

Editorial

Interview with David Kirby concerning “Evidence of Harm” associated with Thimerosal-containing vaccines

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Abstract

David Kirby, author of the book *Evidence of Harm*, presents a summary of his investigation concerning increasing use of Thimerosal in vaccines and the potential association with increasing rates of neurological developmental disorders (NDDs), including autism, in the United States. He details how exposure levels to mercury exceeded the Environmental Protection Agencies (EPA) guidelines. He quotes Lyn Redwood who uses an illustration that clarifies that bolus exposures to mercury are significant: “You can take two Tylenol® a day for 60 days and you will be fine. But if you took 120 Tylenol® in one day, that’s a lethal dose and you’ll probably die.” David Kirby has chronicled the different “generations” of analyses that Thomas Verstraeten and the CDC produced. Despite the fact that the risk factor for autism and neurological disorders decreased with each successive manipulation of the data and generation of results, Verstraeten, on a number of occasions, relates that the statistical significance of higher risk of neurodevelopmental disorders as a function of higher doses of mercury “just won’t go away.” Also discussed is the collusion between the drug companies and federal health bureaucracy.

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Good morning and thank you for joining us for this special edition interview with David Kirby, author of the book, Evidence of Harm, which will be released April 1st. I'm your host, Teri Small.

David Kirby has been a professional journalist for over 15 years, writing extensively for The New York Times for the past seven years. He has also written for a number of national magazines. David was a foreign correspondent in Mexico and Central America from 1986-1990, where he covered the wars in El Salvador and Nicaragua, and covered politics, corruption and natural disasters in Mexico. From Latin America, he reported for UPI, the San Francisco Examiner, Newsday, The Arizona Republic, Houston Chronicle and the NBC Radio Network.

David Kirby has also worked in politics, medical research and public relations, such as for New York City Council President Carol Bellamy as a special assistant for healthcare, cultural affairs and civil rights, followed by employment as chief scheduler to Manhattan Borough President David N. Dinkins. David Kirby is a former Director of Public Information at the American Foundation for AIDS Research, where he witnessed first-hand the inner workings of Congress, the White House and powerful Federal agencies like the FDA, CDC and NIH.

Thank you, David, for joining us on Autism One Radio for this special edition. It's a pleasure to welcome you.

Thanks Teri, it's great to be here. I am really happy to join you today.

David, how did you come to be involved in this?

That's a question that I always get asked first. I was doing some research for freelance magazine articles and someone had told me about some mothers in Los Angeles who were researching alternative treatments for their children with autism. I was writing for women's magazines and thought it sounded interesting. So, I talked to some of the women out in L.A. One of them rather casually mentioned that she thought, or some people thought, that the cause of autism might be the mercury in vaccines, and I had never heard of such a thing. I thought maybe she was a little, not crazy, but mistaken, and I put it in back of my mind. Still, I thought it was interesting, and then a week later, the Homeland Security Bill passed and I found out there was a secret rider in there to dismiss lawsuits against Eli Lilly. And that's when the journalist in me said, “I think there is more to this story.”

I think you have already alluded to this, but what was your opinion, if any, on this issue before embarking upon writing the book?

I had never met a person with autism in my life and I had never heard of Thimerosal. And I had certainly never heard of any connection between any form of mercury and autism, although I did know mercury was not good for you. But I don't think I realized the extent to which it could do damage in your body. So, I was 100% unfamiliar with this story right up until November of 2002.

So, I guess you don't have any affected relatives either?

No relatives. Growing up in school, I have tried...I have searched my brain going back class by class, trying to think, “Could *that* kid have been autistic?” But, I have seen autistic kids and no, I don’t believe I had ever met anybody—certainly no one who was diagnosed.

That’s a really good point David. It’s sure not the same in schools now as it was when you and I were going to school is it?

No it’s not. And people who insist or say that there is no epidemic—that it is just better reporting and better diagnostics—I really would like to pose the question to them that Mark Blaxill, from Safe Minds, asks: Where *are* all those people? Where are the 1 in 166 autistic adults? We can’t find them. So, they have either been institutionalized, or they passed away, or they somehow had a miraculous recovery because they don’t seem to be around. And Mark calls that the “hidden horde” and I think it’s a really good point.

Yes. David, when does Evidence of Harm begin? When did parents begin to investigate the possible connection between Thimerosal and autism?

Well the big moment, and there is an actual date, would be July 9th of 1999 when the Public Health Service and the American Academy of Pediatrics issued a joint statement announcing that they had added up mercury burden in children’s vaccines and found out they were over the EPA limit. Up until that time, parents were certainly researching alleged connections between vaccines themselves—particularly MMR, but also DTP—but not necessarily mercury. With one notable exception, a man named Albert Enayati out of New Jersey. He was the head of Cure Autism Now in New Jersey. And he started researching this on his own—even before the joint statement was issued. But he was not entirely convinced, and couldn’t get a lot of information on it at the time. But then when the joint statement was issued, he put it all together.

I think that one statement in your book that really hit me was that Albert had called Merck and a representative told him that Thimerosal was as safe as lemon juice that you put on your food. Is that correct?

I could not confirm that with Merck. They wouldn’t return my calls when I called to inquire. I had no reason to doubt Albert. He seems like a perfectly believable and rational person to me. I wasn’t on the phone call. I reported what Albert said. I tried to confirm it with Merck, and I couldn’t. I imagine that the young man from Merck who was answering the phone that night wasn’t speaking off some official script, I think he was just giving his own personal knowledge—or misinformation.

