THIMEROSAL TIMELINE PRE 1999 TO 2004

Source: Put Children First Chapter I: pre-1999

There's Mercury in Vaccines?

"The recognition that some children could be exposed to a cumulative level of mercury over the first six months of life that exceeds one of the federal guidelines on methyl mercury now requires a weighing of two different types of risks when vaccinating infants. On the one hand, there is the known serious risk of diseases and deaths caused by failure to immunize our infants against vaccine-preventable infectious diseases; on the other, there is the unknown and probably much smaller risk, if any, of neuro-developmental effects posed by exposure to thimerosal. The large risks of not vaccinating children far outweigh the unknown and probably much smaller risk, if any, of cumulative exposure to thimerosal-containing vaccines over the first six months of life.

Nevertheless, because any potential risk is of concern, the Public Health Service, the American Academy of Pediatrics, and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible. Similar conclusions were reached this year in a meeting attended by European regulatory agencies, the European vaccine manufacturers, and the US FDA which examined the use of thimerosal-containing vaccines produced or sold in European countries."

Joint Statement of The American Academy of Pediatrics and the Public Health Service (FDA & CDC),
 July 7, 1999, 4:15pm

At 4:15 pm Eastern time on a Friday afternoon in July 1999, a joint statement by the AAP and Public Health Service was released to the press advising Americans that the amount of mercury in vaccines administered to children, through a preservative called Thimerosal, exceeded Federal Health guidelines. This statement did not reveal the amount of panic, backdoor negotiating, and concern federal health officials had been engaged in for the past few weeks, after the levels of mercury had been calculated by dumbfounded federal officials reviewing submissions from vaccine manufacturers responding to a broad FDA inquiry regarding mercury in consumer products. While this article from Pediatrics ultimately looks at the policy makers favorably, it does help explain how frenetic the process was.

How could July 1999 be the first time Federal Officials realized there was mercury in vaccines exceeding our own safety standards? There are many answers to this question. For some officials, this was the first time they had learned mercury was even in vaccines. Others clearly knew and had been concerned for some time, and at least one vaccine manufacturer realized the levels were high eight years earlier, in 1991.

Thimerosal was first used as a preservative in vaccines in the late 1930s, long before we understood the extreme neurotoxicity of mercury. As the FDA ratcheted up safety standards, Thimerosal was grandfathered through due to its history without ever having to undergo any safety testing. We may not be reading so much about Thimerosal today if the CDC hadn't embarked upon an aggressive plan to add vaccines to the Recommended Childhood and Adolescent Immunization Schedule in the late 1980's. In 1988, the Haemophilus Influenzae type B (Hib) vaccine was added to the schedule, followed by the Hepatitis B (HepB) vaccine in 1991. Together, these two vaccines added six shots to the schedule, and tripled the amount of mercury children born after 1991 received compared to the previous generation.

The joint statement above downplayed the risk of mercury injected in newborns, and it downplayed the degree to which mercury exceeded federal safety standards. Doing the simple math, a child following the recommend schedule and receiving vaccines at birth, 2 months, 4 months, and 6 months was receiving mercury in excess of the EPA safe standards by a factor of 36x, 120x, 77x, and 66x, respectively. That's 120 times the safe Federal standard!! (See chart).

The start of the sharp increase in autism and other neurodevelopmental disorders matches the change in the vaccine schedule. In the 1980s the incidence of autism was somewhere between 1 in 10,000 and 1 in 5,000, today it is 1 in 150. (See <u>chart</u>).

"The Food and Drug Administration (FDA) Modernization Act of 1997 called for the FDA to review and assess the risk of all mercury containing food and drugs. In line with this review, U.S. vaccine manufacturers responded to a December 1998 and April 1999 FDA request to provide more detailed information about the thimerosal content of their preparations which include this compound as a preservative," said the statement.

The Federal Health authorities were well aware of the potential damage their public announcement could cause to the National Immunization Program, and they did their best to downplay risks, slow down change, and avoid blame or liability. Perhaps most astonishing of all, there is still Thimerosal, at high levels, being injected in our children before their first birthday, 7 years after this joint statement was released.

What's Egregious About This Time Period?

- 1. The FDA missed (or tolerated) mercury being injected in babies at levels well in excess of Federal safety standards and despite thousands of studies documenting Thimerosal's extreme toxicity. The job of the FDA is to protect our children from, amongst other things, unsafe drugs.
- 2. When the FDA realized its mistake, they did not choose to recall vaccines.
- 3. Merck, a vaccine manufacturer, was aware of the mercury issue in vaccines in 1991, yet failed to do anything to protect children.
- 4. When adding vaccines to the schedule in the late 80s and early 90s, the FDA only required vaccines to be tested independently. No testing was ever done to determine the risk of cumulative exposure of multiple vaccines, often received on the same day.
- 5. When faced with the information regarding high mercury levels in vaccines, the federal health authorities seemed more concerned with the risk of undermining the National Immunizations Program and creating liability for pharmaceutical companies than the health of our children.
- 6. In 2006, Thimerosal remains in vaccines, despite statements like this that are on the FDA's own website today: "During the past ten years, the FDA has provided informal and formal advice to manufacturers recommending that new vaccines under development be formulated without thimerosal as a preservative."
- 7. In 2006, despite the 1999 announcement, both <u>CDC</u> and <u>AAP</u> are actively fighting laws at the state level intended to ban mercury once and for all from children's vaccines.

Where is the Evidence?

1. Merck Internal Memo Citing Dangerous Levels of Mercury In Vaccines ⚠ Read ▶ March 1991

Written By Dr. Maurice Hilleman and sent to Dr. Gordon Douglas, President of Merck Vaccine Division

This memo was written 8 years before the FDA "discovered" there was mercury in vaccines well in excess of Federal safety standards. Among the many unsettling comments, Dr. Hilleman notes that, "Sweden is requiring Thimerosal-free single-dose packaging of all products...The U.S. Food & Drug Administration (CBER) does not have this concern." He writes:

"If 8 doses of Thimerosal-containing vaccine were given in the first 6 months of life (3 DPT, 2 HIB, and 3 Hepatitis B) the 200 ug of mercury given, say to an average size of 12 lbs., would be about 87X the Swedish daily allowance of 2.3 ug of mercury for a baby of that size. When viewed in this way, the mercury load appears rather large."

What happened to this memo? Did FDA ever see it? Did CDC ever see it? What did Merck do with this information?

Source: Leaked transcript from sealed court filings.

2. Patriarca FDA/CBER Internal Email: "Asleep at the Switch" ☑ Read ▶ July 2 1999

Written by Dr. Peter Patriarca, CBER/FDA, and sent to Dr. Lawrence Bachorik, FDA.

This memo was written by Dr. Peter Patriarca, who at the time was the Director of the Office of Vaccines Research and Review, within the FDA Division of the Center for Biologics Evaluation and Research. This is the division of the FDA with responsibility for vaccine safety. The email was written to Dr. Lawrence Bachorik, Ph.D, the FDA's Senior Adviser for communication. It was written in the frenzy leading up to the public announcement on July 7. It highlights the concern on vaccination policy over the safety of our children and the genuine concern FDA had for how this announcement would cause their inaction to be perceived. He writes:

"You should also be aware that if the U.S. (and perhaps the EU) adopts a position that the theoretical risk of ethyl mercury exposure outweigh its potential benefits to the point where no vaccines used in the US or Europe will contain thimerosal [which is where things appear to be headed}, this could also have a severe impact on global ('third world') vaccination programs, particularly for hepatitis B and whole-cell DTP vaccines. which for various reasons, will almost certainly have to have thimerosal as an ingredient for potentially many years to come. WHO has already made a plea to the American Academy of Pediatrics to "tread lightly" and "consider the global ramifications" of their evolving policy. Finally, in my own personal opinion - and as a headsup because I believe it could come up -- 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 and on an ongoing basis as the childhood immunization schedule became more complex. The calculations done by FDA are not complex. I'm not sure if there will be an easy way out of the potential perception that the FDA, CDC and immunization policy bodies may have been 'asleep at the switch' re: thimerosal until now."

Source: FOIA filing by parents.

3. Patriarca FDA/CBER to CDC Email: "A Plan is In Place" Read > June 29 1999

Written by Dr. Peter Patriarca and sent to Dr. Roger Bernier and Dr. Jose Cordero, CDC

This memo was also written by Dr. Peter Patriarca, a few days before the memo above, and sent to two of the leaders of the National Immunization Program at CDC, Dr. Roger Bernier and Dr. Jose Cordero. In it, Dr. Patriarca shows even more fully how concerned FDA was about their image after the pending announcement, and Dr. Patriarca stresses that a plan to deal with Thimerosal has "already been in place for many years." He writes:

"The fact of the matter is that an 'interim plan' (for potential removal of thimerosal) has already been in place for many years we just need to 'speed up' the existing plan not create a 'new' interim plan."

Patriarca noted that hastening the removal of thimerosal would, "...raise questions about FDA being 'asleep at the switch' for decades by allowing a potentially hazardous compound to remain in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about various advisory bodies regarding aggressive recommendations for use. We must keep in mind that the dose of ethylmercury was not generated by 'rocket science'. Conversion of the percentage thimerosal to actual micrograms of mercury 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?"

Source: FOIA filing by parents.

