

LEXSTAT 42 USCS 300AA-10-33

UNITED STATES CODE SERVICE
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*** CURRENT THROUGH P.L. 109-6, APPROVED 3/31/05 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
PROGRAM REQUIREMENTS

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION*42 USCS § 300aa-10 (2005)***§ 300aa-10. Establishment of program**

(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.

(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.

(c) Publicity. The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2110, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3758; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(b), 103 Stat. 2285.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Explanatory notes:

A prior § 300aa-10 (Act July 1, 1944, ch 373, Title XXI[V], § 2111 [511], 58 Stat. 711; April 26, 1983, P.L. 98-24, § 2(a)(1), 97 Stat. 176) was redesignated § 2709 of Title XXVII of such Act and now appears as *42 USCS § 300aaa-8*.

A prior § 2110 of Act July 1, 1944, ch 373, Title XXI, which formerly appeared as *42 USCS § 300aa-9*, was redesignated § 2708 of Title XXVII of such Act and now appears as *42 USCS § 300aaa-7*.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1989. Act Dec. 19, 1989, § 6601(b) (applicable as provided by § 6601(s) of such Act, which appears as a note to this section) added subsec. (c).

Other provisions:

Applicability of amendments made by § 6601 of Act Dec. 19, 1989. Act Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(s), 103 Stat. 2293, provides:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending 42 USCS § § 300aa-10 et seq., generally; for full classification, consult USCS Tables volumes] shall apply as follows:

"(A) Petitions filed after the date of enactment of this section shall proceed under the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [42 USCS § § 300aa-1 et seq.] as amended by this section.

"(B) Petitions currently pending in which the evidentiary record is closed shall continue to proceed under the Program in accordance with the law in effect before the date of the enactment of this section, except that if the United States Claims Court [United States Court of Federal Claims] is to review the findings of fact and conclusions of law of a special master on such a petition, the court may receive further evidence in conducting such review.

"(C) Petitions currently pending in which the evidentiary record is not closed shall proceed under the Program in accordance with the law as amended by this section.

All pending cases which will proceed under the Program as amended by this section shall be immediately suspended for 30 days to enable the special masters and parties to prepare for proceeding under the Program as amended by this section. In determining the 240-day period prescribed by section 2112(d) of the Public Health Service Act [42 USCS § § 300aa-12(d)], as amended by this section, or the 420-day period prescribed by section 2121(b) of such Act [42 USCS § § 300aa-21(b)], as so amended, any period of suspension under the preceding sentence shall be excluded.

"(2) The amendments to section 2115 of the Public Health Service Act [42 USCS § 300aa-15] shall apply to all pending and subsequently filed petitions."

NOTES:

Research Guide:

Federal Procedure:

10 Moore's Federal Practice (Matthew Bender 3d ed.), Judgments; Costs § 54.171.

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § 35:727.

Am Jur:

32B Am Jur 2d, Federal Courts § 2232.

63B Am Jur 2d, Products Liability § 1573.

Am Jur Proof of Facts:

23 Am Jur Proof of Facts 3d, Optician's negligence: Proof that an optician negligently dispensed an optical device, p. 1.

Annotations:

Products liability: pertussis vaccine manufacturers. 57 ALR4th 911.

Interpretive Notes and Decisions:

Vaccine table injury in federal act has no bearing on issue of causation in civil tort action. Rohrbough v Wyeth Laboratories, Inc. (1990, CA4 W Va) 916 F2d 970, CCH Prod Liab Rep P 12629.

Government's motion for 90 day suspension of proceedings in vaccine cases, filed under 42 USCS § § 300aa-10 et seq., would not be granted, even though government claimed combination of 365-day decision requirement, lack of resources and court's procedure for handling cases threatened program, since government's lack of resources could not be used to penalize petitioners. Gregson v Secretary of HHS (1989) 17 Cl Ct 19.

Special master was not arbitrary or capricious in determining that cause of child's transverse myelitis was respiratory virus, rather than inoculation for oral polio vaccine, and special master's decision was supported by record evidence. Morris v Sec'y of HHS (2003) 57 Fed Cl 383.

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GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-11 (2005)

§ 300aa-11. Petitions for compensation

(a) General rule.

(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 containing the matter prescribed by subsection (c) with the United States Claims Court [United States Court of Federal Claims]. The clerk of the United States Claims Court [United States Court of Federal Claims] shall immediately forward the filed petition to the chief special master for assignment to a special master under section 2112(d)(1) [42 USCS § 300aa-12(d)(1)].

(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 administrator or 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 part, 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 a petition has been filed, in accordance with section 2116 [42 USCS § 300aa-16], for compensation under the Program for such injury or death and--

(i) (I) the United States Claims Court [United States Court of Federal Claims] has is sued a judgment under section 2112 [42 USCS § 300aa-12] on such petition, and

(II) such person elects under section 2121(a) [42 USCS § 300aa-21(a)] to file such an action, or

(ii) such person elects to withdraw such petition under section 2121(b) [42 USCS § 300aa-21(b)] or such petition is considered withdrawn under such section.

(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 [42 USCS § 300aa-16], 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.

(3) No vaccine administrator or 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 part.

(4) If in a civil action brought against a vaccine administrator or manufacturer before the effective date of this part 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 part 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 part or before judgment, whichever occurs

first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, 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 administrator or 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.

(8) If on the effective date of this part there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court [United States Court of Federal Claims] is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners.

(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, if the person meets the requirements of subsection (c)(1), 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 part if compensation has been paid under this subtitle [42 USCS § 300aa-10 et seq.] 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) except as provided in paragraph (3), 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 6 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 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 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

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

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information. A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule. The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition 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.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2111, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3758; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § § 4302(b), 4304(a), (b), 4306, 4307(1), (2), 101 Stat. 1330-221, 223, 224; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(c)(1)-(7), 103 Stat. 2285; Nov. 3, 1990, P.L. 101-502, § 5(a), 104 Stat. 1286; Nov. 26, 1991, P.L. 102-168, Title II, § 201(h)(1), 105 Stat. 1104; June 10, 1993, P.L. 103-43, Title XX, § 2012, 107 Stat. 214; Oct. 21, 1998, P.L. 105-277, Div C, Title XV, § 1502, 112 Stat. 2681-741; Oct. 17, 2000, P.L. 106-310, Div A, Title XVII, Subtitle A, § 1701(a), 114 Stat. 1151.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

The "effective date of this part", referred to in this section, is Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Explanatory notes:

The bracketed words "United States Court of Federal Claims" were inserted in subsec. (a) of this section on the authority of § 902(b)(1) of Act Oct. 29, 1992, P.L. 102-572, which appears as *28 USCS § 171* note, and which provides that reference to the United States Claims Court in any Federal law or document shall be deemed to refer to the United States Court of Federal Claims.

A prior § 300aa-11 (Act July 1, 1944, ch 373, Title XXI[V], § 2112 [512], as added Oct. 15, 1968, P.L. 90-574, Title V, § 503(a), 82 Stat. 1012; April 26, 1983, P.L. 98-24, § 2(a)(1), 97 Stat. § 176) was redesignated § 2710 of Title XXVII of such Act and now appears as *42 USCS § 300aaa-9*.

A prior § 2111 of Act July 1, 1944, ch 373, Title XXI, which formerly appeared as *42 USCS § 300aa-10*, was redesignated § 2709 of Title XXVII and now appears as *42 USCS § 300aaa-8*.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by § 323 of Act Nov. 14, 1986, P.L. 99-660, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), in para. (1), substituted "with the United States Claims Court" for "with the United States district court for the district in which the petitioner resides or the injury or death occurred", in para. (2), in subpara. (A), in the introductory matter, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer"

and "effective date of this part" for "effective date of this subtitle", in cl. (ii), substituted "the United States Claims Court" for "a district court of the United States", in paras. (3) and (4), substituted "effective date of this part" for "effective date of this subtitle", in para. (5), in subpara. (A), substituted "effective date of this part" for "effective date of this subtitle" and substituted "effective date of this part" for "effective date of this title", in subpara. (B) and para. (6), substituted "effective date of this part" for "effective date of this subtitle" wherever appearing, in para. (7), substituted "vaccine administrator of manufacturer" for "vaccine manufacturer", and added para. (8); in subsec. (b)(1), in subpara. (A), substituted "may, if the person meets the requirements of subsection (c)(1), file" for "may file", and, in subpara. (B), substituted "effective date of this part" for "effective date of this subtitle" wherever appearing; and, in subsec. (c)(1)(D), substituted "for more than 6 months" for "for more than 1 year", substituted "and" for ", (ii)" preceding "incurred" and substituted "(ii)" for "(iii)".

1989. Act Dec. 19, 1989, § 6601(c)(1)-(7) (applicable as provided by § 6601(s) of such Act, which appears as 42 USCS § 300aa-10 note), in subsec. (a), in para. (1), inserted "containing the matter prescribed by subsection (c)" and added the sentence which begins "The clerk . . .", in para. (2)(A)(i), deleted "under subsection (b)" preceding "for compensation", in para (5), in subpara. (A), substituted "petition to have such action dismissed without prejudice or costs" for "elect to withdraw such action", in subpara. (B), substituted "has" for "on the effective date of this part had" and deleted "does not withdraw the action under subparagraph (A)" preceding "such person", in para. (6), substituted "November 15, 1988" for "the effective date of this part" in two places, redesignated para. (8) as para. (9), and added a new para. (8); in subsec. (c), in paras. (1) and (2), inserted "except as provided in paragraph (3)", redesignated paras. (2) and (3) as subsecs. (d) and (e), respectively, and added new paras. (2) and (3).

Such Act further (applicable as above), in subsec. (d) as so redesignated, added the subsec. heading and substituted "A petition may also include other available" for "all available", deleted "(including autopsy reports, if any)" following "medical records", deleted "and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and", following "vaccine" and added the concluding period; and, in subsec. (e) as so redesignated, added the subsec. heading and substituted "The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition" for "appropriate".

1990. Act Nov. 3, 1990 (effective 9/30/90 as provided by § 5(h) of such Act, which appears as a note to this section), in subsec. (a), in para. (2)(A), substituted "unless a petition has been filed, in accordance with section 2116, for compensation under the Program for such injury or death and--" and cls. (i) and (ii) for:

"unless--

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

"(ii) the United States Claims Court has issued a judgment under section 2112 on such petition, and

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

Such Act further (effective as above), in para. (5), in subpara. (A), deleted "without prejudice" following "costs" and, in subpara. (B), substituted "plaintiff" for "plaintiff who".

Such Act further (effective as above), in subsec. (d), deleted "(d) except as provided in paragraph (3),"; and, in subsec. (e), deleted the second subsec. designator "(e)".

1991. Act Nov. 26, 1991, made technical corrections which did not affect the text of this section.

1993. Act June 10, 1993 (effective on enactment as provided by § 2101 of such Act, which appears as 42 USCS § 201 note), in subsec. (a), added para. (10).

1998. Act Oct. 21, 1998, in subsec. (c)(1)(D)(i), deleted "and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than \$ 1,000" preceding ", or (ii)".

2000. Act Oct. 17, 2000 (effective as provided by §§ 1701(b) and 2901 of such Act, which appear as notes to 42 USCS §§ 300aa-11 and 201, respectively), in subsec. (c)(1)(D), substituted "or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and" for "and".

Other provisions:

Effective dates of Nov. 3, 1990 amendments. Act Nov. 3, 1990, P.L. 101-502, § 5(h), 104 Stat. 1289, provides: "The amendments made by subsections (f)(1) and (g) [amending 42 USCS § 300aa-21(a) and 42 USCS § 300aa-1 note] shall take effect as of November 14, 1986, and the amendments made by subsections (a) through (e) and subsection (f)(2) [amending 42 USCS §§ 247b, 300aa-2, 300aa-6, 300aa-11-300aa-13, 300aa-15, 300aa-16, 300aa-21(b)] shall take effect as of September 30, 1989."

Effective date of amendments made by § 201 of Act Nov. 26, 1991. Act Nov. 26, 1991, P.L. 102-168, Title II, § 201(i), 105 Stat. 1104, provides:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending 42 USCS § § 300aa-11, 300aa-12, 300aa-15, 300aa-16, 300aa-19, 300aa-21] shall take effect on the date of the enactment of this Act.

"(2) The amendments made by subsections (d) and (f) [amending 42 USCS § § 300aa-12(g), 300aa-15(f)(4), 300aa-16(c), 300aa-21(b)] shall take effect as if the amendments had been in effect on and after October 1, 1988."

Effective date of Oct. 17, 2000 amendments. Act Oct. 17, 2000, P.L. 106-310, Div A, Title XVII, Subtitle A, § 1701(b) 114 Stat. 1151, provides: "The amendment made by subsection (a) [amending subsec. (c)(1)(D) of this section] takes effect upon the date of the enactment of this Act, including with respect to petitions under section 2111 of the Public Health Service Act [this section] that are pending on such date."

NOTES:

Code of Federal Regulations:

Department of Health and Human Services--Service of process, 45 CFR Part 4.

Related Statutes & Rules:

This section is referred to in 42 USCS § § 300aa-12-300aa-16, 300aa-21 300aa-23, 300aa-34; 26 USCS 4131.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § § 35:727-731, 733, 736, 739, 741.

Am Jur:

39 Am Jur 2d, Health § 67.

63B Am Jur 2d, Products Liability § 1573.

Interpretive Notes and Decisions: 1. Generally 2. Bringing civil action construed 3. Civil action as bar to suit 4. -- Settlement as bar to recovery 5. Dismissal of Vaccine Act claim 6. Contents of petition

1. Generally

State rule prohibiting plaintiff from refile more than once action previously dismissed voluntarily is not preempted by Vaccine Act. *Evans v Lederle Lab.* (1999, CA7 Ill) 167 F3d 1106, cert den (1999, US) 68 USLW 3249.

One way to make sense of 42 USCS § 300aa-11(a)(5)(A) and (B) is to read them in reverse; thus, (a)(5)(B) states general rule barring filing of petition for compensation if petitioner has civil action pending; (a)(5)(A) provides escape hatch for would-be petitioner if petitioner obtains dismissal before judgment; jurisdictional defect cannot be cured by state nunc pro tunc order of dismissal. *Matos by Rivera v Secretary of the Dep't of Health & Human Servs.* (1994, CA FC) 35 F3d 1549.

Binding election provision of Vaccine Act cannot be avoided simply by asserting that state law refuses to recognize such elections when made on behalf of minor who subsequently files Vaccine Act petition. *Salceda v Secretary of Health & Human Servs.* (1995, CA FC) 70 F3d 608.

Parents of children allegedly injured by vaccines administered at Air Force hospital may not maintain federal court action alleging that defendants precluded them from pursuing claims under 42 USCS § § 300aa-1 et seq., where parents failed to file VICA petition in Court of Federal Claims or to elect in writing to deny judgment of that court, because 42 USCS § 300aa-11(a)(2) clearly requires filing such petition prior to filing suit in federal court. *Brown v Secretary of the Dep't of Health & Human Servs.* (1994, SD Ind) 874 F Supp 238, affd without op (1995, CA7 Ill) 61 F3d 905, reported in full (1995, CA7 Ill) 1995 US App LEXIS 16451.

Fact that different legal representatives brought state and federal action seeking compensation for child does not mean that different "persons" filed action for purposes of applying 42 USCS § 300a-11; focus is on person who sustained injury or death, not on representative. *Salceda v Secretary of Dep't of Health & Human Servs.* (1994) 30 Fed Cl 316, on remand, dismd (1994, Ct Fed Cl) 1994 US Claims LEXIS 75, affd (1995) 33 Fed Cl 164, affd (1995, CA FC) 70 F3d 608.

References in Vaccine Act to "petitioners under 300aa-11" do not indicate that 42 USCS § 300aa-11(b) is intended to abrogate right of estate of vaccine-injured person to receive compensation on person's behalf. *Andrews v Secretary of the Dep't Health & Human Servs.* (1995) 33 Fed Cl 767.

Filing of administrative claim with agency (for example, under Federal Tort Claims Act) does not constitute relevant date for application of saving provisions of 42 USCS § 300aa-11(a)(2)(B). *Brown v Secretary of the HHS* (1996) 36 Fed Cl 435, affd (1997, CA FC) 1997 US App LEXIS 7616.

Effective date to which 42 USCS § 300aa-11(a)(5) refers is 10/1/88. *Bouley by & Through Collier v Secretary of HHS* (1997) 37 Fed Cl 227, affd without op (1998, CA FC) 152 F3d 940, reported in full (1998, CA FC) 1998 US App LEXIS 4056.

Three qualifying classes of petitioners under Act are (1) living persons who have sustained vaccine-related injury, (2) those who are legal representatives of living persons who have sustained vaccine-related injury, and (3) those who are legal representatives of estates of persons who died as result of administration of vaccine. *Cohn v United States* (1999) 44 Fed Cl 658.

Those persons who are legal representatives of estates of persons who were injured, but did not die, as result of administration of vaccine, but who died before petition was filed, do not qualify as petitioners under Act. *Cohn v United States* (1999) 44 Fed Cl 658.

Mere temporal association was not sufficient to prove causation in fact, and treating neurologist's opinion that MMR vaccine was possible cause of minor's epilepsy and speech deficit did not satisfy parents' burden to show that vaccine probably caused illness. *Finley v Sec'y of the HHS* (2002, Ct Fed Cl) 2002 US Claims LEXIS 163, affd (2003) 55 Fed Cl 355.

Mother was entitled to reasonable compensation in her action filed on behalf of her son for compensation under National Childhood Vaccine Injury Act of 1986, 42 USCS § 300aa-1 et seq., when mother proved prima facie case of causation in fact that HiB vaccine was substantial factor in causing her son's acute transverse myelitis and/or acute disseminated encephalomyelitis and that, but for his vaccination, he would not have endured his catastrophic illness. *Camerlin v Sec'y of HHS* (2003, Ct Fed Cl) 63 Fed Rules Evid Serv 186.

2. Bringing civil action construed

42 USCS § 300aa-11 refers to withdrawal of "action" and state law defines action as one or more claims; thus, order dismissing case without prejudice under authority of § 300aa-11 dismissed case in its entirety, plaintiff was free to pursue state action, and defendant's motion for summary judgment on ground of claim preclusion was properly denied. *Knox v Lederle Lab., Div. of Am. Cyanamid Co.* (1993, CA10) 4 F3d 875.

Suit by parents against manufacturers and distributors of antibiotic medication with which deceased child was treated prior to receipt of final DPT vaccination, was not "civil action" within meaning of Vaccine Act inasmuch as it was not against vaccine administrator or manufacturer. *Schumacher v Secretary of Dep't of Health & Human Servs.* (1993, CA FC) 2 F3d 1128.

Proceedings in state probate court approving settlement between plaintiff parent and child's physician did not constitute civil action in bar of suit under Vaccine Act. *Schindler v Secretary of the Dep't of Health & Human Servs.* (1994, CA FC) 29 F3d 607.

Word "bring" in phrase "bring a civil action" in 42 USCS § 300aa-11 is equivalent to "filing" or "commencing" action. *Lamb v Secretary of HHS* (1991) 24 Cl Ct 255.

Because dismissing parents' individual claims during pendency of Court of Federal Claim's jurisdiction might preclude parents from bringing their claims in any forum, parents' individual causes of action were stayed until their son's claims had been administered in Court of Federal Claims under National Childhood Vaccine Injury Act of 1986. *Liu v Aventis Pasteur, Inc.* (2002, WD Tex) 219 F Supp 2d 762.

Vaccine Act's tort suit ban does not apply to individuals who cannot file petition in Vaccine Court except in representative capacity; Act does not preclude parents of children allegedly injured by vaccine ingredient from filing individual civil action for losses incurred by them. *Blackmon v Am. Home Prods. Corp.* (2002, SD Tex) 267 F Supp 2d 667.

Petitioner's filing of writ of summons in state court initiating civil action against vaccine manufacturers and treating hospital, stating nothing about nature of claim on its face and requiring no response from defendants, does not deprive plaintiff of right to proceed under Vaccine Act. *Joseph v Secretary of Dep't of Health & Human Servs.* (1993) 29 Fed Cl 796.

Where plaintiff suing on behalf of her daughter in federal court under Vaccine Act was named guardian in civil suit brought in state court by child's father, and where plaintiff had signed original state complaint, thereby acquiescing in its filing, she is deemed to have brought state action and her federal action will therefore be dismissed. *Salceda v Secretary of the Dep't of Health & Human Servs.* (1995) 33 Fed Cl 164, affd (1995, CA FC) 70 F3d 608.

3. Civil action as bar to suit

Vaccine Act does not bar family of vaccine victim from bringing tort suit in state court to obtain compensation for their own, related injuries, in particular loss of consortium. *Schafer v American Cyanamid Co.* (1994, CA1 Mass) 20 F3d 1, CCH Prod Liab Rep P 13850.

Vaccine Act contains favorable remedy for those who deny themselves relief under 42 USCS § 300aa-11(a)(5)(B), which prohibits filing of Vaccine Act petition in which petitioner has co-pending civil action, irrespective of date of that co-pendency; under § 300aa-11(a)(2)(B), petitioner may retain benefit of filing date of dismissed civil action for purpose of statutory limitations period, if she files petition within one year of dismissal. *Flowers v Secretary of the Dep't of Health & Human Servs.* (1995, CA FC) 49 F3d 1558.

Claimants were barred from filing petition for compensation under Vaccine Act alleging that child suffered paralysis in legs as result of oral polio vaccine, where they had previously filed and voluntarily dismissed state action alleging that child suffered paralysis in his legs as result of DPT vaccination. *Martin by & Through Martin v Secretary of Health & Human Servs.* (1995, CA FC) 62 F3d 1403.

If claimant elects to pursue claim under Vaccine Act, claimant must dismiss any other pending action. *Amendola v Secretary of HHS* (1991) 23 Cl Ct 621, affd (1993, CA) 989 F2d 1180.

Parents' claim is not dismissed against pharmaceutical company, where their child's death was allegedly caused by diphtheria, pertussis and tetanus vaccination, because most recent congressional legislation--National Childhood Vaccine Injury Act--shows no intent to forbid state tort remedies for vaccine-related injuries. *Patten v Lederle Laboratories* (1987, DC Utah) 655 F Supp 745.

Federal Food, Drug, and Cosmetic Act (21 USCS § § 301 et seq.) and National Childhood Vaccine Injury Act of 1986 (42 USCS § § 300aa-1 et seq.) do not preempt state tort remedies for DPT-vaccine-related injuries, in action against manufacturer by parents of child allegedly injured by vaccine. *Foyle v Lederle Laboratories* (1987, ED NC) 674 F Supp 530, CCH Prod Liab Rep P 11710, 6 UCCRS2d 89.

Tort claims for children's injuries were barred for failure to file vaccine program petition under the National Childhood Vaccine Injury Act, 42 USCS § § 300aa-1--300aa-34, but the children's representatives' derivative tort claims were not barred, nor were tort claims barred against manufacturers of vaccine ingredient. *Owens v Am. Home Prods. Corp.* (2002, SD Tex) 203 F Supp 2d 748.

Because state did not recognize parent's claim for loss of consortium of child, such claims were dismissed, however, parent could make claim for loss of services of child in state court and, therefore, parents' loss of services claims survived dismissal; moreover, loss of services claims were not subject to exhaustion under 42 USCS § 300aa-11 of National Childhood Vaccine Injury Act, 42 USCS § 300aa-1 to -34, but because they were derivative of children's vaccine-related claims, claims were stayed pending exhaustion and resolution of children's claims before Court of Federal Claims. *Laughter v Aventis Pasteur, Inc.* (2003, MD NC) 291 F Supp 2d 406.

