

**Testimony of**

**Lyn Redwood, RN, MSN, CRNP  
President, SafeMinds**

**Before the Subcommittee on Human Rights and Wellness  
Committee on Government Reform  
U.S. House of Representatives**

**September 8, 2004**

**Hearing**

**“Truth Revealed: New Scientific Discoveries  
Regarding Mercury in Medicine and Autism”**

## **Introduction**

Good morning Chairman Burton and Members of the Subcommittee. My name is Lyn Redwood. As President of the Coalition for SafeMinds, I want to thank you on behalf of the entire thimerosal-induced autism community for holding this important hearing today.

Given the prescribed time to make my comments, I am providing a copy of a newly released report from SafeMinds entitled “*A Brief Analysis of Recent Efforts in Medical Mercury Induced Neurological and Autism Spectrum Disorders.*” I ask that it be entered into the hearing record today.

It has been five years since the Public Health Service (PHS) and the American Academy of Pediatrics (AAP) first announced that thimerosal should be removed from vaccines. At that time, taking the appropriate position of caution, the PHS and AAP announced to the public and practitioners:

*“...because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible.”*

In July 2000 when SafeMinds presented to the Government Reform Committee the paper, *Autism a Novel Form of Mercury Poisoning*, publishing the evidence pointing to the synonymous nature of the symptoms of mercury poisoning and autism spectrum disorders, we could not have imagined that in 2004 thimerosal would still be in vaccines and that the government agencies tasked with protecting the public would have failed to take aggressive action to get the mercury out and protect our nation’s children. We could not have imagined that they would, instead, have focused their energies on avoiding or hiding the truth that is before them, and in doing so undercut the public’s trust and continue to put babies at risk for mercury injury.

## **Government and Regulatory Failures Abound**

### **Food and Drug Administration**

The first in a series of regulatory failures of our government agencies belongs to the Food and Drug Administration (FDA) for failing to remain open minded and objective about the possibility that vaccines might at times be harmful and requiring valid scientific evidence from manufacturers to prove safety of vaccines, their preservatives and adjuvants. Over the course of seventy years since Thimerosal was first introduced into the marketplace, FDA has repeatedly failed to ask the tough questions and to require proof of safety while allowing its increased use in vaccines. Federal regulations provide review procedures for biological products, including vaccines, and submission of animal safety data for the finished biological product. One must ask why was Thimerosal, destined for childhood vaccines, was allowed to bypass toxicological testing, the bedrock of pharmaceutical development. FDA openly admits that original safety data submitted in the 1930’s where Thimerosal was administered to adult rats, mice, dogs and guinea

pigs, no histopathology on the brain reported. Only one study in humans was received where Thimerosal was used as an experimental agent to treat meningitis.

“The earliest published report of thimerosal use in humans was published in 1931 (Powell and Jamieson 1931). In this report, 22 individuals received 1% solution of thimerosal intravenously for unspecified therapeutic reasons. Subjects received up to 26 milligrams thimerosal/kg (1 milligram equals 1,000 micrograms) with no reported toxic effects, although 2 subjects demonstrated phlebitis or sloughing of skin after local infiltration. Of note, this study was not specifically designed to examine toxicity; 7 of 22 subjects were observed for only one day, the specific clinical assessments were not described, and no laboratory studies were reported.”<sup>1</sup> Although those who received this experimental treatment suffered high mortality and morbidity, these poor outcomes were attributed to the severity of the disease and not to Thimerosal. From these initial investigations Thimerosal was assumed “safe” by FDA and its use was “grandfathered” without further toxicity testing required.

In the early 1980’s concerns regarding Thimerosal arose and an expert panel was convened by FDA to review its use in topical over the counter products. The panel reported in 1982, Vol. 47 no. 2 that Thimerosal was “toxic, caused cell damage, was not effective in killing bacteria or halting their replication” and that Thimerosal is “not generally recognized as being safe or effective”. It was not until 16 years later in 1998 that the final rule was issued which required Thimerosal to be removed from OTC products. And to this day it can still be found on the shelves in some pharmacies.

Even with heightened awareness within FDA that the use of thimerosal was questionable, the Center for Biologic Evaluation and Research at FDA appears to have been asleep at the switch. For two decades after thimerosal’s safety was called into question within the agency, CBER didn’t look to ban its use, rather they encouraged its increase use. On their own website the FDA states the one human study used to gain FDA approval for Thimerosal had limitations.

But worse than this initial series of failures is that which has occurred since the July 1999 announcement. The Coalition for SafeMinds asked the FDA to immediately conduct a recall and protect every child from the potential of mercury-injury. The FDA denied this request, as they denied yours Chairman Burton, citing their fear industry would sue because the FDA had no ‘proof of harm’. Two citizens petitions have also been submitted to the FDA asking for a recall and ban of thimerosal-containing vaccines - one by the National Vaccine Information Center<sup>2</sup> in January 2002 and another by the Coalition for Mercury Free Medicine (CoMeD)<sup>3</sup> in July 2004. Convinced that the FDA is abdicating its responsibility to protect our population from the neurotoxin mercury, still present in excess of EPA safety limits in vaccines and other drugs to which the unborn and newborn are routinely exposed without informed consent, CoMeD’s Citizen Petition 2004P-0349 seeks to make FDA enforce its own regulations that, unless a component of a drug has been proven safe, it must be removed. (See the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(e)(3), and 21 C.F.R 10.30) This petition, which asserts this unwarranted and uninformed exposure to a known neurotoxin is a violation of the Constitutional Right of Bodily Integrity, is accompanied by 1000 pages of epidemiological and clinical research

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<sup>1</sup> <http://www.fda.gov/cber/vaccine/thimerosal.htm#t1>

<sup>2</sup> <http://www.fda.gov/ohrms/dockets/CITPETS/02citpet.doc>

<sup>3</sup> <http://www.fda.gov/ohrms/dockets/dailys/04/aug04/080404/04p-0349-cp00001-01-vol1.pdf>

demonstrating a causal association between mercury exposure and autism. Neither of these petitions have been responded to or acted upon.

The truth is that even before the 1999 announcement, FDA had over the preceding decade received early warnings they chose to ignore. Between 1990 and 1998 the FDA received 47 adverse events reported through the Vaccine Adverse Events Reporting System (VAERS) regarding mercury or thimerosal. From 1998 to July 2000 another 15 reports were received. These 'red flags' were ignored.

