

111TH CONGRESS
1ST SESSION

H. R. 2618

To improve vaccine safety research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 2009

Mrs. MALONEY (for herself and Mr. SMITH of New Jersey) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To improve vaccine safety research, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Vaccine Safety and Public Confidence Assurance Act of
6 2009”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Purpose.

Sec. 4. Establishment of Agency for Vaccine Safety Evaluation.

1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) The Nation's vaccine program has greatly
4 reduced human suffering from infectious disease by
5 preventing and reducing the outbreak of vaccine-pre-
6 ventable diseases.

7 (2) The prestigious scientific journal Nature
8 has noted that to maintain public confidence in vac-
9 cines "there is a strong case for a well-resourced
10 independent agency that commends the trust of both
11 the government and the public". Nature 439, 1–2.

12 (3) Public confidence in governmental vaccine-
13 safety monitoring agencies is critical to building and
14 maintaining public confidence in vaccine safety.

15 (4) Actual or perceived conflicts of interest un-
16 dermine the credibility of vaccine-safety assurances
17 and reports issued by those with conflicts of interest.

18 (5) The Federal Government has a responsi-
19 bility to take all steps feasible to ensure that re-
20 search evaluating the safety of existing and future
21 vaccines is of the highest quality and free from con-
22 flicts of interest.

23 (6) The Centers for Disease Control and Pre-
24 vention is responsible for promoting both high im-
25 munization rates and vaccine safety, duties perceived
26 by some to constitute a conflict of interest.

1 (7) The actual or perceived conflict of interest
2 between vaccine promotion and vaccine safety has
3 been compounded by the fact that vaccine-safety
4 programs and the National Immunization Program
5 have needed to compete against each other for
6 funds. Funding for vaccine-safety research should be
7 completely independent from other vaccine-related
8 budget priorities.

9 (8) There are numerous vaccines presently in
10 the development pipeline for disease prevention and
11 treatment, and it is critical that the Nation develop
12 longer term and more specific safety monitoring
13 mechanisms.

14 (9) It is critical that the Federal Government
15 revamp vaccine-safety monitoring programs to focus
16 increasingly on developing prevaccination screening
17 tools to prevent injury, thereby raising public con-
18 fidence and reducing vaccine injuries.

19 (10) The current structure for monitoring for
20 vaccine safety, postlicensure, primarily focuses on
21 epidemiology. There is inadequate funding directed
22 toward independent research, including research di-
23 rected at understanding underlying biological mecha-
24 nisms and biological susceptibilities and designed to

1 understand why some children and adults develop
2 serious adverse outcomes after vaccination.

3 (11) Because most serious adverse reactions to
4 vaccines are rare, epidemiology studies may be lim-
5 ited in their ability to establish or rule out causal as-
6 sociation or biological plausibility.

7 (12) The vaccine-safety monitoring functions of
8 the Department of Health and Human Services have
9 tended to focus on monitoring for acute adverse
10 events rather than chronic adverse events. There is
11 little coordination and inadequate effort to inves-
12 tigate the biological mechanisms underlying vaccine-
13 related adverse events.

14 **SEC. 3. PURPOSE.**

15 The purpose of this Act is to direct that vaccine safe-
16 ty monitoring and research focus on active surveillance,
17 researching biological mechanisms for acute and chronic
18 adverse events following vaccination, developing
19 prevaccination screening methods within a framework that
20 is free from actual and perceived biases, and developing
21 a vaccine safety research agenda.

1 **SEC. 4. ESTABLISHMENT OF AGENCY FOR VACCINE SAFETY**
2 **EVALUATION.**

3 Title XXI of the Public Health Service Act (42
4 U.S.C. 300aa–1 et seq.) is amended by adding at the end
5 the following:

6 **“Subtitle 3—Agency for Vaccine**
7 **Safety Evaluation**

8 **“SEC. 2141. ESTABLISHMENT.**

9 “There is established in the Office of the Secretary
10 the Agency for Vaccine Safety Evaluation, to be headed
11 by the Director for Vaccine Safety Evaluation.

