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Friday, 14 March 2014

On 23 February 2014, Paul G. King, PhD, downloaded an on-line February 22, 2014 article by "**Emily Willingham**", which is titled "**Is The CDC Hiding Data About Mercury, Vaccines, And Autism?**" from http://www.forbes.com/sites/emilywillingham/2014/02/22/is-the-cdc-hiding-data-about-mercury-vaccines-and-autism/.

Dr. King's rebuttals to narrative assertions in that article follow these introductory remarks and a "table of contents" page.

This analytical response is titled **"Rebuttal to 'Is The CDC Hiding Data About Mercury, Vaccines, And Autism?'"**.

Introductory Remarks

First, each portion of article's text is quoted in a grayed "Georgia" font.

Second, Dr. King's comments follow in a "Verdana" font and are indented.

Third, when quoting from the item's text, the quoted portions of the text are in an *italicized* "*Times New Roman*" font.

Fourth, when quoting/referencing other sources, the text is in an "Arial Narrow" font.

Finally, should anyone find any significant factual error in this rebuttal for which they have independent[a], scientifically sound, peer-reviewed-published-substantiating documents, please submit that information to Dr. King so that he can improve his understanding of factual and/or theological reality and, where appropriate, revise his views and this formal response.

Respectfully,

<s>

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Tel. 1-973-997-1321, after 21:00 Eastern Time
[To whom all responses should be directed]

[a] To qualify as an independent document, the study should be published by researchers who have no direct or indirect conflicts of interest from their ties to either those commercial entities who profit from the sale of any product or practice addressed in this response or those entities, academic, commercial or governmental, who directly or indirectly, actively promote any product or practice, the development of any product or practice, and/or programs using any product or practice covered in this response.

Table of Contents for:

"Rebuttal to 'Is The CDC Hiding Data About Mercury, Vaccines, And Autism?'"

Rebuttal to:
"Is The CDC Hiding Data About Mercury, Vaccines, And Autism?"

Dr. King's Introductory Remarks

King's unequivocal answer to the title's question,

"*Is The CDC Hiding Data About Mercury, Vaccines, And Autism?*",

is "Yes", the CDC [U.S. Centers for Disease Control and Prevention] is hiding "*Data*" (information) about the link between the administration of vaccines preserved with Thimerosal[1] (49.55% mercury by weight) to pregnant woman, neonates and developing children and the subsequent risk of neurodevelopmental harm, including autism; other developmental harm; and behavioral harm to some of those children who have been previously, directly or indirectly, administered Thimerosal-preserved vaccines during their development.

In addition, in hiding this information, it seems clear that the CDC is more concerned about protecting and expanding its recommended vaccination programs than it is in protecting the overall health of the children of the United States of America (USA).

The Review

"You know the rule. The answer is, 'No.' But the assertion has gone viral on social media thanks to the zombie-like resurrection of a long-told, oft-debunked story that the US Centers for Disease Control (CDC) is hiding its own data linking autism and mercury in vaccines. If you see such assertions in your timelines and newsfeeds (sample headline: 'CDC Caught Hiding Data Showing Mercury in Vaccines Linked to Autism'), send the disseminators here. Why? Read on."

On "*the rule*", "Lost" Datasets, and Concealed Information

Here the "Contributor", Dr. Emily Willingham, begins with,

"*You know the rule. The answer is, 'No.'*",

where "*the rule*" link is to http://en.wikipedia.org/wiki/Betteridge's_law_of_headlines, which states (emphasis added, without the internal references):

> "Betteridge's law of headlines is an adage that states: "Any headline which ends in a question mark can be answered by the word *no*." It is named after Ian Betteridge, a British technology journalist,[1] although the general concept is much older.[2] The observation has also been called "Davis' law"[3][4] or just the "journalistic principle".[5]
>
> Betteridge explained the concept in a February 2009 article, regarding a TechCrunch article with the headline 'Did Last.fm Just Hand Over User Listening Data To the RIAA?':

[1] Because Thimerosal is a trade name for sodium ethylmercurithiosalicylate, in American English, it should be capitalized every time it is used in a text.

This story is a great demonstration of my maxim that any headline which ends in a question mark can be answered by the word 'no'. The reason why journalists use that style of headline is that they know the story is probably bullshit, and don't actually have the sources and facts to back it up, but still want to run it.[6]"

Beyond emphasizing the last statement in the link cited by Willingham and noting that, *in scientific journals, not mainstream media periodicals, like* ***Forbes***, the usual answer to a title ending in a question mark is "Yes", King sees no need to add his thoughts to hers.

However, King notes that Willingham provides no independent citations to rebut the assertion that "*the US Centers for Disease Control (CDC) is hiding its own data linking autism and mercury in vaccines*".

Unfortunately, the original datasets from the VSD (Vaccine Safety Datalink) database that Verstraeten et al. studied in the 1999-2002 timeframe to evaluate the link between Thimerosal-preserved vaccine inoculations and the subsequent risk of various neurodevelopmental disorders, including "autism", were "lost"[2], including the datasets used

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[2] In an August 23, 2004, IOM Review of NIP's Research Procedures and Data Sharing Program meeting (http://www.iom.edu/activities/healthservices/nipdatasharing/2004-aug-23.aspx) held at the Keck Center (Room 100),500 Fifth St. NW, Washington, DC 20001, when addressing the VSD (Vaccine Safety Datalink) database access in general and dataset availability for confirming the studies that the CDC had published using the VSD, specifically the Verstraeten et al 2003 study in **Pediatrics** and the earlier analyses, two of the presenters' slides clearly indicated that the critical datasets were not available:

a. http://www.iom.edu/~/media/Files/Activity%20Files/HealthServices/NIPDataSharing/Geier82204.pdf, slide 22 (emphasis added),

"• On 3 January 2003 we submitted a new set of 11 proposals to the CDC requesting that we be allowed to re--analyze data from CDC published studies that examined the VSD database.

Examples of the CDC's Responses:

- Safety of Neonatal Hepatitis B Administration, we were informed that the CDC spoke with the study's primary author and determined that the datasets for the study will not be available in a format acceptable for re-analysis. Subsequent communication revealed that the dataset was stored on obsolete media, then it was acknowledged that the dataset had been damaged, and finally it was revealed that the dataset containing the raw data no longer existed. [Note: That is to say that they had been "lost"!]
- Risk of Chronic Arthropathy Among Women After Rubella Vaccination, we were informed that the dataset for this study did not reside at the CDC, but rather at one of the CDC's participating VSD sites, and that the primary author was still conducting a search of these data elements even though the study was published many years earlier.
- Thimerosal Screening Analysis, we were informed that the intermediate datasets (February 2000, June 2000, July 2001, etc.) for this study showing a significant relationship between [T]himerosal exposure and neurodevelopmental disorders no longer exist". [**Note:** That is to say that these datasets had been lost!]

b. http://www.iom.edu/~/media/Files/Activity%20Files/HealthServices/NIPDataSharing/Wharton82204.pdf, slide 13 (emphasis added),

"Challenges Encountered With VSD Data Sharing Program

- Limited experience outside of NCHS using the data enclave approach to access data
- Learning along the way:
  - Revision of data sharing guidelines
    - More explicit
  - Not all IRBs approved proposals
  - Some VSD final datasets not available" [**Note:** All of the Verstraeten et all datasets for the evaluation of Thimerosal risks were reportedly "lost".]

"The purpose of this meeting was to review the design and the implementation to date of the new Vaccine Safety Datalink Data Sharing Program to assess compliance with the current standards of practice for data sharing in the scientific community".

in the published "Verstraeten" study[3].

These dataset "losses" have made it impossible to independently confirm or assess the findings in the earlier iterations of the studies or the information published in the 2003 article in ***Pediatrics***.

Based on the CDC's claimed loss of the published Verstraeten et al. study's datasets, the published study should have been withdrawn[4] as the cited Institute of Medicine (IOM) document clearly concludes,

> "... if intermediate datasets from the studies no longer exist, the studies will never be able to be confirmed by independent researchers, then the published studies must be withdrawn from the peer-reviewed literature".

Therefore, this example clearly shows that "*US Centers for Disease Control (CDC) is hiding its own data linking autism and mercury in vaccines*" and violating scientific ethics by <u>not</u> withdrawing the Verstraeten et al. 2003 paper in 2004, when the "loss" of the datasets supporting the published study was first revealed.

Moreover, to date, this study has <u>not</u> been withdrawn <u>nor</u>, *if the "lost" datasets have been found*, have independent researchers been given access to those datasets.

"In 1999, four authors affiliated with the CDC presented an abstract at a conference ... a CDC conference for fellows of its <u>Epidemic Intelligence Service</u> (EIS). The EIS, by the way, serves as the Interpol of infectious disease, tracking down elusive perpetrators worldwide and stopping them before they can harm again. In other words, they are people who dedicate their lives to saving lives. Every year, the program also <u>sponsors a conference</u>. And 1999 was no exception."

The Crucial Abstract and Timeline Misrepresentations

Here, Dr. Willingham seems to be confused.

According to the supporting slides used by Dr. DeStefano in his presentation to the IOM in 2004[5], the preliminary VSD data analyses were conducted in November 1999 through February 2000.