Fact that state court dismissed civil action nunc pro tunc, to date prior to plaintiff's filing Vaccine Act petition in federal court, did not cure fact that petitioner had pending civil action in state court, and federal court therefore had no jurisdiction. *Hamilton v Secretary of Health & Human Servs.* (1993) 28 Fed Cl 315.

Although federal court ruled that state court's nunc pro tunc order had effect of voluntarily dismissing civil action against vaccine administrator, thereby establishing federal court's jurisdiction to award petitioner compensation under 42 USCS § 300aa-11(a)(5)(A), federal court remained without jurisdiction to award compensation under § 300aa-11(a)(5)(B). *Matos by Rivera v Secretary of the Dep't of Health & Human Servs.* (1993) 30 Fed Cl 223.

Suit filed in state court against various defendants by parents of child who sustained vaccine-related injuries on their own behalf is bar to suit under Vaccine Act on child's behalf where prior suit is replete with statements describing damages to child and where such recitations are not merely descriptive of extent of loss of services experienced by parents but are specific allegations of damages and expenses suffered by child. *Benedict v Secretary of Health & Human Servs.* (1993) 29 Fed Cl 587, app dismd without op (1993, CA FC) 22 F3d 1102, reported in full (1993, CA FC) 1993 US App LEXIS 38144.

State court's nunc pro tunc order, dismissing state civil action brought by parent against drug manufacturer, as of 1988, was bar to Vaccine Act suit brought in 1990. *Hood v Secretary of the Dep't of Health & Human Servs.* (1995) 34 Fed Cl 175, affd (1996, CA FC) 1996 US App LEXIS 17721.

4. --Settlement as bar to recovery

Settlement in prior damage action brought by petitioner against county health department and state department of health barred subsequent recovery under Vaccine Act on both evidentiary and jurisdictional grounds. *Head v Secretary of Dep't of Health & Human Servs.* (1992) 26 Cl Ct 546, affd without op (1993, CA) 996 F2d 318, reported in full (1993, CA FC) 1993 US App LEXIS 8402.

Petitioner's prior settlement of civil action for vaccine injuries bars further recovery under Vaccine Act even though settlement did not fully compensate petitioner for injuries. *Snowdon v Secretary of Health & Human Servs.* (1993) 27 Fed Cl 434.

Either award of damages, or settlement, in civil action against administrator of vaccine bars plaintiff from access to Vaccine Act's compensation program, despite fact that suit was begun prior to effective date of Act. *Wiggins v Secretary of HHS (1990, CA) 898 F2d 1572*.

Petitioners who had sued physicians who administered vaccine, and, who had collected settlement, were barred by 42 USCS § 300aa-11 from recovering under Vaccine Injury Compensation Program. *Massing v Secretary of HHS (1991, CA) 926 F2d 1133*.

IDEA and Vaccine Act have different objectives; therefore, what may suffice as acceptable special education plan under IDEA is not to be taken as measure of compensation awardable under Vaccine Act; compensation is awardable under Vaccine Act Program for educational needs not addressed in IEP. *Thomas v Secretary of Health & Human Servs. (1992) 27 Fed Cl 384*.

5. Dismissal of Vaccine Act claim

Petitioners' claim was properly dismissed under 42 USCS § 300aa-11 on ground that they still had action pending in state court when they filed petition under Vaccine Act, where petitioners' attorney mailed both motion to dismiss to state court clerk and petition for compensation under Act to Claims Court on same day but motion to dismiss arrived at state court one day after petition arrived at Claims Court. *Weddel ex rel. Weddel v Secretary of the Dep't of Health & Human Servs. (1994, CA FC) 23 F3d 388*, reh, en banc, den (1994, CA FC) 1994 US App LEXIS 18031.

Because thimerosal was not adulterant or contaminant under National Childhood Vaccine Injury Act of 1986, plaintiff child's alleged injuries were vaccine-related, and Act required court to dismiss plaintiffs' claims without prejudice to refiling after they had exhausted requirements under Vaccine Act. *Liu v Aventis Pasteur, Inc. (2002, WD Tex) 219 F Supp 2d 762*.

Because thimerosal was not adulterant or contaminant under National Childhood Vaccine Injury Act of 1986, plaintiff child's alleged injuries were vaccine-related, and Act required court to dismiss plaintiffs' claims without prejudice to refiling after they had exhausted requirements under Act. *Liu v Aventis Pasteur, Inc. (2002, WD Tex) 219 F Supp 2d 762*.

Court deferred to interpretation of Office of Special Masters (OSM) that thimerosal was constituent, rather than contaminant, which gave jurisdiction over action to OSM under 42 USCS 300aa-11(a)(2)(A), and court stayed plaintiffs' action under National Vaccine Injury Compensation Program, 42 USCS § 300aa-10 et seq., for injuries caused by thimerosal to allow adjudication in Vaccine Court, rather than dismissing it, due to statute of limitations concerns. *Wax v Aventis Pasteur, Inc. (2002, ED NY) 240 F Supp 2d 191*.

Parent's claim that defendants were liable for son's exposure to mercury was dismissed where, inter alia, corporation producing substance with mercury used in vaccine lacked special relationship with parent requiring duty to warn. *Murphy v Aventis Pasteur (2003, ND Ga) 270 F Supp 2d 1368*.

Because plaintiff parents had not first exhausted their remedies under National Childhood Vaccine Injury Act, 42 USCS § § 300aa-1 to 300aa-34, by filing suit against government in Court of Federal Claims before filing civil proceedings on behalf of their children, claims were dismissed without prejudice pending exhaustion and resolution of their petitions filed with Court of Federal Claims pursuant to procedures of Act. *Laughter v Aventis Pasteur, Inc. (2003, MD NC) 291 F Supp 2d 406*.

Vaccine Act claim will be dismissed where plaintiffs, although unsuccessful, had previously sued doctor who administered vaccine for malpractice. *Amendola v Secretary, HHS (1993, CA) 989 F2d 1180*.

42 USCS § 300aa-11(a) does not prohibit jurisdiction over vaccine claim where petitioner has filed parallel state civil claim; after filing vaccine claim, dismissal of state action, rather than vaccine claim, is appropriate to cure procedural situation. *Klahn v Secretary of the Dep't of Health & Human Servs. (1994) 31 Fed Cl 382* (criticized in *Brown v Secretary of the Health & Human Servs. (1995) 34 Fed Cl 663*).

While claimant's symptoms after Tetanus vaccinations were similar to those occurring from brachial neuritis, injury listed in Vaccine Injury Table, there were also many other illnesses which possibly caused symptoms, and dismissal of claimant's petition was warranted since claimant failed to provide expert medical evidence categorizing symptoms as specific manifestations of listed injury. *Keith v Sec'y of HHS (2003) 55 Fed Cl 791*.

Dismissal of petition was warranted where claimant failed to provide expert medical evidence that causal link existed between Tetanus vaccinations and asserted aggravation of claimant's pre-existing brain stem defect, or that aggravation of condition in fact occurred. *Keith v Sec'y of HHS (2003) 55 Fed Cl 791*.

In action by nurse, alleging neurological injury after she received two hepatitis B vaccinations and seeking recovery under National Childhood Vaccine Injury Act, 42 USCS § 300aa-1 et seq., court found that nurse had not met her burden of proving special master's decision dismissing claim was arbitrary, capricious, abuse of discretion, or otherwise not in accordance with law; in absence of valid medical opinion supporting logical sequence of cause and effect to

explain alleged injury, special master reasonably concluded that nurse did not present prima facie case of vaccine injury. *Gardner-Cook v Sec'y of HHS* (2003) 59 Fed Cl 38.

6. Contents of petition

Where original, timely petition failed to show unreimbursed expenses of \$ 1000, supplemental petition may be used to show additional expenses incurred within period of limitations even though filed after expiration of period of limitations for showing expenses. *Black v Secretary of Health & Human Servs.* (1996, CA FC) 93 F3d 781.

Provision in Vaccine Injury Compensation Act eliminating threshold requirement that petitioners show they incurred unreimbursable expenses related to vaccine injury in excess of \$ 1000 applies to all cases pending when Act went into effect. *Lowry by & Through Lowry v Secretary of HHS* (1999, CA FC) 189 F3d 1378.

Term "return" as contemplated by 42 USCS § 300aa-11(c)(1)(B)(III), establishing jurisdiction under Vaccine Act in respect of injured person who has returned to United States no later than 6 months after vaccination, means permanent return and not physical presence for any fleeting period of time. *McGowan v Secretary of the Dep't of Health & Human Servs.* (1994) 31 Fed Cl 734.

Word "incurred" in 42 USCS § 300aa-11 requires that obligation to pay unreimbursable expense be incurred prior to filing petition, not that expense actually be paid. *Black v Secretary of the Dep't of Health & Human Servs.* (1995) 33 Fed Cl 546 (criticized in *Long v Secretary of the Dep't of Health & Human Servs.* (1995, Ct Fed Cl) 1995 US Claims LEXIS 244) and affd (1996, CA FC) 93 F3d 781 and (criticized in *Jessen v Secretary of Health & Human Servs.* (1997, Ct Fed Cl) 1997 US Claims LEXIS 20).

Petitioners did not satisfy requirement that they incur unreimbursable vaccine-related expenses in excess of \$ 1000 where such expenses were funded by Medicaid. *Rodriguez v Secretary of Health & Human Servs.* (1995) 34 Fed Cl 57, affd (1996, CA FC) 93 F3d 781.

LEXSTAT 42 USCS 300AA-12

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*** CURRENT THROUGH P.L. 109-6, APPROVED 3/31/05 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
PROGRAM REQUIREMENTS

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-12 (2005)

§ 300aa-12. Court jurisdiction

(a) General rule. The United States Claims Court [United States Court of Federal Claims] and the United States Claims Court [United States Court of Federal Claims] special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 2111 [42 USCS § 300aa-11] is entitled to compensation under the Program and the amount of such compensation. The United States Claims Court [United States Court of Federal Claims] may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties.

(1) In all proceedings brought by the filing of a petition under section 2111(b) [42 USCS § 300aa-11(b)], the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28, United States Code.

(2) Within 30 days after the Secretary receives service of any petition filed under section 2111 [42 USCS § 300aa-11] 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--

(A) relating to the existence of the evidence described in section 2113(a)(1)(B) [42 USCS § 300aa-13(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) [42 USCS § 300aa-11(c)(1)(C)(ii)].

(c) United States Claims Court [United States Court of Federal Claims] special masters.

(1) There is established within the United States Claims Court [United States Court of Federal Claims] an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Claims Court [United States Court of Federal Claims] shall appoint the special masters, 1 of whom, by designation of the judges of the United States Claims Court [United States Court of Federal Claims], shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Claims Court [United States Court of Federal Claims] for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Claims Court [United States Court of Federal Claims] determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters upon the date of the enactment of this subsection [enacted Dec. 19, 1989] shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on the date of the enactment of this subsection [enacted Dec. 19, 1989] shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Claims Court [United States Court of Federal Claims], upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5, United States Code. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5, United States Code.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts [United States Court of Federal Claims] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrates shall be applied to the special masters.

(D) Coordinating with the United States Claims Court [United States Court of Federal Claims] the use of services, equipment, personnel, information, and facilities of the United States Claims Court [United States Court of Federal Claims] without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Claims Court [United States Court of Federal Claims] on the number of petitions filed under section 2111 [42 USCS § 300aa-11] and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters.

(1) Following the receipt and filing of a petition under section 2111 [42 USCS § 300aa-11], the clerk of the United States Claims Court [United States Court of Federal Claims] shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Claims Court [Court of Federal Claims] and, taking into account such recommended rules, the Claims Court [Court of Federal Claims] shall promulgate rules pursuant to section 2071 of title 28, United States Code. Such rules shall--

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Claims Court [United States Court of Federal Claims].

(3) (A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall--

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Claims Court [United States Court of Federal Claims] in accordance with subsection (e).

- (B) In conducting a proceeding on a petition a special master--
- (i) may require such evidence as may be reasonable and necessary,
 - (ii) may require the submission of such information as may be reasonable and necessary,
 - (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,
 - (iv) shall afford all interested persons an opportunity to submit relevant written information--
 - (I) relating to the existence of the evidence described in section 2113(a)(1)(B) [42 USCS § 300aa-13(a)(1)(B)],
- or
- (II) relating to any allegation in a petition with respect to the matters described in section 2111(c)(1)(C)(ii) [42 USCS § 300aa-11(c)(1)(C)(ii)], and
 - (v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before the effective date of this part, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4) (A) Except as provided in subparagraph (B), information submitted to a special master or the court 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.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information--

- (i) which is trade secret or commercial or financial information which is privileged and confidential, or
- (ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by the United States Claims Court [United States Court of Federal Claims].

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Claims Court [United States Court of Federal Claims] a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Claims Court [United States Court of Federal Claims] no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Claims Court [United States Court of Federal Claims] shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter--

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
 - (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law,
- or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Claims Court [United States Court of Federal Claims] takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Claims Court [United States Court of Federal Claims] shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals. The findings of fact and conclusions of law of the United States Claims Court [United States Court of Federal Claims] 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 Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's [United States Court of Federal Claims'] judgment with such court of appeals.

(g) Notice. If--

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Claims Court [United States Court of Federal Claims] fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 2121(b) [42 USCS § 300aa-21(b)] or the petitioner may choose under section 2121(b) [42 USCS § 300aa-21(b)] to have the petition remain before the special master or court, as the case may be.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2112, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3761; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § § 4303(d)(2)(A), 4307(3), 4308(a), (b), 101 Stat. 1330-222, 224; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(o)(3)(A), 102 Stat. 808; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(d)-(i), 103 Stat. 2286; Nov. 3, 1990, P.L. 101-502, § 5(b), 104 Stat. 1286; Nov. 26, 1991, P.L. 102-168, Title II, § 201(c), (d)(1), (h)(2), (3), 105 Stat. 1103, 1104; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch B, Part IV, § 13632(c), 107 Stat. 646.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

The "effective date of this part", referred to in this section, is Oct. 1, 1988, as provided by § 323 of Act Nov. 14, 1986, P.L. 99-660, which appears as 42 USCS § 300aa-1 note.

Explanatory notes:

A prior § 300aa-12 (Act July 1, 1944, ch 373, Title XXI[V], § 2113 [513], as added June 30, 1970, P.L. 91-296, Title IV, § 401(a), 84 Stat. 351; Oct. 7, 1980, P.L. 96-398, Title VIII, § 804(c), 94 Stat. 1608; Aug. 13, 1981, P.L. 97-35, Title IX, Subtitle A, § 902(g)(3), 95 Stat. 560; April 26, 1983, P.L. 98-24, § 2(a)(1), 97 Stat. 176) was redesignated § 2711 of Title XXVII of such Act and appears as 42 USCS § 300aaa-10.

A prior § 2112 of Act July 1, 1944, ch 373, Title XXI, which formerly appeared as 42 USCS § 300aa-11 was redesignated § 2710 of Title XXVII of such Act and now appears as 42 USCS § 300aaa-9.

The bracketed words "United States Court of Federal Claims" and "Court of Federal Claims" were inserted in this section pursuant to § 902(b) of Act Oct. 29, 1992, P.L. 102-572 (28 USCS § 171 note), which provides that reference in any Federal law or document to the United States Claims Court shall be deemed to refer to the United States Court of Federal Claims and that reference in any Federal law or document to the Claims Court shall be deemed to refer to the Court of Federal Claims.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as 42 USCS § 300aa-1 note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), substituted "United States Claims Court" for "district courts of the United States" and "the court" for "the courts"; in subsec. (c)(1), substituted "the United States Claim Court" for "the district court of the United States in which the petition is filed"; redesignated former subsec. (g) as subsec. (e); and deleted subsecs. (e) and (f), which read:

"(e) 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)

(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."

Such Act further, as amended July 1, 1988 (effective as if included in Act Dec. 22, 1987, P.L. 100-203, as provided by § 411(a)(2) of Act July 1, 1988, which appears as *1 USCS 106* note), in subsec. (c)(2), in the introductory matter, inserted ", shall prepare and submit to the court proposed findings of fact and conclusions of law," in subpara. (C), inserted "and" following "compensation," in subpara. (D), substituted a period for ", and", and deleted subpara. (E), which read: "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."; and, in subsec. (e)(1) as redesignated, substituted "the United States Claims Court" for "a district court of the United States", substituted "for the Federal Circuit" for "for the circuit in which the court is located", and inserted "within 60 days of the date of the judgment".

1988. Act July 1, 1988 amended Act Dec. 22, 1987 by correcting the directory language of § 4307 of such Act to make it apply to subsec. (e) as redesignated, instead of subsec. (g), and added § 4308 to Act Dec. 22, 1987, P.L. 100-203, containing the amendments to subsecs. (c) and (e) of this section.

1989. Act Dec. 19, 1989 (applicable as provided by § 6601(s) of such Act, which appears as *42 USCS § 300aa-10* note), in subsec. (a), substituted "and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction" for "shall have jurisdiction (1)", inserted a period following "compensation", and substituted "The United States Claims Court may issue" for ", and (2) to issue" and "deems" for "deem"; in subsec. (b), substituted para. (1) for one which read: "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."; redesignated subsecs. (c)-(e) as subsecs. (d)-(f), respectively and added a new subsec. (c); substituted a new subsec. (d) for subsec. (d) as redesignated, which read:

"(d) Special masters.

(1) Following receipt of a petition under subsection (a), the United States Claims Court 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, shall prepare and submit to the court proposed findings of fact and conclusions of law, 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 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, and

"(D) conduct such hearings as may be appropriate.

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.";

and substituted a new subsec. (e) for subsec. (e) as redesignated, which read:

"(e) Action by the court.

(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."

Such Act further (applicable as above), in subsec. (f) as redesignated, inserted "within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals".

1990. Act Nov. 3, 1990 (effective 9/30/90 as provided by § 5(h) of such Act, which appears as 42 USCS § 300aa-11 note), in subsec. (d)(3), added subpara. (D); and added subsec. (g).

1991. Act Nov. 26, 1991 (effective on enactment, as provided by § 201(i)(1) of such Act, which appears as 42 USCS § 300aa-11 note), in subsec. (d)(3)(D), substituted "540 days" for "180 days"; and made technical corrections which did not affect the text of this section.

Such Act further (effective on and after 10/1/88, as provided by § 201(i)(2) of such act, which appears as 42 USCS § 300aa-11 note), in subsec. (g), in the concluding matter, substituted "or the petitioner may choose under section 2121(b) to have the petition remain before the special master or court, as the case may be" for "and the petition will be considered withdrawn under such section if the petitioner, the special master, or the court do not take certain actions".

1993. Act Aug. 10, 1993, in subsec. (d)(3)(D), substituted "30 months (but for not more than 6 months at a time)" for "540 days".

Other provisions:

Review under subsec. (f). Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 322(c), as added Nov. 3, 1990, P.L. 101-502, § 5(g)(2), 104 Stat. 1288, provides: "If the review authorized by section 2112(f) [subsec. (f) of this section] is held invalid because the judgment of the United States Claims Court [United States Court of Federal Claims] being reviewed did not arise from a case or controversy under Article III of the Constitution, such judgment shall be reviewed by a 3-judge panel of the United States Claims Court [United States Court of Federal Claims]. Such panel shall not include the judge who participated in such judgment."

NOTES:

Related Statutes & Rules:

This section is referred to in 42 USCS § § 300aa-11, 300aa-15, 300aa-21.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § § 35:729-730, 732-734, 737.

Law Review Articles:

National Senior Citizens Law Center, Financing Expanded Medicare Benefits Under the Medicare Catastrophic Coverage Act of 1988. 22 *Clearinghouse Rev* 1393.

National Health Law Program, Health Care for the Poor in 1988. *Clearinghouse Rev* 981, January, 1989.

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Interpretive Notes and Decisions: **I. SPECIAL MASTERS** 1. Authority 2. Evidence 3. Decisions

II. UNITED STATES COURT OF FEDERAL CLAIMS 4. Statute of limitations 5. Judicial review 6. --Standard of review

III. APPEALS 7. Jurisdiction 8. Standard of review

I. SPECIAL MASTERS

1. Authority

It was not necessary for Special Master to take testimony of petitioner's medical expert where Special Master concluded that expert based his opinion on facts not substantiated by record. *Burns v Secretary of Dep't of Health & Human Servs.* (1993, CA FC) 3 F3d 415.

Unlike court, which has express authority under Rule 60 to afford relief from final judgment, special master is without such power under Vaccine Act; thus, special master exceeded authority in amending her judgment to correct inadvertent

omission of award for pain and suffering. *Patton v Secretary of the Dep't of Health & Human Servs.* (1994, CA FC) 25 F3d 1021, 29 FR Serv 3d 682.

It is not abuse of Special Master's discretion to consider new pertinent medical evidence that was not available at time of original petition. *Hanlon v Secretary of HHS* (1999, CA FC) 191 F3d 1344, reh, en banc, den (1999, CA FC) 1999 US App LEXIS 29880 and cert den, motion den (2000, US) 147 L Ed 2d 245, 120 S Ct 2212.

Absent congressional direction to deprive Court of Appeals of jurisdiction under facts presented in 42 USCS § 300aa-11, Special Master is not divested of jurisdiction when petitioner files second suit in state court. *Mass ex rel. Mass v Secretary of Health & Human Servs.* (1994) 31 Fed Cl 523.

Special master lacks power to relieve parties from final judgment; once clerk of court enters judgment in accordance with special master's decision, special master may not re-assert jurisdiction to amend that decision. *Patton v Secretary of Dep't of Health & Human Servs.* (1993) 28 Fed Cl 532, affd, remanded (1994, CA FC) 25 F3d 1021, 29 FR Serv 3d 682.

Because Special Master's jurisdiction ended when clerk entered judgment, Special Master had no authority to vacate judgment and issue amended judgment to correct typographical error; Court of Federal Claims has jurisdiction to set aside judgment and correct clerical error. *Garcia v Secretary of Health & Human Servs.* (1994) 31 Fed Cl 276.

Petitioner's motion to correct judgment on ground that final award did not reflect agreement to make separate award for pain and suffering will be denied, where judgment was not void for lack of jurisdiction or because court violated petitioner's due process rights; award for pain and suffering is discretionary rather than ministerial act, and no relief can be provided even if Special Master intended to award pain and suffering; absent evidence of record that Special Master intended to grant award for pain and suffering, judgment's failure to reflect such award cannot be termed clerical mistake. *Bridgham by Libby v Secretary of the Dep't of Health & Human Servs.* (1995) 33 Fed Cl 101.

Special masters lack jurisdiction after judgment is entered; thus, once clerk of court entered special master's dismissal order, every subsequent order entered by special master was rendered nullity because special master no longer had jurisdiction over case. *Reitz v United States* (1997) 37 Fed Cl 330, subsequent app (1998, Ct Fed Cl) 1998 US Claims LEXIS 102.

Special master, who is both trier of fact and decider of law, is not simply arbiter of expert's opinions; since determining weight and credibility of evidence is special province of trier of fact, special master is free to accept or reject portions of expert medical opinions presented to him in light of entire record. *Lampe v Secretary of HHS* (1998) 42 Fed Cl 632.

Special master was adjudicative fact finder charged with applying existing legal precedent to decide particular case based on record before him or her but ultimately was not law maker or interpreter, and special master was not authorized to impose or even determine particular analytical framework to be used in Vaccine Act claims; thus, court completed its own analysis and reversed special master's denial of petitioner's claim for non-table injury, optic neuritis and subsequent demyelinating illness symptoms, and remanded for award of compensation to petitioner, reasonable attorneys fees, and other costs. *Althen v Sec'y of HHS* (2003) 58 Fed Cl 270, CCH Prod Liab Rep P 16763, 62 Fed Rules Evid Serv 1386.

