

108TH CONGRESS
1ST SESSION

S. 754

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

APRIL 1, 2003

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.**

4 This Act may be cited as the “Improved Vaccine Af-
5 fordability and Availability Act”.

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

14 “(B) The authorization of appropriations established
15 in subparagraph (A) shall not be effective for a fiscal year
16 unless the total amount appropriated under paragraphs
17 (1) and (2) for the fiscal year is not less than such total
18 for fiscal year 2000.

19 “(C) The purposes for which amounts appropriated
20 under subparagraph (A) are available to the Secretary in-
21 clude providing for improved State and local infrastruc-
22 ture for influenza immunizations under this subsection in
23 accordance with the following:

24 “(i) Increasing influenza immunization rates in
25 populations considered by the Secretary to be at

1 high risk for influenza-related complications and in
2 their contacts.

3 “(ii) Recommending that health care providers
4 actively target influenza vaccine that is available in
5 September, October, and November to individuals
6 who are at increased risk for influenza-related com-
7 plications and to their contacts.

8 “(iii) Providing for the continued availability of
9 influenza immunizations through December of such
10 year, and for additional periods to the extent that
11 influenza vaccine remains available.

12 “(iv) Encouraging States, as appropriate, to de-
13 velop contingency plans (including plans for public
14 and professional educational activities) for maxi-
15 mizing influenza immunizations for high-risk popu-
16 lations in the event of a delay or shortage of influ-
17 enza vaccine.

18 “(D) The Secretary shall submit to the Committee
19 on Energy and Commerce of the House of Representa-
20 tives, and the Committee on Health, Education, Labor,
21 and Pensions of the Senate, periodic reports describing the
22 activities of the Secretary under this subsection regarding
23 influenza vaccine. The first such report shall be submitted
24 not later than June 6, 2003, the second report shall be

1 submitted not later than June 6, 2004, and subsequent
2 reports shall be submitted biennially thereafter.”.

3 **SEC. 102. PROGRAM FOR INCREASING IMMUNIZATION**
4 **RATES FOR ADULTS AND ADOLESCENTS; COL-**
5 **LECTION OF ADDITIONAL IMMUNIZATION**
6 **DATA.**

7 (a) ACTIVITIES OF CENTERS FOR DISEASE CONTROL
8 AND PREVENTION.—Section 317(j) of the Public Health
9 Service Act (42 U.S.C. 247b(j)), as amended by section
10 101, is further amended by adding at the end the fol-
11 lowing:

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

21 “(B) In expending amounts appropriated under sub-
22 paragraph (A), the Secretary shall give priority to adults
23 and adolescents who are medically underserved and are
24 at risk for vaccine-preventable diseases, including as ap-

1 appropriate populations identified through projects under
2 subsection (k)(2)(E).

3 “(C) The purposes for which amounts appropriated
4 under subparagraph (A) are available include (with re-
5 spect to immunizations for adults and adolescents) the
6 payment of the costs of storing vaccines, outreach activi-
7 ties to inform individuals of the availability of the immuni-
8 zations, and other program expenses necessary for the es-
9 tablishment or operation of immunization programs car-
10 ried out or supported by States or other public entities
11 pursuant to this subsection.

12 “(5) The Secretary shall annually submit to Congress
13 a report that—

14 “(A) evaluates the extent to which the immuni-
15 zation system in the United States has been effective
16 in providing for adequate immunization rates for
17 adults and adolescents, taking into account the ap-
18 plicable year 2010 health objectives established by
19 the Secretary regarding the health status of the peo-
20 ple of the United States; and

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

23 “(6) In carrying out this subsection and paragraphs
24 (1) and (2) of subsection (k), the Secretary shall consider
25 recommendations regarding immunizations that are made

1 in reports issued by the Institute of Medicine of the Na-
2 tional Academy of Sciences.”.

3 (b) RESEARCH, DEMONSTRATIONS, AND EDU-
4 CATION.—Section 317(k) of the Public Health Service Act
5 (42 U.S.C. 247b(k)) is amended—

6 (1) by redesignating paragraphs (2) through
7 (4) as paragraphs (3) through (5), respectively;

8 (2) by inserting after paragraph (1) the fol-
9 lowing:

10 “(2)(A) The Secretary, directly and through grants
11 under paragraph (1), shall provide for a program of re-
12 search, demonstration projects, and education in accord-
13 ance with the following:

14 “(i) The Secretary shall coordinate with public
15 and private entities (including nonprofit private enti-
16 ties), and develop and disseminate guidelines, toward
17 the goal of ensuring that immunizations are rou-
18 tinely offered to adults and adolescents by public
19 and private health care providers.

