Statement

Vaccine safety research requires the creation of a separate and wholly independent office

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Abstract

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.

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 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.

Keywords: vaccine safety research, adverse reactions, conflicts of interest

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 protecting 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

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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 approve 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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H.R. 5887 - Vaccine Safety and Public Confidence Assurance Act of 2006

Section 1. Short Title; Table of Contents

This act may be cited as the "Vaccine Safety and Public Confidence Assurance Act of 2006.'

Section 2 Findings

Section 3 Purpose

To direct that vaccine safety monitoring and research focus on active surveillance, researching biological mechanisms for acute and chronic adverse events following vaccination, developing prevaccination screening methods within a framework that is free from actual and perceived biases, and developing a vaccine safety research agenda.

Section 4. Establishment of Agency for Vaccine Safety Evaluation
(inserted as Subtitle 3 of Title XXI of the Public Health Service Act)

Sec. 2141 Establishment

The Agency for Vaccine Safety Evaluation (AVSE) is established within HHS, to be directed by the Director for Vaccine Safety Evaluation.

Sec. 2142 Authorities

a) With respect to vaccines, the Director shall:
   (1) Conduct or support safety research, including research on:
      a. Acute and chronic adverse reactions
      b. Vaccine components
      c. Delivery mechanisms
      d. Potential presence of adventitious agents in vaccines
   (2) Conduct or support long- and short-term monitoring
   (3) Develop a vaccine safety research agenda
   (4) Conduct or support research across a range of disciplines
   (5) Conduct or support research to address claims of injury
   (6) Develop, evaluate, and test hypotheses about potential adverse reactions
   (7) Evaluate and promote compliance of healthcare providers and vaccine manufactures with Federal requirements related to adverse event reporting
   (8) Conduct or support research for the purpose of developing tools to prescreen individuals at risk for a vaccine-related adverse reactions
   (9) Conduct or support research into the biological mechanisms of potential adverse reactions
   (10) Conduct long-term monitoring of new or altered vaccines, including monitoring changes to the childhood and adolescent immunization schedule of CDC
   (11) Provide a public database of pre and post licensure vaccine studies.
b) Personnel conflict-of-interest issues:
   1) Senior management positions (GS15 and higher) may not be filled by individuals who have been previously employed by CDC, FDA vaccine manufacturers to carry out any function related to vaccine safety or monitoring or vaccine development or by NIH in vaccine development for a period of 5 years.
   2) All personnel must be free of professional, familial, or financial conflicts of interest.
c) Grant recipients are also subject to conflict-of-interest requirements, including financial conflicts that may compromise the perceived integrity of the research.
d) Vaccine Safety Datalink Project
   (1) Responsibility for overseeing the VSD is transferred to the AVSE.
   (2) CDC and FDA have access to the VSD as needed to support their efforts.
   (3) External access to the VSD is facilitated by the AVSE in a manner similar to that recommended by the IOM in their 2005 report.
e) The Director is also directed to review international activities of the Federal Government related to vaccine safety and develop plans for reducing any conflicts of interest uncovered during the review. A report of the review must be submitted to Congress.
f) The Director may also establish a fellowship program for training individuals in vaccine safety research. Fellowship recipients are also subject to certain conflict of interest provisions.
g) Grants will be awarded using the peer review system, subject to the provisions of the NIH peer review system.
h) The FDA shall provide the agency complete access to vaccine safety information, but the agency must

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keep this information confidential, subject to the same confidentiality provisions as FDA.

i) The Director shall submit a report on the Agency's activities to: ACIP, NVAC, NVPO, NVICP, HRSA, and any other entity deemed appropriate. These reports shall be made publicly available.

Sec. 2143 Post-marketing vaccine safety

a) The Director shall, in consultation with the FDA, require manufacturers to provide for post-marketing surveillance and clinical testing for any acute or chronic reactions associated with all vaccines approved after January 1, 2006. These trials shall be conducted by researchers, free from conflicts of interest, recommended by the Advisory Council and approved by the Director. The protocols must be similarly approved, and the data must be made available for objective, independent evaluation.
b) FDA and CDC maintain the ability to monitor vaccine safety through VAERS.
c) The Director may also award grants to conduct comparative studies of vaccines licensed for preventing or mitigating the same disease, and the results of these studies shall be made publicly available.
d) Clinical Trials (pre- and post-licensure) must be registered—prior to their completion—subject to requirements similar to those imposed by the International Committee of Medical Journal Editors.

Sec. 2144 Transfer of CDC Functions related to monitoring adverse reactions related to licensed vaccines.

a) The following are transferred from CDC to the AVSE:
    (1) The Vaccine Safety Datalink Project
    (2) The Clinical Immunization Safety Assessment Centers
    (3) Other vaccine safety assets of CDC
b) This transfer will be overseen by the Secretary of HHS, in an orderly fashion.
c) Nothing in this bill, except with respect to the functions listed in (a) shall be construed so as to prohibit CDC from conducting vaccine surveillance and response, particularly with respect to acute reactions.

Sec. 2145 Advisory Council (p. 23)

a) The Secretary is directed to establish an Advisory Council
b) The Advisory Council's duties include: formulating recommendations for research on vaccines, developing a vaccine safety research agenda, reviewing grant applications and making recommendations to the Secretary regarding funding of those applications.
c) The Secretary is required to consider the recommendations of the Advisory Council when making final funding decisions. If the Secretary decides not to accept the recommendations of the council, he/she must explain in writing to the Advisory Council the reasons for these decisions. This letter should be made publicly available.
d) The Advisory Council shall be composed of 18 members, including:
    a. Not more than two representatives of the vaccine manufacturing industry
    b. One practicing pediatrician
    c. One infectious disease expert
    d. Five adults who are each either a victim of a vaccine injury or a parent of the victim of a vaccine-related injury.
    e. One representative of the general public who is free from bias
    f. One toxicologist
    g. One neurologist
    h. One geneticist
    i. One immunologist
    j. One state or local public health official
    k. Not less than 4 and not more than 6 additional representatives

At least one-third of the council must be selected from among individuals who are vaccine-injured or who have a child who has been vaccine injured (regardless of whether or not there has been a judicial or administrative finding of injury).

The Advisory Council is also subject to certain conflict of interest provisions with following exceptions: 2 of the vaccine-injured parents may have claims pending in the Vaccine Injury Compensation Program, and the 2 industry representatives are not subject to the conflict of interest provisions.

Sec. 2146 Full-time liaisons The agency shall employ individuals as full-time liaisons to other agencies involved with vaccine research and development, including DoD, NIH, FDA, CDC.

Sec. 2147 Definitions

Sec. 2148 Authorization of Appropriations
$80,000,000 for the first year, such sums thereafter.

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