

Researcher Experience with the Vaccine Safety Datalink (VSD) Data Sharing Program

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President, The Genetic Centers of America

Expert witness and consultant in cases involving vaccines before the no-fault National Vaccine Injury Compensation Program (NVICP) and in civil litigation.

David A. Geier, B.A.

President, MedCon, Inc.

Consultant in cases involving vaccines before the no-fault NVICP and in civil litigation.

“The right to search for truth implies also a duty: one must not conceal any part of what one has recognized to be true.”

A. Einstein

Dr. Mark Geier & David Geier

- *Published > 20 articles in the peer-reviewed medical literature dealing with the Vaccine Adverse Event Reporting System (VAERS) database.*
- *The only outside investigators who have had any access at all to the VSD database.*
- *Supporters of safe and effective vaccines.*

THE CRISIS



AUTISM A.L.A.R.M.

**1 OUT OF 6 CHILDREN ARE
DIAGNOSED WITH A
DEVELOPMENTAL DISORDER**

**1 IN 166 CHILDREN ARE DIAGNOSED
WITH AN AUTISM SPECTRUM
DISORDER**



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- Stock Quotes & Charts

Columnists

- James Flanigan
- Michael Hiltzik
- Kathy M. Kristof
- Tom Petruno

The World
The Nation
California | Local

August 7, 2004

COLUMN ONE

Taking It to Vaccine Court

■ Parents say mercury in shots caused their children's autism, and they want drug firms to pay. The industry calls its defense rock-solid.

By Myron Levin, Times Staff Writer

As parents of two severely autistic boys, Kevin and Cheryl Dass of Kansas City, Mo., face a world of heartache and worry.

Dr. Stephen Cochi, head of the national immunization program at the U.S. Centers for Disease Control and Prevention, argues that only "junk scientists and charlatans" support the thimerosal-autism link.

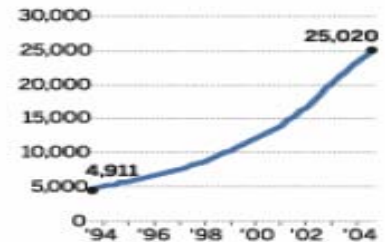
4,200 families, including the Dasses, are demanding compensation to help pay for their kids' special needs. Their claims have inundated an obscure branch of the U.S. Court of Federal Claims in Washington, sometimes called the "vaccine court."

E-mail story Print ad

Graphics

Autism on the rise

Total number of known cases of autism in California



Source: California Department of Developmental Services

Los Angeles Times

August 7, 2004

Photos



'It's torn our life apart'
(Dan Ipock / For the Times)

Times Headlines

Drug Firms Cautious on Vaccine for West Nile

Nominee for State Post Is Scrutinized

UNL

MAJOR RESEARCHERS SUPPORT

Thimerosal-Neurodevelopmental Disorder Relationship

Dr. James Adams

Mercury Retention in Autistic Children Analyses

Chairman, Department of Materials and Engineering, Arizona State University

Dr. Ruma Banerjee

Thimerosal Neuro-Tissue Culture Analyses

University of Nebraska

Dr. David Baskin

Thimerosal Neuro-Tissue Culture Analyses

Department of Neurosurgery and Anesthesiology, Baylor College of Medicine

Dr. John Bernard

Mercury Retention in Autistic Children Analyses

Director, Nuclear Reactor Laboratory, Massachusetts Institute of Technology

Dr. Richard Deth

Thimerosal Neuro-Tissue Culture Analyses

Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University

Dr. Mark R. Geier

Epidemiology of Vaccines-Autism, Mercury Retention, Biochemical, & Genetic Analyses in Autistic Children Analyses

President, The Genetic Centers of America

Dr. Sudhir Gupta

Thimerosal Immune-Cell Tissue Culture Analyses

Chief, Basic and Clinical Immunology, Department of Medicine, University of California, Irvine

Dr. Boyd Haley

Thimerosal Neuro-Tissue Culture & Mercury Retention in Autistic Children Analyses

Chairman, Department of Chemistry, University of Kentucky

Dr. Mady Hornig

Thimerosal Mouse Model of Autism

Columbia University

Dr. Joel Mason

Thimerosal Neuro-Tissue Culture Analyses

Tufts University

Dr. Jill James

Thimerosal Neuro-Tissue Culture, Mercury-Biochemical Pathways Analyses in Autistic Children

University of Arkansas

Dr. Walter Spitzer

Epidemiology of Vaccines-Autism

Department of Epidemiology, McGill University

Dr. S Sukumar

Thimerosal Neuro-Tissue Culture Analyses

Johns Hopkins University

MERCURY IN MEDICINE REPORT - SUBCOMMITTEE ON HUMAN RIGHTS & WELLNESS

Thimerosal used as a preservative in vaccines is likely related to the autism epidemic. This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of safety data regarding injected thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry.



