

Conflicts of Interest: How the CDC Exerted Influence over the 5 Epidemiological Studies Used to Dismiss the Thimerosal-Autism Link

November 29, 2005

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Summary

- *The CDC is highly motivated to increase vaccination rates among children in the U.S.*
- The National Immunization Program (NIP) is given the charge to increase childhood vaccination rates in the United States, as per the “2010 Healthy People Goal (Press Release, 7/26/05).”
- The NIP minimizes concerns over vaccine adverse events (e.g., “Vaccines, the Safe Choice, document on NIP website”)
- Up until May 2005, The Institute of Vaccine Safety (safety “watchdog” for vaccinations) was located within the National Immunization Program (advocacy arm with goal of increasing infant vaccination rates).
- The CDC represents itself as a key interested party in investigations on vaccine safety and autism via the National Center of Birth Defects and Development Disorders (NCBDDD).
- The autism branch of the CDC was led by a former official of NIP, Dr. Jose Cordero

Summary (2)

- CDC commissioned IOM to establish the Vaccine Safety Review (VSR) Committee under negotiations in 2000, leading to contract execution on 8/1/2000
- Final conclusion of the IOM VSR Committee “Thus, based on *this body of evidence*, the committee concludes that the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.” (italics added):
- This body of evidences consisted of 5 “well-designed” epidemiology studies
 - Verstraeten et al. 2003
 - Madsen et al. 2003
 - Stehr-Green et al. 2003
 - Hviid et al. 2003
 - Miller et al. 2004
- *All the epidemiological research on links to autism and thimerosal exposure that the IOM VSR Committee cites as the basis for its final report conclusion, rejecting a causal link between thimerosal exposure and autism, was undertaken with CDC money or by researchers with close ties to the CDC.*

Institute of Medicine Vaccine Safety Review Committee

- Established in 2001 based on a contract (IAA) from the CDC through the NIH (obtained by FOIA)
- Committee was charged to look at up to three vaccine safety hypotheses by the DHHS Interagency Vaccine Group:
 - CDC (NIP and NCID)
 - NIH (NIAID)
 - NVICP
 - FDA
 - Center for Medicare and Medicaid Services
- One of the vaccine safety hypotheses investigated was the causal linkage between thimerosal and autism

IOM VSR Contract (IAA) Documents (Obtained via FOIA)

- **Vaccine safety review** described as, “until more definitive scientific evidence becomes available, an *interim* review by an independent body could help evaluate for providers and the public the *credibility* of a new vaccine safety hypothesis.
- **Credibility of a hypothesis** based on “biologic plausibility, competing alternative hypotheses, as well as the available scientific evidence to date.”
- **Further research needed**, “knowledge gaps and research needs would also have been identified.”

Statement of Work [SOW], pg. 2,
emphases added

IOM VSR Committee Meetings

- A total of 9 meetings and reports
 - Meeting 1 laid the foundation of the reviews
 - Meetings 2, 3 and 9 specifically covered autism and vaccinations
 - MMR/IBD/Autism Hypothesis (3/8/2001)
 - Thimerosal-Containing Vaccines and Neurodevelopmental Outcomes (7/16/2001)
 - Vaccines and Autism (2/9/2004)
- Meeting conduct
 - Open, public forum for invited presentations regarding scientific, medical and policy information, followed by public comment
 - Closed-door session(s) based on presentations and literature supplied by the contractor
 - Subsequent report released generally within 3 months of the open forum

IOM VSR Contract (IAA) Documents (cont'd)

- Vaccine policy recommendations ranged between:
 - “Minimal unintended disruption of routine immunization services”
 - “Changes in recommendations for vaccine use pending further investigation” (SOW, pg. 2)
- Meeting topics to be considered in meetings
 - Dictated by Contracting (NIH/CDC) Officer and Project Officers (presumably K. Stratton, IOM and M. McCormick, HSPH; SOW, pg. 3)
 - For a given topic, the “contractor is responsible in compiling and summarizing background data,” although others may have input (SOW, pg. 3)

Reach of IOM VSR Committee Results

- Vaccination policy
- Research agenda
- Refereed publications
- Vaccine injury compensation litigation (results of committee deliberations given to ACIP and NVICP Special Masters)
- Other issues

Conclusions from Relevant IOM VSR Committee Meetings

- Meeting 1:
 - Informational meeting to set up the committee and review specific guidelines for deliberation (no conclusions)
- Meeting 2:
 - “Existing evidence rejects MMR/IBD/autism causality” (from an epidemiological perspective)
 - “Moreover, the committee can find no proven biological *mechanisms* that would explain such a relationship” (from an individual, clinical perspective, *italics added*)
- Meeting 3:
 - “Not sufficient information to accept or reject causality between thimerosal and neurodevelopmental disorders in children”

Conclusions from Final IOM VSR Committee Meeting (Vaccines and Autism, 5/16/04 Report)

Epidemiology

“Epidemiological studies examining thimerosal-containing vaccines and autism, including three controlled observational studies (*Hviid et al., 2003; Verstraeten et al., 2003; Miller, 2004*) and two uncontrolled observational studies (*Madsen et al., 2003; Stehr-Green et al., 2003*), consistently provided evidence of no association between thimerosal-containing vaccines and autism, despite the fact that these studies utilized different methods and examined different populations (in Sweden, Denmark, the United States, and the United Kingdom).” [IOM VSR Committee 5/14/04 report, Exec. Summary, pg. 5]

Final Conclusion

“Thus, based on *this body of evidence*, the committee concludes that the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.” (ibid., italics added)

Conflict of Interest in 5 “Well-Designed” Studies (IOM VSR Committee 5/14/04)

- Verstraeten et al. 2003 (US)
 - Funded by the CDC
 - Majority of authors employed by CDC
- Madsen et al. 2003 (Denmark)
 - Many Coauthors received funding from CDC during conduct of Madsen et al. 2003 study
 - Poul Thorsen affiliated with the CDC during conduct of study
 - Dr. Cordero’s letter of support may have accompanied manuscript submittal to the journal Pediatrics
- Hviid et al. 2003 (Denmark)
 - 3 of 4 coauthors were receiving financial support from the CDC
- Stehr-Green et al. 2003 (Denmark and Sweden)
 - Funded by CDC
- Miller et al. 2004 (UK)
 - Chen and Verstraeten exerted control of WHO funding for the UK cohort study (nature of stake in WHO is indeterminate)
 - Email correspondences from Chen are still outstanding

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LONE STUDY ON CHILDREN IN UNITED STATES