20 “(ii) The Secretary shall cooperate with public
21 and private entities to obtain information for the an-
22 nual evaluations required in subsection (j)(5)(A).

23 “(iii) The Secretary shall (relative to fiscal year
24 2003) increase the extent to which the Secretary col-
25 lects data on the incidence, prevalence, and cir-

1 cumstances of diseases and adverse events that are
2 experienced by adults and adolescents and may be
3 associated with immunizations, including collecting
4 data in cooperation with commercial laboratories.

5 “(iv) The Secretary shall ensure that the enti-
6 ties with which the Secretary cooperates for pur-
7 poses of subparagraphs (A) through (C) include
8 managed care organizations, community-based orga-
9 nizations that provide health services, and other
10 health care providers.

11 “(v) The Secretary shall provide for projects to
12 identify racial and ethnic minority groups and other
13 health disparity populations for which immunization
14 rates for adults and adolescents are below such rates
15 for the general population, and to determine the fac-
16 tors underlying such disparities.

17 “(B) AUTHORIZATION OF APPROPRIATIONS.—There
18 are authorized to be appropriated to carry out this sub-
19 section, such sums as may be necessary for each of fiscal
20 years 2003 through 2007.”.

21 **SEC. 103. IMMUNIZATION AWARENESS.**

22 (a) DEVELOPMENT OF INFORMATION CONCERNING
23 MENINGITIS.—

24 (1) IN GENERAL.—The Secretary of Health and
25 Human Services (in this Act referred to as the “Sec-

1 retary’'), in consultation with the Director of the
 2 Centers for Disease Control and Prevention, shall
 3 develop and make available to entities described in
 4 paragraph (2) information concerning bacterial men-
 5 ingitis and the availability and effectiveness of vac-
 6 cinations for populations targeted by the Advisory
 7 Committee on Immunization Practices (an advisory
 8 committee established by the Secretary, acting
 9 through the Director of the Centers for Disease
 10 Control and Prevention).

11 (2) ENTITIES.—An entity is described in this
 12 paragraph if the entity—

13 (A) is—

14 (i) a college or university; or

15 (ii) any other facility with a setting
 16 similar to a dormitory that houses age-ap-
 17 propriate populations for whom the Advi-
 18 sory Committee on Immunization Practices
 19 recommends such a vaccination; and

20 (B) is determined appropriate by the Sec-
 21 retary.

22 (b) DEVELOPMENT OF INFORMATION CONCERNING
 23 HEPATITIS.—

24 (1) IN GENERAL.—The Secretary, in consulta-
 25 tion with the Director of the Centers for Disease

1 Control and Prevention, shall develop and make
2 available to entities described in paragraph (2) infor-
3 mation concerning hepatitis A and B and the avail-
4 ability and effectiveness of vaccinations with respect
5 to such diseases.

6 (2) ENTITIES.—An entity is described in this
7 paragraph if the entity—

8 (A) is—

9 (i) a health care clinic that serves in-
10 dividuals diagnosed as being infected with
11 HIV or as having other sexually trans-
12 mitted diseases;

13 (ii) an organization or business that
14 counsels individuals about international
15 travel or who arranges for such travel;

16 (iii) a police, fire, or emergency med-
17 ical services organization that responds to
18 natural or man-made disasters or emer-
19 gencies;

20 (iv) a prison or other detention facil-
21 ity;

22 (v) a college or university; or

23 (vi) a public health authority or chil-
24 dren's health service provider in areas of
25 intermediate or high endemicity for hepa-

1 titis A as defined by the Centers for Dis-
2 ease Control and Prevention; and

3 (B) is determined appropriate by the Sec-
4 retary.

5 **SEC. 104. SUPPLY OF VACCINES.**

6 (a) IN GENERAL.—The Secretary of Health and
7 Human Services, acting through the Director of the Cen-
8 ters for Disease Control and Prevention, shall prioritize,
9 acquire, and maintain a supply of such prioritized vaccines
10 sufficient to provide vaccinations throughout a 6-month
11 period.

12 (b) PROCEEDS.—Any proceeds received by the Sec-
13 retary of Health and Human Services from the sale of vac-
14 cines contained in the supply described in subsection (a),
15 shall be available to the Secretary for the purpose of pur-
16 chasing additional vaccines for the supply. Such proceeds
17 shall remain available until expended.