2. Evidence

Where evidentiary record contains life plan from both petitioner and respondent, 3 supplemental life plans submitted by petitioner, information from treating physicians, and video tape of petitioner demonstrating his range of movement, record was sufficient to permit special master to make reasoned decision without evidentiary hearing. *Plummer v Secretary of HHS* (1991) 24 Cl Ct 304.

State law does not govern decisions under Vaccine Act; thus, state law recognizing, as satisfactory, testimony as to medical possibility rather than probability is inapplicable. *Van Epps v Secretary of HHS* (1992) 26 Cl Ct 650.

Under 42 USCS § 300aa-12(d)(2)(B), special master is allowed to include flexible and informal standards of admissibility of evidence; special master is not bound by Federal Rules of Evidence, and is free to consider all relevant evidence presented in case. *Epstein v Secretary of the HHS* (1996) 35 Fed Cl 467.

Vaccine Act does not oblige special master to hold evidentiary hearing; decision to convene hearing is discretionary one. *Hovey v Secretary of HHS* (1997) 38 Fed Cl 397, app dismd (1997, CA FC) 135 F3d 773, reported in full (1997, CA FC) 1997 US App LEXIS 36209.

Range of evidence that special master may consider is not governed by discovery or evidentiary rules applicable in federal district courts. *Wittner v Secretary of HHS* (1999) 43 Fed Cl 199.

In case under National Childhood Vaccine Injury Act of 1986, 42 USCS § § 300aa-11 to -34, special master's findings that medical conditions child had at birth had not been completely resolved were not arbitrary and capricious or

abuse of discretion; special master relied upon statements of experts about relevant events in medical records. *Tebcherani v Sec'y of HHS (2003) 55 Fed Cl 460.*

3. Decisions

Date of "issuance" of special masters' decision is not date on which it is received by petitioners' counsel, but date on which decision is filed with *Clerk of Court of Federal Claims*. *Hervey v Secretary of HHS (1996, CA FC) 88 F3d 1001, cert den (1996) 519 US 1010, 136 L Ed 2d 404, 117 S Ct 515.*

Despite fact that special master's ground for denying party's motion to amend was unreasonable, motion will not be granted where party submits information casting substantial doubt on its ability to prevail on its own claim; leave to amend would therefore be futile. *Koston v Secretary of HHS (1991) 23 Cl Ct 597, affd (1992, CA) 974 F2d 157.*

Fact that Chief Special Master relied upon cases decided after Vaccine Act hearing to support his opinion does not indicate that he was attempting to "justify his personal bias" as alleged by petitioners; it simply indicates that he relied on most recent cases to ensure proper decision. *Aea v United States (1992) 26 Cl Ct 878, affd without op sub nom Aea v Secretary of Dep't of Health & Human Servs. (1993, CA FC) 6 F3d 787, reported in full (1993, CA FC) 1993 US App LEXIS 23947.*

Special Master's decision, issued during tolling of limitations period, under 42 USCS § 300aa-12(d)(3), is "issued" for purpose of triggering 30-day period in which to file motion to review decision under § 300aa-12(e)(1). *Widdoss v Secretary of Health & Human Servs. (1993, CA) 989 F2d 1170, cert den (1993) 510 US 944, 126 L Ed 2d 331, 114 S Ct 381.*

Special Master's sua sponte reversal of her own findings was understandable and appropriate where she was required to reopen case and reexamine evidence in light of new case rulings. *Brown v Secretary of the Dep't of Health & Human Servs. (1995) 34 Fed Cl 152.*

Petitioner parents were denied compensation under National Vaccine Injury Compensation Act, 42 USCS § § 300 aa-10 through aa-23, where special master's ruling that their child's measles-mumps-rubella vaccination was not cause of his epilepsy was based on testimony of qualified witness with opinions fully backed by medical literature, and thus was held not to be arbitrary and capricious. *Finley v Sec'y of the HHS (2003) 55 Fed Cl 355.*

II. UNITED STATES COURT OF FEDERAL CLAIMS

4. Statute of limitations

30-day time period in which to file motion for review under 42 USCS § 300aa-12 is jurisdictional; thus, motion to review filed 63 days after special master's dismissal of petition with prejudice must be dismissed. *Dodson v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 550.*

Court cannot discern from 42 USCS § 300aa-12 any legislative intent to preclude equitable tolling; thus, where petitioner filed motion for review one day beyond 30-day statutory time period because established overnight carrier failed to live up to its guarantee, and exercised due diligence in preserving her legal rights, motion for reconsideration will be granted. *Raspberry v Secretary of the Dep't of Health & Human Servs. (1995) 32 Fed Cl 777, subsequent app (1995) 33 Fed Cl 420.*

Petitioners failed to proceed with due diligence, and 30-day time limit for filing review of Special Master's decision was not tolled by one day, where they failed to secure copy of transcript at earlier date and then relied on same-day, next-flight out delivery. *Her by Her v Secretary of the Dep't of Health & Human Servs. (1995) 33 Fed Cl 542.*

In interests of fundamental fairness, court will vacate dismissal and grant petition for review where, although petition was untimely, petitioner acted properly upon finding she was no longer represented by counsel and showed concern with conforming to time requirements, and untimeliness of filing was due to circumstances beyond her control. *Thornton v Secretary of the Dep't of Health & Human Servs. (1995) 34 Fed Cl 72.*

Rule 6(c), which provides additional time after service, is inapplicable to filing of motion for review pursuant to 42 USCS § 300aa-12(e)(1) of National Childhood Vaccine Injury Act, since special master's decision is not required to be served before it is considered issued. *Decker v Sec'y of the HHS (2001) 51 Fed Cl 288.*

Excusable neglect standard of Rule 60(b) cannot be invoked to escape thirty-day time period in which petitioner must file motion for review pursuant to 42 USCS § 300aa-12(e)(1) of National Childhood Vaccine Injury Act. *Decker v Sec'y of the HHS (2001) 51 Fed Cl 288.*

Equitable tolling does not apply to thirty-day time period in which petitioner must file motion for review as provided in 42 USCS § 300aa-12(e)(1). *Decker v Sec'y of the HHS (2001) 51 Fed Cl 288.*

5. Judicial review

In actions brought under National Childhood Vaccine Injury Act (42 USCS § § 300aa-1 et seq.), authority of Court of Federal Claims to grant new trial is limited to reconsidering its decision under standards set forth in 42 USCS § 300aa-12(e)(2). *Turner v Sec'y of HHS (2001, CA FC) 268 F3d 1334.*

Voluntary withdrawal of motion brought under 42 USCS § 300aa-12 for Claims Court review deprived Claims Court of jurisdiction, and court therefore may not entertain motion for reconsideration where it did not have opportunity to pass on sufficiency of findings and conclusions of law. *Wilson v Secretary of HHS (1991) 23 Cl Ct 169.*

Special master's award of attorney fees will not be reviewed where government failed to show sufficient reason why arguments raised in motion for review were not raised earlier. *McMillan v Secretary of HHS (1992) 26 Cl Ct 357.*

Although plaintiffs were awarded costs when they took voluntary dismissal in state court, no jurisdictional impediment existed in federal court under Act. *Goodwin v Secretary of the Dep't of Health & Human Servs. (1992) 27 Fed Cl 1*, reaffirmed, mod, reconsideration den (1992) 27 Fed Cl 374.

Where petitioner's state claim was voluntarily dismissed to pursue federal claim, petitioner is not barred from bringing federal claim even though state court inexplicably taxed costs to defendant. *Goodwin v Secretary of HHS (1992) 27 Fed Cl 374.*

Petitioners' one-page memorandum merely stating their wish to obtain review of special master's decision failed to state any specific objection to decision and will therefore be dismissed. *Malcome v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 529.*

Regardless of whether one could have reached different conclusion about substance of expert testimony, it cannot be said that Special Master's determination in Vaccine Act case was arbitrary and capricious where he plainly articulated rational basis for decision and reduced testimony to its critical elements. *Walker v Secretary of the Dep't of Health & Human Servs. (1995) 33 Fed Cl 97.*

To preserve issue for review, petitioners must argue issue below before special master; argument is not preserved by pointing to facts supporting argument in record. *Hellenbrand-Sztaba v Secretary of Health & Human Servs. (1996) 35 Fed Cl 222*, affd without op (1997, CA FC) 106 F3d 426, reported in full (1997, CA FC) 1997 US App LEXIS 1291.

Decision may be set aside under arbitrary and capricious standard where special master relied on factors that Congress did not intend to be considered, entirely failed to consider important aspect of problem, or offered explanation of decision that runs counter to evidence or is so implausible it could not be ascribed to difference in view or be product of expertise. *Jordan v Secretary of HHS (1993) 38 Fed Cl 148; Thornton v Secretary of the HHS (1996) 35 Fed Cl 432.*

Court of Federal Claims, in reviewing special master's involuntary dismissal of case brought under National Childhood Vaccine Injury Act (42 USCS § § 300aa-1 et seq.), utilizes standards applicable under Court of Federal Claims Rule 41(b). *Sapharas v Secretary of HHS (1996) 35 Fed Cl 503.*

With respect to arbitrary and capricious standard applied to special master's findings of fact, court must consider whether decision was based on consideration of relevant facts and whether there has been clear error of judgment; if special master has considered relevant evidence in record, drawn plausible inferences, and articulated rational basis for decision, reversible error will be extremely difficult to demonstrate. *Dickerson v Secretary of the HHS (1996) 35 Fed Cl 593.*

Court of Federal Claims may review only final decisions of special master; court may not review interim decisions of special master. *Spratling v Secretary of HHS (1997) 37 Fed Cl 202.*

Court of Federal Claims should accord deference to special master's decision and may not substitute its own judgment for that of special master if special master has considered all relevant factors, and has made no clear error of judgment. *Lampe v Secretary of HHS (1998) 42 Fed Cl 632.*

In exercising its jurisdiction, Court of Federal Claims acts not as trial court, but as reviewing authority; that role does not lend itself easily to resolving differing accounts of causation or other factual disputes, nor to weighing credibility and strength of testimony. *Sword v United States (1999) 44 Fed Cl 183.*

In case under National Childhood Vaccine Injury Act of 1986, 42 USCS § § 300aa-11 to -34, where special master found evidence insufficient to determine whether child had viral infection on day child received vaccination, special master committed abuse of discretion by continuing to discuss issue; special master's discussion constituted unreasonable inference that virus may have been somehow related to child's injuries; moreover, special master apparently inappropriately imposed on parent burden of proving that viral infection did not cause child's injuries; pursuant to 42 USCS § 300aa-13(a)(2), Government had burden to prove viral infection was principally responsible for causing child's illness. *Tebcherani v Sec'y of HHS (2003) 55 Fed Cl 460.*

Where alternate claims of Table measles infection and autism were pending, and special master had not yet determined whether parents were entitled to compensation, special master had not issued final decision, and parents' request for review of special master's order that struck portion of expert's affidavits and determination that parents' son had not suffered Table encephalopathy was denied. *Weiss v Sec'y of HHS (2004) 59 Fed Cl 624.*

Special master's denial of individual's request for compensation for injuries allegedly suffered as result of Hepatitis B vaccinations was upheld under 42 USCS § 300aa-12(e)(2)(A) where special master had applied correct legal standard to individual's case, by analyzing whether individual would have been injured but for vaccinations and whether vaccinations were substantial factor in causing alleged neurological defects, and had correctly applied Daubert framework to individual's expert testimony and where nothing in medical literature would have required court to set aside special master's findings. *Guillory v United States* (2003) 59 Fed Cl 121.

6. --Standard of review

In actions brought under National Childhood Vaccine Injury Act (42 USCS § 300aa-1 et seq.), authority of Court of Federal Claims to grant new trial is limited to reconsidering its decision under standards set forth in 42 USCS § 300aa-12(e)(2). *Turner v Sec'y of HHS* (2001, CA FC) 268 F3d 1334.

Claims Court's review of special master's determination of law in child vaccine injury case, although de novo, is limited by congressional intent, and confined to determining whether special master's decision articulates rational connection between facts found and choices made, or whether it is arbitrary and capricious. *Schwenk v Secretary of HHS* (1991) 23 Cl Ct 287, affd without op (1992, CA) 956 F2d 1173, reported in full (1992, CA FC) 1992 US App LEXIS 2741.

Special master's decision should be set aside only if reviewing court finds it to be arbitrary, capricious, abuse of discretion, or otherwise not in accordance with law. *Guy v Secretary of HHS* (1997) 38 Fed Cl 403 (criticized in *Hayden v Secretary of HHS* (1998, Ct Fed Cl) 1998 US Claims LEXIS 179).

Claims Court now applies the arbitrary or capricious standard in its review of the master's decision. *Bunting v* (1991 CA) 931 F2d 867, reh den (1991, CA FC) 1991 US App LEXIS 13225.

A petitioner's burden is not to show a generalized "cause and effect relationship" with listed illnesses, but only to show causation in the particular case.. *Bunting v* (1991 CA) 931 F2d 867, reh den (1991, CA FC) 1991 US App LEXIS 13225.

Determinations of fact entered by special master on basis of evidence contained in record before him are subject to review by Court of Federal Claims under substantial evidence standard; although 42 USCS § 300aa-12(e)(2)(B) employs phrasing "arbitrary, capricious, or abuse of discretion" in describing standard for review of special master's factual findings, these words, when applied to administrative determinations drawn from adjudicated facts, are legally synonymous with term "substantial evidence." *Raines by Raines v Secretary of the HHS* (1991) 35 Fed Cl 356.

Each standard articulated in 42 USCS § 300aa-12(e)(2)(B) applies to different aspect of special master's decision; court evaluates findings of fact under arbitrary and capricious standard, legal conclusions under not in accordance with law standard, and discretionary rulings under abuse of discretion standard. *Epstein v Secretary of the HHS* (1996) 35 Fed Cl 467; *Snyder by Snyder v Secretary of the HHS* (1996) 36 Fed Cl 461, affd (1997, CA FC) 117 F3d 545.

Review by Court of Federal Claims of question of statutory construction requires utilization of "not in accordance with law" standard, which is applicable to review of questions of law. *Grice v Secretary of Health & Human Servs.* (1996) 36 Fed Cl 114.

In determining legal question of whether National Childhood Vaccine Injury Act itself authorizes award of attorney's fees and costs, Court of Federal Claims is not required to give deference to special master's decision on this matter; in contrast, when reviewing special master's decision to award attorney's fees and costs in particular case, Court applies abuse of discretion standard, because determination to award fees and costs is based on discretionary function. *Grice v Secretary of Health & Human Servs.* (1996) 36 Fed Cl 114.

"Not in accordance with law" standard (42 USCS § 300aa-12(e)(2)(B)) which applies to legal questions warrants de novo review. *Giles v Secretary of HHS* (1997) 37 Fed Cl 525, affd (1998, CA FC) 1998 US App LEXIS 11828.

Court must examine whether special master's decision was based on consideration of relevant factors and whether there has been clear error of judgment; error is difficult to demonstrate if special master has considered relevant evidence in record, drawn plausible inferences, and articulated rational basis for decision. *Hovey v Secretary of HHS* (1997) 38 Fed Cl 397, app dismd (1997, CA FC) 135 F3d 773, reported in full (1997, CA FC) 1997 US App LEXIS 36209.

Departure from norm of practice in proceedings under Act (i.e. evidentiary flexibility and informality) does not, in itself, provide sufficient reason to invalidate special master's ruling; what is required is assessment of likelihood that error affected outcome of case. *Kaminski v Secretary of HHS* (1997) 39 Fed Cl 253.

On appeal, issue of whether evidence of record warranted conclusion that vaccine caused injury calls for review under arbitrary and capricious standard. *Huston v Secretary of HHS* (1997) 39 Fed Cl 632.

Special master's decision not to reopen question of liability to consider new exhibits offered by respondent can only be reversed for abuse of discretion. *Erve by & Through Erve v Secretary of HHS* (1997) 39 Fed Cl 607.

Special master's rulings regarding evidence are reviewed for abuse of discretion. *Erve by & Through Erve v Secretary of HHS (1997) 39 Fed Cl 607.*

Special master's decision to credit expert testimony is subject to reversal only if shown to be arbitrary and capricious. *Flanagan v HHS (2000) 48 Fed Cl 169.*

Petitioner parents were denied compensation under National Vaccine Injury Compensation Act, 42 USCS § § 300 aa-10 through aa-23, where special master's ruling that their child's measles-mumps-rubella vaccination was not cause of his epilepsy was based on testimony of qualified witness with opinions fully backed by medical literature, and thus was held not to be arbitrary and capricious. *Finley v Sec'y of the HHS (2003) 55 Fed Cl 355.*

Special master's denial of individual's request for compensation for injuries allegedly suffered as result of Hepatitis B vaccinations was upheld under 42 USCS § 300aa-12(e)(2)(A) where special master had applied correct legal standard to individual's case by analyzing whether individual would have been injured but for vaccinations and whether vaccinations were substantial factor in causing alleged neurological defects, had correctly applied Daubert framework to individual's expert testimony, and nothing in medical literature cited by individual would have required court to set aside special master's findings. *Guillory v United States (2003) 59 Fed Cl 121.*

Special master was not arbitrary or capricious in determining that cause of child's transverse myelitis was respiratory virus, rather than inoculation for oral polio vaccine, and special master's decision was supported by record evidence. *Morris v Sec'y of HHS (2003) 57 Fed Cl 383.*

III. APPEALS

7. Jurisdiction

Petitioner may not seek review in Court of Appeals without first appealing special master's decision to Court of Federal Claims. *Grimes v Secretary of HHS (1993, CA) 988 F2d 1196.*

Neither Office of Special Masters nor Court of Federal Claims has jurisdiction to hear petitioner's claim that authority of Secretary of Health and Human Services to revise Vaccine Injury Table (42 USCS § 300aa-14(c)) represents impermissible delegation of congressional law-making authority; claim for such declaratory relief is only appropriate for consideration by U.S. Court of Appeals. *O'Connell v Secretary of the HHS (1998) 40 Fed Cl 891.*

8. Standard of review

Special master was not arbitrary and capricious where he consulted Institute of Medicine's study commissioned under Vaccine Act, and noted its scope of mission and currency. *Cucuras v Secretary of Health & Human Servs. (1993, CA) 993 F2d 1525.*

Court of Appeals may not disturb judgment of Claims Court unless Court of Appeals finds judgment to be arbitrary, capricious, or abuse of discretion. *Munn v Secretary of Dep't of Health & Human Servs. (1992, CA) 970 F2d 863, 92 Daily Journal DAR 10867.*

Court of Federal Claims reviews fact findings under arbitrary and capricious standard, legal questions under not in accordance with law standard, and discretionary rulings under abuse of discretion standard. *Camery v United States (1998) 42 Fed Cl 381.*

Plain language of statute prohibits de novo standard of review by Court of Federal Claims; thus, special master's conclusions of law, which are entitled to deference, are not subject to de novo review. *Camery v United States (1998) 42 Fed Cl 381.*

Court of Federal Claims should not second-guess credibility determinations of special master unless they are proven to be arbitrary, capricious, abuse of discretion or otherwise not in accordance with law; special master's determinations regarding credibility are virtually unreviewable. *Lampe v Secretary of HHS (1998) 42 Fed Cl 632.*

"Not in accordance with law" standard of review which applies to legal questions warrants de novo review. *Lampe v Secretary of HHS (1998) 42 Fed Cl 632.*

Abuse of discretion standard of review will rarely come into play except where special master excludes evidence. *Lampe v Secretary of HHS (1998) 42 Fed Cl 632.*

In fact and in operation, three of five Stevens elements either significantly changed statutory burden of proof or directly contravened language of Vaccine Act and therefore were erroneous as matter of law, so court reversed and vacated special master's entitlement decision denying petitioner compensation, which applied Stevens elements, and considered petition de novo and concluded that petitioner established causation in fact, though not to medical certainty, and was thus entitled to Vaccine Act relief. *Althen v Sec'y of HHS (2003) 58 Fed Cl 270, CCH Prod Liab Rep P 16763, 62 Fed Rules Evid Serv 1386.*

In action by nurse, alleging neurological injury after she received two hepatitis B vaccinations and seeking recovery under National Childhood Vaccine Injury Act, 42 USCS § 300aa-1 et seq., court found that nurse had not met her burden of proving special master's decision dismissing claim was arbitrary, capricious, abuse of discretion, or otherwise not in accordance with law; in absence of valid medical opinion supporting logical sequence of cause and effect to explain alleged injury, special master reasonably concluded that nurse did not present prima facie case of vaccine injury. *Gardner-Cook v Sec'y of HHS* (2003) 59 Fed Cl 38.

LEXSTAT 42 USCS 300AA-13

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*** CURRENT THROUGH P.L. 109-6, APPROVED 3/31/05 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
PROGRAM REQUIREMENTS

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-13 (2005)

§ 300aa-13. Determination of eligibility and compensation

(a) General rule.

(1) Compensation shall be awarded under the Program to a petitioner if the special master or 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) [42 USCS § 300aa-11(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 special master or 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 special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record--

(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 special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or 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, condition, 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 the special masters of the United States Claims Court [United States Court of Federal Claims] in a proceeding on a petition filed under section 2111 [42 USCS § 300aa-11].

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2113, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3763; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4307(4), 101 Stat. 1330-224; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(j), 103 Stat. 2290; Nov. 3, 1990, P.L. 101-502, § 5(c), 104 Stat. 1287.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Explanatory notes:

A prior § 300aa-13 (Act July 1, 1944, ch 373, Title XXI[V], § 2114 [514], as added Nov. 9, 1978, P.L. 95-623, § 11(e), 92 Stat. 3456; April 26, 1983, P.L. 98-24, § 2(a)(1), 97 Stat. 176) was redesignated § 2712 of Title XXVII of such Act and now appears as 42 USCS § 300aaa-11.

A prior § 2113 of Act July 1, 1944, ch 373, Title XXI, which formerly appeared as 42 USCS § 300aa-12 was redesignated § 2711 of Title XXVII of such Act and now appears as 42 USCS § 300aaa-10.

The bracketed words "United States Court of Federal Claims" were inserted in subsec. (c) on the authority of Act Oct. 29, 1992, P.L. 102-572, Title IX, § 902(b)(1), 106 Stat. 4516, which appears as 28 USCS § 171 note, and which provides that any reference to the United States Claims Court in any Federal law or document shall be deemed to refer to the United States Court of Federal Claims.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as 42 USCS § 300aa-1 note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (c), substituted "the United States Claims Court" for "a district court of the United States".

1989. Act Dec. 19, 1989 (applicable as provided by § 6601(s) of such Act, which appears as 42 USCS § 300aa-10 note), in subsecs. (a) and (b), substituted "special master or court" for "court" wherever appearing; and, in subsec. (c) inserted "special masters of".

1990. Act Nov. 3, 1990 (effective 9/30/90 as provided by § 5(h) of such Act, which appears as 42 USCS § 300aa-11 note), in subsec. (c), inserted "the" after "special masters of".

NOTES:

Related Statutes & Rules:

This section is referred to in 42 USCS § 300aa-12.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § 35:735.

Interpretive Notes and Decisions: 1. Establishing causation in fact 2. Burden and standard of proof 3. Factors unrelated to administration of vaccine 4. Substantiation of claim 5. Consideration of evidence 6. --Weight given to evidence 7. --Evaluating conflicting evidence 8. --Medical and scientific testimony 9. Aggravation of pre-existing condition 10. --Sudden Infant Death Syndrome 11. Review of Special Masters' decision

1. Establishing causation in fact

Absence of specific, alternative cause of death does not meet petitioners' affirmative duty to show causation; petitioners are required to prove logical sequence of cause and effect. *Hodges v Secretary of Dep't of Health & Human Servs.* (1993, CA FC) 9 F3d 958.