Verstraeten et al. 2003

- *The only thimerosal/autism epidemiological study completed involving U.S. children exposed to U.S. vaccine schedule*
- *The remaining studies serving as the basis for the 5/18/04 IOM report recommendations were based on countries with distinctly different vaccination policies, ALL resulting in a much less aggressive exposure to thimerosal.*
 - *Lower overall exposure*
 - *No thimerosal exposure prior to 2 months of age*
- Verstraeten findings were generated via the Vaccine Safety Datalink (VSD)
- 5 generations of the study showed the relative relationship between thimerosal exposure and the autism diagnosis decrease dramatically after each subsequence revision

Regarding Public Oversight of the VSD: Subsequent IOM NIP Datasharing Committee Report, “Vaccine Safety Research, Data Access, and Public Trust”, 2/17/05

- Dr. Melinda Wharton, Deputy Director of NIP, stated “*data sets may not allow all the re-analyses that one might want to do, or in fact may not be available at all..*” (IOM NIP Datasharing Committee Meeting 8/23/04).
- Geiers’ experience with the VSD CRO clearly shows a pattern of data mismanagement by the CDC (ibid.)
- CDC NIP attempted to block Geiers’ VSD access in February, 2004, prior to testimony of Dr. Wharton on 8/23/04. *It remains unclear whether CDC official intentionally or inadvertently destroyed Verstraeten et al. 2003 study datasets.*
- As pointed out in the final report (2/17/05), destruction of such data whether accidental or intentional could constitute violation of the IQA and the Shelby Amendment.
- Numerous recommendations were made in the IOM NIP Datasharing Committee final report, raising serious questions regarding the data management practices resulting in the various versions of the Verstraeten et al. study.

The study lead author, Dr. Thomas Verstraeten

- Left the CDC for a position at GlaxoSmithkline (GSK), effective 7/16/01
- Employed as a vaccine scientist at GSK for over two years prior to the publication of the final version of the Verstraeten et al. study in the November 2003 edition of the journal Pediatrics
- The fifth and final reanalysis of the VSD leading to the dismissal of any linkage between thimerosal and autism was completed while Verstraeten was employed at GSK
- GSK manufactured thimerosal containing pediatrics vaccines prior to the 1999 voluntary phase out
- GSK is the defendant in several U.S. civil court cases involving thimerosal containing vaccines and autism

What did Verstraeten do after leaving CDC

- Collaborated with the NIP on six separate publications regarding vaccine safety (besides the thimerosal study)
 - Immunity to tetanus is protective against the development of multiple sclerosis. *Med Hypotheses*. 2005;65(5):966-9. (Verstraeten, Destefano, Davis)
 - Vaccine safety surveillance using large linked databases: opportunities, hazards and proposed guidelines. *Expert Rev Vaccines*. 2003 Feb;2(1):21-9. Review. (Verstraeten, Destefano, Chen, Miller)
 - Hepatitis B vaccine and risk of multiple sclerosis. *Expert Rev Vaccines*. 2002 Dec;1(4):461-6. Review. (Verstraeten, Destefano, Chen)
 - A retrospective cohort study of the association of varicella vaccine failure with asthma, steroid use, age at vaccination, and measles-mumps-rubella vaccination. *Pediatrics*. 2003 Aug;112(2):e98-103. (Verstraeten, Jumaan, Mullooly, Seward, Izurieta, DeStefano, Black, Chen)
 - Vaccinations and risk of central nervous system demyelinating diseases in adults. *Arch Neurol*. 2003 Apr;60(4):504-9. (DeStefano, Verstraeten, Jackson, Okoro, Benson, Black, Shinefield, Mullooly, Likosky, Chen)
 - Enhancing vaccine safety surveillance: a capture-recapture analysis of intussusception after rotavirus vaccination. *Am J Epidemiol*. 2001 Dec 1;154(11):1006-12. (Verstraeten, Baughman, Cadwell, Zanardi, Haber, Chen)

What did Verstraeten do after leaving CDC

- Recruited CDC employees to come to GSK

Jackson, Janis

From: Destefano, Frank
Sent: Monday, March 15, 2004 9:27 AM
To: 'thomas.verstraeten@gskbio.com'
Subject: RE: Open position for epidemiologist at GSK Biologicals in Belgium

Tom,
I will forward to potential candidates.

Thanks, Frank

-----Original Message-----

From: thomas.verstraeten@gskbio.com [mailto:thomas.verstraeten@gskbio.com]
Sent: Monday, March 15, 2004 4:34 AM
To: Chen, Robert (Bob) (NIP); Destefano, Frank; katrin@bellsouth.net
Subject: Open position for epidemiologist at GSK Biologicals in Belgium

Bob, Frank, Katrin,

If you know of anyone who wants to move to Europe...

(See attached file: GSK Epidemiologist 2004 (EIS).doc)
Thomas Verstraeten, MD, MSc

Associate Director, Worldwide Epidemiology and Safety GlaxoSmithKline Biologicals Rue de
l'Institut 89 B-1330 Rixensart, Belgium Email
thomas.verstraeten

What did Verstraeten do after leaving CDC

- Set up an industry/FDA/CDC collaboration of epidemiologists to unify techniques and share data (Data Mining of Spontaneous Reporting Databases for Vaccines, a joint FDA-CDC-Industry initiative)
- Used industrial funds to pay U.S. Government collaborators in this initiative
- Recruited former U.S. Government employees now in industry to assist in the collaboration
 - Michael Blum, Wyeth, former FDA
 - Alena Khromava, Sanofi, former CDC

Set up of FDA-CDC-Industry initiative

From: thomas.verstraeten
Sent: Wednesday, March 23, 2005 6:52 AM
To: Iskander, John; miles.braun@fda.hhs.gov; Alena.Khromava@BLUMM Sharrar, Robert G; larry_gould
Cc: Destefano, Frank; Dominique.Millet
Subject: RE: Vaccine Data Mining Workshop -- April 19, 2005

Dear All,

ISPE has confirmed we can have this workshop at their mid-year meeting, following the advanced topics course.

The information should appear on the mid-year website soon. ISPE has requested a fee to facilitate this and to avoid complicated counts and money transfers, GSK will pay for this (first ?) meeting. The original idea of registration fees is too complex to still get organized. The meeting is therefore open to anyone interested, in practice this will mean mostly to all attendees of the mid-year meeting. Feel free to invite any colleagues you think could be interested from your or other agency/firm.