U.S. Office of Special Counsel
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

OSC Forwards Public Health Concerns on Vaccines to Congress

For Immediate Release: 5/20/04

The Office of Special Council (OSC) today forwarded to Congress hundreds of disclosures alleging public health and safety concerns about childhood vaccines that include a mercury-based preservative known as thimerosal, and its possible link to neurological disorders, including autism. Notwithstanding a new Institute of Medicine study released yesterday that concludes there is no link between thimerosal and autism, the OSC sent copies of the letters to both Senator Judd Gregg and Rep. Joe Barton, to ensure the proper Congressional oversight committees are aware of these serious allegations...In addition, the disclosures allege, among other things, that some datasets showing a relationship between thimerosal/mercury and neurological disorders no longer exist, that independent researchers have been arbitrary denied access to CDC databases...The disclosures also allege that the CDC and FDA colluded with pharmaceutical companies at a conference in Norcross, Georgia, in June 2000, to prevent the release of a study which showed a statistical correlation between thimerosal/mercury exposure through pediatrics vaccines and neurological disorders...**I believe that these allegations raise serious continuing concerns about the administration of the nations' vaccine program and the government's possible inadequate response to the growing body of scientific research on the public health danger of mercury in vaccines.**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Investigations

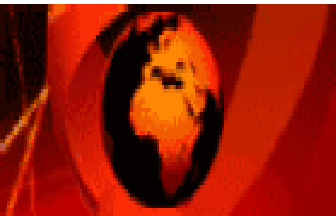
Memorandum

JUL 19 2004

The Reverend Lisa Karen Sykes
3604 Milbrier Place
Richmond, Virginia 23233

Dear Reverend Sykes:

This letter is in response to you April 3, 2004 correspondence, which arrived at our office from Mr. Kenneth M. Donohue, acting in his capacity as Chairman of the Investigations Committee, President's Council on Integrity and Efficiency (PCIE). In his letter to this office, Mr. Donohue expressed concern over your allegation Thimerosal is being used "in order to increase the manufacturer's profit margins"...**Upon review of the correspondence you provided to the PCIE, in conjunction with further research into the matter, we have determined that your above allegation represents a potential conflict-of-interest issue which may be criminal in nature and therefore falls within the Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Investigations' (OI) authority to investigate.**



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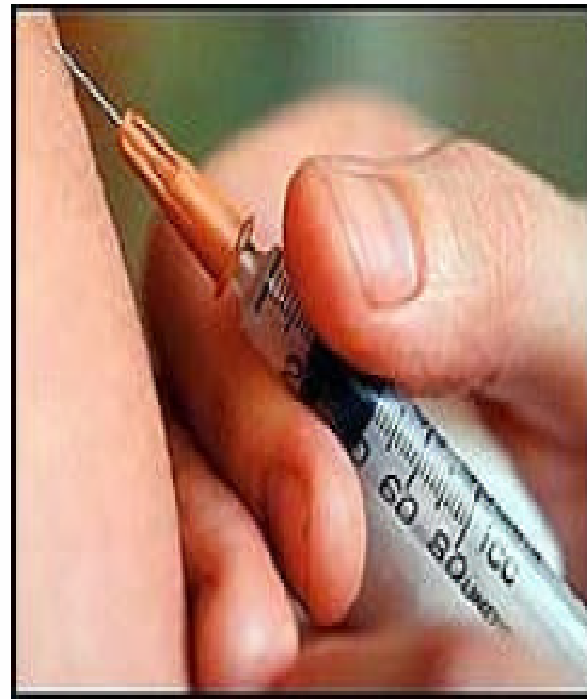
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Vaccine scrapped over autism fear

A vaccine containing mercury given to babies when they are eight weeks old is to be scrapped amid fears of a link with autism.

The move follows recent research in America that suggests a connection between the mercury used to preserve the whooping cough vaccine, and autism.

The jab, without mercury, will be given as part of a new five-in-one vaccine.



