

Statement of Rep. Dave Weldon, M.D. (FL-15)
Introduction of The Vaccine Safety and Public Confidence Assurance Act of 2007
April 19, 2007

Federal agencies charged with overseeing vaccine safety research have failed. They have failed to provide sufficient resources for vaccine safety research. They have failed to adequately fund extramural research. And, they have failed to free themselves from conflicts of interest that serve to undermine public confidence in the safety of vaccines.

The American public deserves better and increasingly parents and the public at large are demanding better.

I'm a physician. I understand the importance of immunizations in protection children and the public at large from infectious disease. As a society we benefit from vaccines and as such it is important that we guard carefully vaccine safety research to ensure its objectivity.

When I first began working on this issue about seven years ago, I was shocked at the dearth of resources dedicated to vaccine safety research. The federal government dedicates far more resources to promoting the immunizations than in safety evaluations. And most of that promotion is coordinated by the CDC. Most vaccine safety resources which are predominantly administered by the CDC are dedicated to considering short-term, or acute adverse reactions, while very few resources are dedicated to considering potential longer-term or chronic adverse reactions.

When I first tasked my staff with investigating federal vaccine safety research we got a lot of confused responses and blank stares from federal officials. The FDA told us to check in with the CDC, telling us that CDC did most of the vaccine safety research. The CDC referred us over to the NIH. Then, the NIH referred us back to the CDC. One thing is clear: there is little coordination among federal agencies on vaccine safety research and very little funding.

Ironically, 20 years ago Congress established The National Vaccine Program Office (NVPO) and charged NVPO with coordinating vaccine safety research. Along with safety, however, NVPO was charged with coordinating vaccine development, vaccine promotion and vaccine supply – the very conflicts that plague the CDC, and to some extent the NIH. It is no wonder that vaccine safety has been on the back burner at NVPO for all of these years – NVPO has conflicting missions and higher priorities. NVPO is now swamped with Avian Flu preparedness including vaccine development.

The prestigious journal *Nature*, in January 2006 stated with regard to vaccine safety: “there is a strong case for a well-resourced independent agency that commends the trust of both the government and the public.”

Several issues relating to vaccine safety have persisted for years. The response from public health agencies has been largely defensive from the outset and the studies have been plagued by conflicts of interest. Legitimate questions persist regarding the possible association between the mercury-based preservative, thimerosal, and the childhood epidemic of neurodevelopmental disorders (NDDs), including autism. There are unresolved questions about the MMR vaccine that arose in 1998 that should be fully investigated. Gardasil, the HPV vaccine, has been recommended by CDC for millions of young girls – yet the long term safety studies—conducted by the manufacturer themselves—are years away from completion. Vaccine manufacturers have dozens of new vaccines in the pipeline. The failure of public health officials to make safety a priority and to free safety research from conflicts

of interest will only serve to further erode public confidence at a time when we should be working to build public confidence. It is incumbent upon us to fully investigate these issues in an independent manner.

Food and Drug Administration reform legislation has been the subject of considerable discussion. Unfortunately, these legislative efforts thus far curiously exempt vaccines from those reforms. If anything, vaccine safety should be given a higher priority, after all, vaccines are compulsory while taking prescription drugs is not compulsory. Many school children are mandated to take vaccines before they can attend school.

In his book on the subject of immunizations, Dr. Graham Wilson, the former Director of the Public Health and Laboratory Service for England and Wales, warned the public health community of the need to remain ever vigilant when it comes to vaccine safety. In 1967 he warned:

“Over confidence must at all costs be avoided... It is for us, and for those who come after us, to see that the sword which vaccines and antisera have put into our hands is never allowed to tarnish through over-confidence, negligence, carelessness, or want of foresight on our part.”

Federal agencies in the U.S. charged with carrying out vaccine safety have failed to adequately heed this warning. If we continue down the current path, confidence in vaccines will continue to erode and this “sword” against disease will be tarnished.

Today, we rarely come face to face with vaccine preventable disease, but we are at risk of seeing vaccine preventable diseases rear their ugly head. Why? Because, we are confronted with the side effects of vaccines, adverse reactions and perceived adverse reactions – many of them mild, but some of them severe. This is the new and increasing challenge that we face in fighting disease.

There are two approaches we can take in the face of this new challenge.

First we can downplay the existence of adverse reactions or otherwise pretend they do not exist all-the-while such questions persists unanswered and continue to fester. Such approaches have failed to work in the past and over the long-run they can do irreparable harm to public confidence in vaccines, breaking the trust with the public and leading to the rise of infectious disease.

