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FDA Knew Danger of Thimerosal - Vaccines for 60 Years

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In order to enroll in day care or attend public schools in this country, children are forced to participate in a mandatory vaccine program. According to a report by the General Accounting Office released in 1999, over the 1990s, an estimated 12 million vaccinations were given each year and more than 40 million children were vaccinated.

Since the 1930s, mercury-based Thimerosal has been added to vaccines as a preservative to boost drug company profits by allowing vaccine makers to package in bulk instead of individual doses.

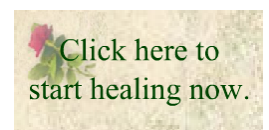
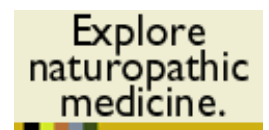
According to newly discovered research, which was supported by a grant from the American Medical Association, government agencies have known for 60 years ago that Thimerosal was neither safe or effective, and that it should have been removed as a preservative in pharmaceutical products.

In 1948, Dr Morton of the Department of Bacteriology, University of Pennsylvania School of Medicine, Dr North of the Philadelphia General Hospital, and Mr Engley of Camp Detrick, published the results of their study in the Journal of the American Medical Association evaluating the use of mercurials in medicine.

The article, "The Bacteriostatic and Bactericidal Action of Some Mercurial Compounds on Hemolytic Streptococci: In Vivo and In Vitro Studies" explained that "Mercurial compounds have been employed as disinfectants since the beginning of bacteriology."

"Indeed, for a long period mercurial compounds, such as bichloride of mercury, headed the list of chemical which were thought to be effective in the killing of microorganisms," it said.

However, the authors basically state that Thimerosal as a preservative is useless, "It is not highly germicidal and especially does not possess high germicidal value in the presence of serum and other protein mediums. The loss of antibacterial activity of mercurials in the presence of serum proves their incompatibility with serum."



In addition, the researchers warned of the toxicity of Thimerosal. "The comparative in vitro studies of mercurochrome, metaphen and merthiolate [Thimerosal] on embryonic (developing) tissue cells and bacterial cells by Salle and Lazarus [Proceedings of the Society of Experimental Biology & Medicine, February 1935] cannot be ignored," they said.

These investigators found Thimerosal was 262 times more toxic for embryonic tissue cells than for *Staphylococcus aureus*.

More than 10 years before the results of the above study were published, Nye [Journal of the American Medical Association, January 1937] and Welch [from the Food and Drug Administration, Journal of Immunology 1939] also found the same mercurial compound more toxic. "Not only is there a direct toxic action of the mercurial compounds on the cellular and humoral components of the animal body, but there is also the possibility of sensitization," they said.

In addition, Mr Engley subsequently published an article in the Annals of the New York Academy of Sciences in 1950, titled, "Evaluation of Mercurials as Antiseptics" in which he declared, "...mercurials are ineffective in vivo and may be more toxic for tissue cells than bacterial cells, as shown in mice (Nungester and Kempf, 1942) (Sarber, 1942) (Spaulding and Bondi, 1947) tissue culture (Salle and Catlin, 1947) and embryonic eggs (Witlin, 1942) (Green and Kirkeland, 1944), and with leucocytes (Welch and Hunter, 1940)."

Due to the FDA ignoring the scientific findings and warnings of its own researchers, Thimerosal remained in vaccines for the second half of the century and has now been linked to an epidemic in autism, attention deficit disorder, attention deficit hyperactivity disorder, and a wide range of other neurological problems.

The epidemic began as the number of vaccines added to the immunization schedule rose dramatically. American children born in 1948 were only required to show proof of a smallpox vaccination to enter school. By 1991 the number of mandated vaccines had increased from 9 to 21 and children born in 1998 were required by most states to receive 33 or 34 doses of nine or ten different vaccines to enter school.

Beginning in about 1987, as each new vaccine was added to the schedule, no one apparently thought to keep track of the cumulative amount of Thimerosal that would be injected into children with each new shot. As a direct result of the increased mercury, cases of autism began doubling every four years.

