

107TH CONGRESS
2D SESSION

S. 2053

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 SENATE OF THE UNITED STATES

MARCH 21, 2002

Mr. FRIST introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

TITLE I—STATE VACCINE GRANTS

- 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. Application.
- Sec. 206. Clarification of when injury is caused by factor unrelated to administration of vaccine.
- Sec. 207. Increase in award in the case of a vaccine-related death and for pain and suffering.
- Sec. 208. Basis for calculating projected lost earnings.
- Sec. 209. Allowing compensation for family counseling expenses and expenses of establishing guardianship.
- Sec. 210. Allowing payment of interim costs.
- Sec. 211. Procedure for paying attorneys' fees.
- Sec. 212. Extension of statute of limitations.
- Sec. 213. Advisory commission on childhood vaccines.
- Sec. 214. Clarification of standards of responsibility.
- Sec. 215. Clarification of definition of manufacturer.
- Sec. 216. Clarification of definition of vaccine-related injury or death.
- Sec. 217. Clarification of definition of vaccine.
- Sec. 218. Conforming amendment to trust fund provision.
- Sec. 219. Ongoing review of childhood vaccine data.
- Sec. 220. Pending actions.
- Sec. 221. Report.

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Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following:

“(3)(A) For the purpose of carrying out activities re-
lating to influenza vaccine under the immunization pro-
gram under this subsection, there are authorized to be ap-
propriated such sums as may be necessary for each of fis-
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 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 The second sentence of section 2114(c)(1) of the
 10 Public Health Service Act (42 U.S.C. 300aa–14(c)(1)) is
 11 amended to read as follows: “In promulgating such regula-
 12 tions, the Secretary shall provide for notice and for at
 13 least 90 days opportunity for public comment.”.

14 **SEC. 202. EQUITABLE RELIEF.**

15 Section 2111(a)(2)(A) of the Public Health Service
 16 Act (42 U.S.C. 300aa–11(a)(2)(A)) is amended by strik-
 17 ing “No person” and all that follows through “and—” and
 18 inserting the following: “No person may bring or maintain
 19 a civil action against a vaccine administrator or manufac-
 20 turer in a State or Federal court for damages arising
 21 from, or equitable relief relating to, a vaccine-related in-
 22 jury or death associated with the administration of a vac-
 23 cine after October 1, 1988 and no such court may award
 24 damages or equitable relief for any such vaccine-related
 25 injury or death, unless the person proves present physical

1 injury and a timely petition has been filed, in accordance
 2 with section 2116 for compensation under the Program
 3 for such injury or death and—”.

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

5 Section 2111(a)(2) of the Public Health Service Act
 6 (42 U.S.C. 300aa–(a)(2)) is amended—

7 (1) in subparagraph (B), by inserting “or (B)”
 8 after “subparagraph (A)”;

9 (2) by redesignating subparagraph (B) as sub-
 10 paragraph (C); and

11 (3) by inserting after subparagraph (A) the fol-
 12 lowing:

13 “(B) No parent or other third party may bring
 14 or maintain a civil action against a vaccine adminis-
 15 trator or manufacturer in a Federal or State court
 16 for damages or equitable relief relating to a vaccine-
 17 related injury or death, including but not limited to
 18 damages for loss of consortium, society, companion-
 19 ship or services, loss of earnings, medical or other
 20 expenses, and emotional distress, and no court may
 21 award damages or equitable relief in such an action
 22 unless the action is joined with a civil action brought
 23 by the person whose vaccine-related injury is the
 24 basis for the parent’s or other third party’s action

1 and that person has satisfied the conditions of sub-
2 paragraph (A).”.

3 **SEC. 204. JURISDICTION TO DISMISS ACTIONS IMPROP-**
4 **ERLY BROUGHT.**

5 Section 2111(a)(3) of the Public Health Service Act
6 (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the
7 end the following: “If any civil action which is barred
8 under subparagraph (A) or (B) of paragraph (2) is filed
9 or maintained in a State court, or any vaccine adminis-
10 trator or manufacturer is made a party to any civil action
11 brought in State court (other than a civil action which
12 may be brought under paragraph (2)) for damages or eq-
13 uitable relief for a vaccine-related injury or death associ-
14 ated with the administration of a vaccine after October
15 1, 1988, the civil action may be removed by the defendant
16 or defendants to the United States Court of Federal
17 Claims, which shall have jurisdiction over such civil action,
18 and which shall dismiss such action. The notice required
19 by section 1446 of title 28, United States Code, shall be
20 filed with the United States Court of Federal Claims, and
21 that court shall proceed in accordance with sections 1446
22 through 1451 of title 28, United States Code.”.