Pls find below the agenda as it stands today. I still need confirmation from the PhRMA-FDA Collaborative Working Group and from Merck on the speakers

For all practical purposes, it would be easiest for you all to send me your presentations beforehand to avoid switching computers during the meeting or last-minute file transfers

I propose everyone uses his/her own template for the presentations.

The idea of the presentations is not to go into too much technical detail, but to focus on three questions:

1. how far have you developed and applied data mining techniques in your setting
2. What are you planning to do in the future (nothing, wait&see, a lot ...) and reasons why
3. what do you think could be done in a collaborative manner

Don't hesitate to contact me for further questions. I will be away from the 26th of March till the 6th of April and only reachable on mobile on the 7th and 8th. I'll be in the office in the last week before the meeting and in Barcelona from Saturday night (April 16th) onwards.

Looking forward to a great workshop.

Federal employees being paid by industry to attend conference

Joint industry consortia and meetings undermine confidence in vaccination program

Industry is setting standards for its own products. Industry wants to "collaborate" with CDC/FDA on safety issues

What did Verstraeten do after leaving CDC

Jackson, Janis

From: Destefano, Frank
Sent: Tuesday, July 05, 2005 1:41 PM
To: 'thomas.verstraeten'
Subject: RE: FW: VSD extended FU for intussusception

I'm back. If you could send me the age distribution data, maybe I will be able to determine where it comes from. I've attached the ICAAC talk on the extended follow-up, although it is pretty much the same as the data in Phil Rhode's talk that you got previously.

Frank

-----Original Message-----

From: thomas.verstraeten
Sent: Tuesday, July 05, 2005 3:54 AM
To: Destefano, Frank
Cc: Chen, Robert (Bob)
Subject: RE: FW: VSD extended FU for intussusception

Frank,
Could you pls contact me as soon as you're back to discuss these data?

Also, we have data on the age distribution of IS that Bruce Innis would have received from Bob a few years ago for which we have no reference. Any idea where those came from?

Thanks

Thomas Verstraeten, MD, MSc

Director
Head Worldwide Epidemiology
GlaxoSmithKline Biologicals
Rue de l'Institut 89
B-1330 Rixensart, Belgium

"Destefano, Frank"
<fxd1@cdc.gov>

To: "Chen, Robert (Bob) (NIP)" <rtc1@cdc.gov>, Thomas M
Verstraeten

05/05/2003 22:41

cc:
Subject: RE: FW: VSD extended FU for intussusception

Continued to involve Robert Chen in vaccine safety analyses (rotavirus and intussusception) despite his transfer to "Global AIDS"

Frank DeStefano (Chief of Vaccine Safety at CDC) also is continuing to correspond with Chen regarding vaccine safety issues, despite Chen's strong, demonstrated conflict of interest.

Jackson, Janis

From: thomas.verstraeten
Sent: Monday, June 27, 2005 2:54 AM
To: Davis, Robert(Bob) L; Destefano, Frank
Subject: Fw: ***ISPE News Items***

Dear both,

I am standing in the board election for the industry non-US position. I hope to get at least your 2 votes! (Anyone else you know at CDC or the VSD bunch, put in a good word for me.)

Thanks

Tom

Thomas Verstraeten, MD, MSc

Director
Head Worldwide Epidemiology
GlaxoSmithKline Biologicals
Rue de l'Institut 89
B-1330 Rixensart, Belgium

----- Forwarded by Thomas M Verstraeten

on 24/06/2005 16:26 -----

"Mark Epstein"

23/06/2005 00:18

To: "ISPE" <ISPE@
cc: (bcc: Thomas M Verstraeten/
Subject: ***ISPE News Items***

Dear ISPE Members,

Just a few information items to share with you.

ELECTION 2005

Members are invited to vote for two Officers: President-Elect and Vice President Finance — Elect, and five (5) Directors in Election -2005. Members can vote online (Members Only section) or by mailing in a ballot (A ballot and biographical information have been mailed to all current ISPE members.) **DEADLINE:** Ballots must be received at ISPE office by 5:00pm (EDT/USA) **July 20.** Vote for the Society's future!

**Verstraeten solicits U.S.
Government officials for
votes in a prestigious
professional society based
on his past employment at
the CDC.**

DENMARK STUDIES

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CDC (Autism Study) Funding to Authors of “Independent” Studies: Hviid et al. 2003 and Madsen et al. 2003

- Co-investigators in these “independent” studies were funded simultaneously on three separate CDC studies specifically involving autism causal factors
- Both principal investigators were:
 - Involved in these studies
 - Co-investigators (Madsen, lead; Hviid second) on the autism-MMR study funded by CDC
- The majority of these investigators were affiliated with the Danish Epidemiology Science Centre

CDC (Autism Study) Funding to Investigators in Hviid et al. 2003 and Madsen et al. 2003 “independent” studies

Madsen et al. 2003

KM Madsen*

P Thorsen

P Mortensen

CDC Funded Studies

Madsen et al.

Stehr-Green et al.

Larssen et al.

Hviid et al. 2003

A Hviid*

M Melbye

J Wohlfahrt

M Stellfeld

Author Affiliation (Denmark)

Danish Epidemiology Science Centre

Staten Serum Institut

National Center for Registry-Based Research

CDC Funded Study Publications

Madsen et al. 2002, NEJM 347:1477

Stehr-Green et al. 2003, Am J Prev Med 25:101

Larssen et al. 2005, Am J Epi 161:916

Denmark Study Coauthors Employed by the “for profit” Danish Vaccine Manufacturer: Staten Serum Institut (SSI)

