

TITLE III. —VACCINE COMPENSATION

National Childhood Vaccine Injury Act of 1986.

42 USC 201.

SEC. 301. SHORT TITLE.

This title may be cited as the “National Childhood Vaccine Injury Act of 1986”.

PART A. —VACCINES

SEC. 311. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.

42 USC 300aa *et seq.*, 300cc *et seq.*

(a) NEW TITLE.—The Public Health Service Act is amended by redesignating title XXI as title XXIII, by redesignating sections 2101 through 2116 as sections 2301 through 2316, respectively, and by inserting after title XX the following new title:

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“TITLE XXI. —VACCINES

“Subtitle 1. —National Vaccine Program

“ESTABLISHMENT

“SEC. 2101. The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

42 USC 300aa-1.

“PROGRAM RESPONSIBILITIES

“SEC. 2102. (a) The Director of the Program shall have the following responsibilities:

42 USC 300aa-2.

“(1) VACCINE RESEARCH.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

“(2) VACCINE DEVELOPMENT.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

“(3) SAFETY AND EFFICACY TESTING OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

“(4) LICENSING OF VACCINE MANUFACTURERS AND VACCINES.— The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 353.

42 USC 263a.

“(5) PRODUCTION AND PROCUREMENT OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

“(6) DISTRIBUTION AND USE OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the Centers for Disease PUBLIC LAW 99–660—NOV. 14, [1986 100](#) STAT. 3757

Control and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

“(7) EVALUATING THE NEED FOR AND THE EFFECTIVENESS AND ADVERSE EFFECTS OF VACCINES AND IMMUNIZATION ACTIVITIES.— The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Health Care Financing Administration in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

“(8) COORDINATING GOVERNMENTAL AND NON-GOVERNMENTAL ACTIVITIES.— The Director of the Program shall, through the plan issued under section 2103, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

“(9) FUNDING OF FEDERAL AGENCIES.—The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 2103 funds appropriated under section 2106 to supplement the funds otherwise available to such agencies for activities under the plan.

“(b) In carrying out subsection (a) and in preparing the plan under section 2103, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

“PLAN

“SEC. 2103. The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 2102. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1, of each succeeding year.

42 USC 300aa-3.

“REPORT

“SEC. 2104. The Director shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than January 1, 1988, and annually thereafter on the implementation of the Program and the plan prepared under section 2103.

42 USC 300aa-4.

“NATIONAL VACCINE ADVISORY COMMITTEE

“SEC. 2105. (a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

42 USC 300aa-5.

“(b) The Committee shall—

“(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

“(2) *recommend* research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

“(3) advise the Director of the Program in the implementation of sections 2102, 2103, and 2104, and

“(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102, 2103, and 2104.

“AUTHORIZATIONS

“SEC. 2106. (a) To carry out this subtitle other than section 2102(9) there are authorized to be appropriated \$2,000,000 for fiscal year 1987, \$2,500,000 for fiscal year 1988, \$3,000,000 for fiscal year 1989, \$3,500,000 for fiscal year 1990, \$4,000,000 for fiscal year 1991.

42 USC 300aa-6.

“(b) To carry out section 2102(9) there are authorized to be appropriated \$20,000,000 for fiscal year 1987, \$22,500,000 for fiscal year 1988, \$25,000,000 for fiscal year 1989, \$27,500,000 for fiscal year 1990, \$30,000,000 for fiscal year 1991.

“Subtitle 2. —National Vaccine Injury Compensation Program

“PART A. —PROGRAM REQUIREMENTS

“ESTABLISHMENT OF PROGRAM

“SEC. 2110. (a) PROGRAM ESTABLISHED.—There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

42 USC 300aa-10.

“(b) ATTORNEY’S OBLIGATION.—It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death.

“PETITIONS FOR COMPENSATION

“SEC. 2111. (a) GENERAL RULE.—

42 USC 300aa-11.

“(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition with the United States district court for the district in which the petitioner resides or in which the injury or death occurred.

