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Wednesday, September 15, 2010

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Dear Mr. Levinson:

In 2008, the global economy nearly collapsed due, in large part, to the failure of our federal government, specifically the Securities and Exchange Commission, to properly regulate the financial industry.

In 2010, America suffered the worst ecological disaster in its history due, in large part, to the failure of our federal government, specifically the Mineral Management Service, to properly regulate the oil industry.

More serious, however, is the on-going failure of the US government, specifically the Secretary of the Department of Health and Human Services (Secretary, HHS) and the Food and Drug Administration (FDA), which reports to the Secretary, to properly regulate the drug industry, which continues its illegal use of poisonous mercury compounds in the manufacture of drugs, especially vaccines.

Despite substantiated allegations that US national health agencies, including but not limited to the Centers for Disease Control and Prevention (CDC), have been compromised by egregious conflict-of-interest, the Office of Investigations for the Department of Health and Human Services (HHS-OIG), by its inaction in the face of this urgent public health crisis, is now party to this greatest of federal failures.

Your failure to act has permitted, and still permits, the ongoing administration of Thimerosal-preserved vaccines to the population without the required proof of safety or the opportunity of informed consent, in violation of American law.

The unnecessary and systematic injection of mercury, in the form of Thimerosal (49.6% mercury by weight) dubiously used as a 'preservative', into children and pregnant women represents one of the greatest catastrophes facing our nation, far exceeding those already publicized by the media.

With more than:

- ◆ One in every six children now diagnosed with a behavioral and/or developmental disorder,
- ◆ 25% of our children currently suffering one or more persistent chronic illnesses, and
- ◆ One in every 70 boys now diagnosed with an autism spectrum disorder,

the federal failure to lawfully regulate this industry has allowed mercury to compromise the minds of children just as it has permitted greed to compromise the economy and oil to compromise the Gulf of Mexico.

Using the National Immunization Program of this nation to administer unsafe, unnecessary and undisclosed mercury to American citizens is unjustifiable, damaging and criminal.

Investigations by HHS-OIG have already substantiated the validity of allegations regarding ‘conflict of interest and Thimerosal’ made to the Office of Special Counsel (OSC) in 2004 by fifteen families with mercury-toxic children.

Furthermore, in a December of 2009 report published by HHS-OIG (under the direction of Daniel R. Levinson), “CDC’s Ethics Program for Special Government Employees on Federal Advisory Committees,” your agency determined that: numerous serious conflict-of-interests, lack of ethics training, and failure to complete appropriate ethics paperwork, were common among CDC-associated special Government employees.

Despite the established credibility of these allegations, and a call for Congressional Investigations by OSC into Thimerosal, neither HHS-OIG nor any other government agency has taken any action so as to protect the public health from the ravages of this known poison, neurotoxin, developmental toxin, carcinogen, mutagen, teratogen, and immune-system disruptor.

Based upon new information, enclosed with this letter, we add a tenth allegation to the nine previously submitted to HHS-OIG: *the illegal presence of mercury in FDA-approved medicines, especially vaccines, is being defended by apparently fraudulent studies.*

Criminal investigations now ongoing in Denmark reveal key ‘independent’ studies, purportedly showing mercury does not cause autism, were, in some cases, financially and ethically compromised by our own national health agencies.

For example, the CDC assisted in the design, data manipulation, review and publication of these studies.

The resulting and seemingly biased epidemiological studies cannot prove safety or establish the current levels of mercury in vaccines as “safe.”

Moreover, the original datasets have been “lost” or withheld from independent review so that even the published findings cannot be confirmed, much less properly reviewed.

Nonetheless, the FDA and other national health agencies and authorities repeatedly cite these studies in their sanctioning of the ongoing use of mercury in medicine.

One such authority, a 2004 Institute of Medicine committee report, which purportedly exonerated vaccine-derived Thimerosal as a cause of autism in its landmark decision,¹ relied heavily upon these non-reviewable, and, in most cases, provably biased and probably fraudulent epidemiological studies.