Madsen et al. 2003

KM Madsen
M Lauritsen
C Petersen
P Thorsen
A Plesner
P Andersen
P Mortensen

Staten Serum Institute

Department of Medicine,
SSI

Danish Epidemiology
Science Centre,
Department of
Epidemiology, SSI

Hviid et al. 2003

A Hviid
M Melbye
J Wohlfahrt
M Stellfeld*

*Department Head

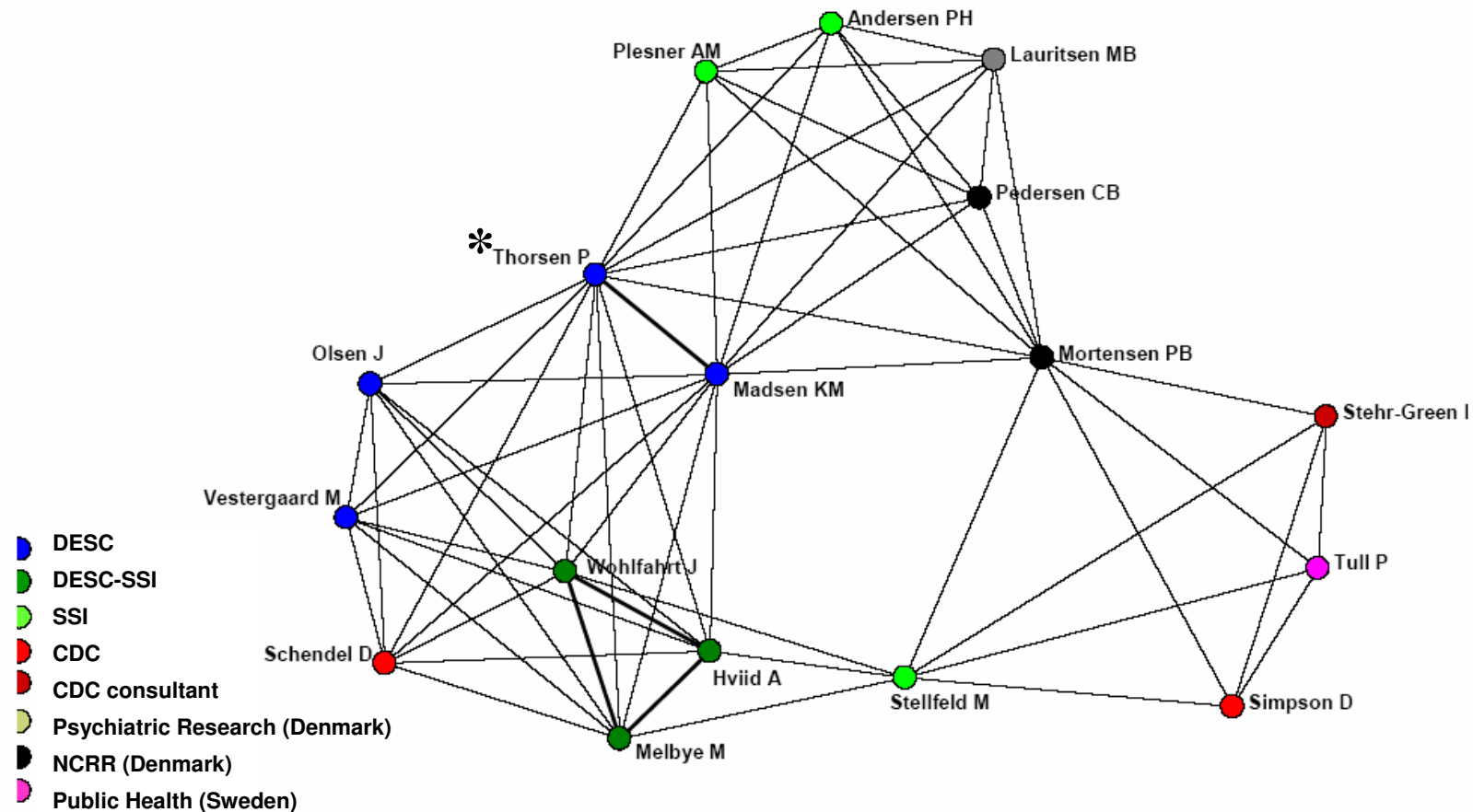
Connectivity between authors in CDC funded and “Independent” Investigations (Blaxill et al. 2004)

FOUR ARTICLES FROM DENMARK

NEW ENGLAND JOURNAL OF MEDICINE	AMERICAN JOURNAL OF PREVENTIVE MEDICINE	PEDIATRICS	JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION
A population-based study of measles, mumps, and rubella vaccination and autism	Autism and thimerosal-containing vaccines: lack of consistent evidence for an association.	Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data.	Association between thimerosal-containing vaccine and autism
N Engl J Med. 2002;347(19):1477-82	Am J Prev Med. 2003;25(2):101-6	Pediatrics. 2003;112(3 Pt 1):604-6	JAMA. 2003;290(13):1763-6
Madsen KM Hviid A Vestergaard M Schendel D Wohlfahrt J Thorsen P Olsen J Melbye M	Stehr-Green P Tull P Stellfeld M Mortenson PB Simpson D	Madsen KM Lauritsen MB Pedersen CB Thorsen P Plesner AM Andersen PH Mortensen PB	Hviid A Stellfeld M Wohlfahrt J Melbye M
CDC Funded		Independent	

Connectivity between authors in CDC funded and “Independent” Investigations (Blaxill et al. 2004)

AUTHORS BY ORGANIZATION



*CDC – Visiting Scientist, Affiliation Unreported

Dr. Poul Thorsen – CDC “Visiting Scientist”

- Published as principal investigator (Thorsen et al. 2001 Ped Perinatal Epi 15[Suppl 2]: 90-103) under affiliation – National Center for Environmental Health, CDC
- Listed as “Guest Researcher” Developmental Disabilities Branch (NCEH), CDC, MICHEP 1998 Workshop, <http://www.uic.edu/sph/dataskills/liveconf/CDCconfpgm.htm>
- Listed in 5/30/2000 email correspondence from Marshelyn Yeargin-Allsop to Jose Cordero, regarding initiation of Denmark autism-MMR study (attached)
 - Thorsen served as CDC representative regarding funding in CDC(NIP) to Principle Investigators
- Thorsen email message (personal correspondence) affirming
 - **“I am and was Principal Investigator on CDC projects on Autism during those years.” 11/24/04 (Poul Thorsen email)**
 - ***to my direct question* “I would like to determine your role at the CDC during the span of time where you were involved in the 2003 Pediatrics study that you co-authored with K. Madsen et al.” 11/23/04 (personal correspondence)**

Other COI Issues within “Independent” Denmark Studies

- Danish Medical Research Counsel listed as CDC-NCBDDD “External Partner”
- Acknowledgement on Madsen et al. 2003 Publication:

“We thank Coleen Boyle, Diana Schendel, and Jose F. Cordero [All CDC] for comments and advice during preparation of the manuscript.”
- Cordero recommendation letter (Madsen et al. 2003) to the journal Pediatrics

Stehr-Green et al. 2003

- Investigation of pediatric cohorts from Denmark and Sweden
- Critical review of studies involving Denmark pediatric cohort and California ecological data
- Funded directly by CDC
- Study first author, Paul Stehr-Green was a consultant for the CDC
- Study author, Diane Simpson was employed by the CDC
- Danish co-authors Michael Stellfeld and Preben-Bø Mortensen are not appropriate for critical review of their own studies, Hviid et al. 2003 and Madsen et al. 2003, respectively
- Danish co-author Michael Stellfed was employed by the Staten Serum Institut, a Danish vaccine manufacturer