Since 1990, FDA's CBER has funded 31 studies with its own scientists evaluating thimerosal, yet none of those studies appear to have been about toxicity, rather they have been studies to understand and enhance stability, analysis of total mercurial content, and other studies one conducts on materials whose use you want to promote. Resources they could have used to conduct the much needed pharmacokinetic studies, determining toxicity and maximum safe exposure levels, were not conducted (or have not been made available to the public if they have been done) rather staff time and limited FDA research resources have done the work of industry in looking to make thimerosal more widely used.<sup>4</sup>

The FDA has failed the American public by ignoring its own data and the published data of numerous respected academic institutions showing that thimerosal is highly allergic to a significant portion of the population and that it does indeed harm the brain. Just a simple Medline search reveals hundreds of peer reviewed articles which document the toxicity of Thimerosal, including sever morbidity and mortality from high level exposure. They have repeatedly failed the public by putting the profits and preferences of industry above the safety of children.

I and many of my medical colleagues remain astonished that we even have to ask the FDA to stop allowing mercury to be injected into babies. We have trusted that the FDA was doing its job and assuring the safety of all of the drugs and biologics it regulates and that trust has been proven undeserved in this instance. Mercury in all of its forms is a known toxin. The unborn, the newborn, and the very young are particularly susceptible to brain injury from exposure, yet the FDA approved the use of Thimerosal to be administered in Rho-D immune globulin products injected into pregnant (and nursing) women with Rh-negative blood. They also approved the use of Hepatitis B vaccine with mercury to be given to babies within hours of birth. They approved DTaP, Hep B, Hib, Hep A, and the flu vaccine for use in children with the mercury-based preservative thimerosal.

When faced with the facts that children in the first six months of life were receiving excessive levels of mercury through vaccines, the FDA has chosen to allow industry to determine its phase out period rather than to give them hard deadlines or refuse to allow its continued use at all.

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<sup>4</sup> Information gleaned from CRISP (Computer Retrieval of Information on Scientific Projects) is a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions and noted in Appendix D of "A Brief Analysis of Recent Efforts in Medical Mercury Induced Neurological and Autism Spectrum Disorders."

## Centers for Disease Control and Prevention

The CDC's failures are even more egregious. At every turn, when the CDC could have alerted the public and taken a strong stand against the use of thimerosal, they rather have promoted flawed epidemiology studies as proof that no evidence of harm existed. If the uninformed public takes the statements on the CDC's website at face value, they could conclude that rigorous evaluations have been conducted and that no risks are associated with the use of thimerosal vaccines. Nothing could be further from the truth.

In July 2000 when you had the CDC before your Committee they made no mention of their own research looking at the thimerosal link. SafeMinds obtained relevant documentation through a Freedom of Information Act request which showed that by December of 1999 the CDC knew thimerosal could be linked to the increased incidence of neurodevelopmental disorders.

Using taxpayer resources, and access to the Vaccine Safety Datalink datasets, CDC research fellow Dr. Thomas Verstraeten and his team looked the medical records of children in a number of HMOs to see if there was any truth to the thimerosal-autism hypothesis that had been proffered. Between February 2000 and November 2003 Dr. Verstraeten and his supervisors at the National Immunization Program produced four separate generations of an analysis designed to assess the impact of vaccine mercury exposures on neuro-developmental disorders in children. With each generation, elevated and statistically significant risks were reduced and/or eliminated.

But before these four generations of report were produced, Verstraeten conducted an earlier analysis of these issues in November and December of 1999. He never prepared a formal report on this work, but statistical tables obtained by Safe Minds in a FOIA request (and not previously analyzed) demonstrate large and statistically significant mercury exposure effects that in many cases exceeded the findings of the later reports.

These "Generation Zero" analyses followed a straightforward methodology that was relatively unaffected by biases applied later and was considerably more sensitive with respect to detecting mercury exposure effects than the later reports. Most notably, these initial analyses compared disease risk in the *highest exposure* population groups to disease risk in *zero exposure* population groups. In addition, the target study population had not yet been subject to numerous exclusions and adjustments applied later, the cumulative effect of which was to reduce the reported impact of mercury exposure on children's health outcomes.

The results of the Generation Zero analyses are striking and more supportive of a causal relationship between vaccine mercury exposure and childhood developmental disorders (especially autism) than any of the results reported later

- Relative risks of autism, ADD, sleep disorders and speech/language delay were consistently elevated relative to other disorders and frequently significant. Disease risk for the high exposure groups ranged from lows of 1.5X-2 times to as high as 11 times the disease risk of the zero exposure group.

- Many other outcomes showed no consistent effect, while a few appeared to show a protective effect from vaccine mercury exposure (most likely children with these diagnoses were immunized later).
- The strongest effect was for the highest levels of mercury exposure at the earliest time of exposure, consistent with the idea that infant brain development is most sensitive to the earliest exposures.
- The elevated risk of autism for the highest exposure levels at one month ranged from 7.6 to 11.4 times the zero exposure level. This increased risk level corresponds to the tenfold increase in autism rates seen since vaccine mercury exposures increase starting in 1990

The difference in these results in comparison to the later reports reveal a number of methodological choices that may have been powerful sources of bias in later publications, including the exclusion of children with less than two polio vaccines. These children would have been most reliably in the zero exposure group, whereas children with two polio vaccines and also with low reported mercury exposure would be more likely to have exposure reporting errors and the elimination of zero exposure categories in general as the referent category for risk assessment as well as the reduction in the measured exposure in the highest category.

Even with alteration in the inclusion criteria the strong dose dependant associations between thimerosal exposure and several adverse neurological outcomes remained as described in an email from Dr. Verstraeten to his colleagues December 17, 1999 titled “It just won’t go away” where Dr. Verstraeten informs the team of investigators that “these neurological outcomes are very much related (odds of having one when also having the other go from 20 to 100!) As you see some of the RR’s increase over the categories and I haven’t yet found an alternative explanation.”

Their results were so striking and disturbing that the CDC would next call a private meeting away from the CDC complex and away from the public eye to discuss. At the now infamous “Simpsonwood Meeting” Dr. Verstraeten presented his findings to a closed group of CDC and HHS officials and selected outside experts many of whom were academic scientists with very close ties to vaccine manufacturers. This Committee, SafeMinds, and other vaccine injury advocacy organizations were not invited or even informed about this event, however, representatives from all five major vaccine manufacturers were present. Here, the beginning of a great injury to the public’s trust in our nation’s immunization programs would be crafted.