Additionally, the apparent embezzlement of approximately 2 million US dollars and serious professional misconduct²:

“The Danish Agency for Science, Technology and Innovation (DASTI) has been a grant recipient as part of a cooperative agreement with the US National Center for Birth Defects and Developmental Disabilities, CDC, since 2001. The grant has been administered by Odense University Hospital and Aarhus University (AU) under the direction of Dr. Poul Thorsen. The grant has multiple components and involves collaborators at other institutions in Denmark, including the University of Copenhagen and SSI (Statens Serum Institut) ... Unfortunately, a considerable shortfall in funding at Aarhus University associated with the CDC grant was discovered. In investigating the shortfalls associated with the grant, DASTI and Aarhus University became aware of two alleged CDC funding documents as well as letter regarding funding commitments allegedly written by Randolph B. Williams of CDC’s Procurement Grants Office which was used to secure advances from Aarhus University. Upon investigation by CDC, a suspicion arose that the documents are forgeries. DASTI conducted an internal investigation of the authenticity of the documents and have filed a police report...A police investigation is ongoing.”

and serious academic misconduct:

¹ Institute of Medicine of the National Academies. **Immunization Safety Review: Vaccines and Autism**. Washington, DC: National Academy Press, 2004.

² See Exhibit 1 as well as Exhibit 2 – an official statement from Aarhus University dated January 22, 2010.

“Aarhus University wishes to confirm that Dr Poul Thorsen no longer has any connection to Aarhus University, and that Aarhus University will not be able to collaborate with Poul Thorsen in the future” (see Footnote 2).

by one of the key researchers involved in Scandinavian epidemiological studies³, Dr. Poul Thorsen, calls the validity of these studies into question.

In addition, the revelation that CDC provided substantial funds to authors of these studies as well as significant political influence on the part of CDC staff in helping to force their publication⁴:

“Dr. Jose Cordero, Assistant Surgeon General, Director of the National Center on birth Defects and Developmental Disabilities letter of December 10, 2002 to the Editor in Chief, Dr. Jerold Lucey, of Pediatrics, ‘I am writing in support of an expedited review and consideration of the enclosed manuscript that examines the association between Thimerosal, and ethyl mercury containing preservative, and autism...The Danish study is a powerful epidemiologic study of this issue...Its findings provide one strong piece of evidence that Thimerosal is not causally linked to autism.’”

adds further doubts about the validity of these studies.

Similarly, the validity of the British ‘independent’ studies⁵ is also called into question by the revelation that CDC staff was involved in helping to fund:

Elizabeth Miller from the U.K. writing an email to Robert Chen of the CDC on Tuesday, June 26, 2001⁶ specifically questioned,

“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”.

³ Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Association between Thimerosal-containing vaccines and autism. *JAMA* 2003; **290**: 1763-1766.

Madsen KM, Lauritsen MB, Pedersen CB, Thorsen P, Plesner AM, Andersen PH, Mortensen PB. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. *Pediatrics* 2003; **112**: 604-606.

Stehr-Green P, Tull P, Stellfeld M, Mortenson, Simpson D. Autism and Thimerosal-containing vaccines: lack of consistent evidence for an association. *Am J Prev Med* 2003; **25**: 101-106.

⁴ See Exhibit 3.

⁵ Andrew N, Miller E, Grant A, Stowe J, Osbrone V, Taylor B. Thimerosal exposure in infants and developmental disorders: a retrospective cohort study in the United Kingdom does not support a causal association. *Pediatrics* 2004; **114**: 584-591. Heron J, Golding J, ALSPAC Study Team. Thimerosal exposure in infants and developmental disorders: a prospective cohort study in the United Kingdom does not support a causal association. *Pediatrics* 2004; **114**: 577-583.

⁶ See Exhibit 4, Item 1.

and design:

Thomas Verstraeten of the CDC to Robert Chen of the CDC regarding the UK vaccine schedule and Thimerosal exposure on June 26, 2001 questioned⁷,

“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 DTAP trial kids...Tom”.

these studies.

Finally, the repeated failure of and/or the refusal by the researchers in question, as well as the US the Centers for Disease Control and Prevention (CDC), to provide the redacted patient records from relevant studies examining the issue of mercury-in-vaccines to independent researchers for review further destroys their credibility.

Given the preceding realities, we call for an immediate and urgent investigation into the likelihood that the national health agencies in this country were involved in the collusion, conspiracy, and fraud, which characterize these studies.

We also demand an immediate ban on the use of Thimerosal or any other mercury compound in the manufacture of all drugs and an immediate Class 1 recall of Thimerosal-preserved vaccines and other drugs before one more child is unnecessarily disabled for life due to medicines containing any form of added mercury.