Conclusion

Network of Danish Researchers is highly interconnected with the CDC, the “for profit” vaccine manufacturer Staten Serum Institut and Danish research organizations

UK STUDIES

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Miller et al. 2004 (unpublished)

- Led to publications
 - Andrews et al. 2004 Pediatrics (GPRD) – Thimerosal exposure vs. autism incidence epidemiology
 - Heron et al. 2004 Pediatrics (ALSPAC) – Thimerosal exposure vs. autism incidence case definitions
- Dr. Miller has served as an expert witness for GSK, Aventis Pasteur and Merck (all named as defendants in ongoing civil litigation)

CDC connection

- FOIAed email exchange between Miller, Verstraeten and Chen (Head of Vaccine Safety, CDC), June to Nov. 2001
 - Dilemma on thimerosal exposure in UK via DTP (either 75 or 150 ug total)

-----Original Message-----

X-Sybari-Trust: 44falcaF 050014dd 00000000 0000003D

From: rtcl@cdc.gov [mailto:rtcl@cdc.gov]

Sent: 26 June 2001 14:50

To: EMiller@phls.org.uk

Subject: UK vaccine schedule and thimerosal exposure

Liz,

In our brief discussions in Geneva, did I recall correctly that you said the vaccines used in the UK contained 50 micrograms thimerosal (or 25 micrograms ethyl Hg) per dose? If this is correct, at the end of 3 doses at 4 months of age, the exposure would have been to 150 micrograms of thimerosal or 75 microgram ethyl Hg. The range of exposures at 4-5 months of age (after the 2nd dose of DTP, Hib and Hep B) in the VSD study was from 150-250 micrograms of thimerosal or 75-125 micrograms of ethyl Hg.

We look forward to hearing more about your study with Jean Golding's cohort.

Best regards,

Bob

Elizabeth Miller's prompt reply (only 75 ug Hg by age 4 months)

From: EMiller@phls.org.uk [mailto:EMiller@phls.org.uk]
Sent: Tuesday, June 26, 2001 11:25 AM
To: rtdcl@cdc.gov
Subject: RE: UK vaccine schedule and thimerosal exposure

Dear Bob

The information given to me by the licensing authority is that the whole cell DTP/Hib vaccine we currently use contains 50 micrograms thiomersal per dose so that our children would if on schedule have 75 micrograms of ethyl Hg by 4 months of age. They originally told me that the whole cell DTP vaccine that we used on its own from 1990 (when we adopted our accelerated schedule) up to 1992/3 contained 100 micrograms thiomersal so exposure to ethyl Hg would have been 150 ug by 4 months. We then started using combined DTP/Hib vaccines for which the thiomersal content apparently was 50ug /dose. The authority is now saying that they may have made a mistake and the vaccine we used up to 1992/3 only contained 50ug thiomersal /dose! If this is true then do we have sufficient exposure to ethyl Hg by 4-6 months of age to pick up an effect? Do I have to give my GPRD grant money from WHO back???

Liz

"Do I have to give my GPRD grant money from WHO back???"

Robert Chen elicits Tom Verstraeten's input on Dr. Miller's email

-----Original Message-----

From: Chen, Robert (Bob) (NIP) Sent: Tuesday, June 26, 2001 11:45 AM
To: Verstraeten, Thomas
Subject: FW: UK vaccine schedule and thimerosal exposure

Tom, what do you think?

Dr. Verstraeten's response

-----Original Message-----

From: Verstraeten, Thomas Sent: Tuesday, June 26, 2001 12:05 PM

To: Chen, Robert (Bob) (NIP)

Subject: RE: UK vaccine schedule and thimerosal exposure

Bob,

I think two issues are important in assessing the potential strength of the GPRD study:

1. Maximum exposure and 2. Unbiased controls

The maximum exposure is indeed relatively low if that was the only T containing vaccine used. My estimate would be that you need at least >50 by 3 months or >100 by 6 months to see an effect if there is one, which you barely make (50 at 2 mo and 75 at 4 mo in the UK)

The quality of the comparison group is maybe even more important if you consider all the criticism we have received on comparing high T exposure to no or low T exposure. I'm not sure if the GPRD is that reliable that you can be sure that low exposure is really low exposure and not underascertainment in the database.

I hate to say this, but given these concerns, it may not be worth doing this after all. On the other hand, maybe the grant can be given to Harald in Sweden to do his follow-up of the DTAf trial kids...

Tom

- Maximum exposure is too low to see an effect (if there is one)
- The "low exposure data" in the GPRD are unreliable
- Verstraeten quote: *"I hate to say this, but given these concerns, it may not be worth doing this after all."*

Maybe the grant can be given to Harald in Sweden"

Dr. Miller's response

Chen, Robert (Bob) (NIP)

From: EMiller@phls.org.uk
Sent: Wednesday, June 27, 2001 1:58 PM
To: rnc1@cdc.gov
Subject: RE: UK vaccine schedule and thimerosal exposure

The licensing authority has now definitely confirmed that the whole cell vaccine we used prior to 1996 did only contain the 50ug thiomersal dose. This is really annoying as we checked with them several times. I will need to discuss the implications of this with WHO. What is the thiomersal exposure in the Harald Heibel study because I believe they used the UK whole cell vaccine for their 2 4 6 vs 3 5 12 month so even with the most accelerated schedule the Swedish children would get less exposure than our kids routinely get. What do you know about this study design? We still have the opportunity of using another cohort (the one I briefly mentioned) for which there is much more detailed quantitative information on development and much more information on potential confounders. The exposure would be the same - max 75 ug ethyl hg by 4 months.

