



Research Support for H.R. 1757 The Vaccine Safety Study Act

July 2013

HR 1757 - Vaccine Safety Study Act Introduced by Rep. Posey & Maloney

Directs the Secretary of Health and Human Services to conduct or support a comprehensive study comparing total health outcomes, including risk of autism, in vaccinated populations in the United States with such outcomes in unvaccinated populations in the United States, and for other purposes.

- Calls for a study comparing total health outcomes
- Provides for independent scientific research
- Does not discourage vaccination

Bi-Partisan Legislation includes these findings:

- (1) Securing the health of the Nation's children is our most important concern as parents and stewards of the Nation's future.
- (2) The Nation's vaccine program has greatly reduced human suffering from infectious disease by preventing and reducing the outbreak of vaccine-preventable diseases.
- (3) Total health outcomes are the best measure of the success of any public health effort, including security from both chronic and infectious disease.
- (4) Childhood immunizations are an important tool in protecting children from infectious disease.
- (5) The number of immunizations administered to infants, pregnant women, children, teenagers, and adults has grown dramatically over recent years.
- (6) The incidence of chronic, unexplained diseases such as autism, learning disabilities, and other neurological disorders appears to have increased dramatically in recent years as well.
- (7) Individual vaccines are tested for safety, but little safety testing has been conducted for the interactive effects of multiple vaccines.
- (8) The total strategy of aggressive, early childhood immunization against a large number of infectious diseases has never been tested against alternative strategies, either for safety or for total health outcomes.
- (9) Childhood immunizations are the only health interventions required by all citizens to participate in civic society.
- (10) Public confidence in the management of public health can only be maintained if these State government-mandated, mass vaccination programs need –
 - (A) rigorous testing individually and in their totality against all reasonable safety concerns; and
 - (B) verification in their totality to produce superior health outcomes.
- (11) Numerous United States sub-populations prohibit vaccination for religious or personal beliefs and can therefore provide a natural comparison group for measuring total health outcomes.
- (12) No comparative study of such health outcomes has ever been conducted.
- (13) Given rising concern over the high rates of childhood neurodevelopmental disorders such as autism and other chronic conditions, the need for such studies has even greater urgency than even a few years ago.

Why Compare Total Health Outcomes?

Many unanswered questions cannot be resolved using current FDA methodology --

The current FDA research guidelines for any new vaccine:

- **Cannot compare placebo-controlled studies. (no comparison of vaccinated versus unvaccinated patients, rather it can only compare vaccinated with vaccine 1 versus vaccinated with vaccine 2)**
- **Are typically only short term in their duration.**
- **Only focus on 'obvious' reactions (seizures and anaphylaxis immediately after vaccination; swelling of vaccination site; high fever the first 48 hours, etc.) and blood titer levels of immunity to vaccine-related disease post-immunization.**

Parents and experts such as Dr. Bernard Rimland, the 'grandfather of autism,' noted a dramatic shift between classical autism (born with it) to acquired or regressive autism (developed in typically developing children by age 3 years) around 1988.

According to the US Environmental Protection Agency (EPA¹), the epidemic increase in autism rates began in 1988.

In 1988, an entirely new type of vaccine was introduced to childhood vaccine schedules.

This entirely new type of vaccine, introduced in 1988 was never evaluated in a true placebo-controlled randomized control trial, or looked at as a potential link to autism.

Parents have repeatedly told Congress they are

- **unsatisfied with trading reductions in infectious diseases for increases in life-long chronic conditions such as autism, ADHD, asthma, etc., whose incidence have dramatically increased since 1988.**
- **want safer vaccines and realize the only way to truly understand the risks associated with immunization is to look at total health outcomes comparing populations of vaccinated children versus those who were not vaccinated.**

Why Hasn't HHS Already Done this Research?

- **Indications that a lack of funding prevents this study from taking place.**
- **Indications that the study cannot be undertaken due to humanitarian issues related to placebo-based studies in vaccines. (Current FDA approved studies do not contain a true placebo, they use an approved vaccine versus a test vaccine.)**
- **Claims that sufficient evidence exists to prove no problems from vaccines.**
- **Public health officials (FDA, CDC, NIH, HHS, etc.) have actively opposed doing a vaccinated versus unvaccinated study.**
- **They typically point to the “greater good” philosophy that vaccines’ benefits outweigh the risks.**
- **In truth, they may be afraid of what they will find!**

Talking Points To Consider:

- **The ‘change point’ of exponential autism (and other chronic life-long disease) increase was the 1988 birth cohort, per EPA study¹**
- **Vaccination is not the only reason children regress into autism, but is it one significant reason that has been validated in the Vaccine Injury Compensation Program².**
- One Autism Causation Hypothesis: infant is primed towards a pro-inflammatory response, and then subsequent immune challenge (vaccines, infectious disease) triggers inflammation-mediated autism.
- The only way to test this hypothesis is to conduct independent research studying populations who received vaccines alongside those who did not and look at total health outcome including autism.
- Currently, eight infant vaccines have never been studied under a true placebo control – vaccinated children versus those who received no vaccines.
- These eight vaccines including the new type (“conjugate vaccine”) originally introduced at the 1988 birth cohort (the same cohort which the EPA study found to be the ‘change point’).

Public Support Needed to Ensure Action on Ground-Breaking Research

- In 2013, SafeMinds will continue the public discourse on a “SmartVax” approach to vaccine research and policy in order to provide valid, fact-filled information to the public seeking research to determine safe preventions and treatments, with an overarching goal of improving overall public health.
- This necessity exists because the continued research into concerns and ground-breaking research has been trivialized by HHS (WHO, CDC, NIH, FDA) and the vaccine industry to the extent they have proven they will unlikely take any further voluntary actions on safety.
- **The main arguments for this position by HHS:**
 - Vaccine-autism link has been “asked and answered”
 - Even if vaccines cause autism, the benefits of the vaccines far outweigh the risks and therefore research should not be undertaken that casts any doubt on the safety of vaccines (as described in this interview⁵ by Bernadine Healy, former director of NIH)
 - We cannot come back with any findings that might frighten parents away from vaccinating. (Expressed by Dr. Marie McCormick at the IOM Panel reviewing vaccine injury).
- **We need the following to be common discussion amongst the public:**
 - Quantitatively, the disease risk of injury/death associated with forgoing each vaccine is far lower than the risk of autism, ADHD, allergies, & asthma. So, if vaccines cause any of these conditions, then in developed countries, vaccines’ benefits don’t necessarily outweigh their risks.
 - New vaccines haven’t been studied for autism or other modern chronic health conditions (ADHD, food allergies, etc.) in children through a comparison of vaccinated versus not vaccinated with the vaccine
 - The public must advocate for checks and balances in vaccine policy.
 - The public must advocate for unbiased research into vaccine injuries.
 - The public must have a fair and impartial system for compensating any vaccine injury.