12 **“SEC. 2142. AUTHORITIES.**

13 “(a) IN GENERAL.—With respect to vaccines, the Di-
14 rector for Vaccine Safety Evaluation—

15 “(1) shall conduct or support safety research,
16 including research on—

17 “(A) acute and chronic adverse reactions,
18 including with respect to subpopulations;

19 “(B) components of vaccines, including ad-
20 ditives, adjuvants, and preservatives;

21 “(C) delivery mechanisms; and

22 “(D) the potential presence of adventitious
23 agents in vaccines; and

24 “(2) shall conduct or support long- and short-
25 term monitoring of vaccines for which a biologics li-

1 cense is in effect under section 351 of the Public
2 Health Service Act;

3 “(3) shall develop a vaccine safety research
4 agenda;

5 “(4) shall conduct or support research across a
6 range of disciplines, including molecular genetics,
7 toxicology, pharmacokinetics, cell biology, neurology,
8 immunology, pharmacogenomics, virology, and epide-
9 miology;

10 “(5) shall conduct or support research to ad-
11 dress issues raised in claims of injury brought before
12 the Secretary, the Attorney General of the United
13 States, and State and Federal courts;

14 “(6) shall develop, evaluate, and test
15 hypotheses, when appropriate, about potential ad-
16 verse reactions, including those generated by the De-
17 partment of Defense, the National Institutes of
18 Health, the Centers for Disease Control and Preven-
19 tion, the Food and Drug Administration, the Health
20 Resources and Services Administration, other gov-
21 ernmental agencies, and external researchers;

22 “(7) shall, on a regular basis, evaluate, report
23 on, and explore means to promote the compliance of
24 health care providers and vaccine manufacturers
25 with Federal requirements for reporting adverse re-

1 actions related to licensed vaccines, including the re-
2 quirements of section 2125(b);

3 “(8) shall conduct or support research to evalu-
4 ate reports of injury following vaccine administration
5 for the purpose of developing tests to prescreen indi-
6 viduals and subpopulations at greater risk of injury;

7 “(9) shall conduct or support research to evalu-
8 ate biological mechanisms of injury for the purpose
9 of eliminating or reducing the risk of such injury
10 through better prescreening tools or through modi-
11 fication of vaccines;

12 “(10) shall conduct long-term monitoring of
13 new or altered vaccines, including by monitoring the
14 effects of changes to the recommended childhood
15 and adolescent immunization schedule of the Centers
16 for Disease Control and Prevention; and

17 “(11) shall provide, in conjunction with the Na-
18 tional Library of Medicine, a clearinghouse for
19 prelicensure and postlicensure studies of vaccines
20 and make such clearinghouse publicly accessible by
21 means of the Internet.

22 “(b) PERSONNEL.—In carrying out this subtitle, the
23 Director for Vaccine Safety Evaluation—

24 “(1) may not employ any individual as an offi-
25 cer or employee in a position in level I, II, III, IV,

1 or V of the Executive Schedule or level GS–15 of the
2 General Schedule if the individual has been em-
3 ployed within the preceding 5 years—

4 “(A) by the Centers for Disease Control
5 and Prevention or the Food and Drug Adminis-
6 tration to carry out any function relating to
7 monitoring, or research on, adverse reactions
8 related to a licensed vaccine or any function re-
9 lated to vaccine development;

10 “(B) by the National Institutes of Health
11 to carry out any function relating to vaccine de-
12 velopment; or

13 “(C) by a vaccine manufacturer; and

14 “(2) shall ensure that all personnel assigned to
15 carry out functions relating to vaccine monitoring or
16 research on adverse reactions related to vaccines do
17 not have any related professional, familial, or finan-
18 cial conflict of interest.

19 “(c) GRANT APPLICANTS.—In awarding any grant
20 relating to research on adverse reactions to vaccines, the
21 Director for Vaccine Safety Evaluation—

22 “(1) shall require applicants to disclose (and
23 update every 6 months) all potential conflicts of in-
24 terest;

1 “(2) shall provide all disclosures under para-
2 graph (1) to the advisory council for consideration
3 as part of the council’s review of the application for
4 the grant; and

5 “(3) shall ensure that the applicant for the
6 grant does not have—

7 “(A) any financial conflict of interest that
8 might compromise the research findings, such
9 as holding a related patent or having a family
10 member who holds a related patent; or

11 “(B) any conflict of interest resulting from
12 the applicant’s association with an entity with
13 direct or indirect financial interest in the out-
14 comes of vaccine-safety research, such as receiv-
15 ing money or an in-kind contribution from a
16 manufacturer of the particular vaccine or vac-
17 cine components to be investigated pursuant to
18 the grant.

