Statement of Rep. Dave Weldon, M.D.
Member of Congress
Before the Institute of Medicine
February 9, 2004

Good morning. I appreciate the opportunity to address you again.

I continue to be guided by a strong desire to get at the truth in these matters and I believe passionately that we need to protect the integrity of our national vaccine programs. In my clinical practice I dispensed thousands of vaccines. I know that tremendous benefits to humanity of vaccines, and the risks associated with an undermined confidence in vaccines.

However, I continue to be the focus of a great number of phone calls and inquiries from parents, scientists, autism interest groups, and more recently members of the media. All are seeking information and answers to the questions before you.

I am very disturbed by the continued number of reports I receive from researchers regarding their experiences in pursuing these answers. It is past time that individuals are persecuted for asking questions about vaccine safety – we have recognized error before in the case of live polio, whole-cell pertusis, and rotavirus.

Many have described encountering apathy from government officials charged with investigating these matters, difficulty in getting their papers published, and the loss of other research grants. Others report overt discouragement, intimidation and threats, and have abandoned this field of research. Some have had their clinical privileges revoked and others have been hounded out of their institutions.

An example of the latter is Dr. Andy Wakefield who has described to me how the intellectual climate at the Royal Free in London became intolerable for him and he was forced to depart. Virtually all of his ongoing research now has to be privately funded, while those seeking to disprove him receive government money.

I witnessed some of this first hand at a hearing, when a Dr, Brent Taylor made repeated inappropriate comments about Dr. Wakefield and his work causing me to seriously question Dr. Taylor's integrity and motives.

Mind you, half of Dr. Wakefield's theory has been proven correct and accepted in the medical community. Hundreds of children with regressive autism and GI dysfunction have been scoped and clinicians are seeing the inflammatory bowel disease he first described. The NIH is finally funding an attempt to repeat Dr. O'Leary's findings of measles RNA in Wakefield's biopsy specimens, though I am disappointed it has taken this long.

A clinician in New York was poised to repeat Wakefield's work two years ago, but he ultimately was refused by his IRB and then subsequently had his clinical privileges withdrawn.

This atmosphere of intimidation even surrounds today's hearing. I received numerous complaints that this event is not a further attempt to get at the facts but rather a desire to sweep these issues under the rug. I shared these with Dr. Gerberding. Last week she called me to

assure me that this is not the case. She informed me that she wants to meet with me and some of the parents, clinicians, and researchers to work with them to get the proper answers.

I understand that such outreach was attempted prior to her arrival, but that effort turned out not to be a serious endeavor. Perhaps new leadership will yield better results.

I stand ready to help with any funding issues. Though I must say that in recent years both NIH and CDC have seen dramatic increases in their funding, which unfortunately has not been matched with the will to fund the research you called for.

I have considerable confidence in Secretary Thompson, and Dr.'s Zerhouni and Gerberding. However, they have not been well served by the people under them. I was assured by Dr Gerberding over a year ago that she would welcome outside researchers into the Vaccine Safety Datalink (VSD). It then took me over a year to secure access for independent researchers.

Once in, it was quickly discovered that if you sort the VSD looking at the children who in 1997 and later received thimerosal-free DTaP verses those who received thimerosal-containing DTaP, there is a dramatic statistically significant increase in autism for those receiving thimerosal. Unfortunately, the CDC has hampered further research, by refusing to make available post-2000 data.

Last Wednesday I read an article by Dr. Deth in *Molecular Psychiatry* showing a possible biomolecular mechanism whereby thimerosal may act as a neurodevelopmental toxin.

This article was very intriguing. However, I did not expect this article to receive public attention. Amazingly the next morning my secretary told me she heard this study discussed on a local country music station. It has also received widespread attention in Canada.

A thorough medical literature search yields thousands of articles on thimerosal many of them delineating its highly toxic nature, including several recent studies reporting that thimerasol is as toxic as methylmercury. Amazingly, some of these have actually been published by government officials. Yet other officials claim the toxicity of thimerosal is unknown, or not likely harmful.

Thimerosal and Neurodevelopmental Disorders

In 2001 you concluded that "exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders." I urge you not to retract from this conclusion, but to build upon it.

Your recommendation in 2001 that there be an immediate effort to end the administering of thimerosal containing vaccines to infants was wise. Unfortunately, it was ignored. Existing stocks and new lots of such vaccines were administered to millions of infants. Furthermore, the CDC is poised to recommend thimerosal-containing flu vaccine to 6, 7 and 23 month old babies.

Some recent literature gives me further reason for concern:

- *Deth* provides a plausible mechanism to explain why some children are more susceptible.

- *Bradstreet* found that with chelation children with Autism excrete more mercury than controls.
- *Holmes* found less mercury in first baby haircuts for autistic children verses controls.
- *Geier* has found in VSD an association between higher mercury exposure levels and Autism.
- Even the much-maligned *Verstraeten* study found an association between higher exposures to thimerosal and neurodevelopmental disorders in some HMO populations.