People who are still sitting on the fence over whether to believe that Thimerosal is the cause of the epidemic need only consider the staggering statistics. On February 15, 2005, the GAO, released a Report titled, "Special Education Children With Autism," that revealed the number of children ages 6 through 21 diagnosed with autism receiving special education services has increased more than 500% over the past 10 years.

State by state the numbers reveal enormity of this tragic situation. In Oregon, between 1989 and 1999, the number of school age kids with autism increased from 250 to 2,877 cases, according to the state's Department of Education statistics.

The Pennsylvania public school system is feeling the pressure. Statewide, over a 10 year period, the number of children enrolled in special education classes for autism disorders has increased from 634 to 5,145 in 2002-03, the most recent year for which state statistics are available.

Federal Department of Education numbers reveal that Ohio only had 22 reported cases of autism in 1992 and by 2002, the number of cases had increased to 3,057. In Illinois, over the same decade, there was an increase from five cases to 3,802. In the same time frame, every state in the nation had an increase of at least 500 percent.

In addition, consider these odds. Fifteen years ago, autism affected only one in 10,000

children. Today, according to the American Academy of Pediatrics and the CDC in January of 2004, the incidence of autism is one in every 166 kids.

Since 1999-2000, the number of Bucks County Pennsylvania autistic children receiving special education services has jumped at a rate of more than 22% every year, according to the US Department of Education.

Unlike normal kids, children with autism do not instinctively learn from observing other children around them. They must be taught even the simplest skills such as making eye contact, following directions, waiting their turn, or how to hold a conversation. In addition, behaviors, skills, and abilities vary from one child to the next and about 50% of autistic kids have few or no language skills. They often suffer from other problems that impair the learning process as well, such as hearing loss or epilepsy.

Therefore educating these children costs much more than is usually allotted for special education kids. For example, in Bucks County, PA, for tuition, transportation, evaluations, and other services, the cost can reach \$60,000 per child compared to \$7,000 that the average special education student receives, according to David Mandell, co-chairman of the Pennsylvania Autism Task Force, in the September 12, 2004 Bucks County Courier

The question of why some children develop autism and others do not, appears to be the luck of the draw. For various reasons still not completely understood, the bodies of some kids are incapable of ridding themselves of mercury. In fact, an August 2003 International Journal of Toxicology study revealed that healthy normal children excreted eight times more mercury through their hair than did autistic children.

The suspicion that Thimerosal was causing the epidemic arose in 1997, when the FDA Modernization Act was passed which required the FDA to investigate the adverse effects of all products containing mercury. Within a year, the FDA ordered Thimerosal removed from over-the-counter products, which surely indicates that officials knew that far back that it was dangerous.

Once the amount of Thimerosal in vaccines was finally measured in 1999, the FDA discovered that children were receiving more than 100 times the EPA's safe limit for mercury by 18 months of age and yet officials allowed the preservative to remain in vaccines. To this very day flu vaccines given to pregnant women and 6 month old babies contain a full dose of Thimerosal.

There can be no denying that the FDA and CDC have long known of the damage caused by Thimerosal. A June 29, 1999, email from FDA scientist, Peter Patriarca to the head of the CDC office on vaccine safety, warned that the FDA would be criticized for being "'asleep at the switch' for decades by allowing a potentially hazardous compound to remain in many childhood vaccines and not forcing manufacturers to exclude it from new products."

Patriarca also pointed out the fact that calculating the cumulative dose of mercury in vaccines was not "rocket science" and involved only ninth-grade math. He then cited the questions that could be asked of the agencies: "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?"

A secret report from a meeting attended by officials from the FDA and CDC in 2000, obtained with a FOIA request, even contained a graph which specifically illustrated the findings of a child's increasing risk of developing symptoms of autism upon receiving the increased amounts of Thimerosal.

In a transcript of that secret meeting, Pediatrician Bill Weil, acknowledged the epidemic, "There are just a host of neurodevelopmental data that would suggest that we've got a serious problem.... The number of kids getting help in special education is growing nationally and state by state at a rate we have not seen before."