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

22 **SEC. 105. COMMUNICATION.**

23 The Commissioner of Food and Drugs shall ensure
24 that vaccine manufacturers receive all forms of compliance

1 guidelines for vaccines and that such guidelines are kept
2 up to date.

3 **SEC. 106. FAST TRACK.**

4 The Commissioner of Food and Drugs shall issue reg-
5 ulations to revise the policies of the Food and Drug Ad-
6 ministration regarding fast-tracking and priority review
7 approval of vaccine products currently under development,
8 to allow for the use of new forms of existing vaccines in
9 cases where a determination is made that applying such
10 approvals is in the public health interest to address the
11 unmet need of strengthening the overall vaccine supply.

12 **SEC. 107. STUDY.**

13 (a) **IN GENERAL.**—The Secretary shall contract with
14 the Institute of Medicine of the National Academy of
15 Sciences or another independent and competent authority,
16 to conduct a study of the statutes, regulations, guidelines,
17 and compliance, inspection, and enforcement practices and
18 policies of the Department of Health and Human Services
19 and of the Food and Drug Administration that are appli-
20 cable to vaccines intended for human use that are in peri-
21 odic short supply in the United States.

22 (b) **REQUIREMENTS.**—The study under subsection
23 (a) shall include a review of the regulatory requirements,
24 guidelines, practices, and policies—

1 (1) for the development and licensing of vac-
 2 cines and the licensing of vaccine manufacturing fa-
 3 cilities;

4 (2) for inspections and other activities for main-
 5 taining compliance and enforcement of the require-
 6 ments applicable to such vaccines and facilities; and

7 (3) that may have contributed to temporary or
 8 long-term shortages of vaccines.

9 (c) REPORT.—Not later than 6 months after the date
 10 of enactment of this Act, the Secretary shall submit to
 11 the Committee on Health, Education, Labor, and Pen-
 12 sions of the Senate and the Committee on Energy and
 13 Commerce of the House of Representatives a report that
 14 contains—

15 (1) the results of the study under subsection
 16 (a); and

17 (2) recommendations for modifications to the
 18 regulatory requirements, guidelines, practices, and
 19 policies described in subsection (b).

20 **TITLE II—VACCINE INJURY**
 21 **COMPENSATION PROGRAM**

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

23 **TABLE.**

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

1 (1) by striking subsection (c)(1) and inserting
2 the following:

3 “(1) The Secretary may promulgate regulations
4 to modify in accordance with paragraph (3) the Vac-
5 cine Injury Table. In promulgating such regulations,
6 the Secretary shall provide for notice and for at
7 least 60 days of public comment.”; and

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

10 **SEC. 202. EQUITABLE RELIEF.**

11 Section 2111(a)(2)(A) of the Public Health Service
12 Act (42 U.S.C. 300aa-11(a)(2)(A)) is amended by strik-
13 ing “No person” and all that follows through “and—” and
14 inserting the following: “No person may bring or maintain
15 a civil action against a vaccine administrator or manufac-
16 turer in a Federal or State court for damages arising
17 from, or equitable relief relating to, a vaccine-related in-
18 jury or death associated with the administration of a vac-
19 cine after October 1, 1988 and no such court may award
20 damages or equitable relief for any such vaccine-related
21 injury or death, unless the person proves past or present
22 physical injury and a timely petition has been filed in ac-
23 cordance with section 2116 for compensation under the
24 Program for such injury or death and—”.

1 **SEC. 203. DERIVATIVE PETITIONS FOR COMPENSATION.**

2 (a) LIMITATIONS ON DERIVATIVE PETITIONS.—Sec-
3 tion 2111(a)(2) of the Public Health Service Act (42
4 U.S.C. 300aa–11(a)(2)) is amended—

5 (1) in subparagraph (B), by inserting “or (B)”
6 after “subparagraph (A)”;

7 (2) by redesignating subparagraph (B) as sub-
8 paragraph (C); and

9 (3) by inserting after subparagraph (A) the fol-
10 lowing:

11 “(B)(i) No parent or other third party may
12 bring or maintain a civil action against a vaccine ad-
13 ministrator or manufacturer in a Federal or State
14 court for damages or equitable relief relating to a
15 vaccine-related injury or death, including without
16 limitation damages for loss of consortium, society,
17 companionship, or services, loss of earnings, medical
18 or other expenses, and emotional distress, and no
19 court may award damages or equitable relief in such
20 an action, unless—

21 “(I) the person who sustained the under-
22 lying vaccine-related injury or death upon which
23 such parent’s or other third party’s claim is
24 premised has timely filed a petition for com-
25 pensation in accordance with section 2111;

1 “(II) such parent or other third party is
2 the legal representative or spouse of the person
3 who sustained the underlying vaccine-related in-
4 jury or death, and such legal representative or
5 spouse has filed a timely derivative petition, in
6 accordance with section 2116; and

7 “(III)(aa) the United States Court of Fed-
8 eral Claims has issued judgment under section
9 2112 on the derivative petition, and such legal
10 representative or spouse elects under section
11 2121(a) to file a civil action; or

12 “(bb) such legal representative or spouse
13 elects to withdraw such derivative petition
14 under section 2121(b) or such petition is con-
15 sidered withdrawn under such section.

