-dose HBIG preparations that contained Thimerosal as a preservative … Various forms of chelation have been used to treat mercury poisoning; our patient had an excellent response to DMSA. ... Neurological recovery was complete. Physicians should suspect mercury toxicity in patients receiving high-dose HBIG.*"). Zhang J., Clinical Observations in Ethyl Mercury Chloride Poisoning, Am J Ind Med. 5(3):251-8.1984 ("*Forty-one patients in the Peoples Republic of China were poisoned by ethyl mercury chloride, caused by the ingestion of contaminated rice. A dose-response relationship was found. Five months after the onset of the intoxication, the patients, still in poor condition, were treated with two chelating agents. Both agents were effective")*. and Debray P., et al, Acute Mercury Poisoning in Children. Report on four cases, Sem Hop. 1980 Apr 8-15;56(13-14):659-65, ("*The authors report four cases of acute mercury poisoning in children ranged from one week to twelve years of age. All were of favourable course and one of them is particularly well-documented with regard to mercury excretion.*")

[161] Bernard S, et al, Autism: a Novel Form of Mercury Poisoning, Med Hypotheses. 2001 Apr;56(4):462-71., ("*Exposure to mercury can cause immune, sensory, neurological, motor, and behavioral dysfunctions similar to traits defining or associated with autism, and the similarities extend to neuroanatomy, neurotransmitters, and biochemistry … A review of medical literature and US government data suggests that: (i) many cases of idiopathic autism are induced by early mercury exposure from thimerosal; (ii) this type of autism represents an unrecognized mercurial syndrome; and (iii) genetic and non-genetic factors establish a predisposition whereby thimerosal's adverse effects occur only in some children.*")

Scientists have now been able to induce autism in certain mice by exposing them to thimerosal.[162]

In a recent study, former FDA scientist Dr. Jill James uncovered a scientific link that helps explain why thimerosal injures some children and not others. That study found that many autistic children are genetically deficient in their capacity to produce glutathione, an antioxidant generated in the brain that helps remove mercury from the body, a harmless difference until the child is exposed to large quantities of mercury.[163] This explains an earlier observation, based on birth hair mercury analysis, that implied that autistics represent a subset of the population that cannot effectively excrete mercury.[164]

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[162] Hornig M, Chian D, Lipkin WI., Neurotoxic Effects of Postnatal Thimerosal are Mouse Strain Dependent, 9 Mol Psychiatry 9;833-45 (2004). *(Autism-like symptoms are triggered by thimerosal in mice with weak immune systems. The researchers administered Thimerosal to mice mimicking the United States' routine childhood immunization schedule {i.e. dose and timing, adjusted}. The researchers demonstrated a genetically-susceptible mouse strain {with a predisposition to autoimmunity} developed physical, psychological, and pathological symptoms similar to autism, including: growth delay, reduced locomotion, exaggerated response to novelty, increased brain size, decreased numbers of Purkinje cells, significant abnormalities in brain architecture, affecting areas sub-serving emotion and cognition.)*

[163] James SJ, et al, Thimerosal Neurotoxicity is Associated with Glutathione Depletion: Protection with Glutathione Precursors, Neurotoxicology. 2005 Jan;26(1):1-8., (*Environmental methyl mercury has been shown to be highly neurotoxic, especially to the developing brain. Glutathione provides the major intracellular defense against mercury-induced neurotoxicity. Study showed that Thimerosal-induced toxic effects on cells were associated with depletion of intracellular glutathione in cell lines.*) James SJ, et al, Metabolic Biomarkers of Increased Oxidative Stress and Impaired Methylation Capacity in Children with Autism, Am J Clin Nutr. 2004 Dec;80(6):1611-7. (*Study evaluated plasma concentrations of mercury clearing glutathione in children diagnosed with autism. Relative to the control children, the children with autism had significantly lower baseline plasma concentrations of glutathione. This metabolic profile is consistent with impaired mercury clearing in children with autism. The intervention trial was effective in normalizing the metabolic imbalance in the autistic children. The study concluded that an increased vulnerability to oxidative stress and a decreased capacity for glutathione may contribute to the development and clinical manifestation of autism)*. For an overview of the implications of the findings of James et al., see Overloaded: New Science, New Insights About Mercury and Autism in Susceptible Children, Environmental Working Group, (2004), *available at* http://www.ewg.org/reports/autism/. *See also* Westphal GA, Schnuch A, Schulz TG, Reich K, Aberer W, Brasch J, Koch P, Wessbecher R, Szliska C, Bauer A, Hallier E., Homozygous Gene Deletions of the Glutathione S-Transferases M1 and T1 are associated with thimerosal sensitization, Int Arch Occup Environ Health. 73(6):384-8. *(People with gene deletions for two types of glutathione genes {GST M1 and T1} are more likely to have allergic reactions to the mercury-based preservative thimerosal.)*

[164] See footnote 159.