The Simpsonwood meeting, ostensibly designed to be a careful review of a CDC analysis on the impact of thimerosal-containing vaccines on child development, instead became a vehicle for making numerous deliberate choices that took positive findings in a single direction, towards insignificance. Recommendations made by CDC consultants reveal an active interest in suppressing the signal in any way possible and widespread interest in concealing the information.

This meeting provides evidence of the ways in which data can be manipulated in complex epidemiological analyses. Any population based epidemiological analysis involves numerous subtle choices with respect to study design and reporting which allow supervisors of such population based studies wide discretion in the results they choose to report, depending on whether they are interested in reporting a positive or negative finding. In their words and actions

described below, CDC and NIP employees demonstrated clear biases against reporting positive results.

Dr. Rhodes made arguments to exclude the lowest exposure cases, claiming that the fact that their exposures were low suggested family behavior that made them unusual. The low rate of outcomes in this group of children, of course, added significance. Dr. Rhodes: Page 104: *“I am not advocating totally throwing them [the low mercury exposure group] away and never considering them in any analysis, but at least for now let’s think if we can establish if there are differences in this group of 37 to 75, then in a sense we really don’t need them.”*

He made arguments to exclude some cases that had unusually high exposures and outcomes at the same time. Any high exposure, high outcome group would support the signal. Dr. Rhodes: Page 105: *“The other thing that happens at NCK is that even a year or two years after the policy change has been made and all kids are supposedly receiving the combination, there is an odd, small group of kids that supposedly receives separate DTP and Hib (note: with more thimerosal) and an unusually high percentage of those kids are outcomes...For example, if 1,500 kids were receiving one vaccine combination in that month of birth and 20 were receiving some other, I have removed the 20 completely from the analyses.*

He made arguments to include non-comparable cases, all of which would serve to add “noise” that could obscure the signal. Dr Rhodes: Page 107: *“Now I take all those kids that Tom has excluded based on prematurity exclusion codes and throw them in. At one month I think there is some argument that is overdoing it. Throwing them all back in. I think there is a clear argument that is going too far, but that further brings things down. So you can push, I can pull. But there has been substantial movement from this very highly significant result down to a fairly marginal result.”*

An official from the WHO suggests that there could be no value in examining the question regardless of the findings.

Dr. Clements: Page 247: *“I am really concerned that we have taken off like a boat going down one arm of the mangrove swamp at high speed, when in fact there was not enough discussion really early on about which way the boat should go at all. And I really want to risk offending everyone in the room by saying that perhaps this study should not have been done at all, because the outcome of it could have, to some extent, been predicted, and we have all reached this point now where we are left hanging, even though I hear the majority of consultants say to the Board that they are not convinced there is a causality direct link between Thimerosal and various neurological outcomes. I know how we handle it from here is extremely problematic.”*

At the conclusion of the meeting a senior official of the National Immunization Program asks that the analysis remain secret. Dr. Bernier: Page 113: *“We have asked you to keep this information confidential. We do have a plan for discussing these data at the upcoming meeting of the Advisory Committee on Immunization Practices on June 21 and June 22. At that time CDC plans to make a public release of this information, so I think it would serve all of our interests best if we could continue to consider these data. The ACIP work group will be considering also. If we could consider these data in a certain protected environment. So we are*

*asking people who have a great job protecting this information up until now, to continue to do that until the time of the ACIP meeting. So to basically consider this embargoed information. That would help all of us to use the machinery that we have in place for considering these data and for arriving at policy recommendations.*

Rather than take swift and aggressive measures to eliminate all exposures to thimerosal in children, the CDC delayed the publication of the data for years while conducting additional evaluations of the data. These career HHS officials in the highest positions of authority in vaccine programs, charged with protecting the public from harm, crafted and implement a strategy that included: suppressing their own findings of harm; and would re-run the data and re-write the study until all statistically significant correlations between thimerosal and neurological injury were wiped away. Their final conclusions, the message they would proclaim to the public was that no harm was found with the use of thimerosal in babies.

Subsequent attempts for independent review of the VSD data have been met with numerous obstacles. One completed study by Geier and Geier,<sup>5</sup> corroborated Verstraeten et al's initial suspicion of an apparent epidemiological link between Thimerosal and neurodevelopmental disorders, including autism. Unfortunately, since, and some suspect due to, the Geier's efforts, HHS and CDC have placed near impenetrable restrictions on access and study types related to VSD data, and such studies are no longer available for replication. This pattern of behavior constitutes malfeasance and should not be permitted to stand. It is time to remove the parties involved from their role in vaccine safety assessment and to subject the VSD data base to open and independent review.

It is interesting to note that with increasing pressure for scientists and researchers to gain access to the Federally sponsored Vaccine Safety Database, CDC employee Dr. Bob Chen went to a meeting in Europe and created an organization which he named the "Brighton Collaboration"<sup>6</sup> whose mission is "to facilitate the development, evaluation, and dissemination of high quality information about the safety of human vaccines." Their aim is to 'To develop globally accepted and implemented standardized case definitions of Adverse Events Following Immunization.' While on the surface this may seem like a worthy cause, a number of legitimate concerns need to be fully addressed.

1. Are the CDC and its employees suborning their duties to a non-US non-governmental body? Will the Brighton Collaboration become the UN of Vaccine Policy?
2. The CDC (and WHO) began funding the Brighton Collaboration in 1999<sup>7</sup>, before it was even legally formed. What process for approval did Dr. Chen go through to

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<sup>5</sup> *Nuerodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication*, Geier and Geier, Experimental Biology and Medicine, 2003

<sup>6</sup> "The Brighton Collaboration was founded by Robert Chen, Harald Heijbel, Tom Jefferson, Ulrich Heininger, and Elisabeth Loupi in 1999 at a meeting in Brighton, England. It was officially launched in autumn 2000. The Collaboration consists of volunteers from patient care, public health, scientific, pharmaceutical, regulatory and professional organizations coming from developed and developing countries." [www.brightoncollaboration.org](http://www.brightoncollaboration.org)

