
COALITION FOR VACCINE SAFETY

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February 24, 2010

Senator Tom Harkin, Chairman
Senator Mike Enzi, Ranking Member
Senate Health, Education, Labor and Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Harkin and Enzi,

In light of the growing number of questions and concerns regarding vaccine safety, it is imperative that the U.S. government rely on the best, most thorough and rigorous science possible. The Department of Health and Human Services is legally and ethically bound to do everything reasonably possible to ensure the safety of vaccines. The undersigned organizations request congressional hearings to investigate and review the role and performance of HHS and its constituent agencies to ensure vaccine safety. We call on Congress to fulfill its proper oversight function to ensure full compliance with law.

Congress should review the claims of HHS and the Centers for Disease Control (CDC) that vaccines are safe with a jaundiced eye. The existing evidence on vaccine safety is grossly insufficient and fails to meet the requirements of public confidence. In fact, **significant evidence points to suppression of science that could prove or disprove vaccine safety. This suppression may be due to potential liability and financial conflicts of interest involving individuals and organizations responsible for scientific studies and vaccine safety policies. Furthermore, HHS has blatantly disregarded laws that Congress passed requiring it to thoroughly study vaccine safety.**

HHS non-compliance with the congressional Mandate for Safer Vaccines in the 1986 National Childhood Vaccine Injury Compensation Act clearly calls for congressional intervention and investigation. HHS' congressionally-mandated research to reduce vaccine injuries has been flawed and inadequate. The Mandate specifically states, "[M]ake or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." The only way HHS can be in compliance with the mandate is by conducting proper tests using both vaccinated and unvaccinated children, which to date, has not been done.

The Court of Federal Claims, which determines compensation for vaccine injuries, must rely on the best available vaccine safety science for its decisions. The consequences of government agencies willfully providing insufficient or flawed science for determinations of this magnitude

are astounding from the standpoints of public health and justice. Surely ignorance is no substitute for science.

HHS adherence to the spirit and intent of the Combating Autism Act of 2006 is in serious question, resulting in inadequate vaccine safety science and research. An important additional reason for Congress to act now is that the Court of Federal Claims is likely to soon release its Omnibus Autism Proceeding “test cases” on the possible link between the mercury-containing preservative thimerosal and autism. If there has been any suppression of evidence and science or significant conflicts of interest contaminating the research that undergirds the Court’s determinations, there is an urgent need for Congress to act. HHS’ and CDC’s failures to provide adequate science on vaccine safety contribute to judicial decisions being made in a vacuum. Many officials claim there is no link between vaccines and autism when in fact many reputable experts, including the former Chairman of the National Institutes of Health Dr. Bernadine Healy and HHS’ own scientific advisory panel, the National Vaccine Advisory Committee (NVAC), argue that the evidence is insufficient.

Below are just a few examples of suppression of science and conflicts of interest Congress should review; the full texts are available at our website www.coalitionforvaccinesafety.org:

- **Former Chairman of the National Institute of Health (NIH) Dr. Bernadine Healy**, said, about a link between vaccines containing thimerosal and autism, “What we’re seeing in the bulk of the population: vaccines are safe. But there may be this susceptible group. The fact that there is concern, that you don’t want to know that susceptible group is a real disappointment to me. If you know that susceptible group, you can save those children. If you turn your back on the notion that there is a susceptible group... what can I say?” **Regarding whether or not there is a link between vaccines and autism, “The question has not been answered.”**
(http://www.cbsnews.com/stories/2008/05/12/cbsnews_investigates/main4086809.shtml)
- **NIMH Director Dr. Thomas Insel at a January 2009 Interagency Autism Coordinating Committee (IACC) meeting:** “I’m concerned about the optics ... of having HRSA vote on issues related to autism and vaccines when they have a large court case, the optics of having people who have, could be perceived to have, um, or to represent those with a financial investment in this issue. It takes it out of the realm of a scientific question, a research question, and it raises the possibility that some could see whatever comments we make as being biased by nonscientific issues, and I understand that’s a risk in lots of things that we do, this one really feels, since this is a court case that is soon going to become public, and I think it’s fairly close to a large omnibus effort, um, I think that this one really does represent some jeopardy for this process, for this committee, almost any way in which it comes out. If we say, yes we think it’s important to look at this, and to provide additional information, it implies that we believe that there is a relationship between autism and vaccines, and it suggests, um, that, um, in some way this runs opposite to what HHS may define through the HRSA process.” (from the minutes of the meeting)