The industry has long claimed, despite reams of evidence to the contrary, that ethyl mercury is less toxic than methylmercury: for example, Paul Offit, in his May 4, 2005 interview with me, repeated this claim. A recent report by researcher Thomas Burbacher has shown that ethyl mercury from thimerosal crosses the blood-brain barrier and breaks down to release inorganic mercury which stays in the brain longer than methylmercury[165], increasing the likelihood of toxic effects as it would accumulate in the brain following repeated exposures to thimerosal.

Mum's the Word

Despite these findings, the February 2004 IOM proclamation has been used to muzzle the media, to dry up federal funding for studies that might demonstrate that link and by the defendants in Thimerosal litigation, as a basis for arguing for dismissal of 4,500 petitions by parents of autistic children in vaccine court and as a justification for Senator Frist's attempts to pass sweeping protections for the pharmaceutical industry.

Worst of all, most pediatricians take the IOM and CDC's pronouncement at face value and routinely tell their patients' parents that thimerosal-laced vaccines are safe. Many doctors, relying on CDC's assurances, also discourage parents from employing chelating therapies that remove mercury from the human body—therapies that have repeatedly been proven effective. "Pediatricians are not clinical researchers," says Dr. Haley. "They base their opinions on the

[165] Thomas M. Burbacher, Danny D. Shen, Noelle Liberato, Kimberly S. Grant, Elsa Cernichiari, and Thomas Clarkson, "Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal," The National Institute of Environmental Health Sciences, April 21, 2005. Available at http://ehp.niehs.nih.gov/members/2005/7712/7712.pdf. *(Burbacher's study confirmed the earlier results of other scientists showing that mercury from Thimerosal clears from the blood by going into the organs of the body, not by being excreted. Burbacher et al. show that ethylmercury from Thimerosal lodges in the brain.)*

government studies and reassurances from the CDC. The problem is, CDC has terrible conflicts here and as Congressman Weldon has pointed out, the bureaucrats are lying to the public to cover their tracks."[166]

CDC's stellar reputation inspires such reverence that even the press has been reluctant to take them to task. I've met extraordinary resistance in my own efforts to publicize this debate. Newspapers have refused to carry an earlier editorial I wrote on this issue, regardless of the documentation I produced in hours-long meetings with editorial board members. My op-ed was finally picked up by Knight-Ridder but ran in only a tiny handful of its papers—and in abbreviated format. When UPI reporter Mark Benjamin wrote a comprehensive investigative report exposing conflicts of interests in the CDC vaccine program, not a single American daily paper or mainstream news source would run the story. Similarly, when Don Imus referred to the thimerosal conspiracy on his popular radio show, he was denounced viciously by Fox News correspondent Steve Milloy who accepted the CDC world view: "A closer look at the facts," says Milloy, "reveals that while thimerosal is safe, Imus unfortunately appears to be suffering from a case of Charlie McCarthy Syndrome, with his eco-crusader wife as the ventriloquist."[167] I've encountered a wall of resistance about discussing this issue, even within the environmental community. And parents of injured children who raise the association between neurological disorders and thimerosal are often dismissed as whackos. The institutional resistance toward unilaterally questioning CDC has made life easy for the pharmaceutical industry's Congressional allies.

[166] Robert F. Kennedy Jr., Telephone Interview with Boyd Haley, April 9, 2005.
[167] Steven Milloy, "Vaccination-Autism Link Unproven," Fox News, April 1, 2005. Accessed online June 15 at http://www.foxnews.com/story/0,2933,152110,00.html.

Frist Bill

In November 2002, Republican leadership surreptitiously inserted the so-called "Eli Lilly" rider into the massive Homeland Security bill, ordering the Justice Department to seal all the vaccine-related papers and documents, including the Simpsonwood transcripts, and shield them from subpoenas then being issued by plaintiff's attorneys in the cases against vaccine makers.