4. <u>Dr. Maurer to Congressman Burton Email: "Risks which can be avoided" Read</u>

December 4 2002

Written by Dr. Wolfgang Maurer to Congressman Dan Burton (R-IN), Committee on Government Reform

Dr. Maurer is an international expert on mercury in medicine from Vienna University (Austria). His email helps highlight how much was known about Thimerosal's toxicity and how far ahead of the FDA Europe appeared to be on the issue of mercury in vaccines. This email highlights FDA's inexplicable complacency in dealing with Thimerosal in vaccines. He writes:

"... more organic mercury was given with vaccines in the 1st yr of live (sic) compared to food. During all this time I addressed my concerns also to representatives of the pharmaceutical industry at meetings in Austria and abroad, also to representatives of US-manufacturers of vaccines...In a letter to the European Pharmacopoiea (addressed to Jean-Marc Spiesser) dated 21.May 1996 I again formulated my concerns and proposed a ban on organomercurials...To my opinion it was very clear in the [1980s], that [thimerosal] is an unappropiate preservative in medicines. Major toxicity concerns regarding its use in preparations with a high volume per injection and/or low body weight and major concerns due to potential mass sensitization so jeopardizing every vaccination programm (sic)...In medicine risks which can be avoided must be avoided. I urge you to ban organomercurials in medicinal products and also in medical devices."

Source: Committee on Government Reform, U.S. House of Representatives.

Written by Dr. Ruth Etzel, USDA Division of Epidemiology and Risk Assessment, to the American Academy of Pediatrics team involved with the announcement

This email was written soon after Dr. Etzel learned of the strategy regarding the July 9, 1999 announcement. In it, she expresses her concern with the approach being recommended and the risk of loss of trust. Perhaps no better email exists that predicts what has taken place over the last seven years. We only wish Dr. Etzel's advice had been followed. She writes:

"The AAP should be dedicated to promptly providing truthful information about this situation to pediatricians. We must follow the 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...To keep faith, we must be open and honest now and move forward quickly to replace these products...This is what American parents want to hear from their pediatricians. Anything less may cause them to lose faith in our recommendations."

Source: FOIA filing by parents.

Written by Dr. Fred Varrichio to Dr. Leslie Ball, internal FDA email within the FDA Division of the Center for Biologics Evaluation and Research.

This email was from Dr. Varrichio to Dr. Ball. Dr Varrichio was charged with doing research on Thimerosal's toxicity, and this email highlights how much information was already present in the scientific literature on the dangers of Thimerosal. He writes:

"I have some results for you. Problem is that there are 7000 reports that mention Thimerasol. What to do now. Obviously looking at all 7000 is a brute force approach."

Source: FOIA filing by parents.

Written by Dr. Ben Schwartz to all the leaders of the National Immunizations Program at CDC.

This email was from Dr. Ben Schwartz to all the key decision makers at CDC, written just six days before the July 9, 1999 announcement, and it highlights the intense focus of the participants on CYA and moderation, rather than the safety of children. Dr. Schwartz recommends a form of trickery that many members of CDC and FDA have used since: focusing on "cumulative exposure" rather than daily exposure of mercury. This is analogous to a Doctor saying, "Take one aspirin a day for 90 days", the patient instead takes 90 aspirin on one day, and viewing those two events as having equivalent outcomes. Dr. Scwartz is recommending adding up the safe daily dose of mercury, looking at that dosing over a six month period, and comparing it to the amount of mercury children receive, without bothering to note that all the mercury is received in 2 visits to the doctor.

"As a parent of a 3-month old, I was very uncomfortable with the good vaccine/bad vaccine dichotomy and would have been reluctant to accept a Thimerosal containing product for my baby. Given the approach presented below, I would be very comfortable knowing that my child would receive a Thimerosal containing product as long as the defined safe cutoff for mercury is not exceeded [PCF note: it was exceeded, by any standard]...When the focus of the communication was on the vaccine product rather than the child, there was an inherent contradiction: why are we moving to Thimerosal free vaccines if vaccines containing this product are safe? Parents inevitably would want vaccines that don't contain thimerosal, leading to shortages, deferral of vaccination, and receipt of mercury concentrations that exceed the cutoff by some children. The communication problem is avoided by presenting child focused messages."

Source: FOIA filing by parents.

This is a copy of the actual MSDS for Thimerosal from its manufacturer, Eli Lilly. Any scientist at CDC or FDA would have had access to this MSDS. Excerpts:

"Exposure Guidelines: Thimerosal - no known occupational limits established...Exposure to mercury in utero and in children can cause mild to severe mental retardation and mild to severe motor coordination impairment...Use of chelating agents such as BAL may be needed to treat ingestion of mercury...Target Organ Effects: Mercury - Nervous system effects (insomnia, tremor, anorexia, weakness, headache), liver effects (jaundice, digestive effects (hypermotility, diarrhea)."

<u>This article</u> from USA Today from famed whistleblower Dr. David Graham of the FDA highlights the internal climate of the FDA as it relates to people who come forward with safety concerns:

"Graham says he has heard concerns similar to his from counterparts who monitor medical devices and biologics, such as vaccines, but they're reluctant to come forward. "They are absolutely afraid for their jobs," Graham says. "We've got families to support." He's married to his college sweetheart, and they have six children ages 9 to 23."

10.<u>Jon Ryter: Warning to Be Downplayed</u> ☑ Read ► July 1, 1999
Freerepublic.com

This was written 8 days before the announcement and represent one of the few journalists who accurately predicted the strategy and approach of the Public Health Service in "warning" about Thimerosal.

"The CDC, like all other bureaus of government recognizes that when you need to release negative information, release it on Friday since most Americans ignore the news on the weekends. The concern of the IAG staffer who turned this document over to me was that the CDC was engaging in a coverup that was deliberately attempting to play down the danger of the chemical THIMEROSAL, an organomecurial preservative used to stabilize many of the vaccines, immoglobins and some food products simply because the government cannot afford to dispose of its entire inventory of vaccines containing this substance."

Chapter II: 1999-2000 Simpsonwood

"the number of dose related relationships [between mercury and autism] are linear and statistically significant. You can play with this all you want. They are linear. They are statistically significant." - Dr. William Weil, American Academy of Pediatrics. Simpsonwood, GA, June 7, 2000

"the issue is that it is impossible, unethical to leave kids unimmunized, so you will never, ever resolve that issue [regarding the impact of mercury]." - Dr. Robert Chen, Chief of Vaccine Safety and Development, Centers For Disease Control, Simpsonwood, GA, June 7, 2000

"Forgive this personal comment, but I got called out at eight o'clock for an emergency call and my daughter-in-law delivered a son by c-section. Our first male in the line of the next generation and I do not want that grandson to get a Thimerosal containing vaccine until we know better what is going on. It will probably take a long time. In the meantime, and I know there are probably implications for this internationally, but in the meanwhile I think I want that grandson to only be given Thimerosal-free vaccines." - Dr. Robert Johnson, Immunologist, University of Colorado, Simpsonwood, GA, June 7, 2000

"But there is now the point at which the research results have to be handled, and even if this committee decides that there is no association and that information gets out, the work has been done and through the freedom of information that will be taken by others and will be used in other ways beyond the control of this group. And I am very concerned about that as I suspect that it is already too late to do anything regardless of any professional body and what they say...My mandate as I sit here in this group is to make sure at the end of the day that 100,000,000 are immunized with DTP, Hepatitis B and if possible Hib, this year, next year and for many years to come, and that will have to be with thimerosal containing vaccines unless a miracle occurs and an alternative is found quickly and is tried and found to be safe." - Dr. John Clements, World Health Organization, Simpsonwood, GA, June 7, 2000

Soon after the joint statement by the AAP and Public Health Service was released, all hell broke loose, and the CDC moved into damage control mode, where they remain today, seven years later. (Here's a great article from the Hepatitis Control Report on the panic.) Parents of autistic children began to compare the symptoms of autism to the symptoms of mercury poisoning, and a feisty Congressman from Indiana with an autistic grandson, Dan Burton, started using his pulpit as head of the Committee on Government Reform to ask very tough questions. By August, two months after the joint statement, his committee was in a full-scale investigation of conflict in vaccine policy, which the CDC knew.

Shockingly, CDC received letters in July and September 1999 from Merck and SmithKline Beecham, respectively, letting CDC know that full production of Thimerosal-free vaccines for Hepatitis B and DTaP could be made available almost immediately. To SmithKline, CDC responded with a tepid letter thanking them for the offer, but not taking them up on it. Thimerosal would remain in the vaccines on the Childhood Immunization Schedule for three more years, into late 2002, before Thimerosal-free vaccines were finally available for all vaccines, as this letter from FDA to Congressman Dave Weldon demonstrates. CDC's inexplicable complacency in the face of the July 1999 statement to switch over to Thimerosal-free vaccines was highlighted in this March 2006 article by Robert F. Kennedy, Jr in the Huffington Post.

As part of the FDA Modernization act that spurred the joint statement, FDA was required to commission the Institute of Medicine to review the impact of mercury in vaccines. The IOM's study began in late 1999 with an expected publication date in 2001. For the CDC, the walls were starting to close in, particularly for the man responsible for both vaccine development and vaccine safety, Dr. Robert Chen. The knowledge of a looming IOM review spurred CDC to take matter into their own hands.

