"Something is Rotten, But Not Just In Denmark"

Remarks of Rep. Dave Weldon, M.D. (R-FL)
Autism One Conference
Chicago, Illinois

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It is a pleasure to be here with you today. I am pleased to see that the Autism community is more united today than they have ever been. I have said repeatedly that the Autism Community is the 900-pound gorilla that has not had its voice heard adequately on Capitol Hill.

That is largely due to the endless demands on your time, effort, emotions, and money in caring for the unique needs of your children. There is little left to engage the public at large and the Congress in particular. I see that changing. Certainly, last week's Institute of Medicine "report" has had one positive effect, it has united and reinvigorated you and the parents of autistic and vaccine injured children across this nation.

I want to make it clear that I support vaccinations. My 5-year-old son has had all of his vaccinations. Someone in the media last week tried to portray me as a "vaccine skeptic." After reviewing my record on this issue and all of my statements in the past, the newspaper printed a retraction. This however, seems to be part of a pattern – to vilify those who simply ask if our vaccines could be safer.

Friends, I practice what I preach. I support vaccinations and gave them to thousands of my patients and my own son. However I also believe it is appropriate to acknowledge that, like with any medical intervention, different individuals respond differently. We are all unique, we all have a different genetic makeup, and what may cause no harm in one individual just might cause harmful in another.

Since we established the vaccine compensation program in the late 1980s several thousand individuals have been compensated for vaccine injuries. We know there are adverse reactions, and I believe it is important that we dedicate resources to better understand why some children have them.

For too long, those who run our national vaccination program have viewed those who have adverse reactions, including those with severe adverse reactions, as the cost of doing business. Furthermore, the vaccine compensation program which was designed to be a no-fault compensation system has become so adversarial that only the most obvious of cases receive compensation and too many parents feel that the program is not worth the agony.

The questions that I have raised and continue to raise about vaccines are several. The number one question has been whether neurological problems were caused in some children by the high levels of mercury contained in many vaccines in the 1990s. Mercury is a neurotoxin. And, in the

1990s children – infants and unborn children – were exposed to significant amounts of mercury at the most critical point of their development.

Is the Autism community united now in their effort to see that research into the possible association between vaccines and neurodevelopmental disabilities is investigated? You bet!

Autism One, Defeat Autism Now, Cure Autism Now, Unlocking Autism, The Autism Society of America, Unlocking Autism, Moms Against Mercury, The National Autism Association, No Mercury, and The National Alliance For Autism Research have all expressed objections to the IOM report and have united behind the need to ensure that the federal government commits the necessary research to fund the biological and clinical research needed to get at the facts.

Just what is so wrong with the IOM report? What has caused all of the Autism groups to unite against the IOM?

In my 10 years of service in the US Congress, I have never seen a report so badly miss the mark. I have heard some weak arguments around Washington and I can tell you that those in the IOM's recent report are very weak. Examine this report in detail. It is plagued with serious flaws.

On January 15 of this year I wrote Dr. Julie Gerberding, the Director of the CDC, I asked her to post-pone the February 9, IOM meeting and this report because of my concern that this was not an exercise in discovering the truth but was instead a meeting "being driven by a desire to short-circuit important research and draw premature conclusions. If the purpose of this meeting is to seriously consider and address these concerns" I wrote, "then this will not be accomplished."

Allow me to quote further from my letter to Dr Gerberding:

> "It appears to me not only as a Member of Congress but also as a physician that some officials within the CDC's NIP may be more interested in a public relations campaign than getting to the truth about thimerosal."
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> "Pressing forward with this meeting at this time, I believe, will further undermine the credibility of the Centers for Disease Control (CDC) on matters of vaccine safety and do damage to the reputation of the IOM. I believe the proposed date of this meeting, which you have the ability to change, is in the best interests of no one who is seeking the truth about a possible association between vaccines and neurodevelopmental disorders, including autism.