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[3] Verstraeten T, Davis RL, DeStefano F, et al. Safety of [T]himerosal-containing vaccines: a two-phased study of computerized health maintenance organization databases. *Pediatrics* 2003; 112: 1039-1048

[4] http://www.iom.edu/~/media/Files/Activity%20Files/HealthServices/NIPDataSharing/Geier82204.pdf, slide 40 (emphasis added),

"CONCLUSION:

- (1) External researchers should be immediately given unrestricted access to the VSD database updated through 2000, prepared without any patient identifying information such as names, addresses, zip codes, state of residences, phone numbers, HMO membership information or center of examination for each patient
  - Each patient should [be] identified by a randomly assigned number, just as presently done in the VAERS database;
- (2) In addition to providing the VSD database updated through 2000, the CDC needs to develop a protocol to allow external researchers have access to additional VSD datasets as the VSD database is updated on a periodic basis;
- (3) External researchers should be immediately given unrestricted access to VSD datasets containing raw VSD data from CDC publications that utilized VSD data, prepared without any patient identifying information. <u>If the CDC no longer has the raw VSD data, or if intermediate datasets from the studies no longer exist, the studies will never be able to be confirmed by independent researchers, then the published studies must be withdrawn from the peer-reviewed literature</u>."

Since the EIS meetings are held in the Spring (April) of each year, the preliminary findings of links between Thimerosal-preserved vaccine inoculations received and the subsequent increased risk of neurodevelopmental harm to the recipients could not have been presented in the 1999 EIS meeting.

According to the timeline provided by Dr. Frank DeStefano of the CDC to the IOM in 2004[6], the "Presentation of preliminary findings at EIS conference" occurred in April of 2000 at the EIS Conference in Atlanta, Georgia.

Therefore, King is at a loss as to why Willingham is discussing the 1999 EIS Conference.

Furthermore, see **APPENDIX A**, an e-mail with the subject "It just won't go away" [indicating a desire to get the link between Thimerosal exposure at one month and autism to "go away"], the draft Abstract in question was still being prepared by "Thomas Verstraeten, MD" ("Also attached my EIS abstract to get your input.") on Friday, 17 December 1999 for submission by Verstraeten to the 2000 EIS Conference and, *given the date of the e-mail*, was probably not submitted to the EIS Conference until early in 2000, after Verstraeten received input from "Robert Davis" and discussed the "RRs" [relative risks] based on the email's "Frank proposes we discuss this on a call after New Year"[7].

"In 1999, one Thomas Verstraeten and three colleagues submitted an abstract for the EIS conference. It was preliminary, as many, many such submitted abstracts are. They indicated 'no strong preference for a poster presentation', which means that they were OK with getting up in front of the conference attendees and discussing their findings on the

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[5] http://www.iom.edu/~/media/Files/Activity%20Files/HealthServices/NIPDataSharing/DeStefano102004.ash, slide 17 (emphasis added),

"Chronology

- 9/99: "Thimerosal working group" identified VSD study as priority
- 9 - 10/99: Protocol developed in collaboration with [T]himerosal working group and VSD PIs
- 11/99 - 2/00: Preliminary data analyses
- 3 - 4/00: VSD discussions of preliminary findings
- 4/00: VSD annual meeting: alert NIP leadership about preliminary findings (associations with speech or language delay, any developmental delay, ?ADHD)"

[6] http://www.iom.edu/~/media/Files/Activity%20Files/HealthServices/NIPDataSharing/DeStefano102004.ash, slide 18 (emphasis added),

"Chronology (cont'd)

- 4/00: Presentation of preliminary findings at EIS conference
- 4/27/00: Briefing for CDC Associate Director for Science
  - Convene review panel of CDC scientists
- 5/2/00: CDC scientific review panel – Evidence weak but should be explored further
  - Recommendation to replicate in independent data set
- 6/7-8/00: External experts review (Simpsonwood)
  - Evidence weak but should be explored further along several lines of inquiry (including replication in an independent database, and neurodevelopmental testing study)"

[7] The probable reason for the need for a "call" was that Dr. Davis was on outside consultant to the CDC and the vaccine manufacturers.

record. The zombie-like story making the rounds would have you believe that submitting the abstract 'required the approval of top CDC officials prior to its presentation at the Epidemic Intelligence Service (EIS) conference,' but *all* conference abstracts require approval from the people running the conference–which, in this case, was the CDC."

Again, King is at a loss to understand why Willingham is making these statements.

From the DeStefano "Chronology", in the March-April 2000 time-frame, we can see that these preliminary findings were being discussed internally within the VSD researchers.

Moreover, in April of 2000, before the EIS meeting, the researchers did "alert NIP leadership about preliminary findings (associations with speech or language delay, any developmental delay, ?ADHD" and, *since the preliminary findings were then presented at the EIS*, obviously had permission to present their preliminary findings at the EIS.

Next, Dr. DeStefano's "Chronology (cont'd)" clearly shows that the "Preliminary Findings" reflected in the draft Abstract obtained pursuant to FOIA [U.S. Freedom of Information Act] requests and legal actions, aided by a Congressional Representative's office[8], were probably presented in the April 2000 EIS Conference.

"The authors report using raw data from the Vaccine Safety Datalink and HMOs in the Pacific northwest to identify mathematical relationships between [T]himerosal-containing vaccines and developing neurological and renal impairment ([T]himerosal is a preservative that contains ethylmercury and prevents dangerous contamination of large volumes of vaccine. It currently is present in multidose vials of flu vaccine). In their comparison of what they call the 'highest exposure group' to an 'unexposed group,' they reported an increased risk for nondegenerative neurological disorders."

Ignoring the Statistically Significant Thimerosal-Autism Linkage Reported in the Key Draft Abstract for the 2000 EIS Conference

Obviously, *although she reported some of the general information in the draft Abstract in question*, Dr. Willingham did not report the factual findings reflected in the draft Abstract and, it would seem that her actions knowingly omitted the findings reported in the draft Abstract in question.

Factually, the draft Abstract reported (with emphasis added),

"Verstraeten, Thomas M., MD, NIP, Division of Epidemiology and Surveillance, Vaccine Safety and Development Branch, Mailstop E-61, 770-639-8327.

[8] "CDC Epidemic Intelligence Service (EIS) annual conference abstract submission for the EIS conference in April 2000, discovered in August of 2013 in a CDC response to a Congressional Request by an office in the U.S. House of Representatives - the abstract submission is titled, "Increased risk of developmental neurologic impairment after high exposure to [T]himerosal-containing vaccine in first month of life", which was posted on the CoMeD website in 2013.

EIS Class Year of Entry: 1999
No previous EIS Conference presentations
Mackel Award consideration: No
Number of abstracts submitted: 2, priority this abstract: 1
Strong preference for poster presentation: No

Thomas M. Verstraeten, R. Davies, D. Gu, F DeStefano

Increased risk of developmental neurologic impairment after high exposure to [T]himerosal-containing vaccine in first month of life.

Background: Concern has risen on the presence of the ethylmercury containing preservative thimerosal in vaccines. We assessed the risk for neurologic and renal impairment associated with past exposure to [T]himerosal-containing vaccine using automated data from the Vaccine Safety Datalink (VSD). VSD is a large linked database from four health maintenance organizations in Washington, Oregon and California, containing immunization, medical visit and demographic data on over 400,000 infants born between '91 and '97.

Methods: We categorized the cumulative ethylmercury exposure from [T]himerosal-containing vaccines after one month of life and assessed the subsequent risk of degenerative and developmental neurologic disorders and renal disorders before the age of six. We applied proportional hazard models adjusting for HMO, year of birth, and gender, excluding premature babies.

Results: We identified 286 children with degenerative and 3702 with developmental neurologic disorders, and 310 with renal disorders. The relative risk (RR) of developing a neurologic development disorder was 1.8 (95% confidence intervals [CI] = 1.1-2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 µg) to the unexposed group. Within this group we also found an elevated risk for the following disorders: autism (RR 7.6, 95% CI = 1.8-31.5), non organic sleep disorders (RR 5.0, 95% CI = 1.6-15.9}, and speech disorders (RR 2.1, 95% (1=1.1-4.0). For the neurologic degenerative and renal disorders group we found no significantly increased risk or a decreased risk. ...."

Clearly, that preliminary analyses had found a highly significant linkage between Thimerosal exposure and the subsequent risk of an autism diagnosis in children "(RR 7.6, 95% CI = 1.8-31.5)".

Unfortunately, these results cannot be independently verified because, *as reported earlier*, the CDC "lost" the underlying datasets.

"Conference abstracts and the accompanying data are almost always preliminary. In fact, the likelihood that conference material and what finally appears in a peer-reviewed journal will differ is quite high. Much conference material never appears in a full, peer-reviewed article at all because completion of the study yields the much-dreaded 'negative results.'"

While Willingham's comments are generalizations that may be true in many cases, in this instance, her comments are inapplicable because the exact assessment reported in the draft EIS Abstract (emphasis added),

> "We categorized the cumulative ethylmercury exposure from [T]himerosal containing vaccines after one month of life and assessed the subsequent risk of degenerative and developmental neurologic disorders and renal disorders before the age of six",

was not repeated with an "unexposed group" as the comparison basis in any of the subsequent iterations of the CDC ("Verstraeten") study, which went on to analyze these relationships in other manners, but, *based on all of the CDC's concealed records uncovered to date*, did not again revisit this one.

Thus, though not published in any peer-reviewed journal and not capable of being independently confirmed, these findings stand above Dr. Willingham's empty rhetoric as inconvenient findings that the CDC has clearly hidden from the American public from April of 2000 into late 2013 when, *under pressure from multiple FOIA actions and Congressional intervention*, the particular "draft Abstract" document was finally produced by the CDC.

Consequently, the preceding facts clearly indicate that the CDC had apparently "concealed" the cited "draft Abstract" from the public for *more than* 13 years.

"The year of the EIS conference, 1999, was a turning point for [T]himerosal in vaccines. And then in 2000, the Simpsonwood Conference took place, an assemblage of experts from inside and outside the CDC to discuss the [T]himerosal issue. The entire transcript of that conference is available here. Verstraeten was in attendance and presented on the data related to the not-even-remotely concealed results from his two-phase study. One thing he noted–and this issue probably is one of many that drives differences between a conference abstract and a final publication–was variability related to the HMOs gathering the data. Those differences mattered to the outcomes and had nothing to do with [T]himerosal."