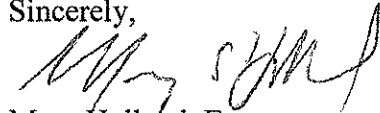
- **Former Congressman David Weldon (R-FL)** “I recently received documents from the Centers for Disease Control confirming that one of the studies upon which they rely heavily, was twice rejected by respectable journals. Both the Journal of the American Medical Association (JAMA) and The Lancet rejected the Madsen study examining rates of autism among children before and after the removal of thimerosal in Denmark in 1992. A top CDC official wrote to Pediatrics urging them to give “expedited” consideration to what he characterized as a “powerful epidemiology study.” Yet the study had significant weaknesses and they knew it. (April 19, 2007 statement from the *Congressional Record*)
- **HHS conceded in a settlement agreement that vaccines led to autism in a child due to mitochondrial dysfunction**, *Poling ex. rel. Poling v. Sec'y of HHS*, 2008 WL 1883059. **The Court of Federal Claims decided in 2007 that child’s autism was due to vaccine-induced acute disseminating encephalomyelitis (ADEM)**, *Banks v. Sec'y of HHS*, 2007 WL 2296047. Despite these determinations of vaccine-induced autism, HHS asserted throughout the Omnibus Autism Proceeding that an autism-vaccine link is “junk science.” <http://www.uscfc.uscourts.gov/omnibus-autism-proceeding>.
- **Former CDC Director Dr. Julie Gerberding (now president of Merck Vaccines)** reluctantly admitted on CNN on March 19, 2008 that “vaccines can occasionally cause fever in kids” and, if a child is predisposed to mitochondrial disorder (which may be 20% or more of autistic children), the fever can result in damage where “some of the symptoms can have the characteristics of autism.” <http://www.youtube.com/watch?v=Dh-nkD5LSIg>.
- The Institute of Medicine’s (IOM) 2004 report on vaccine safety, often cited as exonerating the role of vaccines in autism, specifically left open the potential for environmental triggers, including vaccines, by stating “[a]bsent biomarkers, well defined risk factors, or large effect sizes, **the committee cannot rule out, based on the epidemiological evidence, the possibility that vaccines contribute to autism in some small subset or very unusual circumstances.**” <http://www.iom.edu/Reports/2004/Immunization-Safety-Review-Vaccines-and-Autism.aspx> Despite this IOM statement, HHS has made no effort since to study or screen out possible subsets of vulnerable children.
- Dr. Louis Cooper, former head of the American Academy of Pediatrics, recently stated: “What has been missing in order to give parents confidence that immunization is one of the best ways to protect the health of their children? Our national failure falls into two categories. First, we've had inadequate ongoing, credible education of the public and health professions from trusted public-health officials concerning the known and unknown benefits and risks of vaccines. Today's parents have little fear of diseases they mistakenly think have been eliminated by vaccines. Second, **there's been grossly insufficient investment in research on the safety of immunization. Together, these failures contributed to undermining of public confidence.**” (“*The Confidence Gap: Why the Obama Administration Needs to Restore Public Faith in the Safety of Childhood Vaccines*,” *Newsweek* Feb. 23, 2009) <http://www.newsweek.com/id/185986>.
- Members of the CDC's Advisory Committee on Immunization Practices get money from vaccine manufacturers. Relationships have included: sharing a vaccine patent; owning

stock in a vaccine company; payments for research; getting money to monitor manufacturer vaccine tests; and funding academic departments. The conflict of interest by key decision-makers poses a threat to the health of our nation's children. **A recent report of the HHS Office of Inspector General found that 97% of outside advisers at the CDC in 2007, including those on the Advisory Committee on Immunization Practices, had at least one omission in their financial disclosure forms.** (CDC's Ethics Program for Special Government Employees on Federal Advisory Committees, oig.hhs.gov/oei/reports/oei-04-07-00260.pdf.)

- While the U.S. government has compensated more than 1,300 brain injury claims in the Court of Federal Claims since 1988, it refuses to study those cases or track how many of them result in autism. The Vaccine Injury Compensation Program fund has \$3.1 billion, but if the 4,900 families with claims of autism were to receive awards, **the compensation fund would fall short by \$15 billion to \$25 billion, providing a possible incentive for ignoring or suppressing proper research on vaccine safety and autism.** [ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0110.pdf](http://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0110.pdf).

These examples highlight conflicts of interest and inadequacies in the science that we would like the Congress to explore. We would be happy to provide more examples. We offer our full support, assistance and cooperation with a hearing or series of hearings, and look forward to your response.

Sincerely,



Mary Holland, Esq.

Coalition for Vaccine Safety, Steering Committee

Co-founder of the Elizabeth Birt Center for Autism Law and Advocacy

Members of Coalition (in formation):

Autism Action Network (www.autismactioncoalition.org)

AutismOne (www.autismone.org)

Elizabeth Birt Center for Autism Law and Advocacy (EBCALA)

(www.autismone.org/content/elizabeth-birt-center-autism-law-and-advocacy-ebcala)

Generation Rescue (www.generationrescue.org)

Life Health Choices (www.lifehealthchoices.com)

National Autism Association (www.nationalautismassociation.org)

The Coalition for Safe Minds (www.safeminds.org)

Talk About Curing Autism (www.talkaboutcuringautism.org)

Cc'd

Senator Patrick Leahy, Chairman

Senator Jeff Session, Ranking Member

Senate Judiciary Committee

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