In a follow-up telephone conversation to me on February 3, 2004, Dr. Gerberding assured me that the IOM's February meeting was "not an attempted draw conclusions" but merely to "update on the science" of where we are at this point in time. However, it clearly draws conclusions and in what is perhaps the greatest outrage it goes further to call for a halt to all further research.

A public relations campaign, rather than sound science, seems to be the M.O. of the officials at the CDC's National Immunization Program (NIP) office. Why do I say this? Let's look, not only at the timing of the IOM meeting in February, the content of the IOM report, but also at studies the IOM used as a basis for their decisions. The IOM bases their decision almost entirely on five

epidemiology studies, all of which were conducted by researchers with an interest in not finding an association, all of which have short-comings, and all of which the IOM declares would miss an association if it were in a genetically susceptible subset of children.

Not only the timing of the IOM meeting raises suspicions, but also the narrowing of the scope of inquiry, and the emphasis IOM was to assign to epidemiology.

In 2001, the Institute of Medicine concluded that "exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders." The IOM also recommended that children not be given mercury-containing vaccines. What was the response of the CDC? For this most recent report they narrowed the IOM's scope to looking just at Autism. Does that sound like an agency interested in understanding whether or not thimerosal might be harmful, to some children? Or, does this response lead one to conclude that they are more interested in designing something to reassure an increasingly skeptical public?

Unlike 2001, this time the IOM was directed by CDC to only consider the possible relationship between thimerosal and Autism, rather than NDDs as a whole. Anyone familiar with the Verstraeten study knows exactly why the IOM's scope was narrowed – because the 2003 Verstraeten study found associations between thimerosal and NDDs and some children with autism may have been misdiagnosed as having speech or language delay.

By narrowing the scope – which largely went unnoticed by the media – the CDC has avoided acknowledging that thimerosal very well may have caused NDDs in some children. This latest IOM report is simply part of a P.R. campaign in my view. Would we not have had a much more productive report if the CDC had updated the research on possible associations between thimerosal and NDDs as a whole.

In evaluating thimerosal's relationship to Autism, the IOM relies almost exclusively on five epidemiology studies. The principal authors of all five studies have serious conflicts of interest. All five studies were published in 2003 leading up to the IOM's February 2004 meeting. All were conducted while the CDC and NIH virtually ignored the IOM's 2001 biological and clinical research recommendations.

It is critical to note the instructions that the IOM was given, primarily by the CDC, which has been funding the IOM. Pages 5 and 6 of the IOM report make it clear that epidemiology was to reign supreme. In the absence of epidemiological evidence to support causality, IOM was instructed to give biological evidence little consideration, and was prohibited from allowing biological evidence to lend evidence toward causality.

Is it any wonder that the CDC has spent the past two years dedicating significant funding to epidemiology while starving funding for clinical and biological research? The IOM notes in their report that the epidemiology studies they examined were not designed to pick up a genetically susceptible population. Yet, they attempt to use these five flawed and conflicted statistical studies to quash further research into the possible association between vaccines and autism. This report is extreme in its findings and recommendations. The IOM process became little more than an attempt to validate the CDC's claims that vaccines have caused no harm,

while quashing research to better understand whether or not and how the MMR or thimerosal might contribute to the epidemic of neurodevelopmental disorders, including autism.

I would like to turn now to the specifics of these five studies.

Verstraetn Study – Pediatrics, November 2003

The Verstreaten study has been the subject of considerable criticism. This study, published in November 2003 in *Pediatrics* the journal of the American Academy of Pediatrics was released with much fanfare and public relations "spin." Much has been written exposing the study's methodological problems, findings, and conclusions. Most importantly however, is that this study did not compare children who got thimerosal to those who did not. Instead, its CDC-employed authors focused primarily on a dose response gradient.

In addition to the study itself, it is important to note the public relations "spin" surrounding this study.
On the day the Verstraeten study was released, a top CDC researcher and a coauthor of the study was quick to declare to the news media that, "The final results of the study show no statistical association between thimerosal vaccines and harmful health outcomes in children, in particular autism and attention-deficit disorder." Let me repeat that, "The final results of the study show no statistical association between thimerosal vaccines and harmful health outcomes in children, in particular autism and attention-deficit disorder."