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“(2)(A) No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine

after the effective date of this subtitle, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for such a vaccine-related injury or death, unless—

“(i) a petition has been filed, in accordance with section 2116, under subsection (b) for compensation under the Program for such injury or death,

“(ii) a district court of the United States has issued a judgment under section 2112 on such petition, and

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“(iii) such person elects under section 2121(a) to file such an action.

“(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 2116, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

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“(3) No vaccine manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle.

“(4) If in a civil action brought against a vaccine manufacturer before the effective date of this subtitle damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

“(5)(A) A plaintiff who on the effective date of this subtitle has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effective date of this title or before judgment, whichever occurs first, elect to withdraw such action without prejudice and file a petition under subsection (b) for such injury or death.

“(B) If a plaintiff who on the effective date of this subtitle had pending a civil action for damages for a vaccine-related injury or death does not withdraw the action under subparagraph (A), such person may not file a petition under subsection (b) for such injury or death.

“(6) If a person brings a civil action after the effective date of this subtitle for damages for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subtitle, such person may not file a petition under subsection (b) for such injury or death.

“(7) If in a civil action brought against a vaccine manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death,

(b) PETITIONERS.—

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“(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may file a petition for compensation under the Program.

“(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of this subtitle if compensation has been paid under this subtitle for 3500 petitions for such injuries or deaths.

“(2) Only one petition may be filed with respect to each administration of a vaccine.

“(c) PETITION CONTENT.—A petition for compensation under the Program for a vaccine-related injury or death shall contain—

“(1) an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

“(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

“(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

“(I) received the vaccine in the United States or in its trust territories,

“(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

“(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 5. months after the date of the vaccination,

“(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

“(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

“(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

“(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur

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within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

“(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 1 year after the administration of the vaccine, (ii) incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than \$1,000, or (iii) died from the administration of the vaccine, and

“(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

“(2) all available relevant medical records (including autopsy reports, if any) relating to the person who suffered such injury or who died from the administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and

“(3) appropriate assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

“COURT JURISDICTION

“SEC. 2112. (a) GENERAL RULE.—The district courts of the United States shall have jurisdiction (1) over proceedings to determine if a petitioner under section 2111 is entitled to compensation under the Program and the amount of such compensation, and (2) to issue and enforce such orders as the courts deem necessary to assure the prompt payment of any

compensation awarded.

42 USC 300aa-12.

“(b) PARTIES.—

“(1) The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 2111(b), Except as provided in paragraph (2), no other person may intervene in any such proceeding.

“(2) Within 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

Federal Register, publication.

“(A) relating to the existence of the evidence described in section 2113(a)(1)(B), or

“(B) relating to any allegation in a petition with respect to the matters described in section 2111(c)(1)(C)(ii).

“(c) SPECIAL MASTERS.—

“(1) Following receipt of a petition under subsection (a), the district court of the United States in which the petition is filed shall designate a special master to carry out the functions authorized by paragraph (2).

“(2) A special master shall serve as an adjunct to the court and may—

“(A) require such evidence as may be appropriate for the preparation of proposed findings of fact and conclusions of law with respect to whether compensation is to be provided

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under the Program and the amount of any such compensation,

“(B) require the submission of such information as may be reasonable and necessary to determine if the petitioner is entitled to compensation,

“(C) require the testimony of any person and the production of any document as may be reasonable and necessary to determine if the petitioner is entitled to compensation,

“(D) conduct such hearings as may be appropriate, and

“(E) prepare and submit to the court proposed findings of fact and conclusions of law.

Information submitted to a special master in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express, written consent of the person who submitted the information. There may be no discovery in a proceeding on a petition other than the discovery required under this paragraph.

“(d) ACTION BY THE COURT.—

Records.

“(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court’s own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

“(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

“(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed.