The whooping cough vaccine contains mercury

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[The BBC's Daniel B](#)
"The change is part of
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Chronology

of

our access to the

VSD

Phase I:

CDC Approval

August 2002 – December 2002

- Our first attempts to get access to the VSD database began in **early August 2002**.
- The CDC VSD approval process **lasted approximately 5 months**.
- Our **final proposal submitted in this approval process was almost 200 pages long**.
- CDC stated in their approval letter of 31 December 2002, **“In our previous letters as well as in this final letter, we provide feedback to your proposals, which may facilitate all the steps in the data sharing process.”**

Phase II:

HMO IRB Approval

January 2003 – June 2003

- Our first attempts to get HMO IRB approval began in **early January 2003**.
- We made contact with the HMO IRBs at **Group Health Cooperative, North-West Kaiser, Northern California Kaiser, Southern California Kaiser, Kaiser Colorado, and UCLA-Harbor** (the CDC provided incomplete HMO IRB information – **For example, no contact information was provided for Harvard Pilgrim**).
- Each HMO in VSD had its own policies regarding **Human Subject Forms, patient confidentiality classroom requirements, and the format our proposals needed to be submitted**.

A Case in Point of Difficulties:

UCLA-Harbor

- **UCLA-Harbor did not have its own IRB, but hired a private company to be its IRB.**
- **The private IRB required us to separate all of our 22 projects into separate proposals, and would review only 1 proposal at a time.**
- **The private IRB then requested \$1,500 per proposal to review our materials.**
- **The contact person (Stewart Laidlaw) was unwilling to participate in arranged conference calls between us, him, and representatives of Congress to work-out the issues that had arisen.**

Our Final HMO Approvals:

**Northern California Kaiser, Southern
California Kaiser, North-West Kaiser,
Group Health Cooperative, and
Kaiser Colorado**

Re-Analysis of CDC Publications from VSD Difficulties

- 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.

- *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 thimerosal exposure and neurodevelopmental disorders no longer exist.

Phase III:

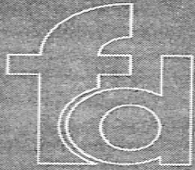
Challenges in CDC Providing us Access to the Physical VSD

July 2003 – October 2003

- **VSD Assembly Issues – CDC restricts data in our VSD datasets.**
- **CDC RDC User Fees: Initial flat rate of \$3,208.85 for 2 days access & VSD dataset assembly; additional daily fee of \$779.58**
- **Number of Access Days: Minimum 2 days to Maximum 10 days.**
- **RDC Access Restrictions: 2 persons per computer, no cell phones, pagers, or other electronic devices, and all output was subject to disclosure review before it could be removed from the RDC.**
- **VSD is in SAS Format – NO HELP PROVIDED – We had to postpone our access to the VSD to get a SAS programmer.**

CDC Attacks our Examination of VSD before we see the Database

**Verstraeten T, DeStefano F, Chen RT, Miller E.
Vaccine surveillance using large linked databases:
opportunities, hazards and proposed guidelines.
Expert Review of Vaccines 2003;2:21-29.**



Vaccine safety surveillance using large linked databases: opportunities, hazards and proposed guidelines

Thomas Verstraeten[†], Frank DeStefano, Robert T Chen and Elizabeth Miller

CONTENTS

LLDBs used for vaccine safety surveillance

Opportunities

Hazards

Expert opinion: proposed guidelines for the use of LLDBs in vaccine safety monitoring

Five-year view

Conclusion

Key issues

References

Affiliations

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KEYWORDS:
epidemiology, medical record linkage, pharmacovigilance

“Another potential hazard lies in the unrestricted use of LLDBs [Large Linked Databases] for screening or hypothesis generating purpose, as has been carried out with the VAERS database [The authors referenced some of our previous studies in VAERS]. When using retrospective cohorts derived from LLDBs, a clear distinction must be made between an exploratory study undertaken as a hypothesis-generating exercise and a study undertaken to test an explicit a priori hypothesis. Ideally, exploratory analyses should be undertaken with a view to conducting a formal hypothesis-testing study if evidence of a significantly increased risk is found in particular postvaccination period. This is ever more important in the current public-health environment of mistrust and litigation, where any suspected association can give rise to further mistrust before it is ever validated in a formal hypothesis-testing study.”

Phase IV:

**VSD Access at the RDC
Part I**

9-10 October 2003

- The RDC is guarded by armed guards, and we were escorted to analyze the VSD in a room with no windows, and one computer (without a printer).
- One monitor to review all of our research activities.
- **NO VSD INTERFACE.**
- **CDC assembled our VSD dataset in pieces**, so that only one type of vaccine was provided per dataset.
- CDC publication re-analysis datasets contained no raw VSD data, **only final datasets with summary VSD data.**
- We were eventually able to run some preliminary programs to begin to analyze the DTaP vaccine dataset.