Father was entitled to compensation for death of child 5 years after DPT shot, since Secretary's concession that child met Table requirements gave rise to presumption of cause, and Secretary failed to meet burden to show death was due to Krabbe's or Schilder's disease; child experienced sudden loss of function, rather than gradual decline as in Krabbe's disease, and autopsy report ruled out by implication these rare genetic diseases. *Matthews v Secretary of HHS* (1989) 18 Cl Ct 514, 29 Fed Rules Evid Serv 1067.

Where child had first seizure within 9 hours of second DPT shot and had more than 25 seizures before her death 13 months later, record demonstrated that child died from residual seizure disorder caused by vaccination, and also that she suffered residual effects of disorder for more than 6 months. *Dunham v Secretary of HHS* (1989) 18 Cl Ct 633.

If shock collapse occurs within 3 days of DPT vaccination and there is any acute complication or sequela, petitioner has established rebuttable presumption of causation; evidence demonstrated 6-month-old girl, who was limp, lay in her crib in apparent sleep one day after receiving DPT vaccination and would not take nourishment, suffered shock collapse and died as result 28 hours after shot. *Bell v Secretary of HHS* (1989) 18 Cl Ct 751.

Although temporal association alone establishes legal causation for table injury, temporal association of onset of injury with vaccination is not sufficient to establish causation in fact, which must be shown by medical theory causally connecting vaccination to injury. *Strother v Secretary of HHS* (1990) 21 Cl Ct 365, affd without op (1991, CA) 950 F2d 731, reported in full (1991, CA FC) 1991 US App LEXIS 27190.

Three factors, normality prior to vaccination, onset of injury within seven days of DPT vaccination, and no known alternative cause, must be viewed together; in light of National Childhood Encephalopathy capital studies, such factors are sound criteria upon which to base finding of causation. *Sumrall v Secretary of HHS* (1991) 23 Cl Ct 1.

Claimants may recover under Act by showing causation in fact if injury is either not included in Table, or if listed Table injury occurred after corresponding time period has run. *McCarren v Secretary of HHS* (1997) 40 Fed Cl 142.

Although temporal association of onset of injury with vaccination alone establishes legal causation for Table Injury, temporal association is not sufficient to establish causation in fact; moreover, similarity of petitioner's injury to those listed on Table does not show causation in fact. *Grant v Secretary of HHS* (1992, CA) 956 F2d 1144.

Special Master was not arbitrary and capricious in finding no causal link between encephalopathy and residual seizure disorder and subsequent speech problems where government's expert found no loss of significant milestones between date of seizures and problems almost 6 months later, that is, no slow brain waves, unusual screaming or crying, intracranial pressure, or loss of consciousness, and where, 5 months after seizures, child was attentive, smiling, and saying "mama" and "dada", and sitting unassisted. *Song v Secretary of Dep't of Health & Human Servs.* (1994) 31 Fed Cl 61, affd without op (1994, CA FC) 41 F3d 1520, reported in full (1995, CA FC) 1994 US App LEXIS 40419.

Proving causation-in-fact requires proof of actual causation as in traditional tort law, wherein petitioners are entitled to no temporal or coincidental presumptions of cause and effect; causation-in-fact requires production of medical theory causally connecting vaccination and injury, and requires proof of logical sequence of cause and effect showing vaccine was reason for injury. *Gurr v Secretary of Health & Human Servs.* (1997) 37 Fed Cl 314.

Under National Vaccine Injury Compensation Act, 42 USCS § 300aa, petitioners have burden of demonstrating by preponderance of evidence that medical condition was caused by vaccination, 42 USCS § 300aa-13(a)(1)(A); petitioners may do this by proving that child suffered injury listed on Vaccine Injury Table within prescribed time periods, 42 USCS § 300aa14, and they may also do this by proving causation in fact if injury does not meet table requirements as set forth in 42 USCS § 300aa-11(c)(1)(ii). *Morris v Sec'y of HHS* (2003) 57 Fed Cl 383.

Petitioner proffered reliable medical records, reputable medical opinion, logical sequence of cause and effect, and medical theory causally connecting vaccination to onset and development of her demyelinating illness; thus, petitioner was entitled to Vaccine Act relief because she established, though not to a medical certainty, causation in fact that, but for vaccine, it was more likely than not that she would not have incurred optic neuritis and subsequent symptoms of demyelinating illness and that it was more likely than not that vaccine was substantial factor in causing her illness. *Athen v Sec'y of HHS* (2003) 58 Fed Cl 270, CCH Prod Liab Rep P 16763, 62 Fed Rules Evid Serv 1386.

2. Burden and standard of proof

Language in 42 USCS § 300aa-13 stating that factors unrelated to administration of vaccine require respondent to prove by preponderance of evidence that supposed alternatives, not vaccine in question, actually caused injury through logical sequence of cause and effect. *McClendon v Secretary of HHS* (1991) 24 Cl Ct 329.

Vaccine Act contains no legal requirement that close questions of causation be resolved in favor of petitioner; petitioner must establish causation by preponderance of evidence. *Thrall v Secretary of HHS* (1992) 26 Cl Ct 1419.

Petitioner's burden is not to show generalized cause-effect relationship with listed illnesses but only to show causation in particular case; thus, petitioner met burden where association of DPT vaccine with onset of illnesses was not negated by medical textbook's assertion of absence of "controlled studies." *Bunting v Secretary of HHS (1991, CA) 931 F2d 867*, reh den (1991, CA FC) 1991 US App LEXIS 13225.

Nothing in Vaccine Act requires application of traditional tort litigation standards of proof; vaccine program provides substitute system of compensation for vaccine injury; showing that injury was "more likely than not" caused by vaccine is enough to establish causation in fact. *Sharpnack v Secretary of Dep't Health & Human Servs. (1993) 27 Fed Cl 457*, affd without op (1994, CA FC) 17 F3d 1442, reported in full (1994, CA FC) 1994 US App LEXIS 427.

Although child died within 72 hours of vaccine, plaintiff's failure to prove beyond preponderance of evidence that child had suffered anaphylactic shock and that death was sequela of shock prevents recovery under Vaccine Act. *Hellebrand v Secretary of Dep't of Health & Human Servs. (1993, CA) 999 F2d 1565*.

Where petitioner never was able to establish that child suffered encephalopathy and that his death was sequela of that injury, burden never shifted to government to establish alternative cause of death, and petition was properly denied. *Frank v Secretary of the Health & Human Servs. (1995) 34 Fed Cl 29*.

In "significant aggravation" cases (42 USCS § 300aa-11(c)(1)(C)(i)), once petitioner has made prima facie case, and therefore benefits from statute's presumption of causation, burden shifts to government to show, by preponderance of evidence, that preexisting condition was, in fact, cause of individual's post-vaccination significant aggravation. *Plavin v Secretary of the HHS (1998) 40 Fed Cl 609*.

Preponderance of evidence standard (42 USCS § 300aa-13(a)(1)(A)) requires petitioner to adduce evidence that makes existence of contested fact more likely than not. *Thornton v Secretary of the HHS (1996) 35 Fed Cl 432*; *Dickerson v Secretary of the HHS (1996) 35 Fed Cl 593*.

Preponderance of evidence standard (42 USCS § 300aa-13(a)(1)(A)) requires more than probability; special master must believe that existence of fact is more probable than its nonexistence before special master may find in favor of party who has burden to persuade special master of fact's existence. *Epstein v Secretary of the HHS (1996) 35 Fed Cl 467*.

Causation in fact requires claimant to prove that vaccine in question actually caused claimed injury by preponderance of evidence; presumption of causation that exists with Table injury is not available. *McCarren v Secretary of HHS (1997) 40 Fed Cl 142*.

Petitioner's burden in Vaccine Act case is to prove case by preponderance of evidence, not by substantial evidence, as plain language of Act makes clear. *Piper v Secretary of Health & Human Servs. (1993) 29 Fed Cl 628*.

Burden is not on petitioner to prove both part (A) and part (B) of 42 USCS § 300aa-13(a)(1); once petitioner puts on prima facie case of causation, burden shifts to government to put on evidence, under part (B), of unrelated factor (part (B) thus acts essentially as defense for government). *Wagner v Secretary of HHS (1997) 37 Fed Cl 134* (criticized in *Gherardi v Secretary of HHS (1997, Ct Fed Cl) 1997 US Claims LEXIS 29*).

In case under National Childhood Vaccine Injury Act of 1986, 42 USCS § § 300aa-11 to -34, where special master found evidence insufficient to determine whether child had viral infection on day child received vaccination, special master committed abuse of discretion by continuing to discuss issue; special master's discussion constituted unreasonable inference that virus may have been somehow related to child's injuries; moreover, special master apparently inappropriately imposed on parent burden of proving that viral infection did not cause child's injuries; pursuant to 42 USCS § 300aa-13(a)(2), Government had burden to prove viral infection was principally responsible for causing child's illness. *Tebcherani v Sec'y of HHS (2003) 55 Fed Cl 460*.

In fact and in operation, three of five Stevens elements either significantly changed statutory burden of proof or directly contravened language of Vaccine Act and therefore were erroneous as matter of law, so court reversed and vacated special master's entitlement decision denying petitioner compensation, which applied Stevens elements, and considered petition de novo and concluded that petitioner established causation in fact, though not to medical certainty, and was thus entitled to Vaccine Act relief. *Althen v Sec'y of HHS (2003) 58 Fed Cl 270*, *CCH Prod Liab Rep P 16763*, *62 Fed Rules Evid Serv 1386*.

3. Factors unrelated to administration of vaccine

Claimant who relies on Vaccine Injury Table set forth in provision of National Childhood Vaccine Injury Act (42 USCS § 300aa-14) in order to establish prima facie case for compensation does not make out such case where claimant's evidence, while indicating claimant experienced symptoms of injury after receiving vaccination, fails to indicate claimant had no symptoms of that injury before vaccination. *Shalala v Whitecotton (1995) 514 US 268*, *131 L Ed 2d 374*, *115 S Ct 1477*, *95 CDOS 2803*, *95 Daily Journal DAR 4844*, on remand, remanded (1996, CA FC) *81 F3d 1099*, reh, en banc, den (1996, CA FC) 1996 US App LEXIS 17581.

Two-month-old's death 33 hours after receiving DPT vaccine was sequela to shock collapse and encephalopathy suffered within 3 days of vaccine, and was not due to dehydration; infant did not lose 22 percent of body weight during 33 hour period but only 7 percent, autopsy did not indicate dehydration, and cerebral edema suffered by infant was inconsistent with dehydration. *Ciotoli v Secretary of HHS (1989) 18 Cl Ct 576*.

Where preponderance of evidence indicated that hypotonia was caused by factor unrelated to administration of vaccine, and that infants did not sustain or have significant aggravation of concurrent pneumonia because of vaccine, decision of special master was correct in denying compensation. *Munn v Secretary of HHS (1990) 21 Cl Ct 345*, affd (1992, CA) 970 F2d 863, 92 Daily Journal DAR 10867.

Cryptogenic infantile spasms do not qualify as factor unrelated to vaccine within meaning of Act where such spasms are rare form of seizure disorder and coincidental occurrence with vaccination was not found credible by Special Master. *Johnston v Secretary of HHS (1990) 22 Cl Ct 75*.

Diagnosis of infantile spasms of unknown origin does not as matter of law establish cause alternative to administration of vaccine. *Hale v Secretary of HHS (1991) 22 Cl Ct 403*.

Diagnosis of infantile spasms may not, as matter of law, constitute alternative condition which is factor unrelated to administration of vaccine, and such diagnosis may not be defense against finding of table injury. *Sorensen v Secretary of HHS (1991) 22 Cl Ct 672*.

If vaccine caused fever and fever caused breakthrough in symptoms, that breakthrough cannot be attributed to factor unrelated to administration of vaccine. *Schumacher v Secretary of HHS (1992) 26 Cl Ct 1033*, affd (1993, CA FC) 2 F3d 1128 and (criticized in *Houtz v Secretary of Health & Human Servs. (1996, Ct Fed Cl) 1996 US Claims LEXIS 206*).

Rett Syndrome, being idiopathic disease, is not factor unrelated to administration of vaccine, and compensation may therefore be awarded where child showed symptoms of Rett Syndrome 12 hours after vaccination. *Koston v Secretary, HHS (1992, CA) 974 F2d 157*.

4. Substantiation of claim

Additional evidence was necessary to establish that collapse of child 20 minutes after receiving measles vaccine and subsequent fainting spells signaled encephalopathy or residual seizure disorder, and even though there was un rebutted testimony by medical experts that vaccine caused injury, evidence of reputable medical theory was necessary to show causation in fact. *Shaw v Secretary of HHS (1989) 18 Cl Ct 646*.

When there is no mention of seizure in any health record and when only evidence of seizure rests on statements of petitioners, requirements of 42 USCS § 300aa-13(a)(1) are not met. *Lett v Secretary of HHS (1997) 39 Fed Cl 259*.

Every determination under 42 USCS § 300aa-13(a)(1)(A) requires specific finding of fact, which must be substantiated by reference to medical records or medical opinion, and special master is required to carefully scrutinize entire record; thus, failure to examine full record and provide sufficient findings constitutes error. *Dickerson v Secretary of the HHS (1996) 35 Fed Cl 593*.

Special master, who is both trier of fact and decider of law, is not simply arbiter of expert's opinions; since determining weight and credibility of evidence is special province of trier of fact, special master is free to accept or reject portions of expert medical opinions presented to him in light of entire record. *Lampe v Secretary of HHS (1998) 42 Fed Cl 632*.

Range of evidence that special master may consider is not governed by discovery or evidentiary rules applicable in federal district courts. *Wittner v Secretary of HHS (1999) 43 Fed Cl 199*.

Special master was adjudicative fact finder charged with applying existing legal precedent to decide particular case based on record before him or her but ultimately was not law maker or interpreter, and special master was not authorized to impose or even determine particular analytical framework to be used in Vaccine Act claims; thus, court completed its own analysis and reversed special master's denial of petitioner's claim for non-table injury, optic neuritis and subsequent demyelinating illness symptoms, and remanded for award of compensation to petitioner, reasonable attorneys fees, and other costs. *Althen v Sec'y of HHS (2003) 58 Fed Cl 270, CCH Prod Liab Rep P 16763, 62 Fed Rules Evid Serv 1386*.

5. Consideration of evidence

In suit involving drowning death of adult, traceable to impairment resulting from administration of vaccine in early childhood, court did not commit reversible error by construing the term "sequela" as it was defined in several well known medical dictionaries as a pathological sequence or result of an existing disease or disorder. *Abbott v Secretary of the Dep't of Health & Human Servs. (1994, CA FC) 19 F3d 39*, reported in full (1994, CA FC) 1994 US App LEXIS 2459.

Where no evidence corroborates mother's single diary entry of child's seizure within 3 days of vaccine, Special Master did not err in refusing evidentiary hearing. *Murphy v Secretary of HHS (1991) 23 Cl Ct 726* (criticized in *Costa v Secretary of the Health & Human Servs. (1992, Cl Ct) 1992 US Cl Ct LEXIS 105*).

Special Master's finding that petitioner's singular reliance on temporal relationships between administration of vaccine and onset of symptoms was not supported by contemporaneous medical evidence was not arbitrary and capricious. *Thibaudeau v Secretary of HHS (1991) 24 Cl Ct 400*.

Trier of fact is not bound to accept expert opinion, even if it is uncontradicted; such testimony is not conclusive if it is intrinsically nonpersuasive. *Perreira v Secretary of Health & Human Servs. (1992) 27 Fed Cl 29*, affd (1994, CA FC) 33 F3d 1375.

Special master did not act arbitrarily and capriciously in considering 32-year old hearsay document that was not created contemporaneously with events it purported to document where it was extracted from relevant contemporaneous office records and special master considered circumstances that tended to show document was reliable. *Estate of Arrowood v Secretary of Health & Human Servs. (1993) 28 Fed Cl 453*.

Petitioner did not meet her burden of proof, and Special Master's conclusion awarding compensation to her was arbitrary and capricious, where reliance was placed on mere speculation that OPT vaccination was administered and petitioner's expert witness provided inconclusive, flawed conclusions about cause of death. *Centmehaiey v Secretary of Health & Human Servs. (1995) 32 Fed Cl 612*, affd without op (1995, CA FC) 73 F3d 381, reported in full (1995, CA FC) 1995 US App LEXIS 40330.

It was arbitrary and capricious for special master to totally disregard opinion of physician whose medical reports contained some reasoning in support of opinion and was not completely conclusory. *Johnson v Secretary of Health & Human Servs. (1995) 33 Fed Cl 712*, affd without op (1996, CA FC) 99 F3d 1160, reported in full (1996, CA FC) 1996 US App LEXIS 28093.

Special master is not bound by opinions of expert witnesses, need only provide rational explanation for relying on particular expert, and may reject expert testimony if he or she finds another expert to be more persuasive. *Hellenbrand-Sztaba v Secretary of Health & Human Servs. (1996) 35 Fed Cl 222*, affd without op (1997, CA FC) 106 F3d 426, reported in full (1997, CA FC) 1997 US App LEXIS 1291.

In case under National Childhood Vaccine Injury Act of 1986, 42 USCS § 300aa-11 to -34, where special master found evidence insufficient to determine whether child had viral infection on day child received vaccination, special master committed abuse of discretion by continuing to discuss issue; special master's discussion constituted unreasonable inference that virus may have been somehow related to child's injuries; moreover, special master apparently inappropriately imposed on parent burden of proving that viral infection did not cause child's injuries; pursuant to 42 USCS § 300aa-13(a)(2), Government had burden to prove viral infection was principally responsible for causing child's illness. *Tebcherani v Sec'y of HHS (2003) 55 Fed Cl 460*.

6. --Weight given to evidence

Discrepancies in mother's statements as to behavior of child immediately after vaccination and dates of vaccination and death, and Special Master's finding that she was substantially lacking in credibility, did not outweigh evidence in record indicating that child sustained table injury and died within 3 days as result of vaccine. Fairl on behalf of *Fairl v Secretary of HHS (1990) 19 Cl Ct 436*.

Where contemporaneous medical records show that symptoms were first observed approximately 6 weeks after vaccination, court cannot award compensation on claimant's own 10-year old recollection that symptoms first occurred within 15 days of vaccination. *Doe v Secretary of HHS (1990) 19 Cl Ct 439*.

Even though petitioner's testimony was taken by telephone conference call, special master was in best position to judge her credibility; master did not abuse discretion in finding unbelievable her testimony that her recollection of when seizures began was more clear 4 years after event than immediately after event. *Tweten v Secretary of HHS (1991) 26 Cl Ct 405*.

Special master committed reversible error where she failed to give necessary weight to evidence of cardiovascular arrest, loss of responsiveness, color change, and loss of consciousness by associating such conditions solely with normal death process. *Widdoss v Secretary of HHS (1992) 25 Cl Ct 251*, vacated on other grounds, remanded (1993, CA) 989 F2d 1170, cert den (1993) 510 US 944, 126 L Ed 2d 331, 114 S Ct 381.

Nothing in Vaccine Injury Compensation Program supports notion that testimony of individuals seeking compensation is entitled to greater weight than contemporaneous medical records. *Cucuras v Secretary of HHS (1992) 26 Cl Ct 537*, affd (1993, CA) 993 F2d 1525.

Expert opinion, even if uncontradicted, is not binding on special master; special master may reject expert's testimony as long as reasonable basis for doing so is explained. *Huston v Secretary of HHS (1997) 39 Fed Cl 632*.

Special master is entitled to weigh expert testimony and other evidence and to draw reasonable inferences, and Court of Federal Claims cannot substitute its judgment for that of special master when he has considered evidence and weighed it accordingly. *Huston v Secretary of HHS (1997) 39 Fed Cl 632.*

7. --Evaluating conflicting evidence

Special master's properly found that petitioner did not carry burden of proof where, in evaluating conflicting expert testimony, he ruled that crying and fever were insufficient grounds for petitioner's expert to conclude encephalopathy within 3 days, and he emphasized that government's expert was neurologist and petitioner's was not. *Summar v Secretary of HHS (1991) 24 Cl Ct 440.*

Temporal association is insufficient to prove causation-in-fact; physician's testimony, giving opinion of temporal association, without discussing contradictory evidence in child's medical record as to when symptoms began, does not establish prima facie case for compensation. *Ware v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 716.*

When Special Master is faced with conflicting expert testimony, court will affirm his conclusion where he discusses pertinent testimony and explains in adequate detail his rationale for relying on one party's expert over another. *Raspberry v Secretary of the Dep't of Health & Human Servs. (1995) 33 Fed Cl 420.*

8. --Medical and scientific testimony

Secretary failed to prove it was more likely than not that rotavirus infection led to child's death so as to preclude compensation under National Childhood Vaccine Injury Act where, because Secretary cannot rely on fact that no one may know order of symptoms in such case, Secretary's physician testified that she did not know of single rotavirus case where encephalopathic symptoms preceded diarrhea; to prove case, Secretary had to place onset of diarrhea prior to encephalopathy in chain of events. *Davis v Secretary of HHS (1990) 20 Cl Ct 168.*

Special master did not err in consulting pediatrics textbook to determine incubation period of measles where petitioner's medical witness was unclear as to incubation periods of wild virus and vaccination virus. *Hines on behalf of Sevier v Secretary of HHS (1990) 21 Cl Ct 634, affd (1991, CA) 940 F2d 1518, 33 Fed Rules Evid Serv 632.*

Special master did not err in concluding that petitioner had not advanced reputable medical or scientific theory causally connecting vaccine and injury where testimony showed only that some members of medical community believed that there was possibility that some cases of juvenile arthritis might be caused by rubella. *Carter v Secretary of HHS (1990) 21 Cl Ct 651.*

Court cannot conclude that special master abused discretion in allowing neuropathologist who was not pediatrician or neurologist to testify as expert as to which of child's actions might be classified as first symptoms of seizure disorder. *Richardson v Secretary of HHS (1991) 23 Cl Ct 674.*

There is sufficient medical evidence to support special master's finding that hyporesponsive episode can cause death; statute does not require that particular death be direct result of post-vaccination table injury. *Zinko v Secretary of HHS (1991) 24 Cl Ct 430, dismd without op (1992, CA) 960 F2d 154.*

Special Master relied on reputable medical evidence that DPT vaccination can cause chronic encephalopathies where experts, although disagreeing whether child actually suffered encephalopathy, agreed that anything that can cause acute encephalopathy can also cause permanent neurologic damage. *Estep v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 664.*

Medical report prepared by physician without personal 20 years after subject experienced first seizure was admissible but was entitled to little or no weight where report provided no reference to medical records to support assertions. *Cox v Secretary of the Dep't of Health & Human Servs. (1993) 30 Fed Cl 136.*

Special Master improperly determined occurrence of encephopathy within Table Injury time period where there was no medical testimony to support conclusion that seizures child experienced within 3 days of vaccine were indicative of encephopathy and where petitioner's own expert conceded that he could not declare to reasonable degree of medical certainty that child had suffered encephopathy within Table period. *Skinner v Secretary of the Dep't of Health & Human Servs. (1994) 32 Fed Cl 196.*

Special Master's award of compensation for pain and suffering for vaccine-related injury was arbitrary and capricious where she did not rely on primary medical evidence but relied instead on legal analysis by medical professional and secondary information about child's medical condition provided by parents and friend, and rendered her own medical determination based on inaccurate application of legal presumptions included in Vaccine Act. *Buxkemper v Secretary of the Dep't of Health & Human Servs. (1994) 32 Fed Cl 213 (criticized in McCarren v Secretary of HHS (1997) 40 Fed Cl 142).*

42 USCS § 300aa-13(a)(1) requires submission of medical records or opinion, but does not require submission of medical literature. *Dickerson v Secretary of the HHS (1996) 35 Fed Cl 593*.