The newspaper headlines of the day read:

- "Study Clears Vaccines Containing Mercury" *Associated Press* and *USA Today*,
- "CDC Says Vaccines are Safe…" *The Seattle Times*

While that was the spin of the day, allow me to quote from the study. "… we found no **consistent** significant associations between TCVs [thimerosal containing vaccines] and neurodevelopmental outcomes. In the first phase of our study, we found an association between exposure to Hg from TCV and some of the neurodevelopmental outcomes screened. In the second phase, these associations were not replicated for the most common disorders in an independent population." They did find associations, but as they changed the study most of the associations, but not all, disappeared.

Furthermore, in a January 2004 article this lead co-author was forced to admit that many children in the study were too young to have received an autism diagnosis. He went on to admit that the study also likely mislabeled young autistic children as having other disabilities thus masking the number of children with autism.

The message from the CDC to media was that there is nothing to be concerned about, but the study said something somewhat different. The news media too a large degree took the CDC's spin hook, line, and sinker, and largely chose not to read the study itself.

Five months after the article was published, and largely after the IOM report had been written, the lead author of the study, Dr. Thomas Verstraeten broke his silence in a letter to Pediatrics

stating: “The bottom line is and has always been the same: an association between thimerosal and neurological outcomes could neither be confirmed nor refuted, and therefore, more study is required.”

Dr Verstraeten the lead author of the study says that an association between TCVs and NDDs cannot be refuted based on his study, yet the IOM in their assessment of the same study state that it is a basis for concluding that “there is no association between thimerosal-containing vaccines and autism.”

The IOM acknowledges that Verstraeten would not have picked up an association in a genetically susceptible population. The IOM also noted that the study was limited in its “ability to answer whether thimerosal in vaccines causes autism because the study tests a dose-response gradient, not exposure versus non-exposure.”

It is also critical to note that the Verstraeten study cannot be validated. The earlier datasets have been destroyed and the only datasets the CDC will make available to outside researchers are the ones that they have already manipulated. The raw, unaltered data is not available. Additionally, outside researchers are held to a much more restrictive access to information than are CDC researchers. Only one independent researcher has been granted access to the CDC’s VSD database and the CDC has kicked those researchers out based on ridiculous reasons. They claimed their research methods might infringe on privacy. Yet the database contains no names. The researchers do not even know what HMO the patient is enrolled in. Nor do they know what state the subjects live in. There is no way for an individual to be identified through their research.

Hviid Study

The IOM sited the 2003 study by Hviid of the Danish Population as one the key studies upon which it bases its conclusions.

Let’s consider first the conflict of interest of the principal author. Hviid works for the Danish Epidemiology Science Center which is housed at the Staten Serum Institute (SSI) the government owned Danish vaccine manufacturer. Also, all of his coauthors either work with him at the Center or are employed by SSI. Staten Serum Institute (SSI) makes a considerable profit off the sale of vaccines and vaccine components and the U.S. is a major market for SSI. SSI has $120 million in annual revenues and vaccines are the fastest growing business segment accounting for 80% of its profits. Both the U.S. and U.K. are important export markets for SSI’s vaccines and vaccine components.

Furthermore, if Hviid were to find an association between thimerosal and autism, SSI with which he and his Center are affiliated would face significant lawsuits. These facts are important and are critical when evaluating this study. Furthermore, this study only looked at Autism and not neurodevelopmental disorders as a whole.

Mercury exposures in the Danish population varied considerably from those in the U.S. Danish children received 75 micrograms of mercury by 9 weeks and another 50mcgs at 10 months. By

comparison, children in the U.S. received 187.5 mcgs of mercury by age 6 months – nearly 2 1/2 times as much mercury as Danish children in just the first 6 months of life.

Dr. Boyd Haley has said that comparing the exposures in the US to those in other countries is like comparing apples and cows. I think there is a lot of truth to that.