Yes, so that’s something that could mislead some parents to the detriment of their children. What are the numbers like—cases of autism in the U.S. and in the United Kingdom?

That’s an excellent question. They appear to be just about the same—60 per 10,000 children, or 1 in 166. Now, that is for

ASD, not full-blown autism. However, in other countries in Europe where they have done extensive studies, and where Thimerosal use has not been a common practice for the last decade or so, the autism rates are considerably lower—particularly in Denmark because that’s where it has been studied, probably, more than anywhere in Europe. I believe the rates are about 7 per 10,000 children; whereas, in the U.K. and U.S. which have been using Thimerosal up until recently, the rates are 60 in 10,000.

Tell us about mercury—the types, the difference between ethyl and methyl, the difference between a bolus and chronic exposure?

Sure. And those are all really important questions because the manifestation of mercury toxicity depends very much on the type of mercury, the route of exposure, the age of the person exposed, and their body weight as well as other issues. We are as humans basically exposed to three or four different kinds of mercury—some as natural environmental pollutants and some as manmade pollutants. There is inorganic mercury and there is also elemental mercury. Elemental mercury is what is found in thermometers and fluorescent light bulbs and things like that. That’s what comes out of a thermometer when you have to clean up a mercury mess. Inorganic mercury, the main sources of that are: in nature—volcanoes; and man-made sources, of course, are coal-fired power plants.

Then we have two forms of organic mercury: we have methyl mercury and ethyl mercury. The inorganic mercury that comes out of the coal plants, according to a report from the National Academies of Science (because this has recently been challenged) goes up into the air, comes back down in the form of rain, washes into the soil, lakes, and rivers, where it is consumed by microorganisms, which then convert it into organic mercury. It then goes into fish and goes up the food chain. My understanding is Thimerosal, or ethyl mercury, is manufactured—but they are both organic forms of the metal which, in terms of neurons, organic mercury seems to be even more neurotoxic than inorganic mercury, because organic mercury is absorbed by fat cells; whereas, inorganic is absorbed by water. So, if you are exposed to organic, the chance of nerve damage is probably higher; whereas, inorganic would be washed out of your system through your kidneys.

How much Thimerosal did infants get prior to it being reduced, in general, recently, and did this exceed EPA guidelines?

At the peak of exposure, if a child had received all mercury-containing vaccines, that is, vaccine brands that contained mercury, they would have received many, many times over the EPA limit on those particular days of the visit to the doctor. That would be a ‘bolus’ exposure—a peak, intermittent exposure, as opposed a chronic, low-dose exposure. So, these children would have received at birth 12.5 micrograms of mercury and, depending upon how much they weighed, for an 8 pound child that would be about 35 times over the EPA limit, but for a 4 pound child it would be double that—so, it would be 70 times over the limit. At 2 months the children were brought back,

that's when they were still relatively small and when many important systems inside the body are still developing. And that's when they received the most amounts of mercury, 3 shots, 62.5 micrograms of mercury. For a 10 pound kid, it's about 137 times over the EPA limit. And then of course, at 4 months they came back, at 6 months, and then a year. So, in that first year most kids who were receiving mercury got about 212 micrograms.

With all these bolus exposures, didn't someone at the FDA realize this is a dangerous thing? Or did they not look at it that why?

It would appear they never looked at it until 1999, when they were ordered by Congress to do so. We know that company officials at Merck did the math way back in 1991, thanks to an excellent report in the *Los Angeles Times* about two weeks ago. The company never bothered to tell the government or the public that they had done this math. When I talk about the 'math,' I mean the simple conversion of percentage of volume into actual micrograms of weight. And no one at the FDA as far as we know did that until 1999. When they *did* do that, that's when they got the statement out and urged companies to start removing mercury from the childhood shots.

So, they didn't originally do the math, and then did they look at bolus exposures or did they average it out to more like a chronic exposure?

They did some very clever mathematical footwork, I would say. They took the first six months of exposures—so, that's 4 bolus exposures—birth, 2 months, 4 months, 6 months—added them up, got I think it was 162.5 micrograms of mercury exposure over a period of 180 days. So, they simply averaged that out and came up with a figure of 0.9 micrograms of exposure per day—on average. That completely discounts the days of exposure where the bolus dose is obviously much higher.

The analogy I use—there are a couple of them. I quote Lyn Redwood, who is of course one of the lead, if not the lead characters in the book and went to great lengths to try to prove this theory. You can take two Tylenol® a day for 60 days and you will be fine. But if you took 120 Tylenol® in one day, that's a lethal dose and you'll probably die.

Right. Excellent, excellent point. Are the symptoms of mercury poisoning and autism similar?

There are many, many similar symptoms that cross over and they are quite remarkable, broken down into various different categories. Again Safe Minds were the first people to really pioneer this work looking into these similarities. They published a paper, authored by Sallie Bernard, et al., called *Autism: A novel form of mercury poisoning*. And in it, they literally went down and compared symptom by symptom, and found in the literature references to behaviors and neurological problems, speech disorders and sensory problems and the list goes on and on, that were virtually identical between mercury poisoning and autism. But then also, we must remember that mercury poisoning does not always manifest itself in the same way

nor does autism. So, that then left them open to attack by their opponents who said you can't make that comparison.