Petitioner parents were denied compensation under National Vaccine Injury Compensation Act, 42 USCS § § 300 aa-10 through aa-23, where special master's ruling that their child's measles-mumps-rubella vaccination was not cause of his epilepsy was based on testimony of qualified witness with opinions fully backed by medical literature, and thus was held not to be arbitrary and capricious. *Finley v Sec'y of the HHS (2003) 55 Fed Cl 355*.

In case under National Childhood Vaccine Injury Act of 1986, 42 USCS § § 300aa-11 to -34, special master's findings that medical conditions child had at birth had not been completely resolved were not arbitrary and capricious or abuse of discretion; special master relied upon statements of experts about relevant events in medical records. *Tebcherani v Sec'y of HHS (2003) 55 Fed Cl 460*.

9. Aggravation of pre-existing condition

In determining whether petitioner has made prima facie claim for significant aggravation of pre-existing condition, special master must assess person's condition prior to administration of vaccine, assess person's current condition, determine if person's current condition constitutes "significant aggravation" of prior condition within meaning of statute, and then determine whether first symptom or manifestation of significant aggravation occurred within time period prescribed by statutory Table. *Whitcotton v Secretary of HHS (1996, CA FC) 81 F3d 1099*, reh, en banc, den (1996, CA FC) 1996 US App LEXIS 17581.

Special master's finding that vaccination did not significantly aggravate pre-existing congenital condition of oculo-cerebral dysgenesis, retardation, and impaired vision, will not be set aside where medical experts disagreed as to extent of original condition and prognosis with and without vaccine. *Misasi v Secretary of HHS (1991) 23 Cl Ct 322* (criticized in *Copeland v Secretary of the Dep't of Health & Human Servs. (1993, Ct Fed Cl) 1993 US Claims LEXIS 194*) and (criticized in *Whitcotton v Secretary of HHS (1996, CA FC) 81 F3d 1099*) and (criticized in *Houtz v Secretary of Health & Human Servs. (1996, Ct Fed Cl) 1996 US Claims LEXIS 206*).

Special master properly found that child suffered from significant aggravation of pre-existing condition where she applied correct standard of finding by preponderance of evidence that condition was due to factors unrelated to vaccine. *O'Connor v Secretary of HHS (1991) 24 Cl Ct 428*, affd without op (1992, CA) 975 F2d 868, reh den (1992, CA FC) 1992 US App LEXIS 19814.

Pre-existing condition of tuberous sclerosis can be characterized either as on-Table seizure disorder or on-Table encephalopathy; thus, parents of child born with such condition have met threshold burden by showing significant aggravation of condition within 3 days of DPT vaccination. *Costa v Secretary of HHS (1992) 26 Cl Ct 866* (criticized in *Houtz v Secretary of Health & Human Servs. (1996, Ct Fed Cl) 1996 US Claims LEXIS 206*).

Misasi's 4-pronged test to determine whether individual experienced significant aggravation of pre-existing condition does not alter petitioner's initial burden of proof set forth in 42 USCS § 300aa-13. *Reusser v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 516*.

Although child experienced severe aggravation of underlying neurological condition, petitioners may not recover under Vaccine Act where underlying condition was almost certain to lead to retardation and was progressing rather than static. *Roedl v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 740*.

Fact that underlying condition of tuberous sclerosis could have produced seizure at any time does not mean that child would have had seizure 2 days after DPT vaccination; because evidence demonstrated that the longer child remained seizure-free, the better his prognosis for normal mental development, correlation between age of seizure onset and level of retardation after vaccination showed that vaccination significantly aggravated child's preexisting condition. *Suel v Secretary of HHS (1993) 31 Fed Cl 1* (criticized in *Houtz v Secretary of Health & Human Servs. (1996, Ct Fed Cl) 1996 US Claims LEXIS 206*) and on remand, motion den, request gr (1997, Ct Fed Cl) 1997 US Claims LEXIS 210.

10. --Sudden Infant Death Syndrome

Even though pathologist concluded that infant who died in crib 45 hours after DPT vaccine died of sudden infant death syndrome, compensation is properly awarded, since § 300aa-13, which expressly precludes consideration of "any ideopathic, unexplained, unknown, hypothetical, or undocumentable cause" prohibits court from denying compensation on basis of SIDS, and since infant's serious physical disturbance after vaccination was inconsistent with SIDS. *Rochester v United States (1989) 18 Cl Ct 379*.

Death of infant in crib 28 hours after DPT shot was not shown to be caused by factor other than shock collapse, where infant was normally developed, despite premature birth, post-mortem examination revealed no sign of other cause of death, and any conclusion that sudden infant death syndrome caused death would be unreasonable, given child's history. *Bell v Secretary of HHS (1989) 18 Cl Ct 751*.

Recovery under Vaccine Act was allowed where government's contention that victim died of Sudden Infant Death Syndrome rather than from vaccination was disproved by evidence that death was not sudden but was culmination of sequence of events beginning with vaccination. *Manley v Secretary of HHS (1989) 18 Cl Ct 799*.

SIDS is sudden and unexpected death of apparently healthy infant, typically occurring between ages of three and five months and not explained by careful post-mortem studies. *Carraggio v Secretary of HHS (1997) 38 Fed Cl 211* (criticized in *McCarren v Secretary of HHS (1997) 40 Fed Cl 142*).

Where parent of infant who died two days after receiving diphtheria-pertussis-tetanus (DPT) vaccination brought claim under National Childhood Vaccine Injury Act of 1986 (Vaccine Act), as amended, 42 USCS § § 300aa-11 to -34, special master's consideration of evidence of sudden infant death syndrome (SIDS) in evaluating whether parent established prima facie case contravened Vaccine Act's bar against idiopathic evidence, and further, special master should not have considered whether SIDS was alternative explanation for cerebral edema and increased brain weight in infant in determining whether infant had encephalopathy. *Davis v Sec'y of the HHS (2002) 54 Fed Cl 230*.

11. Review of Special Masters' decision

Special Master did not act arbitrarily and capriciously in discounting accuracy of parents' recollection of 40-year-old events on ground that events, had they occurred, would have been recounted somewhere in subsequent health care history, where Special Master considered parents' current memory and demeanor. *Snyder by Snyder v Secretary of HHS (1997, CA FC) 117 F3d 545*.

Decision of special master will be set aside where, instead of first determining whether petitioners satisfied their initial statutory burden of proof, special master went right to second step outlined in 42 USCS § 300aa-13 and rejected petitioners' claim because he believed that injuries which occurred could have been caused other than by vaccine. *McClendon v Secretary of HHS (1991) 23 Cl Ct 191*.

Special master erred in obligating government to adduce clear-cut evidence of non-vaccine cause. *Lewis v Secretary of HHS (1992) 26 Cl Ct 233*.

Special Master reasonably found that state was unable to meet child's "peculiar needs" of waking herself and napping between noon and 3:00, and decision refusing to make statute offset for any items of service to extent that payment had been made or could reasonably be expected to be made was rationally based on language of relevant statutory provisions. *McClendon v Secretary of the Dep't of Health & Human Servs. (1993) 28 Fed Cl 1*, affd without op (1994, CA FC) 41 F3d 1521, reported in full (1994, CA FC) 1994 US App LEXIS 33215.

When Special Master's judgment turns on determination that testimony of witnesses is not credible, such credibility determinations are virtually unreviewable. *Phillips v Secretary of Dep't of Health & Human Servs. (1993, CA) 988 F2d 111*.

Special master was not arbitrary or capricious in determining that cause of child's transverse myelitis was respiratory virus, rather than inoculation for oral polio vaccine, and special master's decision was supported by record evidence. *Morris v Sec'y of HHS (2003) 57 Fed Cl 383*.

LEXSTAT 42 USCS 300AA-14

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*** CURRENT THROUGH P.L. 109-6, APPROVED 3/31/05 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
PROGRAM REQUIREMENTS

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-14 (2005)

§ 300aa-14. Vaccine Injury Table

(a) Initial table [Caution: See 42 CFR § 100.3 for Vaccine Injury Table, as revised by the Secretary pursuant to subsec. (e) of this section.]. 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:

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 (b)(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 (b)(2) 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).
- 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
--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 [42 USCS § 300aa-11] 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 table.

(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, 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.

(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.

(e) Additional vaccines.

(1) Vaccines recommended before August 1, 1993. By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include--

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993. When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include--

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2114, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3764; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(k), 103 Stat. 2290; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch B, Part IV, § 13632(a)(2), 107 Stat. 645.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

The Vaccine Injury Table, as revised by the Secretary pursuant to subsec. (e), appears as *42 CFR § 100.3*.

Explanatory notes:

A prior § 300aa-14 (Act July 1, 1944, ch 373, Title XXI[V], § 2115 [515] [Oct. 31, 1963, P.L. 88-164, Title II, Part C, § 225, as added July 29, 1975, P.L. 94-63, Title III, § 303, 89 Stat. 326; Nov. 9, 1978, P.L. 95-622, Title I, § 110(c), 92 Stat. 3420], as added Aug. 13, 1981, P.L. 97-35, Title IX, Subtitle A, § 902(e)(2)(A), 95 Stat. 560; April 26, 1983, P.L. 98-24, § 2(a)(1), 97 Stat. 176; Oct. 22, 1985, P.L. 99-129, Title II, § 226(a), 99 Stat. 546) was redesignated § 2713 of Title XXVII of such Act and now appears as *42 USCS § 300aaa-12*.

A prior § 2114 of Act July 1, 1944, ch 373, Title XXI, which formerly appeared as *42 USCS § 300aa-13*, was redesignated § 2712 of Title XXVII of such Act and now appears as *42 USCS § 300aaa-11*.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1989. Act Dec. 19, 1989 (applicable as provided by § 6601(s) of such Act, which appears as 42 USCS § 300aa-10 note), in subsec. (a), in the table, substituted "(b)(2)" for "(c)(2)" wherever appearing; and, in subsec. (b)(3)(B), substituted "2111" for "2111(b)".

1993. Act Aug. 10, 1993 (applicable as provided by § 13632(a)(3) of such Act, which appears as a note to this section), substituted subsec. (e) for one which read: "Recommendation. The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table."

Other provisions:

Revision of Vaccine Injury Table; effective date. Act Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch B, Part IV, § 13632(a)(3), 107 Stat. 646, provides: "A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa-14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa-14(a))."

[The Vaccine Injury Table, as revised by the Secretary pursuant to 42 USCS § 300a-14(e), appears as 42 CFR § 100.3.]

NOTES:

Code of Federal Regulations:

Public Health Service, Department of Health and Human Services--Vaccine injury compensation, 42 CFR Part 100.

Related Statutes & Rules:

This section is referred to in 42 USCS § § 300aa-25, 300aa-33.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs and Cosmetics § § 35:727, 730.

Am Jur:

39 Am Jur 2d, Health § 67.

63B Am Jur 2d, Products Liability § 1573.

Interpretive Notes and Decisions: 1. Generally 2. Vaccine Table injury 3. --Encephalopathy 4. --Construction of terms

1. Generally

Court of Federal Claims does not have jurisdiction to hear claim that statute allowing Secretary to modify Vaccine Injury Table (42 USCS § 300aa-14(c)) is unconstitutional. *Terran v Secretary of HHS (1998) 41 Fed Cl 330*.

Court remanded to special master's (SM) case under National Childhood Vaccine Injury Act of 1986, 42 USCS § § 300aa-11 to -34; many of SM's findings were not arbitrary and capricious, but SM erred by ignoring school records that supported parent's position that child's symptoms appeared within 72 hours of receiving vaccination, and thus, child suffered injury described in Vaccine Injury Table set forth in 42 USCS § 300aa-14 and 42 C.F.R. § 100.3(a). *Tebcherani v Sec'y of HHS (2003) 55 Fed Cl 460*.

2. Vaccine Table injury

Vaccine Act does not afford compensation to person who contracts polio from person who has received contaminated polio vaccine. *Beard v Secretary of the Dep't of Health & Human Servs. (1994, CA FC) 43 F3d 659*.

Table Injury regulation promulgated by Secretary of Health and Human Services under Vaccine Act did not violate Presentment Clause of Constitution, Article I; Congress itself decided to render Initial Table ineffective upon Secretary's action in promulgating new Table. *Terran v Secretary of HHS (1999, CA FC) 195 F3d 1302*, reh, en banc, den (2000, CA FC) 2000 US App LEXIS 2394.

Diabetes is not listed in injury table and is therefore compensable only if it were proven by preponderance of evidence that polio vaccine administered to petitioner actually caused her diabetes and that diabetes was acute complication of polio. *Dolney v Secretary of HHS (1991) 23 Cl Ct 337*, affd (1991, CA) 950 F2d 730, reh den (1991, CA FC) 1991 US App LEXIS 29267.

First emphasis must be on existence of hypotonic-hyporesponsive and only then on whether death appears to have been outcome of that proven condition, and result must depend on whether there was observable, relatively uninterrupted progression from vaccination to death. *Allen v Secretary of HHS (1991) 24 Cl Ct 295*.

Special Master was justified in requiring "thoroughly credible" witness testimony to establish Table Injury claim when presented with contradictory medical records, and was justified in discounting significance of physician's report written 4 years after vaccination. *Ankenbauer by Ankenbauer v Secretary of the Dep't of Health & Human Servs. (1994) 31 Fed Cl 637*.

Contemporaneous, definitive diagnosis of paralytic polio is not necessary to establish Vaccine Act's Table Injury presumption for oral polio vaccine. *Shifflett v Secretary of the Dep't of Health & Human Servs. (1994) 30 Fed Cl 341*.

Death within requisite time period is not sufficient to establish Table injury or causation in fact. *Hellenbrand-Sztaba v Secretary of Health & Human Servs. (1996) 35 Fed Cl 222*, *affd without op (1997, CA FC) 106 F3d 426*, reported in full (1997, CA FC) 1997 US App LEXIS 1291.

Where each of child's seizures were accompanied by high or moderate fever, she did not suffer "Table injury seizure disorder" under Vaccine Act. *Agarwal v Secretary of Health & Human Servs. (1995) 33 Fed Cl 482*.

Petitioner must show by preponderance of evidence that some logical, direct causal link exists between presumed Table injury and alleged sequela, and Special Master erred in holding that petitioner only needed to show that death "could have" resulted from Table injury. *Hossack v Secretary of the Dep't of Health & Human Servs. (1995) 32 Fed Cl 769*.

Death within requisite time period is not sufficient to establish Table injury or causation in fact. *Hellenbrand-Sztaba v Secretary of Health & Human Servs. (1996) 35 Fed Cl 222*, *affd without op (1997, CA FC) 106 F3d 426*, reported in full (1997, CA FC) 1997 US App LEXIS 1291.

Death is compensable Table Injury only when medically identified as acute complication or sequela of encephalopathy or other listed Table Injury. *Lankford v Secretary of Health & Human Servs. (1996) 37 Fed Cl 723*.

Neither Office of Special Masters nor Court of Federal Claims has jurisdiction to hear petitioner's claim that authority of Secretary of Health and Human Services to revise Vaccine Injury Table (42 USCS § 300aa-14(c)) represents impermissible delegation of congressional law-making authority; claim for such declaratory relief is only appropriate for consideration by U.S. court of appeals. *O'Connell v Secretary of the HHS (1998) 40 Fed Cl 891*.

Court remanded to special master's (SM) case under National Childhood Vaccine Injury Act of 1986, 42 USCS § § 300aa-11 to -34; many of SM's findings were not arbitrary and capricious, but SM erred by ignoring school records that supported parent's position that child's symptoms appeared within 72 hours of receiving vaccination, and thus, child suffered injury described in Vaccine Injury Table set forth in 42 USCS § 300aa-14 and 42 C.F.R. § 100.3(a). *Tebcherani v Sec'y of HHS (2003) 55 Fed Cl 460*.

3. --Encephalopathy

Bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in particular case encephalopathy following DTP vaccination was in fact caused by viral infection present in child and not caused by DTP vaccination. *Knudsen by Knudsen v Secretary of the Dep't of Health & Human Servs. (1994, CA FC) 35 F3d 543*.

Evidence that infant, who died in crib 45 hours after DPT shot became dazed within half-hour of shot, developed 101 degree fever and had lengthy period of high-pitched screaming satisfied criteria for encephalopathy, and evidence that infant lost muscle tone, became unresponsive and pale and suffered pulmonary edema and congestion satisfied criteria for hypotonic-hyporesponsive collapse. *Rochester v United States (1989) 18 Cl Ct 379*.

Presence of 2 or more symptoms of encephalopathy--high pitched screaming and bulging fontanel--together with doctor's testimony that 4-month-old suffered encephalopathy, which was based on doctor's differential diagnosis and autopsy finding of massive cerebral edema, established encephalopathy within 3 days of DPT shot, which resulted in infant's death. *Lolley v United States (1989) 18 Cl Ct 498*.

Two-month-old infant who displayed 6 of 9 symptoms of hypotonic-hyporesponsive collapse described in § 300aa-14 and 6 symptoms of encephalopathy within 3 days of shot suffered both Table injuries within 3 days of vaccine and died from vaccine 4 days after receiving it. *Newton v Secretary of HHS (1989) 18 Cl Ct 665*.

Dramatic swelling of child's entire thigh and not just site of injection is evidence of ongoing anaphylactic reaction sufficient to support recovery under Vaccine Act. *Greene v Secretary of HHS (1989) 19 Cl Ct 57*.

High-pitched screaming and crying alone is insufficient to prove that child suffered encephalopathy after DPT vaccination where no other behavioral change was shown. *Mobley v Secretary of HHS (1991) 22 Cl Ct 423*.

Statute does not specify that seizure is only indication that will demonstrate that child suffered encephalopathy; thus, Special Master erred in refusing to accept staring spell as evidence of first seizure. *Dileo v Secretary of HHS (1991) 23 Cl Ct 796*.

Evidence of inconsolable crying within period of hours following second DPT shot is insufficient to prove that encephalopathy had occurred within 3-day period. *Raley v Secretary of HHS (1992) 25 Cl Ct 247*.

Fact that overlap of symptoms of encephalopathy and HHE can result in masking of symptoms that would be observed if only one condition were present does not mean that masking necessarily occurs; mere absence of symptoms does not mean that masking has occurred. *Shepard v Secretary of HHS (1992) 25 Cl Ct 326*.

Special Master erred in refusing to grant unopposed motion for summary judgment in favor of parents of child who died within 18 hours of vaccine after prolonged crying, where physician testified, based on record and child's previous history of health, that encephalopathy had occurred. *Jay v Secretary of Dep't of Health & Human Servs. (1993, CA) 998 F2d 979, reh, en banc, den (1993, CA FC) 1993 US App LEXIS 27149*.

Where there were no changes in child's underlying disorder within 3-day period following DPT vaccination, child's transition from stage I to stage II of Rett syndrome, while dramatic, is not encephalitic and does not raise prima facie case of vaccine-caused injury. *Chen by Chen v Secretary of HHS (1993) 29 Fed Cl 132*.

Medical records showed that in emergency room, minor was alert, playful, happy, and interacting with his parents; these signs contradicted criteria for table encephalopathy; moreover, minor's two-hour postictal period was not equivalent to 24-hour period of significantly decreased level of consciousness, which Vaccine Act regulation required. *Finley v Sec'y of the HHS (2002, Ct Fed Cl) 2002 US Claims LEXIS 163, affd (2003) 55 Fed Cl 355*.

Petitioner parents were denied compensation under National Vaccine Injury Compensation Act, 42 USCS § § 300 aa-10 through aa-23, where special master's ruling that their child's measles-mumps-rubella vaccination was not cause of his epilepsy was based on testimony of qualified witness with opinions fully backed by medical literature, and thus was held not to be arbitrary and capricious, although epilepsy was Table injury. *Finley v Sec'y of the HHS (2003) 55 Fed Cl 355*.

4. --Construction of terms

Language in 42 USCS § 300aa-14 that "Secretary may not propose a new regulation or any revision thereof" without first furnishing Advisory Committee with copy of "the regulation or revision" is best read as referring to revision of regulation so that, while Secretary may not propose either new regulation or revision without advance notice to Committee, she may proceed to revise proposed regulation without resubmitting it to Committee. *O'Connell v Shalala (1996, CA1) 79 F3d 170*.

Without evidentiary support, court will reject plaintiff's claim that Congress meant term "3 days", as used in statute, to mean 3 calendar days rather than 72 hours, and will therefore accept special master's findings that seizure 75 hours after vaccination was not within statutorily mandated period. *Ultimo v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 148*.

Phrase "any other vaccine containing . . . extracted or partial cell bacteria" in 42 USCS § 300aa-14 does not include typhoid vaccine by description. *Charette v Secretary of the Dep't of Health & Human Servs. (1995) 33 Fed Cl 488*.

Phrase "three days" in 42 USCS § 300aa-14(a) means 72 hours, and not three calendar days. *McCarren v Secretary of HHS (1997) 40 Fed Cl 142*.

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*** CURRENT THROUGH P.L. 109-6, APPROVED 3/31/05 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
PROGRAM REQUIREMENTS

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-15 (2005)

§ 300aa-15. Compensation

(a) General rule. Compensation awarded under the Program to a petitioner under section 2111 [42 USCS § 300aa-11] for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part shall include the following:

(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.

(B) Subject to section 2116(a)(2) [42 USCS § 300aa-16(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.

(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 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.

(b) Vaccines administered before effective date. Compensation awarded under the Program to a petitioner under section 2111 [42 USCS § 300aa-11] for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of \$ 30,000, for--

- (1) lost earnings (as provided in paragraph (3) of subsection (a)),
- (2) pain and suffering (as provided in paragraph (4) of subsection (a)), and
- (3) reasonable attorneys' fees and costs (as provided in subsection (e)[]).

(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.

(1) In awarding compensation on a petition filed under section 2111 [42 USCS § 300aa-11] the special master or court shall also award as part of such compensation an amount to cover--

- (A) reasonable attorneys' fees, and
- (B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Claims Court [United States Court of Federal Claims] on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before the effective date of this part, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 2111(a)(5) [42 USCS § 300aa-11(a)(5)] to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this part 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 [42 USCS § 300aa-11] which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(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) [42 USCS § 300a-21(a)] to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Claims Court [United States Court of Federal Claims] under section 2112 [42 USCS § 300aa-12] awarding the compensation. Such compensation may not be paid after an election under section 2121(a) [42 USCS § 300aa-21(a)] to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 USCS § § 901 et seq.].

(4) (A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury

Compensation Trust Fund established under *section 9510 of the Internal Revenue Code of 1986 [26 USCS § 9510]* in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 2121(a) [42 USCS § 300aa-21(a)] shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under *section 9510 of the Internal Revenue Code of 1986 [26 USCS § 9510]*, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) 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 (other than under title XIX of the Social Security Act [42 USCS § § 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) 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, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 USCS § § 1396 et seq.].

(i) Source of compensation.

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after the effective date of this part shall be made from the Vaccine Injury Compensation Trust Fund established under *section 9510 of the Internal Revenue Code of 1986 [26 USCS § 9510]*.

(j) Authorization. For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part there are authorized to be appropriated to the Department of Health and Human Services \$ 80,000,000 for fiscal year 1989, \$ 80,000,000 for fiscal year 1990, \$ 80,000,000 for fiscal year 1991, \$ 80,000,000 for fiscal year 1992, \$ 110,000,000 for fiscal year 1993, and \$ 110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2115, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3767; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § § 4302(b), 4303(a)-(d)(1), (e), (g), 4307(5), (6), 101 Stat. 1330-221, 222, 223, 225; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(o)(1), 102 Stat. 808; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(c)(8), (l), 103 Stat. 2286, 2290; Nov. 3, 1990, P.L. 101-502, §

5(d), 104 Stat. 1287; Nov. 26, 1991, P.L. 102-168, Title II, § 201(e), (f), 105 Stat. 1103; Oct. 27, 1992, P.L. 102-531, Title III, § 314, 106 Stat. 3507; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch B, Part IV, § 13632(b), 107 Stat. 646.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

The "effective date of this part", referred to in this section, is Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Explanatory notes:

The bracketed parenthesis has been inserted in subsec. (b)(3) to conform to the probable intent of Congress to include such punctuation.

