

107TH CONGRESS
2^D SESSION

H. R. 5282

To amend the Public Health Service Act to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2002

Mr. GREENWOOD (for himself and Mr. TOWNS) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program, 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 “Improved Vaccine Affordability and Availability Act”.

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

Sec. 1. Short title; table of contents.

- Sec. 101. Availability of influenza vaccine.
 Sec. 102. Program for increasing immunization rates for adults and adolescents; collection of additional immunization data.
 Sec. 103. Immunization awareness.
 Sec. 104. Supply of vaccines.

TITLE II—VACCINE INJURY COMPENSATION PROGRAM

- Sec. 201. Administrative revision of vaccine injury table.
 Sec. 202. Equitable relief.
 Sec. 203. Parent petitions for compensation.
 Sec. 204. Jurisdiction to dismiss actions improperly brought.
 Sec. 205. Clarification of when injury is caused by factor unrelated to administration of vaccine.
 Sec. 206. Basis for calculating projected lost earnings.
 Sec. 207. Allowing compensation for family counseling expenses and expenses of establishing guardianship.
 Sec. 208. Allowing payment of interim costs.
 Sec. 209. Procedure for paying attorneys' fees.
 Sec. 210. Extension of statute of limitations.
 Sec. 211. Advisory commission on childhood vaccines.
 Sec. 212. Clarification of standards of responsibility.
 Sec. 213. Clarification of definition of manufacturer.
 Sec. 214. Clarification of definition of vaccine-related injury or death.
 Sec. 215. Clarification of definition of vaccine.
 Sec. 216. Ongoing review of childhood vaccine data.
 Sec. 217. Pending actions.
 Sec. 218. Report.

1 **TITLE I—STATE VACCINE** 2 **GRANTS**

3 **SEC. 101. AVAILABILITY OF INFLUENZA VACCINE.**

4 Section 317(j) of the Public Health Service Act (42
 5 U.S.C. 247b(j)) is amended by adding at the end the fol-
 6 lowing:

7 “(3)(A) For the purpose of carrying out activities re-
 8 lating to influenza vaccine under the immunization pro-
 9 gram under this subsection, there are authorized to be ap-
 10 propriated such sums as may be necessary for each of fis-
 11 cal years 2003 and 2004. Such authorization shall be in

1 addition to amounts available under paragraphs (1) and
2 (2) for such purpose.

3 “(B) The authorization of appropriations established
4 in subparagraph (A) shall not be effective for a fiscal year
5 unless the total amount appropriated under paragraphs
6 (1) and (2) for the fiscal year is not less than such total
7 for fiscal year 2000.

8 “(C) The purposes for which amounts appropriated
9 under subparagraph (A) are available to the Secretary in-
10 clude providing for improved State and local infrastruc-
11 ture for influenza immunizations under this subsection in
12 accordance with the following:

13 “(i) Increasing influenza immunization rates in
14 populations considered by the Secretary to be at
15 high risk for influenza-related complications and in
16 their contacts.

17 “(ii) Recommending that health care providers
18 actively target influenza vaccine that is available in
19 September, October, and November to individuals
20 who are at increased risk for influenza-related com-
21 plications and to their contacts.

22 “(iii) Providing for the continued availability of
23 influenza immunizations through December of such
24 year, and for additional periods to the extent that
25 influenza vaccine remains available.

1 “(iv) Encouraging States, as appropriate, to de-
2 velop contingency plans (including plans for public
3 and professional educational activities) for maxi-
4 mizing influenza immunizations for high-risk popu-
5 lations in the event of a delay or shortage of influ-
6 enza vaccine.

7 “(D) The Secretary shall submit to the Committee
8 on Energy and Commerce of the House of Representa-
9 tives, and the Committee on Health, Education, Labor,
10 and Pensions of the Senate, periodic reports describing the
11 activities of the Secretary under this subsection regarding
12 influenza vaccine. The first such report shall be submitted
13 not later than June 6, 2003, the second report shall be
14 submitted not later than June 6, 2004, and subsequent
15 reports shall be submitted biennially thereafter.”.

16 **SEC. 102. PROGRAM FOR INCREASING IMMUNIZATION**
17 **RATES FOR ADULTS AND ADOLESCENTS; COL-**
18 **LECTION OF ADDITIONAL IMMUNIZATION**
19 **DATA.**

20 (a) **ACTIVITIES OF CENTERS FOR DISEASE CONTROL**
21 **AND PREVENTION.**—Section 317(j) of the Public Health
22 Service Act (42 U.S.C. 247b(j)), as amended by section
23 101, is further amended by adding at the end the fol-
24 lowing:

1 “(4)(A) For the purpose of carrying out activities to
2 increase immunization rates for adults and adolescents
3 through the immunization program under this subsection,
4 and for the purpose of carrying out subsection (k)(2),
5 there are authorized to be appropriated \$50,000,000 for
6 fiscal year 2003, and such sums as may be necessary for
7 each of the fiscal years 2004 through 2006. Such author-
8 ization is in addition to amounts available under para-
9 graphs (1), (2), and (3) for such purposes.

