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.

(July 1, 1944, ch. 373, title XXI, § 2128, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, § 4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

CODIFICATION

In subsec. (a), ''December 22, 1987'' 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—Subsec. (a). Pub. L. 100–203 substituted ''effective date of this subpart'' for ''effective date of this part''.

SUBPART D—GENERAL PROVISIONS

§ 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 part.

(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.

(July 1, 1944, ch. 373, title XXI, § 2131, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 100–203, title IV, § 4305, Dec. 22, 1987, 101 Stat. 1330–224.)

AMENDMENTS

1987—Subsec. (c). Pub. L. 100–203, which directed that subsec. (c) be amended by substituting ''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'', was executed by making the substitution for ''to any party, whenever the court determines such award is appropriate'', to reflect the probable intent of Congress.

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§ 300aa–32. Judicial review

A petition for review of a regulation under this part 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.

(July 1, 1944, ch. 373, title XXI, § 2132, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3778.)

§ 300aa–33. Definitions

For purposes of this part:

(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 300aa–28 of this title, 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 300aa–19 of this title.

(B) The term ''Vaccine Injury Table'' means the table set out in section 300aa–14 of this title.

(July 1, 1944, ch. 373, title XXI, § 2133, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 107–296, title XVII, §§ 1714–1716, Nov. 25, 2002, 116 Stat. 2320, 2321; Pub. L. 108–7, div. L, § 102(a), Feb. 20, 2003, 117 Stat. 528.)

AMENDMENTS

2003—Pars. (3), (5), (7). Pub. L. 108–7 repealed Pub. L. 107–296, §§ 1714–1717, and provided that this chapter shall be applied as if the sections repealed had never been enacted. See 2002 Amendment notes below.

2002—Par. (3). Pub. L. 107–296, § 1714, which directed amendment of first sentence by substituting ''any vaccine set forth in the Vaccine Injury table, including