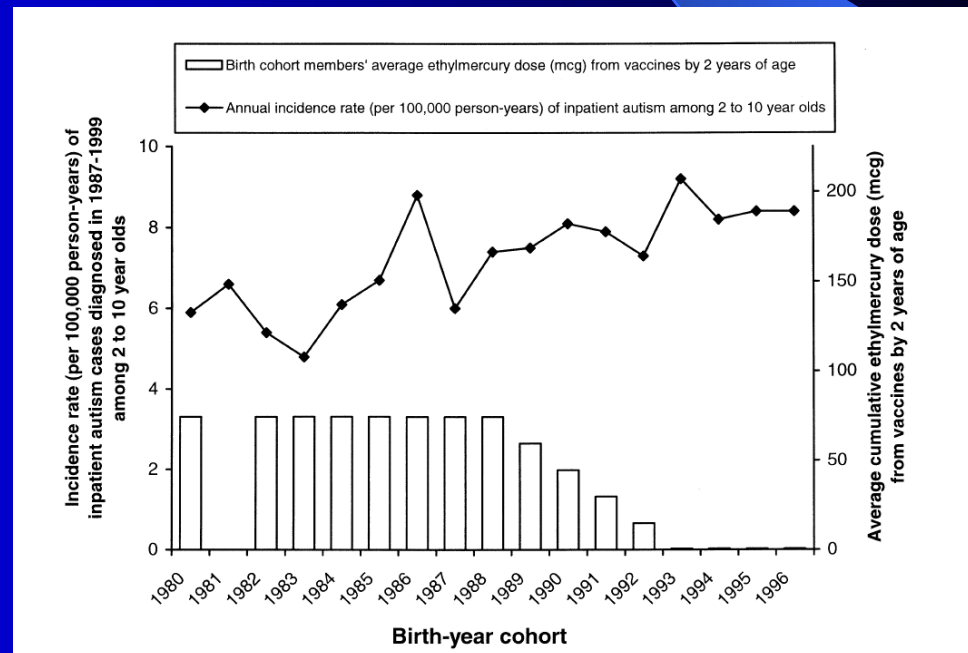
ALSPAC

Liz

- Exposure level in Sweden is less than UK *even under most accelerated schedule (i.e., 75 ug by 6 months age).*

Who is Harald Heijbel?

- Swedish vaccine researcher
- Co-founder of the “off-shore” Brighton Collaboration with Dr. Robert Chen
- His data were presumably presented in the Stehr-Green et al. 2003 publication:



Chen, Robert (Bob) (NIP)

From: EMiller@phls.org.uk
Sent: Tuesday, August 14, 2001 11:01 AM
To: rtc1@cdc.gov
Cc: NAndrews@phls.org.uk
Subject: thiomersal

LIZ GOES FORWARD WITH
GPRD STUDY
(WHERE IS THE EMAIL AFFIRMING
TO LIZ THE ALLOCATION OF WHO
MONEY?)

Dear Bob,

Hope all is well with you and your family. I am just about to receive the GPRD data which we propose to use to do the type of study you did on the VSD data set. It would be very helpful if you had a protocol describing what you did in your study, in particular what the background variables were that you included as possible confounders. I am on leave from 21st August until 10 Sept. but Nick, the statistician who will be working on this data set is around and you could liaise with him directly. Incidentally Nick will be presenting our OPV/intussception work at the forthcoming Washington meeting and would appreciate a chance to talk to you and Tom (whom I see will also be there) about the thiomersal study. Although we don't have the level of exposure that you had in the US there is such a lot of interest here that this study is becoming increasingly important. I have also got funding to look at the ALSPAC cohort which I believe I sent you the protocol for. This cohort has got detailed behavioural and developmental; data available as well as information on other mercury exposures.

With best wishes

Liz

No emails released between 6/27 and 8/14. However, Verstraeten and Chen presumably made the recommendation for Dr. Miller to keep her WHO grant.

January 31, 2005

[REDACTED]
Dear [REDACTED]

This letter is in response to your Freedom of Information Act (FOIA) request of December 14, pertaining to the Miller and Andrews study presented at the 2/9/04 IOM Vaccine Safety Review Committee meeting. Specifically, any correspondence between Elizabeth Miller and/or Nick Andrews and CDC employees up to the date of presentation regarding their study and their presentation. It is also in response to your follow-up E-mail of December 29, which added Brent Taylor, Ph.D. to the list of researchers whose correspondence you wanted CDC to search for.

Enclosed are documents you requested. No documents pertaining to Brent Taylor, Ph.D., were found in our search.

Please note that Dr. Chen did not retain any of his replies to the enclosed E-mails.

The fee is waived in this instance because it falls below our billing threshold.

Sincerely yours,

Lynn Armstrong

Lynn Armstrong
CDC/ATSDR FOIA Officer
Office of the Chief of Staff
(404) 639-7270
Fax: (404) 639-7395

Summary

- Verstraeten and Chen exerted some type of authority in granting (and/or retracting) WHO funds to(/from) Miller
- *The level and mechanism of this authority is indeterminate at this time.*
- The corresponding FOIAed email string was missing correspondences (presumably replies) from Dr. Chen
 - Appealed to DHHS, 2/23/05
 - Letter to Dr. Gerberding by U.S. Senator Patty Murray, 5/19/05

Attempts to get the "Chen emails"

February 23, 2005

PH: 301-443-5252
Fax: 301-443-0925

Dear [REDACTED]

This is to acknowledge receipt of your administrative appeal dated 2/23/2005.

Any questions regarding the status of your appeal should be directed to the Public Health Services (PHS) Freedom of Information (FOI) office.

Your appeal has been assigned the following number PHS-2K5-A-044.

Please reference this number on your correspondence.

Sincerely,

PHS Freedom of Information Office

United States Senate
WASHINGTON, DC 20510-4704

HEALTH, EDUCATION, LABOR
AND PENSIONS
VETERANS AFFAIRS

May 19, 2005

Dr. Julie L. Gerberding, M.D., M.P.H.
Director
Center for Disease Control and Prevention
1600 Clifton Road, N.E.
Atlanta, Georgia 30333

Dear Dr. Gerberding:

In a letter dated March 7, 2005, I was again contacted by one of my constituent [REDACTED] regarding the alleged link between autism and the use of thimerosal in vaccinations. [REDACTED] has requested that I assist him in obtaining information relating to the report conducted on this alleged link by the Centers for Disease Control and Prevention (CDC) and the Institute of Medicine (IOM). Let me quote from his letter:

... Documents have surfaced showing strong conflict of interest within the 6 publications used as the "well-designed" epidemiology studies that were the basis of the 5/18/04 Institute of Medicine Vaccine Safety Review (IOM VSR) Committee report on vaccines and autism. As you most likely recall, the IOM VSR was set up by the CDC via a \$2.7 million contract to the IOM to investigate linkages between vaccines and neurodevelopmental maladies. The 5/18/04 final report of this committee erroneously and fraudulently debunks any type of causal relationship between thimerosal and autism. Within this report, the IOM dismissed many publications elucidating the causal relationship, in favor of these "well-designed" studies.