“(e) ADMINISTRATION OF AWARD.—The Program shall administer the payments of such compensation. The Program shall audit the payments of compensation under a judgment. A petitioner awarded compensation shall notify the Program of any changes which significantly

affect the compensation to be paid.

“(f) REVISION OF AWARD.—

“(1) If the court issues a judgment awarding to a petitioner compensation described in section 2115(a)(1)(A) for unreimbursable expenses and the compensation is insufficient to meet such expenses, such petitioner may petition the court to (A) review such award, and (B) increase the award to make it sufficient to meet such expenses or amend the periodic payment schedule established under section 2115, or both.

“(2) If an audit conducted under subsection (e) discloses the improper use of compensation awarded under a judgment or the termination of a need for an item of compensation, the Program shall petition the court which awarded the compensation to make an appropriate revision in the compensation.

“(g) APPEALS.—The findings of fact and conclusions of law of a district court of the United States on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the circuit in which the court is located upon petition filed with such court of appeals.

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“DETERMINATION OF ELIGIBILITY AND COMPENSATION

“SEC. 2113. (a) GENERAL RULE.—

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42 USC 300aa-13.

“(1) Compensation shall be awarded under the Program to a petitioner if the court finds on the record as a whole—

“(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1), and

“(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

“(2) For purposes of paragraph (1), the term ‘factors unrelated to the administration of the vaccine’—

“(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

“(B) may, as documented by the petitioner’s evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner’s illness, disability, injury, condition, or death.

“(b) MATTERS TO BE CONSIDERED.—

“(1) In determining whether to award compensation to a petitioner under the Program, the court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

Courts, U.S. Records.

“(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death, and

“(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the court.

“(2) The court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condi

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tion, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

“(c) RECORD DEFINED.—For purposes of this section, the term ‘record’ means the record established by a district court of the United States in a proceeding on a petition filed under section 2111.

“VACCINE INJURY TABLE

“SEC. 2114. (a) INITIAL TABLE.—The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

42 USC 300aa-14.

“VACCINE INJURY TABLE

I. DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).

Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
A. Anaphylaxis or anaphylactic shock.....	24 hours
B. Encephalopathy (or encephalitis)...	3 days
C. Shock-collapse or hypotonic-hyporesponsive collapse.....	3 days
D. Residual seizure disorder in accordance with subsection (c)(2).....	3 days
E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed...	Not applicable

II. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.

A. Anaphylaxis or anaphylactic shock.....	24 hours
B. Encephalopathy (or encephalitis)...	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3: days (for DT, Td, or tetanus toxoid).

C. Residual seizure disorder in accordance with subsection 15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (For DT, Td, or tetanus toxoid).
(c)(2).....

D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed... Not applicable

III. Polio Vaccines (other than Inactivated Polio Vaccine).

A. Paralytic polio

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—in a non-immunodeficient recipient..... 30 days
 —in an immunodeficient recipient..... 6 months
 —in a vaccine-associated community case..... Not applicable

B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed... Not applicable

IV. Inactivated Polio Vaccine.

A. Anaphylaxis or anaphylactic shock..... 24 hours

B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed... Not applicable

“(b) QUALIFICATIONS AND AIDS TO INTERPRETATION.—The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

“(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

“(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

“(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

“(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1. year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

“(3)(A) The term ‘encephalopathy’ means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high

pitched and unusual screaming, persistent inconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

“(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 2111(b) for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

“(4) For purposes of paragraphs (2) and (3), the terms ‘seizure’ and ‘convulsion’ include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply,

“(c) ADMINISTRATIVE REVISION OF THE TABLE.—

Regulations.

“(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

“(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

“(A) receipt of any recommendation of the Commission, or

“(B) 180 days after the date of the referral to the Commission,

Federal Register, publication.

whichever occurs first, the Secretary shall conduct a rule-making proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

“(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

“(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

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“(d) ROLE OF COMMISSION.—Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

Regulations.