Hviid states that the rate of autism went up after they began removing thimerosal from vaccines in 1992. The numbers in Hviid study are skewed in that they added outpatient Autism diagnosis to the number after 1992. The IOM notes other limitations of the study including the differences in the dosing schedule and the relative genetic homogeneity of the Danish population.

Yet even with these serious limitations, the committee concludes that this study has a "strong internal validity," finding an increase in autism after removal of thimerosal.

Like the Verstraten study, Hviid would not be able to pick up a group of children who were genetically susceptible to mercury toxicity.

Danish autism rate is about 6 in 10,000 vs. 30 in 10,000 in the U.S. – once again we are comparing apples and cows. Indeed, I believe it can legitimately be argued that the lower rate of Autism in Denmark is attributable to the lower exposure to mercury in their population

Madsen Study

Next the IOM relies on the study by Madsen et al., once again examining virtually the same population that Hviid examined. Again, the relevance of the Danish experience to the U.S. experience is limited in that the Danish population is genetically homogenous and had significantly lower thimerosal exposures than children in the U.S.

Let's consider the conflicts of interest with this study. First of all, two of Madsen's coauthors are employed by the Staten Serum Institute. Additionally, like Hviid, two of Madsen's coauthors work directly for the Staten Serum Institute (SSI) – the Danish vaccine manufacturer which exports vaccines and vaccine components to the U.S. and which faces liability if an association is found. Madsen works for the Danish Epidemiology Science Center – which is affiliated with SSI.

This study, like Hviid, added outpatient cases into the number of cases of autism after 1995. The authors acknowledged that this addition might have exaggerated the incidence of autism after the removal of thimerosal. The IOM acknowledged that this limits the study's contribution to causality.

Stehr-Green Study

The IOM relied on the Stehr-Green study which examined the Danish population (do you see a pattern yet?) and Swedish populations and attempted to compare that to the U.S. population. Furthermore, a key coauthor if this study is employed by the Danish vaccine manufacturer - Staten Serum Institute.

I will not repeat the problems with the Danish data again, but with regard to Sweden it is important to note the children there received even less thimerosal than children in Denmark – receiving only 75 mcgs by age 2. Furthermore, the authors included only inpatient autism diagnoses in the Swedish population. The IOM notes that the ecological nature of this data "limits the study's contribution to causality." But they site it anyway.

Miller et al..

The Miller study examines the population of children in the United Kingdom. This study is still unpublished which limits a critical and public evaluation of its findings.

Dr. Miller has actively campaigned against those who have raised questions about vaccine safety. She and her department receive funding from vaccine manufacturers, and she reportedly serves as an expert witness on behalf of vaccine manufacturers who are being sued.

This study, like the Verstraeten study is a dose response study which is limited in that it does not compare children who received thimerosal to those who did not.

Children in the U.K were exposed to up to 75 mcg of mercury by 4 months of age. This represents about one-half of what children in the US would have been exposed to by this age, plus children in the U.S. got another 50 mcg two months later at age 6 months for a total exposure in the first six months of life of nearly 2 1/2 times what children received in the U.K.

The author concludes that the study found no association between increasing exposures to thimerosal and Autism.

Conclusion on Epi studies.

You can see clearly why the IOM is on very shaky ground in drawing the conclusions they did. They based their decision on five epidemiology studies:

- Three of them examining the genetically homogenous population of Denmark.
- At least one employee of the Staten Serum Institute serves a coauthor of at least 3 of the studies.
- Only one study examining the U.S. population – and that study did not compare those with no mercury exposure to those with exposures.
- Four of them with populations receiving less than half of the mercury exposure that children in the U.S. received
- None of them with any ascertainment of prenatal or postnatal background mercury exposures.
- None of them considering prenatal exposures which may have given children
- None of them able to detect a susceptible subgroup that many have had a genetic susceptibility to mercury toxicity.
- Three of them failing to address how the addition of outpatient cases of Autism in Denmark might have perilously skewed the results.
- Four of them examined populations with autism rates considerably below that in the U.S.
- One of the studies has not been published and not subjected to public review.

