

the adverse reaction reporting requirements of section 300aa-25(b) of this title, 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 part.

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

CODIFICATION

In subsec. (a), “October 1, 1988” substituted for “the effective date of this subpart” on authority of section 323 of Pub. L. 99-660, as amended, set out as an Effective Date note under section 300aa-1 of this title.

AMENDMENTS

1992—Subsec. (a)(2). Pub. L. 102-531 substituted “Centers for Disease Control and Prevention” for “Centers for Disease Control”.

1991—Subsec. (c). Pub. L. 102-168 inserted “present at the meeting” before period at end.

1987—Subsec. (a). Pub. L. 100-203 substituted “effective date of this subpart” for “effective date of this part” in last sentence.

TERMINATION OF ADVISORY COMMISSIONS

Advisory commissions established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a commission established by the President or an officer of the Federal Government, such commission is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a commission established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93-641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SUBPART B—ADDITIONAL REMEDIES

§ 300aa-21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa-12(f) of this title, after the appellate court’s mandate is issued, the petitioner who filed the petition under section 300aa-11 of this title shall file with the

clerk of the 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 October 1, 1988, 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 October 1, 1988, see section 300aa-11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa-11 of this title may submit to the 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 300aa-12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa-12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title) 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 300aa-12(g) of this title.

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

(July 1, 1944, ch. 373, title XXI, §2121, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100

Stat. 3772; amended Pub. L. 100-203, title IV, §§ 4304(c), 4307(8), 4308(c), Dec. 22, 1987, 101 Stat. 1330-224, 1330-225; Pub. L. 100-360, title IV, § 411(o)(3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101-239, title VI, § 6601(n), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101-502, § 5(f), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102-168, title II, § 201(d)(3), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102-572, title IX, § 902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

CODIFICATION

In subsec. (a), “October 1, 1988,” and “October 1, 1988” substituted for “the effective date of this part”.

AMENDMENTS

1992—Subsecs. (a), (b). Pub. L. 102-572 substituted “United States Court of Federal Claims” for “United States Claims Court” wherever appearing.

1991—Subsec. (b). Pub. L. 102-168 substituted “Continuance or withdrawal of petition” for “Withdrawal of petition” in heading, redesignated introductory provisions of par. (1) as introductory provisions of subsec. (b) and substituted “a notice in writing choosing to continue or to withdraw the petition” for “a notice in writing withdrawing the petition”, redesignated subpars. (A) and (B) of former par. (1) as pars. (1) and (2), respectively, and realigned margins, struck out at end of former par. (1) “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.”, and struck out par. (2) which read as follows: “If a special master or the court does not enter a decision or make a judgment on a petition filed under section 300aa-11 of this title within 30 days of the provision of the notice in accordance with section 300aa-12(g) of this title, the special master or court shall no longer have jurisdiction over such petition and such petition shall be considered as withdrawn under paragraph (1).”

1990—Subsec. (a). Pub. L. 101-502, § 5(f)(1), in closing provisions, inserted after second sentence “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 October 1, 1988, 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.” and inserted “for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988” after “actions” in last sentence.

Subsec. (b). Pub. L. 101-502, § 5(f)(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: “If the United States Claims Court fails to enter a judgment under section 300aa-12 of this title on a petition filed under section 300aa-11 of this title within 420 days (excluding any period of suspension under section 300aa-12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title) 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 300aa-11(a)(2) of this title, thereafter maintain a civil action for damages in a State or Federal court without regard to this subpart and consistent with otherwise applicable law.”

1989—Subsec. (a). Pub. L. 101-239, § 6601(n)(1)(A), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: “After the judgment of the United States Claims Court

under section 300aa-11 of this title 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—”

Pub. L. 101-239, § 6601(n)(1)(B), amended last sentence generally. Prior to amendment, last sentence read as follows: “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.”

Subsec. (b). Pub. L. 101-239, § 6601(n)(2), substituted “within 420 days (excluding any period of suspension under section 300aa-12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title)” for “within 365 days” in first sentence and amended second sentence generally. Prior to amendment, second sentence read as follows: “Such a notice shall be filed not later than 90 days after the expiration of such 365-day period.”

1988—Subsec. (a). Pub. L. 100-360 added Pub. L. 100-203, § 4308(c), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100-203, § 4308(c), as added by Pub. L. 100-360, substituted “the court’s final judgment” for “the entry of the court’s judgment” in concluding provisions.

Pub. L. 100-203, § 4307(8), substituted “the United States Claims Court” for “a district court of the United States” and “the court” for “a court” in three places.

Subsecs. (b), (c). Pub. L. 100-203, § 4304(c), added subsec. (b) and redesignated former subsec. (b) as (c).

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-572 effective Oct. 29, 1992, see section 911 of Pub. L. 102-572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102-168 effective as in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102-168, set out as a note under section 300aa-11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 5(f)(1) of Pub. L. 101-502 effective Nov. 14, 1986, and amendment by section 5(f)(2) of Pub. L. 101-502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101-502, set out as a note under section 300aa-11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101-239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 420-day period prescribed in subsec. (b) of this section, see section 6601(s)(1) of Pub. L. 101-239, set out as a note under section 300aa-10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100-360, amendment by Pub. L. 100-360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203, effective as if included in the enactment of that provision in Pub. L. 100-203, see section 411(a) of Pub. L. 100-360, set out as a Reference to OBR A; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99-660, set out as a note under section 300aa-1 of this title.

§ 300aa-22. Standards of responsibility**(a) General rule**

Except as provided in subsections (b), (c), and (e) of this section 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 October 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 U.S.C. 301 et seq.] and section 262 of this title (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 300aa-23(d)(2) of this title, 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 October 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 part.

(July 1, 1944, ch. 373, title XXI, §2122, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3773; amended Pub. L. 100-203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330-221.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2), is act June 25, 1938, ch. 675, 52 Stat.

1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

CODIFICATION

In subsecs. (b)(1), (c), "October 1, 1988" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99-660, as amended, set out as an Effective Date note under section 300aa-1 of this title.

AMENDMENTS

1987—Subsecs. (b)(1), (c). Pub. L. 100-203 substituted "effective date of this subpart" for "effective date of this part".

§ 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 October 1, 1988, which is not barred by section 300aa-11(a)(2) of this title 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 300aa-22 of this title.

(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 300aa-22 of this title 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 300aa-22 of this title 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 [21 U.S.C. 301 et seq.] and this chapter 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 262 of this title,

(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 Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States