

zation 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 sec-

tion 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) 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 preju-