Bio/Clinical Research - Thimerosal

Since the release of the IOM's report in 2001, public health officials in the US virtually ignored the biological and clinical research recommendations. While the CDC had no trouble funding epidemiology studies – all with their flaws and inadequacies – several critical biological and clinical research recommendations were starved of funding:

The IOM recommended that the following studies be done, but the CDC and the NIH failed to dedicate the resources to fund these studies:

- Identify primary sources and levels of prenatal and postnatal background exposures to thimerosal, including Rho (D) Immune Globulin in pregnant women and other forms of mercury (fish) in infants, children and pregnant women – NOT DONE;
- Compare the incidence and prevalence of NDDs before and after removal of thimerosal from vaccines. NOT DONE and the CDC tells me they will not begin such studies until 2006.
- Research how children, including those with NDDs, metabolize and excrete metals – particularly mercury- NOT DONE
- Conduct research on theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal with background mercury exposures from other sources – NOT DONE
- Conduct careful, rigorous and scientific investigations of chelation when used in children with NDDs, especially Autism. NOT DONE though in their latest report they urge that this be highly restricted.
- Conduct comparative animal studies of the toxicity of ethylmercury and methylmercury to better understand the NDD effects of thimerosal – ONLY PARTIALLY DONE – but with very little federal support.

In 2001 the IOM stated that it is "unclear whether ethylmercury [from vaccines] passes readily through the blood-brain barrier…" The IOM recommended several biological and clinical studies to answer this question and whether this mercury could cause developmental problems. These studies were in large part never done. Yet IOM chose to ignore the need for this research and instead has focused its analysis on the data available today, most of which is statistical data.

There is much more research that needs to be done before it can definitively be said that thimerosal does not contribute to NDDs. Even today, the IOM cannot tell you with any degree of certainty what happens to ethylmercury once injected into an infant. Does it go to the brain? Does is cause developmental problems? Who knows?

MMR – Autism Association

Allow me to touch briefly on the IOM's analysis of the MMR-Autism issue. They devoted only one hour of discussion to this topic at the February meeting and failed to invite those who were most intimately involved in this research to present to the IOM.

As with thimerosal, the IOM relied almost exclusively on epidemiology. They made their decision about whether or not measles may be related to Autism in children, by reviewing 13 statistical studies in which many of the authors have conflicts of interest. Some of these authors have been openly hostile in their assessments, which calls into question their objectivity. Also, remember it is epidemiology that reigns supreme in this review – even if the studies are flawed in their design.

The IOM still cannot answer the question as to why measles is in the intestines of some Autistic children. Why is it there? What is it doing? How did it get there? Is it contributing to Autism? The IOM attempts to explain this issue away by saying it's likely that the presence of measles could just be a co morbidity to Autism. This cavalier attitude of the IOM, the CDC, and others in the public health community is unacceptable. We have a moral obligation to fully support research to understand why vaccine strain measles is the intestines and CSF of these children. The government mandated vaccination, the least we should do is fund research to understand why measles is persisting in these children, what harm it might be causing, and how we might best treat these children.

The NIH is only now attempting to duplicate the work of Dr. Andrew Wakefield. Despite being vilified for the last 6 years half of Dr. Wakefield's work has been demonstrated to be correct. Practitioners across the U.S. and in many other parts of the world are finding the same inflammatory bowel disease he first described in Lancet in 1998. Drawing "conclusions" at this time is counterproductive. Statistical studies are of little benefit, only a clinical pathological study will lay this issue to rest.

A Few Final Remarks Regarding The IOM Report

For the reasons outlined above and other reasons, this report is premature, perilously reliant on epidemiology, based on preliminary incomplete information, and I believe may be ultimately repudiated – perhaps in short order.

This report will not deter me nor the Autism community from our commitment to seeing that thimerosal and MMR research is properly done.

This report will do nothing to put to rest the concerns of parents who believe their children were harmed by mercury-containing vaccines or the MMR vaccine.