If One Cannot Attack the Findings Reported, Change the Subject — The By-invitation-only June 2000 Simpsonwood Conference

Since these preliminary findings were clearly presented at the April 2000 EIS conference, King suggests that the reader simply ignore Willingham's initial statement, as it has no bearing on the issue of the information presented in the April 2000 EIS Conference.

Second, Willingham's,

> "*in 2000, the Simpsonwood Conference took place, an assemblage of experts from inside and outside the CDC to discuss the [T]himerosal issue*"

conceals a darker reality that this June 2000 meeting was an apparently illegal, definitely secret, by-invitation-only meeting because neither all of the qualified experts in the government, academia and independent research organizations nor the members of the public

were given adequate notice that this meeting was to be held nor were they, the public or the media allowed to attend this meeting.

When experts representing diverse interests (State and foreign health officials, consultants, academics, and interested-party corporations) outside of federal agencies are formally meeting with governmental officials to discuss issues bearing on the public interest, by law[9], the general public is supposed to be:

- Given adequate notice of such meetings, which should be published in the ***Federal Register*** or, *when appropriate*, elsewhere, and
- Allowed an opportunity to attend such meetings.

Thus, we have an "*assemblage of experts from inside and outside the CDC*", including FDA representatives, consultants, representatives from certain vaccine manufacturers, consultants, and officials from outside health agencies (State and foreign), meeting in secret to discuss how they were going to manage the inconvenient findings from certain iteratively derived VSD analyses.

Next, Willingham states,

> "*The entire transcript of that conference is available here"* (at this Internet location http://skeptico.blogs.com/Simpsonwood_Transcript.pdf [also available at http://www.scribd.com/doc/2887572/Simpsonwood-Transcript20Searchable]).

Alas, though called a "*transcript*" and probably a report derived from a "*transcript*", the document in question is not a legal "*transcript*".

This is the case because, *to be a legal "transcript*", each line on each page would have had to have been numbered in the left margin and the name of the transcriptionist included in the footer with his or her complete certification at the end of the transcript as has been the case for the transcripts that King has received from other governmental meetings that he has attended or from which he has received a transcript.

However, contrary to his experience with other federal meeting documents represented to him as a "transcript" of those meetings, Dr. King found no line numbers or transcriptionist's name or certification in the cited document.

Lacking the required certifications, there is no way that anyone can *unequivocally* state that the document linked to her article by Dr. Willingham is "*[t]he entire*" document.

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[9] 5 U.S. Code § 552b - Open meetings, and any other derivative statutes and regulations that apply to meetings held and/or attended by CDC and/or FDA personnel in their official capacities, where general industry, consultant and/or foreign regulatory officials are invited to attend.

Next, Willingham asserts,

"*Verstraeten was in attendance and presented on the data related to the not-even-remotely concealed results from his two-phase study*".

However, since the "*data*", which Verstraeten presented, are not contained in the supposed "*transcript*", how can she, or anyone, know what exactly was the information Verstraeten presented or that the "*transcript*"/report did not omit some of Verstraeten's remarks?

Furthermore, since no one from the public was allowed to attend this meeting and the "*transcript*"/report was not made available to the public immediately after the meeting, clearly all of the results presented were being concealed from the public.

In addition, Verstraeten left the CDC shortly after this meeting to take a position with a European vaccine manufacturer.

Moreover, all of the meeting attendees were told that what they had heard was to "embargoed" (to be kept secret from both the public and their colleagues).

Finally, Willingham stated,

"*One thing he noted–and this issue probably is one of many that drives differences between a conference abstract and a final publication–was variability related to the HMOs gathering the data. Those differences mattered to the outcomes and had nothing to do with [T]himerosal*".

Since Dr. Willingham does not represent herself to be an epidemiologist nor a biometrician nor even a statistician, Dr. King will overlook her apparent naiveté here.

However, having multiple HMOs, now called MCOs, each with multiple clinics from which to choose, the "*variability related to the HMOs gathering the data*" cited was something that the researchers deliberately allowed by, *for example*, not restricting the clinics in the HMOs studied to those clinics that used the same data gathering practices.

Thus, this study choice bears on the hiding of the signal for a Thimerosal linkage to autism by apparently allowing the knowing addition of data-gathering "uncertainty" to the data.

In addition, although not mentioned by Willingham, the *ad hoc* data-manipulative phase III (called "Phase I: HMOs A and B" in the published CDC ["Verstraeten"] study) and a phase IV analysis of another HMO's data (called "Phase II: HMO C" in the published CDC ["Verstraeten"] study, which contained even more children too young to be reliably diagnosed) were not phases defined in Verstraeten's original study design.

That excess of younger children in HMO C had the effect of: **a)** reducing the percentage of autism cases in HMO C's population and **b)**

increasing the statistical noise in the controls, because many of the controls were too young to be reliably classified (since the average age for an "autism" diagnosis is about 4.5 years).

The impact of that confounding of the data has been partially addressed in a recent paper studying the linkage between Thimerosal exposure(s) and the risk of a subsequent diagnosis of "autism" using the available anonymized VSD records through 2000[10].

That recent VSD study found that there were highly significant linkages between Thimerosal exposures from Thimerosal-preserved hepatitis B vaccination at:

- One (1) [Odds Ratio (95% Confidence Interval {CI}) and p-value of "2.18 (1.74-2.73)" and "< 0.00001"],
- Three (3) [Odds Ratio (95% CI) and p-value of "2.11 (1.68-2.64)" and "< 0.0001"], and
- Six (6) [Odds Ratio (95% CI) and p-value of "3.39 (1.60-7.18)" and "< 0.001"]

months of age and the children's risk of subsequently being diagnosed with autism as compared to the risks for children who did not get a Thimerosal-preserved hepatitis B vaccine inoculation.

In addition, that recent study in the VSD reported that the mean age for an "autism" diagnosis was "4.2" years of age with a standard deviation of "1.54" years.

Disinformation: Verstraeten's Presentation on Other Studies

"In his presentation at the Simpsonwood conference, Verstraeten noted,

> This is the result for autism, in which we don't see much of a trend except for a slight, but not significant, increase for the highest exposure. The overall test for trend is statistically not significant."

Lacking the ability to see the data and the manner in which it had been derived, no one can accurately assess the import of the findings reported at the Simpsonwood conference by Thomas Verstraeten.

Moreover, based on the "Generation Zero" report by SafeMinds, which reflected information that SafeMinds had obtained on the early Thimerosal-preserved vaccine studies in the VSD by the CDC ("Verstraeten") under the U.S. Freedom of Information Act of 1955 as amended (FOIA)[11], it is obvious that the data ranges in the published

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[10] Geier DA, Hooker BS, Kern JK, King PG, Sykes LK, Geier MR. A two-phase study evaluating the relationship between Thimerosal-containing vaccine administration and the risk for an autism spectrum disorder diagnosis in the United States. *Translational Neurodegeneration* 2013 Dec. 16; 2:25 (12 pages).

[11] http://www.safeminds.org/research/library/GenerationZeroPowerPoint.pdf, last accessed on 3 March 2014.

paper for the Thimerosal exposures had been changed from "0" for those receiving no Thimerosal exposure to some confounded/grouped higher level of exposure (e.g., 0-25 µg of mercury at 3 months and 0-75 µg of mercury at 7 months), and the upper limits reduced and confounded by grouping all of the highest exposures at essentially 62.5 micrograms of mercury at 3 months and all exposures of 175 µg of mercury or higher at essentially 175 µg of mercury at 7 months, which had the effect of halving the calculated "ranges" of the exposure variable at each time point while adding in uncertainty by grouping children with differing exposures together.

Thus, having effectively compressed the available exposure variable's range from "0 – 200" µg of mercury to "25 – ≥ 62.5″ at three (3) months and "75 – ≥ 175″ at seven (7) months and grouping the data into the stated three (3) clusters, one would expect the "*trend*" evaluated in the analyses on which Verstraeten presented at Simpsonwood to be considerable less statistically significant than if this grouping and range reduction had not been implemented.

Furthermore, King emphasizes that findings apparently discussed in the Simpsonwood report did not directly address the findings reported in the draft Abstract nor the study analysis presented at the 2000 EIS Conference, which did not group the different levels of Thimerosal exposure and apparently used "0″ µg of mercury (no exposure) as the basis point to which an "RR" [relative risk] of "1.00" was assigned.

"Later in the presentation, we learn that phase I of the study looked only at raw numbers from a database while phase II involved chart examination to confirm diagnoses and added in an HMO. The second phase involved new data following on the study described in the 1999 abstract. This chart review matters. As one of the other authors on the 1999 abstract notes in the Simpsonwood presentation:

> Now with autism, if we limit it to children with exposure at either one month or three months of age... there is a relative risk that is no different than one and that is replicated whether we limit it to children with a diagnosis mentioned in the chart where the child was referred to a specialist, or the child was confirmed by a specialist."

One of the fundamental rules of scientifically sound epidemiological study is that one cannot deviate from the original design, which was to do the screening analyses (phase I); then, do a full chart review (phase IIa) and a case-control study (phase IIb) using the subjects with confirmed charts; and, finally, report the findings of the case-control study using those subjects whose diagnoses had been confirmed by chart review!

In place of doing what the original study design required be done and nothing more, *after finding statistically significant evidence of a link between the child's Thimerosal exposure and the child's subsequent risk of an autism diagnosis*, the study deviated from its design, and did not do a full chart review or a case-control study.

Instead, the CDC researchers started further manipulating the datasets for two (2) of the available HMOs ["HMO A" and "HMO B"] (after apparently eliminating two [2] of the four [4] HMOs available for the initial analysis discussed in the 2000 EIS Abstract).