<sup>7</sup> "It obtained its first funding in 1999. The Brighton Collaboration is presently supported by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO). From 2000 until 2003, the Collaboration also received funding through the European Research Program for Improved Vaccine Safety Surveillance (EUSAFEVAC). In December 2003, the Brighton Collaboration Foundation was established by the University Children's Hospital Basel, Switzerland. The purpose of the Foundation is to protect and preserve public health by



- obtain this funding? How is Dr. Chen, a recognized leader in CDC's vaccine safety responsibilities allowed to form and lead a non-profit with direct correlations to his government duties? How did a CDC employee gain funding from the CDC for his outside activity? The Brighton website cites a salary structure for its leadership which begs the question, "Do Dr. Chen or other HHS employees receive double salaries?"
3. How much funding has the CDC (and WHO) provided each year since 1999? And who approved this funding?
  4. Brighton Collaboration now has offices at the CDC complex in Atlanta. Its employees appear to also be employees of the CDC? How is this possible?
  5. The CDC Foundation, another non-government, not for profit, is also housed at the CDC complex and is raising money to funnel to Brighton. What process did these entities traverse to be afforded these privileges at CDC?
  6. Since the Brighton Collaboration is a private vs. government entity, was one of the purposes of this organization to keep valuable vaccine safety data outside of public scrutiny?

SafeMinds submitted these and other questions to the Director of the CDC earlier this year. Dr. Gerberding provided a response that indicates that she has not been fully and accurately informed on this matter. We are following up with a letter to point out the discrepancies in her responses. In the years since you first pointed out conflicts of interest, and in this year when the public first learned of the hundreds HHS employees that have financial ties to industry, getting this information out in the public is critical. I am providing you a copy of all of these letters and ask your assistance in getting the truth before the public.

Brighton is very troubling to those like Lujene Clark of Nomercury.org who has actively researched the Brighton Collaboration and to parents who have cases before the Vaccine Injury Compensation Program for a number of reasons:

1. Rumors abound that Brighton 'volunteers' are being afforded access to the Vaccine Safety Datalink and other internal data when outside researchers are blocked.
2. Brighton while being promoted as 'independent' is actually a marriage of CDC/FDA employees and pharmaceutical representatives who are coming together to define what constitutes a vaccine adverse event and thus promote those definitions worldwide. One statement on their website states their intention to restrict doctors from reporting adverse events to vaccines that occur more than 48 hours after the delivery of a vaccine.
3. Because information developed and promoted by this entity will be supported by CDC and other government entities, the special masters within the Vaccine Injury Compensation Program will likely accept their findings without question and thus, as was the case with redefining what constitutes encephalopathy, families with vaccine injured children will not receive compensation in this program.

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promoting immunization safety. The Foundation promotes the development and availability, of globally accepted, high quality scientific standards for research on and communication of immunization safety. The Foundation may also conduct immunization safety research itself or support such research projects." [www.brightoncollaboration.org](http://www.brightoncollaboration.org)

4. From a different but equally important view, the international community is being drawn in to this and may feel compelled to ‘volunteer’ their time and resources in order to stay in good graces with the CDC and WHO.

Given these actions, which the community is just this year learning about, combined with their handling of the Vaccine Safety Link data, we see not only failure, but intentional actions to hide the truth.

On a good note, on August 30<sup>th</sup>, 2004 CDC approved a research-funding request from SafeMinds to investigate mechanisms of thimerosal toxicity. This funding will go to further research efforts of Dr. Hornig at Columbia University and Dr. James at the University of Arkansas. We applaud this award and appreciate the opportunity to further this important research. We also hope this is a potential harbinger of a redirection of CDC tone and focus in this discussion. While every research dollar is appreciated, it is still a vastly under-funded area.

### Institute of Medicine

In 2001, the CDC and its Office of the National Immunization Program (NIP), contracted with the Institute of Medicine to create an Immunization Safety Review Committee in order the scientific evidence regarding a number of vaccine injury hypothesis including the correlation between reception of Thimerosal containing vaccines and the onset of neurodevelopmental disorders including autism.

The IOM’s first report on Thimerosal was issued in October of 2001 and addressed the question if exposure to thimerosal containing vaccines could be associated with adverse neurodevelopmental disorders. The committee concluded that the evidence was inadequate to either accept or reject this hypothesis but went on to find the hypothesis “biologically plausible” and called for a clear and scientifically sound path for the requisite research necessary to finding the answers. That path included epidemiology, but also called for animal model, clinical, case study and other relevant research in keeping with the tenets of good science. The committee went even further to recommend that infants, children and pregnant women should not be exposed to thimerosal containing vaccines. This recommendation was not embraced by our Federal agencies.

Although the committee had issued a previous report on thimerosal in 2001, at the request of CDC, the committee was again called to review the issue in advance of causation hearings scheduled for later in the year. Unfortunately, at the time of the hearing, there was little additional science available for review, outside of population based epidemiological studies. In stating the charge to the committee, CDC choose to focus the investigation on only autism instead of a broad range of adverse neurological outcomes and place an emphasis on epidemiological investigations. Rather than reprimand the agency for its failures to adequately address the research recommendations in the 2001 report, the IOM would (1) accept a narrowing of their inquiry to autism alone and (2) would base its final conclusions on epidemiological research proven to be flawed.

On May 18<sup>th</sup> the Institute of Medicine's Immunization Safety Review Committee issued their final report which found that the biological mechanisms presented to the committee, including thimerosal's ability to induce DNA damage apoptosis in neurons, disrupt methionine synthase pathways, a model of autism induced with vaccine level exposure to thimerosal in an autoimmune mouse, elevated levels of mercury in children with autism after challenge with a chelating agent in comparison to controls, along with data that children with autism are not able to effectively excrete mercury theoretical at best. They concluded that the body of epidemiological evidence favors a rejection of a causal relationship between vaccine thimerosal exposure and autism.

A causal relationship between autism and vaccinations cannot be proved or rejected based solely on evidence from population-based epidemiologic studies. Epidemiological studies, by definition, are not designed to prove causality; they can only provide only statistical associations. Therefore, the committee's conclusion that the "body of epidemiologic evidence favors rejection of a causal relationship..." has no scientific meaning.