The bill specifically gave pharmaceutical giant Eli Lilly protection from liability for injuries caused by thimerosal.[168] It barred any judge from issuing compensation to damaged children. All thimerosal cases would be transferred to special "vaccine courts" where compensation is capped and where plaintiffs are not entitled to discovery. Federal officials and drug companies could freely hide the truth from Americans about vaccine and prescription drug risks. The bill meant billions to the drug industry in general and Eli Lilly in particular. The action was so secretive that even a Republican Congressional leader Dan Burton whose committee had jurisdiction over the Homeland Security bill and who had held hearings on thimerosal's dangers, was shocked to learn of its inclusion.[169] The provisions were identical to legislation sponsored the previous March by Senator Bill Frist of Tennessee—which was then stalled in committee. Eli Lilly has been a good friend to Bill Frist, donating $226,250 to Frist's National Republican Senatorial Campaign Committee (NRSC) in 2002, and enriching the senator personally by purchasing 5,000 copies of his book on bioterrorism.[170] The pharmaceutical industry was the

[168] Jonathan Weisman, "A Homeland Security Whodunit In Massive Bill, Someone Buried a Clause to Benefit Drug Maker Eli Lilly," Washington Post, November 28, 2002. Pg. A45.
[169] Jim Acosta, "The Man Behind The Vaccine Mystery," CBS Evening News, December 12, 2002, Accessed online June 15 at: http://www.cbsnews.com/stories/2002/12/12/eveningnews/main532886.shtml.
[170] Maureen Groppe, "Frist brings support for drug companies to majority leader job," Gannett News Service, December 24, 2002, viewed at: http://www.consumerwatchdog.org/healthcare/nw/nw002949.php3

largest single contributor to the NRSC that Frist chaired, ladling out some $4 million, and Frist has received $873,000 from the industry altogether for his Senate races. Lilly is the single biggest contributor to the Republican Party from the pharmaceutical industry, donating $1.6 million in the last national election, 74% to Republicans.[171]

While the mystery of how the provisions were tacked onto the bill, which few members of Congress actually read, was never resolved, most fingers pointed to Frist and the White House where a former Eli Lilly executive, Mitch Daniels (now Indiana Governor), was director of the Office of Management and Budget. The bill passed both houses and President Bush signed it on November 25, 2002.[172] Frist received an additional $10,000 from pharmaceutical companies right after his Homeland Security rider passed.

Under pressure from parent activists who had mounted a letter writing campaign, and chastised Senator Frist and the Republican leadership in an advertisement in the Congressional newspaper *Roll Call*, Congress, in a bi-partisan vote, repealed the provision in 2003. However, now Dr. Frist has returned with his newly proposed "anti-terror" legislation. He and his staff are marketing this provision as a bioterror safeguard that has nothing to do with protecting the pharmaceutical industry. His Legislative Assistant Andy Olsen told me that "this new bill does not affect the thimerosal cases at all. The lawsuits are of such magnitude that they could put vaccine producers out of business and limit our capacity to deal with a biological attack by terrorists." But in fact, the bill would create insurmountable burdens of proof for plaintiffs in

[171] Ibid. *See also* Center for Responsive Politics, "The Big Picture: 2002 Cycle Top Overall Donors." Accessed online June 20, 2005 at http://www.opensecrets.org/bigpicture/topcontribs.asp?cycle=2002&Format=Print.
[172] Sheryl Gay Stolberg, "A Capitol Hill Mystery: Who Aided Drug Maker?," *The New York Times*, November 29, 2002.

thimerosal cases and forbid states from banning thimerosal.[173] Laws have passed in Iowa and California and are pending in New York, Minnesota, Missouri, and many other states.[174] Frist's bill would kill them all by preempting states' rights to ban thimerosal.

Congress will vote on Frist's new bill S3 in the near future. Instead of demanding the immediate removal of thimerosal from all vaccines, and making the drug industry help defray the public and private costs of caring for injured children, Frist's bill would give the industry a free ride at public expense.

Unnecessary Disinfectant

Ironically, thimerosal is probably not nearly as indispensable as the industry portrays. First, study after study shows that thimerosal is ineffective as an anti-bacterial agent.[175] While

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[173] See Protecting America in the War on Terror of 2005, S. 3, 109th Cong. § 126 (1st Sess, 2005). Accessed online June 20, 2005 at http://www.nomercury.org/science/documents/S_3_War_on_Terror_Act_2005.pdf.

[174] "Status of Local, State and Federal Mercury Product Legislation and Laws 2005-2006 Legislative Sessions," Mercury in Schools March 24-28, 2005. Accessed online June 20, 2005 at http://www.mercuryinschools.uwex.edu/legis/legisbystate.htm.