10 “(B) In expending amounts appropriated under sub-
11 paragraph (A), the Secretary shall give priority to adults
12 and adolescents who are medically underserved and are
13 at risk for vaccine-preventable diseases, including as ap-
14 propriate populations identified through projects under
15 subsection (k)(2)(E).

16 “(C) The purposes for which amounts appropriated
17 under subparagraph (A) are available include (with re-
18 spect to immunizations for adults and adolescents) the
19 payment of the costs of storing vaccines, outreach activi-
20 ties to inform individuals of the availability of the immuni-
21 zations, and other program expenses necessary for the es-
22 tablishment or operation of immunization programs car-
23 ried out or supported by States or other public entities
24 pursuant to this subsection.

1 “(5) The Secretary shall annually submit to Congress
2 a report that—

3 “(A) evaluates the extent to which the immuni-
4 zation system in the United States has been effective
5 in providing for adequate immunization rates for
6 adults and adolescents, taking into account the ap-
7 plicable year 2010 health objectives established by
8 the Secretary regarding the health status of the peo-
9 ple of the United States; and

10 “(B) describes any issues identified by the Sec-
11 retary that may affect such rates.

12 “(6) In carrying out this subsection and paragraphs
13 (1) and (2) of subsection (k), the Secretary shall consider
14 recommendations regarding immunizations that are made
15 in reports issued by the Institute of Medicine.”.

16 (b) RESEARCH, DEMONSTRATIONS, AND EDU-
17 CATION.—Section 317(k) of the Public Health Service Act
18 (42 U.S.C. 247b(k)) is amended—

19 (1) by redesignating paragraphs (2) through
20 (4) as paragraphs (3) through (5), respectively; and

21 (2) by inserting after paragraph (1) the fol-
22 lowing:

23 “(2) The Secretary, directly and through grants
24 under paragraph (1), shall provide for a program of re-

1 search, demonstration projects, and education in accord-
2 ance with the following:

3 “(A) The Secretary shall coordinate with public
4 and private entities (including nonprofit private enti-
5 ties), and develop and disseminate guidelines, toward
6 the goal of ensuring that immunizations are rou-
7 tinely offered to adults and adolescents by public
8 and private health care providers.

9 “(B) The Secretary shall cooperate with public
10 and private entities to obtain information for the an-
11 nual evaluations required in subsection (j)(5)(A).

12 “(C) The Secretary shall (relative to fiscal year
13 2001) increase the extent to which the Secretary col-
14 lects data on the incidence, prevalence, and cir-
15 cumstances of diseases and adverse events that are
16 experienced by adults and adolescents and may be
17 associated with immunizations, including collecting
18 data in cooperation with commercial laboratories.

19 “(D) The Secretary shall ensure that the enti-
20 ties with which the Secretary cooperates for pur-
21 poses of subparagraphs (A) through (C) include
22 managed care organizations, community-based orga-
23 nizations that provide health services, and other
24 health care providers.

1 “(E) The Secretary shall provide for projects to
2 identify racial and ethnic minority groups and other
3 health disparity populations for which immunization
4 rates for adults and adolescents are below such rates
5 for the general population, and to determine the fac-
6 tors underlying such disparities.”.

7 **SEC. 103. IMMUNIZATION AWARENESS.**

8 (a) DEVELOPMENT OF INFORMATION CONCERNING
9 MENINGITIS.—

10 (1) IN GENERAL.—The Secretary of Health and
11 Human Services, in consultation with the Director of
12 the Centers for Disease Control and Prevention,
13 shall develop and make available to entities de-
14 scribed in paragraph (2) information concerning
15 bacterial meningitis and the availability and effec-
16 tiveness of vaccinations for populations targeted by
17 the Advisory Committee of Immunization Practices
18 (an advisory committee established by the Secretary
19 of Health and Human Services, acting through the
20 Centers for Disease Control and Prevention).

21 (2) ENTITIES.—An entity is described in this
22 paragraph if the entity—

23 (A) is—

24 (i) a college or university; or

1 (ii) a prison or other detention facil-
2 ity; and

3 (B) is determined appropriate by the Sec-
4 retary of Health and Human Services.

5 (b) DEVELOPMENT OF INFORMATION CONCERNING
6 HEPATITIS.—

7 (1) IN GENERAL.—The Secretary of Health and
8 Human Services, in consultation with the Director of
9 the Centers for Disease Control and Prevention,
10 shall develop and make available to entities de-
11 scribed in paragraph (2) information concerning
12 hepatitis A and B and the availability and effective-
13 ness of vaccinations with respect to such diseases.