While this report will lead many clinicians to believe that thimerosal is safe and there is no problem with the MMR, it may contribute further to an erosion in the doctor-patient relationship.

This report has dragged the IOM under the cloud of controversy that has currently engulfed CDC.

Much like the infamous 1989 study by The National Institute of Child and Human Development (NICHD) which missed the link between folic acid deficiencies and neural tube defects like spina bifida, the epidemiology studies reviewed by the IOM in drawing these findings, could easily have missed associations in susceptible populations

Finally, let's remember that the IOM is not immune to error and has been forced to reverse itself before. Most recently the IOM reversed a long-standing finding that chronic lymphocytic leukemia (CLL) was not due to Agent Orange exposures. A similar reversal is a very real possibility here.

H.R. 4169 – The Mercury Free Vaccines Act of 2004

On April 2, I introduced along with Rep. Carolyn Maloney, H.R. 4169 – The Mercury Free Vaccines Act of 2004. We currently have 15 cosponsors from across the political spectrum.

H.R. 4169 will phase-out the use of mercury in vaccines over the next 3 years, giving particular attention to completely eliminating mercury from childhood vaccines on an expedited schedule.

This bill is in response to the fact that:

- The safety of thimerosal in vaccines is not proven
- Mercury is well-established as a neurotoxin.
- According to the EPA 1 in 6 newborns is born with a blood mercury level considered unsafe.
- The FDA and the EPA recently warned pregnant women, nursing mothers, and young children to limit their consumption of certain fish that are high in mercury.
- No one at the NIH or CDC can tell you what happens to the mercury once injected into an infant – Where does it go? How much goes to critical organs? How much to the brain? Can it cause damage to the developing central nervous system? No one can answer these question and they should before infants are exposed to more mercury.
- The CDC is has adopted a policy reintroducing mercury into childhood vaccines by recommending the flu vaccine for infants at 6, 7, and 23 months of age – most of which contain mercury.

If we are going to move this legislation forward, I am going to need each and everyone of you to go back and get your member of Congress to cosponsor this bill. You need to call them and ask them to cosponsor H.R. 4169. And be persistent, but not rude.

New Legislation to Monitor Adverse Reactions to Vaccines

It is critical that we make improvements in how we monitor for and respond to adverse reactions to vaccines. Today there are three government agencies that have responsibilities related to monitoring the safety of vaccines – the FDA, the CDC, and the NIH.

The Food and Drug Administration (FDA) has a responsibility to monitor vaccine safety. However, their role is largely limited to ensuring that vaccine lots that are released meet FDA standards and collecting information to be entered into the Vaccine Adverse Events Reporting System (VAERS).

The NIH does not have a concerted effort to fund vaccine safety research. They provide funding for research in a haphazard manner - if you happen to submit a proposal and it passes peer

review they may fund it. The NIH has funded only a handful of studies over the past two years investigating vaccine safety issues.

The CDC has the greatest responsibility in this area. Unfortunately, they also have the greatest conflict of interest. The CDC's vaccine safety program amounts to about $30 **M**illion a year, and half of this goes to pay HMOs for access to the Vaccine Safety Database.

The biggest conflict within the CDC is that they are also responsible for a running $1 **B**illion vaccine promotion program. The CDC largely measures it success by how high vaccination rates are. Here lies the largest conflict. Any study raising concerns that there might be adverse reactions is likely to result in safety concerns leading to lower vaccination rates. Lower vaccination rates are in direct conflict with the CDC's top measurement of success. Clearly, due to its overwhelming size and the manner in which the agency measures its success, the vaccine promotion program overshadows and influences the CDC's vaccine safety program.

In fact, rightly or wrongly, the vaccine safety office within the CDC is largely viewed by outside observers as nothing more than another arm of the vaccine promotion program, giving support to vaccine promotion policies and doing very little to investigate and better understand acute and chronic adverse reactions.