19 “(d) VACCINE SAFETY DATALINK PROJECT.—

20 “(1) IN GENERAL.—The Director for Vaccine
21 Safety Evaluation shall have the responsibility for
22 maintaining access to and overseeing the Vaccine
23 Safety Datalink Project (and any successor vaccine
24 database).

1 “(2) RELATION TO CDC AND FDA.—The Direc-
2 tor for Vaccine Safety Evaluation—

3 “(A) shall ensure that the Director of the
4 Centers for Disease Control and Prevention and
5 the Commissioner of Food and Drugs have ac-
6 cess to the Vaccine Safety Datalink Project to
7 the full extent necessary to conduct or support
8 monitoring, or research on, acute adverse reac-
9 tions related to any licensed vaccine; and

10 “(B) shall consider any comments or rec-
11 ommendations of the Director of the Centers
12 for Disease Control and Prevention and the
13 Commissioner of Food and Drugs regarding the
14 Vaccine Safety Datalink Project.

15 “(3) RESPONSIBILITIES.—In carrying out this
16 subsection, the Director for Vaccine Safety Evalua-
17 tion—

18 “(A) shall facilitate external access to the
19 Vaccine Safety Datalink Project for purposes of
20 research, including by—

21 “(i) requiring each participating
22 health care provider or health maintenance
23 organization to use a facilitator and suffi-
24 cient staff for the purpose of assisting ex-
25 ternal researchers in navigating the data

1 collection systems of the provider or orga-
2 nization;

3 “(ii) at the discretion of the Director,
4 reimbursing the provider or organization
5 for the salaries of such facilitator and staff
6 and any other expenses incurred for such
7 purpose;

8 “(iii) allowing researchers to access
9 data that is collected through the Vaccine
10 Safety Datalink Project, or published after
11 derivation from data that is so collected,
12 for review and duplication;

13 “(iv) requiring a researcher seeking
14 such access to demonstrate, for the pro-
15 posed research, the approval of not more
16 than one institutional review board—

17 “(I) from not more than one par-
18 ticipating health care provider or
19 health maintenance organization; or

20 “(II) established by the Secretary
21 or an agency of the Department of
22 Health and Human Services; and

23 “(v) developing guidelines for data
24 sharing, including guidelines for making
25 publicly accessible—

1 “(I) a clarification of the types of
2 studies possible with the Vaccine
3 Safety Datalink Project;

4 “(II) a categorization of the
5 types of studies possible with the Vac-
6 cine Safety Datalink Project; and

7 “(III) a delineation of the skills
8 necessary to work with the Vaccine
9 Safety Datalink Project; and

10 “(B) in carrying out subparagraph (A),
11 may deny access to the Vaccine Safety Datalink
12 Project for purposes of research that is not con-
13 ducted or supported by the Agency only if the
14 Director for Vaccine Safety Evaluation deter-
15 mines that—

16 “(i) the research is not technically
17 feasible because—

18 “(I) the requested data are not
19 available in the database;

20 “(II) enough individuals are not
21 represented in the database with the
22 exposures and outcomes of interest to
23 study the proposed hypothesis; or

1 “(III) the proposed statistical
2 tests are not possible with the avail-
3 able data; or

4 “(ii) the researchers fail to dem-
5 onstrate core competencies in the basic
6 skills needed to analyze the relevant data;

7 “(C) shall provide for transparency, includ-
8 ing by—

9 “(i) making publicly available the re-
10 sults of studies conducted through the Vac-
11 cine Safety Datalink Project; and

12 “(ii) maintaining archives of data sets
13 in the Vaccine Safety Datalink Project for
14 not less than 7 years;

15 “(D) shall ensure that, when external re-
16 searchers access data that is collected through
17 the Vaccine Safety Datalink Project, individ-
18 ually identifiable information is removed to the
19 extent necessary to preserve patient confiden-
20 tiality; and

21 “(E) may take such other actions and im-
22 pose such requirements as the Director for Vac-
23 cine Safety Evaluation deems necessary to fa-
24 cilitate external or public access to the database
25 without compromising patient confidentiality.

1 “(e) REVIEW OF INTERNATIONAL ACTIVITIES.—Not
2 later than 18 months after the date of the enactment of
3 this subtitle, the Director for Vaccine Safety Evaluation
4 shall—

5 “(1) complete a thorough review of all functions
6 transferred to the Agency under section 2144 relat-
7 ing to international agreements, partnerships, and
8 activities in which the United States Government
9 has a fiduciary role, identify any related conflicts of
10 interest, and develop and implement a plan to re-
11 duce such conflicts to the extent possible; and

12 “(2) submit a report to the Congress containing
13 the results of the review conducted under paragraph
14 (1), describing the conflicts of interests identified
15 under such paragraph, and including the plan devel-
16 oped under such paragraph.