14 (2) ENTITIES.—An entity is described in this
15 paragraph if the entity—

16 (A) is—

17 (i) a health care clinic that serves in-
18 dividuals diagnosed as being infected with
19 HIV or as having other sexually trans-
20 mitted diseases;

21 (ii) an organization or business that
22 counsels individuals about international
23 travel or who arranges for such travel;

24 (iii) a police, fire or emergency med-
25 ical services organization that responds to

1 natural or man-made disasters or emer-
2 gencies;

3 (iv) a prison or other detention facil-
4 ity;

5 (v) a college or university; or

6 (vi) a public health authority or chil-
7 dren's health service provider in areas of
8 intermediate or high endemicity for hepa-
9 titis A as defined by the Centers for Dis-
10 ease Control and Prevention; and

11 (B) is determined appropriate by the Sec-
12 retary of Health and Human Services.

13 **SEC. 104. SUPPLY OF VACCINES.**

14 (a) IN GENERAL.—The Secretary of Health and
15 Human Services, acting through the Director of the Cen-
16 ters for Disease Control and Prevention, shall prioritize,
17 acquire, and maintain a supply of such prioritized vaccines
18 sufficient to provide vaccinations throughout a 6-month
19 period.

20 (b) PROCEEDS.—Any proceeds received by the Sec-
21 retary of Health and Human Services from the sale of vac-
22 cines contained in the supply described in subsection (a),
23 shall be available to the Secretary for the purpose of pur-
24 chasing additional vaccines for the supply. Such proceeds
25 shall remain available until expended.

1 (c) AUTHORIZATION OF APPROPRIATIONS.—There
 2 are authorized to be appropriated for the purpose of car-
 3 rying out subsection (a) such sums as may be necessary
 4 for each of fiscal years 2003 through 2008.

5 **TITLE II—VACCINE INJURY**
 6 **COMPENSATION PROGRAM**

7 **SEC. 201. ADMINISTRATIVE REVISION OF VACCINE INJURY**

8 **TABLE.**

9 Section 2114 of the Public Health Service Act (42
 10 U.S.C. 300aa–14) is amended—

11 (1) in subsection (c), by striking paragraph (1)
 12 and inserting the following:

13 “(1) In promulgating such regulations, the Sec-
 14 retary shall provide for notice and for at least 9060
 15 days opportunity for public comment.”; and

16 (2) in subsection (d), by striking “90 days” and
 17 inserting “60 days”.

18 **SEC. 202. EQUITABLE RELIEF.**

19 Section 2111(a)(2)(A) of the Public Health Service
 20 Act (42 U.S.C. 300aa–11(a)(2)(A)) is amended by strik-
 21 ing “No person” and all that follows through “and—” and
 22 inserting the following: “No person may bring or maintain
 23 a civil action against a vaccine administrator or manufac-
 24 turer in a State or Federal court for damages arising
 25 from, or equitable relief relating to, a vaccine-related in-

1 jury or death associated with the administration of a vac-
2 cine after October 1, 1988 and no such court may award
3 damages or equitable relief for any such vaccine-related
4 injury or death, unless the person proves past or present
5 physical injury and a timely petition has been filed, in ac-
6 cordance with section 2116 for compensation under the
7 Program for such injury or death—”.

8 **SEC. 203. PARENT PETITIONS FOR COMPENSATION.**

9 (a) CIVIL ACTIONS.—Section 2111(a)(2) of the Pub-
10 lic Health Service Act (42 U.S.C. 300aa–(a)(2)) is
11 amended—

12 (1) in subparagraph (B), by inserting “or (B)”
13 after “subparagraph (A)”;

14 (2) by redesignating subparagraph (B) as sub-
15 paragraph (C); and

16 (3) by inserting after subparagraph (A) the fol-
17 lowing:

18 “(B) No parent or other third party may bring
19 or maintain a civil action against a vaccine adminis-
20 trator or manufacturer in a State or Federal court
21 for damages or equitable relief relating to a vaccine-
22 related injury or death, including but not limited to
23 damages for loss of consortium, society, companion-
24 ship or services, loss of earnings, medical or other
25 expenses, and emotional distress, and no court may

1 award damages or equitable relief in such an action
2 unless—

3 “(i) the person who sustained the under-
4 lying vaccine-related injury or death upon which
5 such parent or third party’s claim is premised
6 has, in accordance with section 2112, been
7 awarded compensation in a final judgment of
8 the United States Court of Federal Claims and
9 such judgment is subject to no further appeal
10 or review,

11 “(ii) such parent or other third party is
12 the parent, legal guardian or spouse of the per-
13 son who sustained the underlying vaccine-re-
14 lated injury and such parent, legal guardian or
15 spouse timely filed a derivative petition, in ac-
16 cordance with section 2116, and

17 “(iii)(I) the United States Court of Fed-
18 eral Claims has issued judgment under section
19 2112 on the derivative petition, and such par-
20 ent, legal guardian or spouse elects under sec-
21 tion 2121(a) to file a civil action, or

22 “(II) such parent, legal guardian or spouse
23 elects to withdraw such derivative petition
24 under section 2121(b) or such petition is con-
25 sidered withdrawn under such section.