The committee admits in their report that population-based studies would not be able to detect subpopulations that could be genetically more vulnerable to mercury at lower doses than normal. The majority of children without the genetic susceptibility would simply "dilute out" the minority of susceptible children. "The committee recognizes that this line of reasoning as a theoretical explanation for the data presented in this report ..." (i.e., their conclusion of no association). The whole concept of identifying a *direct causal relationship* between vaccinations and autism may be impossible by definition – so the conclusion of "no association" would be inevitable and unavoidable. The mercury exposure is at best a "trigger" not the gun.

The conclusion that the available biological hypotheses for a causal relationship between autism and mercury "lack supporting evidence and are theoretical only" offers no justification for discouraging further research along these lines of investigation. All scientific hypotheses are "theoretical" by definition. By their own admission in the report, an untested and plausible biologic explanation for a causal association is the genetic susceptibility theory – the one theory that could explain their inability to detect an association in their population-based approach. Why was this not emphasized as a worthy hypothesis to explore?

The CDC's National Immunization program (NIP) has once again turned to the IOM for assistance. Just last month the first meeting of a panel was conducted to look at if and how to make the VSD information available to outside investigators and whether or not the CDC should make 'preliminary' data available. Dr. Bob Chen, who takes credit for creating the VSD program, was noticeably absent from this public meeting. How can the IOM be expected to do its job, if the CDC does not bring before the Committee to answer questions, those directly responsibility for these activities?

I would like to bring to your attention that one CDC employee in presenting information to this panel made grossly inaccurate statements in an attempt to excuse the lack of a well designed and executed program for outside research access. Dr. Roger Bernier, who has been before this committee, indicated that the CDC 'rushed' to put together the VSD sharing program (under Congressional pressure) when in fact the agency had a decade to develop a program, and after

your intervention still took two years to design what has turned out to be a cumbersome sharing program. His statements were so blatantly false that another CDC staff person intervened to clarify and a former member of your staff further corrected the record during public comment.

SafeMinds joined a number of other organizations in calling upon the IOM panel to push for transparency and open access. We remain cautious and hopeful.

### Funding Deficits at the National Institutes of Health

Access to data is important, but access means nothing if you do not have the resources to conduct research. The very reason taxpayers support significant resources (\$27 billion) be provided to the National Institutes of Health (NIH) is to conduct research, free of industry or other outside influence, to get timely answers to important health related questions.

Since the mid-1980s we have seen epidemic increases in the rates of autism, yet the NIH and other health agencies have been slow to respond. Autism research in 1997 was only \$22 million.

In 1997 the NIH was investing only \$22 million on autism research. This covered therapeutic interventions, genetic research, and everything in between. That research investment has increased five-fold but remains woefully inadequate:

#### NIH Funding of Autism Research

<b>Fiscal Year:</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005(estimated)</b>
<b>Funding (in millions):</b>	<b>40</b>	<b>52</b>	<b>56</b>	<b>65</b>	<b>93</b>	<b>96</b>	<b>99</b>

The NIH's efforts to conduct and fund studies evaluating Thimerosal have been at times misdirected and continue to be inadequate given the severity of the potential risk associated with the discovery in 1999 that 8,000 children a day were being exposed to potentially dangerous levels of mercury. This premier \$27 Billion biomedical institution comprised of 26 Institutes and Centers has to date failed to provide evidence to confirm that they have made this matter a priority or that they remain open-minded about the potential that thimerosal in vaccines may be linked to a novel form of autism – mercury-induced autism spectrum disorders. As the bastion for high quality research, the one study the NIH's National Institute of Allergy and Infectious Diseases (NIAID) notes on in their May 2004 FAQ Public Page on NIAID-funded studies on the subject is the Rochester Study<sup>8</sup> as proof that thimerosal in vaccines is not linked to autism. In this investigation Pichichero measured blood levels of mercury in infants after exposure to thimerosal-containing vaccines.

There were a number of limitations in this investigation including a small sample size. Although the overall sample size was stated as 61 infants, there were only 33 exposed children who were used for the blood mercury assessment upon which the safety conclusions were made. One major shortcoming of a small sample size is the low chance of including infants who are

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<sup>8</sup> Pichichero ME, Cernichiari E, Lopreiato J, and Treanor J. Mercury concentrations and metabolism in infants receiving vaccines containing thimerosal: a descriptive study. Lancet 360:1737-1741 (2002).

especially sensitive to mercury's effects, or who may have detoxification difficulties. We know from the mercury literature that there is wide variability in the population in regard to mercury sensitivity and clearance. Since vaccines are given to virtually all infants, even if 1% retained mercury to a much greater degree than the "norm", this would represent a large number of injured children. The small sample size means that the study lacks sufficient power to establish safety claims. The sample was not randomly drawn, but was a convenience sample, and therefore not representative of all infants in terms of health status, socio-economic status, ethnicity, and other potentially important factors. The dose of mercury that the infants received was also much lower than what infants received during the 1990's. Blood levels for mercury were obtained days and often times weeks after the vaccine exposure. Given that the half life of ethylmercury appears to be 6-7 days, virtually all, if not all, blood draws missed the peak blood concentrations of mercury. It is impossible to state what the peak values are if they were not measured. It is also impossible to calculate average blood concentrations unless peak concentrations are measured.

In spite of these limitations Pichichero makes the sweeping statement that "This study gives comforting reassurance about the safety of ethyl mercury as a preservative in childhood vaccines." The design and results of the study do not support these statements. In fact, the results suggest that thimerosal exposure from vaccines may have caused neurological damage in some children. Safe Minds questions the objectivity of the study authors, due to their ties to vaccine manufacturers, which may have resulted in a biased study design and biased interpretation of the results. Pichichero has an acknowledged financial tie to Eli Lilly, the developer of thimerosal and the main target of thimerosal litigation. He has also claimed financial ties to a number of vaccine manufacturers, including manufacturers of thimerosal-containing.

In the Pichichero study, there is one infant blood level out of the 17 2-month old blood samples (12%) which was 20.55 nMol/L, or 4.1 ppb. This infant had its blood drawn five days after the exposure and had received just 37.5 mcg/Hg. According to a letter Lancet the following month written by Dr. Neal Halsey of the Vaccine Safety Institute at Johns Hopkins, a dose of 62.5 mcg could well have resulted in a peak blood mercury level of 48.3nmol/l. Applying newly reported brain to blood partition ratio from Brubacher of 4.5 ng/ml (+/- 1.5) for thimerosal, predicted brain levels of mercury would be 217.35 ng/g.