23 **SEC. 205. APPLICATION.**

24 Section 2111(a)(9) of the Public Health Service Act
25 (42 U.S.C. 300aa–11(a)(9)) is amended by striking

1 “This” and inserting “Except as provided in subsection
2 (a)(2), this”.

3 **SEC. 206. CLARIFICATION OF WHEN INJURY IS CAUSED BY**
4 **FACTOR UNRELATED TO ADMINISTRATION**
5 **OF VACCINE.**

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

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

10 (2) by inserting “(without regard to whether
11 the cause of the infection, toxin, trauma, structural
12 lesion, genetic disorder, or metabolic disturbance is
13 known)” after “metabolic disturbances”; and

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

15 **SEC. 207. INCREASE IN AWARD IN THE CASE OF A VACCINE-**
16 **RELATED DEATH AND FOR PAIN AND SUF-**
17 **FERING.**

18 Section 2115(a) of the Public Health Service Act (42
19 U.S.C. 300aa–15(a)) is amended—

20 (1) in paragraph (2), by striking “\$250,000”
21 and inserting “\$350,000”; and

22 (2) in paragraph (4), by striking “\$250,000”
23 and inserting “\$350,000”.

1 **SEC. 208. BASIS FOR CALCULATING PROJECTED LOST**
 2 **EARNINGS.**

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

18 **SEC. 209. ALLOWING COMPENSATION FOR FAMILY COUN-**
 19 **SELING EXPENSES AND EXPENSES OF ESTAB-**
 20 **LISHING GUARDIANSHIP.**

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

25 “(5) Actual unreimbursable expenses that have
 26 been or will be incurred for family counseling as is

1 determined to be reasonably necessary and that re-
 2 sult from the vaccine-related injury from which the
 3 petitioner seeks compensation.”.

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

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

16 (c) CONFORMING AMENDMENT FOR CASES FROM
 17 1988 AND EARLIER.—Section 2115(b) of the Public
 18 Health Service Act (42 U.S.C. 300aa–15(b)) is
 19 amended—

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

22 (2) in paragraph (3), by inserting a closed pa-
 23 renthesis before the period in that paragraph;

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

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

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

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

8 **SEC. 210. ALLOWING PAYMENT OF INTERIM COSTS.**

9 Section 2115(e) of the Public Health Service Act (42
 10 U.S.C. 300aa–15(e)) is amended by adding at the end the
 11 following:

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

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

16 “(B) the award is limited to other costs (within
 17 the meaning of paragraph (1)(B)) incurred in the
 18 proceeding; and

19 “(C) the petitioner provides documentation
 20 verifying the expenditure of the amount for which
 21 compensation is sought.”.

22 **SEC. 211. PROCEDURE FOR PAYING ATTORNEYS’ FEES.**

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

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

5 “(A) the petitioner expressly consents; or

6 “(B) the special master or court determines,
 7 after affording to the Secretary and to all interested
 8 persons the opportunity to submit relevant informa-
 9 tion, that—

10 “(i) the petitioner cannot be located or re-
 11 fuses to respond to a request by the special
 12 master or court for information, and there is no
 13 practical alternative means to ensure that the
 14 attorney will be reimbursed for such fees or
 15 costs expeditiously; or

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

19 **SEC. 212. EXTENSION OF STATUTE OF LIMITATIONS.**

20 (a) **GENERAL RULE.**—Section 2116(a) of the Public
 21 Health Service Act (42 U.S.C. 300aa–16(a)) is
 22 amended—

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

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

3 (b) CLAIMS BASED ON REVISIONS TO TABLE.—

4 Strike all of section 2116(b) of the Public Health Service
 5 Act (42 U.S.C. 300aa–16(b)) and insert the following:

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

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

21 “(2) either—

22 “(A) the petition satisfies the conditions
 23 described in subsection (a); or

24 “(B) the date of the occurrence of the first
 25 symptom or manifestation of onset of the injury

1 occurred more than 4 years before the petition
 2 is filed, and the petition is filed not more than
 3 2 years after the effective date of the revision
 4 of the table.”.

5 **SEC. 213. ADVISORY COMMISSION ON CHILDHOOD**
 6 **VACCINES.**

7 (a) SELECTION OF PERSONS INJURED BY VACCINES
 8 AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of the
 9 Public Health Service Act (42 U.S.C. 300aa–19(a)(1)(B))
 10 is amended by striking “of whom” and all that follows
 11 and inserting the following: “of whom 1 shall be the legal
 12 representative of a child who has suffered a vaccine-re-
 13 lated injury or death, and at least 1 other shall be either
 14 the legal representative of a child who has suffered a vac-
 15 cine-related injury or death or an individual who has per-
 16 sonally suffered a vaccine-related injury.”.