When that alteration was not enough to obscure the original CDC two-phase study, which they had abandoned, the CDC researchers:

- Included another HMO ("HMO C"): one that, *because many of its children were under 3 years of age*, was known to have the effect of diluting the cases because the average age of diagnosis for autism is about 4.5 years and
- Used its analysis as the second phase in the published study (see footnote "**3**"). .

Moreover, for "HMO C", the paper did not even report a relative risk (RR) for "Autism" (footnote "**3**", "TABLE 6. RRs by Increase of 12.5 µg of Hg Exposure From TCVs at HMO C").

Finally, the information in the draft Abstract, which is not dated so that we cannot know whether it was completed very late in 1999 (after mid-December 1999) or, more probably, early in 2000, was apparently not discussed.

The "1999" on the draft Abstract document, produced by the CDC in 2013, refers to the "EIS Class" to which Dr. Verstraeten belonged.

Furthermore, there is no evidence that there was a significant variance between the diagnosis in the original HMOs' records and the chart review's diagnosis for the few children whose records were evaluated even though, *as stated previously*, after the initial analysis reported in the EIS Abstract, two (2) of the original four (4) HMOs available for the initial analysis were apparently excluded from the further analyses in the CDC (called "Verstraeten") study.

Finally, since, at that time, children received Thimerosal-preserved vaccines at 0-1 month, 2-4 months, 4-6 months and 6-18 months as well as later, the quoted passage is not relevant to the actual experience of the children included in the CDC's Thimerosal study, who generally received *more than* one dose of at least two (2) Thimerosal-preserved vaccines at about 2, 4 and 6 months of age in

addition to an earlier ("birth dose") inoculation with a Thimerosal-preserved hepatitis B vaccine.

"In other words, the chart review refined the original raw data and effaced any finding of increased risk. ETA: If you're feeling wonkish, writer Lindsay Beyerstein elaborated at length in 2005 on the Simpsonwood conference and the limitations of the presented study."

Dr. Willingham's statements here should simply be ignored because all of the partial chart review did was to confirm that the diagnoses in the computerized databases were generally accurate.

If the reader wishes to know more about flaws in the CDC studies conducted under Dr. Verstraeten's remit, other than those mentioned in this rebuttal, then, Dr. King suggests reading the Internet web file, http://www.ashotoftruth.org/critique-6-epidemiology-studies-cdc-uses-claim-[T]himerosal-not-linked-autism.

The preceding article cited by King also provides in-depth insights into how the CDC oversaw the cited six (6) studies to obtain "desired" outcomes that "exonerated" Thimerosal as a causal factor for "autism" but still did not *completely* exonerate Thimerosal for the class of neurodevelopmental disorders called "Tics", which includes children with Tourette's syndrome.

"In spite of the openness of this process and the adherence to an original two-phase plan for the study, Verstraeten found himself (and continues to find himself, it seems) the target of accusations of manipulating or hiding data, particularly when the peer-reviewed paper from this study was published in 2003 (abstract here)."

A Further Divergence from the Key Abstract's Findings — Thomas Verstraeten's 2004 Letter to the Editor

In Willingham's alternate world, "*the openness of this process*" is defined by:

- **a.** An apparently illegal, by-invitation-only meeting,
- **b.** Embargoed findings that, as far as King can ascertain, differ significantly from the published results, and
- **c.** A reporting document represented as a "transcript" when, *legally*, it is not.

Similarly, Willingham claiming that the study adhered "*to an original two-phase plan*" is clearly at odds with the facts – the "*original two-phase plan*" was abandoned and a different, *ad hoc*, iterative process was used to fashion a new "*two-phase plan*" that was presented in the published study.

Moreover, Willingham misrepresents "*the target of accusations of manipulating or hiding data, particularly when the peer-reviewed paper from this study was published in 2003*" because the target was, and is, the CDC, which even knowingly published the paper in 2003 as if Thomas Verstraeten were still a CDC employee even though he had left the CDC in mid-2000.

"His having gone to work for 'Big Pharma' –in this case, GlaxoSmithKline **GSK** -0.94%– following completion of his appointment at the CDC brought further accusations of complicity in a cover-up. Indeed, the accusations were so hot that Verstraeten responded to them in a 2004 commentary published in Pediatrics, recounting the history. Bottom line was, he was a foreign citizen whose fellowship with the CDC was ending, and he sought and obtained employment in his home country, in his field."

Here, Dr. Willingham begins by mischaracterizing Verstraeten's response as a "*commentary*", when it was clearly a letter to the editor, "Thimerosal, the Centers for Disease Control and Prevention, and GlaxoSmithKline *To the Editor.—*"[12]

In this letter, Verstraeten clearly admits that the two-phase study did not follow "the original plan",

> "Whereas the original plan was to conduct the second phase as a case-control study, we soon realized this would be too time consuming."

He also claims that he was responsible for the inclusion of "HMO C" and, earlier, that he was "responsible for nearly all aspects of this study, including study design, data gathering, data analysis, and writing of the article".

Based on these statements, it is clear that the published *ad hoc* iterative study repeatedly violated the fundamental tenets of scientifically sound epidemiology and seems to render his protestations as to lack-of-intent-to-deceive on his part, or that of his colleagues at the CDC, or the CDC itself, highly doubtful, to say the least (see, the e-mails in appendices "**A**" and "**B**", which clearly indicate that the analyses performed seem to have been "steered" to a desired "no link" outcome).

Actually, it would seem that, to ensure his career path went the way he wanted it to, Verstraeten, aided by his fellow researchers at the CDC, knowingly deviated from fundamental epidemiological principles in order to get a "desired" result.

"In his 2004 commentary (which is behind a paywall), Verstraeten says, 'Did the CDC water down the original results? It did not.'"

Since Verstraeten opens his remarks with

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[12] Verstraeten T. Thimerosal, the Centers for Disease Control and Prevention, and GlaxoSmithKline, *Pediatrics* 2004; 113: 932.

> "I am the first author of a recent article on a study undertaken by the Centers for Disease Control and Prevention (CDC) to screen for a potential link between [T]himerosal-containing vaccines and neurodevelopmental delays",

why did he *unethically* allow the CDC to misrepresent his current place of employment as the CDC when he had left the CDC *more than* two (2) years before the paper was published?

Why did he, or CDC personnel, want to conceal his employment at GlaxoSmithKline when they published the 2003 paper?

Second, if, as he claims (emphasis added),

> "Because I was responsible for nearly all aspects of this study, including study design, data gathering, data analysis, and writing of the article, I wish to give my opinion on these claims. These are my personal opinions and do not represent the opinion of the CDC or GSK",

for which aspects of the 2003 paper in ***Pediatrics*** was he not responsible?

Moreover, accepting that his response,

> "Did the CDC water down the original results? It did not."

is truthful, then, *since it is clear that the original findings were repeatedly watered down*, he and/or one, or more, of his colleagues must have been the person or persons who watered down "*the original results*".

Finally, based on internal e-mails (see, for example, the e-mail in **APPENDIX A**) that have been obtained from the CDC under FOIA, it is clear that Verstraeten sought help to "make his initial findings go away" as well as felt pressured to "water down" his original findings (see, for example, the e-mail in **APPENDIX B**).

"He goes on to write

> The CDC screening study of [T]himerosal-containing vaccines was perceived at first as a positive study that found an association between [T]himerosal and some neurodevelopmental outcomes. This was the perception both independent scientists and antivaccine lobbyists had at the conclusion of the first phase of the study. It was foreseen from the very start that any positive outcome would lead to a second phase."

While Dr. King agrees that this is what Dr. Verstraeten wrote, the reality that the only "second phase", according to the study he claims to have "designed", was supposed to be a case-control study after a chart review of all of the medical charts of the cases and the controls – which was started, but not completed.

Moreover, the original case-control study was not conducted.

"In other words, when you dig into raw numbers and find some mathematical relationships, then you have a reason to move to the second planned phase of examining the charts. If you don't find anything, phase II is a non-starter."

Apparently, Willingham is back in her alternate world because, as reported in the draft Abstract, the original "*CDC screening study of [T]himerosal-containing vaccines*" study did find a link between Thimerosal exposure and the subsequent risk of an autism diagnosis ("RR = 7.6"), which, in a subsequent article[13], Willingham clearly acknowledges even though she incorrectly refers to this result value as if it were "data".

Moreover, both here and in her second article, Dr. Willingham attempts to downplay the significance of the draft Abstract and evidence that those findings were presented at the April 2000 EIS Conference in Atlanta.

However, unlike the prior reportings of the "RR = 7.6" value, which she accepts as factual, the draft Abstract and the related evidence demonstrate that this information was discussed at the April 2000 EIS conference and, therefore, was not just some unpublished finding.

In addition, some chart reviews were done and, when no significant discrepancies were found, the chart review (phase IIa) was stopped – possibly because the initial reviews found no discrepancies that could be used to discredit the original findings.

However, instead of performing the predesigned (phase IIb) case-control study as called for in the original study plan, the existing datasets were massaged, altered and different analyses were *iteratively repeated* with the apparent goal, based on the graphs obtained under FOIA for various time points, of reducing the statistical significance of the linkage between the level of Thimerosal-exposure and the subsequent risk of an "autism" diagnosis (an epidemiologically invalid, *iterative* "phase III" procedure by which the datasets and analyses were repeatedly adjusted with the obvious goal of reducing the resultant relative risk value for "autism" until it was not significant).

When the statistical significance had been sufficiently reduced, another HMO, which had records keeping problems, used a different

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[13] http://www.forbes.com/sites/emilywillingham/2014/03/01/who-was-first-with-shocking-cdc-autism-data/, last accessed on 2 March 2014, underlining added by Dr. King, "The presentation cites on slide 41 these same "long-awaited" data, from an "unpublished study obtained through FOIA (freedom of information act)" request. For those not wanting to download the PowerPoint–although it certainly is an interesting walk through how the mercury-vaccines-autism argument solidified–here's what slide 41 says:

Recently rediscovered. First run of the numbers. Very high relative risks for outcomes.
Autism RR = 7.6
UNPUBLISHED STUDY OBTAINED THROUGH FOIA

Italics mine. This slide was presented in January 2005 and specifically references the "recently rediscovered" data as resulting from a "first run of numbers.""

coding scheme, and had an excess of children too young to be properly diagnosed, was introduced and a similar confounded study design used to evaluate that HMO's data (phase IV) in order to have a second phase.