“(e) RECOMMENDATION.—The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table.

“COMPENSATION

“SEC. 2115. (a) GENERAL RULE.—Compensation awarded under the Program to a petitioner

under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle shall include the following:

42 USC 300aa-15.

“(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

“(i) result from the vaccine-related injury for which the petitioner seeks compensation,

“(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

“(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

“(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 2111(c)(1)(D)(ii).

“(B) Subject to section 2116(a)(2), actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

“(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

“(ii) were incurred by or on behalf of the person who suffered such injury, and

“(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 2111(c)(1)(D)(ii).

“(2) In the event of a vaccine-related death, an award of \$250,000 for the estate of the deceased.

“(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning

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capacity is or has been impaired by reason of such person’s vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

“(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person’s vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

“(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed \$250,000.

Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum.

“(b) VACCINES ADMINISTERED BEFORE THE EFFECTIVE DATE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subtitle shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a).

“(c) RESIDENTIAL AND CUSTODIAL CARE AND SERVICE.—The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

“(d) TYPES OF COMPENSATION PROHIBITED.—Compensation awarded under the Program may not include the following:

“(1) Punitive or exemplary damages.

“(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

“(e) ATTORNEYS’ FEES.—

Courts, U.S.

“(1) The judgment of a court on a petition filed under section 2111 awarding compensation shall include an amount to cover—

“(A) reasonable attorneys’ fees, and

“(B) other costs,

incurred in any proceeding on such petition. If the judgment of a court on such a petition does not award compensation, the court may include in the judgment an amount to cover petitioner’s reasonable attorneys’ fees and other costs incurred in any proceeding on such petition if the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action was brought.

“(2) If the petitioner, before the effective date of this title, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Pro

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gram, and elected under section 2111(a)(4) to withdraw such action and to file a petition for compensation under the Program, the judgment of the court on such petition may include an amount limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this subtitle in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney’s time if the civil action was filed under contingent fee arrangements).

“(3) No attorney may charge any fee for services in connection with a petition filed under section 2111 which is in addition to any amount included under paragraph (1) in a judgment on such petition.

“(f) PAYMENT OF COMPENSATION.—

“(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 2121(a) to receive compensation.

“(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the district court of the United States under section 2112 awarding the compensation. Such compensation may not be paid after an election under section 2121(b) to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

“(3) Payments of compensation shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985.

2 USC 901 *et seq.*

“(f) PROGRAM NOT PRIMARILY LIABLE.—Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program, or (2) by an entity which provides health services on a prepaid basis.

“(g) LIABILITY OF HEALTH INSURANCE CARRIERS, PREPAID HEALTH PLANS, AND BENEFIT PROVIDERS.—No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

“(1) no State, and

“(2) no entity which provides health services on a prepaid basis or provides health benefits, may make the provision of health services or health benefits secondary to the payment of compensation under the Program.

“LIMITATIONS OF ACTIONS

“SEC. 2116. (a) GENERAL RULE.—In the case of—

42 USC 300aa-16.

“(1) a vaccine set forth in the Vaccine Injury Table which is administered before the effective date of this title, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 24 months after the effective date of this title,

“(2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this title, if a vaccine-related injury occurred as a result of the administration of such

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vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

“(3) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this title, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

“(b) EFFECT OF REVISED TABLE.—If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, such person may file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

“(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

“(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

“(c) STATE LIMITATIONS OF ACTIONS.—If a petition is filed under section 2111(b) for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date a final judgment is entered on the petition.

“SUBROGATION

“SEC. 2117. (a) GENERAL RULE.—

42 USC 300aa-17.

“(1) Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

“(2) In any case in which it deems such action appropriate, a district court of the United States

may, after entry of a final judgment providing for compensation to be paid under section 2115 for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1),

Courts, U.S. Records.

Claims.

“(b) DISPOSITION OF AMOUNTS RECOVERED.—Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the trust fund which has been established to provide compensation under the Program.