However, notwithstanding this clear recognition of injury to kids, and although individual states have passed laws banning Thimerosal, the FDA has never required drug makers to eliminate the preservative from any vaccines.

In 2000, the independent father and son research team of David and Mark Geier, conducted a study using the same CDC data used by the government in 1999, to compare children who received vaccines with Thimerosal to kids who received vaccines without it. In the relevant time frame, they knew that fully vaccinated kids received four shots by the age of 18 months, and so they devised a computer program to separate the children who received no Thimerosal from those who received four doses.

The results were astounding. The children who received no Thimerosal had no autism, which caused the Geiers to question their own findings and rerun the program several more times. Each time it came back the same, kids receiving Thimerosal were over ten times more likely to have autism than the kids who received no mercury.

Three years later, on May 21, 2003, the Mercury in Medicine Report was published by the Subcommittee on Human Rights and Wellness of the Committee on Government Reform. Based on an investigation spanning several years, the report rendered a specific finding that linked the preservative to autism. Included in the report was the following conclusion:

"Thimerosal used as a preservative in vaccines is directly 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 a lack of safety data regarding injected Thimerosal and the sharper eyes of infant exposure to this known neurotoxin. The public health agencies' failure to act is indicative of institutional malfeasance for self protection and misplaced protectionism of the pharmaceutical industry."

The Reform Report concluded that, "Because the FDA chose not to recall Thimerosal-containing vaccines in 1999, in addition to all of those already injured, 8,000 children a day continued to be placed at risk for overdose for at least an additional two years."

Over 2 years have passed since that report was issued, and FDA and CDC officials are still allowing vaccine makers to use Thimerosal in the manufacturing process of vaccines and to add a full doses of the product to flu vaccines which are injected into pregnant women, children, and the elderly.

In addition, officials still allow drug companies to ship mercury-laced vaccines for use on kids all over the world. As a result, autism rates are exploding in other countries. In China for instance, autism was unheard of five years ago. Since Chinese children began receiving vaccines with Thimerosal, well over one and a half million cases of autism have been reported. Autism is also on the rise in Argentina, India and Nigeria, according to Robert F Kennedy, Jr, in a June 20, 2005 interview on MSNBC.

Drug companies deserve to be sued. Proof has surfaced that shows they have been knowingly injecting this poison into children for many years. A 1991 company memo which surfaced last fall in a lawsuit involving vaccine maker, Merck, proves beyond any doubt, that the company knew infants were being injected with unsafe amounts of Thimerosal in 1991.

A copy of the memo was obtained by attorneys for Vera Easter, a Texas woman who blames drug makers for injuring her 7-year-old son, who is autistic and mentally retarded. The lawsuit was filed in the Eastern District of Texas against vaccine makers Merck, GlaxoSmithKline, Aventis Pasteur, Wyeth; as well as Thimerosal inventor Eli Lilly.

The 7 page memo describes how a 6-month-old baby who received shots on schedule would receive doses of mercury many times higher than established safety guidelines and specifically states: "If eight doses of Thimerosal-containing vaccine was given in the first six months of life (3 DTP, 2 HIB, and 3 Hepatitis B) the 200 micrograms of mercury given, say to an average size of 12 pounds, would be about 87 times the Swedish daily allowance of 2.3 micrograms for a baby of that size."

The memo even warned that "the best way to go is to switch to dispensing the actual vaccines without adding preservatives." However, it went on to point out the potential loss of profits and said that while eliminating preservatives was the best solution, there was "a cost consideration the head of Health Services has to consider. Several large ampoules or bottles are more expensive than a smaller number of larger packages."

Authored by Merck's then senior Vice-President, Maurice Hilleman, the memo was sent to Dr Gordon Douglas, head of the company's vaccine division. A disclosure of this information in 1991 could have prevented millions of children from being injured.

Even after drug makers began claiming they had removed Thimerosal from vaccines, they left all previously manufactured vaccines on the market which was clearly deceptive to parents who believed they were injecting Thimerosal-free vaccines into their babies. In September 1999, Merck declared in a press release: "Now, Merck's infant vaccine line is free of all preservatives."