Given that Baskin *et al.* (2003) have documented DNA damage, caspase-3 activation, nuclear membrane damage and cell death in cultured adult human neurons and fibroblasts exposed to 201 mcg/l ethyl mercury (the lowest concentration tested) after 6 hours or less of incubation, routine vaccination practices during the 1990's levels may have resulted in neurodevelopmental injury to some infants. That the NIAID would fund a small and poorly controlled study and then promote the findings, despite the numerous letters to the editor of Lancet questions the authors conclusions, as if it were meeting the gold standards of scientific rigor is highly suspect.

While the entire research portfolio on autism spectrum disorders remains inadequate, the investment on thimerosal research remains miniscule. You have heard previously from scientists who for decades were funded by NIH and then once they asked for funding on vaccine adverse events, they were suddenly turned down. In the issue of thimerosal, what could have been accomplished in months has still not been accomplished five years later.

In previous hearings, HHS staff testified to you that they have nominated thimerosal to the National Toxicology Program<sup>9</sup> managed by the NIH's National Institute of Environmental Health Sciences. In their 2001 literature review and submission they conclude:

*Limited data were found on the comparative toxicology of ethylmercury vs. methylmercury. One animal study directly compared the toxicity of these compounds in rats administered 5 daily doses (8.0 or 9.6 mg/kg) of equimolar concentrations of ethyl- or methylmercury by gavage. Tissue distribution, and the extent and severity of histological changes in the brain and kidney were assessed. Neurotoxicity of ethyl and methylmercury was similar, with higher levels of inorganic mercury observed in the brains of ethylmercury treated rats. Renal damage was greater in rats receiving ethylmercury. Although the data are limited, similar toxicological profiles between ethylmercury and methylmercury raise the possibility that neurotoxicity may also occur at low doses of thimerosal.*

*Thimerosal is nominated to the NTP for further study to assess gaps in knowledge regarding toxicokinetics and the potential for neurodevelopmental toxicity. These gaps include comparative toxicity of ethyl- and methylmercury, the metabolism and elimination of ethylmercury compared with methylmercury, the effect of intermittent intramuscular doses of thimerosal from vaccines compared with chronic low dose oral exposure to methylmercury, and the susceptibility of the infant compared with the fetus to adverse effects from organicmercurials. In order to provide a more complete assessment of the toxicity of thimerosal during the critical period of neurodevelopment, well-designed studies are needed to address these gaps in knowledge in appropriate animal model(s).<sup>10</sup>*

Yet for Thimerosal, the NTP as of September 1, 2004 posts on their website the following information:

- ⇒ No bioassay studies are available evaluating standard toxicology and carcinogenesis
- ⇒ No reproductive studies are available
- ⇒ No developmental studies available
- ⇒ No immunology studies are available
- ⇒ In 1983, one *in vitro* salmonella study was conducted evaluating genetic toxicity for hamsters and rats (which was negative)

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<sup>9</sup> The National Toxicology Program (NTP) was established in 1978 by the Department of Health and Human Services (DHHS) to coordinate toxicological testing programs within the Department, strengthen the science base in toxicology; develop and validate improved testing methods; and provide information about potentially toxic chemicals to health regulatory and research agencies, the scientific and medical communities, and the public. The Program is administered by the NTP Director, who is also the Director of the NIEHS.

<sup>10</sup> Thimerosal Nomination to the National Toxicology Program [http://ntp-server.niehs.nih.gov/htdocs/Chem\\_Background/ExSumPDF/Thimerosal.pdf](http://ntp-server.niehs.nih.gov/htdocs/Chem_Background/ExSumPDF/Thimerosal.pdf)

A further search of the NTP site finds that of the more than 8,000 chemicals in the market-place, zero have been approved for general toxicology study by the program. After more than 3 years of waiting, thimerosal has yet to hit the radar of the NTP. There are currently 31 chemicals with a project leader assigned and a study in design – thimerosal is not among them.

### Existing Studies Support a Link Between Thimerosal Exposure and the Onset of Autism.

So is there scientific evidence to support parent's claim that after receiving thimerosal laden vaccines their children became ill? Is there evidence to validate that the presence of mercury in the bodies of young children, who also happen to be autistic, is of concern?

To those who remain open-minded, there is ample evidence to support these concerns. When HHS failed to fund the studies the IOM asked for, non-profit organizations, such as SafeMinds have funded or supplemented research at some of our country's most respected academic institutions. While then NIH spends less than \$59 per autistic child on research, families who are paying tens of thousands of dollars out of pocket for the therapeutic care of their thimerosal-injured children have been forced to devote energy and resources to raise money research from art auctions, dinners, and t-shirt sales because for five years NIH and HHS have chosen not to make this a priority.

While HHS continues to state there is no evidence to support a link between thimerosal and exposure to the onset of autism and that science does not yet know if ethylmercury is as toxic as methylmercury, the evidence has indeed been mounting.

A discourse between Congressman Dave Weldon, MD and Dr. David Baskin during the December 10, 2002 hearing of the Committee on Government Reform provides a fair analysis of this quandary:

***Dr. Weldon.** I have a couple of questions for Dr. Baskin about ethyl mercury versus methyl mercury. I have had some people say that data on methyl mercury is fairly good, but we don't have good data on ethyl mercury. I take it from your testimony there is actually quite a bit of data on ethyl mercury and that it's as toxic as methyl mercury.*

***Dr. Baskin.** There is more data, more and more data on ethyl mercury. The cells that I showed you dying in cell culture are dying from ethyl mercury. Those are human frontal brain cells. You know, there has been a debate about, well, ethyl versus methyl. But from a chemical point of view, most chemical compounds that are ethyl penetrate into cells better than methyl. Cells have a membrane on them, and the membrane is made of lipids, fats. And ethyl as a chemical compound pierces fat and penetrates fat much better than methyl. And so, you know, when I've began to work with some of the Ph.D.s in my laboratory and discuss this, everyone said, oh, gosh, you know, we've got to adjust for ethyl because it's going to be worse; the levels are going to be much higher in the cells. So, I mean, I think at best they're equal, but it's probably highly*

likely that they are worse. And some of the results that we are seeing in cell culture would support that...<sup>11</sup>

Research by Clarkson, Magos and Meyers<sup>12</sup> and Gossel and Bricker's<sup>13</sup> determined, that ethyl mercury (thimerosal) has the capacity to attack and injure various neurodevelopment centers.