16 “(ii) Any civil action brought in accordance
17 with this subparagraph shall be subject to the stand-
18 ards and procedures set forth in sections 2122 and
19 2123, regardless of whether the action arises directly
20 from a vaccine-related injury or death associated
21 with the administration of a vaccine. In a case in
22 which the person who sustained the underlying vac-
23 cine-related injury or death upon which such legal
24 representative’s or spouse’s civil action is premised
25 elects under section 2121(a) to receive the com-

1 pensation awarded, such legal representative or
2 spouse may not bring a civil action for damages or
3 equitable relief, and no court may award damages or
4 equitable relief, for any injury or loss of the type set
5 forth in section 2115(a) or that might in any way
6 overlap with or otherwise duplicate compensation of
7 the type available under section 2115(a).”.

8 (b) ELIGIBLE PERSONS.—Section 2111(a)(9) of the
9 Public Health Service Act (42 U.S.C. 300aa–11(a)(9)) is
10 amended by striking the period and inserting “and to a
11 parent or other third party to the extent such parent or
12 other third party seeks damages or equitable relief relating
13 to a vaccine-related injury or death sustained by a person
14 who is qualified to file a petition for compensation under
15 the Program.”.

16 (c) PETITIONERS.—Section 2111(b) of the Public
17 Health Service Act (42 U.S.C. 300aa–11(b)) is amend-
18 ed—

19 (1) in paragraph (1)—

20 (A) in subparagraph (A), by striking “(B)”
21 and inserting “(C)”;

22 (B) by redesignating subparagraph (B) as
23 subparagraph (C); and

24 (C) by inserting after subparagraph (A)
25 the following:

1 “(B) Except as provided in subparagraph (C),
2 any legal representative or spouse of a person—

3 “(i) who has sustained a vaccine-related in-
4 jury or death; and

5 “(ii) who has filed a petition for compensa-
6 tion under the Program (or whose legal rep-
7 resentative has filed such a petition as author-
8 ized in subparagraph (A));

9 may, if such legal representative or spouse meets the
10 requirements of subsection (d), file a derivative peti-
11 tion under this section.”; and

12 (2) in paragraph (2)—

13 (A) by inserting “by or on behalf of the
14 person who sustained the vaccine-related injury
15 or death” after “filed”; and

16 (B) by adding at the end the following: “A
17 legal representative or spouse may file only 1
18 derivative petition with respect to each under-
19 lying petition.”.

20 (d) DERIVATIVE PETITION CONTENTS.—Section
21 2111 of the Public Health Service Act (42 U.S.C. 300aa-
22 11) is amended—

23 (1) by redesignating subsections (d) and (e) as
24 subsections (e) and (f), respectively; and

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

3 “(d) DERIVATIVE PETITIONS.—

4 “(1) If the legal representative or spouse of the
5 person who sustained the vaccine-related injury or
6 death seeks compensation under the Program, such
7 legal representative or spouse shall file a timely de-
8 rivative petition for compensation under the Pro-
9 gram in accordance with this section.

10 “(2) Such a derivative petition shall contain—

11 “(A) except for records that are unavail-
12 able as described in subsection (c)(3), an affi-
13 davit, and supporting documentation, dem-
14 onstrating that—

15 “(i) the child or spouse of such person
16 has, in accordance with section 2111, time-
17 ly filed a petition for compensation for the
18 underlying vaccine-related injury or death
19 upon which such legal representative’s or
20 spouse’s derivative petition is premised;

21 “(ii) the derivative petition was timely
22 filed;

23 “(iii) such legal representative or
24 spouse suffered a loss compensable under
25 section 2115(b) as a result of the vaccine-

1 related injury or death sustained by such
2 person; and

3 “(iv) such legal representative or
4 spouse has not previously collected an
5 award or settlement of a civil action for
6 damages for such loss; and

7 “(B) records establishing such legal rep-
8 resentative’s or spouse’s relationship to the per-
9 son who sustained the vaccine-related injury or
10 death.”.