17 “(f) FELLOWSHIP PROGRAM.—

18 “(1) ESTABLISHMENT.—The Director for Vac-
19 cine Safety Evaluation may establish a program of
20 awarding fellowships to individuals for research on
21 vaccine safety.

22 “(2) REQUIREMENTS.—The Director for Vac-
23 cine Safety Evaluation may not award a fellowship
24 to an individual for research under this subsection
25 unless the individual agrees—

1 “(A) to refrain from accepting any pay-
2 ment or other benefit for such research from a
3 manufacturer of a vaccine or vaccine component
4 to be subject to the research;

5 “(B) to refrain from employment by, or ac-
6 ceptance of payment from, a vaccine manufac-
7 turer or any organization that receives substan-
8 tial funding from a vaccine manufacturer before
9 the date that is 2 years after the end of such
10 research; and

11 “(C) to disclose (and update every 6
12 months) all potential conflicts of interest.

13 “(3) APPLICATION.—To seek a fellowship under
14 this subsection, an individual shall submit to the Di-
15 rector for Vaccine Safety Evaluation an application
16 in such form, in such manner, and containing such
17 information as the Director for Vaccine Safety Eval-
18 uation may reasonably require.

19 “(4) PEER REVIEW.—The Director for Vaccine
20 Safety Evaluation shall establish peer review mecha-
21 nisms to evaluate applications for fellowships under
22 this subsection.

23 “(g) PEER REVIEW.—

24 “(1) IN GENERAL.—The requirements of sec-
25 tion 492 (relating to peer review) shall apply to re-

1 search and development conducted or supported by
2 the Agency in the same manner and the to same ex-
3 tent as such requirements apply to research and de-
4 velopment conducted or supported by the National
5 Institutes of Health.

6 “(2) TECHNICAL AND SCIENTIFIC PEER REVIEW
7 GROUPS.—The Director for Vaccine Safety Evalua-
8 tion may, without regard to the provisions of title 5,
9 United States Code, governing appointments in the
10 competitive service, and without regard to the provi-
11 sions of chapter 51 and subchapter III of chapter 53
12 of such title relating to classification and General
13 Schedule pay rates, establish such technical and sci-
14 entific peer review groups as are needed to carry out
15 the requirements of this subtitle and appoint and
16 pay the members of such groups, except that officers
17 and employees of the United States shall not receive
18 additional compensation for service as members of
19 such groups.

20 “(h) FDA INFORMATION.—At the request of the Di-
21 rector for Vaccine Safety Evaluation, the Commissioner
22 of Food and Drugs shall provide the Director with com-
23 plete access to all vaccine-related information submitted
24 to the Food and Drug Administration by vaccine manufac-
25 turers, irrespective of whether the information was sub-

mitted before or after approval of the vaccine under section 351. The Director shall keep such information confidential to the same extent as the Commissioner of Food and Drugs is required to keep such information confidential, and the Director shall not disclose such information under section 552 of title 5, United States Code.

“(i) REPORT.—

“(1) SUBMISSION.—Not less than twice each year, the Director for Vaccine Safety Evaluation shall submit a report on the Agency’s activities under this section to the Advisory Committee on Immunization Practices, the National Vaccine Advisory Committee, the National Vaccine Program Office, the National Vaccine Injury Compensation Program, the Health Resources and Services Administration, and any other entity deemed appropriate by the Director or by the Secretary of Health and Human Services.

“(2) PUBLIC AVAILABILITY.—The Director for Vaccine Safety Evaluation shall make each report under this subsection publicly available.

“SEC. 2143. POSTMARKETING VACCINE SAFETY.

“(a) SURVEILLANCE AND CLINICAL TRIALS.—

“(1) IN GENERAL.—The Director for Vaccine Safety Evaluation, in consultation with the Commis-

1 sioner of Food and Drugs, shall require the manu-
2 facturer of each covered vaccine to provide for post-
3 marketing surveillance and clinical testing for any
4 acute or chronic adverse reactions associated with
5 the vaccine.