Boyd Haley, PhD, professor and chair at the University of Kentucky, Department of Chemistry provided clear and specific conclusions from his research and the evidence he has reviewed:

- Thimerosal is the major toxic component of most vaccines
- Thimerosal is a more potent inhibitor of many metabolic enzymes than is mercuric chloride
- Due to synergistic toxicity, thimerosal exposure through vaccines with aluminum should be considered quite capable of causing severe neurological and systemic damage.
- There appears to be a subset of the population that cannot effectively excrete mercury and are at a greater risk to exposures to mercury than are the general population. Genetic susceptibility is critical.
- Presence of other heavy metals, antibiotics, etc. may enhance the toxicity of thimerosal. Synergistic toxicities must be considered.
- Estrogen decreases thimerosal toxicity whereas testosterone increases the toxicity. Gender effects are involved.

In 2003, Holmes et al<sup>14</sup> published a paper showing that that lower overall rate of (excreted) mercury in the infants' hair for children diagnosed with autism. This finding strongly supported the hypothesis connecting autistic children's inability for excreting mercury, and as a precursor to mercury induced neurotoxicity and subsequent development disorders. Non-autistic children were found to have substantially higher mercury levels in their first cuts, purporting that their excretion capacity for mercury is less hindered, at least in comparison to the capacity of autistic children.

Dr. H. Vasken Aposhian, provided a similar perspective to the IOM in February: He put forward the possibility that there is an efflux impairment to which thimerosal is introduced into an unfavourable environment. Thimerosal would then be a final insult or "trigger" leading to autism.<sup>15</sup> The second postulate Aposhian put forward relies on the efflux impairment, but provides that the thimerosal introduction simply provides an increased mercury burden in the child. This postulate provides that the thimerosal exacerbates pre and post expected environmental exposure, putting the mercury burden over the threshold to neurotoxicity. Only

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<sup>11</sup> Vaccines and the Autism Epidemic: Reviewing the Federal Governments Track Record and Charting a Course for the Future, Serial No. 107-153

<sup>12</sup> Thomas W. Clarkson, Ph.D., Laszlo Magos, M.D., and Gary J. Myers, M.D., *The Toxicology of Mercury — Current Exposures and Clinical Manifestations*, N Engl J Med 2003;349:1731-7.

<sup>13</sup> Gossel TA, Bricker JD. Principles of clinical toxicology. 2nd ed. New York: Raven Press, 1990.

<sup>14</sup> Reduced Levels of Mercury in First Baby Haircuts of Autistic Children, International Journal of Toxicology, 22:277–285, 2003

<sup>15</sup> Immunization Safety Review: Meeting 9: Aposhian Presentation, <http://www.iom.edu/includes/dbfile.asp?id=18390> - Slide 16



through research can these questions be answered. Supportive to Aposhian's presentation were findings that "thimerosal pharmacokinetics obtained using non-autistic children are not the same as those expected for autistic children."<sup>16</sup> This furthered not only the issue of an efflux disorder, but to the variance in kinetics involved.

Bradstreet presented data to the IOM showing that single nucleotide polymorphism found in children with autism spectrum disorders provides the mapping from exposure to injury. Specifically, SNP's inhibited by thimerosal involving methylation and sulfation disallow a "normal process" for mercurial excretion. This event creates and maintains the elevated mercury body burden, which provides for the neurotoxic atmosphere, thus providing the architecture for neurodevelopmental injury resulting in injuries such as autism spectrum disorders.

What Bradstreet and James have accomplished is the initial recognition and mapping to the trigger mechanism(s) involved between the thimerosal (mercury) exposure and the end stage resultant disease. In reviewing the history of research regarding this issue, like so many other medical finds, it has been a process of reverse engineering. First was the recognition of the epidemic; next the suggested likeness between mercury poisoning and autism spectrum disorders; then the potential ties discovered through efforts in epidemiology; and now the causal trigger mechanism/event.

Deth et al,<sup>17</sup> found that "Neurodevelopment toxins, such as ethanol and heavy metals [thimerosal], interrupt growth factor signaling, raising the possibility that they might exert adverse effects on methylation..."Our findings outline a novel growth factor signaling pathway that regulates MS activity and thereby modulates methylation reactions, including DNA methylation. The potent inhibition of this pathway by ethanol, lead, mercury, aluminum and thimerosal suggests that it may be an important target of neurodevelopmental toxins."

What Deth et al are continuing is a the building of the path to understanding of the role thimerosal plays in interruption of various developmental processes which lead to neurological development disorders, including autism.

Furthermore, Burbacher et al's<sup>18</sup> research effort investigating mercury blood levels in primates exposed to vaccine levels of methyl mercury and ethyl mercury provides that there are clear differences between ethyl and methyl mercury in blood and tissue levels over time. Unlike Dr. Sager's presentation of Burbachers primate research data at both CDC's Advisory Committee for Immunization Practice (ACIP) meeting on June 19th, 2003 and at the Institute of Medicine meeting held February 9th, 2004, I was surprised to find that earlier data presentations were incorrect and that the take home message that there was little accumulation of mercury in the brain of the primates dosed with thimerosal may not be a correct assumption. According to Dr.

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<sup>16</sup> Immunization Safety Review: Meeting 9: Aposhian Presentation, <http://www.iom.edu/includes/dbfile.asp?id=18390> - Slide 18

<sup>17</sup> M Waly, H Olteanu, R Banerjee, S-W Choi, J B Mason, B S Parker, S Sukumar, S Shim, A Sharma, J M Benzecry, V-A Power-Charnitsky and R C Deth "Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal", *Molecular Psychiatry*, April 2004, Volume 9, Number 4, Pages 358-370

<sup>18</sup> Burbacher, Shen, Clarkson, "Comparative Toxicokinetics of Methyl mercury and Thimerosal in Infant *Macaca fascicularis*" presentation to Institute of Medicine, Immunization Safety Review Committee, 9 February 2004

Burbacher's presentation at a recent EPA sponsored symposium on mercury, the half life of mercury in the brains of primates dosed with thimerosal is 28 days, not 18 days as presented previously by Dr. Sager. And even more concerning is additional data which found that ethyl mercury more rapidly converted to toxic form of mercury in the brains of the primates which resulted in increasing levels of inorganic mercury. Once mercury converts to its inorganic form in the brain it is very difficult for it to be removed. Per Dr. Burbacher, this new data directly contradicts recent assertions made by Magos regarding the lower neurotoxic character of thimerosal relative to methylmercury.