Soon after the AAP statement a young CDC epidemiologist, Dr. Thomas Verstraeten, was given the task of comparing neurodevelopmental outcomes of children exposed to Thimerosal using the CDC's internal database, the Vaccine Safety Datalink (VSD). CDC hoped to run their own analysis, establish no relationship between Thimerosal and autism, give the analysis to the IOM, and close this chapter for good. By November of 1999, just 5 months after the joint statement, Dr. Verstraeten was in a near panic as the data he was analyzing was showing a clear, unassailable, ugly truth: there was a statistically significant relationship between the amount of mercury children were receiving through their vaccines and autism. No matter how he tried to run the numbers, he wrote, the association "just won't go away."

In June of 2000, six months after Dr. Verstraeten's analysis revealed a clear correlation, the CDC commissioned a private meeting at the Simpsonwood Conference Center in Atlanta, GA, with representatives from the CDC, other health organization (WHO, FDA) and representatives of vaccine manufacturers to share some startling news: despite six full months of trying to dumb down the data, CDC's analysis was still showing a statistically significant relationship between neurodevlopmental disorders, especially autism, and Thimerosal children received through their vaccines.

The Simpsonwood meeting set that stage for the way the CDC has conducted themselves ever since: control the damage, bury the data, and ensure that the National Immunization Program never misses a beat. The candor and incriminating statements of the Simpsonwood attendees is at times breathtaking, as some of the above quotes demonstrate, and a whole website could be devoted to analyzing the words of the participants. A great summary of the Simpsonwood meeting is available through this excellent article written by Dr. Russell Blaylock. The transcript from the meeting was stamped with the words "Do Not Copy or Release" and "Confidential", but was obtained by parents through FOIA.

- 1. Dr. Verstaeten's analysis of the CDC's VSD showed a clear and unassailable relationship between Thimerosal received and neurodevelopmental disorders. Recent emails now show how Dr. Verstraeten began the complex task of managing the relationship down and the advice he received in doing so. By the time his work was actually published in *Pediatrics*, almost 3 years later, the data had been manipulated to the point of showing no association between Thimerosal and autism. For an explanation of how the CDC removed the association, click here.
- 2. In the midst of the controversy surrounding Thimerosal, CDC was given the opportunity to switch to Thimerosal-free versions of Hepatitis B and DTaP immediately following the joint statement by two vaccine manufacturers in the Fall of 1999 and chose not to.
- 3. The Simpsonwood meeting was unprecedented: a secret meeting convened by a public government agency (CDC) that also included vaccine manufacturers. Why were vaccine manufacturers involved in policy decision and reviewing data that could potentially make them liable for billions in damages? No document more clearly demonstrates the inability of public health officials to put our children first than the Simpsonwood transcript.

Where is the Evidence?

This transcript, at 238 pages, is a challenging read, and Dr. Blaylock's <u>article</u> is a great place to start. The scope of the transcript is breathtaking, as it shows the wide range of concerns, very few of which have anything to do with the safety of children, that the individuals responsible for US vaccine policy wrestled with as they were confronted with data unassailably linking thimerosal from vaccines and damaged children. Perhaps Dr. Robert Chen of CDC summed it up best towards the end of the meeting, setting the stage for a cover-up now in its seventh year:

"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..."

Source: FOIA filing by parents.

Verstraeten CDC Internal Email: "It Just Won't Go Away" Read ▶
 December 17, 1999
 Written by Dr. Thomas Verstraeten, CDC, and sent to Dr. Robert Davis and Dr. Frank Destefano, title, CDC.

Dr. Verstraeten was responsible for the preliminary analysis of the CDC's Vaccine Safety Datalink to determine if a relationship existed between Thimerosal and autism. The "It" in Dr. Verstraeten's subject line of "It just won't go away" is the correlation between Thimerosal and autism. Dr. Verstraten also notes that "all the harm is done in the first month."

Dr. Verstraeten's email is a working email describing the analysis he is doing with references to spreadsheets that contain specific data. Not until a recent FOIA was that data available which you can now see here. This new information, through the data known as "Generation Zero", highlights just how extreme the correlations were between Thimerosal and neurodevelopmental disorders.

As one example, on the first page of the spreadsheet, if you look under the "2990" category for autism, it shows a 7.62 incidence for children who receive the largest mercury dose in month 1, called "HgCat1 (3)", a highly statistically-significant correlation.

Source: FOIA filing by parents.

Written by Dr. Thomas Verstraeten, CDC, and sent to Dr. Phillipe Grandjean

This email was written one month after the Simpsonwood secret meeting. Dr. Verstraeten, as the lead CDC epidemiologist analyzing the Generation Zero data showing a high correlation between mercury and autism, was very frustrated by the focus of participants in the Simpsonwood meeting on managing information, liability, and reputations, rather than the science and data at hand. He complains:

"Unfortunately, I have witnessed how many experts, looking at this thimerosal issue, do not seem bothered to compare apples to pears at the best and insist that if nothing is happening in these studies [referring to some old science on other types of mercury exposure] then nothing should be feared of thimerosal.

I do not wish to be the advocate of the anti-vaccine lobby and sound like being convinced that thimerosal is or was harmful, but at least I feel we should use sound scientific argumentation and not let our standards be dictated by our desire to disprove an unpleasant theory."

Source: SafeMinds

 Merck and Smithkline letters, 1999: We can be thimerosal-free today July 7, 1999 and July 31, 1999

Letters sent from vaccine manufacturers to the CDC.

These letters were only recently acquired through parent filings of FOIA. Merck wrote:

"Beginning in early September 1999...the Company believes it could provide sufficient thimerosal-free vaccine."

SmithKline wrote:

"SB is in a position to to supply...the only DTPa vaccine that does not use Thimerosal as a preservative in enough quantities to supply the estimated U.S. market needs for the remainder of 1999."

CDC responded to SmithKline:

"[The CDC NIP staff] has communicated this updated information regarding your supply to the 64 immunization projects. CDC also plans to monitor DTaP ordering patterns and continue to provide the States with a choice among currently licensed brands of DTaP vaccines."

Translation: Although we just said mercury should be removed from vaccines quickly, we are not going to take you up on your offer to do just that. Robert F. Kennedy's recent <u>article</u> on this letter exchange helps capture the outrage many feel.

Source: FOIA filing by parents.

5. Boyle CDC Internal Email: "What happens if you do this?" ☑ Read ► April 25, 2000

Written by Dr. Coleen Boyle, Acting Assistant Director for Science to Dr. Frank Destefano, title, CDC.

Dr. Boyle wrote this email after reviewing the Verstraeten analysis in an internal CDC meeting. By this time, CDC had begun to manipulate the data in order to reduce the correlation between mercury and childhood disorders, although the correlation was still strong enough for the Simpsonwood meeting to take place two months later.

Dr. Boyle's questions reveal much about the nature of the manipulation. She writes:

"Since most of the dx's [diagnosis] are generally not picked up until the 2nd or 3rd year of life had you considered eligibility criteria of at least 18 months or 2 years?? What happens if you do this?"

What Dr. Boyle is noting is that the current analysis CDC is doing includes children as young as six months of age in their analysis, who have no chance of being diagnosed with autism yet, which allows the relative incidence level to decline. The average age of autism diagnosis is estimated to be 4. So, a reasonable cutoff for any analysis trying to find autism incidence would be 2 1/2 or 3 (rather than the 18 months Dr. Boyle mentions), not 6 months old. The only reason to include 6 month-olds in the analysis of the incidence of an autism diagnosis is to lower the incidence and exonerate Thimerosal. She continues:

"For me the big issue is the missed cases - and how this relates to exposure. Clearly there is a gross underreporting."

Dr. Boyle is pointing out the limitations of the CDC's analysis. The CDC relied on two large West Coast HMOs to get data on the number of patients with an autism diagnosis. CDC maintained the internal data on the vaccines these children received and put the two sets of information together to establish if those receiving more mercury had higher rates of autism. The problem is that HMOs materially underreport the number of cases of autism relative to national averages because many parents go outside of their HMO to get the diagnosis and to seek treatment for their children.

CDC had considerably lower incidence levels to start with based on their data source. They lowered the age they were looking at, before children can receive an autism diagnosis, to lower the incidence even further, and they still had a material correlation strong enough to warrant an emergency meeting in Simpsonwood.

Source: FOIA filing by parents.

6. <u>Letter From FDA to Congressman Dave Weldon, M.D. (R-FL)</u> ✓ Read ▶ June 18, 2003

Letter from the FDA confirming the actual expiration dates of Thimerosal-containing vaccines for children to Congressman Dave Weldon, M.D. (R-FL)

This letter refutes the often-reported fallacy that Thimerosal was removed from children's vaccines in 1999. In fact, Thimerosal-containing vaccines were in the market with expiration dates as late as September 2002, as this letter explicitly states. (It's also worth noting that the FDA has no

mechanism for tracking vaccines on the shelf, so its plausible that vaccines were in the supply chain well past their expiration dates.)

Today, the timing of the removal of Thimerosal is becoming even more murky, as CDC has recently placed Influenza vaccine on the recommended schedule, the vast majority of which are loaded with mercury, as this UPI article, "Mercury Creeps Back In", notes.