Well there are some examples in history, are there not, of mercury poisoning, Pink disease, etc?

Probably most famous is Mad Hatter's disease. And of course, people who made hats up until not too long ago, were exposed to large amounts of mercury vapor used in the making of the felt. Mad Hatters were prone to outbursts of emotion, at the same time they would withdraw from social venues. They would have lack of eye contact, they would be very irritable, huge bouts of depression. And of course, it was exposure to mercury that made them "mad."

Pink disease is even more interesting, probably less known in this country. It appeared in the western world, mostly in Europe, Canada, and Australia, in the 1930's up until about the 1950's. And for a long time people suspected that it was inorganic mercury in the teething powder that was put in the teething rings for their children. And indeed, in the end, it did turn out that *was* the cause. The symptoms, the reason it was called Pink's disease, is the peeling of the skin, a rash that was red in color, and that's how the word came about. Now, autistic children generally don't have that symptom. So, Pink disease obviously is not the same thing as autism. But many, many of the other symptoms overlap remarkably. And I discuss them in the book. There is an actual adult survivor of Pink disease who describes her symptoms from the inside out. And they are identical. I think any parent of an autistic child reading what this woman went through, or reading the general symptoms of Pink disease, (knows) they equally match autism. And of course, finally, industry very reluctantly in the 1950's, did not want to remove the mercury but thought they might have a problem and potential law suits on their hands, so they did. And within years, Pink disease disappeared, and today it's virtually unheard of.

So, when did American and European agencies begin to assess the risks of Thimerosal in pharmaceutical products and what did they report?

European agencies, I think, got a head start on us. And if you go even a little further east to the Soviet Union, Russia, they took mercury out of vaccines apparently back in 1982. There is a paper that was published that's in my book, it was published saying mercury was completely inappropriate for use of this kind and it was toxic. Scandinavia removed mercury from vaccines in 1992. And the Europeans started looking at this issue. Well, actually, back in 1985 also there was a paper published by, basically, the equivalent of the head of the FDA in the United Kingdom saying the same thing, "Thimerosal is not safe and should not be used." That document, one has to assume, was in the library of the FDA, but they never bothered to look at it. Right around 1998, the European Union started moving to propose banning Thimerosal in vaccines in Europe. And of course in this country it started in 1999.

You may have alluded to this earlier, but when did the FDA think there might be a cause for concern with Thimerosal in vaccines? And did anyone talk about doing or not doing a re-

call? I think you have some quotes from Dr. Patriarca and Dr. Halsey?

Yes, Dr. Patriarca, just before the joint statement was issued—so, back in July of 1999 when he knew this was coming out and he had seen the math—updated his colleagues and sent out a couple of e-mails to them. The first one saying, “How did this happen? This is 9th grade algebra. Anybody could have sat down and done these conversions—why didn’t we?” In the second e-mail he writes that he is afraid that “the perception when this all comes out will be that the FDA, CDC, and others were asleep at the switch.” Which seems like *that’s* what they were. As far as recall is concerned, Safe Minds attempted repeatedly, over and over again, both in person and in letter form, to have the FDA recall these Thimerosal-containing vaccines, as did Dan Burton, chairman of the Government Reform Committee, several times, and the FDA simply refused.

Wasn’t there even some resistance on an agency’s part for delaying the birth Hep B vaccine?

That’s correct. That was one of the recommendations in the Joint Statement in 1999—was to move the birth dose of Hepatitis B back at least I believe until 4 to 6 months. And they did in the statement say that the schedule allowed that flexibility.

Was there some resistance to that on the part of the agency?

There was resistance apparently in a Hepatitis Control Report published on the part of the CDC. They were afraid that if people didn’t get the birth dose, they might not start the Hepatitis B series at all. The American Academy of Pediatrics, to their credit, fought very hard to have the recommendation included to postpone the birth dose.

Was Thimerosal ever studied for safety by the FDA or anyone else?

Not by the FDA. The only safety study on record and on file at the FDA actually predates the FDA. It concerns a 1929 trial by Eli Lilly & Company, shortly after Thimerosal was first invented. They decided to test it on a group of 22 patients who were dying of acute meningitis. So, they injected the patients and followed them for about 3 days, after which time most of the patients had died from meningitis. And in that period they noted no adverse effects from the Thimerosal. So, that was the safety study and that, to this day, sits in the FDA as the only proof of safety of the substance.

So, what did Eli Lilly know and when did they know it?

We don’t know, exactly, actually.

Were there any warnings to Eli Lilly?

Over the decades, beginning in the 1930’s and going right up to 1990’s from scientists, from medical academics, and even from their own employees. And this has all been produced

through the discovery process by Andy Waters, the main attorney in a lot of the civil cases.

All of this time, tell us about the parents who were digging for information and what they found.

A lot of them all started on their own, I think without even knowing that other parents were doing the same thing—just looking into this all over the country. My book follows the story of mostly, but not entirely, the Safe Minds parents, in particular Lyn Redwood, Sallie Bernard, Liz Birt, Albert Enayati, Heidi Roger, and Mark Blaxill. And of course more parents come into the story as it progresses. Safe Minds I think gets credit for really spearheading this and really taking on the government and the drug companies. They’re the ones, a group of parents, with the exception of Lyn a nurse practitioner, with very little medical experience. They wrote their paper and they got it out there and they banged down the doors of government to get in, to get meetings, to talk to these officials to present what they found. And they really thought that, once they had done that, the government would take their concerns seriously and get on the ball and try to figure this out. And that’s not the response that they received at all—which I think is very disheartening for them.

