Remarks of Rep. Dave Weldon, M.D. (R-FL)

Defeat Autism Now (DAN) Conference

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We have an epidemic of Autism in this nation that must be addressed. We must leave no stone unturned in our efforts to understand its causes and prescribe proper treatments. The human toll and costs of this epidemic are staggering, and will worsen if we fail to direct the necessary attention and resources to this national problem.

The numbers out of the Department of Education continue to show an unsustainable upward spiral of affected children. I just saw the most recent numbers out of New Jersey showing that those seeking services for Autism under IDEA increased 18% over last year, increasing from 4180 children in 2003 to 4,933 in 2004.

The Department of Health and Human Services (HHS) issued an Autism A.L.A.R.M. earlier this years to the nation's pediatricians urging them to conduct better screenings of children so that children with Autism and other developmental disabilities can be diagnosed earlier, and therefore interventions can begin early. That ALARM stated that one out of every 163 children has an autism spectrum disorder.

Friends, this is unsustainable. And is indeed an alarm to our nation. We must fully engage this battle against autism for the sake of the next generation of Americans and for the sake of our children and grandchildren.

While these numbers tell a troubling story, there is hope. Testimony after testimony from parents and practitioners tell us that early intervention works.

Many of you in this very room know that first hand. I have had numerous parents tell me that their child was diagnosed with Autism at age 3 or 4, and today after following the DAN protocol, you would not know their child from the child he was 2 or 3 years ago. It is stories like this that bring us here together today. We are here to learn what works. To learn from each other and to build upon the successes we have seen.

It is time to fully embrace the reality that early intervention can work for children diagnosed with Autism Spectrum Disorders (ASDs). As a nation we must focus on early diagnosis and early intervention. It is time for federal policies to reflect the reality that these children can and should be helped.

This last year we were successful in securing $2 million for the Centers for Disease Control to initiate a program directed toward early diagnosis for Autism. I am currently working with others in the Congress to build on this success. We are finally making progress in the Congress and in the federal bureaucracies.

I would like to focus my remarks primarily around the issues of vaccinations and possible associations with neurodevelopmental disorders and Autism in particular. I would like to make clear at the outset that I am very supportive of our national immunization program. Vaccines and our national

immunization program have saved our nation and the world untold suffering and human misery. This must not be forgotten.

While I am very supportive of our nation's vaccine program, I also believe that we can do a much better job of monitoring the safety of our vaccines. We must engage in a more aggressive review of adverse reactions - both acute and chronic adverse reactions. This has been severely lacking for years.

That means continual monitoring for adverse reactions, specific research to understand why some children have adverse reactions, and ensuring independent oversight of vaccine safety research to ensure that this research is free from real and perceived conflicts of interest.

Since 1998, I have followed this issue with considerable interest. When reports first surfaced in 1998 about the MMR, I met with top officials from the NIH and CDC. I urged them to dedicate funding to investigating this issue. The next year I urged them again to invest in this research. And, again. And, again. Unfortunately, it was not until 2003 that funding was freed up within the federal government to attempt to duplicate the findings of Dr. Wakefield and Dr. O'Leary. Finally this effort is underway.

While the federal government dragged its feet, many other researchers have been pursuing this research independently – although many of them have faced considerable intimidation.

I am very concerned about the number of reports I continue to receive from researchers regarding their difficulties in pursuing answers to questions about the possible association between vaccines or vaccine components and the epidemic of Autism. Some 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.

This should not be the case. 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, and it is not out of the realm of possibilities that a vaccine, or a vaccine component like mercury, might serve as an environmental exposure that triggers Autism or neurodevelopmental disorders in some children.

One researcher in particular, Dr. Andy Wakefield, has been subjected to excessive criticism and abuse. The recent treatment of him by public officials, the media, and public health officials in the United Kingdom is inexcusable. Recent criticisms of a possible "conflict of interest" on the part of Dr. Wakefield are erroneous. They pale in comparison to many of the very real conflicts that exist today, including those of some of his strongest critics. In my view they may be driven more by a desire to preserve the status quo and squelch research aimed at making existing vaccines safer.