The bracketed words "United States Court of Federal Claims" were inserted in subsecs. (e)(1) and (f)(2) of this section on the authority of § 902(b)(1) of Act Oct. 29, 1992, P.L. 102-572, which appears as *28 USCS § 171* note, and which provides that reference to the United States Claims Court in any Federal law or document shall be deemed to refer to the United States Court of Federal Claims.

A prior § 300aa-15 (Act July 1, 1944, ch 373, Title XXI, § 2116, as added April 7, 1986, P.L. 99-272, Title XVII, § 17003, 100 Stat. 359) was redesignated § 2714 of Title XXVII of such Act and now appears as *42 USCS § 300aaa-13*.

A prior § 2115 of Act July 1, 1944, ch 373, Title XXI, which formerly appeared as *42 USCS § 300aa-14*, was redesignated § 2713 of Title XXVII of such Act and now appears as *42 USCS § 300aaa-12*.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), in the introductory matter, substituted "effective date of this part" for "effective date of this subtitle", in para. (1), in subparas. (A) and (B), deleted concluding matter, which read: "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).", and deleted the concluding matter of subsec. (a), which read: "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."; in subsec. (b), substituted "effective date of this part" for "effective date of this subtitle", and substituted "may not include the compensation described in paragraph (1)(B) of subsection (a) and may include attorneys' fees and other costs included in a judgment under subsection (e), except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) and included as attorneys' fees and other costs under subsection (e) may not exceed \$ 30,000" for "shall only include the compensation described in paragraphs (1)(A) and (2)"; in subsec. (e), in para. (1), in the introductory matter, substituted "of the United States Claims Court" for "of a court" and, in para. (2), substituted "effective date of this part" for "effective date of this title" and "effective date of this part" for "effective date of this subtitle"; in subsec. (f), in para. (2), substituted "United States Claims Court" for "district court of the United States", and added para. (4); redesignated the former second subsec. (f) and subsec. (g) as subsecs. (g) and (h), respectively; and added subsecs. (i) and (j).

1988. Act July 1, 1988 (applicable as provided by § 411(a)(2) of such Act, which appears as *1 USCS § 106* note), in subsec. (i), inserted "by the Secretary from appropriations under subsection (j)"; and, in subsec. (j), inserted "to the Department of Health and Human Services".

1989. Act Dec. 19, 1989 (applicable as provided by § 6601(s) of such Act, which appears as *42 USCS § 300aa-10* note), in subsec. (b), substituted "may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of \$ 30,000, for--" and paras. (1)-(3) for "may not include the compensation described in paragraph (1)(B) of subsection (a) and may include attorneys' fees and other costs included in a judgment under subsection (e), except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) and included as attorneys' fees and other costs under subsection (e) may not exceed \$ 30,000."; in subsec. (e), in para. (1), in the introductory matter, substituted "In awarding compensation on a petition filed under section 2111 the special master or court shall also award as part of such compensation an amount to cover" for "The judgment of the United States Claims Court on a petition filed under section 2111 awarding

compensation shall include an amount to cover", in subpara. (B), substituted "special master or court" for "court" wherever appearing, and "may award an amount of compensation to cover" for "may include in the judgment an amount to cover", and "petition" for "civil action" wherever appearing, in para. (2), substituted "and petitioned under section 2111(a)(5) to have such action dismissed" for "and elected under section 2111(a)(4) to withdraw such action", and "in awarding compensation on such petition the special master or court may include" for "the judgment of the court on such petition may include", and purported to substitute "the special master or court may also award an amount of compensation" for "the judgment of the court on such petition may include an amount" (However, such amendment could not be executed because § 6601(c)(8)(B) of this Act already similarly amended this paragraph.), in para. (3) substituted "awarded as compensation by the special master or court under paragraph (1)" for "included under paragraph (1) in a judgment on such petition"; in subsec. (f), in para. (3), inserted "under the Program and the costs of carrying out the Program", in para. (4), in subpara. (A), deleted "made in a lump sum" following "the Program shall be" and inserted "and shall be paid from the trust fund in a lump sum of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner", in subpara. (B), substituted "determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum." for "paid in 4 equal annual installments"; in subsec. (g), inserted "(other than under title XIX of the Social Security Act)"; in subsec. (h)(2), inserted ", except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act"; in subsec. (i), purported to substitute "(j)" for "(i)" (However, such amendment was previously made by Act July 1, 1988, P.L. 100-360; see 1988 amendment note.); and, in subsec. (j), deleted "and" following "1991," and inserted ", \$ 80,000,000 for fiscal year 1993".

1990. Act Nov. 3, 1990 (effective 9/30/90 as provided by § 5(h) of such Act, which appears as *42 USCS § 300aa-11* note), in subsec. (e)(2), substituted "the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs" for "the Program, in awarding compensation on such petition the special master or court may include an amount limited to the costs"; in subsec. (f), in para. (2), substituted "section 2121(a)" for "section 2121(b)" and, in para. (4)(B), substituted "subsection (j)" for "subsection (i)" and "the limitation on civil actions prescribed by section 2121(a)" for "section 2111(a)"; and, in subsec. (j), inserted ", and \$ 80,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B)".

1991. Act Nov. 26, 1991 (effective on enactment, as provided by § 201(i)(1) of such Act, which appears as *42 USCS § 300aa-11* note), in subsec. (f)(4), in subpara. (A), deleted "of the proceeds" preceding "may be used" and substituted "Vaccine Injury Compensation Trust Fund established under *section 9510 of the Internal Revenue Code* of 1986" for "trust fund".

Such Act further (effective as above) purported to amend subsec. (f)(4)(B) by substituting "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion" for "paid in 4 equal installments of which all or portion of the proceeds"; however, the substitution was made for "paid in 4 equal installments of which all or a portion of the proceeds" in order to effectuate the probable intent of Congress.

Such Act further (effective on and after 10/1/88, as provided by § 201(i)(2) of such Act which appears as *42 USCS § 300aa-11* note), in subsec. (f)(4), added subpara. (C).

1992. Act Oct. 27, 1992, in subsec. (j), substituted "\$ 110,000,000 for fiscal year 1993," for "\$ 80,000,000 for fiscal year 1993,".

1993. Act Aug. 10, 1993, in subsec. (j), substituted "\$ 110,000,000 for each succeeding fiscal year" for "\$ 80,000,000 for each succeeding fiscal year".

NOTES:

Code of Federal Regulations:

Public Health Service, Department of Health and Human Services--Vaccine injury compensation, 42 CFR Part 100.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § 35:736.

Am Jur:

32 Am Jur 2d, Federal Courts § 280.

63B Am Jur 2d, *Products Liability* § § 1972, 1988.

Interpretive Notes and Decisions: 1. Generally 2. Damages 3. Annuity or lump sum payments 4. Special education awards 5. Limitation on awards 6. Attorneys' fees, generally 7. --Effect of electing to reject judgment 8. --Calculation of award 9. --Reduction of fees requested 10. --Denial of award 11. Other awards

1. Generally

Where vaccination occurred before enactment of Vaccine Act, court may not award pre-judgment medical or rehabilitative expenses, but may award attorney fees and costs, pain and suffering, lost wages, and post-judgment medical and rehabilitative expenses. *Hanagan v Secretary of HHS (1989) 19 Cl Ct 7*; *Strother v Secretary of HHS (1989) 18 Cl Ct 816*.

Award for purpose of leisure and recreational equipment, although not specifically permitted by Vaccine Act, will be awarded where such equipment is therapeutic in nature as well as necessary to encourage child's future development. *Clark v Secretary of HHS (1989) 19 Cl Ct 113*.

42 USCS § 300aa-15, which allows compensation to be awarded for expenses which have been or will be for rehabilitation, developmental evaluation, special education, vocational training, and placement, may be construed to support Special Master's award of compensation for vocational training and evaluation. *Metzger v Secretary of HHS (1990) 22 Cl Ct 123*.

Vaccine Act restricts compensation to expenses which have been or will be incurred by or on behalf of person who suffered injury and will immediately benefit claimant; counseling that equips parents with expertise necessary to properly manage their injured child would be compensable while counseling for parents' own mental rehabilitation would not be compensable. *Huber v Secretary of HHS (1991) 22 Cl Ct 255*.

Vaccine Act limits compensation for community-acquired polio to those who contract polio from recipients of oral vaccine; polio contracted from recipients of contaminated, inactivated polio vaccine is not compensable. *Staples v Secretary of the Dep't of Health & Human Servs. (1994) 30 Fed Cl 348*.

Although Vaccine Act originally permitted subsequent increase of award if award proved insufficient, congressional amendment deleting such provisions suggests congressional intent to limit entitlement to costs reasonably anticipated at time of award; there is no authority for adding "flexibility" to plan. *Neher v Secretary, HHS (1993, CA) 984 F2d 1195, 129 ALR Fed 663*.

2. Damages

Suit seeking damages from Department of Biological Services for injuries caused by polio vaccine approved in violation of regulations is not governed by National Vaccine Injury Compensation Program Act, but by Federal Tort Claims Act. *In re Sabin Oral Polio Vaccine Products Liability Litigation (1993, CA4 Md) 984 F2d 124*.

For purpose of calculating lost earnings, term "appropriate taxes" as used in Vaccine Act, include *FICA tax*. *Euken by Euken v Secretary of the Dep't of Health & Human Servs. (1994, CA FC) 34 F3d 1045*.

Statutory cap of § 300aa-15(b) applies to total compensation for pain, suffering, and attorneys fees and costs, in case where vaccination occurred before enactment of Act. *Shaw v Secretary of HHS (1989) 18 Cl Ct 646*.

Petitioner was not entitled under Court of Federal Claims Rule 60 to relief from judgment omitting damages agreed upon for pain and suffering; damages for pain and suffering are not mandated by Vaccine Act but rather are discretionary, and Rule 60 does not apply when alleged error arises out of performance of non-ministerial duty; moreover, where delay was unexplained and respondent stated it did not recall discussing pain and suffering with petitioner, court would be unable to conclude that respondent was not prejudiced by petitioner's 9-month delay in seeking correction. *Bucci by Bucci v Secretary of the Dep't of Health & Human Servs. (1994) 32 Fed Cl 330*.

Potential entitlement to compensation related to initial vaccine injury does not depend on whether eventual death was also vaccine related. *Lawson v Secretary of HHS (1999) 45 Fed Cl 236*.

3. Annuity or lump sum payments

Attorney fees are not "compensation" for purpose of Vaccine Act and are therefore payable in lump-sum rather than through quarterly installments. *Manley v Secretary of HHS (1989) 18 Cl Ct 799*.

Because Vaccine Act provides no guidance in setting reasonable attorney fee, court may look to Equal Access to Justice Act in using \$ 75 hourly rate as lodestar amount. *Pusateri v Secretary of HHS (1989) 18 Cl Ct 828*.

Special Master did not abuse discretion in awarding annuity rather than lump sum payment, despite fact that state oversees guardianship in question; increased level of protection for child is itself sufficient to support Special Master's

order without finding that father or other possible guardian is disposed to waste or mismanagement. *Ruben v Secretary of HHS (1991) 22 Cl Ct 264*.

Annuity, rather than lump sum payment, is in best interest of child where it insures beneficiary steady stream of income throughout his life, protects corpus from mismanagement or waste, and relieves parents from burden of having to speculate as to child's life expectancy. *Loe v Secretary of HHS (1991) 22 Cl Ct 430*.

Vaccine Act contemplates specific award of annuity or lump-sum and does not contemplate contingency fund to embody element of either type of award; therefore, \$ 50,000 awarded by special master for "excess inflation" must be reallocated. *Potter v Secretary of HHS (1991) 22 Cl Ct 701*.

Vaccine Act does not authorize award of contingency fund; thus, special master's "one-time up-front allotment" does not augment inadequate annuity but, rather, compensates petitioner for uncertain future expenses not within purview of Act, and will therefore be set aside. *Leung v Secretary of HHS (1991) 23 Cl Ct 217*.

Award by special master of damages in annual amounts by group categories comports with Congressional intent to permit masters broad and flexible discretion in awarding compensation. *Neher v Secretary of HHS (1991) 23 Cl Ct 508*, affd (1993, CA) 984 F2d 1195, 129 ALR Fed 663.

42 USCS § 300aa-15 permits all allowable elements of compensation to be addressed in single award rather than requiring all such elements to be addressed in single award; post-judgment proceeding on issue of attorney fees may occur after election has been made. *Saunders v Secretary of Dep't of Health & Human Servs. (1992) 26 Cl Ct 1221*, affd (1994, CA FC) 25 F3d 1031.

Net present value of impaired earning capacity under 42 USCS § 300aa-15 may not be determined by cost of deferred annuity where cost of annuity reflects contingency factors under which aggregate lost earnings might not have to be paid in full. Edgar on behalf of *Edgar v Secretary of Dep't of Health & Human Servs. (1993, CA) 989 F2d 473*, reh den (1993, CA FC) 1993 US App LEXIS 12505.

Special master does not have authority to issue compensation covering attorneys' fees and costs directly to counsel. *Newby by & Through Newby v Secretary of the HHS (1998) 41 Fed Cl 392*.

4. Special education awards

Special Master is not required to offset award for special education and therapy services by value of services school system is required to furnish under 20 USCS § 1401. *Stotts v Secretary of HHS (1991) 23 Cl Ct 352*.

Special master's conclusion that 42 USCS § 300aa-15 precluded award of private education was reasonable where she awarded child 4 hours of daily attendant care through age 20 and petitioners made no showing that school district would not reasonably provide for child's educational needs. *Mackler v Secretary of HHS (1992) 26 Cl Ct 120*.

5. Limitation on awards

In calculating amount of compensation for pain and suffering and emotional distress under Vaccine Act, statutory cap must be applied when determining amount of compensation, and then discount provision must be applied to compensation amount to determine immediate lump sum to be paid. *Youngblood v Secretary of the Dep't of Health & Human Servs. (1994, CA FC) 32 F3d 552*.

Statutory cap of \$ 250,000 for pain and suffering awards is to be applied before reduction of future pain and suffering to net value. *McAllister v Secretary of Health & Human Servs. (1995, CA FC) 70 F3d 1240*.

Statutory construction shows Congressional intent that Vaccine Act places \$ 30,000 ceiling on attorney fees and other costs. *Mikulich v Secretary of HHS (1989) 18 Cl Ct 253*; *Bazan v Secretary of HHS (1989) 18 Cl Ct 309*.

Thirty thousand dollar limit of § 300aa-15(b), applicable to vaccination administered before effective date of statute, embraces all attorney's fees and costs, rather than only those fees associated with proof of loss of earnings and pain and suffering. *Shepherd v Secretary of HHS (1989) 18 Cl Ct 774*.

Statutory scheme of National Vaccine Injury Compensation Program, when read as whole clearly indicates that vaccine-related injuries are to be compensated differently than vaccine-related deaths; because compensation for deaths is explicitly limited, court will not award additional compensation for lost wages or for pain and suffering. *Sheehan v Secretary of HHS (1990) 19 Cl Ct 320*.

42 USCS § 300aa-15 places \$ 30,000 ceiling on totality of 3 elements of compensation under Vaccine Act--lost wages, pain and suffering, and all attorneys' fees and other costs associated with claim--not on each element individually. *Davis v Secretary of HHS (1990) 19 Cl Ct 395*.

Meaning of last clause of 42 USCS § 300aa-15(b), when read in conjunction with § 300aa-15(e), is that in retrospective vaccine injury cases, petitioner who is eligible for compensation may also be reimbursed for up to but not more than \$ 30,000 for total of pain and suffering, impaired wages, attorney fees and other costs. *Morris v Secretary of HHS (1990) 20 Cl Ct 14*.

Where petitioner pled 2 separate compensable injuries in 2 separate petitions, one for each DPT vaccination, attorney fees are limited by law to \$ 30,000. *Tom v Secretary of HHS (1990) 22 Cl Ct 214.*

Inconsistent language of 42 USCS § 300aa-15 precludes categorical distinctions and terminology urged by plaintiff's attorney that "attorneys' fees" refers only to charges for lawyer's time while "costs" only covers other expenses; thus, cap on collecting any additional "fees for services" includes advance costs as well as hourly charges for lawyer time. *Beck v Secretary of HHS (1991, CA) 924 F2d 1029* (criticized in *Cain v Secretary of Health & Human Servs. (1992, Ct Fed Cl) 1992 US Claims LEXIS 25*).

Vaccine Act's statutory cap of \$ 250,000 should be applied to special master's award after discounting award for future pain and suffering to net present value. *Youngblood v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 566.*

6. Attorneys' fees, generally

Awarding of attorneys' fees to parents, who filed action on behalf of their minor child under National Childhood Vaccine Injury Act of 1986, 42 USCS § § 300aa-1 through 300aa-34, was not authorized under 42 USCS § 300aa-15(e)(1)(B), part of Vaccine Act, because parents' petition was dismissed on appeal for lack of jurisdiction; they did not properly file petition under 42 USCS § 300aa-11, and, therefore, jurisdiction to issue award of attorneys' fees did not exist. *Brice v Sec'y of HHS (2004, CA FC) 358 F3d 865.*

In permitting award of attorney fees and barring counsel from collecting directly from client, Congress intended that fees and costs be paid first from award. *Willcox v Secretary of HHS (1989) 18 Cl Ct 870.*

Timeliness of motions for attorney fees under Vaccine Act are governed by Vaccine Act, not by Federal Rules of Civil Procedure. *Hines v Secretary of HHS (1992) 26 Cl Ct 114.*

Judgment of voluntary withdrawal (42 USCS § 300aa-21(b)) entered in National Childhood Vaccine Injury Act case is judgment envisioned by Congress under 42 USCS § 300aa-15(e)(1), which provides for award of attorney's fees and costs in certain circumstances. *Grice v Secretary of Health & Human Servs. (1996) 36 Fed Cl 114.*

Inconsistent language of 42 USCS § 300aa-15 precludes categorical distinctions and terminology urged by plaintiff's attorney that "attorneys' fees" refers only to charges for lawyer's time while "costs" only covers other expenses; thus, cap on collecting any additional "fees for services" includes advance costs as well as hourly charges for lawyer time. *Beck v Secretary of HHS (1991, CA) 924 F2d 1029* (criticized in *Cain v Secretary of Health & Human Servs. (1992, Ct Fed Cl) 1992 US Claims LEXIS 25*).

Special Master's award of attorney fees and costs to petitioner despite petitioner's refusal to accept judgment of special master was not clearly erroneous. *Munn v Secretary of Dep't of Health & Human Servs. (1993) 28 Fed Cl 490*, dismd (1994, CA FC) 36 F3d 1110.

Special Master's decision to grant attorney fees despite fact that Special Master denied petitioner's underlying claim for damages is in accord with congressional intent to allow separate decision and judgment for attorney fee compensation following decision on underlying claim. *Mitchell v Secretary of Dep't of Health & Human Servs. (1993) 29 Fed Cl 150*, dismd (1994, CA FC) 36 F3d 1110.

For purposes of award of attorney's fees and costs under 42 USCS § 300aa-15(e)(1), both petitioner and government are entitled to presumption of good faith; thus, in absence of direct evidence of bad faith, special master is justified in presuming good faith. *Grice v Secretary of Health & Human Servs. (1996) 36 Fed Cl 114.*

"Reasonableness" requirement of 42 USCS § 300aa-15(e)(1), which authorizes special master to award reasonable attorney's fees and other costs, applies to both attorney's fees and costs. *Guy v Secretary of HHS (1997) 38 Fed Cl 403* (criticized in *Hayden v Secretary of HHS (1998, Ct Fed Cl) 1998 US Claims LEXIS 179*).

Special masters do not have authority to award compensable attorney's fees and related costs incurred in prosecution of Vaccine Act petition directly to counsel rather than to petitioner. *Heston by & Through Heston v Secretary of HHS (1998) 41 Fed Cl 41.*

Special master is given broad discretion in determining reasonable amount of attorney's fees and costs. *Guy v Secretary of HHS (1997) 38 Fed Cl 403* (criticized in *Hayden v Secretary of HHS (1998, Ct Fed Cl) 1998 US Claims LEXIS 179*).

National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 USCS § § 300aa-1 to-34, claim ran afoul of prohibition on suit expressly set forth in Vaccine Act, so claim was beyond court's jurisdiction; because court had no jurisdiction to hear claim in the first instance, it had no jurisdiction to award attorneys' fees. *Hebern v United States (2002) 54 Fed Cl 548.*

Parents did not satisfy either prong of requirements of 42 USCS § 300aa-15(e)(1) because parents could not have had either good faith or reasonable basis for claim underlying their petition under National Childhood Vaccine Injury Act, 42 USCS § 300aa-10 et seq., when they filed their petition after statute of limitations had run; "necessity" ground based

on Court of Appeals for Federal Circuit's requiring parents' child to have attorney represent him in order to pursue his appeal did not exist as applied to award of fees and costs. *Brice v Sec'y of HHS (2002, Ct Fed Cl) 2002 US Claims LEXIS 214*, affd (2003) 55 Fed Cl 366.

7. --Effect of electing to reject judgment

Petitioner's election to reject judgment of Claims Court on merits of her own claim did not bar her from recovering attorney's fees and costs incurred in her action under Vaccine Act; requirement that election in favor of judgment precede payment of compensation is requirement for election in favor of judgment on merits granting compensation and attorney's fees are wholly separate matters. *Saunders ex rel. Saunders v Secretary of the Dep't of Health & Human Servs. (1994, CA FC) 25 F3d 1031*.

Petitioner's election to reject Special Master's judgment pursuant to 42 USCS § 300aa-21 is not election to reject award of attorney fees also, even where voluntary dismissal may be based on petitioner's failure to obtain adequate medical testimony, where Special Master has found that petition was not frivolous. *Wells v Secretary of Dept't of Health & Human Servs. (1993) 28 Fed Cl 647*.

Special Master may not order payment of attorney fees and costs to petitioner who is found to be ineligible for award of compensation under Vaccine Act when petitioner has not made election to receive compensation or to accept judgment pursuant to 42 USCS § 300aa-15. *Ashe-Cline v Secretary of Dep't of Health & Human Servs. (1993) 30 Fed Cl 40*.

8. --Calculation of award

Conclusory assertions by fellow attorney that \$ 100 hourly rate charged by plaintiff's attorney was fair and reasonable for attorneys with same experience and expertise does not constitute prima facie evidence of reasonableness and is void of demonstrative showing that \$ 100 is reasonable fee; court will therefore award hourly rate of \$ 75. *Kue v Secretary of HHS (1989) 18 Cl Ct 777*.

Attorney seeking compensation under Vaccine Act bears burden of proof on reasonableness of hourly rate; one affidavit from fellow attorney is insufficient to demonstrate that \$ 125 hourly rate is in line with rate prevailing in community for similar services by attorneys of comparable skill, experience, and reputation. *First Commercial Bank v Secretary of HHS (1989) 19 Cl Ct 226*.

Same modicum of generosity applicable to merits of vaccine case is not applicable to determination of reasonable attorney's fees; both hours and rate must be appropriately documented, and undated, self-serving piece of paper is insufficient to document claimed hours. *Monteverdi v Secretary of HHS (1990) 19 Cl Ct 409*.