Merck appears to have contributed to this misunderstanding, with this <u>press release</u> in 1999, which was extremely misleading. As this *Los Angeles Times* <u>article</u> in 2005 noted:

"Drug maker Merck & Co. continued to supply infant vaccine containing a mercury-based preservative for two years after declaring that it had eliminated the chemical.

In September 1999, amid rising concern about the risks of mercury in childhood vaccines, Merck announced that the Food and Drug Administration had approved a preservative-free version of its hepatitis B vaccine.

"Now, Merck's infant vaccine line," the company's press release said, "is free of all preservatives."

But Merck continued to distribute vaccine containing the chemical known as thimerosal, along with the new product, until October 2001, according to an FDA letter sent in response to a congressional inquiry.

The thimerosal-containing supplies had expiration dates in 2002."

Chapter III:2001

IOM: Biologically Plausible

"When members of an advisory committee have financial relationships with different companies whose products are being reviewed, subtle pressures can be brought to bear to respect the parochial interests of other committee members. This sort of clubby relationship can lead to an overall decline in vigilance in matters under review. Such a lack of vigilance was noted in the deliberations over the Rotavirus vaccine." - Conflicts of Interest in Vaccine Policy Making, Committee on Government Reform, U.S. House of Representatives, August 21, 2000

"Mr. Speaker, I will say tonight that mercury should be taken out of every vaccine in the country, and it should be taken out today. There should be an instant recall on any vaccine that is going into our children that has mercury in it." - Congressman Dan Burton, Speech before the US House of Representatives, May 15, 2001

"The Committee concludes that although the hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders is not established and rests on indirect and incomplete information, primarily from analogies with methylmercury and levels of maximum mercury exposure from vaccines given in children, the hypothesis is biologically plausible." - October 2001, Immunization Safety Review: Thimerosal - Containing Vaccines and Neurodevelopmental Disorders, Institute of Medicine

Late 2000 and 2001 was a rough time for the CDC. Simpsonwood had already highlighted the challenges CDC faced with the data they were sitting on. In August of 2000, two months after Simpsonwood, Dan

Burton's Government Reform Committee released a highly critical <u>document</u> on the conflicts of interest at CDC and FDA for decision made on the Rotavirus vaccine, recently recalled due to intussusception in children (a severe bowel disorder), and critical of vaccine policy making in general.

In January 2001, parents associated with the nonprofit group SafeMinds published an article in a peer-reviewed journal titled <u>Autism: A Novel Form of Mercury Poisoning</u>. Chairman Burton continued to hold hearings, browbeating public health officials over the lapse on thimerosal and what was being done about it. This was followed up that May by a <u>speech</u> by Chairman Burton demanding FDA recall any vaccine containing thimerosal at once (they didn't).

Once it was clear that unsafe levels of mercury were in the vaccine supply, FDA was required to hire the Institute of Medicine to review thimerosal and any role it may play in damaging children. With the weight IOM carried with the scientific community, IOM's conclusions, expected to be published in late 2001, were of grave concern to CDC. By the summer of 2001, CDC was aware of IOM's likely conclusion, which was not particularly favorable to CDC: they were going to say that the notion that thimerosal created neurological disorders was "biologically plausible" and merited further study. CDC had already given IOM their data from the VSD, which had been manipulated enough to neither prove nor disprove an association.

Perhaps most frustrating about the recommendations of the IOM in October 2001 is that CDC did not pursue any of them. Where IOM recommended further work to assess biologically plausibility (like measuring mercury levels in autistic children), CDC would focus exclusively on epidemiology, a statistical science easily manipulated. Where IOM encouraged CDC to explore the growing reports of autistic children recovering after chelation therapy, a treatment to remove mercury and other metals from the body, CDC never did anything to explore the reports further. Where IOM encouraged CDC to replace any thimerosal containing vaccines immediately, CDC still has vaccines with thimerosal targeted at infants today, five years later.

Luckily for the children, what CDC did not realize was that parents would dig into their own pockets to fund biological research to prove what had been done to their children, as we will discuss in Chapter 5.

CDC was in a bind. They knew what the Generation Zero data had shown and how explosive that information, if released, would be to the National Immunization Program, their jobs, and vaccine manufacturer liability. They also knew IOM was not going to let them off the hook, and that more work and analysis would be recommended. It left only two alternatives for CDC, both of which they continue to follow today:

- Never, ever let anyone else see the Generation Zero data nor any of CDC's other internal data. Given all the shortcuts and assumptions CDC made to manage down the risks, independent researchers would most assuredly come to a different conclusion. Even though laws required CDC to share this data publicly, they would become experts at buying time and "losing" data when pressured.
- 2. Since the U.S. data shows a high correlation, go to other countries and find willing participants to manufacture data that will "prove" thimerosal and autism are unrelated.

With that strategy in place, a few months prior to the release of the IOM study, CDC employees, under the guidance of their bosses, Dr. Walter Orenstein, Director of the NIP and Dr. Roger Bernier, Associate Director

of Science for the NIP, began a world-wide inquiry to find data from other countries that would be used bail them out. Not only would CDC initiate, fund, and structure these studies, but their own employees would also end up as published authors in the studies exonerating thimerosal's role in autism.

What's Egregious About This Time Period?

- 1. In 2000-2001, after Simpsonwood, CDC slowed down the timing of the release of their own analysis on thimerosal and autism (the analysis, begun in mid-1999, and discussed at Simpsonwood in 2000, would not get published until late-2003), with CDC leaders aware that the data implicated Thimerosal.
- 2. Almost all of the 2001 recommendations of the IOM were ignored by CDC.
- 3. A Congressman on the floor of the House or Representatives made an impassioned plea to recall vaccines with thimerosal and nothing was done about it.
- 4. 2001 was the beginning of a pattern that continues to this day of CDC stalling and not allowing independent researchers access to the data behind their VSD analysis of autism and thimerosal.

Where is the Evidence?

This document from the Institute of Medicine noted the "biological plausibility" of thimeorsal causing neurological damage in children and directed more research to be done. What's most alarming about the 2001 IOM study is how few of their recommendations CDC actually followed, which highlights the clear path CDC was already on: find epidemiology studies that can be manipulated, hire IOM once the studies have been created (which they did in 2004), and close the door on the debate. IOM makes many recommendations in here that were never pursued including:

IOM Recommendation: "The committee recommends the use of thimerosal-free DTaP, Hib, and hepatitis B vaccines in the United States, despite the fact that there might be remaining supplies of thimerosal-containing vaccines available [effectively echoing Congressman Burton's call for a recall]."

CDC response: Nothing, and thimerosal remains in vaccines today given to infants.

IOM Recommendation: "The committee recommends case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines."

CDC Response: No case-control studies ever done.

IOM Recommendation: "The committee recommends further analysis of neurodevelopmental outcomes in these populations [children who received no thimerosal in their vaccines]"

CDC Response: No analysis ever done.

IOM Recommendation: "The committee recommends research on how children, including those diagnosed with neurodevelopmental disorders, metabolize and excrete metals, particularly mercury."

CDC Response: No research ever done.

IOM Recommendation: "The committee recommends continued research on theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal on background mercury from other sources."

CDC Response: No research ever done.

IOM Recommendation: "The committee recommends careful, rigorous, and scientific investigations of chelation when used in children with neurodevelopmental disorders, especially autism."

CDC response: Nothing. We know of no case where CDC investigated claims of a fully recovered autistic child or explored in any way biomedical treatment of autistic children.

IOM Recommendation: "The committee recommends research to identify a safe, effective, and inexpensive alternative to thimerosal for countries that decide they need to switch."

CDC response: No research done. Thimerosal was developed in the 1930s, no safety testing has ever been done on it, and yet the vaccine industry cannot develop a safer preservative that doesn't include mercury, the second most toxic substance on earth?

Source: IOM

2. Letter from Dave Weldon to Julie Gerberding: "Absurd results" The Read

October 31, 2003

From Congressman Dave Weldon, M.D. to the Director of the CDC, Julie Gerberding.

This letter was written in 2003, but highlights the conduct of CDC in the previous few years, including the management of data and the unwillingness to share data with outside researchers.

"A review of these documents leaves me very concerned that rather than seeking to understand whether or not some children were exposed to harmful levels of mercury in childhood vaccines in the 1990s, there may have been a selective use of the data to make the associations in the earliest study [Generation Zero] disappear...This demonstrates to me how excessive manipulation of data can lead to absurd results."

Source: FOIA filing by parents.

3. Instant Recall Speech, Dan Burton 🔼 Read 🕨

May 15, 2001

Speech by Congressman Dan Burton before the U.S. House of Representatives

We only wish Congressman Burton's request had been honored. In 2006, Thimerosal remains in vaccines given to infants and pregnant women.

Source: Committee on Government Reform.