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

14 (1) in subparagraph (A), by striking “and” and
15 inserting “or, as applicable, section 2111(d),”;

16 (2) in subparagraph (B), by striking the period
17 and inserting “, and”;

18 (3) by inserting before the flush matter at the
19 end, the following:

20 “(C) in the case of a derivative petition,
21 that the person who sustained the underlying
22 vaccine-related injury or death upon which the
23 derivative petition is premised has timely filed
24 a petition for compensation in accordance with
25 section 2111 and that, with respect to such un-

1 derlying petition, the special master or court
2 has made the findings specified in subpara-
3 graphs (A) and (B) of this paragraph.”.

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

6 (1) by redesignating subsections (b) through (j)
7 as subsections (c) through (k), respectively;

8 (2) by inserting after subsection (a) the fol-
9 lowing:

10 “(b) DERIVATIVE PETITIONS.—

11 “(1) IN GENERAL.—Compensation awarded
12 under the Program to a legal representative or
13 spouse who files a derivative petition under section
14 2111 for a loss sustained as a result of a vaccine-
15 related injury or death sustained by such petitioner’s
16 child or spouse shall only include compensation for
17 any loss of consortium, society, companionship, or
18 services, in an amount not to exceed the lesser of
19 \$250,000 or the total amount of compensation
20 awarded to the person who sustained the underlying
21 vaccine-related injury or death.

22 “(2) MULTIPLE INDIVIDUALS.—Where more
23 than 1 person files a derivative petition under sec-
24 tion 2111 for losses sustained as a result of the
25 same underlying vaccine-related injury or death, the

1 aggregate compensation to such persons shall not
2 exceed the lesser of \$250,000, or the total amount
3 of compensation awarded to the person who sus-
4 tained the underlying vaccine-related injury or
5 death. The special master or court shall apportion
6 compensation among the derivative petitioners in
7 proportion to their respective losses.”;

8 (3) in subsection (e)(2), as so redesignated by
9 paragraph (1)—

10 (A) by striking “(2) and (3)” and inserting
11 “(2), (3), (4), (5), and (6)”;

12 (B) by inserting “and subsection (b),”
13 after “(a),”;

14 (4) in subsection (g), as so redesignated by
15 paragraph (1), in paragraph (4)(B), by striking
16 “subsection (j)” and inserting “subsection (k)”;

17 (5) in subsection (j), as so redesignated by
18 paragraph (1)—

19 (A) in paragraph (1), by striking “sub-
20 section (j)” and inserting “subsection (k)”;

21 (B) in paragraph (2), by inserting “, or to
22 a legal representative or spouse of a person who
23 sustained a vaccine-related injury or death,”
24 after “death”;

1 (6) in subsection (k), as so redesignated by
2 paragraph (1), by striking “subsection (f)(4)(B)”
3 and inserting “subsection (g)(4)(B)”.

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

6 Section 2111(a)(3) of the Public Health Service Act
7 (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the
8 end the following: “If any civil action which is barred
9 under subparagraph (A) or (B) of paragraph (2) is filed
10 or maintained in a State court, or any vaccine adminis-
11 trator or manufacturer is made a party to any civil action
12 brought in State court (other than a civil action which
13 may be brought under paragraph (2)) for damages or eq-
14 uitable relief for a vaccine-related injury or death associ-
15 ated with the administration of a vaccine after October
16 1, 1988, the civil action may be removed at any time be-
17 fore final judgment by the defendant or defendants to the
18 United States Court of Federal Claims. Once removed, the
19 United States Court of Federal Claims shall have jurisdic-
20 tion solely for the purpose of adjudicating whether the civil
21 action should be dismissed pursuant to this section. If the
22 United States Court of Federal Claims determines that
23 the civil action should not be dismissed, the court shall
24 remand the action to the State Court. The notice required
25 by section 1446 of title 28, United States Code, shall be

1 filed with the United States Court of Federal Claims, and
 2 that court shall, except as otherwise provided in this sec-
 3 tion, proceed in accordance with sections 1446 through
 4 1451 of title 28, United States Code.”.

