

114TH CONGRESS
1ST SESSION

H. R. 1636

To direct 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.

IN THE HOUSE OF REPRESENTATIVES

MARCH 25, 2015

Mr. POSEY (for himself and Mrs. CAROLYN B. MALONEY of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To direct 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Vaccine Safety Study
5 Act”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) Securing the health of the Nation's children
4 is our most important concern as parents and stew-
5 ards of the Nation's future.

6 (2) The Nation's vaccine program has greatly
7 reduced human suffering from infectious disease by
8 preventing and reducing the outbreak of vaccine-pre-
9 ventable diseases.

10 (3) Total health outcomes are the best measure
11 of the success of any public health effort, including
12 security from both chronic and infectious disease.

13 (4) Childhood immunizations are an important
14 tool in protecting children from infectious disease.

15 (5) The number of immunizations administered
16 to infants, pregnant women, children, teenagers, and
17 adults has grown dramatically over recent years.

18 (6) The incidence of chronic, unexplained dis-
19 eases such as autism, learning disabilities, and other
20 neurological disorders appears to have increased dra-
21 matically in recent years.

22 (7) Individual vaccines are tested for safety, but
23 little safety testing has been conducted for inter-
24 action effects of multiple vaccines.

25 (8) The strategy of aggressive, early childhood
26 immunization against a large number of infectious

1 diseases has never been tested in its entirety against
2 alternative strategies, either for safety or for total
3 health outcomes.

4 (9) Childhood immunizations are the only
5 health interventions that are required by States of
6 all citizens in order to participate in civic society.

7 (10) Public confidence in the management of
8 public health can only be maintained if these State
9 government-mandated, mass vaccination programs—

10 (A) are tested rigorously and in their en-
11 tirety against all reasonable safety concerns;
12 and

13 (B) are verified in their entirety to produce
14 superior health outcomes.

15 (11) There are numerous United States popu-
16 lations in which a practice of no vaccination is fol-
17 lowed and which therefore provide a natural com-
18 parison group for comparing total health outcomes.

19 (12) No comparative study of such health out-
20 comes has ever been conducted.

21 (13) Given rising concern over the high rates of
22 childhood neurodevelopmental disorders such as au-
23 tism and other chronic conditions, the need for such
24 studies is becoming urgent.

1 **SEC. 3. STUDY ON HEALTH OUTCOMES IN VACCINATED**
2 **AND UNVACCINATED AMERICAN POPU-**
3 **LATIONS.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services (in this Act referred to as the “Sec-
6 retary”), acting through the Director of the National In-
7 stitutes of Health, shall conduct or support a comprehen-
8 sive study—

9 (1) to compare total health outcomes, including
10 the incidence and risk of autism, in vaccinated popu-
11 lations in the United States with such outcomes in
12 unvaccinated populations in the United States; and

13 (2) to determine whether exposure to vaccines
14 or vaccine components is associated with autism
15 spectrum disorders, chronic conditions, or other neu-
16 rological conditions.

17 (b) RULE OF CONSTRUCTION.—Nothing in this Act
18 shall be construed to authorize the conduct or support of
19 any study in which an individual or population is encour-
20 aged or incentivized to remain unvaccinated.

21 (c) QUALIFICATIONS.—With respect to each investi-
22 gator carrying out the study under this section, the Sec-
23 retary shall ensure that the investigator—

24 (1) is objective;

1 (2) is qualified to carry out such study, as evi-
2 denced by training experiences and demonstrated
3 skill;

4 (3) is not currently employed by any Federal,
5 State, or local public health agency;

6 (4) is not currently a member of a board, com-
7 mittee, or other entity responsible for formulating
8 immunization policy on behalf of any Federal, State,
9 or local public health agency or any component
10 thereof;

11 (5) has no history of a strong position on the
12 thimerosal or vaccine safety controversy; and

13 (6) is not currently an employee of, or other-
14 wise directly or indirectly receiving funds from, a
15 pharmaceutical company or the Centers for Disease
16 Control.

17 (d) TARGET POPULATIONS.—The Secretary shall
18 seek to include in the study under this section populations
19 in the United States that have traditionally remained
20 unvaccinated for religious or other reasons, which popu-
21 lations may include Old Order Amish, members of clinical
22 practices (such as the Homefirst practice in Chicago) who
23 choose alternative medical practices, practitioners of
24 anthroposophic lifestyles, and others who have chosen not
25 to be vaccinated.

1 (e) TIMING.—Not later than 120 days after the date
2 of the enactment of this Act, the Secretary shall issue a
3 request for proposals to conduct the study required by this
4 section. Not later than 120 days after receipt of any such
5 proposal, the Secretary shall approve or disapprove the
6 proposal. If the Secretary disapproves the proposal, the
7 Secretary shall provide the applicant involved with a writ-
8 ten explanation of the reasons for the disapproval.

9 (f) TRANSPARENCY.—To facilitate further research
10 by the Secretary or others, the Secretary shall ensure the
11 preservation of all data, including all data sets, collected
12 or used for purposes of the study under this section.

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Vaccines Do Not Cause Autism

<https://www.cdc.gov/vaccinesafety/concerns/autism.html>

[Autism spectrum disorder \(ASD\)](#) is a developmental disability that is caused by differences in how the brain functions. People with ASD may communicate, interact, behave, and learn in different ways. Recent estimates from [CDC's Autism and Developmental Disabilities Monitoring Network](#) found that about 1 in 68 children have been identified with ASD in communities across the United States. CDC is committed to providing essential data on ASD, searching for causes of and factors that increase the risk for ASD, and developing resources that help identify children with ASD as early as possible.

There is no link between vaccines and autism.

Some people have had concerns that ASD might be linked to the vaccines children receive, but studies have shown that there is no link between receiving vaccines and developing ASD. In 2011, an Institute of Medicine (IOM) [report](#) on eight vaccines given to children and adults found that with rare exceptions, these vaccines are very safe.

A [2013 CDC study \[PDF – 204 KB\]](#) added to the research showing that vaccines do not cause ASD. The study looked at the number of antigens (substances in vaccines that cause the body's immune system to produce disease-fighting antibodies) from vaccines during the first two years of life. The results showed that the total amount of antigen from vaccines received was the same between children with ASD and those that did not have ASD.

Vaccine ingredients do not cause autism.

One vaccine ingredient that has been studied specifically is [thimerosal](#), a mercury-based preservative used to prevent contamination of multidose vials of vaccines. Research shows that thimerosal does not cause ASD. In fact, a 2004 [scientific review](#) by the IOM concluded that “the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.” Since 2003, there have been [nine CDC-funded or conducted studies \[PDF – 357 KB\]](#) that have found no link between thimerosal-containing vaccines and ASD, as well as no link between the measles, mumps, and rubella (MMR) vaccine and ASD in children.

Between 1999 and 2001, thimerosal was removed or reduced to trace amounts in all childhood vaccines except for some flu vaccines. This was done as part of a broader national effort to reduce all types of mercury exposure in children before studies were conducted that determined that thimerosal was not harmful. It was done as a precaution. Currently, the only childhood vaccines that contain thimerosal are flu vaccines packaged in multidose vials. Thimerosal-free alternatives are also available for flu vaccine. For more information, see the [Timeline for Thimerosal in Vaccines](#).

Besides thimerosal, some people have had concerns about other [vaccine ingredients](#) in relation to ASD as well. However, no links have been found between any vaccine ingredients and ASD.