In determining what constitutes reasonable attorney fee, Vaccine Act is to be compared to Black Lung Act, in which fees are significantly lower than in routine civil litigation; Equal Access to Justice Act is also to be consulted, under which up to \$ 75 per hour is deemed reasonable absent special factors; thus, attorneys are unreasonable in seeking hourly rates higher than they normally charge. Hines on behalf of *Sevier v Secretary of HHS (1991) 22 Cl Ct 750*.

Special master properly evaluated petitioner's request for attorney fees based on general guidelines rather than on line-by-line analysis where 82-page documentation cryptically listed hours and descriptions of work. *Wasson v Secretary of HHS (1991) 24 Cl Ct 482*.

Special master's award of attorney fees to mother in action under National Childhood Vaccine Injury Act of 1986, 42 USCS §§ 300aa-1 to 300aa-34, had to be remanded because his decision was ambiguous as his adoption of mother's attorney's affidavit, followed by finding that mother's requested rates were "not per se unreasonable," but nevertheless not "inherently reasonable" for such cases, did not correlate to express finding of prevailing market rate. *Rupert v Sec'y of the HHS (2002) 52 Fed Cl 684*.

In setting lodestar amount, although personal injury, medical malpractice, and products liability were comparable fields to Vaccine Act litigation, special master acted contrary to statute and precedent when he considered existence of risk assumed by attorneys in those areas of law by taking such cases on contingency basis, so special master's findings were arbitrary and capricious; however, while contractual nature of relationship between insurance defense attorneys and insurance companies tended to lower rates paid to former, similar corollary was lacking in Vaccine Act context, and respondent failed to show that insurance defense was appropriate analogue to Vaccine Act practice. *Rupert v Sec'y of HHS (2003) 55 Fed Cl 293*.

9. --Reduction of fees requested

Special Master was justified in awarding attorney fees and costs only up to hearing where Special Master found, upon reviewing petitioner's expert's opinion prior to hearing, that petitioner no longer had reasonable basis for claim because

opinion was unsupported by either medical literature or studies and was therefore of no value in establishing causation-in-fact. *Perreira v Secretary of the Dep't of Health & Human Servs.* (1994, CA FC) 33 F3d 1375.

Hourly rate of \$ 250, rather than \$ 290 requested, was adequate to compensate experienced DPT litigator, where risk of litigative loss was minimal and no difficult or complex facts or issues were raised. *Newton v Secretary of HHS* (1989) 18 Cl Ct 665.

Conclusory assertions by fellow attorney that \$ 100 hourly rate charged by plaintiff's attorney was fair and reasonable for attorneys with same experience and expertise does not constitute prima facie evidence of reasonableness and is void of demonstrative showing that \$ 100 is reasonable fee; court will therefore award hourly rate of \$ 75. *Kue v Secretary of HHS* (1989) 18 Cl Ct 777.

Special master's decision in award of attorney fees to reduce hourly rate for partners will not be disturbed based on evaluation of complexity of case and determination that case did not call for full range of attorneys' abilities; amount claimed for paralegal time will not be reduced where paralegal's background as registered nurse would be uniquely suited to assisting in evaluating vaccine claim. *Bailey v Secretary of HHS* (1989) 22 Cl Ct 550.

Attorney fee should be reasonable for nature of work actually performed, such that hourly rate of "eminently qualified" attorney will be reduced to reflect simplicity of claim where high level of expertise was not required. *Lemon v Secretary of HHS* (1990) 19 Cl Ct 621.

In awarding attorney fees, Special Master's reduction of 2 attorney's hours by 49 percent and 25 percent was arbitrary and failed to take into account realities of conducting law practice, which involves extensive work within time limits imposed by Vaccine Act. *Holton v Secretary of HHS* (1991) 24 Cl Ct 391.

Special Master correctly allowed only five hours rather than 14 hours for preparing attorney fee application, disallowed six hours spent by two attorneys as redundant, and disallowed 28 hours involving petitioner's economist, whose role was found to be minimal. *Estrada v Secretary of Dep't of Health & Human Servs.* (1993) 29 Fed Cl 78.

Special Master's award of attorney fees in amount one-half of requested amount was not arbitrary and capricious where he considered size of petitioner's law firm, experience of its practitioners, complexity of issues, firm's location in New York City, and he analyzed hours expended in 7 other complicated cases. *Edgar ex rel. Edgar v Secretary of the Dep't of Health & Human Servs.* (1994) 32 Fed Cl 506.

10. --Denial of award

Court of Federal Claims erred in holding that Special Master's decision awarding only one half of amount of attorney fees requested based on prior experience with attorneys in question was arbitrary and erroneous; Special Master's past experience is relevant factor. *Saxton v Secretary of Dep't of Health & Human Servs.* (1993, CA FC) 3 F3d 1517.

Compensation under Vaccine Act will be denied where, although rubella arthritis was shown to be caused by rubella vaccine, injury lasted less than 6 months. *Fricano v United States* (1991) 22 Cl Ct 796.

Special master may not award attorney fees to time-barred plaintiff, although plaintiff had reasonable factual basis for bringing claim. *Jessup v Secretary of HHS* (1992) 26 Cl Ct 350 (criticized in *Long v Secretary of the Dep't of Health & Human Servs.* (1995, Ct Fed Cl) 1995 US Claims LEXIS 244).

Special Master was justified in denying attorney fees to plaintiff who failed on merits of claim where it was shown that child had been well for over a year after DPT shot and where Special Master indicated that he had "serious questions" as to whether claim was pursued in good faith. *Perez v Secretary of Health & Human Servs.* (1992) 27 Fed Cl 200.

Special Master did not abuse discretion in denying attorney fees where petitioner failed to establish good faith and reasonable basis for claim, as where questionnaire answered by petitioner prior to litigation denies any reaction to vaccination and where petitioner failed to explain disparities between contemporaneous medical records and her claims. *Murphy v Secretary of Dep't of Health & Human Servs.* (1993) 30 Fed Cl 60, affd without op (1995, CA FC) 48 F3d 1236, reported in full (1995, CA FC) 1995 US App LEXIS 2964.

Where, as part of settlement agreement, Secretary of Health and Human Services required plaintiff parents to deposit portion of settlement into court supervised guardianship account, attorney's fees attributable to establishment of state court guardianship were not compensable under 42 USCS § 300aa-15(e)(1), since fees were not incurred in proceeding on Vaccine Act petition. *Mol v Sec'y of the HHS* (2001) 50 Fed Cl 588.

11. Other awards

Where evidence does not support conclusion that petitioner will become permanently non-ambulatory, \$ 15,000 per year in home aid assistance is unjustified. *Brown v Secretary of HHS* (1989) 18 Cl Ct 834, revd, in part on other grounds (1990, CA) 920 F2d 918.

Where patient in Vaccine Act case is afflicted with progressive disease and is awarded nursing care 8-hours per day, Special Master cannot set date in future when 24-hour custodial care will be required, without obtaining further evidence as to likelihood and rate of further deterioration and nature and extent of appropriate care. *Zeagler v Secretary of Dep't of Health & Human Servs.* (1989) 19 Cl Ct 151.

Reasonable costs under Vaccine Act include telephone, postage, and travel costs incurred in supplying evidence requested by special master, but do not include attorney's fees related to probate of decedent's estate. *Siegfried v Secretary of HHS* (1990) 19 Cl Ct 323.

Despite fact that victim in National Vaccine Injury Compensation Program cannot be expected to manage own finances after age of majority, there is no statutory authority to support award of costs for fiduciary services; "case management services" encompasses coordination of social and medical services but does not encompass fiduciary services. *Hulsey on behalf of Hulsey v Secretary of HHS* (1990) 19 Cl Ct 331.

Under National Vaccine Injury Compensation Program, award for future living expenses should be based on premise that victim will move into life care center when parents are no longer able to provide care, rather than on premise that victim will remain in own home. *Shaw v Secretary of HHS* (1990) 19 Cl Ct 334.

42 USCS § 300aa-15, which allows compensation to be awarded for expenses which have been or will be for rehabilitation, developmental evaluation, special education, vocational training, and placement, may be construed to support Special Master's award of compensation for vocational training and evaluation. *Metzger v Secretary of HHS* (1990) 22 Cl Ct 123.

Vaccine Act restricts compensation to expenses which have been or will be incurred by or on behalf of person who suffered injury and will immediately benefit claimant; counseling that equips parents with expertise necessary to properly manage their injured child would be compensable while counseling for parents' own mental rehabilitation would not be compensable. *Huber v Secretary of HHS* (1991) 22 Cl Ct 255.

Award of \$ 14,000 is not unreasonable for home costs based on physician's recommendation that home be modified to create "adaptive room"; fact that award was not broken down into components of construction costs is not error where award was based on diligent estimates by experts. *Kleinert v Secretary of HHS* (1992) 25 Cl Ct 173.

Court has no authority to award post-judgment interest in Vaccine Act case. *Edgar ex rel. of Edgar v Secretary of the Dep't of Health & Human Servs.* (1993) 29 Fed Cl 339.

42 USCS § 300aa-15(a)(3)(B) may not be interpreted to mean that lost earnings must be awarded whenever vaccine-injured person will likely have substantially impaired earning capacity as adult regardless of whether that person will still be able to earn as much as average non-farm wage; rather, statute guarantees basic level of income based upon typical wages of non-farm worker and authorizes compensation only when vaccine-injured person will not be capable of earning average non-farm wage. *Holihan v Secretary of HHS* (1999) 45 Fed Cl 201.

LEXSTAT 42 USCS 300AA-16

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*** CURRENT THROUGH P.L. 109-6, APPROVED 3/31/05 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
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PROGRAM REQUIREMENTS

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-16 (2005)

§ 300aa-16. Limitations of actions

(a) General rule. In the case of--

(1) a vaccine set forth in the Vaccine Injury Table which is administered before the effective date of this part, 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 28 months after the effective date of this part and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this part, if a vaccine-related injury occurred as a result of the administration of such 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 part, 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, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 2111(b)(2) [42 USCS § 300aa-11(b)(2)], 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 [42 USCS § 300aa-11] 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 (1) an election is made under section 2121(a) [42 USCS § 300aa-21(a)] to file the civil action or (2) an election is made under section 2121(b) [42 USCS § 300aa-21(b)] to withdraw the petition.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2116, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3769; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4302(b)(2), 101 Stat. 1330-221; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(m)(1), 103 Stat. 2291; Nov. 3, 1990, P.L. 101-502, § 5(e), 104 Stat. 1287; Nov. 26, 1991, P.L. 102-168, Title II, § 201(d)(2), 105 Stat. 1103; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch B, Part IV, § 13632(a)(1), 107 Stat. 645.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

The "effective date of this part", referred to in this section, is Oct. 1, 1988, as provided by Act Nov. 14, 1986, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Explanatory notes:

A prior § 2116 of Act July 1, 1944, ch 373, Title XXI, which formerly appeared as *42 USCS § 300aa-15*, was redesignated as § 2714 of Title XXVII of such Act and now appears as *42 USCS § 300aaa-13*.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), substituted "effective date of this part" for "effective date of this title" wherever appearing.

1989. Act Dec. 19, 1989, (applicable as provided by § 6601(s) of such Act, which appears as *42 USCS § 300aa-10* note), in subsec. (c), substituted "2111" for "2111(b)".

1990. Act Nov. 3, 1990 (effective 9/30/90 as provided by § 5(h) of such Act, which appears as *42 USCS § 300aa-11* note), in subsec. (a)(1), substituted "28 months" for "24 months" and inserted "and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine"; and, in subsec. (c), substituted "and ending on the date (1) an election is made under section 2121(a) to file the civil action, (2) an election is made under section 2121(b) to withdraw the petition, or (3) the petition is considered withdrawn under section 2121(b)" for "and ending on the date a final judgment is entered on the petition".

1991. Act Nov. 26, 1991 (effective on and after 10/188, as provided by § 201(i)(2) of such Act, which appears as *42 USCS § 300aa-11* note), in subsec. (c), substituted "or (2)" for ", (2)" and deleted ", or (3) the petition is considered withdrawn under section 2121(b)" preceding the concluding period.

1993. Act Aug. 10, 1993, in subsec. (b), substituted "or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 2111(b)(2), file" for "such person may file".

NOTES:

Related Statutes & Rules:

This section is referred to in *42 USCS § § 300aa-11, 300aa-15, 300aa-21*.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § § 35:730, 739, 740.

Am Jur:

63B Am Jur 2d, Products Liability § 1573.

Interpretive Notes and Decisions: 1. Generally 2. Equitable tolling

1. Generally

42 USCS § 300aa-16(a)(2) is to be construed to require pre-existing condition prior to vaccination; Congress did not intend that worsening of condition brought on by vaccination would make new date for commencing running of 3-year limitations period. *Childs v Secretary of Health & Human Servs.* (1995) 33 Fed Cl 556.

Phrase "significant aggravation," as used in 42 USCS § 300aa-16(a)(2), refers to condition that predated administration of vaccine; thus, where petitioner alleges that vaccine caused injury and that later there was significant aggravation of that same injury, petitioner must file petition within 36 months of first symptom or manifestation of onset of injury, and petitioner does not have option to file within 36 months after alleged significant aggravation. *Brice v Secretary of the HHS* (1996) 36 Fed Cl 474.

Congress, as indicated by 42 USCS § § 300aa-11(c)(1)(D), 300aa-14(b)(2) and 300aa-16, intended 42 USCS § 300aa-16(a)(2) statute of limitations to commence running upon first symptom or manifestation of onset of injury, and not to be delayed until time petitioner has actual knowledge that vaccine recipient suffered from injury that could result in viable cause of action under *Vaccine Act*. *Brice v Secretary of the HHS* (1996) 36 Fed Cl 474.

Parents did not satisfy either prong of requirements of 42 USCS § 300aa-15(e)(1) because parents could not have had either good faith or reasonable basis for claim underlying their petition under National Childhood Vaccine Injury Act, 42 USCS § 300aa-10 et seq., when they filed their petition after statute of limitations had run. *Brice v Sec'y of HHS* (2002, Ct Fed Cl) 2002 US Claims LEXIS 214, affd (2003) 55 Fed Cl 366.

Where symptoms of autism develop insidiously over time and child's behavior cannot readily be connected to injury or disorder, court may rely on child's medical or psychological evaluations for guidance in ascertaining when "manifestation of onset" occurred under 42 USCS § 300aa-16(a)(2). *Setnes v United States* (2003) 57 Fed Cl 175.

2. Equitable tolling

43 USCS § 300aa-16 is a statute of repose, and therefore not subject to equitable tolling. *Weddel v Secretary of Health & Human Servs.* (1996, CA FC) 100 F3d 929; *Lombardo v Secretary of Health & Human Servs.* (1995) 34 Fed Cl 21.

Equitable tolling doctrine does not apply in cases brought after enactment of *National Childhood Vaccine Injury Act*. *Brice v Secretary of HHS* (2001, CA FC) 240 F3d 1367, reh den, reh, en banc, den (2001, CA FC) 2001 US App LEXIS 13324.

Doctrine of equitable tolling is not applicable to Vaccine Act; Congress intended 28-month limitation period to serve as cutoff for filing. Smith on behalf of *Smith v Secretary of HHS* (1992) 26 Cl Ct 116, affd without op (1992, CA) 983 F2d 1088, reported in full (1992, CA FC) 1992 US App LEXIS 30883.

Doctrine of equitable tolling may be applicable to claims under National Childhood Vaccine Injury Act. *Brown v Secretary of the HHS* (1996) 36 Fed Cl 435, affd (1997, CA FC) 1997 US App LEXIS 7616.

Equitable tolling applies to statute of limitations provided in 42 USCS § 300aa-16(a)(2). *Brice v Secretary of the HHS* (1996) 36 Fed Cl 474.

Where equitable tolling is invoked to suspend statute of limitations, plaintiff must bring suit within reasonable time after he has obtained, or by due diligence could have obtained, necessary information. *Brice v Secretary of the HHS* (1999) 44 Fed Cl 673.

LEXSTAT 42 USCS 300AA-17

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TITLE 42. THE PUBLIC HEALTH AND WELFARE
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42 USCS § 300aa-17 (2005)

§ 300aa-17. Subrogation

(a) General rule. Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated [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.

(b) Disposition of amounts recovered. Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, fund which has been established to provide compensation under the Vaccine Injury Compensation Trust Fund established under *section 9510 of the Internal Revenue Code* of 1986 [26 USCS § 9510].

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2117, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3770; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4307(7), 101 Stat. 1330-225; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(m)(2), 103 Stat. 2291.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Explanatory notes:

The bracketed word "subrogated" has been inserted in subsec. (a) as the word probably intended by Congress.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), deleted the designator for para. (1), altered the printing style, and deleted para. (2), which read: "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).".

1989. Act Dec. 19, 1989, (applicable as provided by § 6601(s) of such Act, which appears as a note to this section), in subsec. (b), substituted "the Vaccine Injury Compensation Trust Fund established under *section 9510 of the Internal Revenue Code of 1986*" for "the trust fund which has been established to provide compensation under the Program".

LEXSTAT 42 USCS 300AA-19

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42 USCS § 300aa-19 (2005)

§ 300aa-19. Advisory Commission on Childhood Vaccines

(a) Establishment. There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(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 Prevention, 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 part. 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 present at the meeting.

(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 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.

(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 [42 USCS § 300aa-27] 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) [42 USCS § 300aa-25(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 [42 USCS § § 300aa-10 et seq.].

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2119, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3771; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4302(b) (1), 101 Stat. 1330-221; Nov. 26, 1991, P.L. 102-168, Title II, § 201(g), 105 Stat. 1104; Oct. 27, 1992, P.L. 102-531, Title III, § 312(d)(14), 106 Stat. 3505.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

The "effective date of this part", referred to in this section, is Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as 42 USCS § 300aa-1 note.

The "General Schedule", referred to in this section, is set out under 5 USCS § 5332.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as 42 USCS § 300aa-1 note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), substituted "effective date of this part" for "effective date of this subtitle".

1991. Act Nov. 26, 1991 (effective on enactment as provided by § 201(i)(1) of such Act, which appears as 42 USCS § 300aa-11 note), in subsec. (c), inserted "present at the meeting".

1992. Act Oct. 27, 1992, in subsec. (a)(2), substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

NOTES:

Related Statutes & Rules:

This section is referred to in 42 USCS § 300aa-33.

LEXSTAT 42 USCS 300AA-21

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*** CURRENT THROUGH P.L. 109-6, APPROVED 3/31/05 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
ADDITIONAL REMEDIES

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-21 (2005)

§ 300aa-21. Authority to bring actions

(a) Election. After judgment has been entered by the United States Claims Court [United States Court of Federal Claims] or, if an appeal is taken under section 2112(f) [42 USCS § 300aa-12(f)], after the appellate court's mandate is issued, the petitioner who filed the petition under section 2111 [42 USCS § 300aa-11] shall file with the clerk of the United States Claims Court [United States Court of Federal Claims]--

(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 court's final judgment with respect to which the election is to be made. If a person required to file an election with the 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 the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988], see section 2111(a)(2) [42 USCS § 300aa-11(a)(2)].

(b) Continuance or withdrawal of petition. A petitioner under a petition filed under section 2111 [42 USCS § 300aa-11] may submit to the United States Claims Court [United States Court of Federal Claims] a notice in writing choosing to continue or to withdraw the petition if--

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 2112(d)(3)(A)(ii) [42 USCS § 300aa-12(d)(3)(A)(ii)] (excluding (i) any period of suspension under section 2112(d)(3)(C) or 2112(d)(3)(D) [42 USCS § 300aa-12(d)(3)(C) or (D)], and (ii) any days the petition is before a special master as a result of a remand under section 2112(e)(2)(C) [42 USCS § 300aa-12(e)(2)(C)], or

(2) the court fails to enter a judgment under section 2112 [42 USCS § 300aa-12] on the petition within 420 days (excluding (i) any period of suspension under section 2112(d)(3)(C) or 2112(d)(3)(D) [42 USCS § 300aa-12(d)(3)(C)

or (D)], and (ii) any days the petition is before a special master as a result of a remand under section 2112(e)(2)(C) [42 USCS § 300aa-12(e)(2)(C)] after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 2112(g) [42 USCS § 300aa-12(g)].

(c) 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 [42 USCS § 300aa-11] shall, except as provided in section 2116(c) [42 USCS § 300aa-16(c)], be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part B, § 2121, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3772; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § § 4304(c), 4307(8), 101 Stat. 1330-224, 225; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(o)(3)(A), 102 Stat. 808; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(n), 103 Stat. 2292; Nov. 3, 1990, P.L. 101-502, § 5(f), 104 Stat. 1288; Nov. 26, 1991, P.L. 102-168, Title II, § 201(d)(3), 105 Stat. 1103.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Explanatory notes:

The bracketed words "United States Court of Federal Claims" were inserted in subsecs. (a) and (b) of this section on the authority of § 902(b)(1) of Act Oct. 29, 1992, P.L. 102-572, which appears as 28 USCS § 171 note, and which provides that reference to the United States Claims Court in any Federal law or document shall be deemed to refer to the United States Court of Federal Claims.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as 42 USCS § 300aa-1 note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), in the introductory matter, substituted "the United States Claims Court" for "a district court of the United States", and, in the concluding matter, substituted "the court" for "a court" following "election with" and preceding "or is deemed", and ", such person"; redesignated subsec. (b) as subsec. (c); and added a new subsec. (b).

Such Act further, as amended by Act July 1, 1988 (effective as if included in Act Dec. 22, 1987 amendments as provided by § 411(a)(2) of Act July 1, 1988, which appears as 1 USCS § 106 note), in subsec. (a), in the concluding matter, substituted "the court's final judgment" for "the entry of the court's judgment".

1989. Act Dec. 19, 1989 (applicable as provided by § 6601(s) of such Act, which appears as a note to this section), in subsec. (a), in the introductory matter, substituted "After judgment has been entered by the United States Claims Court or, if an appeal is taken under section 2112(f), after the appellate court's mandate is issued, the petitioner who filed the petition under section 2111 shall file with the clerk of the United States Claims Court" for "After the judgment of the United States Claims Court 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", and in the concluding matter, substituted the sentence beginning "For limitations . . ." for one which read: "If a person elects to receive compensation under a judgment of the court or is deemed to have accepted the judgment of the court, 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."; and, in subsec. (b), substituted "within 420 days (excluding any period of suspension under section 2112(d) and excluding any days the petition is before a special master as a result of a remand under section 2112(e)(2)(C))" for "within 365 days", and substituted "An election shall be filed under this subsection not later than 90 days after the date of the entry of the Claims Court's judgment or the appellate court's mandate with respect to which the election is to be made." for "Such a notice shall be filed not later than 90 days after the expiration of such 365-day period."

1990. Act Nov. 3, 1990, (effective 11/14/86 as provided by § 5(h) of such Act, which appears as 42 USCS § 300aa-11 note), in subsec. (a), in the concluding matter, inserted the sentence beginning "If a person elects to receive

compensation . . ." and inserted "for vaccine-related injuries or deaths associated with the administration of a vaccine after the effective date of this part".

Such Act further (effective Sept. 30, 1990, as provided by § 5(h) of such Act, which appears as 42 USCS § 300aa-11 note), substituted subsec. (b) for one which read: "If the United States Claims Court fails to enter a judgment under section 2112 on a petition filed under section 2111 within 420 days (excluding any period of suspension under section 2112(d) and excluding any days the petition is before a special master as a result of a remand under section 2112(e)(2)(C) after the date on which the petition was filed, the petitioner may submit to the court a notice in writing withdrawing the petition. An election shall be filed under this subsection not later than 90 days after the date of the entry of the Claims Court's judgment or the appellate court's mandate with respect to which the election is to be made. A person who has submitted a notice under this subsection may, notwithstanding section 2111(a)(2), thereafter maintain a civil action for damages in a State or Federal court without regard to part B and consistent with otherwise applicable law."