However, On March 8, 2005, the LA Times reported, "Merck & Co continued to supply infant vaccine containing a mercury preservative for two years after declaring that it had eliminated the chemical."

As it turns out, the company continued to distribute vaccines containing Thimerosal until October 2001, according to a June, 2003 FDA letter sent to Rep David Weldon (R-Fla), a doctor, in response to his inquiry. Weldon called what Merck did "misleading."

"You had people literally into 2002 getting shots with mercury, having been told it was all taken out in 1999," he told the Times. To this day, vaccines with full doses of Thimerosal are still out there. Last time I checked, I found products with expiration dates as late as September 2005.

The oft asked question is why would regulatory agencies allow Thimerosal to remain in vaccines? As usual, their initial motive was to protect the profits of the pharmaceutical industry that would be lost if the preservative was removed and packaging was limited to single dose vials, because many of the same researchers, advisory board members, and officials who were involved in the vaccine approval process were also benefiting financially from drug company money.

An investigation by United Press International, found that members of the CDC's Vaccine Advisory Committee, received financial benefits from sharing a vaccine patent; owning stock in a vaccine company; payments for research; payments to monitor manufacturer vaccine tests; and funding to academic departments.

What kind of money are we talking about here? Picture this. The annual global market for vaccines is expected to rise to \$10 billion by 2006, according to UPI.

However by this late date, the effort to hide the truth about Thimerosal by the FDA and CDC, is fueled by fear over the amount of money the industry, and quite possibly the government agencies it conspired with to conceal the harm, are going to end up paying out in law suits for injuring millions of children.

With that in mind, officials make sure the media steadily repeats the mantra of a May 2004 Institute of Medicine report that claims there is no link between Thimerosal and autism. However, since that report was released, Steven Goodman, MD, MHS, Ph.D, an associate professor at Johns Hopkins School of Medicine and member of the IOM panel, has backed off from the report's certainty and said:

"It was clear from the report that we were not giving thimerosal a clean bill of health. Mercury is definitely a neurotoxin. ... We only said that the evidence favored that there was not a connection between autism and thimerosal exposure," according to the Naples Sun Times on April 27, 2005.

Researcher, Mark Geier, is a doctor with a PhD in genetics and a court-certified expert on vaccines. He has determined through numerous studies that Thimerosal is to blame and has this to say, "the current epidemic of autism may well be the greatest iatrogenic epidemic in history. The damage already done to our society is already in the trillions of dollars. The damage of the 9/11 terrorist attacks, and that of the AIDS epidemic pale when compared to the current epidemic of autism."

Parents of injured children and tax payers are already paying an enormous price for this man-made epidemic. According to a June 19, 2002 Written Supplement to Oral Testimony at the Hearing of the Government Reform Committee, by James Bradstreet, MD, FAAFP, Clinical Director, The International Child Development Resource Center, "the cost of education, medical care, and therapies for behavioral and physical symptoms is staggering. Many of our families report having paid \$50,000 per year to care for their child."

"Custodial care for autism can exceed \$100,000/year," Bradstreet said, "The public education system is literally swamped with children." Schools lack the therapists and specially trained educators to deal with the epidemic.

Back in 2002, according to Bradstreet, the Resource Center estimated the minimal cost to care for the 420,000 existing children with autism to be \$1,260,000,000,000 (based on \$3 million/lifetime). So a little over a \$1 trillion over the next 50 years would be required if the rising number of new cases ceased in 2002.

However, because autism was doubling every four years, Bradstreet warned, "this is likely an overly conservative estimate. The societal cost could easily be \$3-4 trillion."

And that's just the tip of the iceberg. The amount of potential earnings lost as a result of the large number of children who will never be self-supporting is impossibly to calculate. Many parents are currently unable to work because they must stay home to care for a disabled child. Anything short of a miracle cure means these children will be disabled for life.

If the Republicans succeed in passing legislation that will immunize vaccine makers from liability for the injuries they caused by Thimerosal, Americans had better be prepared to pay higher taxes to cover the cost of live-long care for the millions of kids who have been damaged.

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