There was a memo that said, “It just won’t go away.” Please fill us in about that and what it meant.

At one point I actually toyed with the idea of making that the title of my book, because “evidence of harm” of course occurs many, many times as a phrase in my book. But so does the term, “It won’t go away.” That particular one that you referenced is from another e-mail sent by Thomas Verstraeten, who was hired by the CDC. He came over from Belgium and his first assignment was to sort through the Federal Vaccine Safety Datalink database and look for adverse outcomes among children who were vaccinated with mercury – to see if there was a higher rate among children who had higher levels of exposure. At his first run of the numbers, he came up with some extremely high and very statistically significant associations, including autism outcomes and Thimerosal exposures. He then went back and re-cut the numbers—literally. He stratified them.

In the first round, basically there was this large group of kids broken down into exposure/no exposure. Then he broke them down by different ages and by different exposure rates, and really started to break them down. And the relative risk for autism and other disorders came down considerably, but they did not come down all the way. Many of them were still extremely elevated—alarmingly elevated—and many of them were statistically significant. At this time, when he wrote the memo, the relative risk of autism was at 2.48. Anything over 2.0 is considered causation in a court of law, however it was not completely statistically significant—it is a little complicated to explain the reason why—but it was still high and it was close to statistically significant.

When did the CDC know it had a grave problem?

The CDC still won't admit that it has a grave problem. So, I don't know how to answer that question. I think they knew they had a PR problem. At the same time, they were fully informed by the people of the FDA what was going on in 1999 as the e-mails will attest. I think when Thomas Verstraeten, then in November/December of 1999, first ran the numbers, that's when the NIP, the National Immunization Program officials, I think must have known they had a problem. But they will not to this date admit that there was a problem

David, tell us about Generations 0 through 4?

That's a lot of what I was just referring to. Generation 0 is so-called because it was sort of discovered after the first 4 generations were discovered. Of these 5 generations, by the way, the only generations that were ever meant to see the light of day were generations 3 and 4, the last two. The last one being published in the Journal *Pediatrics*. What is called 'Generation 0,' again was the first run of the numbers. I am not a biostatistician, so, I don't know how valuable this data is, but it does exist, it is CDC data. And Verstraeten basically took kids at 1 month of age who had received more than 25 micrograms, and then kids who had received 0 micrograms at 1 month of age, and compared them. And he found out that for the kids in the exposure group, the rates were astounding. For autism it was 7.62, for ADHD it was even a little bit higher, for ADD it was a little bit lower—but they were all way up there and statistically significant. That's when he cut the numbers again and came out with what is now referred to as the 'Generation 1' numbers, when autism fell to 2.48.

Was that the VSD Phase 1 study?

That's the VSD Phase 1, yes, which is also referred to as '2/2000.' There was a paper that he wrote for his colleagues in February, 2000—so, it was his second run of the numbers, and that document, which was produced for it, is stamped, every single page, "Confidential. Do not distribute." That was never meant to see the light of day. That then became 'Generation 1.' Only people inside the CDC knew about it.

What then became 'Generation 2' [note: audio incorrectly stated 'Generation 3'] was in June of 2000, at a top-secret meeting outside of Atlanta, held at a resort called Simpsonwood, where the CDC invited people from the FDA, other government agencies, the medical academies, and the vaccine-producing drug companies to come review the data that Verstraeten had analyzed. By this time, when Verstraeten presented, he was now on 'Generation 2,' and the relative risk for autism had since dropped to 1.69. The other risks had dropped, although there were some that were still elevated, particularly speech and language delay. And an umbrella category that they did—they took all of the disorders, including autism, and put them into something called NDDs, neurological developmental disorders. And they took them and grouped them together and looked at them. They were elevated, and they were statistically significant, and there was a dose response curve. In other words, for every increment—for every increase—in mercury exposure, there was a relative increase in risk for one of these outcomes. That got presented.

Shortly thereafter Verstraeten presented more or less the same numbers in a public meeting—at a CDC meeting in Atlanta, a vaccine committee meeting. That was entered onto the record, however to this day his report is not posted online. The only way I got to see it was because Lyn Redwood was there and somehow got an early transcript.

After the Verstraeten VSD Phase 1 data was revealed, was there a political fallout, for example, was there any activity on the part of lobbyists?

Not at that point. I don't think they were quite aware of what was going on until Simpsonwood. It is my understanding that nobody had access to that Phase 1 outside of the NIP until it was produced...

But a couple of months later, Verstraeten *did* present findings where the risks were lower than in the Phase 1 study, but they were still elevated and many of them were still significant. At that point, I think the drug companies were aware that there was potentially at least a PR problem out there, and that did eventually start lobbying activities on Capitol Hill to protect the companies from liability.

Was there a political apparatus in place that connected Eli Lilly with legislators, political appointees, or pending legislation?