Something that is virtually forgotten is that half of Dr. Wakefield's theory has been proven correct and widely 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 in the Lancet in 1998. Dr. Wakefield has contributed significantly to a better understanding of what is plaguing these children and how we might treat their bowel problems rather than ignore them. He should be applauded for his contribution, not maligned. I only wish his critics would pursue the treatments of Autism with as much vigor as they pursue him. (We'd likely have a cure by now!)

In addition to matters surrounding the MMR, serious questions have arisen about the vaccine additive – thimerosal. The agency with the greatest responsibility in monitoring for adverse vaccine reactions, the Centers for Disease Control, has significant conflict of interest that may inhibit their ability to conduct independent and unbiased research. Also, it appears that no federal agency has undertaken an aggressive enough research effort to help us better understand and avoid serious adverse reactions.

In July 1999, the U.S. Public Health Service and the American Academy of Pediatrics issued a joint statement, which was later endorsed by the American Academy of Family Physicians, proclaiming: ''[The] Public Health Service, the American Academy of Pediatrics, and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible." As you know thimerosal is 50% ethylmercury.

In 2000 these groups reaffirmed this statement.

Then, in 2001, the Institute of Medicine concluded that "exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders." The IOM recommended that children not be given mercury-containing vaccines. Rather than implementing this policy immediately as was recommended by the IOM, this policy was gradually implemented, as mercury was phased-out. This phasing-out allowed many more children in the early part of this decade to receive high levels of mercury from pediatric vaccines.

By early 2003, very few mercury containing childhood vaccines remained on the shelves.

On November 3, 2003, the Verstraeten study was released in *Pediatrics*. This study had been four years in the making. Many casual observers believed that the issue of whether or not the mercury in vaccines was a contributing factor to autism and neurodevelopmental disorders was finally put to rest with the publication of this study as newspaper headlines that day read:

- "Study Clears Vaccines Containing Mercury" *Associated Press* and *USA Today*,
- "Study Finds No Link Between Vaccines, Autism" *Reuters*

- "Vaccine-Autism Link Denied" *The Detroit News*
- "CDC Says Vaccines are Safe…" *The Seattle Times*

While the "spin" on the study misled the public to believe that this study concluded there was no link between mercury in vaccines and neurodevelopmental disorders, the principle author of that study recently wrote a different viewpoint in *Pediatrics* – four months after his study was first published. Dr. Verstraeten writes, "The article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended…." Dr. Verstraeten goes on to state, "The authors could neither confirm nor exclude an association."

In other words, according to the principle author of that *Pediatrics* study, each of those headlines was wrong. The jury is still out on mercury.

Mercury from childhood vaccines continues to be a possible culprit:

- The CDC's own study – four years in the making - was unable to specifically exonerate mercury.

- Mercury is a neurotoxin and is particularly harmful to the developing central nervous system of fetuses and infants.
- The Deth study, published in Molecular Psychiatry earlier this year showed that concentrations of thimerosal of 1nm were inhibitory of critical enzymes involved in neurodevelopment.
- Studies of children with Autism continue to show high levels of mercury – chelation studies show that children with autism excrete high levels of mercury compared to normal controls, suggesting that these children might have a problem handling mercury.

Given these concerns about mercury and the possibility that vaccine exposures to mercury may have been a contributing factor in the epidemic of autism and neurodevelopmental disorders, it is critical that we err on the side of caution. We have the ability to eliminate this mercury exposure for infants and we should do so.

We know mercury is a neurotoxin and we know that exposures for developing fetuses and infants can only cause harm. In January, the Environmental Protection Agency (EPA) issued a report finding that 1-in-6 infants is born with a blood mercury level above a level considered safe by the EPA.

Also recently, the U.S. Food and Drug Administration and the EPA warned pregnant women, nursing mothers, and young children to limit their consumption of certain fish that are high in mercury in order to reduce their mercury exposure.

Unfortunately, the CDC is now poised to adopt a recommendation from the Advisory Committee on Immunization Practices (ACIP) that infants 6, 7, and 23 months of age receive a flu vaccine which may contain mercury. I have urged the CDC to alter the ACIP recommendation to recommend that infants, children, and pregnant and nursing mothers receive the mercury-free dose of this vaccine. To date, the CDC has failed to adopt this recommendation.