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“INCREASE FOR INFLATION

“SEC. 2118. The compensation under subsections (a)(2) and (a)(4) of section 2115 and the civil penalty under section 2127(b) shall, effective December 1 of each year beginning 1 year after the effective date of this title, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding

year, adjusted to the nearest $\frac{1}{10}$ of 1 percent. For purposes of this section, the term ‘base quarter’, as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

Effective date.

42 USC 300aa-18.

“ADVISORY COMMISSION ON CHILDHOOD VACCINES

“SEC. 2119. (a) ESTABLISHMENT.—There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

42 USC 300aa-19.

“(1) Nine members appointed by the Secretary as follows:

“(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

“(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

“(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

“(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of the effective date of this subtitle. The members of the Commission shall select a Chair from among the members.

“(b) TERM OF OFFICE.—Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

“(c) MEETINGS.—The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission.

“(d) COMPENSATION.—Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the

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Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for employees serving intermittently.

5 USC 5332.

“(e) STAFF.—The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

“(f) FUNCTIONS.—The Commission shall—

“(1) advise the Secretary on the implementation of the Program,

“(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

“(3) advise the Secretary in implementing the Secretary’s responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

“(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

“(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this subtitle,

“PART B. —ADDITIONAL REMEDIES

“AUTHORITY TO BRING ACTIONS

“SEC. 2121. (a) ELECTION.—After the judgment of a district court of the United States under section 2111 on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—

42 USC 300aa-21.

“(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

“(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the entry of the court’s judgment with respect to which the election is to be made. If a person required to file an election with a court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of a court or is deemed to have accepted the judgment of a court,

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such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered.

“(b) LIMITATIONS OF ACTIONS.—A civil action for damages arising from a vaccine-related

injury or death for which a petition was filed under section 2111 shall, except as provided in section 2116(c), be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

State and local governments

“STANDARDS OF RESPONSIBILITY

“SEC. 2122. (a) GENERAL RULE.—Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

State and local governments.

Claims.

42 USC 300aa-22.

“(b) UNAVOIDABLE ADVERSE SIDE EFFECTS; WARNINGS.—

“(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

“(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (including regulations issued under such provisions; applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

21 USC 301 note.

42 USC 262.

“(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2), or

“(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

“(c) DIRECT WARNINGS.—No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle solely due to the manufacturer’s failure to provide direct warnings to the injured party (or the injured party’s legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

“(d) CONSTRUCTION.—The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

“(e) PREEMPTION.—No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle.

State and local governments.

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“TRIAL

“SEC. 2123. (a) GENERAL RULE.—A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle which is not barred by section 2111(a)(2) shall be tried in three stages.

42 USC 300aa-23.

“(b) LIABILITY.—The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 2122.

“(c) GENERAL DAMAGES.—The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

“(d) PUNITIVE DAMAGES.—

“(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

Fraud.

“(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

21 USC 301 note.

42 USC 201 note.

“(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 351,

42 USC 262. Safety.

“(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

Safety.

“(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.

“(e) EVIDENCE.—In any stage of a civil action, the Vaccine Injury Table, any finding of a district court of the United States or a master appointed by such court in a proceeding on a petition filed under section 2111 and the final judgment of a district court of the United States on such a petition shall not be admissible.

“PART C. —ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

“RECORDING AND REPORTING OF INFORMATION

“SEC. 2125. (a) GENERAL RULE.—Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person’s permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

42 USC 300aa-25.

“(1) the date of administration of the vaccine,

“(2) the vaccine manufacturer and lot number of the vaccine,

“(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

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“(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

“(b) REPORTING.—

“(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

“(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 2114(b) which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

“(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer’s package insert, and

“(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this subtitle. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

Federal Register, publication.

“(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

“(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this subtitle.

Regulations.

“(c) RELEASE OF INFORMATION.—

“(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except—

State and local governments.

“(A) the person who received the vaccine, or

“(B) the legal representative of such person.