Oh yes. And there still is. It is hard to know where to begin, Teri. In terms of the Bush administration, and at the time of, particularly, the Homeland Security Bill, Bush had installed Eli Lilly vice-president for corporate strategy, Mitch Daniels, as his Director of the Office of Management and Budget—a highly powerful position within the White House. He also named Mitch Daniels to the National Security Council and the National Homeland Security Advisory Counsel. The CEO and President of Eli Lilly, Sidney Taurel, was likewise named to the president's Homeland Security Advisory Counsel. Only, I think, 13 positions were made open—highly coveted spots for people in industry because, as the government started to formulate its terrorism response after 9/11, it needed to incorporate the private sector into its plan. And for a pharmaceutical company to be in there was very beneficial for them. The list goes on.

Of course George Bush Sr. sat on the Board of Directors of Eli Lilly for many years, and other Eli Lilly company officials have been appointed to different Homeland Security advisory panels within the bureaucracy. And of course, Eli Lilly is a very generous donor to political campaigns—historically, about 80% of which has gone to Republican candidates. In the 2000 election they were one of the most generous donors of all, and they have also donated to the campaigns of Senator Bill Frist and also the Republican Senate Campaign Committee.

So, is it just conceivable with all these bills that we've seen that any part of the legislative system, in essence, has been blackmailed by pharmaceutical companies when our country was deemed vulnerable?

I would never use ‘blackmail,’ though some people did. I think I probably quoted them in the book. And not only in Congress, but the state level at well. This is not my work or study, but people and organizations, particularly Washington, have looked into the influence of large industries on Congress, and also in the bureaucracy, as a matter of fact, in terms of writing regulations. And again the pharmaceutical industry is among the most generous of donors. Now the soft money ban has reduced that somewhat and large contributions are not as large as they use to be. But the amount of influence that drug companies and others seem to get in return for their investment is well documented.

But are there any instances where any vaccine manufacturers actually have said, “If this or that legislation does or does not go through, we are going to walk—we’re not going to make such and such a vaccine that you’re going to need”?

Nobody has ever said that on the record as far as I know—and that would indeed be as close to blackmail, I think, as you could get. However, and I did confirm this through many, many sources on Capitol Hill, it’s there at several times in the narrative, lobbyists for the drug companies *did* make the rounds in key House and Senate staff offices, basically delivering that message: that without liability protection from Thimerosal and other vaccine injury cases, they would become so crippled through litigation that they might not be able to make vaccines to protect the American people against bio-terror attack.

So, tell us about the different bills that have been introduced and the Homeland Security Bill riders. How did that get in there and what do disabled kids have to do with Homeland Security anyway?

That is an excellent question. Dan Burton ran to the House floor to ask that exact same question as soon as he found out that the rider had been inserted. They are all related and it is a very complicated web of intrigue, in terms of all those different bills, and also the Homeland Security Bill. As far as the Homeland Security Bill is concerned, that was inserted by Representative Richard Armey, Republican of Texas. He was the House Majority Leader at the time and about to retire. He retired at the end of the year. At first he said that the order to do it had come from the White House. The White House denied this, I believe. The White House said it may have come from Senator Frist’s office. Senator Frist denied that, and later Dick Armey retracted his statement that it had come from the White House. He insisted he had acted alone to protect the nation and our bioterrorism response system. It’s hard to know if Dick Armey himself would have known exactly which passages from a many, many page bill of Senator Frist, to cut and paste into the Homeland Security Bill. Either he knew exactly which language, or someone in his office knew which language, or of course it was furnished to them by sources unknown.

That provision, which was inserted into the bill and passed in November and signed by the President, was then rescinded when Congress came back in 2003. The new Majority Leader, Senator Bill Frist, to his credit, honored a pledge made by the outgoing Majority Leader of the Senate, Trent Lott, to revisit the

issue—and he indeed did. And the unsettling language was removed—I say unsettling in terms of the way it was put into the bill—but he vowed and Eli Lilly vowed, and others vowed to fight to get most of that language back *in*. Now, the language basically gets very complicated and technical and is explained in the book. The language of the Homeland Bill was basically to proclaim Thimerosal a vaccine ingredient and therefore Eli Lilly would be a vaccine maker and therefore protected under the Federal Vaccine Compensation Program. In other words, plaintiffs could not file private cases in private court, they would have to go into the Federal program, which happens to have a 3 year statute of limitations. So, if your child was injured more than 3 years ago, you’re not eligible—leaving most parents in a terrible “catch 22”—they couldn’t file in civil court, and yet they can’t file in the vaccine court either.

Ever since then, Frist and others have introduced several different versions of similar bills, and none of these passed, obviously. Most recently Senate Bill 3, which is rather Draconian in its reach. Not only would it prevent families from filing in state courts—it does not include the Homeland Security Bill provision of proclaiming Thimerosal as an ingredient, however—there is now a version in the House that does do that. And eventually if these pass, they’re going to have to work together as one bill.

But some of the other things that the Senate bill does that are really quite alarming and possibly unconstitutional includes things like prohibiting the states from passing their own individual bans against mercury in vaccines. And, as we know, this is already happening in Iowa and California. It is not clear if the Senate and Federal government can tell the states what laws they can pass in terms of federal health policy. So, that will be an interesting debate if the Senate bill were to pass. I can assure you that parents are out there right now, from Safe Minds and other groups... And particularly, I want to give note to Laura Bono, at the National Autism Association, because she has really led the fight against Frist. But there are many, many people in the fight, and they all contribute equally.