1 Any civil action brought in accordance with this sub-
2 paragraph shall be subject to the standards and pro-
3 cedures set forth in section 2122 and 2123, regard-
4 less of whether the action arises directly from a vac-
5 cine-related injury or death associated with the ad-
6 ministration of a vaccine. Where the person who sus-
7 tained the underlying vaccine-related injury or death
8 upon which such parent, legal guardian, or spouse’s
9 civil cause of action is premised elects under section
10 2121(a) to receive the compensation awarded, such
11 parent or third party may not bring a civil action for
12 damages or equitable relief, and no court may award
13 damages or equitable relief, for any injury or loss of
14 the type set forth in section 2115(a) or that might
15 in any way overlap with or otherwise duplicate com-
16 pensation of the type available under section
17 2115(a).”.

18 (b) APPLICABILITY.—Section 2111(a)(9) of the Pub-
19 lic Health Service Act (42 U.S.C. 300aa–11(a)(9)) is
20 amended by inserting before the period the following: “and
21 to a parent or other third party to the extent such parent
22 or other third party seeks damages or equitable relief re-
23 lating to a vaccine-related injury or death sustained by
24 a person who is qualified to file a petition for compensa-
25 tion under the Program”.

1 (c) PETITIONERS.—Section 2111(b) of the Public
2 Health Service Act (42 U.S.C. 300aa–11(b)) is
3 amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (A), by striking “(B)”
6 and inserting “(C)”;

7 (B) by redesignating subparagraph (B) as
8 subparagraph (C); and

9 (C) by inserting after subparagraph (A)
10 the following:

11 “(B) Except as provided in subparagraph (C),
12 any parent, legal guardian or spouse of a person—

13 “(i) who has sustained a vaccine-related in-
14 jury or death,

15 “(ii) who has filed a petition for compensa-
16 tion under the Program (or whose legal rep-
17 resentative has filed a petition as authorized in
18 subparagraph (A)), and

19 “(iii) who has, in accordance with section
20 2112, been awarded compensation in a final
21 judgment of the United States Court of Federal
22 Claims that is subject to no further appeal or
23 review,

1 may, if such parent, legal guardian or spouse meets
2 the requirements of subsection (d) of this section,
3 file a derivative petition under this section.”; and

4 (2) in paragraph (2)—

5 (A) by inserting after “filed” the following:

6 “by or on behalf of the person who sustained
7 the vaccine-related injury or death”; and

8 (B) by adding at the end the following:

9 “No parent, legal guardian, or spouse may file
10 more than one derivative petition with respect
11 to each administration of a vaccine.”.

12 (d) DERIVATIVE PETITIONS.—Section 2111 of the
13 Public Health Service Act (42 U.S.C. 300aa–11) is
14 amended—

15 (1) by redesignating subsections (d) and (e)
16 and subsections (e) and (f), respectively; and

17 (2) by inserting after subsection (c) the fol-
18 lowing subsection:

19 “(d) DERIVATIVE PETITIONS.—If the parent, legal
20 guardian, or spouse of the person who sustained the vac-
21 cine-related injury or death seeks compensation under the
22 Program, such parent, legal guardian or spouse shall file
23 a timely derivative petition for compensation under the
24 Program in accordance with this section. Such a derivative
25 petition shall contain—

1 “(1) an affidavit, and supporting documenta-
2 tion, demonstrating that—

3 “(A) the child, ward, or spouse of such
4 person was, in accordance with section 2112,
5 previously awarded compensation for the under-
6 lying vaccine-related injury or death upon which
7 such parent’s, legal guardian’s, or spouse’s de-
8 rivative claim is premised in a final judgment of
9 the United States Court of Federal Claims and
10 such judgment is subject to no further appeal
11 or review,

12 “(B) the derivative petition was filed no
13 later than 60 days after the date on which such
14 judgment became final and subject to no fur-
15 ther appeal or review,

16 “(C) such parent, legal guardian or spouse
17 suffered a loss compensable under section
18 2115(b) as a result of the vaccine-related injury
19 or death sustained by such person’s child, ward,
20 or spouse, and

21 “(D) such parent, legal guardian or spouse
22 has not previously collected an award or settle-
23 ment of a civil action for damages for such loss,
24 and

1 “(2) records establishing such parent’s, legal
2 guardian’s, or spouse’s legal relationship to the per-
3 son who sustained the vaccine-related injury or
4 death.”.

5 (e) DETERMINATION OF ELIGIBILITY AND COM-
6 PENSATION.—Section 2113(a)(1) of the Public Health
7 Service Act (42 U.S.C. 300aa–13(a)(1)) is amended—

8 (1) in subparagraph (A), by inserting before “,
9 and” the following: “or, where applicable, section
10 2111(d)”; and

11 (2) in subparagraph (B), by inserting before
12 the period the following: “or, as applicable, that the
13 injury or loss described in the derivative petition is
14 due to factors unrelated to the vaccine-related injury
15 or death”.