Chapter IV: 2001-2002 CDC World Travel

"Thus these data [referring to some anecdotal information in his email] do not support and in fact argue strongly against the allegation that the thimerosal in vaccines (or variation on this theme, increase in the number of antigens) is responsible for the increase in autism. Research into better understanding autism and its possible increase is needed, but following red herrings do (sic) not help anyone." - Private email from Dr. Robert Chen, Chief of Vaccine Safety, National Immunization Program, CDC, June 13, 2001

Dr. Chen was Chief of Vaccine Safety for the CDC's National Immunization Program (NIP) and the man ultimately responsible for monitoring the safety of vaccines (Dr. Chen was quietly removed from this position in early 2005, largely due to his conduct during this time. Most of the emails from Dr. Chen received through FOIA look like this, with all correspondence deleted by CDC lawyers). Dr. Chen's comments above, and the time he made them, are very revealing:

- -Dr. Chen's comments are twelve months after Simpsonwood, where he and Dr. Verstraeten shared information regarding the troubling correlation between thimerosal and autism from their own data. Dr. Chen also had access to the "Generation Zero" data, which had shown an even higher correlation between thimerosal and autism. He knew there was a problem!
- -In the twelve months since Simpsonwood, no new scientific studies had been published, and Dr. Verstraeten was working to dumb-down the CDC's internal data.
- -Dr. Chen was actively working to keep the CDC's data from being reviewed by outside researchers, which CDC has successfully done through today.
- -Dr. Chen was involved in a worldwide search for data on autism and thimerosal, the brainchild of Dr. Roger Bernier, Associate Director for Science of the NIP and headed by Dr. Diane Simpson, the Deputy Director of the NIP.

CDC's effort, beginning in the summer of 2001, was in anticipation of the IOM's <u>report</u> coming out in the October 2001. They knew what it was going to say and they knew it was going to be trouble. The CDC's subsequent worldwide effort was an attempt to find corroborative data showing no link between autism and thimerosal and get it to the IOM or release it at the same time as the IOM report was released. As Dr. Diane Simpson says in this August 7, 2001 <u>email</u>:

"I don't have any new data at the moment and am frantically trying to see what is available and how best to get it in time for the expected IOM report release (we have given up trying to submit it in time for the report as they are in the process of writing it)."

Dr. Simpson's actions beginning in June of 2001, the same month when Dr. Chen made the above comment, require some context. The Deputy Director of the NIP, Dr. Simpson, was given the task of finding data on autism and thimerosal in other countries. And not just any data, she was looking for data that would support

the statement of her colleague up above, Dr. Robert Chen, that there was no relationship, despite the fact that they had both seen the Generation Zero data and both attended Simpsonwood. Further, you have the division of the CDC that is responsible for keeping vaccination rates high, the division that would be held most responsible for creating the autism epidemic, and one of the leaders of that division, Dr. Robert Chen, who had the most to lose, directly involved in a process to find data about the relationship between thimerosal and autism.

Would CDC be "frantic" to find data that would corroborate the conclusion coming from IOM, that the thimerosal-autism relationship was "biologically plausible"? No, she was frantic to find data to disprove it. In the same month, she tells a Swedish researcher in this email that they could fly to Sweden immediately to look at data, "because our IOM committee's work is in process and we expect them to issue their report in the next several weeks, we expect increased public concern and questions in the near future." In an email with another CDC employee, referring to data she may have unearthed in Denmark, she writes, "it is also possible that the data won't help us at all, but we won't know until we see it." How won't it help? It won't help unless it can be used to exonerate Thimerosal and the CDC.

As an example, Dr. Simpson's communication with the State of California (where autism data is the best in the country) produced a stunning data set, and one quickly buried. In this <u>email</u>, we see data provided by Dr. Loring Dales from the California Dept of Health showing the relationship between the vaccination rates of DTP by second birthdays, and the number of autism cases in California. One of Dr. Simpson's colleagues mentions "this looks like material for a graph." The graph is created, page 3 of the email, and there is a clear, linear relationship between the increase in vaccination rates (from 50.9% to 75.7%) and the number of autism cases per year (from 176 to 1182, a 6.7x increase) between 1980-1994. Needless to say, California was not the source of additional follow-up.

Dr. Simpson was an interesting choice to lead this initiative. She was oblivious to the full-blown epidemic of autism, as this <u>email</u>, on June 8, 2001 shows:

"I have seen statements claiming huge increases in the incidence rate of autism in the US over the past 10-15 years. The only data I have seen from California. Are there national estimates for autism in the US or is everything extrapolated from the California data?"

Nonetheless, Dr. Simpson began her search, as introductory emails to <u>California</u>, <u>Sweden</u>, <u>Belgium</u>, and <u>Denmark</u> show. Dr. Simpson's goal, through her emails, was very clear: exonerate thimerosal. Not all of Dr. Simpson's correspondence was well received, and in fact some of it was quite comical. A Swedish Doctor, Dr. Marta Granstrom, responded in this <u>email</u> to Dr. Simpson with a clear point of view on thimerosal:

"I am very well aware of the recent concerns in the US over thiomersal (an alternative name for thimerosal). On the expert committee of the European Pharmacopoeae I represent Sweden and had in vain tried to get Europe to ban its use in single dose vials until the US interest in the issue...I thanked Neal Halsey [AAP member who spearheaded the joint statement in 1999] in the name of European infants for the help when I met him again last year."

By August, Dr. Simpson was getting desperate as she lamented in an <u>email</u> that, "events have slightly accelerated with Walt's return [Walter Orenstein, Director of the NIP] and anxiety over trying to get these

data. Consequently, we are TENTATIVELY planning for you and I to go to Denmark and Sweden on August 22...if a trip is to occur in time for the IOM it has to be in this time frame." In many ways, the trip to Sweden and Denmark was Dr. Simpson's last shot at finding data, as her August 6 email shows:

"Should we find that any other country has good data on both autism and vaccines, we will work to get that data on a case by case basis. i.e., I don't know what we are going to do and don't want to think about it right now- but we will do something."

The "something" Dr. Simpson did was find a Danish vaccine company, Status Serum Institute, willing to work with CDC. A company who sold thimerosal-containing vaccines and a company who would soon see an enormous rise in the number of vaccines sold to the United States. Along with her colleague, Dr. Paul Stehr-Green, Dr. Simpson was heading to Denmark. Two years later, Dr. Simpson and Dr. Stehr-Green would be published authors, along with employees of SSI, letting the world know that the Danish data proved that thimerosal does not cause autism. These Danish studies would then form the basis for a NEW IOM, initiated by CDC, that in 2004 would declare that the thimerosal-autism hypothesis was without merit, and has since been referenced as "proof" that thimerosal is safe. It all started with Dr. Diane Simpson's trip to Denmark. We even found a copy of her travel voucher.

Separately, in 2002, the CDC outsourced the maintenance and analysis of the Vaccine Safety Datalink database to a private lobbying organization that represents health insurance companies, America's Health Insurance Plans, in a contract valued at more than \$190 million. This private outsourcing of government data, contracted in the midst of the furor over the CDC's mishandling of Thimerosal-autism data, has served to insulate VSD data from the Freedom of Information Act ever since. As of today, no outside scientists have been able to review the American data CDC used to exonerate Thimerosal.

In contrast, the VAERS (Vaccine Adverse Events Reporting System) database, a reporting system on vaccine adverse events available to the public, is maintained with \$21 million (over a comparable time period) by the <u>Constella Group</u>. At a very large expense to taxpayers, the most meaningful vaccine injury data, the VSD Data, are hidden from the American public.

What's Egregious About This Time Period?

- 1. CDC actively shopped for studies in other countries that would exonerate thimerosal, and wielded influence with international researchers through their ability to make grants and purchase large quantities of vaccines. Rather than relying on independent researchers, they orchestrated the studies within CDC's headquarters, often from the same division responsible for advocating for administering vaccines. CDC employees would actually co-author a number of these international studies. This email show the leaders of CDC debating which studies from Denmark to provide funding for.
- 2. The Chief of Vaccine Safety, Dr. Robert Chen, was on the record in 2001 referring to the thimerosal-autism hypothesis as a "red herring" and a waste of time.
- 3. Through their correspondence, it is clear that CDC employees were only looking for one kind of data, data to exonerate thimerosal. When they came across data that showed the opposite, they moved on.

4. CDC outsourced all of the VSD data to a private lobbying organization for more \$190 million to insulate the data from the Freedom of Information Act.

Where is the Evidence?

1. Email from Chen to Unknown recipient: "Red Herrings" A Read June 13, 2001

Email between Dr. Robert Chen, Chief of Vaccine Safety, NIP, and unknown recipient.

"Thus these data [referring to some anecdotal information in his email] do not support and in fact argue strongly against the allegation that the thimerosal in vaccines (or variation on this theme, increase in the number of antigens) is responsible for the increase in autism. Research into better understanding autism and its possible increase is needed, but following red herrings do (sic) not help anyone."

Dr. Chen's comments and the time he made it are revealing because: they are twelve months after Simpsonwood, when he and Dr. Verstraeten shared information regarding the troubling correlation between thimerosal and autism from their own data. Dr. Chen also had access to the "Generation Zero" data, which had shown an even higher correlation between thimerosal and autism. He knew there was a problem! In the twelve months since Simpsonwood, no new scientific studies had been published, and Dr. Verstraeten was working to dumb-down the CDC's internal data. Dr. Chen was actively working to keep the CDC's data from being reviewed by outside researchers, which CDC has successfully done through today. Dr. Chen was involved in a worldwide search for data on autism and thimerosal, the brainchild of Dr. Roger Bernier, Associate Director for Science of the NIP and headed by Dr. Diane Simpson, the Deputy Director of the NIP.

Source: FOIA filing by parents.