“(2) For purposes of paragraph (1), the term ‘information which may identify an individual’ shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person’s legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

“(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

Public information.

“VACCINE INFORMATION

“SEC. 2126. (a) GENERAL RULE,—Not later than 1 year after the effective date of this subtitle, the Secretary shall develop and

42 USC 300aa-26.

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disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

Federal Register, publication.

“(b) DEVELOPMENT AND REVISION OF MATERIALS.—Such materials shall be developed or revised by rule—

“(1) after notice to the public, opportunity for a public hearing, and 90 days of comment thereon, and

“(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control, and the Food and Drug Administration.

“(c) INFORMATION REQUIREMENTS.—The information in such materials shall be presented in understandable terms and shall include—

“(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

“(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

“(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

“(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

“(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

“(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

“(7) the contraindications to (and bases for delay of) the administration of the vaccine,

“(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

“(9) a summary of relevant State and Federal laws concerning the vaccine, including information on—

“(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

“(B) the availability of the Program, and

“(10) such other relevant information as may be determined by the Secretary.

“(d) HEALTH CARE PROVIDER DUTIES.—On and after a date determined by the Secretary which is—

“(1) after the Secretary develops the information materials required by subsection (a), and

“(2) not later than 6 months after the date such materials are published in the Federal Register, each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), or other written information which meets the requirements

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of this section. Such materials or other information shall be provided prior to the administration of such vaccine.

“MANDATE FOR SAFER CHILDHOOD VACCINES

“SEC. 2127. (a) GENERAL RULE.—In the administration of this subtitle and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

42 USC 300aa-27.

“(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this subtitle and promote the refinement of such vaccines, and

“(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions,

distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

“(b) REPORT.—Within 2 years after the effective date of this subtitle, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

“MANUFACTURER RECORDKEEPING AND REPORTING

“SEC. 2128. (a) GENERAL RULE.—Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after the effective date of this subtitle—

State and local governments.

42 USC 300aa-28.

“(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

“(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer’s representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test, Safety.

“(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

“(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

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“(b) SANCTION.—Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

Fraud.

“(1) be subject to a civil penalty of up to \$100,000 per occurrence, or

“(2) be fined \$50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

“PART D. —GENERAL PROVISIONS

“CITIZEN’S ACTIONS

“SEC. 2131. (a) GENERAL RULE.—Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person’s own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this subtitle.

42 USC 300aa-31.

“(b) NOTICE.—No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

Courts, U.S.

“(c) COSTS OF LITIGATION.—The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court determines such award is appropriate.

“JUDICIAL REVIEW

“SEC. 2132. A petition for review of a regulation under this subtitle may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

Regulations.

42 USC 300aa-32.

“DEFINITIONS

“SEC. 2133. For purposes of this subtitle:

42 USC 300aa-33.

“(1) The term ‘health care provider’ means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

“(2) The term ‘legal representative’ means a parent or an individual who qualifies as a legal guardian under State law.

“(3) The term ‘manufacturer’ means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 2128, such term shall include the manufacturer of any other vaccine cov

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ered by that section. The term ‘manufacture’ means to manufacture, import, process, or distribute a vaccine.

“(4) The term ‘significant aggravation’ means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

“(5) The term ‘vaccine-related injury or death’ means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

“(6)(A) The term ‘Advisory Commission on Childhood Vaccines’ means the Commission established under section 2119.

“(B) The term ‘Vaccine Injury Table’ means the table set out in section 2114.” (Ante, p. 3764).

(b) CONFORMING AMENDMENTS.—

(1) Sections 217(c), 465(f), and 497 of the Public Health Service Act (42 U.S.C. 218(c), 286(f), 289(f)) are each amended by striking out “2101” and inserting in lieu thereof “2301”.

42 USC 218, 286, 289f.

(2) Section 305(h) of such Act (42 U.S.C. 242c(h)) is amended by striking out “2113” each place it occurs and inserting in lieu thereof “2313”.