In response, I have introduced, along with Rep. Carolyn Maloney of New York, H.R. 4169, the Mercury-Free Vaccine Act of 2004. This bill 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. By January 1, 2006, mercury would be completely removed from all childhood vaccines – consistent with the goal stated by the AAP, PHS and AAFP back in 1999. Furthermore, H.R. 4169 provides that adult vaccines not contain more than 1microgram of mercury after January 1, 2007.

This is a very reasonable bill. It focuses on eliminating this exposure completely for children in the short-term, while also reducing this exposure for adults on a schedule that allows manufacturers to phase out its use in a reasonable timeframe but with a fixed date.

We have the ability to eliminate this exposure to mercury and it is inexcusable not to. We know that mercury is a neurotoxin. And, we know that mercury levels are too high.

Vaccines can be made without mercury, so why not remove the mercury and remove any doubt?

There are three government agencies that have responsibilities related to monitoring vaccine safety – 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 FDA does conduct some monitoring of the VAERS data to track and understand adverse events. However, the CDC has a greater responsibility in this arena and the FDA largely defers to the CDC.

The Centers for Disease Control (CDC) has the greatest responsibility in this area. Unfortunately, they are also the agency with the greatest conflict of interest. The CDC's vaccine safety monitoring program amounts to between $20 and $30 Million a year. However, it is housed within a $1 Billion plus vaccine promotion program. In fact the CDC spends Millions of dollars a year simply encouraging Americans to get vaccinated. The success of the CDC's vaccine promotion program is largely judged based on how high vaccination rates are. Here lies the greatest conflict. Any study raising concerns that there might be adverse reactions to a vaccine is likely to result in safety concerns which will lead to lower vaccination rates.

Lower vaccination rates are in direct conflict with one of the CDC's greatest measurements of their 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 monitoring 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 vaccine 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.

On March 10, I discussed my concerns about a conflict of interest within the CDC's Director, Dr. Julie Gerberding. In that conversation she indicated to me that she recognized that there are problems and that she was taking several steps to try and address them.

She is in the process of appointing a blue ribbon commission charged with reviewing the CDC's vaccine safety monitoring and research activities. One of the key responsibilities of this panel will be to assess the most appropriate organizational location of the vaccine safety-monitoring program. It is critical that this program be located outside of the CDC.

Conflicts of interest are not new to federal agencies and we have taken some positive steps to remove these conflicts. One of the most recent was moving the Office of Human Subjects Protection out of the NIH due to inherent conflicts. It is long overdue that we remove from the CDC the responsibility of monitoring for adverse outcomes from vaccines.

The National Institutes of Health has no coordinated program that is specifically charged with monitoring or funding research related to vaccine safety. The extent of involvement by the NIH, based on what they have told me thus far, is uncoordinated and limited to funding a study here or there that

happens to pass peer review. Within the NIH there is very little if any coordinated effort to fund research aimed at examining the safety of particular vaccines.

So, as you can see, the work is really not being done.

- Not by the CDC.
- Not by the FDA.
- And, not by the NIH.

It is critical that we take action to eliminate the conflicts of interest that are inherent within the CDC's vaccine safety monitoring office, and that we ensure that there is a concerted and independent effort within the federal government to monitor for adverse reactions to vaccines. Unfortunately, this is not the case today.

I am working on legislation 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. The CDC has internal conflicts of interest. The FDA also has conflicts of interest, does very little in this regard, and largely looks to the CDC to perform these duties.

And, the NIH has no concerted effort to fund research related to vaccines safety. Clearly, greater oversight and complete independence is needed.

As I develop this proposal, I will be working to ensure that those responsible for this duty are free from 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.

Autism is a difficult challenge facing our nation. We have made considerable progress through groups like DAN and other autism organizations. The work you are doing here today, is work that must continue. I commend you for all that you are doing. I commend in particular, 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 those down at the NIH and the CDC will be more supportive of your work.

I also 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 you to take your story to your Member of Congress and your Senator. Share it with all who are willing to listen. It is through your testimony that others will know of this hope.

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 true honor.

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