2. Email from Simpson to Stehr-Green: "Data Won't Help Us" The Read ▶

August 2, 2001

Email between Dr. Diane Simpson, Deputy Director of NIP, CDC, and Dr. Paul Stehr-Green, CDC

Dr. Simpson was charged with spearheading a worldwide effort for CDC to find data in other countries with a clear goal: exonerate thimerosal. In this email, referring to data she may have unearthed in Denmark, she writes:

"It is also possible that the data won't help us at all, but we won't know until we see it."

How won't it help? It won't help unless it can be used to exonerate thimerosal and the CDC. If it doesn't help, like the data in #3 below, CDC would not pursue it.

Source: FOIA filing by parents.

3. Email from Dales to Simpson: "Looks like a graph" The Read June 8, 2001

Email from Dr. Loring Dales, California Dept. of Health, to Dr. Diane Simpson, Deputy Director of NIP, CDC

Dr. Simpson's communication with the State of California (where autism data is the best in the country) produced a stunning data set, and one quickly buried. The data provided here by Dr. Loring Dales from the California Dept of Health shows the relationship between the vaccination rates of DTP by second birthdays, and the number of autism cases in California. One of Dr. Simpson's colleagues mentions "this looks like material for a graph." The graph is created, page 3 of the email, and there is a clear, linear relationship between the increase in vaccination rates (from 50.9% to 75.7%) and the number of autism cases per year (from 176 to 1182, a 6.7x increase) between 1980-1994. Needless to say, California was not the source of additional follow-up.

Source: FOIA filing by parents.

4. Email from Granstrom to Simpson: "In the name of infants" ☑ Read ▶
June 22, 2001

Email from Dr. Marta Granstrom of Sweden to Dr. Diane Simpson, Deputy Director of NIP, CDC

In CDC's effort to find data to exonerate thimerosal, they reached out to many different scientists. In Dr. Granstrom, CDC received a stern reply on the dangers of Thimerosal in vaccines:

"I am very well aware of the recent concerns in the US over thiomersal. On the expert committee of the European Pharmacopoeae I represent Sweden and had in vain tried to get Europe to ban its use in single dose vials until the US interest in the issue...I thanked Neal Halsey [AAP member who spearheaded the joint statement in 1999] in the name of European infants for the help when I met him again last year."

Source: FOIA filing by parents.

5. Email from Simpson to Gilberg: "Increased public concern" ☑ Read ► August 7, 2001

Email from Dr. Diane Simpson, Deputy Director of NIP, CDC, to Dr. Christopher Gillberg, Sweden

This email highlights the concern CDC had regarding the release of the 2001 IOM report and the publicity around the conclusion that the thimerosal-autism hypothesis is "biologically plausible" In this email, she tells a Swedish researcher that she and Dr. Stehr-Green could fly to Sweden immediately to look at data:

"because our IOM committee's work is in process and we expect them to issue their report in the next several weeks, we expect increased public concern and questions in the near future."

Source: FOIA filing by parents.

6. <u>VSD Contract to America's Health Plan Excerpt</u> ☑ Read ► September 20, 2002

Contract signed by CDC to outsource analysis of the VSD data

The CDC outsourced the maintenance and analysis of the Vaccine Safety Datalink database to a private lobbying organization that represents health insurance companies, America's Health Insurance Plans, in a contract valued at more than \$190 million. This private outsourcing of government data, contracted in the midst of the furor over the CDC's mishandling of Thimerosal-autism data, has served to insulate VSD data from the Freedom of Information Act ever since. As of today, no outside scientists have been able to review the American data CDC used to exonerate Thimerosal. Here is a copy of AHIP's 2003 Annual Report on the VSD.

Interestingly, on AHIP's <u>website</u>, they state their priorities for 2005-06, which includes "Thimerosal and Autism", despite the recommendation of the 2004 IOM to no longer pursue the link between Thimerosal and autism:

"2005-06 Priority Studies Include:

Risk of Alopecia following Hepatitis B Vaccination

Influenza Vaccine and Bell's palsy

Thimerosal and Autism

Yellow Fever in Children and Adults

The Safety of the Pediatric Influenza Vaccine: A Population-based Study 1993 - 2003"

Chapter V: 2003 It's Rotten in Denmark

"Mercury is hazardous to humans. Its use in medicinal products is undesirable, unnecessary and should be minimized or eliminated entirely. Manufacturers of vaccines and thimerosal, (an ethlymercury compound used in vaccines), have never conducted adequate testing on the safety of thimerosal. The FDA has never required manufacturers to conduct adequate safety testing on thimerosal and ethlymercury compounds...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 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" - Mercury In Medicine: Taking Unnecessary Risks, Committee On Government Reform, U.S. House of Representatives, May 21, 2003

The Mercury In Medicine <u>report</u>, from Chairman Burton's Committee on Government Reform, was released in May 2003, and provided a scathing indictment of the Federal Health bureaucracy and their inexplicable complacency regarding mercury and vaccines. Despite the entire report being publicly available in the Congressional Record, it has gotten little publicity.

While the Mercury In Medicine report was certainly not welcome by CDC, they knew that by the Fall of 2003 the pendulum would swing back towards exonerating Thimerosal with the near simultaneous release of four separate studies between September and November in four separate medical journals that would provide the basis for "proof" that vaccines and autism are unrelated as cited by the IOM six months later in their 2004 report. Three of those studies, in Pediatrics, The American Journal of Preventative Medicine, would be based on the Danish data, and one study, also in Pediatrics, would be the data finally released by CDC of their analysis of the VSD.

For practicing Doctors, medical journals are their primary source of information from the outside world. For pediatricians, tasked with administering the lengthy <u>U.S. Immunization Schedule</u>, *Pediatrics*, the Journal of the American Academy of Pediatrics, is their trusted source of information. We believe few pediatricians are remotely aware of the conflicts, limitations, and manipulation that the published studies were subjected to, and that few realize many of the published authors were CDC employees or SSI employees, a Danish vaccine manufacturer. Because Pediatrics is the trusted source of information for Doctors, and because the two

Pediatrics studies are most often cited regarding "proof", we will focus our time analyzing these two.

In September 2003, Pediatrics published <u>Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data</u>. Thimerosal was removed from Danish vaccines in 1992, and the study showed that not only did autism rates not go down after its removal, they actually went up. The study's lead other, Kristeen Madsen, had been one of the Danish researchers Dr. Diane Simpson reached out to early on in her world travel of 2001. This study was highly flawed for the following reasons (read SafeMinds' critique here):

-The data as it was captured was blatantly obscured. The study looked at data between 1970-2000. In 1995, the Danish registry added "Outpatient Clinics" to their count of autism cases. It turns out that Outpatient Clinics are where 93% of Danish children are diagnosed with autism, so the number of autism cases before 1995 did not include the clinics. More surprising, the authors even note this in the study: "since 1995 outpatient activities were registered as well...the proportion of outpatient to inpatient activities was about 4 to 6 times as many outpatients as inpatients...this may exaggerate the incidence rates."

Exaggerate the incidence rates? It is the equivalent of doing a study on "Divorce Rates in North America" and counting Mexico and Canada only for the first few years, then adding in the United States, and noting that divorce rates went up. As a SafeMinds critique of the study noted, "Therefore, their purported increase after 1994 can be explained entirely by the registration of an existing autism population that did not require hospitalization." To compound the problem, Denmark also changed the diagnostic code they used, to the more universal ICD10 code, beginning in 1993, which would have further raised the rates.

Dr. Madsen, in his communications with Dr. Diane Simpson two years earlier, actually noted this discrepancy in Danish data in an <a href="mailto:email

Dr. Simpson: "Did they [autism rates] increase after 1993??"

Dr. Madsen: "Yes but not very dramatically and there could be more reasons for that. First of all we had a change from ICD8 to ICD10 in 1994 and furthermore our outpatient clinics were registered in our surveillance from 1995."

- -The rates of autism in Denmark and the number of vaccines and amount of mercury received in children are markedly lower than the U.S. Danish children receive 75% less Thimerosal than American children, they receive immunizations when they are older, and the U.S. autism rate is TEN TIMES the rate of Denmark (Denmark is 1 in 1,600, U.S. is 1 in 166). As an example, here is an email exchange back in 2001 discussing data from Great Britain between Dr. Verstraeten, the author of the CDC's internal analysis, and Robert Chen. Dr. Verstraeten notes that the British numbers will probably not be helpful because the Thimerosal received by British children is too low relative to American children: "The maximum exposure is indeed relatively low...it may not be worth doing this after all." Denmark's Thimerosal was as low or lower than Britain, but they proceeded with the study anyway.
- -The study authors were conflicted, and the conflicts were not reported in the study, as they should have been. Of the seven co-authors of the study, three had received direct funding from the CDC on vaccine-safety related projects. One of the authors, Poul Thorsen, was a CDC employee. And, two of the authors were employees of Statens Serum Institute, a Danish vaccine manufacturer. Here's SSI's Annual Report.

Interestingly, page 28 shows that sales of vaccine products to the U.S. were particularly high in 2002. None of these conflicts are mentioned anywhere in the study.

-CDC actual wrote a letter to Pediatrics recommending publication of the study. This <u>letter</u>, written prior to the official date of submission, reveals how involved in the study CDC was (remember, one of their employees was a co-author). Jose Cordero, Director of the Division of the CDC responsible for developmental disabilities, oversees the CDC's efforts to fight autism. He notes, "its findings provide one strong piece of evidence that thimerosal is not causally linked to autism." Dr. Cordero, too, had seen the Generation Zero data and attended the meeting in Simpsonwood.