SEC. 312. RELATED STUDIES.

(a) REVIEW OF PERTUSSIS VACCINES AND RELATED ILLNESSES AND CONDITIONS.

—Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information (including information obtained from the studies required under subsection (e)) on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the following illnesses and conditions:

42 USC 300aa-1 note.

- (1) Hemolytic anemia.
- (2) Hypsarrhythmia.
- (3) Infantile spasms.
- (4) Reye's syndrome.
- (5) Peripheral mononeuropathy.
- (6) Deaths classified as sudden infant death syndrome.
- (7) Aseptic meningitis.
- (8) Juvenile diabetes.
- (9) Autism.
- (10) Learning disabilities.
- (11) Hyperactivity.
- (12) Such other illnesses and conditions as the Secretary may choose to review or as the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act recommends for inclusion in such review. (*Ante*, p. 3771).

The review under this subsection shall include notice and opportunity for a public hearing, consideration of written information submitted by the public, and consultation with such Advisory Commission.

(b) FINDINGS WITH RESPECT TO PERTUSSIS.—Not later than 3 years after the effective date of this title, the Secretary shall make, and publish in the Federal Register, the following specific findings:

Federal Register, publication.

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- (1) Whether each of the illnesses or conditions set forth in subsection (a) can reasonably be determined in some circumstances to be caused or significantly aggravated, by pertussis-containing vaccines.
- (2) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), the circumstances under which such causation or aggravation can reasonably be determined to occur.
- (3) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), and for each illness or condition set forth in the Vaccine Injury Table under section 2114 of the Public Health Service Act, the time periods within which the first symptom or manifestation of onset or aggravation of each such illness or condition can reasonably be determined to occur after pertussis vaccination,

Ante, p. 3764.

(c) REVISION OF TABLE WITH RESPECT TO PERTUSSIS VACCINES.—At the same time the Secretary publishes in the Federal Register findings under subsection (b), the Secretary shall propose regulations to amend the Vaccine Injury Table under section 2114 of the Public Health Service Act as a result of such findings, Not later than 42 months after the effective date of this title, the Secretary shall promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

Regulations.

(d) REVIEW OF MMR VACCINES AND RELATED ILLNESSES AND CONDITIONS.—Not

later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review similar to the review conducted under subsection (a) with respect to the potential relationship between vaccines containing rubella (including MMR) and radiculoneuritis. The review under this subsection shall include notice and opportunity for a public hearing, consultation with the Advisory Commission on Childhood Vaccines and consideration of written information submitted by the public. Not later than 3 years after the effective date of this title, the Secretary shall make and publish in the Federal Register findings similar to those required by subsection (b) and shall, if appropriate, propose similar regulations (and thereafter promulgate such regulations) to those required by subsection (c), with respect to compensation under the National Vaccine Injury Compensation Program established under section 2110 of the Public Health Service Act for radiculoneuritis caused, contributed to, or significantly aggravated by vaccines containing rubella.

Federal Register, publication.

Ante, p. 3758.

(e) PERTUSSIS AND MMR STUDIES.—

(1) In order to assist the Secretary in making the findings required under subsections (b) and (d), the Secretary shall, in accordance with subparagraph (B), arrange for the conduct of studies of—

(A) the relationship between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the illnesses or conditions set forth in paragraphs (1) through (11) of subsection (a),

(B) the relationship between vaccines containing pertussis and any other illnesses and conditions, as selected by the Secretary or the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act, and

Ante, p. 3771.

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(C) the relationship between vaccines containing rubella (including MMR) and radiculoneuritis.

(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the studies required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in paragraph (3).

Reports.

(C) The Institute of Medicine or other group or association conducting the studies required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act.

Ante, p. 3771.

(3) Reports on the results of the studies required by paragraph (1) shall be completed and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate and to the Secretary not later than 32 months after the effective date of this title. Upon submission to the Secretary, the reports shall be made available to the public.