David, you mention Congressman Burton. What did the Mercury in Medicine report show?

It showed a lot of things. It showed reasonably there might be collusion between the drug companies and the federal health bureaucracy. It showed varying conflicts of interest among people who sit on these panels and decide which vaccines get approved by the FDA, and which vaccines get put on the childhood list by the CDC. And incidentally, there is an astounding article in the *New York Times* today (February 28, 2005)—well there are two. One concerns the National Vaccine Program and Thimerosal—I urge everybody to read it. And the other one concerns the Vioxx[®] scandal. And last week an FDA panel rather controversially voted to basically give the green light to Vioxx[®] and other cox-inhibitor drugs to go back on the shelf. The vote was close. There were several votes—there were, I think, two to three votes on each drug and *The Times* did the math. They did a great job, and they looked into these people and what kind of ties they had to Merck and other drug companies. And sure enough, all the people voting to re-approve the drug, or approve its sale back on the market, were the ones re-

ceiving contributions and funding from the drug companies. Those panelists who were not receiving funding, tended to vote against these drugs. When they finally did the math, and they looked at how many times that the money-receiving people had voted for the drugs compared to people who weren't receiving money, the ratio was 10 to 1. So, if you were receiving money and you sat on this panel, you were 10 times more likely to vote in favor of the drug companies than if you weren't.

Well, David, I guess if you've used up all your math energy counting the bills in your billfold in your pocket, you're worn out to do the math when it comes to drug safety.

That's right, 'Just give me my check and tell me what to do.' It's pretty blatant. That could not possibly happen by chance. So, I'm hoping that this *Times* article really sparks some further investigation—not just for what's going on at the FDA, but what's going on at CDC. So, anyway, the Burton report also categorized and catalogued these conflicts. It was a far-reaching report. I encourage everyone to read it—it's an excellent document, worked on very hard by people like Beth Clay, Elizabeth Birt, and others, and of course, Chairman Burton. It looked into the history of Thimerosal, everything that went on at the FDA in the 1980's and 1990's, and of course the entire CDC study with the vaccine data, access to the vaccine data, which is what the other *New York Times* article is about today.

Getting into the VSD is like getting into nuclear secrets—the most heavily guarded data, certainly in the public health realm, I would think, and still fairly off limits to outside researchers, although that seems to be changing. And what the *Times* is reporting on today, is that a new panel set up by the IOM (Institute of Medicine) to review access to Federal data, especially this vaccine data, and also the preservation of data that has already been analyzed, datasets that have already been constructed. And the report is a scathing rebuke of the CDC by this IOM panel, which basically advises the CDC to seek legal counsel, because they did not properly maintain datasets. The language they used is that they were 'not archived in a standard manner'—meaning they were lost or destroyed. And now, nobody can try to replicate what Thomas Verstraeten and his colleagues did. Nobody knows where these datasets are. The technicians were ordered to remove them from the computers at the CDC center, put them on to CD-ROMs and send them back to headquarters in Atlanta. So, we don't know where those datasets are. They were supposed to be preserved; they were supposed to be made available to other researchers that could come in and then replicate the work of the government scientists—as any hallmark of good science would allow. And the fact that they were lost or destroyed is a violation of the Federal Data Quality Act. That is a federal law, and if someone is responsible for the loss or destruction of these datasets, they could conceivably face criminal prosecution.

So, agencies such as the IOM, CDC, etc., it doesn't sound like they were trying to help parents. In fact, it seems as if they were trying to hinder parents from getting to the bottom of this.

I can't ascribe their motives, I can't get inside their heads. They would certainly deny that. The parents would certainly

deny their denial and say that's exactly what they were trying to do.

The IOM is not a government agency, it's an independent agency. It's a quasi-government agency in that it is hired by the government and does work for the government, but it is actually independent. If you go back to 2001, when the IOM issued its first report on this issue, they came down pretty much in the middle. They said there was not enough evidence one way or the other; that it was biologically plausible; and that experimental treatments, like chelation therapy, should probably be looked into. So, I would say at least in 2001, the IOM was taking a more open-minded view than say the CDC or pediatrics' academies. Leaving the IOM aside for a minute, if you look at FDA, CDC, the American Academy, and certainly the drug companies, they all have a very strong interest in proving this theory wrong. So, for many, many different complicated reasons, it's going to be difficult, if not impossible, for the parents to extract any kind of confessions out of them—or any kind of admission of wrongdoing, or guilt, or even just simple human error.

Well, let's fast-forward a little bit. Didn't the IOM more recently say there was no causal relationship?

Yes, that was the second report issued in May of 2004, based on a hearing held in February, 2004 which the IOM panel, the immunization panel, listened to evidence of data presented basically from both sides of the controversy. The data presented to refute the Thimerosal theory was almost exclusively large population studies—epidemiology.

Let's look at the IOM's epidemiological proof. Can you tell us about study authors being connected to the Statens Serum Institut?

I can a little bit. The experts on this are Mark Blaxill and Sallie Bernard. They really investigated the tangled web. The Statens Serum Institut supposedly call themselves a non-profit, quasi-government agency out of Denmark, responsible for developing, producing, and selling vaccines, not only in that country, but overseas. They still claim that they're non-profit, although there might be evidence to suggest otherwise. People who were on staff at that institute, or consulting with that institute, and who worked on several of the major studies that were done in Denmark, do have ties to drug companies and they certainly have ties to the CDC.