In order to guide your investigation, we make the following specific charges:

- CDC helped to establish a for-profit institute: North Atlantic Neuro-Epidemiology Alliances (NANEA), which published studies falsely legitimating Thimerosal while taking tens of millions of dollars of undisclosed US Government funding over a decade.
- While NANEA purports to be an independent research institute, CDC personnel: Drs. Diana Schendel, Marshalyn Yeargin-Allsopp, and Catherine Rice were affiliated with NANEA while it was receiving government funding. Dr. Schendel was also listed as a “coordinator at Centers for Disease Control and Prevention, Atlanta, USA” during this time period.
- Dr. Poul Thorsen’s involvement in the key studies on the safety of

⁷ See Exhibit 4, Item 2.

Thimerosal that were conducted by NANEA calls the integrity of these studies into question, as he is being sought in an on-going investigation regarding forged documents purportedly signed by CDC, and the embezzlement of CDC grant money.

- Dr. Poul Thorsen is also being sought in an on-going fraud investigation.

Not only the Denmark Studies but also another critical study from the United States, the Verstraeten Study⁸, shows evidence of apparent fraud.

This ersatz study, favored by our government, is characterized by, among other issues:

- a. E-mails between various parties that clearly show improper adjustment of the statistical analyses to reduce the magnitude of the statistical connection between the level of mercury exposure in vaccinated children and their risk of developing autism,
- b. The CDC's failure to disclose that the lead author, Thomas Verstraeten, was actively involved in iteratively reworking data analysis to reduce the statistical significance of the links found between vaccine exposure and the risk of autism and other neurodevelopmental disorders and helping to publish data from the Vaccine Safety Datalink (VSD) database, while employed by a vaccine maker, GlaxoSmithKline,
- c. "Loss" of the original datasets used in the "Verstraeten" study preventing any independent review of the reported outcomes,
- d. Failure of the researchers in the other government-favored studies to provide their original datasets to independent reviewers,
- e. Failure of the researchers in the government-favored studies to disclose their significant conflicts and/or the source(s) of their funding, and
- f. Condemnation of the study designs used in these government-favored studies by a subsequent Institute of Medicine Committee.⁹

⁸ Verstraeten T, Davis RL, DeStefano F, Lieu TA, Rhodes PH, Black SB, Shinefield H, Chen RT; Vaccine Safety Datalink Team. Safety of Thimerosal-containing vaccines: a two-phased study of computerized health maintenance organization database. *Pediatrics* 2003; **112**: 1039-48.

⁹ Institute of Medicine of the National Academies. **Vaccine Safety Research, Data Access, and Public Trust**. Washington, DC: National Academy Press, 2005.

As published in the Congressional Record on May 20, 2003, the “Mercury in Medicine Report” written by the Subcommittee on Human Rights and Wellness,

Committee on Government Reform made the findings that included:

“14. The CDC in general and the National Immunization Program in particular are conflicted in their duties to monitor the safety of vaccines, while also charged with the responsibility of purchasing vaccines for resale as well as promoting increased immunization rates...17. To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, under powered and fatally flawed. The CDC’s rush to support and promote such research is reflective of a philosophical conflict in looking fairly at emerging theories and clinical data related to adverse reactions from vaccinations.”

Based upon our government’s reliance on these apparently fraudulent studies, unsafe drugs containing mercury are still being foisted upon an unsuspecting American public, as well as the rest of the world.

To summarize, we offer the following observations for your consideration:

- 1.** In regard to the mercury-autism issue, the conclusion, and not the credibility, of any peer-reviewed published scientific study appears to be the standard by which research is accepted or rejected by federal agencies and supposedly independent professional organizations, who share culpability for having knowingly permitted more than two generations of children to be damaged by mercury.
- 2.** In an era in which federal regulation has failed, epidemiological studies (based on the analysis of medical records) which cannot be validly used to prove safety, are knowingly being misused to sanction the injection Thimerosal-preserved vaccines into pregnant women and children as, to use the FDA’s phrase, “not unsafe”.
- 3.** Worse, only those epidemiological studies that fail to show a statistically significant link between the level of Thimerosal exposure and the risk of neurodevelopmental harm because of flawed design or other conscious post-study iterative manipulation are categorically accepted by those agencies and organizations, which have, directly or indirectly, failed in their responsibility to ensure vaccine safety and to protect the public health.