Reports.

Public information.

(4) There are authorized to be appropriated such sums as are necessary for the purpose of making payments for the conduct of the studies required under this subsection.

Appropriation authorization.

(f) DEFINITIONS.—For purposes of this section:

(1) The term “medical and scientific information” includes epidemiologic, clinical, biostatistical, pathological, toxicologic, and other laboratory data and case study information, observations, studies, and reports in peer-reviewed literature or official Government publications, as well as relevant unpublished information, data, studies, and observations.

(2) The term “MMR” means a vaccine containing material intended to prevent or confer immunity against measles, mumps, and rubella disease.

SEC. 313. STUDY OF OTHER VACCINE RISKS.

(a) STUDY.—

42 USC 300aa-1 note.

(1) Not later than 3 years after the effective date of this title, the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act—

(A) arrange for a broad study of the risks (other than the risks considered under section 102) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act, and

Ante, p. 3764.

(B) establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include—

(i) the circumstances under which any such vaccine should not be administered,

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(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study.

(C) The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act.

Ante, p. 3771.

(b) REVISION OF GUIDELINES.—The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

Federal Register, publication.

(c) FACTORS AFFECTING GUIDELINES.—Guidelines under subsection (a) shall take into account—

(1) the risk to potential recipients of the vaccines with respect to which the guidelines are established,

(2) the medical and other characteristics of such potential recipients, and

(3) the risks to the public of not having such vaccines administered.

(d) DISSEMINATION.—The Secretary shall widely disseminate the guidelines established under subsection (a) to—

- (1) physicians and other health care providers,
- (2) professional health associations,
- (3) State and local governments and agencies, and
- (4) other relevant entities,

Physicians.

Hospitals.

Nurses.

State and local governments.

SEC. 314. REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION.

42 USC 300aa-1 note.

Not later than 1 year after the effective date of this title and after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act and with other appropriate entities, the Secretary of Health and Human Services shall review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 2114 of the Public Health Service Act and shall by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such

Ante, p. 3764.

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vaccines. If the Secretary determines that any such warning, instruction, or information is inadequate for such purpose in any respect, the Secretary shall at the same time require the manufacturers to revise and reissue such warning, instruction, or information as expeditiously as practical, but not later than 18 months after the effective date of this title.

SEC. 315. RECALL AUTHORITY,

Subsection (d) of section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

Ante, p. 3751.

(1) by inserting “(1)” after “(d)”, and

(2) by adding at the end thereof the following new paragraph:

“(2)(A) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code.

“(B) Any violation of subparagraph (A) shall subject the violator to a civil penalty of up to \$100,000 per day of violation. The amount of a civil penalty under this subparagraph shall, effective December 1 of each year beginning 1 year after the effective date of this subparagraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest

$\frac{1}{10}$ of 1 percent. For purposes of this subparagraph, the term ‘base quarter’, as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.”

Law enforcement and crime.

SEC. 316. STUDY OF IMPACT ON SUPPLY OF VACCINES.

42 USC 300aa-4 note.

On June 30, 1987, and on June 30 of each second year thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate—

(1) an assessment of the impact of the amendments made by this title on the supply of vaccines listed in the Vaccine Injury Table under section 2114 of the Public Health Service Act, and (Ante, p. 3764). style="padding-left: 2em;">(2) an assessment of the ability of the administrators of vaccines (including public clinics and private administrators) to provide such vaccines to children.

PART B. —MISCELLANEOUS

SEC 321. WAIVER OF PAPERWORK REDUCTION.

Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this title and implementing the amendments made by this title.

44 USC 3501 *et seq.*

42 USC 300aa-1 note.

SEC. 322. NONSEVERABILITY.

42 USC 300aa-1 note.

If any provision of this title or the application of any provision of this title to any person or circumstance is held invalid by reason of a violation of the Constitution, the entire title shall be considered invalid.