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

21 **SEC. 214. CLARIFICATION OF STANDARDS OF RESPONSI-**
 22 **BILITY.**

23 (a) GENERAL RULE.—Section 2122(a) of the Public
 24 Health Service Act (42 U.S.C. 300aa–22(a)) is amended
 25 by striking “and (e) State law shall apply to a civil action

1 brought for damages” and inserting “(d), and (f) State
 2 law shall apply to a civil action brought for damages or
 3 equitable relief”; and

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

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

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

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

16 (2) by inserting “or relief” after “which dam-
 17 ages”.

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

21 (1) by redesignating subsections (d) and (e) as
 22 subsections (e) and (f), respectively; and

23 (2) by inserting after subsection (c) the fol-
 24 lowing:

1 “(d) PRESENT PHYSICAL INJURY.—No vaccine man-
 2 ufacturer or vaccine administrator shall be liable in a civil
 3 action brought after October 1, 1988, for equitable or
 4 monetary relief absent proof of present physical injury
 5 from the administration of a vaccine, nor shall any vaccine
 6 manufacturer or vaccine administrator be liable in any
 7 such civil action for claims of medical monitoring, or in-
 8 creased risk of harm.”.

9 **SEC. 215. CLARIFICATION OF DEFINITION OF MANUFAC-**
 10 **TURER.**

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

13 (1) in the first sentence, by striking “under its
 14 label any vaccine set forth in the Vaccine Injury
 15 Table” and inserting “any vaccine set forth in the
 16 Vaccine Injury table, including any component or in-
 17 gredient of any such vaccine”; and

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

21 **SEC. 216. CLARIFICATION OF DEFINITION OF VACCINE-RE-**
 22 **LATED INJURY OR DEATH.**

23 Section 2133(5) of the Public Health Service Act (42
 24 U.S.C. 300aa–33(5)) is amended by adding at the end the
 25 following: “For purposes of the preceding sentence, an

1 adulterant or contaminant shall not include any compo-
 2 nent or ingredient listed in a vaccine’s product license ap-
 3 plication or product label.”.

4 **SEC. 217. CLARIFICATION OF DEFINITION OF VACCINE.**

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

8 “(7) The term ‘vaccine’ means any preparation or
 9 suspension, including but not limited to a preparation or
 10 suspension containing an attenuated or inactive micro-
 11 organism or subunit thereof or toxin, developed or admin-
 12 istered to produce or enhance the body’s immune response
 13 to a disease or diseases and includes all components and
 14 ingredients listed in the vaccines’s product license applica-
 15 tion and product label.”.

16 **SEC. 218. CONFORMING AMENDMENT TO TRUST FUND PRO-**
 17 **VISION.**

18 Section 9510(c)(1)(A) of the Internal Revenue Code
 19 of 1986 is amended by striking “October 18, 2000” and
 20 inserting “the effective date of the Improved Vaccine Af-
 21 fordability and Availability Act”.

1 **SEC. 219. ONGOING REVIEW OF CHILDHOOD VACCINE**
2 **DATA.**

3 Part C of title XXI of the Public Health Service Act
4 (42 U.S.C. 300a–25 et seq.) is amended by adding at the
5 end the following:

6 **“SEC. 2129. ONGOING REVIEW OF CHILDHOOD VACCINE**
7 **DATA.**

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

16 “(b) REPORTS.—Not later than 3 years after the date
17 on which the contract is entered into under paragraph (1),
18 the Institute of Medicine shall submit to the Secretary a
19 report on the findings of studies conducted, including find-
20 ings as to any adverse events associated with childhood
21 vaccines, including conclusions concerning causation of ad-
22 verse events by such vaccines, together with recommenda-
23 tions for changes in the Vaccine Injury Table, and other
24 appropriate recommendations, based on such findings and
25 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. 220. 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.

15 **SEC. 221. REPORT.**

16 Not later than 1 year after the date of enactment
 17 of this Act, the Secretary of Health and Human Services
 18 shall submit recommendations regarding how to address
 19 the growing surplus in the Vaccine Trust Fund, and the
 20 rationale for such recommendations to—

- 21 (1) the Health, Education, Labor and Pensions
- 22 Committee of the Senate;
- 23 (2) the Finance Committee of the Senate;
- 24 (3) the Energy and Commerce Committee of
- 25 the House of Representatives; and

- 1 (4) the Ways and Means Committee of the
- 2 House of Representatives.