16 (f) COMPENSATION.—Section 2115 of the Public
17 Health Service Act (42 U.S.C. 300aa–15) is amended—

18 (1) by redesignating subsections (b) through (j)
19 as subsections (c) through (k), respectively; and

20 (2) by inserting after subsection (a) the fol-
21 lowing:

22 “(b) DERIVATIVE PETITIONS.—Compensation
23 awarded under the Program to a parent, legal guardian,
24 or spouse who files a derivative petition under section
25 2111 for a loss sustained as a result of a vaccine-related

1 injury or death sustained by such petitioner’s child, ward,
2 or spouse shall include compensation for loss of consor-
3 tium, society, companionship or services, in an amount not
4 to exceed the lesser of \$250,000 or the total amount of
5 compensation awarded to the person who sustained the
6 underlying vaccine-related injury or death.”;

7 (3) in subsection (e), by inserting “, (3), and
8 (4)” after “(2)” and by inserting “and subsection
9 (b) of this section,” following “section,“;

10 (4) in subsection (g)(4)(B), by striking “sub-
11 section (j)” and inserting “subsection (k)”;

12 (5) in subsection (j)(1), by striking “(j)” and
13 inserting “(k)”;

14 (6) in subsection (j)(2), by inserting “, or to a
15 parent or spouse of a person who sustained a vac-
16 cine-related injury or death,” following “death”; and

17 (7) in subsection (k), by striking “subsection
18 (f)(4)(B)” and inserting “subsection (g)(4)(B)”.

19 **SEC. 204. JURISDICTION TO DISMISS ACTIONS IMPROP-**
20 **ERLY BROUGHT.**

21 Section 2111(a)(3) of the Public Health Service Act
22 (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the
23 end the following: “If any civil action which is barred
24 under subparagraph (A) or (B) of paragraph (2) is filed
25 or maintained in a State court, or any vaccine adminis-

1 trator or manufacturer is made a party to any civil action
2 brought in State court (other than a civil action which
3 may be brought under paragraph (2)) for damages or eq-
4 uitable relief for a vaccine-related injury or death associ-
5 ated with the administration of a vaccine after October
6 1, 1988, the civil action may be removed at any time be-
7 fore final judgment by the defendant or defendants to the
8 United States Court of Federal Claims, which shall have
9 jurisdiction over such civil action, and which shall dismiss
10 such action. The notice required by section 1446 of title
11 28, United States Code, shall be filed with the United
12 States Court of Federal Claims, and that court shall, ex-
13 cept as provided herein, proceed in accordance with sec-
14 tions 1446 through 1451 of title 28, United States Code.”.

15 **SEC. 205. CLARIFICATION OF WHEN INJURY IS CAUSED BY**
16 **FACTOR UNRELATED TO ADMINISTRATION**
17 **OF VACCINE.**

18 Section 2113(a)(2)(B) of the Public Health Service
19 Act (42 U.S.C. 300aa-13(a)(2)(B)) is amended—

20 (1) by inserting “structural lesions, genetic dis-
21 orders,” after “and related anoxia”;

22 (2) by inserting “(without regard to whether
23 the cause of the infection, toxin, trauma, structural
24 lesion, genetic disorder, or metabolic disturbance is
25 known)” after “metabolic disturbances”; and

1 (3) by striking “but” and inserting “and”.

2 **SEC. 206. BASIS FOR CALCULATING PROJECTED LOST**
3 **EARNINGS.**

4 Section 2115(a)(3)(B) of the Public Health Service
5 Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by strik-
6 ing “loss of earnings” and all that follows and inserting
7 the following: “loss of earnings determined on the basis
8 of the annual estimate of the average (mean) gross weekly
9 earnings of wage and salary workers age 18 and over (ex-
10 cluding the incorporated self-employed) in the private non-
11 farm sector (which includes all industries other than agri-
12 cultural production crops and livestock), as calculated an-
13 nually by the Bureau of Labor Statistics from the quarter
14 sample data of the Current Population Survey, or as cal-
15 culated by such similar method as the Secretary may pre-
16 scribe by regulation, less appropriate taxes and the aver-
17 age cost of a health insurance policy, as determined by
18 the Secretary.”.

19 **SEC. 207. ALLOWING COMPENSATION FOR FAMILY COUN-**
20 **SELING EXPENSES AND EXPENSES OF ESTAB-**
21 **LISHING GUARDIANSHIP.**

22 (a) FAMILY COUNSELING EXPENSES IN POST-1988
23 CASES.—Section 2115(a) of the Public Health Service Act
24 (42 U.S.C. 300aa–15(a)) is amended by adding at the end
25 the following:

1 “(5) Actual unreimbursable expenses that have
2 been or will be incurred for family counseling as is
3 determined to be reasonably necessary and that re-
4 sult from the vaccine-related injury from which the
5 petitioner seeks compensation.”.