5 **SEC. 205. CLARIFICATION OF WHEN INJURY IS CAUSED BY**
 6 **FACTOR UNRELATED TO ADMINISTRATION**
 7 **OF VACCINE.**

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

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

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

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

17 **SEC. 206. INCREASE IN AWARD IN THE CASE OF A VACCINE-**
 18 **RELATED DEATH AND FOR PAIN AND SUF-**
 19 **FERING.**

20 (a) IN GENERAL.—Section 2115(a) of the Public
 21 Health Service Act (42 U.S.C. 300aa-15(a)) is amend-
 22 ed—

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

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

3 (b) DEATH AWARDS.—Section 2115(a)(2) of the
4 Public Health Service Act (42 U.S.C. 300aa–15(a)(2)) is
5 amended by inserting “(if the deceased incurred unreim-
6 bursable expenses due to the vaccine-related injury prior
7 to death in excess of \$50,000, the award shall also include
8 reimbursement for those unreimbursable expenses that ex-
9 ceed \$50,000)” before the period.

10 **SEC. 207. BASIS FOR CALCULATING PROJECTED LOST**
11 **EARNINGS.**

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

1 age cost of a health insurance policy, as determined by
2 the Secretary.”.

3 **SEC. 208. ALLOWING COMPENSATION FOR FAMILY COUN-**
4 **SELING EXPENSES AND EXPENSES OF ESTAB-**
5 **LISHING AND MAINTAINING GUARDIANSHIP.**

6 (a) FAMILY COUNSELING EXPENSES IN POST-1988
7 CASES.—Section 2115(a) of the Public Health Service Act
8 (42 U.S.C. 300aa–15(a)) is amended by adding at the end
9 the following:

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

15 (b) EXPENSES OF ESTABLISHING AND MAINTAINING
16 GUARDIANSHIPS IN POST-1988 CASES.—Section 2115(a)
17 of the Public Health Service Act (42 U.S.C. 300aa–15(a)),
18 as amended by subsection (a), is further amended by add-
19 ing at the end the following:

20 “(6) Actual unreimbursable expenses that have
21 been, or will be reasonably incurred to establish and
22 maintain a guardianship or conservatorship for an
23 individual who has suffered a vaccine-related injury,
24 including attorney fees and other costs incurred in

1 a proceeding to establish and maintain such guard-
2 ianship or conservatorship.”.

3 (c) CONFORMING AMENDMENT FOR CASES FROM
4 1988 AND EARLIER.—Section 2115 of the Public Health
5 Service Act (42 U.S.C. 300aa–15) is amended in sub-
6 section (c), as so redesignated by section 203(f)—

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

9 (2) in paragraph (3), by striking “(e)” and in-
10 sserting “(f)”;

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

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

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

17 “(4) expenses of establishing and maintaining
18 guardianships (as provided for in paragraph (6) of
19 subsection (a)); and”.

20 **SEC. 209. ALLOWING PAYMENT OF INTERIM COSTS.**

21 Section 2115 of the Public Health Service Act (42
22 U.S.C. 300aa–15) is amended in subsection (f), as so re-
23 designated by section 203(f), by adding at the end the fol-
24 lowing:

1 “(4) A special master or court may make an in-
2 terim award of costs subject to final adjustment if—

3 “(A) the case involves a vaccine adminis-
4 tered on or after October 1, 1988;

5 “(B) the special master or court has deter-
6 mined that the petitioner is entitled to com-
7 pensation under the Program;

8 “(C) the award is limited to other costs
9 (within the meaning of paragraph (1)(B)) in-
10 curred in the proceeding;

11 “(D) not more than 1 prior award has
12 been made with respect to such petition; and

13 “(E) the petitioner provides documentation
14 verifying the expenditure of the amount for
15 which compensation is sought.”.

16 **SEC. 210. PROCEDURE FOR PAYING ATTORNEYS’ FEES.**

17 Section 2115 of the Public Health Service Act (42
18 U.S.C. 300aa–15), is amended in subsection (f), as so re-
19 designated by section 203(f) and amended by section 209,
20 by adding at the end the following:

21 “(5) When a special master or court awards at-
22 torney fees or costs under paragraph (1) or (4), it
23 may order that such fees or costs be payable solely
24 to the petitioner’s attorney if—

25 “(A) the petitioner expressly consents; or

1 “(B) the special master or court deter-
2 mines, after affording to the Secretary and to
3 all interested persons the opportunity to submit
4 relevant information, that—

5 “(i) the petitioner cannot be located
6 or refuses to respond to a request by the
7 special master or court for information,
8 and there is no practical alternative means
9 to ensure that the attorney will be reim-
10 bursed for such fees or costs expeditiously;
11 or

12 “(ii) there are otherwise exceptional
13 circumstances and good cause for paying
14 such fees or costs solely to the petitioner’s
15 attorney.”.

