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 OBRA; 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 Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

(July 1, 1944, ch. 373, title XXI, § 2123, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §§ 4302(b)(1), 4307(9), Dec. 22, 1987, 101 Stat. 1330–221, 1330–225; Pub. L. 101–239, title VI, § 6601(*o*), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–572, title IX, § 902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (d)(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 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. (e). Pub. L. 102–572 substituted ''United States Court of Federal Claims'' for ''United States Claims Court'' in two places.

1989—Subsec. (e). Pub. L. 101–239 substituted ''finding of fact or conclusion of law'' for ''finding'', ''special master'' for ''master appointed by such court'', and directed substitution of ''the United States Claims Court and subsequent appellate review'' for ''a district court of the United States'' which was executed by inserting ''and subsequent appellate review'' after ''the United States Claims Court'' the second place it appeared to reflect the probable intent of Congress and the amendment by Pub. L. 100–203, § 4307(a), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, § 4302(b)(1), substituted ''effective date of this subpart'' for ''effective date of this part''.

Subsec. (e). Pub. L. 100–203, § 4307(9), substituted ''the United States Claims Court'' for ''a district court of the United States'' in two places.

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 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, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

SUBPART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN UNITED STATES

§ 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