6 (b) EXPENSES OF ESTABLISHING GUARDIANSHIPS IN
7 POST-1988 CASES.—Section 2115(a) of the Public Health
8 Service Act (42 U.S.C. 300aa–15(a)), as amended by sub-
9 section (a), is further amended by adding at the end the
10 following:

11 “(6) Actual unreimbursable expenses that have
12 been, or will be reasonably incurred to establish and
13 maintain a guardianship or conservatorship for an
14 individual who has suffered a vaccine-related injury,
15 including attorney fees and other costs incurred in
16 a proceeding to establish and maintain such guard-
17 ianship or conservatorship.”.

18 (c) CONFORMING AMENDMENT FOR CASES FROM
19 1988 AND EARLIER.—Section 2115(c) of the Public
20 Health Service Act (42 U.S.C. 300aa–15(c)) is
21 amended—

22 (1) in paragraph (2), by striking “and” at the
23 end;

1 (2) in paragraph (3), by inserting a closed pa-
2 renthesis before the period in that paragraph, and
3 by striking “(e)” and inserting “(f)”;

4 (3) by redesignating paragraph (3) as para-
5 graph (5); and

6 (4) by inserting after paragraph (2), the fol-
7 lowing:

8 “(3) family counseling expenses (as provided for
9 in paragraph (5) of subsection (a));

10 “(4) expenses of establishing guardianships (as
11 provided for in paragraph (6) of subsection (a));
12 and”.

13 **SEC. 208. ALLOWING PAYMENT OF INTERIM COSTS.**

14 Section 2115(f) of the Public Health Service Act (42
15 U.S.C. 300aa–15(f)) is amended by adding at the end the
16 following:

17 “(4) A special master or court may make an interim
18 award of costs if—

19 “(A) the case involves a vaccine administered
20 on or after October 1, 1988;

21 “(B) the special master or court has determined
22 that the petitioner is entitled to compensation under
23 the Program;

1 “(C) the award is limited to other costs (within
2 the meaning of paragraph (1)(B)) incurred in the
3 proceeding; and

4 “(D) the petitioner provides documentation
5 verifying the expenditure of the amount for which
6 compensation is sought.”.

7 **SEC. 209. PROCEDURE FOR PAYING ATTORNEYS’ FEES.**

8 Section 2115(f) of the Public Health Service Act (42
9 U.S.C. 300aa–15(f)), as amended by section 205, is fur-
10 ther amended by adding at the end the following:

11 “(5) When a special master or court awards attorney
12 fees or costs under paragraph (1) or (4), it may order
13 that such fees or costs be payable solely to the petitioner’s
14 attorney if—

15 “(A) the petitioner expressly consents; or

16 “(B) the special master or court determines,
17 after affording to the Secretary and to all interested
18 persons the opportunity to submit relevant informa-
19 tion, that—

20 “(i) the petitioner cannot be located or re-
21 fuses to respond to a request by the special
22 master or court for information, and there is no
23 practical alternative means to ensure that the
24 attorney will be reimbursed for such fees or
25 costs expeditiously; or

1 “(ii) there are otherwise exceptional cir-
2 cumstances and good cause for paying such fees
3 or costs solely to the petitioner’s attorney.”.

4 **SEC. 210. EXTENSION OF STATUTE OF LIMITATIONS.**

5 (a) GENERAL RULE.—Section 2116(a) of the Public
6 Health Service Act (42 U.S.C. 300aa–16(a)) is
7 amended—

8 (1) in paragraph (2) by striking “36 months”
9 and inserting “6 years”; and

10 (2) in paragraph (3), by striking “48 months”
11 and inserting “6 years”.

12 (b) EFFECT OF AMENDMENT ON PREVIOUSLY UN-
13 TIMELY CLAIMS.—Section 2121 of the Public Health
14 Service Act (42 U.S.C. 300aa–21) is amended by adding
15 at the end the following:

16 “(d) PREVIOUSLY UNTIMELY CLAIMS.—Notwith-
17 standing subsection (a), (b), or (c) of this section, if a
18 petition is filed under section 2111(a), and such petition
19 would have been untimely under the statute of limitations
20 set forth in section 2116, as in effect prior to the effective
21 date of this subsection, the special master shall dismiss
22 the petition if the special master determines that the peti-
23 tioner did not sustain a vaccine-related illness, disability,
24 injury or condition as listed on the Vaccine Injury Table.”.