16 **SEC. 211. EXTENSION OF STATUTE OF LIMITATIONS.**

17 (a) **GENERAL RULE.**—Section 2116(a) of the Public
18 Health Service Act (42 U.S.C. 300aa–16(a)) is amend-
19 ed—

20 (1) in paragraph (2), by striking “36 months”
21 and inserting “6 years”; and

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

24 (b) **CLAIMS BASED ON REVISIONS TO TABLE.**—Sec-
25 tion 2116 of the Public Health Service Act (42 U.S.C.

1 300aa–16) is amended by striking subsection (b) and in-
2 serting the following:

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

14 “(1) the vaccine-related death or injury with re-
15 spect to which the petition is filed occurred not more
16 than 10 years before the effective date of the revi-
17 sion of the table; and

18 “(2) either—

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

21 “(B) the date of the occurrence of the first
22 symptom or manifestation of onset of the injury
23 occurred more than 4 years before the petition
24 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 (c) 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 later
8 than the earlier of—

9 “(1) the last day on which the petition for com-
10 pensation for the underlying claim of the person who
11 sustained the vaccine-related injury or death upon
12 which the derivative petition is premised may be
13 timely filed; or

14 “(2) 60 days after the date on which the special
15 master has issued a decision pursuant to section
16 2112(d)(3) on the underlying claim of the person
17 who sustained the vaccine-related injury or death
18 upon which the derivative petition is premised.”.

19 (d) TIMELY RESOLUTIONS OF CLAIMS.—

20 (1) SPECIAL MASTER DECISION.—Section
21 2112(d)(3)(A) of the Public Health Service Act (42
22 U.S.C. 300aa–12(d)(3)(A)) is amended by adding at
23 the end the following: “For purposes of this sub-
24 paragraph, the petition shall be deemed to be filed
25 on the date on which the special master issues a cer-

1 tificate of completeness, indicating that all petition
2 contents and supporting documents required under
3 section 2111(c) and, when applicable, section
4 2111(d) and the Vaccine Rules of the United States
5 Court of Federal Claims, such as an affidavit and
6 supporting documentation, have been served on the
7 Secretary and filed with the clerk of the United
8 States Court of Federal Claims.”.

9 (2) DERIVATIVE PETITIONS.—Section
10 2112(d)(3)(C) of the Public Health Service Act (42
11 U.S.C. 300aa–12(d)(3)(C)) is amended by adding at
12 the end the following: “With respect to any deriva-
13 tive petition filed under section 2111, the period of
14 time during which the petition for compensation for
15 the underlying vaccine-related injury or death upon
16 which such derivative petition is premised is pending
17 shall be treated as a suspension for purposes of this
18 subparagraph.”.

19 (3) COURT OF FEDERAL CLAIMS DECISION.—
20 Section 2121(b) of the Public Health Service Act
21 (42 U.S.C. 300aa–21(b)) is amended by adding at
22 the end the following: “For purposes of this sub-
23 section, the petition shall be deemed to be filed on
24 the date on which the special master issues a certifi-
25 cate of completeness, indicating that all petition con-

1 tents and supporting documents required under sec-
2 tion 2111(c) and, when applicable, section 2111(d)
3 and the Vaccine Rules of the United States Court of
4 Federal Claims, such as an affidavit and supporting
5 documentation, have been served on the Secretary
6 and filed with the clerk of the United States Court
7 of Federal Claims.”.

8 **SEC. 212. ADVISORY COMMISSION ON CHILDHOOD VAC-**
9 **CINES.**

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

20 (b) MANDATORY MEETING SCHEDULE ELIMI-
21 NATED.—Section 2119(c) of the Public Health Service Act
22 (42 U.S.C. 300aa–19(c)) is amended by striking “not less
23 often than four times per year and”.

1 **SEC. 213. CLARIFICATION OF STANDARDS OF RESPONSI-**
2 **BILITY.**

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

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

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

16 (d) CONSTRUCTION.—Section 2122(d) of the Public
17 Health Service Act (42 U.S.C. 300aa–22(d)) is amend-
18 ed—

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

21 (2) by inserting “or relief” after “which dam-
22 ages”.