Furthermore, all of these machinations did reduce the statistical significance of the link between Thimerosal exposure and subsequent risk of an "autism" diagnosis (which the final/published study analyses did not even explicitly report in all instances) though some of the linkages between Thimerosal exposure and "Tics" ("HMO A") or "Language delay"("HMO B") were still statistically significant, even though the significance of those relative risks (RRs) were minimized by expressing those results in terms of "RRs by Increase of 12.5 µg of Hg Exposure From TCVs" instead of a per-"nominal" total scheduled dose exposure.

In addition, instead of making the least-exposed group those with no exposure to a Thimerosal-preserved vaccine, the paper reported that the researchers lumped the data together in categories, "0-25" µg of mercury, which was defined as having a relative risk of "1.00"; "37.5-50" µg of mercury; and "≥ 62.5" µg of mercury for the 3-months analyses shown in the paper's "TABLE 5. RRs by Category of Cumulative Hg Exposure at 3 and 7 Months" thereby reducing the effective range of exposures to "25" to "62.5" µg of mercury with an effective range of 37.5 µg of mercury when the actual range was at least "75" µg of mercury – effectively compressing the actual range by about 50%.

Similarly, at "7 months", the lowest level was "0-75″ µg of mercury with an assigned relative risk of "1.00" and the other levels were "87-162.5″ µg of mercury and "≥ 175″ µg of mercury, which also effectively reduced the Thimerosal-related mercury range of from "0" to about "200" µg of mercury to a range of from 75-175 µg of mercury or 100 µg of mercury – similarly compressing the actual range by about 50%.

Clearly, those choices were intentionally made to minimize the probability of finding any significant effects.

Non-science: Goal-directed Iterative Epidemiological Study

"He then notes

> Because the findings of the first phase were not replicated in the second phase, the perception of the study changed from a positive to a neutral study. Surprisingly, however, the study is being interpreted now as negative by many, including the anti-vaccine lobbyists. The article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended, which is the conclusion to which a neutral study must come."

Having examined most of the available information on these multiple, iteratively defined analyses miscast as a "single study" and seen some of the internal e-mails, especially the July 14, 2000 e-mail from Dr. Verstraeten to Dr. Phillippe Grandjean (see **APPENDIX B**), Dr. King has reached the conclusion that an *ad hoc* phase IV study, misrepresented here as "*the second phase*", was conducted using the same data distortions (grouping and stratification) knowing that it would did not replicate "*the findings of the first phase*", alluded to in the published paper, which was actually phase III of the studies conducted by Verstraeten, et al.

This distortion of sound science led to his reported outcome, "*additional study is recommended, which is the conclusion to which a neutral study must come*".

However, see footnote "**10**", a recent independent study analyzing records in the VSD in the same time period that records were available for the CDC ("Verstraeten") study and found multiple statistically significant linkages between the children's Thimerosal exposure and the subsequent risk of an autism diagnosis using a cohort study design, where the risks for autism in children receiving a Thimerosal-preserved hepatitis B vaccine were compared to the risks for autism in children who received no hepatitis B vaccination or a no-Thimerosal hepatitis B vaccine.

A Government "Investigation" Designed to Placate the Constituents

"Perhaps you don't want to take Verstraeten's word for it because he went to work for Big Pharma. Those who oppose vaccines often rely on the US Congress, for better or for worse, to make their arguments. So, here's a link to the findings of the Senate Committee on Health, Education, Labor and Pensions from their 2007 investigation into allegations that the CDC used Simpsonwood to cover up a [T]himerosal-autism link and that Verstraeten manipulated data.

Here's what the Senate committee concluded regarding allegations against Verstraeten:

> Allegation # 2: The Centers for Disease Control (CDC) convened the Simpsonwood Conference to cover up the finding that [T]himerosal causes autism.
> Findings: The allegation is not substantiated. ... Instead of hiding the data or restricting access to it, CDC distributed it, often to individuals who had never seen it before, and solicited outside opinion regarding how to interpret it. The transcript of these discussions was made available to the public. The data was also discussed at the Advisory Committee on Immunization Practices, a public forum held on June 21 and 22, 2000. Simpsonwood participants generally agreed that the VSD data set was weak, it was difficult to assess causality, and further study and investigation were warranted.

Not exactly the behavior of government scientists bent on a cover-up."

First, King notes that the CDC is not run by "*government scientists*" but rather mostly by pro-industry administrators and bureaucrats.

Second, holding a secret meeting at Simpsonwood, a church retreat in Norcross, Georgia, where only certain people are invited to attend, and the public was apparently illegally excluded, seems to be the actions of a governmental agency, to use Willingham's words, "*bent on a cover-up*".

To tell the people at the conference that the information shared there was "embargoed" seems to be the action of a governmental agency "*bent on a cover-up*".

The 2007 committee's spin, "*Instead of hiding the data or restricting access to it, CDC distributed it, often to individuals who had never seen it before, and solicited outside opinion regarding how to interpret it*", ignores at least two (2) established facts:

- "Public" access to the "*data*", upon which the various reported findings rest, has never been provided — instead when access to the "*data*" was sought, the CDC claimed it had "lost" the "*data*" (see footnote "**2**"); and
- The information that the public has "seen" was only obtained some time after the fact by groups, who were forced to submit FOIA requests, which, as has been discovered, were incompletely answered.

Moreover, the assertion,

"*The transcript of these discussions was made available to the public*",

is at odds with the fact that what was furnished to the public was a "report" and not a copy of an original legal transcript of the meeting, which would have had line numbers in the left-hand margin of each page with an appropriate transcriptionist's footer and a certification on the last page signifying that the transcript was complete and accurate.

Finally, the statements,

"*The data was also discussed at the Advisory Committee on Immunization Practices, a public forum held on June 21 and 22, 2000. Simpsonwood participants generally agreed that the VSD data set was weak, it was difficult to assess causality, and further study and investigation were warranted*"

differs from reality in that,

1. Only some of the results found were discussed, and
2. Since: **a)** the Simpsonwood participants were staunch pro-vaccination supporters handpicked by the CDC; **b)** the meeting was held in secret; and **c)** the public was excluded, what else would one expect the participants to do but agree, "*that*

the VSD data set was weak, it was difficult to assess causality, and further study and investigation were warranted"?

Since the 2007 committee failed to subpoena all of the CDC's records on this matter, including all emails, and that investigation occurred seven (7) years after the fact, it seems obvious to Dr. King that this committee's investigation was not intended to substantiate any allegations but was rather intended to placate the demands of some of the Senators' constituents.

However, the Senate committee did report finding that two-plus of the allegations of impropriety were confirmed[14] (without the internal footnotes):

"Allegation # 1b: There were conflicts of interest among the members of the Immunization Safety Review Committee (ISR Committee) and the studies they relied upon.

Finding: The allegation is partially substantiated. While we identified shortcomings in IoM procedures for screening potential committee members for possible conflicts of interest, there is no evidence to support the allegation that the work of the IoM's ISR Committee was compromised by conflicts of interest. To evaluate this allegation the committee reviewed thousands of pages of documents relating to the background of the ISR Committee members and the IoM process for screening potential committee members for possible conflicts of interest.

A number of irregularities in the IoM screening process were identified. The irregularities include:

- Inconsistent exclusionary criteria.
- No verification of self-reported data.
- Inadequate documenting of the screening process.
- Inadequate screening of committee consultants for potential conflicts of interest.

While these shortcomings in the screening process call for corrective measures, there is no evidence to support the allegation that the work of the IoM's ISR Committee was compromised by conflicts of interest.

Allegation # 6: Thimerosal remains in childhood vaccines being supplied to third-world and developing countries.

Findings: The allegation is substantiated. The contention that [T]himerosal is used in vaccines provided to third-world and developing countries is accurate. According to the CDC, NIP, the vaccination of children in much of the world will continue to require the use of multiple-dose vials for reason of cost, production, and storage capacity.[13] The less expensive multiple-dose vials require the presence of a preservative. If developing countries were unable to buy the less expensive multiple-dose vials containing [T]himerosal, diseases would spread more rapidly. The position of the IoM is that: "given the lack of direct evidence for a biological mechanism and the fact that all well designed epidemiological studies provide no evidence of association between [T]himerosal and autism, it recommends that cost benefit assessments regarding the use of [T]himerosal-containing versus [T]himerosal-free vaccines, whether in the U.S. or other countries, should not include autism as a potential risk."[14]

Allegation #7: FDA inappropriately utilized Environmental Protection Agency (EPA) guidelines regarding the dangers of mercury in vaccines containing [T]himerosal.

Findings: The allegation is substantiated. In the spring of 1998, staff within the FDA's Center for Biologics Evaluation and Research (CBER) began to informally consider the increased number of recommended vaccines and the amount of substances, such as mercury, contained in them to which vaccine recipients were exposed. Section 413(a) of the Food and Drug Administration Modernization Act required the FDA to compile a list of drugs and food that contain "intentionally introduced" mercury compounds within two years of enactment.[15]

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[14] http://vaccines.procon.org/sourcefiles/Thimerosal_and_ASD_Enzi_Report.pdf, last visited on 24 February 2014.