And there is now evidence surfacing showing that a lot of these overseas studies done in Denmark and the U.K., even though they didn't officially receive CDC funding to be conducted, it would appear the CDC was calling a lot of the shots. I just now saw some information that Brian Hooker out of Washington just received a few days ago—very revealing e-mails between the head of the study in the U.K. and Robert Chen and Thomas Verstraeten here in Atlanta, indicating that the CDC was basically deciding whether this study should proceed or not and deciding who at the World Health Organization (WHO) should give its funding to and worrying that because they found out that exposures in the U.K. were lower than they thought they were, they thought they might not have enough exposure to show a significant number of outcomes—which also would

suggest that they knew that with higher exposure you do get outcomes. Anyway, Elizabeth Miller the head of the U.K. wrote to Bob Chen and was so upset she wrote, “Do I have to give my grant back to WHO?” In other words, she was asking the CDC, “Do I have to give my money back to the World Health Organization?” And in another e-mail Vertraeten wrote to Chen and said, “I don’t think this is a good study; I don’t think we should do this. I think the money should go to researchers in Sweden.” So, the CDC was obviously having influence over the funding of these studies that, in theory, they had nothing to do with. CDC also wrote letters in support of some of these studies to be published in the *Journal of Pediatrics*.

David, let’s talk about science now that uses real biological tissue for study. Please tell us about the science substantiating the link between Thimerosal and the autism epidemic.

Sure. And when I mentioned the IOM meeting, which I was at in February of 2004, the evidence presented to refute the theory was all epidemiology, for the most part. And most of the evidence presented to support the theory was biological evidence, done in the clinic, in animal models, in the test tube, and in children themselves. This was given a lot less emphasis and importance by the IOM panel than the epidemiology—they themselves admit that. And a lot of these studies had not yet been published when they were presented in February. Of course now, many now *have* been published, but because they weren’t published at the time, the IOM decided to discount them even further.

The most important ones among them are the work of Jeff Bradstreet, Jill James, and Dr. Richard Deth, who was on NBC news last night, and others looking into this: Boyd Haley, of course, from the University of Kentucky. Mark and David Geier have looked more into the epidemiology than the biology of this. The bottom line of what their studies are showing is that autistic kids retain heavy metals at a much greater rate than normal kids; that they seem unable, in fact, to actually excrete it. Following chelation, autistic children excrete far higher levels of mercury than normal kids. And yet, in their baby haircuts, we’re finding that normal kids have much *higher* levels of mercury in their hair than the autistic kids. And that would then make sense, because they were excreting it properly; the autistic kids were holding onto it.

What Jill James and Richard Deth have found are mechanisms by which mercury exposure can interrupt very important processes in the body, and particularly in susceptible individuals, and the effect this can have on the production of ‘thiols,’ sulfur-based proteins, also referred to as ‘mercaptans’ or ‘mercury capturers.’

Jill James has shown that autistic children have much lower rates of these proteins—glutathione, cysteine, things like that—in their system, which would naturally chelate the body, that would naturally bind with the heavy metals and help eliminate them from the system. So, working with the theories of Richard Deth about what is interrupting this process, she and others are trying to restore the process, particularly through the use of Methyl B-12. Once she started giving a cocktail that included Methyl B-12 to these children, she noticed that their levels of thiols, their sulfur-based proteins, their ‘mercury capturers,’ if

you will, returned to normal levels. And now, she is at least anecdotally seeing clinical improvement, as are other people who have given their children or their patients this therapy.

The work of Mady Hornig, at Columbia [University], basically took different strains of mice—one strain which was genetically predisposed to have auto-immune disorders—and exposed them all to the same level of vaccines, at the same schedule, roughly, that children would have received. In the sensitive group of mice, then, she noticed autistic-like behavior. She noticed physiological development such as increased brain size that you see in autistic children. Of course, she has been attacked for the study. And people said, ‘How can you tell if a mouse has autism or not?’ And I’m not quite sure that was the point of the study. I think the point of the study was to show that certain members of the same species, with a genetic difference, will react differently to the same level of mercury exposure due to a genetic variance.

But there’s never been reported a genetic epidemic, right?

Not to my knowledge. This could then implicate an environmental factor (a trigger), probably on top of a genetic predisposition.

One thing I neglected to mention about Pink’s disease: only 1 in 500 children exposed to the mercury developed the disease. So, that would therefore indicate a minority of children were genetically predisposed to develop hypersensitivity to the metal.

Legislators and appointees such as in the Office of Special Counsel and Congressman Weldon seem to think we’re onto something. Please tell us something about that.

There are investigations or preliminary investigations seemingly going on all over Washington and down in Atlanta as well. Congressman Weldon has certainly led the fight to ban mercury in vaccines. He has a bill that was just reintroduced, along with Congresswoman Carolyn Maloney, Democrat of New York, and I urge everybody to take a look at that bill. By the way, it is not clear what would happen if that bill passed and the Frist bill passed at the same time. I’m trying to find out who resolves that one. He has also worked with parents such as yourself, Teri, and others to get some federal investigative branches looking into this, including the Office of Special Counsel, the President’s Counsel on Integrity and Efficiency—which is sort of an umbrella group of investigative bodies at different federal agencies. The Office of the Inspector General at HHS has put some agents on this case as well. There are a couple of internal investigations that at least are preliminary in nature. There are a few criminal investigations going on, mostly looking at malfeasance and fraud and conflict of interest issues at CDC and FDA, and also looking at, apparently at least, Eli Lilly and some of the drug companies, about why they didn’t share information they had with federal authorities about toxicity.