Further complicating the CDC's role and undermining their research is the fact that the vaccine safety studies produced by the CDC are impossible to reproduce. External researchers are not granted the same level of access to the raw datasets that the CDC's internal researchers are granted. The bottom line is that the CDC's studies related to vaccine safety cannot be validated by external researchers – a critical component in demonstrating the validity of scientific findings.

The CDC recently announced that a Blue Ribbon Panel will meet to examine how the CDC might better review vaccine safety. I do not hold out much hope for this panel, however, because the panel is limited in their scope. Much like the IOM was limited in the outcome they were allowed to draw, this panel is limited to deciding where within CDC, vaccine safety monitoring should be housed. The NIH recently recognized the importance of moving patient safety monitoring outside of NIH – I believe the same should be done with vaccine monitoring. It should be completely removed from the CDC's jurisdiction. The CDC is too conflicted to oversee this function.

In order to ensure that there is a concerted and independent effort within the federal government to monitor for adverse reactions to vaccines, I have prepared legislation which I will soon introduce that will ensure that vaccine safety monitoring is completely independent. It has become clear to me that the federal government has failed miserably and has not given this issue the attention that is needed. Clearly, greater oversight and complete independence is needed.

My legislation will ensure that those responsible for vaccine safety research are free from all conflicts of interest and have as their sole focus the following:

- Determining what these adverse reactions are
- Understanding why some individuals have adverse reactions, and
- How we might best ensure that such reactions are avoided.

Brighton Collaboration

Finally, I want to turn my attention to something known as the Brighton Collaboration.

I am very concerned about the development of the Brighton Collaboration which began in 2000. This is an international group comprised of public health officials from the CDC, Europe, and world health agencies like WHO, and vaccine manufacturers.

This first task of the Brighton Collaborations, created several years ago, is to define what constitutes and adverse reaction to a vaccine. They have established committees to work on various adverse reactions to vaccines. Particularly troubling is the fact that serving on the panels defining what constitutes an adverse reaction to a vaccine, are vaccine manufacturers. What is even worse is the fact that some of these committees are chaired by vaccine manufacturers. It is totally inappropriate for a manufacturer of vaccines to be put in the position of determining what is and is not an adverse reaction to their product.

Do we allow GM, Ford and Chrysler to define the safety of their automobiles?

Do we let airlines set the safety standards for their airlines and determine the cause of an airline accident?

Do we allow food processors to determine whether or not their food is contaminated or caused harm?

Then, why I ask, are we allowing vaccine manufactures to define what constitutes an adverse reaction to a vaccine?

This collaboration is fraught with pitfalls and merges regulators and the regulated into an indistinguishable group.

It is critical that the American public look at what is going on here and how this entity may further erode their ability to fully understand the true relationships between various vaccines and adverse reactions.

I plan to devote additional attention to this effort.

Concluding Remarks

Finally, Autism is a difficult challenge facing our nation. We have made considerable progress through groups like Autism One and the other autism organizations represented here. The work you are doing is work that must continue. I commend each of you.

I commend the researchers who are engaged to develop a deeper understanding of what is going on with these children and how we might improve their treatments. I am hopeful that the folks down at the NIH, the CDC, and the IOM will be more supportive of your work. I will do all that

I can to see that critical research in all areas of autism research continue to receive increased funding.

I commend the parents who have failed to give up on their children. I commend you for your dedication to want the best for your children and for the sacrifices you have made for them.

I urge each of you to take your story to your Member of Congress and your Senator. Share your struggles with them. If I, along with the few others who have made defeating autism a top priority are to be successful, it is critical that every Member of Congress know what Autism is and that they have constituents who are watching them and asking for their help.

I urge you to tell your local television reporters and newspaper reporters your story and your struggles. Tell everyone who are willing to listen. It is through your testimony that others will know of this devastating epidemic plaguing our children.

I also urge you to share with others what is working in the treatment of your children. You are blessed with the resources that are available to you at this conference. Listen and learn from the providers here who have a lot to offer.

Finally, let me know what I can do to help. I stand in partnership with each of you.

Thank you for inviting me to join you today. It has been a great honor.

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