Some have argued that there is no need for concern because methyl- and ethyl-mercury react very differently in the body and that ethylmercury exposure levels were too low to cause harm. There is very little science to back up claim of no harm. In fact, a review of the medical literature appears to show just how harmful thimerosal is. Even Dr. Neal Halsey's evaluation of the *Pichichero* (Pediatrics 2003) data found toxic exposure levels in some children.

In 2001 you recommended studies to compare children receiving thimoersal with those who did not. You urged a monitoring of the prevalence of neurodevelopmental disorders as thimerosal was removed.

Unfortunately, government officials have done neither. Outside researchers have made some progress, but they have been hampered in gaining adequate access to the VSD.

MMR and Autism

With regard to MMR and Autism, I urge the Committee to build upon its 2001 conclusions and recommendations. A strong signal from you could lessen the intimidation obstructing this research. You concluded that since the MMR was mandatory it was the responsibility of the government to ensure its safety, even if hypothesized adverse outcomes are rare. I concur.

As with thimerosal, my concerns about MMR have not subsided:

- The NIH is presently funding an effort to duplicate *Wakefield*.
- Vaccine strain measles virus has been identified in the inflamed GI tract of children with regressive autism
- Measles virus antibodies have been found in the CSF of children with regressive autism.
- Rechallenge cases of children with regressive autism have been observed and documented.
- The medical community has largely accepted a new form of bowel disease in children with regressive Autism.

Federal research funding has not been directed to investigating many of your MMR research recommendations.

Also, a significant shortcoming of today's meeting is that Dr. Wakefield was not invited. In 2001 you found that cases of MMR "rechallenge" would provide evidence in favor of causality. It is my understanding that Dr. Wakefield has developed such a case series. The lack of an invitation is puzzling.

CDC Built-In Conflict of Interest

While I have considerable respect for Dr. Gerberding, I am concerned about the ability of the CDC's National Immunization Program to objectively investigate this matter. The CDC has a built-in conflict of interest that is likely to bias any reviews.

CDC is tasked with promoting vaccination, ensuring high vaccination rates, and monitoring the safety of vaccines. They serve as their own watchdog – neither common nor desirable when seeking unbiased research. This has been a recipe for disaster with other agencies.

Congress recently saw the wisdom of splitting the FAA because its dual functions left it conflicted between promoting flying and regulating the flying public.

In the aftermath of the Space Shuttle Columbia accident, The Gehman Comisssion found that a critical problem in the Shuttle program was that the same individuals were responsible for flying the shuttle on time and flying it safely.

This same conflict is inherent in the CDC. Unfavorable safety reports lead to lower vaccination rates. An association with between vaccines and autism would also force CDC officials to admit that their policies irreparably damaged thousands of children.
Who among us would easily accept such a conclusion about ourselves? Yet, this is what the CDC is asked to do. Also, the relationship between the CDC and vaccine manufactures has become extremely close.

Given these facts, studies conducted for or by the CDC should be evaluated with in this context.

Evaluating how best to eliminate this conflict of interest would be a worthwhile endeavor for the IOM. I urge the IOM to take this matter under review.

Further undermining my confidence in the CDC's ability to monitor safety is the experience I had in assisting an independent researcher gain access to the VSD and what we have discovered subsequently. The CDC erected excessive barriers and has imposed severe limits on access to the data.

- Researchers are not provided data collected beyond December 2000 – seriously limiting the ability to provide for independent research to observe the effects of the removal of thimerosal.
- The IRB approval process forces researchers to receive approval from as many as 7 IRBs – each with its own requirements.
- CDC places strict limits on what data is available to researchers, access to the complete database is virtually impossible, and the data is made available on an inadequate PC.
- Raw datasets used by the CDC to conduct their studies are not made available to independent researchers – only altered datasets are provided, thus the CDC's work cannot be evaluated by outside researchers. Does science not demand the ability to fact check and replicate work?

Conclusions

To summarize:

Last week, Dr. Gerberding shared with me that she would be devoting additional time personally to this issue and that she believed the research should not end with this meeting. She indicated her desire to see this research continue and emphasized that we should let the truth prevail, regardless of the consequences.

- I urge you to build on the recommendations and findings of possible associations established in your 2001 reports on MMR and Thimerosal. There are increased reasons for concern.
- The evidence of persistent measles infection in the GI tract and CSF of children with regressive autism continues to expand and further research should be encouraged.
- Many of the research recommendations you set forth in your 2001 reports have been ignored by federal research agencies.
- Results of the Wakefield duplication study will not be known until this summer.
- Studies conducted by or in conjuction with the CDC should be considered in the context of the CDC's inherent conflict of interest.
- Neither the entire VSD, nor the datasets used by the CDC for their studies are being made available for independent review.
- More investigation is needed to answer these questions with the degree of certainty that science demands.

In closing I would quote from the Verstraeten study. While I have serious concerns about some of the findings in that study, I do concur with one of their closing recommendations. The authors stated:

> "We believe that additional investigation is required because of the widespread exposure from vaccinating virtually the entire birth cohort of the United States and the importance of speech and language disorders among children and adolescents. For elucidating further whether a causal association exists between thimerosal exposure and neurodevelopmental conditions, additional studies with different designs will be needed."

I concur full with these remarks and encourage you to adopt this recommendation by calling for a redoubling of these research efforts.

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