Just a few more questions. We are being barraged with bills withholding compensation from kids. What do you think about that?

I am a journalist not a politician, I don't want to take a position one way or another. But as an American, I think that we have a judicial system for a reason. I don't think that members of Congress really should be deciding whether the American people have a right to their day in court or not. I think that's why we have judges, that's why we have juries. It's up to the judge to decide if it meets the standard of proof of evidence to proceed to trial anyway. That's where these complaints belong. First of all, we have a Federal Compensation Program, which is closed to the majority of people who might want to enter it. So, in a general, constitutional, Federalist point of view, I know as an American citizen, I think that if people can show reasonable cause, or reasonable evidence that this may have happened, they deserve their day in court. And let the jury decide, and let the judge decide, and let the lawyers for the other side argue their case. And I believe that's the way it should be decided.

Well, David, even with the limited funding and all the adversity, do you see scientific progress being made for these kids in the future?

I see it being made already. I think there is cause for tremendous optimism. Despite the obstacles these parents have, I have seen kids get better with my own eyes and with my own ears, and heard them get better, and speak more clearly, and be more attentive, and have better eye contact. I have to say whether it turns out that Thimerosal is absolutely fingered as the culprit or not, the mere fact that some kids, when you remove heavy metals from their body, seem to improve clinically—that in itself is wonderful and in a way, again I am not a lawyer and have no personal interest in these lawsuits, who cares what the cause is? If the kids are getting better, the kids are getting better—or at least some of them. And I don't mean to be flip about that, but I think people need to keep their eye on the goal—which is these children getting better, and perhaps even recovering some, if not all their cognitive abilities. So, I think that everyone deserves to take 5 minutes off and pat themselves on the back and look at how far they've come since even I started reporting this book 2 or 3 years ago. Particularly in terms of public awareness of Thimerosal and mercury; in terms of legislation in Congress; in terms of the investigations; and in terms of the media coverage. Even if you were upset at what NBC was doing, NBC did the autism community a service, because the debate has begun. Even if you were opposed to what Bob Bazell or anybody said, this was not being said on national television even a year ago. Some people would say, 'No publicity is bad publicity.' And there is a certain amount of wisdom in that

We do have an e-mail question. A woman writes, "I understand that sometime after the controversy of Thimerosal and immunizations arose, it was removed from the shots our children received. When did this occur? If it is no longer used, why did I find it listed as an undetectable levels ingredient in immunization that bundle several together as one?"

Complicated question. Mercury began to be removed slowly from vaccines in late 1999. That means new vaccines being produced, *started* to be produced without mercury in them. But as we know, all the vaccines on the shelf with mercury stayed

on the shelves—there was never a recall. We have no idea how long it took to use up all that mercury-containing vaccine, or even if it *has* all been used up. The OSC has said that there may be vaccine out there with an expiration date of 2005 that still contains the full amount of mercury. We don't know *when* those lots were released; we don't know *where* they were released; we don't know *what* kids in what part of the country were getting mercury and what kids were not post 2000. We *do* know that kids were getting mercury, and were getting it right up through 2002, and perhaps later. We also know that it is in the flu shot.

The trace amounts that the woman refers to—Thimerosal is still used in most vaccines, except for MMR and others, in the production process—in order to preserve sterility in the production line. So, in other words, if bacteria get introduced into the solution, the Thimerosal at the end of the production line will kill it, theoretically. This, by the way, did not happen with the Chiron flu shot at that Liverpool plant. That particular vaccine was infected with Serratia bacteria—which are famously resistant to mercury. It's my contention that Thimerosal failed to do its job in that case. And that may be the reason why 45 million doses of flu shots were pulled.

They use the mercury to wash the solution, to kill the bacteria. And then, what they do is *literally* chelate the vaccine. They introduce cysteine, the sulfur-based protein, to withdraw the mercury out of the solution. And what is left is a 'trace amount.' I think it's about 0.5 micrograms per dose, so, 1/2 microgram, as opposed to 25 micrograms—obviously a lot less. I see no evidence that that could be harmful.¹ But, it is possible, in some people any amount is harmful. But if it said 'trace amounts' on the label, that is what they are referring to—the residual mercury that was left over from the production process.

David, on behalf of AutismOne Radio, thank you for being with us and for this wonderful resource you've provided. It is a powerful and riveting account with helpful and interesting information for parents of newly diagnosed children, seasoned advocates, relatives, neighbors, legislators, and mainstream medical practitioners.

Thank you, Teri. I appreciate that promotion and hope that people will take a look at the book. Even people sitting on the fence or on the other side—I hope they will keep an open mind on this issue. I would also like to mention the website <http://www.evidenceofharm.com> where they can go to get supporting documents and further information on this issue.

¹**Editor's note:** According to Dr. Boyd Haley, Chairman and Professor of the Dept. of Chemistry, University of Kentucky, trace amounts of mercury may still pose a risk to a subset of infants.