> Available literature to help quantify the FDA's concern was limited.[16] The risk assessment that followed evaluated the potential for exposure to [T]himerosal and the amount of mercury by weight present in the vaccines. Because no guidelines existed for ethyl mercury exposures, the FDA used the guidelines for safe exposure to methyl mercury, formulated by EPA, as a guide for determining whether the dose from [T]himerosal in vaccines approached levels of concern.17 In July 1999, HHS agencies, the American Academy of Pediatrics (AAP), and vaccine manufacturers agreed that [T]himerosal should be reduced or eliminated in infant and childhood vaccines as a precautionary measure and to reduce human exposure to mercury from all sources.
>
> The use of inappropriate guidelines from EPA was a source of confusion and contention in determining the appropriate response to concern regarding [T]himerosal in vaccines. Nevertheless, the existing methyl mercury guidelines were the best information available at the time for assessing risk from ethyl mercury exposure.[18] This error has caused countless individuals to conclude that ethyl mercury can be linked causally to autism."

Additionally, a finding by a Senate congressional committee that: "*The allegation is not substantiated*" is <u>not</u> the same as a finding that the CDC did <u>not</u> act as alleged but rather, *based on the cursory look at the records and information provided to the committee*, the committee could <u>not</u> substantiate that the alleged action had occurred.

Moreover, the committee obviously ignored the illegal and secret nature of the Simpsonwood meeting.

"The committee also found that

> Allegation # 3: Dr. Thomas Verstraeten, MD, MSc, was pressured into changing his research position regarding a causal link between [T]himerosal and autism.
> Finding: The allegation is not substantiated. ... HELP Committee staff interviewed Dr. Verstraeten with regard to his findings and his participation in the Simpsonwood Conference. ...Review of the phases of Dr. Verstraeten's study, 'Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases,' and examination of his voluntary response to Committee questions during his interview reflect that his intention was always to conduct a two-phase study. ... there is no evidence that GlaxoSmithKline hired Dr. Verstraeten for the purpose of pressuring him to manipulate his data on a causal link between [T]himerosal and autism. ... Dr. Verstraeten was working in the United States at CDC on a temporary visa. Near the completion of his tenure with CDC, he began searching for employment in his native country and found employment with GlaxoSmithKline where he continues to be employed."

Here, King first notices that the Senate committee apparently failed to subpoena all of the CDC's e-mails that Verstraeten sent or received because, if they had, they would have found, as others have, clear evidence that he was being pressured to change the study to get the "desired" outcome (<u>see</u>, for example, the e-mails in appendices "**A**" and "**B**").

Since, in 2007, Verstraeten was working overseas, the statements,

"*HELP Committee staff interviewed Dr. Verstraeten with regard to his findings and his participation in the Simpsonwood Conference. …Review of the phases of Dr. Verstraeten's study, "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases," and examination of his voluntary response to Committee questions during his interview reflect that his intention was always to conduct a two-phase study*",

seem to indicate that the interview was probably by telephone and that the committee made little, or no, effort to subpoena, or otherwise collect, all of the e-mail Dr. Verstraeten sent and received.

Also, the statement,

"*examination of his voluntary response to Committee questions during his interview reflect that his intention was always to conduct a two-phase study*",

indicates that the committee failed to understand that the "second phase" study that he actually conducted was not the phase II study that his original study design called for (a case-control study after a full chart review) but rather an *ad hoc* phase III/IV study that:

a. Apparently did not include the data from two (2) of the original four (4) HMOs mentioned in the "draft Abstract";

b. Multiply manipulated the existing datasets from the two (2) "studied" HMOs;

c. Added a third HMO with record keeping problems, a different coding system, and an excess of younger children (3 years of age or less) to further diluted the cases effect and conducted a confounded study on its Thimerosal-autism linkage; and

d. Grouped and stratified the resulting data records until the linkage between Thimerosal exposure from a Thimerosal-preserved vaccine and the risk subsequently being diagnosed with autism became non-significant.

Finally, it should be obvious that, *had Dr. Verstraeten not gone along with the CDC's desire for a favorable outcome*, his chances of being gainfully employed by GlaxoSmithKline or any other vaccine manufacturer in Europe probably would have been diminished.

Willingham's Attempt to Rewrite History and the WHO's Fatally Flawed Non-science-based Position

"In spite of the neutral findings from Verstraeten's study, the US Public Health Service (USPHS) and the American Academy of Pediatrics (AAP) jointly recommended in 1999 that [T]himerosal should be phased out of use in the handful of childhood vaccines that included it. In the wake of considerable further study showing no link between [T]himerosal and developmental disorders, that recommendation was retired in 2002. Now, say AAP doctors in a 2012 commentary:

Had the AAP (and, we suspect, the USPHS) known what research has revealed in the intervening 14 years, it is inconceivable to us that these organizations would have made the joint statement of July 7, 1999. The World Health Organization recommendation to delete the ban on [T]himerosal must be heeded or it will cause tremendous damage to current programs to protect all children from death and disability caused by vaccine-preventable diseases."

Here, Dr. Willingham begins by attempting to rewrite history.

First, the 1999 joint recommendation was made in July of 1999.

Second, the CDC's VSD studies involving Thimerosal-preserved vaccines and autism and other neurodevelopmental disorders did not start until November of 1999 and the initial analyses were not available until early 2000.

Third, the CDC's published study (Verstraeten, et al. 2003) did not assert that the published study's findings were "*neutral*" but rather, in its "Abstract" concluded,

> "No consistent significant associations were found between TCVs and neurodevelopmental outcomes. Conflicting results were found at different HMOs for certain outcomes. For resolving the conflicting findings, studies with uniform neurodevelopmental assessments of children with a range of cumulative [T]himerosal exposures are needed".

Fourth, the word "neutral" is not even used in the CDC's 2003 "Verstraeten" paper (see footnote "**3**").

Fifth, the phrase "*neutral findings*" does not occur in Verstraeten's 2004 letter to the editor, which contains the word "'neutral'" (once) and the phrases, "neutral study" (3 times) and "neutral outcome" (once) (see footnote "**12**").

Thus, in 1999, there is no way that the non-existent "*neutral findings from Verstraeten's study*" could have had any impact on the issuing of the referenced joint statement.

With respect to the rest of Willingham's statements, those statements should be ignored because the information upon which the World Health Organization's (WHO) Global Advisory Committee on Vaccination Safety (GACVS) relied in reaching its published conclusions is, and was, fatally flawed[15].

Specifically, questionable blood clearance half-life data for ethylmercury species was improperly used as a surrogate for the body clearance half-life data for Thimerosal's mercury-containing metabolites; the bioaccumulative toxicity of Thimerosal and its metabolites in

[15] http://mercury-freedrugs.org/docs/20120928_CoMeD_WHO_GACVS_UNEPINC5Submission_ReviewOfGACVSJune2012ReportOnSafety_ThimerosalInVaccines_rev1b.pdf with reference "21" being found at: http://mercury-freedrugs.org/docs/20120928_Footnote_21_inCoMeD_GACVSRevu_FDA_CBER_MarionJ_GruberPhD_PreclinicalReproductiveToxStudies_forVaccines_b.pdf .

the primate brain was ignored, and a 2009 NOAEL [No-Observed-Adverse-Effect Level] for injected Thimerosal in developing human children, which was estimated to be *less than* o.oo86 micrograms of Thimerosal per kilogram of body weight (per day)[16], was not even considered.

Misplaced WHO Priorities: Putting Protecting the Status Quo for Vaccination Programs Ahead of Protecting the Overall Health of the World's Children

With respect to the WHO's

> "*recommendation to delete the ban on [T]himerosal must be heeded or it will cause tremendous damage to current programs to protect all children from death and disability caused by vaccine-preventable diseases*",

Dr. King notes that the WHO's statement seems to be focused more on preventing "*damage to current programs*" for vaccination than it is focused on protecting the overall health of the world's children.

Furthermore, King respectfully notes that the overall harm caused by the chronic medical conditions that are being caused, and will continue to be caused, by the use of Thimerosal-preserved vaccines is *significantly more than* 10 times the harm from the acute childhood diseases that the WHO represents as "*vaccine-preventable diseases*" even though, in the USA, the manufacturers' package inserts for these vaccines not claim that these vaccines prevent disease.

Instead, the vaccine makers' package inserts indicate that:

a. Vaccines produce some "sufficient" level of purportedly disease-protective antibodies, or, *in the case of the "pertussis"-component-containing vaccines*, some other indicators of protection in some to most of those who are repeatedly (usually two to five-plus times) inoculated with them during childhood and

b. The protections provided by these antibodies or other substances "decline" over time.

Interestingly, in the countries that were part of the former USSR, which abandoned the use of Thimerosal as a preservative in vaccines starting in 1983, the anecdotal reports are that there are no "autism" epidemics in those countries.

Conversely, China, which only started using Thimerosal-preserved vaccines in the late 1990s, reportedly has a growing "autism" problem.

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16 http://dr-king.com/docs/090812_fnldrft_TheTruthAboutTheToxicityOfThimerosalr5b.pdf .

Recommending Continued Use of Thimerosal-preserved Vaccines: Discriminatory or Genocidal?

Furthermore, there are an ever-increasing number of independent studies, including those in the VSD, showing that Thimerosal is causally linked to "autism" and other neurodevelopmental disorders as well as: **a)** proving how incredibly toxic Thimerosal exposure is to various tissues at the sub-ppm [below one part-per-million] level[17], **b)** showing that Thimerosal breaks down in mammalian tissues into ethylmercury species, methylmercury species, and inorganic mercuric species (Hg^{2+})[18] and establishing that the half-life of the tissue-retained mercury in the human brain is on the order of 20 years[19].

At a minimum, condemning the children in developing countries to significant exposures to Thimerosal-preserved vaccines while the children in the developed countries mostly get no-Thimerosal vaccines is discriminatory.