[REDACTED] continues, stating: "The FOIA transmittal letter from Ms. Lynn Armstrong makes it clear that there were additional e-mails from Dr. Chen that were omitted from this FOIAed information. I have appealed my original FOIA request to the DHHS, in order to obtain Dr. Chen's missing e-mails. [REDACTED] has not received a response to his request for information and I would ask for your assistance in resolving this matter.

If possible, please forward all documents requested by [REDACTED] directly to his [REDACTED] home.

I appreciate your assistance in this matter and look forward to hearing from you about your decision in the near future.

Sincerely,

Patty Murray
Patty Murray
United States Senator

[REDACTED] continues, stating: "The FOIA transmittal letter from Ms. Lynn Armstrong makes it clear that there were additional e-mails from Dr. Chen that were omitted from this FOIAed information. I have appealed my original FOIA request to the DHHS, in order to obtain Dr. Chen's missing e-mails." Dr. Hooker has not received a response to his request for information and I would ask for your assistance in resolving this matter.

If possible, please forward all documents requested by [REDACTED] directly to his [REDACTED] home.

I appreciate your assistance in this matter and look forward to hearing from you about your decision in the near future.

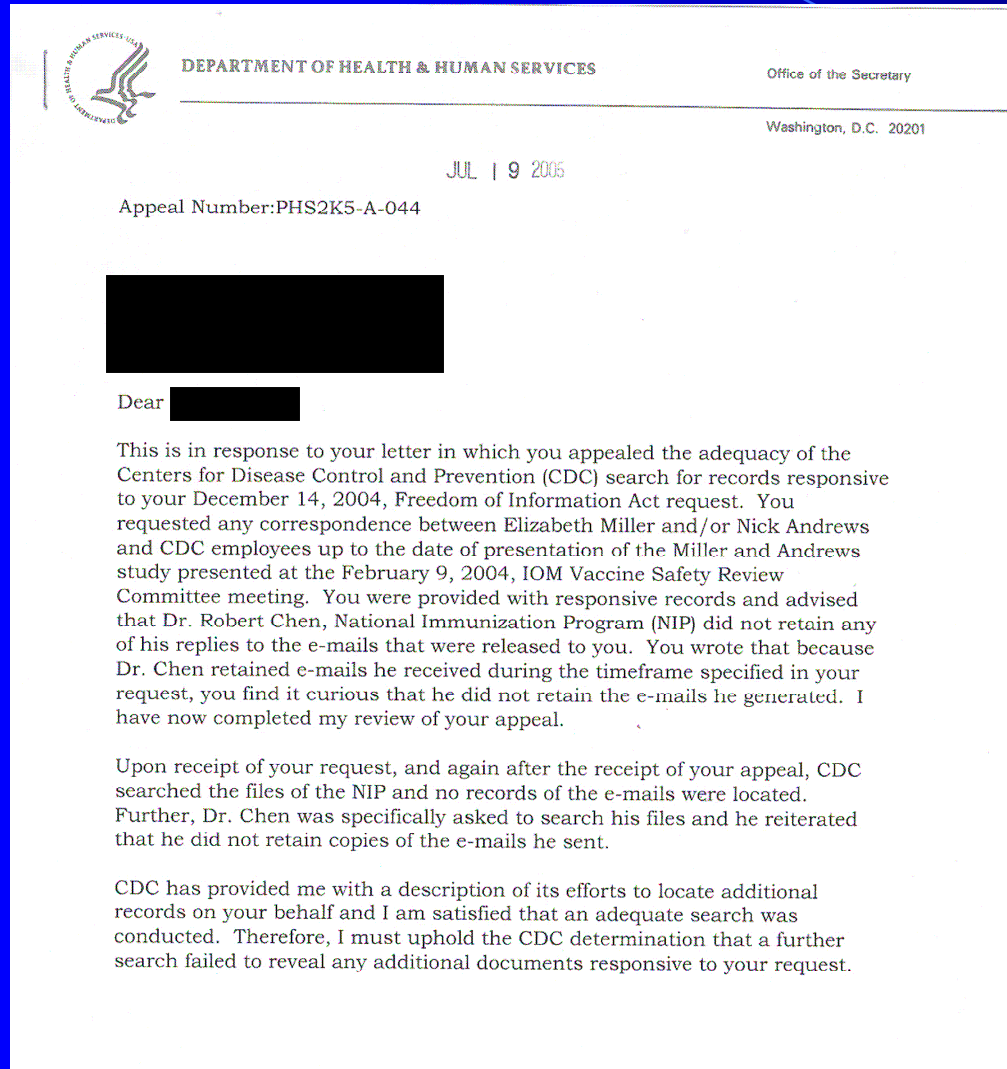
Ms. Lorine Spencer's* response to Sen. Murray

- “My understanding from the FOIA office regarding Bob Chen’s emails is -- that CDC’s response to your administrative appeal went to the appeals officer on 5/10. The response will come from that office – *You should address all communications about your appeal to the PHS FOIA Office at the contact address you used to file it.*” (personal email correspondence, 5/31/05, italics added)
- In other words, Senator Murray should have appealed to the DHHS FOIA Appeals office...

Dr. Gerberding has not responded to Sen. Murray’s letter

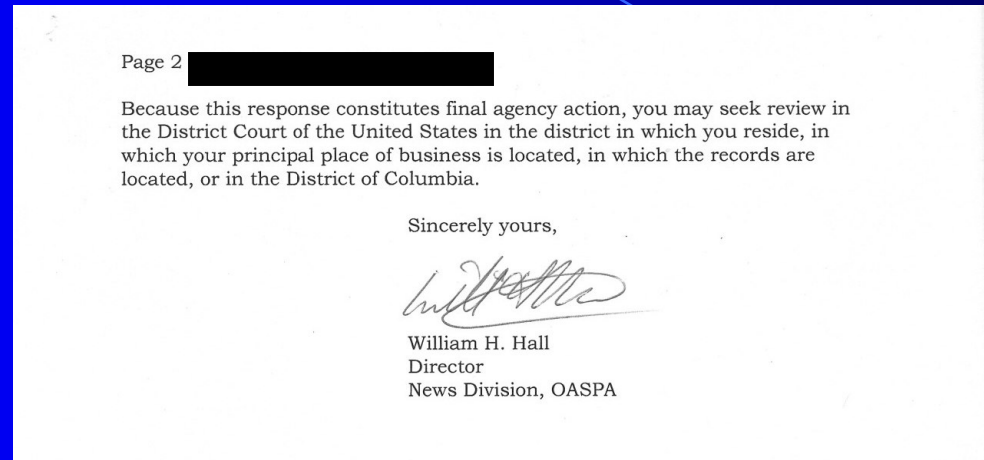
*Community Outreach Liaison, CDC

DHHS Appeal to Receive Chen Emails



“CDC searched the files of the NIP and no records of the e-mails were located. Further, Dr. Chen was specifically asked to search his files and he reiterated that he did not retain copies of the e-mails he sent.”