23 (e) PAST OR PRESENT PHYSICAL INJURY.—Section
24 2122 of the Public Health Service Act (42 U.S.C. 300aa–
25 22) is amended—

1 **SEC. 215. CLARIFICATION OF DEFINITION OF VACCINE-RE-**
2 **LATED INJURY OR DEATH.**

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

9 **SEC. 216. CLARIFICATION OF DEFINITION OF VACCINE AND**
10 **DEFINITION OF PHYSICAL INJURY.**

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

14 “(7) The term ‘vaccine’ means any preparation or
15 suspension, including a preparation or suspension con-
16 taining an attenuated or inactive microorganism or
17 subunit thereof or toxin, developed or administered to
18 produce or enhance the body’s immune response to a dis-
19 ease or diseases and includes all components and ingredi-
20 ents listed in the vaccine’s product license application and
21 product label.

22 “(8) The term ‘physical injury’ means a manifest
23 physical illness, condition, or death, including a neuro-
24 logical disease or disorder.”.

1 **SEC. 217. AMENDMENTS TO VACCINE INJURY COMPENSA-**
2 **TION TRUST FUND.**

3 (a) EXPANSION OF COMPENSATED LOSS.—Section
4 9510(c)(1)(A) of the Internal Revenue Code of 1986 is
5 amended by inserting “, or related loss,” after “death”.

6 (b) INCREASE IN LIMIT ON ADMINISTRATIVE EX-
7 PENSES.—Subparagraph (B) of section 9510(c)(1) of the
8 Internal Revenue Code of 1986 is amended—

9 (1) by striking “(but not in excess of the base
10 amount of \$9,500,000 for any fiscal year)”; and

11 (2) by striking the period and inserting “, pro-
12 vided that such administrative costs shall not exceed
13 the greater of—

14 “(i) the base amount of \$9,500,000
15 for any fiscal year,

16 “(ii) 125 percent of the base amount
17 for any fiscal year in which the total num-
18 ber of claims pending under such subtitle
19 exceeds 150 percent of the average number
20 of claims pending in the preceding 5 years,

21 “(iii) 175 percent of the base amount
22 for any fiscal year in which the total num-
23 ber of claims pending under such subtitle
24 exceeds 200 percent of the average number
25 of claims pending in the preceding 5 years,

1 “(iv) 225 percent of the base amount
2 for any fiscal year in which the total num-
3 ber of claims pending under such subtitle
4 exceeds 250 percent of the average number
5 of claims pending in the preceding 5 years,
6 or

7 “(v) 275 percent of the base amount
8 for any fiscal year in which the total num-
9 ber of claims pending under such subtitle
10 exceeds 300 percent of the average number
11 of claims pending in the preceding 5
12 years.”.

13 (c) CONFORMING AMENDMENT.—Section
14 9510(c)(1)(A) of the Internal Revenue Code of 1986 is
15 amended by striking “October 18, 2000” and inserting
16 “the date of enactment of the Improved Vaccine Afford-
17 ability and Availability Act”.

18 **SEC. 218. ONGOING REVIEW OF CHILDHOOD VACCINE**
19 **DATA.**

20 Part C of title XXI of the Public Health Service Act
21 (42 U.S.C. 300a–25 et seq.) is amended by adding at the
22 end the following:

1 **“SEC. 2129A. ONGOING REVIEW OF CHILDHOOD VACCINE**
2 **DATA.**

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

11 “(b) REPORTS.—Not later than 3 years after the date
12 on which the contract is entered into under subsection (a),
13 the Institute of Medicine shall submit to the Secretary a
14 report on the findings of the studies conducted under such
15 contract, including findings as to any adverse events asso-
16 ciated with childhood vaccines, including conclusions con-
17 cerning causation of adverse events by such vaccines, and
18 other appropriate recommendations, based on such find-
19 ings and conclusions.

20 “(c) FAILURE TO ENTER INTO CONTRACT.—If the
21 Secretary and the Institute of Medicine are unable to
22 enter into the contract described in subsection (a), the
23 Secretary shall enter into a contract with another qualified
24 nongovernmental scientific organization for the purposes
25 described in subsections (a) and (b).

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

5 **SEC. 219. PENDING ACTIONS.**

6 The amendments made by this Act shall apply to all
7 actions or proceedings pending on or after the date of en-
8 actment of this Act, unless a court of competent jurisdic-
9 tion has entered judgment (regardless of whether the time
10 for appeal has expired) in such action or proceeding dis-
11 posing of the entire action or proceeding.

12 **SEC. 220. REPORT.**

13 Not later than 1 year after the date of enactment
14 of this Act, and annually thereafter, the Advisory Commis-
15 sion on Childhood Vaccines shall report to the Secretary
16 regarding the status of the Vaccine Injury Compensation
17 Trust Fund, and shall make recommendations to the Sec-
18 retary regarding the allocation of funds from the Vaccine
19 Injury Compensation Trust Fund.

○