At worse, *if Thimerosal is the human teratogen*[20, 21], *mutagen*[22,23], *carcinogen*[24,25], *reproductive toxicant*[26, 27], *and an*

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17 Ida-Eto M, Oyabu A, Ohkawara T, Tashiro Y, Narita N, Narita M. Prenatal exposure to organomercury, [T]himerosal, persistently impairs the serotonergic and dopaminergic systems in the rat brain: implications for association with developmental disorders. *Brain Dev*. 2013 Mar; 35(3): 261-4. doi: 10.1016/j.braindev.2012.05.004. Epub 2012 Jun 1. Abstract.

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20 Heinonen OP, Slone D, Shapiro S. BIRTH DEFECTS AND DRUGS IN PREGNANCY, Kaufman DW (ed.), Publishing Sciences Group, Inc 1977 or "John Wright♦ PSG Inc" for the 4th printing, pages "301-313" (for topical Thimerosal/Thiomersal), "For [T]hiomersal, on the basis of extremely limited numbers (56 exposures) was associated with malformations overall, and with uniform malformations" [page "313"]), and "APPENDIX 4 Drug Exposure During the First Four Lunar Months of Pregnancy in Relation to Specific Malformation Entities", pages "466-474" "Influenza virus vaccine", "Cleft palate only", "Hospital Standardized Relative Risk", "7.1", page "474"; and "APPENDIX 5 Drug Exposure at Anytime During Pregnancy in Relation to Specific Malformation Entities", pages "480-488", "Influenza virus vaccine", "Microcephaly", "Hospital Standardized Relative Risk", "2.6", page "488", and "Pyloric stenosis", "Hospital Standardized Relative Risk", "2.0", page "488".

21 Kidd PM. Autism, An Extreme Challenge to Integrative Medicine. Part 1: The Knowledge Base [Review]. *Alternative Med Rev* 2002; 7(4): 292-316.

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26 Goncharuk GA. Experimental investigation of the effect of organomercury pesticides on generative functions and on progeny. *Hyg Sanit.* 1971; 36: 40-43.

27 Goldman GS. Comparison of VAERS fetal-loss reports during three consecutive influenza seasons Was there a synergistic fetal toxicity associated with the two-vaccine 2009/2010 season? *Hum Exp Toxicol* 2013 May; 32(5): 464-475.

autoimmunity inducer[28,29] *that experiments in mammals and primates seems to indicate it is*, then, the deliberate on-going use of Thimerosal-preserved vaccines would seem to be callous, if not genocidal.

Dr. King's Concluding Remarks

In this rebuttal to Dr. Willingham's approach to avoiding the substantive issues raised by a draft Abstract that was intentionally hidden from the public for 13 years by the CDC, Dr. King has addressed what has been hidden and what he thinks should be done about the "lost" datasets.

In addition, Dr. King has addressed the implications of a now-14-plus-year campaign on the part of the CDC, the vaccine makers and various vaccine acolytes and apologists to conceal the reality that injecting Thimerosal at the levels in the Thimerosal-preserved vaccines are, *at a minimum*, seriously toxic to some of those administered those vaccines to the point that the survivors of those vaccinations are maimed or have one or more serious chronic medical conditions that, *for most of those who are significantly damaged*, will be a lifetime burden.

However, for those who appear to escape the serious toxicities, it seems clear that even they sustain genotoxic insults that they probably will pass to their offspring – a gift that will keep on giving with ever-growing cumulative damage to each successive generation that is administered any of the Thimerosal-preserved vaccines (see footnote "**26**").

Based on the preceding realities, it would appear that any vaccination program that continues to use Thimerosal-preserved or Thimerosal-containing vaccines is a genocidal program that:

a. Directly and indirectly reduces the fertility of the people;

b. Increases the burden of chronic illness on the people, including dementias in adults and the elderly; and

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28 Vojdani A1, Pangborn JB, Vojdani E, Cooper EL. Infections, toxic chemicals and dietary peptides binding to lymphocyte receptors and tissue enzymes are major instigators of autoimmunity in autism. *Int J Immunopathol Pharmacol*. 2003 Sep-Dec; 16(3): 189-199. Abstract.

29 Havarinasab S, Björn E, Ekstrand J, Hultman P. Dose and Hg species determine the T-helper cell activation in murine autoimmunity. *Toxicology.* 2007 Jan 5; 229(1-2): 23-32. Epub 2006 Sep 24. Abstract.

c. Incrementally increases the number of neonates in the USA who do not survive past their initial exposures to Thimerosal-containing vaccines in their first year of life[30].

Additionally, *except for those who directly or indirectly profit from increasing levels of chronic diseases and those in the disease control and prevention business who would suffer if the overall level of chronic disease were to decrease significantly*, for those childhood diseases for which we have a vaccine, what parent would *knowingly*

- ❑ Choose an uncertain level and duration of possible, but not guaranteed, protection from the covered childhood diseases where:
  1. Multiple inoculations are required or recommended over the child's lifetime;
  2. There is no guarantee that the levels of antibodies developed or other measures of "disease protection" will protect the age-appropriately inoculated child from contracting the disease when subsequently exposed to the disease-causative organism(s);
  3. Many develop chronic diseases from the adverse effects of vaccination on the human immune system;
  4. Some who are vaccinated have crippling reactions to their vaccination; and
  5. Some who are vaccinated die because they were vaccinated,
- ❑ When the natural childhood disease process provides long-term to lifetime protection from those diseases after one infectious exposure to the causative agent to most who are exposed for each covered childhood disease, where:
  1. Most acquire a clinical case of a childhood disease, recover, and have long-term (typically, *greater than* 30 years) to lifetime (typically, *greater than* 50 years) disease protection (immunity) from ever contracting that disease again;
  2. There is little to no risk of the child's developing a chronic immune/autoimmune-related medical condition;

[30] Dr. King currently estimates that these make up about 5% to 10% of the infant mortalities in the USA, where Thimerosal-containing inactivated-influenza vaccines are still being routinely, but unnecessarily, given to pregnant women and children at 6 months and 7 months of age).

3. Some have serious adverse outcomes mainly precipitated by nutritional deficiencies and/or inappropriate medical care;
4. A few die from the complications of the disease; and
5. Having the childhood diseases and recovering from them provides other long-term health benefits to the child that vaccination cannot or does not provide, including, for females, the ability to provide extended protection to their offspring from contracting the covered childhood diseases provided they breastfeed their babies for at least six (6) months or, ideally, two (2) years or more?

Moreover, those, who tout vaccines and vaccination, have misled parents by:

a. Equating "vaccination" to "immunization", thereby *implying* that vaccination provides disease immunity (lifetime protection) when it does not; and

b. Repeatedly initially claiming that only one (1) dose of some vaccine would provide us with lifetime protection from a given disease.

However, the reality is that multiple vaccinations are required to provide some percentage of those who were vaccinated some disease protection that does not last for the person's lifetime or, in many instances, not even five (5) years.

Thus, vaccination obviously requires the use of additional vaccine doses to provide longer-term antibody titer boosting ("disease protection") to only some of those who are multiply inoculated with them, while each additional vaccination increases the inoculated individual's risk of developing one or more immune/autoimmune-induced chronic medical conditions[31].

Finally, for those who seek to understand King's science-based views on all vaccination issues, they need only visit King's web site, http://www.dr-king.com and read the pertinent posts in the "Publications (by year)" section of the "Documents" web page.

Acknowledgments

[31] Tsumiyama K, Miyazaki Y, Shiozawa S. Self-Organized Criticality Theory of Autoimmunity. *PLoS ONE* 2012 Dec 31; 4(12): e8382 (9 pages).

For contributing valuable insights and providing their personal experience-based knowledge in various areas, Dr. King thanks Mayer Eisenstein, MD, JD, MPH; Gary S. Goldman, PhD; Boyd E. Haley, PhD; Melissa and Doug Troutman; Eileen Dannemann; Brian Hooker, PhD; Janet K. Kern, PhD; Catherine J. Frompovich; Neil Z. Miller; Mark R. Geier, MD, PhD; and David A. Geier.

Additionally, Dr. King specifically thanks Catherine J. Frompovich, Gary S. Goldman, Janet K. Kern, and Eileen Danneman for their support, suggestions, corrections and alternate wordings that helped him to finalize this response.

About Dr. Emily Willingham, Author of the Article

Source: http://www.forbes.com/sites/emilywillingham/

"Emily Willingham

I write about the science they're selling you."

Scientist, writer, editor. Founder of http://www.doublexscience.org/. Work has appeared at Slate, Scientific American, Grist, and The New York Times, among others. I focus on how science filters to consumers and how consumers make decisions about science. Frequent honorable mentions: autism, parenting, and the news media."