[175] Stetler et al. (See footnote 65) [One of the co-authors is Dr. Walter Orenstein who was later to become Director of the National Immunization Program (NIP), CDC] *(CDC evaluated the use of Thimerosal as a preservative in vaccines in 1985. The authors reported that Thimerosal was ineffective as a vaccine preservative. Specifically, the study found that Stretococcus survived 14 days after inoculation into a multi-dose DTP vaccine vial. "Neither research to develop a better preservative nor recommendations to consider single-dose packaging appear to be warranted…The Thimerosal preservative present in DTP vaccine requires substantial time to kill organisms and cannot be relied upon to prevent transmission of bacteria under conditions of practice when a vial is used over a short period. Instead, the most important means of preventing abscesses secondary to DTP vaccination is to prevent contamination by careful attention to sterile technique.) See also* Seal D, Ficker L, Wright P, Andrews V., The Case Against Thimerosal. Lancet 1991;338:315-316. (*Thimerosal is a weak antibacterial agent that is rapidly broken down to products, including ethylmercury residues, which are neurotoxic. Its role as a preservative in vaccines has been questioned, and the pharmaceutical industry considers its use as historical.)* and Engley, F.B. Soap and Chemical Specialties 1956; 200-5, 223-5 *(Thimerosal and other mercury-containing preservatives were not effective to reduce bacterial contamination.)* and Heyworth MF, Truelove SC., Problems Associated with the Use of Merthiolate as a Preservative in Anti-Lymphocytic Globulin, Toxicology 1979;12:325-333. *("When it was first introduced as an anti-microbial preservative, little information about the fundamental biological effects of organic mercury compounds was available. We should like to suggest that Merthiolate should now be regarded as an inappropriate preservative for materials which are intended for administration to human subjects.")*

stopping bacteriological activity, it does not easily kill the most dangerous bacteria, leaving them alive to cause mischief after injection. It is far more lethal to human brain cells than it is to streptococcus. The bacteriological contamination that derailed last year's thimerosal-containing flu shot is a poignant example of the chemical's ineffectiveness as a disinfectant.[176] And some critics have said that thimerosal's presence actually precipitated the contamination by making lab workers less careful.[177]

Second, the many thimerosal apologists from the scientific and public health community with whom I've spoken argue that removing thimerosal from vaccinations would jeopardize the World Health Organization's (WHO) vital international vaccine program by forcing elimination of the cheaper multi-dose vaccines. (Multi-dose vials require microbial protection because they are more easily contaminated via multiple needle entries.) Leading thimerosal proponents Dr. Neal Halsey and Dr. Paul Offit, both of whom have webs of troubling financial ties to the

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[176] Hil Anderson, "Facing the Flu All Alone," UPI, (October 13, 2004), and PR Newswire, Author of New Book on Thimerosal Says: Flu Vaccine Shortage -- Thimerosal to Blame, (October 8, 2004), PR Newswire reprint of news release from St. Martin's Press, (Oct. 7, 2004). Accessed online June 20, 2005 at http://www.vaccinetruth.org/serratia_marcescens.htm. "Everyone is asking how the Chiron (vaccine manufacturing plant) shut-down will affect vaccination rates, but few are asking how this could have happened, (the week of October 4, 2004 Chiron's Fluvirin vaccine was pulled after the potentially dangerous serratia bacteria was found in some lots) … Chiron used the mercury-based preservative thimerosal as a sterilizing agent in making Fluvirin, to prevent exactly this type of contamination … By definition, no thimerosal-containing solution should have live bacteria present in its final formula ... Vaccine making is nasty business, and microorganisms thrive in the warm egg-based brew used to produce the flu shot ... This vaccine was contaminated with serratia at the company's factory in Liverpool, England. 'But with so much thimerosal in the mix, how was the bacteria able to survive?' Thimerosal, it seems, is not a perfect preservative. In 1982, an FDA panel reported that thimerosal only prevents the growth of new bacteria rather than killing all the organisms altogether, … and proposed that thimerosal was 'not generally recognized as safe and effective.' In fact, thimerosal was singled out as being 'no better than water in protecting mice from fatal streptococcal infection.' And it was 35.3 times more toxic for embryonic chick heart tissue than for Staphylococcus aureus. Other studies found that up to 26 percent of the population was hypersensitive to thimerosal. Fluvirin's package insert warns that it should not be given to 'anyone with a history of hypersensitivity to any component of the vaccine, including thimerosal.' 'This raises some troubling questions … If thimerosal doesn't work, why are we using it? And why did it take the British Government to intervene on behalf of the safety of Americans? Now we face an imminent flu season with only half the vaccine needed. Millions will go unvaccinated and people could die because thimerosal failed to perform its job. Government and industry must work to develop a safe AND effective way of making flu vaccine.'"