Two months later, Dr. Vestraeten's data, which began with a panic in late 1999 ('It just won't go away"), was published in Pediatrics titled <u>Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organizations</u>. Perhaps most frustrating about this study is that it is often referenced as "proof" that vaccines do not cause autism when it was actually a neutral-outcome study, as Dr. Verstraeten himself noted, in a letter to <u>Pediatrics:</u>

"Surprisingly, however, the study is being interpreted now as negative [where 'negative' implies no association was shown between Thimerosal and autism] by many...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...A neutral study carries a very distinct message: the investigators could neither confirm nor exclude an association, and therefore more study is required."

This study was highly flawed for the following reasons (read SafeMinds' critique here):

-The data was manipulated to remove the strong correlation between mercury and autism. As Chapter II discussed, the initial analysis using Vaccine Safety Datalink data (VSD) showed a high correlation between Thimerosal and autism, called "Generation Zero." The CDC used many techniques to dumb-down the numbers including removing comparisons to children who had received no Thimerosal, lowering the age of children available for the analysis, and including a bankrupt HMO, with notoriously faulty data systems, in their final round of analysis. This HMO helped neutralize the findings reviewed at Simpsonwood. As SafeMinds reported:

"The general drift of their design changes was clear, to reduce the statistical power through conscious manipulation of statistical methods, data classifications, and samples."

- -Dr. Verstraeten, the study's author, had been an employee of Glaxo SmithKline for more than 2 years by the time the study was published. This blatant conflict, with a study author employed by a company being sued by parents for Thimerosal in vaccines, was never noted in the Pediatrics study.
- -Even with all the manipulation, the study was still a neutral outcome study. Many people would be surprised to know that the study itself cites a correlation between Thimerosal-containing vaccines and both "tics" and "language delay." Beyond that, the study neither proves nor disproves an association between Thimerosal and autism and recommends that more work needs to be done.

What's Egregious About This Time Period?

- 1. CDC and SSI employees were the primary study authors of studies that would exonerate their own policies (CDC) and products (SSI).
- 2. Conflicts of the study authors were never cited in any of the studies published.
- 3. CDC knew about the limitations of the Danish data, but moved towards publication any way, with a senior official actually lobbying *Pediatrics* for publication.
- 4. CDC manipulated evidence of a correlation between Thimerosal and autism from their own VSD data, despite the overwhelming evidence of "Generation Zero" and the data presented at Simpsonwood.
- 5. We have never proven, using American data, that Thimerosal didn't cause the autism epidemic, yet "proof" is often cited of exactly that.

Where is the Evidence?

Chapter VI: 2004 IOM Slams the Door (Quickly)

"The body of epidemiological evidence favors the rejection of a causal relationship between thimerosal-containing vaccines and autism." - March 2004, Immunization Safety Review, Institute of Medicine

The Institute of Medicine (IOM) is a private institution. According to their website, "the IOM's mission is to serve as adviser to the nation to improve health. The Institute provides unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large." The IOM is often requested by government institutions to weigh in on matters of public concern or issues that are controversial.

In the medical community, the IOM is viewed as having a pristine reputation and the highest ethical standards, and therefore their word is considered final on many different matters. That's why the 2004 report, dismissing the link between vaccines and autism, is so devastating for our kids. It is the "proof" so often cited by journalists that autism is not caused by vaccines, and their conclusion in 2004 inhibits Federal funding from exploring the vaccine-autism connection. And, it renders exploration of treatment for autism, like the removal of mercury from our children's bodies, moot.

Many were concerned about the likely conclusions of the IOM, including Congressman Dave Weldon (R-FL), who in this <u>speech</u> to the IOM prior to the release of the study, noted:

"This atmosphere of intimidation even surrounds today's hearing. I received numerous complaints that this event is not a further attempt to get at the facts but rather a desire to sweep these issues under the rug."

The 2004 IOM was a kangaroo court with a pre-ordained outcome. Unlike the CDC, the Institute of Medicine is a private institution and not subject to the Freedom of Information Act. The IOM Committee Members, particularly Dr. Kathleen Stratton, was apparently livid when they learned these transcripts had been leaked. She should have been profoundly embarrassed.

The Committee Members own words betray them: the fix was in. The 2004 IOM Report, so roundly cited as "proof" that vaccines don't cause autism, was tainted because:

- The CDC was the client and paying for the study. Here's a copy of the study parameters.
- 2. The committee members made the CDC's expectations clear from the beginning. Here's a discussion between Dr. Marie McCormick, Chairman of the Committee, and Dr. Kathleen Stratton, Study Director of the Committee, BEFORE they had reviewed any of the evidence on either side of the debate:
 - **Dr. McCormick:** ...[CDC] wants us to declare, well, these things are pretty safe on a population basis (p. 33).
 - **Dr. Stratton:** ...The point of no return, the line we will not cross in public policy is pull the vaccine, change the schedule. We could say it is time to revisit this, but we would never recommend that level. Even recommending research is recommendations for policy. We wouldn't say compensate, we wouldn't say pull the vaccine, we wouldn't say stop the program. (p. 74)
 - **Dr. McCormick:** ...we are not ever going to come down that [autism] is a true side effect...(p. 97)
 - IOM Committee Meeting, 1/12/2001 Closed-Door Meeting Transcript
- 3. The committee was largely made up of health policy advocates, who were concerned with vaccination rates, not the health of our children. There were no toxicologists or doctors of autistic children on the committee, and time was dedicated to discussing issues of vaccination policy, rather than whether or not there was evidence that vaccines caused harm. Here Dr. Stratton discusses the benefits of putting the debate to rest "no matter what" in order to allay parents concerns "to vaccinate or not vaccinate."

"I think that as Alicia just point (sic) out is I think when CDC was thinking about significance and we were thinking about, it's more is this such a concern, and the risk of putting it rest (sic), or not putting it to rest does not relate to a recommendation to change the schedule, but parent decisions and actions to vaccinate or not vaccinate. So I think it is not would there be a policy recommendation about it, but do we have reason to believe, or is even a theoretical concern that this is not put to rest. And more and more parents are going to follow this, and get involved, and stop getting immunized, therefore the risk of disease will go up. So it's not a policy recommendation that would lead to measles going up, but the true on the street worry about this. And is there a benefit to putting to rest no matter what."

- Kathleen Stratton, IOM Committee Meeting, 3/9/2001 Closed-Door Meeting Transcript, pp. 120-1 (emphases added)
- 4. The committee refused to look at hundreds of case reports showing the relationship between vaccinations and autism.
 - **Dr. Johnston:** Barbara Loe Fisher [NVIC] could give you names. Mrs. Fisher said she had cases. I think she came up to say if you needed any cases to demonstrate the points, you could have them.

Dr. McCormick: She was demonstrating causality. She was taken by your case series that you did-the Guillaume Barre (sic) and whatever, the tetanus. She was all ready to get you cases to prove causality.

Dr. Wilson: Well, let's see them.

Dr. McCormick: Let's not do that. Do you have a free weekend that you want to plod through them?

- IOM Committee Meeting, 1/12/2001 Closed-Door Meeting <u>Transcript</u>, pp. 149 & 150 (emphasis added)
- 5. The committee based their conclusions SOLELY on epidemiology: the Danish studies and the CDC's own analysis of the VSD. As Chapter 5 showed, the Danish studies were highly flawed, originated by the CDC, authored by CDC and a Danish vaccine manufacturer employees, and based on a change to the Danish database that any Ninth grade math student could understand. And, by the admission of the author of the CDC's study using their VSD data, a neutral outcome was produced, meaning it should not have contributed in any way to the IOM's conclusion. Denmark was all they had.
- 6. The IOM was informed that a number of biological studies were awaiting publication, and the IOM rushed their report in ADVANCE of those studies.

The IOM refused to review any drafts of biological studies linking vaccines and autism, and rushed their report, relying solely on epidemiology, in advance of biological studies in the next twelve months from scientists at <u>Columbia University</u>, <u>University of Arkansas</u>, <u>Northeastern University</u>, <u>Johns Hopkins University</u>, <u>Harvard University</u>, and the <u>University</u> of <u>Washington</u>.

Dr. Thomas Burbacher, a professor from the University of Washington, produced compelling research demonstrating how injected Thimerosal ended up as high levels of inorganic mercury in the brains of chimps. In his study, he noted:

"A recently published IOM review (IOM 2004) appears to have abandoned the earlier recommendation [of studying mercury and autism] as well as back away from the American Academy of Pediatrics goal [of removing mercury from vaccines]. This approach is difficult to understand, given our current limited knowledge of the toxicokinetics and developmental neurotoxicity of thimerosal, a compound that has been (and will continue to be) injected in millions of newborns and infants."

The 2004 IOM Report did the opposite of its goal of putting the vaccines-autism debate to rest, it reignited parents and increased activism. In fact, it sparked the courageous FOIA requests filed by parents, completed despite some personal retaliation by the CDC and IOM, that have led to the paper trail of evidence highlighted on this site, and it sickened certain employees of the IOM enough to cause them to leak the transcripts of Committee deliberations. As Congressman Dave Weldon said in remarks to Congress soon after the report's release:

"In my 10 years of service in U.S. Congress, I have never seen a report so badly miss the mark. I have heard some weak arguments here in Washington, D.C., and

I can tell my colleagues that the arguments put forward in this IOM report are indeed very weak...