Source: https://en.wikipedia.org/wiki/Emily_Willingham **Contact:** http://www.doublexscience.org/contact/

Emily Jane Willingham	
Born	1968 (age 45–46) Waco, Texas
Fields	Endocrinology, urology
Institutions	UCSF, Texas State University, St. Edward's University[1][2]
Alma mater	University of Texas at Austin
Thesis	*Embryonic exposure to low-dose pesticides : dose response and effects on growth in the hatching red-eared slider turtle* (2001)
Known for	Scientific skepticism, work on endocrine disruptors
Notable awards	UT-Austin department of biological sciences professional development award, 1998
Children	Three

"Education

Willingham has a bachelor's degree in English (1989) and a PhD in biological sciences (2001), both from the University of Texas at Austin. She completed her fellowship in pediatric urology at the University of California, San Francisco, from 2004 to 2006,[3][4] where she studied under Laurence S. Baskin.[1]

Blogging

Willingham formerly ran the blog "A Life Less Ordinary", which she started in 2007 and which published its last post on November 25, 2011.[5] Willingham currently blogs for Forbes.com, where she states she writes about "the science they're selling you," which includes the disproven link between vaccines and autism,[6] as well as the Seralini affair.[7] She has also written three posts for Slate.com about, among other topics, what the motivation might have been for Adam Lanza to carry out the Sandy Hook elementary school shooting. Her view is that his Asperger's syndrome was not a contributing factor to him carrying out the shooting.[8] In addition, she has contributed to Discover, where she has argued that the autism epidemic may, in fact, just be the result of diagnostic substitution and increased awareness of the disorder.[9] She was called "one of the sharpest science writers in the blogosphere" by Steve Silberman.[10]

Research]

Willingham has published 44 scientific papers, and, according to Google Scholar, her h-index is 19.[11] With regard to her research, Willingham has said that talking about it "has always carried a frisson of the risque,"[3] which is not surprising, given that it often has to do with hypospadias, a birth defect of the penis, and how they can be caused by synthetic chemical compounds, including vinclozolin.[12] In addition, she has conducted research on endocrine disrupting chemicals such as atrazine with well-known anti-atrazine activist Tyrone Hayes.[13][14]

Selected publications

Scientific papers[edit]

- Sheehan, D. M.; Willingham, E.; Gaylor, D.; Bergeron, J. M.; Crews, D. (1999). "No threshold dose for estradiol-induced sex reversal of turtle embryos: How little is too much?". *Environmental health perspectives* 107 (2): 155–159. doi:10.1289/ehp.99107155. PMC 1566346. PMID 9924012.
- Willingham, E.; Baldwin, R.; Skipper, J. K.; Crews, D. (2000). "Aromatase Activity during Embryogenesis in the Brain and Adrenal–Kidney–Gonad of the Red-Eared Slider Turtle, a Species with Temperature-Dependent Sex Determination". *General and Comparative Endocrinology* 119 (2): 202–207. doi:10.1006/gcen.2000.7505. PMID 10936040.
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Books

- Willingham, Emily (2010). *The Complete Idiot's Guide to College Biology*. Alpha Books.
- Willingham, Emily; Myers, Jennifer Byde; Ditz, Liz (2011). *Thinking Person's Guide To Autism*. Deadwood City Publishing.
- Willingham, Emily (2011). *When Worlds Collide: The Troubled History of Bears and People in Texas*. Amazon Digital Services.

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About Dr. Paul G. King, The Generator of This Rebuttal

In addition to the information available on his web site, http://www.dr-king.com/, Dr. Paul G. King, a PhD analytical chemist with an MS in inorganic chemistry, is the Science Advisor to the Coalition for Mercury-Free Drugs (CoMeD, Inc., which is a 501(3)(c) not-for-profit corporation (http://www.mercury-freedrugs.org/) as well as the Science Advisor to the National Coalition of Organized Women (NCOW).

Additionally, he has been an author of papers bearing on issues related to the toxicity of Thimerosal and other compounds and, if any, their connection to a range of chronic neurodevelopmental, other developmental and behavioral abnormalities, which appear to be well-above (> 1 in 10 children; asthma and obesity), above (> 1 in 100 children; the autism spectrum disorders), at (> 1 in 1000 children; non-genetic childhood diabetes), or nearing (peanut allergy), epidemic childhood levels in the USA.

More recently, Dr. King was the co-author of a review paper in the journal ***Vaccine*** with Gary S. Goldman, PhD, which evaluated the CDC-recommended universal varicella vaccination program[32].

That paper established that the current CDC-recommended two-dose vaccination program was not effective in preventing all those who have been fully vaccinated from subsequently contracting chickenpox.

Since that program has greatly increased the public's risk of having clinical cases of shingles, it is also not societally cost-effective for universal use.

In addition, Dr. King was a co-author of a follow-up paper[33] published by the journal *Human & Experimental Toxicology* with Gary S. Goldman, PhD, that provided more evidence that the U.S. "universal varicella vaccination program is neither effective nor cost-effective".

Moreover, Dr. King was also one of the authors of a paper in the journal *Int. J. Environ. Res. Public Health*, where the lead author was Janet K. Kern, PhD. This paper reviewed Thimerosal exposure and the roles of sulfation chemistry and thiol availability in autism[34].

Furthermore, Dr. King was one of the authors in a review chapter, "Mercury Induced Autism"[35] (pages 1411-1432), in Comprehensive Guide to Autism Editors: Vinood B. Patel, Victor R. Preedy, Colin R. Martin. Springer New York (2014), where the lead author was Mark R. Geier, MD, PhD. This chapter presented updated evidence that mercury, including the bolus doses delivered when certain preserved vaccines and preserved serum products are given to pregnant women and young children, is a significant causal factor in "autism" and other developmental disorders, dysfunctions, and syndromes.

Finally, Dr. King was one of the authors of a paper, "A two-phase study evaluating the relationship between Thimerosal-containing vaccine administration and the risk for an autism spectrum disorder diagnosis in the United States", in the journal, *Translational Neurodegeneration*, where the lead author was David A. Geier. This open-access paper contributed more evidence to the actuality that there is a causal relationship between Thimerosal-preserved vaccine administration and the subsequent risk of a child's being diagnosed with autism in the USA[36].

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33 Goldman GS, King PG. Vaccination to prevent varicella: Goldman and King's response to Myers' interpretation of Varicella Active Surveillance Project data . *Hum Exp Toxicol*. 2013 Dec. [http://het.sagepub.com/content/early/2013/12/10/0960327113512340.full.pdf+html.] .

34 Kern JK, Haley BE, Geier DA, Sykes LK, King PG, Geier MR. Thimerosal Exposure and the Role of Sulfation Chemistry and Thiol Availability in Autism [Review]. *Int. J. Environ. Res. Public Health* 2013 Aug, 10, 3771-3800. OPEN ACCESS

35 See, http://www.researchgate.net/publication/258009647_Mercury_Induced_Autism/file/60b7d526955a643330.pdf for the complete chapter.

36 Geier DA, Hooker BS, Kern JK, King PG, Sykes LK, Geier MR. A two-phase study evaluating the relationship between Thimerosal-containing vaccine administration and the risk for an autism spectrum disorder diagnosis in the United States. *Translational Neurodegeneration* 2013 Dec. 16; 2:25 (12 pages). In the first month after publication, it was accessed *more than* 10,500 times.

###

APPENDIX A

Cleaned-up Copy of a CDC-provided, December 17, 1999 Email from Thomas Verstraeten to Robert Davis and Frank DeStefano

Graham, Laverne

From: Verstraeten, Thomas
Sent: Friday, December 17,1999 4:40 PM
To: 'Robert Davis'
Cc: DeStefano, Frank
Subject: It just won't go away

Hi,
Attach please find four tables with RRs and three SAS programs:
Sumstat_alldi8_sort (created by TH_anal_nonbob_expl3.tx.t) has the RRs after PH models adjusted for gender, site and birthyear for all diagnoses included.
SumstaLa!!dia_sort2 has the RR for the conditions that came out to be relevant from the first list.
Sumstat_a!1dia_strat (created by TH_anal_bob_str) has the same after stratification for site, year and month of birth, adjusting for gender and leaving out the kids that got HepB immunoglobulines. It differs very little from the previous, except for the coordination disorders.
SumstaLbob (created by TH_anal_bob_expl3.tct) has the RRs for the categories of diagnoses, adjusted, not stratified (I did it for one and got basically the same result).
In the lists you'll also see the sample size for each category and the referent category, some of which are quite small when making 4 categories, reason for using 3 slightly different categories with similar results (Hg3cat1 vs. hg4cat1 and hg3cat3 vs. hg4cat3).
I added another exposure variable (addcat) in one !list that looks at the increase of mercury each month for the first three months, divided by the average bodyweight in the first, second and third month and takes the maximum value of this. This does not show much, to which I would conclude that, except for epilepsy, all the harm is done in the first month.

As these neurologic developmental conditions are very much related (odds of having one when also having the other go from 20 to 1001), I added the first five (called mix) and checked what happened to the RRs. (You get some sort of average.) I will explore the possibility of some sort of factor analysis to replace the conditions by one variable.

As you'll see some of the RRs increase over the categories and I haven't yet found an alternative explanation ... Please let me know if you can think of one. Frank proposes we discuss this on a call after New Year.

Also attached my EIS abstract to get your input.

Happy holidays!

Thomas Verstraeten, M.D.
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Vaccine Safety and Development Branch
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APPENDIX B

Copy of a CDC-provided, July 14, 2000 Email from "Verstraeten, Thomas**" to "**'Phillippe Granjean'; Verstraeten, Thomas**" copying "**Chen, Robert (Bob) (NIP); DeStefano, Frank; Pless, Robert; Bernier, Roger; Tom Clarkson; Pal Weihe**" with the subject "**RE: Thimerosal and neurologic outcomes**"

Verstraeten, Thomas

From:	Verstraeten, Thomas
Sent:	Friday, July 14, 2000 10:42 AM
To:	'Philippe Grandjean'; Verstraeten, Thomas
Cc:	Chen, Robert (Bob) (NIP); Destefano, Frank; Pless, Robert; Bernier, Roger; Tom Clarkson; Pal Weihe
Subject:	RE: Thimerosal and neurologic outcomes

Dear Dr. Grandjean,
Thank you for a very rapid response!
I apologize for dragging you into this nitty gritty discussion, which in Flemish we would call "muggeziften" . I know much of this is very hypothetical and personally I would rather not drag the Faroe and Seychelles studies in this entire thimerosal debate, as I think they are as comparable to our issue as apples and pears at the best.
Unfortunately I have witnessed how many experts,looking at this thimerosal issue, do not seem bothered to compare apples to pears and insist that if nothing is happening in these studies then nothing should be feared of thimerosal. I do not wish to be the advocate of the anti-vaccine lobby and sound like being convinced that thimerosal is or was harmful, but at least I feel we should use sound scientific argumentation and not let our standards be dictated by our desire to disprove an unpleasant theory.
Sincerely,
Tom Verstraeten.