

Statement of Rep. Dave Weldon, M.D. (FI-15)
Introduction of H.R. 5887, The Vaccine Safety and Public Confidence Assurance Act of 2006
July 26, 2006

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 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. Most vaccine safety resources 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 this issue we got a lot of confused responses from federal agencies. The FDA told us to check in with the CDC, saying 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. It was apparent to me that there is little coordination and very few resources dedicated to vaccine safety research.

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 and is not an appropriate place for this.

I agree with the prestigious journal *Nature* when in January of this year stated: “there is a strong case for a well-resourced independent agency that commends the trust of both the government and the public.” That is why we are here today.

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 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 was just recommended by the CDC. Vaccine manufactures have dozens of new vaccines in the pipeline. The failure of public health officials to make this a priority and to free this 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.

The Senate is turning its attention to FDA reform. Unfortunately, the legislation moving through the Senate HELP Committee is deafeningly silent when it comes to improving vaccine safety research. This is particularly ironic given that federal and state governments do not mandate drugs in order to enter schools or obtain employment, yet, as a society we do impose such mandates with regard to vaccination. This is all the more reason to be particularly mindful of issues related to vaccine safety.

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.

We have seen fit to eliminate such conflicts across 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 a scientific review panel, similar to NIH's study sections, to evaluate the scientific merits of investigator-initiated research as the Institute of Medicine has recommended.
- Establishes a balanced 18 Member Advisory Committee to formulate a safety research agenda and to prioritize research approved by the scientific study group. Committee Includes:
 - 2 vaccine industry reps
 - A pediatrician
 - An immunologist
 - A toxicologist
 - An infectious disease expert
 - A geneticist
 - Not less than 1/3rd of the members of the Committee have a vaccine-related injury or injured child.

Finally, as you may know the CDC has acknowledged this internal conflict. Last year, Dr. Gerberding moved the CDC's Immunization Safety Office out from under the National Immunization Program (NIP), however vaccines safety remains within 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.

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