On the other hand,

- ◆ Toxicological studies, which show a lack of safety,

- ◆ Patient case and case-control, which clearly show mercury-related harm, and
- ◆ Epidemiological studies sounding an urgent alarm that the continuing administration of medicinal mercury is fueling the epidemics of chronic illness and developmental disorders among children,

are summarily dismissed as flawed or uninterpretable, no matter how sound.

As the numbers of children damaged by the ongoing, unconscionable and unnecessary use of Thimerosal in vaccines and other medicines climb into the millions, it is time for the conclusions of science to be separated from the exercise of political influence.

Compounding this tragic failure of federal regulation and violation of the public health are knowingly false government statements published on agency websites by the FDA and others that falsely claim:

- ◆ The mercury (Thimerosal) was removed from childhood vaccines in 2001, when in fact, some childhood vaccines still contain some level of Thimerosal today, and the Thimerosal-preserved flu shots have been recommended for pregnant women and children since 2002, and
- ◆ The government's "recommendation" to inject pregnant women and children 6 months of age and older with inactivated-influenza vaccines, most doses of which are Thimerosal ("mercury")-preserved, was made in 2004, when in fact, the April 12, 2002 issue of the CDC's Morbidity and Mortality Weekly Report recommended flu shots for pregnant women and young children at a time when all FDA-approved flu shots were mercury-preserved flu shots.

These statements reflect not only passive acceptance of an errant policy but also active misguidance by government officials.

Such misinformation deprives already-confused Americans of the chance to protect their own health and denies parents the opportunity to safeguard their own children from being mercury poisoned.

Tragically, the 'toxic assets' we hold in this scandal are our affected children, who will never enjoy the full measure of personal autonomy and independence conferred by the health they have been denied.

Though priceless in value, these children, whose minds and bodies have been maimed by mercury, will need lifetime care.

The contribution they would have made to our society is gone, because our “health” agencies, and the medical, pharmaceutical, and political establishments are dedicated to denying the ongoing mercury poisoning by medicine rather than to protecting the persons who are being poisoned.

Paralyzed by inaction, inertia or denial, your agency has contributed significantly to this national tragedy by:

- ❖ Tolerating this ongoing fraud of “mercury in medicine” and
- ❖ Failing to take any meaningful and effective action to stop the unnecessary and unacceptable mercury poisoning of the American public, and especially American children

since at least 2004, when you received hundreds of written entreaties to take action.

These letters contained, in detail, nine specific allegations of wrongdoing on the part of the US health agencies involved.

With this letter, we now present you with a tenth allegation, which requires your immediate investigation.

This letter will stand in historic witness against you, should you continue pursuing a course of inaction, further diminishing this nation’s future by tacitly sanctioning the on-going administration of drugs containing added mercury in any form to its children.

Sincerely,

Reverend Lisa K. Sykes
President, CoMeD, Inc.

The list of Enclosures included with this letter and the Organizations and Persons supporting this CoMeD letter are listed on the pages that follow.

Undertaken in memory of Jo Pike, Alan Clark, MD, and Elizabeth Birt, who did not live to see the vaccine reforms for which they fought become a reality.

Enclosures:

1. 2010 statement from “AARHUS UNIVERSITET” regarding “Dr. Poul Thorsen’s involvement in Aarhus University projects” (Exhibit 2)
2. 2010 article on the North Atlantic Neuro-Epidemiology Alliances (NANEA) by Sanne Maja Funch in Danish with an English translation (Exhibit 1)
3. 2004 OSC letter and 2004 OSC press release
4. 2004 letter from Michael E. Little, Deputy Inspector for Investigations, Office of Investigations (OI), Office of Inspector General (OIG), Department of Health and Human Services (HHS) to Rev. Lisa Karen Sykes
5. 2001 email correspondence involving Tom (“Thomas Verstraeten”), Bob (“Robert Chen”) and UK’s Dr. Elizabeth Miller (“Liz”) regarding problems with lower Thimerosal exposure levels in the UK with respect to any mercury-autism linkage study (Exhibit 4)
6. 2002 letter from José F. Cordero, MD, MPH, Assistant Surgeon General, Director National Center on Birth Defects and Developmental Disabilities to Jerold F. Lucey, MD, Editor in Chief, **PEDIATRICS**, encouraging the journal to publish the “Verstraeten” study (Exhibit3)
7. 2004 letter from Rev. Lisa K. Sykes to Office of Special Counsel(OSC) outlining 9 original allegations to the OSC

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