1991. Act Nov. 26, 1991 (effective on and after 10/1/88, as provided by § 201(i)(2) of such Act, which appears as 42 USCS § 300aa-11 note), in subsec. (b), in para. (2), in the introductory matter, substituted "a notice in writing choosing to continue or to withdraw the petition" for "a notice in writing withdrawing the petition" and, in the concluding matter, deleted "If such a notice is not filed before the expiration of such 30 days, the petition with respect to which the notice was to be filed shall be considered withdrawn under this paragraph." following "by section 2112(g).", deleted para. (2), which read: "If a special master or the court does not enter a decision or make a judgment on a petition filed under section 2111 within 30 days of the provision of the notice in accordance with section 2112(g), the special master or court shall no longer have jurisdiction over such petition and such petition shall be considered as withdrawn under paragraph (1).", deleted the para. designator "(1)" preceding "A petitioner", redesignated former subparas. (1)(A) and (B) as paras. (1) and (2), respectively, and substituted the subsec. heading for one which read: "Withdrawal of petition."

NOTES:

Related Statutes & Rules:

This section is referred to in 42 USCS § § 300aa-11, 300aa-12, 300aa-15, 300aa-16, 300aa-34.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § § 35:728, 738-740.

Am Jur:

63B Am Jur 2d, Products Liability § 1573.

Annotations:

Products liability: pertussis vaccine manufacturers. 57 ALR4th 911.

Interpretive Notes and Decisions:

Vaccine Act gives Court of Federal Claims no authority to waive 90-day time limit Congress provided for filing election to accept judgment or file civil action. *Gilbert by Gilbert v Secretary of Health & Human Servs.* (1995, CA FC) 51 F3d 254.

Petitioner's election under 42 USCS § 300aa-21(a) to reject judgment of court dismissing petition for compensation, apparently in order to file civil action, was not revocable. *Evans v Secretary of the Dep't of Health & Human Servs.* (1994) 30 Fed Cl 709.

Petitioners cannot file late election to reject Special Master's judgment after 90 day time limit; Congress established binding deadlines for filing of such election, and filing of civil action in district court does not satisfy request to file election with clerk of Court of Federal Claims. *Gilbert by Gilbert v Secretary of the Dep't of Health & Human Servs.* (1994) 31 Fed Cl 379, affd (1995, CA FC) 51 F3d 254.

Judgment of voluntary withdrawal (42 USCS § 300aa-21(b)) entered in National Childhood Vaccine Injury Act case is judgment envisioned by Congress under 42 USCS § 300aa-15(e)(1), which provides for award of attorney's fees and costs in certain circumstances. *Grice v Secretary of Health & Human Servs.* (1996) 36 Fed Cl 114.

Unambiguous and explicit language and basic design of 42 USCS § 300aa-21(a) prevent Court of Federal Claims from permitting filing of untimely election; such filing would vitiate carefully constructed and detailed statutory scheme Congress provided for in litigation of vaccination injuries. *Bailiss v Secretary of the HHS* (1996) 37 Fed Cl 64.

42 USCS § 300aa-21

Court of Federal Claims cannot use Rule 60(b), which deals with relief from judgments and orders, to extend time of election under 42 USCS § 300aa-21(a). *Bailiss v Secretary of the HHS* (1996) 37 Fed Cl 64.

LEXSTAT 42 USCS 300AA-22

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TITLE 42. THE PUBLIC HEALTH AND WELFARE
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42 USCS § 300aa-22 (2005)

§ 300aa-22. Standards of responsibility

(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.

(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 part [effective Oct. 1, 1988] 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 [21 USCS § § 301 et seq.] and section 351 of the Public Health Service Act [42 USCS § 262] (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--

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2) [42 USCS § 300aa-23(d)(2)(A) or (B)], 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 part [effective Oct. 1, 1988] 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 [42 USCS § § 300aa-10 et seq.].

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part B, § 2122, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3773; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4302(b)(1), 101 Stat. 1330-221.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as 42 USCS § 300aa-1 note.

Amendments:

1987. Act Dec. 22, 1987, in subsecs. (b)(1) and (c), substituted "effective date of this part" for "effective date of this subtitle".

NOTES:

Related Statutes & Rules:

This section is referred to in 42 USCS § 300aa-23.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § § 35:722, 740, 741.

Law Review Articles:

Gameran. Regulation of biologics manufacturing: questioning the premise, 49 *Food & Drug LJ* 213, 1994.

Flannery. One advocate's viewpoint: conflicts and tensions in the Baby K [In the *Matter of Baby K*, 16 F.3d 590 (4th Cir. 1994)] case, 23 *JL Med & Ethics* 7, Spring 1995.

Schwartz; Mahshigian. National Childhood Vaccine Injury Act of 1986: an ad hoc remedy or a window for the future? 48 *Ohio St LJ* 387, 1987.

Dark. Is the National Childhood Vaccine Injury Act of 1986 the solution for the DTP controversy? 19 *U Tol L Rev* 799, Summer 1988.

The National Childhood Vaccine Injury Act: implications for DPT vaccine manufacturers and victims, 28 *Washburn LJ* 274, Winter 1988.

Interpretive Notes and Decisions:

Parents' products liability/tort claims against vaccine manufacturer will not be summarily dismissed, where daughter contracted subacute sclerosing panencephalitis after being inoculated with measles, mumps, and rubella vaccine, because preemption of state tort law does not automatically follow from extensive federal regulation of vaccine production, labeling, and distribution under Food, Drug and Cosmetic Act and Public Health Service Act, as indicated by language of 42 USCS § 300aa-22. *Mazur v Merck & Co.* (1990, ED Pa) 742 F Supp 239.

State statute of limitation establishing "one filing rule" is not preempted by Public Health Service Act (42 USCS § § 300aa-1 et seq.) in negligence action on behalf of minor against manufacturer of vaccine, because although 42 USCS § 300aa-22(e) prevents states from establishing laws prohibiting individual from bringing civil action against vaccine manufacturer, § 300aa-22(a) specifically provides that state law applies to such actions and Act's legislative history clearly establishes that Congress did not intend to preempt state statutes of limitations. *Evans v Lederle Lab.* (1995, CD Ill) 904 F Supp 857.

LEXSTAT 42 USCS 300AA-23

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TITLE 42. THE PUBLIC HEALTH AND WELFARE
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GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-23 (2005)

§ 300aa-23. Trial

(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 part [effective Oct. 1, 1988] which is not barred by section 2111(a)(2) [42 USCS § 300aa-11(a)(2)] shall be tried in three stages.

(b) Liability. The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 2122 [42 USCS § 300aa-22].

(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 [42 USCS § 300aa-22] 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 [42 USCS § 300aa-22] shall be required to pay.

(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--

(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 USCS § 262],

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

(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 fact or conclusion of law of the United States Claims Court [United States Court of Federal Claims] or a special master in a proceeding on a petition filed under section 2111 [42 USCS § 300aa-11] and the final judgment of the United States Claims Court [United States Court of Federal Claims] and subsequent appellate review on such a petition shall not be admissible.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part B, § 2123, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3774; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § § 4302(b)(1), 4307(9), 101 Stat. 1330-221, 225; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(o), 103 Stat. 2292.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Explanatory notes:

The bracketed words "United States Court of Federal Claims" were inserted in subsec. (e) of this section on the authority of § 902(b)(1) of Act Oct. 29, 1992, P.L. 102-572, which appears as *28 USCS § 171* note, and which provides that reference to the United States Claims Court in any Federal law or document shall be deemed to refer to the United States Court of Federal Claims.

Effective date of section:

This section became effective Oct. 1, 1988, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), substituted "effective date of this part" for "effective date of this subtitle"; and, in subsec. (e), substituted "the United States Claims Court" for "a district court of the United States".

1989. Act Dec. 19, 1989 (applicable as provided by § 6601(s) of such Act, which appears as *42 USCS § 300aa-10* note), in subsec. (e), substituted "finding of fact or conclusion of law" for "finding", "special master" for "master appointed by such court", and "the United States Claims Court and subsequent appellate review" for "a district court of the United States".

NOTES:

Related Statutes & Rules:

This section is referred to in *42 USCS § 300aa-22*.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § § 35:741, 742.

LEXSTAT 42 USCS 300AA-25

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TITLE 42. THE PUBLIC HEALTH AND WELFARE
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GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-25 (2005)

§ 300aa-25. Recording and reporting of information

(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--

- (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
- (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) [42 USCS § 300aa-14(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 part [effective Dec. 22, 1987]. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(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 part [effective Dec. 22, 1987].

(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--

- (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.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part C, § 2125, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3774; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4302(b) (1), 101 Stat. 1330-221.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Effective date of section:

This section became effective Dec. 22, 1987, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (b), in para. (1), in the concluding matter, and in para. (3), substituted "effective date of this part" for "effective date of this subtitle".

NOTES:

Code of Federal Regulations:

Food and Drug Administration, Department of Health and Human Services--Biological products; general, 21 CFR Part 600.

Related Statutes & Rules:

This section is referred to in *42 USCS § 300aa-19*.

Research Guide:

Annotations:

Products liability: pertussis vaccine manufacturers. *57 ALR4th 911*.

LEXSTAT 42 USCS 300AA-26

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TITLE 42. THE PUBLIC HEALTH AND WELFARE
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GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-26 (2005)

§ 300aa-26. Vaccine information

(a) General rule. Not later than 1 year after the effective date of this part [effective Dec. 22, 1987], the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials. Such materials shall be developed or revised--

- (1) after notice to the public and 60 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 Prevention, and the Food and Drug Administration.

(c) Information requirements. The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include--

- (1) a concise description of the benefits of the vaccine,
- (2) a concise description of the risks associated with the vaccine,
- (3) a statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) 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 or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part C, § 2126, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3775; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4302(b)(1), 101 Stat. 1330-221; Dec. 19,

1989, P.L. 101-239, Title VI, Subtitle D, § 6601(p), 103 Stat. 2292; Oct. 27, 1992, P.L. 102-531, Title III, § 312(d)(15), 106 Stat. 3505; Dec. 14, 1993, P.L. 103-183, Title VII, § 708, 107 Stat. 2242.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Effective date of section:

This section became effective Dec. 22, 1987, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), substituted "effective date of this part" for "effective date of this subtitle".

1989. Act Dec. 19, 1989 (applicable as provided by § 6601(s) of such Act, which appears as *42 USCS § 300aa-10* note), in subsec. (c), substituted para. (9) for one which read:

"(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".

1992. Act Oct. 27, 1992, in subsec. (b)(2), substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1993. Act Dec. 14, 1993, in subsec. (a), in the introductory matter, inserted "or to any other individual"; in subsec. (b), in the introductory matter, deleted "by rule" following "developed or revised", in para. (1), substituted "and 60" for ", opportunity for a public hearing, and 90"; in subsec. (c), in the introductory matter, inserted "shall be based on available data and information," and deleted paras. (1)-(10), which read:

"(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--

"(A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and

"(B) the availability of the Program, and

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

and added new paras. (1)-(4); in subsec. (d), in the concluding matter, inserted "or to any other individual", substituted "supplemented with visual presentations or oral explanations, in appropriate cases." for "or other written information which meets the requirements of this section.", and deleted "or other information" following "Such materials".

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 ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-27 (2005)

§ 300aa-27. Mandate for safer childhood vaccines

(a) General rule. In the administration of this subtitle [*42 USCS § § 300aa-10 et seq.*] and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall--

(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 part [effective Dec. 22, 1987] 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) Task force.

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report. Within 2 years after the effective date of this part [effective Dec. 22, 1987], 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.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part C, § 2127, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3777; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4302(b)(1), 101 Stat. 1330-221; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(q), 103 Stat. 2292.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

With respect to the Committee on Energy and Commerce of the House of Representatives, referred to in this section, § 1(a)(4), (c)(1) of Act June 3, 1995, P.L. 104-14, which appears as a note preceding 2 USCS § 21, provides that any reference to such Committee in any provision of law enacted before January 4, 1995, shall be treated as referring to the Committee on Commerce of the House of Representatives, except that it shall be treated as referring to (A) the Committee on Agriculture of the House of Representatives, in the case of a provision of law relating to inspection of seafood or seafood products, (B) the Committee on Banking and Financial Services of the House of Representatives, in the case of a provision of law relating to bank capital markets activities generally or to depository institution securities activities generally, and (C) the Committee on Transportation and Infrastructure of the House of Representatives, in the case of a provision of law relating to railroads, railway labor, or railroad retirement and unemployment (except revenue measures related thereto).

Effective date of section:

This section became effective Dec. 22, 1987, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as 42 USCS § 300aa-1 note.

Amendments:

1987. Act Dec. 22, 1987, in subsecs. (a)(1) and (b), substituted "effective date of this part" for "effective date of this subtitle".

1989. Act Dec. 19, 1989 (applicable as provided by § 6601(s) of such Act, which appears as 42 USCS § 300aa-10 note) redesignated subsec. (b) as subsec. (c) and added a new subsec. (b).

NOTES:

Related Statutes & Rules:

This section is referred to in 42 USCS § 300aa-19.

Research Guide:

Law Review Articles:

Gameran. Regulation of biologics manufacturing: questioning the premise, *49 Food & Drug LJ* 213, 1994.

Flannery. One advocate's viewpoint: conflicts and tensions in the Baby K [In the *Matter of Baby K*, 16 F.3d 590 (4th Cir. 1994)] case, *23 JL Med & Ethics* 7, Spring 1995.

Schwartz; Mahshigian. National Childhood Vaccine Injury Act of 1986: an ad hoc remedy or a window for the future? *48 Ohio St LJ* 387, 1987.

Dark. Is the National Childhood Vaccine Injury Act of 1986 the solution for the DTP controversy? *19 U Tol L Rev* 799, Summer 1988.

The National Childhood Vaccine Injury Act: implications for DPT vaccine manufacturers and victims, *28 Washburn LJ* 274, Winter 1988.

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GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

42 USCS § 300aa-28 (2005)

§ 300aa-28. Manufacturer recordkeeping and reporting

(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 part [effective Dec. 22, 1987]--

(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,

(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.

(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--

(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.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part C, § 2128, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3777; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4302(b)(1), 101 Stat. 1330-221.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Effective date of section:

This section became effective Dec. 22, 1987, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (a), in the introductory matter, substituted "effective date of this part" for "effective date of this subtitle".

NOTES:

Code of Federal Regulations:

Food and Drug Administration, Department of Health and Human Services--Civil money penalties hearings, 21 CFR Part 17.

Related Statutes & Rules:

This section is referred to in *42 USCS § 300aa-33*.

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § 35:727.

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42 USCS § 300aa-31 (2005)

§ 300aa-31. Citizen's actions

(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 USCS § 300aa-10 et seq.*].

(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.

(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 plaintiff who substantially prevails on one or more significant issues in the action.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part D, § 2131, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3778; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4305, 101 Stat. 1330-224.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Effective date of section:

This section became effective Dec. 22, 1987, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

Amendments:

1987. Act Dec. 22, 1987, in subsec. (c), substituted "to any plaintiff who substantially prevails on one or more significant issues in the action" for "to any party, whenever the court determines that such award is appropriate".

NOTES:

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § 35:743.

Annotations:

Products liability: pertussis vaccine manufacturers. *57 ALR4th 911*.

Interpretive Notes and Decisions:

Plaintiff's failure to dismiss prior civil action in state court precludes district court from exercising jurisdiction over Vaccine Act claim. *Allison v Secretary of United States HHS (1991) 23 Ct Ct 551*.

Question whether plaintiffs, 2 attorneys, have standing to sue Department of Health and Human Services for Secretary's failure to perform obligations imposed on him by *42 USCS § 300aa-10*, being unsettled, requires attorneys to file memorandum on issue. *McDowell v Sullivan (1990, ND Ill) 132 FRD 498*, dismd (1990, ND Ill) *132 FRD 501*.

Court lacked subject matter jurisdiction over suit, brought by 2 attorneys suing Department of Health and Human Services for Secretary's failure to perform obligation imposed upon him by *42 USCS § 300aa-10* to inform public of availability of National Vaccine Injury Compensation Program; persons who are aware of Program do not have standing to complain of failure of Secretary to give Program publicity, and persons who are not aware of Program lack knowledge to bring such suit. *McDowell v Sullivan (1990, ND Ill) 132 FRD 501*.

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42 USCS § 300aa-32 (2005)

§ 300aa-32. Judicial review

A petition for review of a regulation under this subtitle [*42 USCS § § 300aa-10 et seq.*] 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.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part D, § 2132, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3778.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Effective date of section:

This section became effective Dec. 22, 1987, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.

NOTES:

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § 35:744.

Interpretive Notes and Decisions:

Secretary's failure to participate in proceedings before special master does not preclude Secretary's appeal to Claims Court. *Brown v Secretary of HHS (1990, CA) 920 F2d 918.*

Amendment to Vaccine Act permitting petitioner, after appeal, to elect not to accept final judgment of Claims Court, does not circumvent case or controversy requirement of Constitution and is therefore no bar to Court of Appeals jurisdiction. Hines on behalf of *Sevier v Secretary of HHS (1991, CA) 940 F2d 1518, 33 Fed Rules Evid Serv 632.*

There is nothing in statutes or Vaccine Rules of Office of Special Masters that require special masters to issue written decision; thus, special master did not abuse discretion in issuing bench ruling and then requiring plaintiffs, in order to receive written decision, to file written memorandum pointing out errors they perceived in ruling. *Bradley v Secretary of Health & Human Servs. (1993, CA) 991 F2d 1570.*

Petition challenging adoption of regulations revising table must be filed in court of appeals, not in Court of *Federal Claims*. *Muchnick v Secretary of the Health & Human Servs.* (1998) 42 Fed Cl 365.

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42 USCS § 300aa-33 (2005)

§ 300aa-33. Definitions

For purposes of this subtitle [42 USCS § § 300aa-10 et seq.]:

(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 [42 USCS § 300aa-28], such term shall include the manufacturer of any other vaccine covered 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 [42 USCS § 300aa-19].

(B) The term "Vaccine Injury Table" means the table set out in section 2114 [42 USCS § 300aa-14].

(7) [Repealed]

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part D, § 2133, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3778.)

(As amended Nov. 25, 2002, P.L. 107-296, Title XVII, § § 1714-1716, 116 Stat. 2320; Feb. 20, 2003, P.L. 108-7, Div L, § 102(a), 117 Stat. 528.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Effective date of section:

This section became effective December 22, 1987, as provided by § 323 of Act Nov. 14, 1986, P.L. 99-660, which appears as *42 USCS § 300aa-1* note.

Amendments:

2002. Act Nov. 25, 2002 (effective 60 days after enactment, as provided by § 4 of such Act, which appears as *6 USCS § 101* note, and repealed by Act Feb. 20, 2003), in para. (3), substituted "any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine" for "under its label any vaccine set forth in the Vaccine Injury Table", and inserted "including any component or ingredient of any such vaccine" following "distribute a vaccine", in para. (5), added "For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label." following "vaccine.", and added para. (7), which read: "(7) The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label."

2003. Act Feb. 20, 2003 (applicable as provided by § 102(b) of such Act, which appears as a note to this section), repealed the amendments made by Act Nov. 25, 2002.

Other provisions:

Repeal of provisions relating to application of Nov. 25, 2002 amendments. Act Nov. 25, 2002, P.L. 107-296, Title XVII, § 1717, 116 Stat. 2321, which formerly appeared as a note to this section, was repealed by Act Feb. 20, 2003, P.L. 108-7, Div L, § 102(a), 117 Stat. 528. Such note provided that the Nov. 25, 2002 amendments applied to all actions pending on or after enactment, with certain exceptions.

Application of repeal of Nov. 25, 2002 amendments. Act Feb. 20, 2003, P.L. 108-7, Div L, § 102(b), 117 Stat. 528, provides: "The Public Health Service Act (*42 U.S.C. 201* et seq.) shall be applied and administered as if the sections repealed by subsection (a) [amending this section and appearing in part as a note to this section] had never been enacted."

Nov. 25, 2002 amendments and repeal of such amendments; rule of construction. Act Feb. 20, 2003, P.L. 108-7, Div L, § 102(c), 117 Stat. 528, provides: "No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107-296) [amending this section and appearing in part as a note to this section], or from this repeal, regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107-296). Further, no inference shall be drawn that subsection (a) [repealing such sections 1714-1717] or (b) [note to this section] affects any change in that prior law, or that *Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02-392V* (October 11, 2002), was incorrectly decided."

NOTES:

Research Guide:

Federal Procedure:

13 Fed Proc L Ed, Food, Drugs, and Cosmetics § 35:727.

Am Jur:

63B Am Jur 2d, Products Liability § 1573.

Interpretive Notes and Decisions:

Court deferred to interpretation of Office of Special Masters (OSM) that thimerosal was constituent, rather than contaminant under *42 USCS 300aa-33(5)*, which gave jurisdiction over action to OSM under *42 USCS 300aa-11(a)(2)(A)*, and court stayed plaintiffs' action under National Vaccine Injury Compensation Program, *42 USCS § 300aa-10* et seq., for injuries caused by thimerosal to allow adjudication in Vaccine Court, rather than dismissing it, due to statute of limitations concerns. *Wax v Aventis Pasteur, Inc. (2002, ED NY) 240 F Supp 2d 191.*

Interpretation of what makes up "vaccine-related injury" was not sufficient to create federal question jurisdiction where complaint made no reference to federal standards in Vaccine Act, *42 USCS § 300aa* et seq., and federal issue was relevant only to affirmative defense. *Shadie v Aventis Pasteur (2003, MD Pa) 254 F Supp 2d 509.*

Mercury containing preservative was adulterant or contaminant because it was intended and approved component of vaccines themselves; as such, parent's claims alleging injuries arising from exposure to compound were vaccine-related injuries and action was brought in wrong court. *Murphy v Aventis Pasteur (2003, ND Ga) 270 F Supp 2d 1368.*

References in Vaccine Act to "petitioners under 300aa-11" do not indicate that 42 USCS § 300aa-11(b) is intended to abrogate right of estate of vaccine-injured person to receive compensation on person's behalf. *Andrews v Secretary of the Dep't Health & Human Servs.* (1995) 33 Fed Cl 767.

LEXSTAT 42 USCS 300AA-34

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42 USCS § 300aa-34 (2005)

§ 300aa-34. Termination of program

(a) Reviews. The Secretary shall review the number of awards of compensation made under the program to petitioners under section 2111 [42 USCS § 300aa-11] for vaccine-related injuries and deaths associated with the administration of vaccines on or after the effective date of this part as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on the effective date of this part.

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) Report.

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 2121(a) [42 USCS § 300aa-21(a)] exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)--

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after the effective date of this part may be filed under section 2111 [42 USCS § 300aa-11].

Section 2111(a) and part B [42 USCS § 300aa-11(a), § § 300aa-21 et seq.] shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows:

Period reviewed:	Total number of awards by the end of the period reviewed
12 months after the effective date of part	150
13th through the 15th month after such date	188
16th through the 18th month after such date	225
19th through the 21st month after such date	263
22nd through the 24th month after such date	300
25th through the 27th month after such date	338
28th through the 30th month after such date	375

31st through the 33rd month after such date	413
34th through the 36th month after such date	450
37th through the 39th month after such date	488
40th through the 42nd month after such date	525
43rd through the 45th month after such date	563
46th through the 48th month after such date	600.

HISTORY:

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part D, § 2134, as added Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, § 4303(f), 101 Stat. 1330-222.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

The "effective date of this part", referred to in this section, is Dec. 22, 1987, as provided by Act Nov. 14, 1986, P.L. 99-660, Title III, Part B, § 323, 100 Stat. 3784, which appears as *42 USCS § 300aa-1* note.