6 “(2) REQUIREMENTS.—The Director for Vac-
7 cine Safety Evaluation shall require the following:

8 “(A) Postmarketing surveillance and clin-
9 ical testing under paragraph (1) shall be con-
10 ducted—

11 “(i) by one or more individuals re-
12 ferred to the advisory council by the manu-
13 facturer or by the Agency, recommended
14 by the advisory council under section
15 2145(b)(3), and approved by the Director
16 for Vaccine Safety Evaluation under para-
17 graph (3); and

18 “(ii) in accordance with a research
19 protocol referred to the advisory council by
20 the manufacturer or by the Agency, rec-
21 ommended by the advisory council under
22 section 2145(b)(3), and approved by the
23 Director for Vaccine Safety Evaluation.

24 “(B) The data and analysis of post-
25 marketing surveillance and clinical testing

1 under paragraph (1) shall be made available for
2 objective, independent evaluation.

3 “(3) APPROVAL OF RESEARCHERS.—The Direc-
4 tor for Vaccine Safety Evaluation may not approve
5 an individual for the purpose of conducting post-
6 marketing surveillance or clinical testing under para-
7 graph (1) unless the individual demonstrates to the
8 Director’s satisfaction that the individual has no
9 present conflict of interest that might compromise
10 such surveillance or testing, including any employ-
11 ment or financial relationship with a vaccine manu-
12 facturer.

13 “(4) DEFINITION.—For purposes of this sub-
14 section, the term ‘covered vaccine’ means a vaccine
15 licensed under section 351 after January 1, 2009.

16 “(b) RELATION TO CDC, FDA, AND VAERS.—This
17 subtitle shall not be construed to diminish the authority
18 of the Director of the Centers for Disease Control and
19 Prevention or the Commissioner of Food and Drugs to im-
20 plement the Vaccine Adverse Event Reporting System.
21 The postmarketing surveillance conducted by the Director
22 for Vaccine Safety Evaluation under this section shall be
23 in addition to the postmarkeing surveillance conducted
24 under the Vaccine Adverse Event Reporting System.

25 “(c) RECOMMENDATIONS ON VACCINE SAFETY.—

1 “(1) GRANTS.—If more than 1 vaccine is li-
2 censed under section 351 for the purpose of pre-
3 venting or mitigating the effects of the same disease,
4 the Director for Vaccine Safety Evaluation may
5 award grants to conduct comparative studies to de-
6 termine, for each such vaccine, whether the vaccine
7 is associated with fewer acute or chronic serious ad-
8 verse reactions (in the population as a whole or in
9 any subpopulation) than any other vaccine licensed
10 for the purpose of preventing or mitigating the ef-
11 fects of the same disease. Such studies may focus on
12 administering vaccines in isolation or in combination
13 with other vaccines.

14 “(2) DETERMINATION.—If the Director for
15 Vaccine Safety Evaluation determines that a vaccine
16 described in paragraph (1) is associated with fewer
17 acute or chronic adverse reactions (in the population
18 as a whole or in any subpopulation) than another
19 vaccine licensed for the purpose of preventing or
20 mitigating the effects of the same disease, the Direc-
21 tor shall make this determination publicly available.

22 “(d) REGISTRATION OF CLINICAL TRIALS.—

23 “(1) REQUIREMENT.—The Director for Vaccine
24 Safety Evaluation shall require the manufacturer of
25 a vaccine that is licensed under section 351, or for

1 which the manufacturer will seek licensure under
2 section 351, to register in a qualified public registry
3 each clinical trial conducted or supported by the
4 manufacturer with respect to the vaccine, irrespec-
5 tive of whether such trial is suspended before com-
6 pletion.

7 “(2) MINIMUM INFORMATION.—In carrying out
8 subsection (a), the Director for Vaccine Safety Eval-
9 uation shall require the manufacturer to include in
10 the registration for each clinical trial the following
11 information:

12 “(A) A unique identifying number.

13 “(B) A statement of each intervention and
14 comparison studied.

15 “(C) A statement of the study hypothesis.

16 “(D) Definitions of the primary and sec-
17 ondary outcome measures.

18 “(E) Eligibility criteria.

19 “(F) Key trial dates (including the reg-
20 istration date, the anticipated or actual start
21 date, the anticipated or actual date of last fol-
22 low-up, the planned or actual date of closure to
23 data entry, and the date on which trial data is
24 considered to be complete).

25 “(G) The target number of subjects.

1 “(H) The funding source.

2 “(I) Contact information for the principal
3 investigator.