Now, I had a follow-up conversation on February 3 of this year [2004] with Dr. Gerberding [head of the CDC], and she assured me that the Institute of Medicine's February meeting was not an attempt to "draw conclusions," but merely to "update the science," of where we are, basically. However, it is clear that this report draws conclusions; and what is perhaps the greatest outrage, it goes further to call for the halt of further research...

The Institute of Medicine bases their decision almost entirely on five epidemiological studies. Epidemiology is essentially the statistical analysis of disease in populations. All of these studies were conducted by researchers with an interest in not finding an association. All of the studies had significant shortcomings, all of which the IOM itself declares would miss the association with autism in a genetically susceptible subset of children...

The latest IOM report is simply part of a PR campaign, in my view."

IOM President Harvey Fineberg defended the committee in this <u>statement</u>, explaining that, "the members of the committee underwent a stringent review process that ensured all were free of financial conflicts of interest and were not biased for or against any vaccine safety hypothesis." Yet, these secretly obtained handwritten <u>meeting notes</u> reveal that many Committee members had conflicts of interest and they were openly discussed, like the notes stating "Pharma company" and "\$5000 Merck" and "vaccines should be continued" and "Smith-Kline Beecham" and "American Home Products" and "financial push to approve vaccines."

The fix was in, our kids couldn't win. This is the "proof" so often written about that vaccines, and a preservative in vaccines made of mercury, do not cause autism. If you were a parent, would it feel like proof to you?

What's Egregious About This Time Period?

- From the beginning, the outcome of the 2004 IOM study, often cited as "proof" that
 vaccines do not cause autism, was pre-ordained by the CDC, as the words of the IOM
 Committee members demonstrate. Not only was the CDC paying for the study, but their
 needs were clearly stated by the Chairman of the Committee: protect the National
 Immunization Program.
- 2. IOM Committee members rushed the report to the public, despite knowing that peer-reviewed biological studies were being published soon.
- 3. The IOM Committee looked solely at epidemiological studies, notorious for their ease of manipulation. Further, the studies they based their decision on were from Denmark, where fatal flaws in the data pool used in Denmark made the results meaningless. This, despite compelling biological evidence presented to the committee by leading scientists.
- 4. In an extraordinary step, the IOM recommended no further research dollars be dedicated to the vaccine-autism hypothesis.

Where is the Evidence?

1. <u>Conflicts of Interest: Presentation for Senatorial Inquiry</u> ☑ Read ► November 15, 2005

Presentation compiled for Senate Committees spelling out how the CDC constructed the IOM Committee to reach a pre-determined outcome.

This 55 page document provides a complete summary of the methodology employed by the CDC to influence the outcome of the 2004 IOM. It has been shared with key members of both the Senate and the House as of November 2005 and has never been publicly released. It summarizes:

"All the epidemiological research on links to autism and thimerosal exposure that the IOM ISR Committee cites as the basis for its final report conclusion, rejecting a causal link between thimerosal exposure and autism, was undertaken with CDC money or by researchers with close ties to the CDC."

And, this <u>second presentation</u> spells out in detail for the IOM Committee proceedings were managed to produce the outcome CDC was looking for including changing their charter, avoiding case reports, and disregarding biological evidence.

Source: Private Source.

2. IOM Closed Door Committee Meeting 🔼 Read 🕨

January 12, 2001

Leaked transcript of IOM Committee Deliberations. As a private institution, the IOM is not subject to the Freedom of Information Act.

This transcript, in a meeting held long before ANY evidence was reviewed; show how the conclusion had already been pre-determined by CDC:

Dr. McCormick: ...[CDC] wants us to declare, well, these things are pretty safe on a population basis (p. 33).

Dr. Stratton: ...The point of no return, the line we will not cross in public policy is pull the vaccine, change the schedule. We could say it is time to revisit this, but we would never recommend that level. Even recommending research is recommendations for policy. We wouldn't say compensate, we wouldn't say pull the vaccine, we wouldn't say stop the program. (p. 74).

Dr. McCormick: ...we are not ever going to come down that [autism] is a true side effect...(p. 97)

On pages 149 & 150, you see the following exchange, showing how the IOM Committee avoided looking at case studies demonstrating how vaccines caused autism in children:

Dr. Johnston: Barbara Loe Fisher [NVIC] could give you names. Mrs. Fisher said she had cases. I think she came up to say if you needed any cases to demonstrate the points, you could have them.

Dr. McCormick: She was demonstrating causality. She was taken by your case series that you did -- the Guillaume Barre (sic) and whatever, the tetanus. She was all ready to get you cases to prove causality.

Dr. Wilson: Well, let's see them.

Dr. McCormick: *Let's not do that.* Do you have a free weekend that you want to plod through them?

Source: Private source provided leaked transcript.

3. IOM Committee Meeting Talkead

February 9, 2004

Transcript of IOM Committee Meeting, including multiple presentations from biological scientists.

This transcript, a lengthy 355 pages, includes presentations by six scientists showing a clear correlation between mercury and autism, including 2 scientists who were on the cusp of publishing their research. None of the information provided by these scientists was considered in the IOM's conclusion. As two examples, here is a statement provided by David Baskin, M.D., Professor of Neurosurgery, Baylor College of Medicine (p.228):

"...it is an example of a quantitative assessment of live cells from autistic individuals using molecular biological tools, and it suggests...that a subset of autistic children appear to be more sensitive than their unaffected siblings to thimerosal."

And, Boyd Haley, Ph.D., the Chair of the Chemistry Department of the University of Kentucky (p. 270):

"...there appears to be a subset of the population that cannot effectively excrete mercury, and they are at a greater risk for exposure in the general population...But the rate of autism in Denmark is somewhere -- I looked at the chart in the paper, and the highest level was around five [5 cases of autism per 10,000 children], and younger age groups it was even lower, down to less than two. In this country, I see numbers where it is 67 per 10,000. So I don't think that comparison of that piece of research is really very relevant."

Source: Institute of Medicine.

4. Special Order by Congressman Dave Weldon, M.D. The Read

June 18, 2004

Speech before the House of Representatives

This speech was delivered on the House floor after the IOM report was released:

"In my 10 years of service in U.S. Congress, I have never seen a report so badly miss the mark. I have heard some weak arguments here in Washington, D.C., and I can tell my colleagues that the arguments put forward in this IOM report are indeed very weak...

Now, I had a follow-up conversation on February 3 of this year [2004] with Dr. Gerberding [head of the CDC], and she assured me that the Institute of Medicine's February meeting was not an attempt to "draw conclusions," but merely to "update the science," of where we are, basically. However, it is clear that this report draws conclusions; and what is perhaps the greatest outrage, it goes further to call for the halt of further research...

The Institute of Medicine bases their decision almost entirely on five epidemiological studies. Epidemiology is essentially the statistical analysis of disease in populations. All of these studies were conducted by researchers with an interest in not finding an association. All of the studies had significant shortcomings, all of which the IOM itself declares would miss the association with autism in a genetically susceptible subset of children...

The latest IOM report is simply part of a PR campaign, in my view."

Source: Congressional Record.

This private email was written by Marie McCormick, Chairperson of the 2004 IOM Committee. It highlights how misused and misquoted the 2004 IOM report is, often referred to as proof that thimerosal is "safe", which the report never concluded. In it, she quotes a portion of the IOM report:

"The committee accepts that under certain conditions, infections and heavy metals, including thimerosal, can injure the nervous system."

Something that can "injure the nervous system" is not safe. Thimerosal has never been tested for safety and no proof exists that it is safe. On the contrary, there are thousands of documents in the literature that discuss its extreme toxicity, starting with thimerosal's own Material Safety Data Sheet that, amongst other things, states:

"Exposure Guidelines: Thimerosal - **no known occupational limits established...** Exposure to mercury in utero and in children can cause mild to severe mental retardation and mild to severe motor coordination impairment... Target Organ Effects: Mercury - Nervous system effects (insomnia, tremor, anorexia, weakness, headache), liver effects (jaundice, digestive effects (hypermotility, diarrhea)."

Thimerosal is made of mercury. Mercury is 1000x more toxic than lead. If lead were in vaccines, the world would be in an uproar because lead's toxicity is well known, and thimerosal is ONE THOUSAND TIMES WORSE. Some of the many studies documenting thimerosal's extreme toxicity, at levels well below what our children receive through vaccines, include:

<u>Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal</u>

<u>Uncoupling of ATP-mediated Calcium Signaling and Dysregulated IL-6 Secretion in Dendritic Cells by Nanomolar Thimerosal</u>

Thimerosal induces neuronal cell apoptosis by causing cytochrome c and apoptosis-inducing factor release from mitochondria

<u>Thimerosal Neurotoxicity is Associated With Glutathione Depletion: Protection with Glutathione Precursors</u>

Activation of Methionine Synthase by Insulin-like Growth Factor-1 and Dopamine: a Target for Neurodevelopmental Toxins and Thimerosal

<u>Thimerosal Induces DNA Breaks, Caspase-3 Activation, Membrane Damage, and Cell Death in Cultured Human Neurons and Fibroblasts</u>