[177] Ibid.

vaccine industry, told me that the single dose vaccine costs five to ten times the price of the multiple dose inoculations and would put many vaccinations beyond WHO's financial reach. Lujene Clark, perhaps thimerosal's most encyclopedic opponent, describes this argument as "scare tactics right off the vaccine industry talking point cheat sheet." In fact, industry price lists and a comprehensive peer-reviewed analysis of the pricing issue by the WHO, support Clark's assertion. The per dose production cost of a multi-dose vial is 10 cents, compared to 25 cents for a single-dose vial. The WHO study acknowledges that, with the more expensive vaccines this additional packaging cost becomes insignificant and is more than offset by high (60%) wastage rates that accompany the multi-dose vials. The single-dose format, according to WHO, offers other important benefits, including reduced contamination risks and improved injection safety (by discouraging multiple use of the same needles). Single doses provide far better coverage because of the reluctance of health care workers to open a multi-dose vial for one or two children.[178]

Congressman Weldon told me that the added costs of thimerosal-free vaccines could quickly be found by health agencies in the U.S., Europe and China. "I think the European community and the government of the United States will cough up the added funds to go over to a mercury-free product. I certainly would find the money somewhere. I think the Europeans and Japanese and the Chinese can also afford to contribute to that added cost burden for WHO."

Conclusion

[178] Drain, Paul K., Nelson, Carib M. and Lloyd, John S., "Single-Dose Versus Multi-Dose Vaccine Vials for Immunization Programmes in Developing Countries," Bull World Health Organ. Oct. 2003, vol.81, no.10, pgs.726-731. Accessed online June 15, 2005 at http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S0042-96862003001000007&lng=en&nrm=iso>. ISSN 0042-9686.

Like the Geiers, Boyd Haley and many of the scientists who are now spending time on this issue, I got sucked into the thimerosal controversy reluctantly. I was working on environmental mercury issues for years and kept running across mothers of autistic children who were absolutely convinced that their kids were injured by vaccines. Privately, I was skeptical. I doubted that autism could be blamed on a single source, and I certainly understood the government's need to reassure parents that vaccinations are safe; the eradication of deadly childhood diseases depends on it. I tended to agree with skeptics like Rep. Henry Waxman (D-CA), who criticized his colleagues on the House Government Reform Committee for leaping to conclusions about autism and vaccinations. "Why should we scare people about immunization," Waxman pointed out at one hearing, "until we know the facts."

It was only after seeing the Simpsonwood transcripts, reading the leading scientific studies, and talking with the nation's pre-eminent authorities on mercury toxicity that I became convinced that the link between thimerosal and the epidemic of childhood neurological diseases is real. Five of my own children are members of the thimerosal generation and it's unusual to find a teacher or public health worker who is unaware of the unusual pandemic of thinking abnormalities from learning disorders to autism that afflict their peers. I devoted time to study this issue because I believe that this is a national and moral imperative that must be addressed. If our public health authorities knowingly allowed the pharmaceutical industry to poison an entire generation of American children, as the evidence suggests, their actions arguably constitute one of the biggest scandals in medical history.

We may now be tainting U.S. foreign relations by exporting this scandal to the Third World. In 1999, the federal government began purchasing tens of millions of dollars of thimerosal-containing vaccines for export to developing countries. At that time autism was virtually unknown in the developing world. Our export of thimerosal-containing vaccines has been followed by exploding autism rates in India, Argentina and Nicaragua, and other lands where the disease had not previously been reported. At the same time, GlaxoSmithKline and Merck began aggressively marketing thimerosal-containing vaccines to China's communist government. As David Kirby reports in his new book Evidence of Harm, Mercury in Vaccines and the Autism Epidemic: A Medical Controversy, a few years after the vaccine manufacturers launched their campaign, the number of cases of children suffering from autism "unexpectedly skyrocketed."[179] This past August, Xin Hua, China's news agency, reported that autism rates in China have risen from almost zero previously to 1.8 million cases reported last year. Scientists estimate an astonishing annual growth rate of 20% for the disease in China.

It's hard to calculate the damage to our country and to the international efforts to eradicate epidemic diseases if Third World countries come to believe that America's most heralded foreign aid initiative is poisoning young brains in the developing world. It's not hard to predict how this scenario will be interpreted by America's enemies abroad.

The scientists and researchers—many of them sincere, even idealistic—now participating in efforts to hide the science on thimerosal—claim that they are trying to advance the lofty goal of protecting Third World children from disease pandemics. They are badly misguided. Their

[179] David Kirby, Evidence of Harm: Mercury in Vaccines and the Autism Epidemic; A Medical Controversy (New York: St. Martin's Press, 2005 (citing "Growth Rate for Vaccine Mark in China – 15%," *Isis Monthly Mark Watch* 1, no. 3 (March 20, 2004):10).

choices will come back horribly to haunt our country and the world's poorest populations in the future.