**Congressman
Dr. Dave Weldon
Expresses his Views
About Our Access to the
VSD Database**

**Letter to Dr. Julie Gerberding, Director, CDC
31 October 2003**

“The only way these issues are going to be resolved – and I have only mentioned a few of them – is by making this particular dataset and the entire VSD database open for independent analysis. One such independent researcher, Dr. Mark Geier, has already been approved by the CDC and the various IRBs to access this dataset. They have requested the CDC allow them to access this dataset. They have requested the CDC allow them to access this dataset and your staff indicated to my office that they would make this particular dataset available after the Pediatrics study is published. Earlier this month the CDC had prepared three similar datasets for this researcher to review to allow him to reanalyze CDC study datasets. However when they accessed the datasets – which the researchers paid the CDC to assemble – the datasets were found to have no usable data in them. I request that you personally intervene with those in the CDC who are assembling this dataset to ensure that they provide the complete dataset, in a usable format, to these researchers within two weeks. **The treatment that these well-published researchers have received from the CDC thus far as been abysmal and embarrassing.** I would also be curious to know whether Dr. Verstraeten, an outside researcher for more than two years now, was required to go through the same process as Dr. Geier in order to continue accessing the VSD.”

Phase V:

**VSD Access at the RDC
Part II**

29-30 January 2004

- **TWO MONITORS EMPLOYED TO REVIEW ALL OF OUR RESEARCH ACTIVITIES.**
- **TOTAL INABILITY TO ACCESS PRINTOUTS – THE REPRESENTATIVE FROM THE RDC WHO HAD ACCESS TO THIS ROOM DECIDED TO GO ON A 3 HOUR LUNCH BREAK.**
- **THE MONITORS DECIDED TO EMPLOY NEW DISCLOSURE REVIEW PROCEDURES LIMITING THE AMOUNT OF DATA THAT WE WERE ABLE TO VIEW ON OUR PRINTOUTS (For example, they decided to allow us to not be able to view data on printouts with numeric counts < 5 , even through the Verstraeten et al. study published in Pediatrics in November 2003 contains numeric counts < 5 in multiple places).**

Example of a Printout from our VSD Access Session that had Undergone the New Disclosure Review Procedure

Austism After 1997

08:19 Friday, January 30, 2004 1

The FREQ Procedure

Table of Hg_Total by Doses

Hg_Total	Doses				Total
Frequency Percent Row Pct Col Pct	1	2	3	4	
0	0 0.00 0.00 0.00	0 0.00 0.00 0.00	0 0.00 0.00 0.00		
25		0 0.00 0.00 0.00	0 0.00 0.00 0.00	0 0.00 0.00 0.00	
50	0 0.00 0.00 0.00		0 0.00 0.00 0.00	0 0.00 0.00 0.00	
75	0 0.00 0.00 0.00	0 0.00 0.00 0.00			
100	0 0.00 0.00 0.00	0 0.00 0.00 0.00	0 0.00 0.00 0.00	9 45.00 100.00 64.29	9 45.00
Total					20 100.00

Phase VI:

CDC Calls
to end our Access to
the VSD Database

(Note: CDC sent this letter only to the HMOs, even ones with no data in our VSD dataset, but NEVER to us.)

13 February 2004

- **Three days following our presentation to the Institute of Medicine hearing on 'Vaccines & Autism,' (9 February 2004) where we presented some early results from our analysis of the VSD database, Jeane Santoli, Acting Director for Science, NIP, CDC sent a letter to all the HMOs that had provided access to their data in the VSD.**

CDC Accusations:

- **Protocol Issue (1): Geiers compared autism rates in those receiving 100 mg of thimerosal from DTaP to those receiving zero mg from DTaP.**
- **Protocol Issue (2): Geiers attempted to merge datasets – creating more complete medical records on subjects**
- **Confidentiality Concerns: A VSD file was misnamed.**

All the HMOs Suspend our Access to the VSD Database

February 2004 – June 2004

Phase VII:

**We Appeal the HMOs
Suspension Decisions**

February 2004 – Today

In response to the suspensions we received from each of the HMOs, we prepared a formal letter to each where we categorically denied the baseless allegations made by Dr. Santoli.

Significant Points Addressed in Our Letter:

- CDC VSD Assembled Datasets **DID NOT CONTAIN**: names, addresses, zip codes, state of residences, phone numbers, HMO membership information or center of examination for each patient – Each patient identified by a randomly assigned number, distinct in each dataset.
- We only accessed VSD Table codes provided to us by CDC that were specified in our proposals.
- We examined the VSD in the RDC under the supervision of a monitor and with the CDC's stringent access rules.
- We ran no illegal programs, and the illegal file name was an accidental error that was in fact caught by our computer programmer and brought to the attention of the monitor.
- We resent the implication that we would try, even if we could, which we could not, to breach patient confidentiality. We have always and will continue to guard patient confidentiality with the greatest care.

RESULT:

**Northern California Kaiser
Permanente Reinstates our
Access to Their Data in VSD**

22 July 2004

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. 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.