Conversely, we can take such hypotheses and evaluate them in an independent and objective manner. That is what we are proposing here today. Our bill corrects past mistakes. Presently, vaccine safety research is an in-house function conducted predominantly by the CDC – the very agency that makes vaccine recommendations and promotes their uptake. This should not be.

Congress has eliminated similar conflicts of interest across several federal agencies.

- At the National Institutes of Health we recognized the inherent conflicts of interest and created the Office of Human Subjects Protection as a separate office within HHS.
- When we established the Superfund program, Congress established the Agency for Toxic Substances and Disease Registry (ATSDR) – Superfund’s science evaluation office - as a separate agency in another department. Safety evaluation is independent of all other decisions.

- After the Space Shuttle Columbia accident, the Gehman Commission recommended that decisions about shuttle safety and launching the shuttle should be completely separate – we adopted this recommendation.

What does our bill do? It:

- Creates a new agency of vaccine safety that reports directly to the Secretary of HHS.
- Vaccine safety research is conducted in a manner that is completely independent of any and all other vaccine-related decisions.
- Establishes scientific review mechanisms, similar to those employed by the NIH, to evaluate the scientific merits of investigator-initiated research.
 - Establishes a balanced 18 Member Advisory Committee to formulate a safety research agenda and to prioritize research approved by the scientific study group

Finally, as you may know the CDC has acknowledged this internal conflict. In 2005, Dr. Gerberding moved the CDC's Immunization Safety Office out from under the National Immunization Program (NIP), the office at CDC charged with vaccine promotion. However vaccine safety duties remain the responsibility of the CDC. While I appreciate this initiative, and I understand her limitations in not being able to move vaccine safety outside of her agency, vaccine safety research remains woefully short of the degree of independence and funding commitment that is needed to garner wide public support and acceptance.

If government-funded vaccine safety research is to be broadly accepted, we must eliminate all real and perceived conflicts of interest. Otherwise, we will fail to achieve the level of acceptance that is necessary to restore, build, and secure public confidence over the long-run. A vaccine safety program housed anywhere within the CDC fails to achieve this independence.

We will create a separate and wholly independent office for vaccine safety research. The question that we face at present is:

‘Will we create this office now in a proactive manner before public confidence further erodes, or will we do it later in reaction to growing loss of public confidence in the hope of restoring lost trust.

I suggest we act now and that is what Rep. Maloney and I plan to do. It is the wiser course.

There is a pattern of behavior at the CDC in which I see the agency draw broad and perhaps misleading conclusions based on incomplete research. Allow me to share with you an example or two of this concern.

Study of Danish Children, Thimerosal and Autism, Madsen et. al. (Pediatrics)

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.

Thimerosal Study Using VSD, Verstraeten et. al.

In November 2003, a study was published in the journal *Pediatrics* examining the possible relationship between mercury (thimerosal) in vaccines and neurodevelopmental disorders (NDDs). This study was conducted using the VSD, an extensive database of patient records paid for by the CDC which includes HMO data from around the country. The study's principle author stated:

"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."

However, a top CDC vaccine safety official characterized the findings of the study much more broadly:

"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," said Dr. Frank DeStefano, a CDC researcher who helped carry out the study.

(National Post, November 4, 2003)

In relation to this VSD study in particular, Senator Lieberman, with my support, directed the NIH to hold a workshop to review the feasibility of using the CDC's vaccine safety database (VSD) to conduct such studies. An expert panel met in May 2006 and issued a report to the Congress in October 2006. That report outlined serious flaws in the way the database has been used and in turn exposed a host of limitations of the CDC's Verstraeten study. Yet this is the study CDC uses over and over again to say the case is virtually closed on the issue of thimerosal and autism. In view of this recent NIH report, such broad assertions based on the Verstraeten study are unwise.

Clearly, a more objective perspective is needed to thoroughly investigate issues of vaccine safety. That is what our bill does.

Conclusions

In the past couple of years, we have heard a lot about the dangers of a potential avian flu pandemic. Vaccines will be a critical component of our efforts to combat such a disaster should it materialize. But in order to be effective, the public will need to be convinced that the vaccines they are receiving are safe. Fears about vaccine safety halted the nation's efforts to vaccinate against the swine flu epidemic several decades ago. The federal government's effort to immunize health care workers for Smallpox was a dismal failure. Fears about vaccine safety led many of those in the public health community to refuse the smallpox vaccine. We cannot let flagging public confidence leave our nation vulnerable to these devastating diseases, but that is the path we are on absent the creation of an independent vaccine safety office.