This project, funded by NIAID, has forwarded nearly as many questions as it has answered. Specifically, while the mercury/blood level modeling has been mapped, the true levels, and increased propensity, for ethyl mercury to cross, and potentially to remain past, the blood-brain barrier has not been adequately characterized. A request by the researchers to fund further study this issue, given the findings promoting caution to the use of ethyl mercury (thimerosal), has to date gone unfulfilled, and may need to be accomplished privately to provide further answers.

The next recently released study is from the Mailman School of Public Health at Columbia University. In this study,<sup>19</sup> Hornig et al looked at the effects of vaccine level thimerosal exposure on mice with a specific genetic susceptibility. This research postulate was created following the increasing body of scientific evidence promoting that the Thimerosal-NDD link is predicated upon certain genetic predispositions/genomic defects, which refer to autoimmune disease sensitivity.

Hornig et al found that the selected mice universally showed an implication of "genetic influences" that led to responses and activities that mimic those found in Autism Spectrum Disorders (including growth retardation, hypoactivity, social withdrawal, gross motor coordination, repetitive motions/movements, confusion or dissociation with familiar surrounds, and other dysfunctional behaviours. Hornig et al's research also found physiological effects relevant to the brain and cranium in the creation of abnormalities resultant from vaccine level thimerosal exposure.

What all of the arena's researchers, regardless of position, are in agreement is the need for additional research to follow these matters through, for better understanding, potential treatments, and establishing policies and practices which will reverse the current epidemic trend.

## **What is being done to address these concerns?**

### Office of Special Counsel

The Office of Special Counsel (OSC) is an independent investigative and prosecutorial agency and operates as a secure channel for disclosures of whistleblower complaints and abuse of authority. Its primary mission is to safeguard the merit system in federal employment by

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<sup>19</sup> Hornig, Chian, Lipkin, *Molecular Psychiatry* (2004), 1-13, *Neurotoxic effects of postnatal thimerosal are mouse strain dependent*

protecting federal employees and applicants from prohibited personnel practices, especially retaliation for whistleblowing. OSC also has jurisdiction over the Hatch Act and the Uniformed Services Employment and Reemployment Rights Act.

Earlier this year, individuals within the thimerosal-induced autism community contacted the OSC out of concern that individuals within HHS knew that harm was possible and that they have acted to cover up the truth in order to protect their careers and their friends in industry. After an extensive review of the data, in May 2004, the Office of Special Counsel wrote to Senator Judd Gregg and Congressman Joe Barton asking them in their capacity as Chairman of the relevant legislative committees to investigate. Special Counsel Scott Bloch states in his letter, " ...based on the publicly available information...it appears there may be sufficient evidence to find a substantial likelihood of a substantial and specific danger to public health caused by the use of thimerosal/mercury in vaccines because of its inherent toxicity. Due to the gravity of the allegations, I am forwarding a copy of the information disclosed to you in your capacity as Chairmen of the Senate Committee and House Committee with oversight authority for HHS. I hope that you will review these important issues and press HHS for a response to this very serious public health danger...I believe these allegations raise serious continuing concerns about the administration of the nation's vaccine program and the government's possibly inadequate response to the growing body of scientific research on the public health danger of mercury in vaccines. The allegations also present troubling information regarding children's cumulative exposure to mercury and the connection of that exposure to the increase in neurological disorders such as autism and autism-related conditions among children in the U.S."<sup>20,21</sup>

The OSC took what I believe is an unusual step, they issued a press release publishing this letter, which stated that without a whistleblower they could not move forward. It is our understanding that whistleblowers have come forward and the OSC investigation is going forward. The OSC has the capacity to hold the individuals within HHS who have failed the American public responsible for their actions.

## HR 4169

For more than two years now, the CDC and others within HHS have reported to Congress and the media that thimerosal is out of all the vaccines being given to children anyway. However, this past year the CDC chose not to state a preference for the use of thimerosal-free vaccines in children, rather promoting the reintroduction of thimerosal into the pediatric vaccine schedule by recommending that all children over the age of six months receive flu vaccine of which some brands continue to contain thimerosal.

Responding to HHS's failure to get the mercury out, Chairman Burton joined the bipartisan effort of Congressman Dave Weldon and Congresswoman Carolyn Maloney in introducing HR 4169, "The Mercury Free Vaccine Act of 2004". To date, there are 31 cosponsors. SafeMinds supports the passage of the bi-partisan Bill as well as the bills passed in Iowa, \_\_\_\_\_, and

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<sup>20</sup> [www.osc.gov/documents/press/2004/pr04\\_07.htm](http://www.osc.gov/documents/press/2004/pr04_07.htm)

<sup>21</sup> <http://www.cbsnews.com/htdocs/pdf/oscpdf.pdf>

California. We hope that Governor Schwarzenager will sign \_\_\_\_\_ immediately. We also hope that the Congress, in its waning days of the 108<sup>th</sup> Congress will pass HR4169.

## **Conclusions**

Chairman, when you first began your oversight investigation into vaccine safety concerns you were accused of being ‘anti-vaccine’ – in fact, this is the first attack on the credibility of anyone who dares to ask questions regarding vaccine safety. It is important to state that neither SafeMinds, as an organization, or myself, as a parent and health care professional, is opposed to vaccination. Nor are the independent researchers involved in this research. The investigation you initiated in 1999 has raised awareness about the need for good communication between parents, health care providers and our Federal agencies.

Vaccine safety is an important public health issue. Concerns voiced by parents, physicians and the scientific community regarding vaccine safety issues must be addressed with thoughtful, complete and unbiased investigations. Because vaccines are so widely used and because state laws require that children be vaccinated to enter daycare or school, vaccine safety issues, even if theoretical in nature, deserve to be investigated to the fullest extent possible.

Your investigations have highlighted the paucity of science in the field of vaccine adverse events and have created interest among academicians who likely would not have risked their careers asking these tough questions.

Although the removal of Thimerosal in medical products, including vaccines, has taken over 5 years to accomplish, we may be starting to see some the effects of this policy decision.

Thank you for the opportunity to present this information to the Subcommittee today. I would be happy to answer any questions.