1 (c) CLAIMS BASED ON REVISIONS TO TABLE.—
2 Strike all of section 2116(b) of the Public Health Service
3 Act (42 U.S.C. 300aa–16(b)) and insert the following:

4 “(b) EFFECT OF REVISED TABLE.—If at any time
5 the Vaccine Injury Table is revised and the effect of such
6 revision is to make an individual eligible for compensation
7 under the program, where, before such revision, such indi-
8 vidual was not eligible for compensation under the pro-
9 gram, or to significantly increase the likelihood that an
10 individual will be able to obtain compensation under the
11 program, such person may, and must before filing a civil
12 action for equitable relief or monetary damages, notwith-
13 standing section 2111(b)(2), file a petition for such com-
14 pensation if—

15 “(1) the vaccine-related death or injury with re-
16 spect to which the petition is filed occurred not more
17 than 8 years before the effective date of the revision
18 of the table; and

19 “(2) either—

20 “(A) the petition satisfies the conditions
21 described in subsection (a); or

22 “(B) the date of the occurrence of the first
23 symptom or manifestation of onset of the injury
24 occurred more than 4 years before the petition
25 is filed, and the petition is filed not more than

1 2 years after the effective date of the revision
2 of the table.”.

3 (d) DERIVATIVE PETITIONS.—Section 2116 of the
4 Public Health Service Act (42 U.S.C. 300aa–16) is
5 amended by adding at the end the following:

6 “(d) DERIVATIVE PETITIONS.—No derivative petition
7 may be filed for compensation under the Program after
8 the expiration of 60 days after the date on which the
9 United States Court of Federal Claims has entered final
10 judgment and the time for all further appeals or review
11 has expired on the underlying claim of the person who sus-
12 tained the vaccine-related injury or death upon which the
13 derivative petition is premised.”.

14 (e) TIMELY RESOLUTIONS OF CLAIMS.—

15 (1) SPECIAL MASTER DECISION.—Section
16 2112(d)(3)(A)(ii) of the Public Health Service Act
17 (42 U.S.C. 300aa–12(d)(3)(A)(ii)) is amended by
18 adding at the end the following: “For purposes of
19 this provision, the petition shall be deemed filed on
20 the date on which all petition contents and sup-
21 porting documents required under section 2111(c)
22 and, when applicable, section 2111(d) and the Vac-
23 cine Rules of the United States Court of Federal
24 Claims, including an affidavit and supporting docu-
25 mentation, are served on the Secretary and filed

1 with the clerk of the United States Court of Federal
2 Claims.”.

3 (2) COURT OF FEDERAL CLAIMS DECISION.—
4 Section 2121(b)(2) of the Public Health Service Act
5 (42 U.S.C. 300aa–21(b)(2) is amended by adding at
6 the end the following: “For purposes of this provi-
7 sion, the petition shall be deemed filed on the date
8 on which all petition contents and supporting docu-
9 ments required under section 2111(c) and, when ap-
10 plicable, section 2111(d) and the Vaccine Rules of
11 the United States Court of Federal Claims, includ-
12 ing an affidavit and supporting documentation, are
13 served on the Secretary and filed with the clerk of
14 the United States Court of Federal Claims.”.

15 **SEC. 211. ADVISORY COMMISSION ON CHILDHOOD VAC-**
16 **CINES.**

17 (a) SELECTION OF PERSONS INJURED BY VACCINES
18 AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of the
19 Public Health Service Act (42 U.S.C. 300aa–19(a)(1)(B))
20 is amended by striking “of whom” and all that follows
21 and inserting the following: “of whom 1 shall be the legal
22 representative of a child who has suffered a vaccine-re-
23 lated injury or death, and at least 1 other shall be either
24 the legal representative of a child who has suffered a vac-

1 vaccine-related injury or death or an individual who has per-
2 sonally suffered a vaccine-related injury.”.

3 (b) MANDATORY MEETING SCHEDULE ELIMI-
4 NATED.—Section 2119(c) of the Public Health Service Act
5 (42 U.S.C. 300aa–19(c)) is amended by striking “not less
6 often than four times per year and”.

7 **SEC. 212. CLARIFICATION OF STANDARDS OF RESPONSI-**
8 **BILITY.**

9 (a) GENERAL RULE.—Section 2122(a) of the Public
10 Health Service Act (42 U.S.C. 300aa–22(a)) is amended
11 by striking “and (e) State law shall apply to a civil action
12 brought for damages” and inserting “(d), and (f) State
13 law shall apply to a civil action brought for damages or
14 equitable relief”; and

15 (b) UNAVOIDABLE ADVERSE SIDE EFFECTS.—Sec-
16 tion 2122(b)(1) of the Public Health Service Act (42
17 U.S.C. 300aa–22(b)(1)) is amended by inserting “or equi-
18 table relief” after “for damages”.

19 (c) DIRECT WARNINGS.—Section 2122(c) of the Pub-
20 lic Health Service Act (42 U.S.C. 300aa–22(c)) is amend-
21 ed by inserting “or equitable relief” after “for damages”.

22 (d) CONSTRUCTION.—Section 2122(d) of the Public
23 Health Service Act (42 U.S.C. 300aa–22(d)) is
24 amended—

1 (1) by inserting “or equitable relief” after “for
2 damages”; and

3 (2) by inserting “or relief” after “which dam-
4 ages”.