DHHS Appeal to Receive Chen Emails



I am highly troubled that Dr. Chen was asked personally to search his own hard drive for the emails in question.

This response will be appealed to the District Court of the United States.

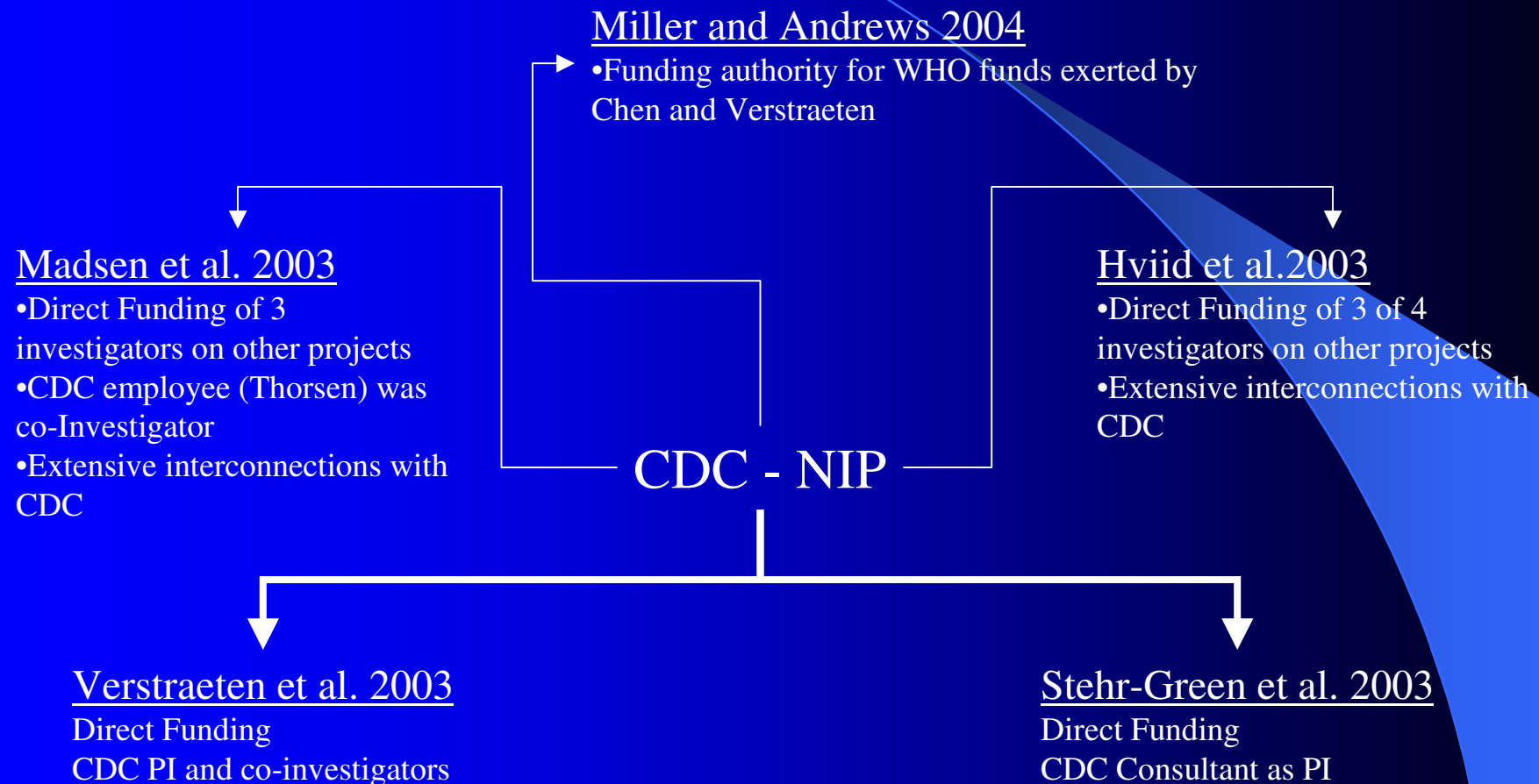
Did the Brighton Collaboration provide a connect to allow Verstraeten and Chen to exercise authority over WHO grants?

- “The Brighton Collaboration is an international voluntary collaboration to facilitate the development, evaluation, and dissemination of high quality information about the safety of human vaccines.”
“(www.brightoncollaboration.com)”
- The Brighton Collaboration was founded by *Robert Chen, Harald Heijbel*, Tom Jefferson, Ulrich Heininger, and Elisabeth Loupi in 1999 at a meeting in Brighton, England. It was officially launched in autumn 2000.
- WHO connection (funding):
 - It is funded by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).
- Lujene Clark (www.nomercury.org) has compiled a significant amount of information on the Brighton Collaboration.



Dr. Elizabeth Miller makes a diagnostic assertion for an individual case of autism in the U.K. in an active effort to persecute a psychologist who suggested a linkage between thimerosal and autism. It should be noted that Dr. Miller never met the patient nor examined the records of the patient in question.

Summary – Monetary Connections of 5 “Well Designed” Studies to CDC



Ties between epidemiology studies and vaccine manufacturers

Study	Vaccine Manufacturer Tie
Verstraeten et al. 2003	Verstraeten employed by GSK starting 7/16/01
Madsen et al. 2003	2 coauthors employed by the SSI
Hviid et al. 2003	All 4 coauthors employed by the SSI
Stehr-Green et al. 2003	Stellfeld (coauthor) was Head of the Department of Medicine, SSI
Miller et al. 2004	Miller has served as an expert witness for GSK, Aventis Pasteur and Merck (all named as defendants in ongoing civil litigation)

Conclusions

- The CDC NIP is both vaccine advocate and vaccine safety watchdog for the United States, which constitutes a huge conflict of interest
- The CDC funded the IOM VSR Committee and all associated activities
- The CDC had both monetary and personnel connections to all five epidemiology studies used as the basis of the final IOM VSR Committee Reports conclusions on causality between thimerosal and autism
- Coauthors on all five epidemiological studies used as the basis for the IOM VSR Committee 5/14/04 report final conclusion have direct ties to vaccine manufacturers