4 “(J) Such other information as the Direc-
5 tor may require.

6 “(3) TIMING OF REGISTRATION.—In carrying
7 out subsection (a), the Director for Vaccine Safety
8 Evaluation shall require the manufacturer to reg-
9 ister each clinical trial—

10 “(A) if the trial starts on or after the date
11 of the enactment of this section, not later than
12 the onset of patient enrollment; and

13 “(B) if the trial starts before the date of
14 the enactment of this section, not later than the
15 end of the 90-day period following such date of
16 enactment.

17 “(4) DEFINITIONS.—In this subsection:

18 “(A) The term ‘clinical trial’ means a re-
19 search project that prospectively assigns human
20 subjects to intervention or comparison groups
21 to study the cause-and-effect relationship be-
22 tween a medical intervention and a health out-
23 come.

24 “(B) The term ‘qualified public registry’
25 means a registry that—

1 “(i) is accessible to the public at no
2 charge;

3 “(ii) is open to all prospective reg-
4 istrants;

5 “(iii) is managed by a nonprofit orga-
6 nization or a Federal, State, or local gov-
7 ernmental entity;

8 “(iv) has in effect a mechanism to en-
9 sure the validity of the registration data;

10 “(v) is electronically searchable; and

11 “(vi) includes, for each clinical trial,
12 each category of information described in
13 paragraph (2).

14 “(5) APPLICATION.—This subsection applies
15 only with respect to clinical trials that are ongoing
16 on, or start on or after, July 1, 2009.

17 **“SEC. 2144. TRANSFER OF CDC FUNCTIONS RELATING TO**
18 **MONITORING ADVERSE REACTIONS RELATED**
19 **TO LICENSED VACCINES.**

20 “(a) TRANSFER OF CDC FUNCTIONS.—Effective on
21 the date that is 1 year after the date of the enactment
22 of this subtitle, there are transferred to the Agency all
23 the functions, assets, and obligations of the Centers for
24 Disease Control and Prevention relating to—

25 “(1) the Vaccine Safety Datalink Project;

1 “(2) the Clinical Immunization Safety Assess-
2 ment Centers; or

3 “(3) any other post-licensure vaccine safety
4 monitoring activities.

5 “(b) ORDERLY TRANSFER.—The Secretary of Health
6 and Human Services shall take such steps as are nec-
7 essary to ensure the orderly transfer under this section
8 of functions, assets, and obligations from the Centers for
9 Disease Control and Prevention.

10 “(c) RULE OF CONSTRUCTION.—Except with respect
11 to the activities specified in subsection (a), nothing in this
12 subtitle shall be construed to transfer or limit the author-
13 ity of the Director of the Centers for Disease Control and
14 Prevention to conduct surveillance and response activities
15 with respect to vaccine safety or effectiveness, including
16 with respect to acute adverse reactions.

17 **“SEC. 2145. ADVISORY COUNCIL.**

18 “(a) ESTABLISHMENT.—The Secretary shall estab-
19 lish in the Agency an advisory council.

20 “(b) DUTIES.—The advisory council shall—

21 “(1) formulate recommendations on the need
22 for new or improved research on licensed vaccines;

23 “(2) develop and annually update a vaccine
24 safety research agenda;

1 “(3) recommend individuals and research proto-
2 cols for purposes of section 2143(a)(2)(A);

3 “(4) if potentially vaccine-related toxicological
4 damage or subacute infection is observed in vitro, in
5 laboratory animals, or in clinical testing, formulate
6 recommendations on conducting laboratory and clin-
7 ical research even in the absence of epidemiological
8 evidence;

9 “(5) not later than 2 weeks after each quarterly
10 meeting of the advisory council, submit to the Agen-
11 cy a report that includes a summary of the presen-
12 tations made at the meeting, a list of hypotheses
13 proposed, and the recommendations of the advisory
14 council on research described in paragraph (1);

15 “(6) review each application submitted to the
16 Director for Vaccine Safety Evaluation for a grant
17 or other assistance related to vaccine research;

18 “(7) make recommendations to the Director for
19 Vaccine Safety Evaluation regarding each such ap-
20 plication;

21 “(8) make recommendations to the Secretary of
22 Health and Human Services regarding vaccine safe-
23 ty;

1 “(9) not less than quarterly, submit a report to
2 the Secretary of Health and Human Services regard-
3 ing vaccine safety efforts; and

4 “(10) make publicly available—

5 “(A) each report submitted under para-
6 graph (9); and

7 “(B) a transcript of each meeting of the
8 advisory council.