5 (e) PRESENT PHYSICAL INJURY.—Section 2122 of
6 the Public Health Service Act (42 U.S.C. 300aa–22) is
7 amended—

8 (1) by redesignating subsections (d) and (e) as
9 subsections (e) and (f), respectively; and

10 (2) by inserting after subsection (c) the fol-
11 lowing:

12 “(d) PRESENT PHYSICAL INJURY.—No vaccine man-
13 ufacturer or vaccine administrator shall be liable in a civil
14 action brought after October 1, 1988, for equitable or
15 monetary relief absent proof of past or present physical
16 injury from the administration of a vaccine, nor shall any
17 vaccine manufacturer or vaccine administrator be liable in
18 any such civil action for claims of medical monitoring, or
19 increased risk of harm.”.

20 **SEC. 213. CLARIFICATION OF DEFINITION OF MANUFAC-**
21 **TURER.**

22 Section 2133(3) of the Public Health Service Act (42
23 U.S.C. 300aa–33(3)) is amended—

24 (1) in the first sentence, by striking “under its
25 label any vaccine set forth in the Vaccine Injury

1 Table” and inserting “any vaccine set forth in the
2 Vaccine Injury table, including any component or in-
3 gredient of any such vaccine”; and

4 (2) in the second sentence, by inserting “includ-
5 ing any component or ingredient of any such vac-
6 cine” before the period.

7 **SEC. 214. CLARIFICATION OF DEFINITION OF VACCINE-RE-**
8 **LATED INJURY OR DEATH.**

9 Section 2133(5) of the Public Health Service Act (42
10 U.S.C. 300aa–33(5)) is amended by adding at the end the
11 following: “For purposes of the preceding sentence, an
12 adulterant or contaminant shall not include any compo-
13 nent or ingredient listed in a vaccine’s product license ap-
14 plication or product label.”.

15 **SEC. 215. CLARIFICATION OF DEFINITION OF VACCINE.**

16 Section 2133 of the Public Health Service Act (42
17 U.S.C. 300aa–33) is amended by adding at the end the
18 following:

19 “(7) The term ‘vaccine’ means any preparation or
20 suspension, including but not limited to a preparation or
21 suspension containing an attenuated or inactive micro-
22 organism or subunit thereof or toxin, developed or admin-
23 istered to produce or enhance the body’s immune response
24 to a disease or diseases and includes all components and

1 ingredients listed in the vaccines’s product license applica-
2 tion and product label.”.

3 **SEC. 216. ONGOING REVIEW OF CHILDHOOD VACCINE**
4 **DATA.**

5 Part C of title XXI of the Public Health Service Act
6 (42 U.S.C. 300a–25 et seq.) is amended by adding at the
7 end the following:

8 **“SEC. 2129. ONGOING REVIEW OF CHILDHOOD VACCINE**
9 **DATA.**

10 “(a) IN GENERAL.—Not later than 6 months after
11 the date of enactment of this section, the Secretary shall
12 enter into a contract with the Institute of Medicine of the
13 National Academy of Science under which the Institute
14 shall conduct an ongoing, comprehensive review of new sci-
15 entific data on childhood vaccines (according to priorities
16 agreed upon from time to time by the Secretary and the
17 Institute of Medicine).

18 “(b) REPORTS.—Not later than 3 years after the date
19 on which the contract is entered into under paragraph (1),
20 the Institute of Medicine shall submit to the Secretary a
21 report on the findings of studies conducted, including find-
22 ings as to any adverse events associated with childhood
23 vaccines, including conclusions concerning causation of ad-
24 verse events by such vaccines and other appropriate rec-
25 ommendations, based on such findings and conclusions.

1 “(c) FAILURE TO ENTER INTO CONTRACT.—If the
2 Secretary and the Institute of Medicine are unable to
3 enter into the contract described in paragraph (1), the
4 Secretary shall enter into a contract with another qualified
5 nongovernmental scientific organization for the purposes
6 described in paragraphs (1) and (2).

7 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
8 carry out this section, there are authorized to be appro-
9 priated such sums as may be necessary for each of fiscal
10 years 2003, 2004, 2005 and 2006.”.

11 **SEC. 217. PENDING ACTIONS.**

12 The amendments made by this title shall apply to all
13 actions or proceedings pending on or after the date of en-
14 actment of this Act unless a court of competent jurisdic-
15 tion has entered judgment (regardless of whether the time
16 for appeal has expired) in such action or proceeding dis-
17 posing of the entire action or proceeding.

18 **SEC. 218. REPORT.**

19 Not later than 1 year after the date of enactment
20 of this Act, and annually thereafter, the Advisory Commis-
21 sion on Childhood Vaccines shall report to the Secretary
22 of Health and Human Services regarding the status of the
23 Vaccine Trust Fund, and shall make recommendations to

- 1 the Secretary regarding the allocation of disbursements
- 2 from the Fund.

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