9 “(c) EFFECT OF RECOMMENDATIONS.—The Director
10 for Vaccine Safety Evaluation may not approve any appli-
11 cation for a grant or other assistance related to vaccine
12 research until the Director has considered the rec-
13 ommendations of the advisory council regarding such re-
14 search. If the Director decides to approve or disapprove
15 any such application contrary to the recommendations of
16 the advisory council, the Director shall provide the advi-
17 sory council with, and make publicly available, a detailed,
18 written explanation of the reasons for the decision.

19 “(d) MEMBERSHIP.—

20 “(1) COMPOSITION.—The advisory council shall
21 be composed of 18 members appointed by the Sec-
22 retary, including the following:

23 “(A) Not more than 2 representatives of
24 the vaccine manufacturing industry.

25 “(B) One practicing pediatrician.

1 “(C) One infectious disease expert.

2 “(D) Five adults who are each—

3 “(i) a victim of a vaccine injury; or

4 “(ii) a parent of the victim of a vac-
5 cine-related injury.

6 “(E) One representative of the general
7 public who—

8 “(i) is not the victim of a vaccine in-
9 jury; and

10 “(ii) does not have a conflict of inter-
11 est described in paragraph (1)(A), (1)(B),
12 or (2) of section 2142(b).

13 “(F) One toxicologist.

14 “(G) One neurologist.

15 “(H) One geneticist.

16 “(I) One immunologist.

17 “(J) One State or local public health offi-
18 cer.

19 “(K) Not less than 4 and not more than
20 6 additional representatives.

21 “(2) QUALIFICATIONS.—In appointing the
22 members of the Commission, the Secretary shall en-
23 sure that not less than one-third of the members of
24 the advisory council are selected from among indi-
25 viduals who have a vaccine-related injury or who

1 have an immediate family member with a vaccine-re-
2 lated injury (irrespective of whether there is a judi-
3 cial or administration finding of such injury).

4 “(3) CONFLICTS OF INTEREST.—In appointing
5 the members of the Commission, the Secretary shall
6 ensure that such members do not have any related
7 financial conflict of interest. For purposes of this
8 paragraph, the Secretary shall not treat as a conflict
9 of interest the following:

10 “(A) In the case of a member appointed
11 under paragraph (1)(A) who is employed in the
12 vaccine manufacturing industry, the receipt of a
13 salary or other benefits for such employment.

14 “(B) In the case of 2 of the members ap-
15 pointed under paragraph (1)(D), any pending
16 claim for compensation for a vaccine-related in-
17 jury.

18 **“SEC. 2146. FULL-TIME LIAISON.**

19 “The Director for Vaccine Safety Evaluation shall
20 designate an employee of the Agency to serve as a full-
21 time liaison between the Agency and the Department of
22 Defense, the National Institutes of Health, the Food and
23 Drug Administration, and the Centers for Disease Control
24 and Prevention, and any other agency as the Director de-
25 termines necessary.

1 **“SEC. 2147. DEFINITIONS.**

2 “In this subtitle:

3 “(1) The term ‘advisory council’ means the ad-
4 visory council established pursuant to section 2145.

5 “(2) The term ‘Agency’ means the Agency for
6 Vaccine Safety Evaluation.

7 “(3) The term ‘assets’ includes contracts, facili-
8 ties, property, records, unobligated or unexpended
9 balances of appropriations, and other funds or re-
10 sources (other than personnel).

11 “(4) The term ‘functions’ includes authorities,
12 powers, rights, privileges, immunities, programs,
13 projects, activities, duties, and responsibilities.

14 “(5) The term ‘licensed vaccine’ means a vac-
15 cine with a biologics license in effect under section
16 351 of the Public Health Service Act (42 U.S.C.
17 262).

18 “(6) The term ‘personnel’ means officers and
19 employees.

20 “(7) The term ‘Project’ means the Vaccine
21 Safety Datalink Project.

22 **“SEC. 2148. AUTHORIZATION OF APPROPRIATIONS.**

23 “There is authorized to be appropriated—

24 “(1) for conducting and supporting research
25 under this subtitle, \$80,000,000 for fiscal year
26 2010; and

1 “(2) for carrying out responsibilities under this
2 subtitle other than the conduct or support of re-
3 search, such sums as may be necessary for fiscal
4 year 2010.”.

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