

abortion counseling to a pregnant adolescent if such adolescent and the parents or guardians of such adolescent request such referral; and grants may be made only to projects or programs which do not advocate, promote, or encourage abortion.

(b) The Secretary shall ascertain whether programs or projects comply with subsection (a) of this section and take appropriate action if programs or projects do not comply with such subsection, including withholding of funds.

(July 1, 1944, ch. 373, title XX, §2011, as added Pub. L. 97-35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 592.)

SUBCHAPTER XIX—VACCINES

PRIOR PROVISIONS

A prior subchapter XIX (§300aa et seq.), comprised of title XXI of the Public Health Service Act, act July 1, 1944, ch. 373, §§2101 to 2116, was renumbered title XXIII, §§2301 to 2316, of the Public Health Service Act, and transferred to subchapter XXI (§300cc et seq.) of this chapter, renumbered title XXV, §§2501 to 2514, of the Public Health Service Act, and transferred to subchapter XXV (§300aaa et seq.) of this chapter, renumbered title XXVI, §§2601 to 2614, of the Public Health Service Act, renumbered title XXVII, §§2701 to 2714, of the Public Health Service Act, and renumbered title II, part B, §§231 to 244, of the Public Health Service Act, and transferred to part B (§238 et seq.) of subchapter I of this chapter.

PART 1—NATIONAL VACCINE PROGRAM

§ 300aa-1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

(July 1, 1944, ch. 373, title XXI, §2101, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756.)

PRIOR PROVISIONS

A prior section 300aa-1, act July 1, 1944, §2102, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

A prior section 2101 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

EFFECTIVE DATE

Section 323 of title III of Pub. L. 99-660, as amended by Pub. L. 100-203, title IV, §4302(a), Dec. 22, 1987, 101 Stat. 1330-221; Pub. L. 102-168, title II, §201(a), Nov. 26, 1991, 105 Stat. 1102, provided that: "Subtitle 1 of title XXI of the Public Health Service Act [part 1 of this subchapter (42 U.S.C. 300aa-1 to 300aa-6)] shall take effect on the date of the enactment of this Act [Nov. 14, 1986] and parts A and B of subtitle 2 of such title [subparts A and B of part 2 of this subchapter (42 U.S.C. 300aa-10 to 300aa-23)] shall take effect on October 1, 1988 and parts C and D of such title [subparts C and D of part 2 of this subchapter (42 U.S.C. 300aa-25 to 300aa-33)] and this title [probably means provisions of title III of Pub. L. 99-660 other than those that enacted this subchapter and redesignated former sections 300aa to 300aa-15 of this title as sections 300cc to 300cc-15 of this title; these other provisions amended sections 218,

242c, 262, 286, and 289f of this title and enacted provisions set out as notes under sections 201, 300aa-1, and 300aa-4 of this title] shall take effect on the date of the enactment of the Vaccine Compensation Amendments of 1987 [Dec. 22, 1987]."

SEVERABILITY

Section 322 of title III of Pub. L. 99-660, as amended by Pub. L. 101-239, title VI, §6602, Dec. 19, 1989, 103 Stat. 2293; Pub. L. 101-502, §5(g)(1), Nov. 3, 1990, 104 Stat. 1288, provided that:

"(a) IN GENERAL.—Except as provided in subsection (b), if any provision [of] part A or B of subtitle 2 of title XXI of the Public Health Service Act [subparts A and B of part 2 of this subchapter], as added by section 311(a), or the application of such a provision to any person or circumstance is held invalid by reason of a violation of the Constitution, both such parts shall be considered invalid.

"(b) SPECIAL RULE.—If any amendment made by section 6601 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101-239, amending sections 300aa-10 to 300aa-17, 300aa-21, 300aa-23, 300aa-26, and 300aa-27 of this title] to title XXI of the Public Health Service Act [this subchapter] or the application of such a provision to any person or circumstance is held invalid by reason of the Constitution, subsection (a) shall not apply and such title XXI of the Public Health Service Act without such amendment shall continue in effect."

[Amendment by section 5(g)(1) of Pub. L. 101-502 to section 322(a) of Pub. L. 99-660, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101-502, set out as an Effective Date of 1990 Amendment note under section 300aa-11 of this title.]

EVALUATION OF PROGRAM; STUDY AND REPORT TO CONGRESS

Pub. L. 101-239, title VI, §6601(t), Dec. 19, 1989, 103 Stat. 2293, as amended by Pub. L. 102-168, title II, §201(b), Nov. 26, 1991, 105 Stat. 1103, directed the Secretary of Health and Human Services to evaluate the National Vaccine Injury Compensation Program under this subchapter and report results of such study to Committee on Energy and Commerce of House of Representatives and Committee on Labor and Human Resources of Senate not later than Jan. 1, 1993.

RELATED STUDIES

Section 312 of title III of Pub. L. 99-660 directed Secretary of Health and Human Services, not later than 3 years after the effective date of this title (see Effective Date note above), to conduct, through studies by the Institute of Medicine of the National Academy of Sciences or other appropriate nonprofit private groups or associations, a review of pertussis vaccines and related illnesses and conditions and MMR vaccines, vaccines containing material intended to prevent or confer immunity against measles, mumps, and rubella disease, and related illnesses and conditions, make specific findings and report these findings in the Federal Register not later than 3 years after the effective date of this title, and at the same time these findings are published in the Federal Register, propose regulations as a result of such findings, and not later than 42 months after the effective date of this title, promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

STUDY OF OTHER VACCINE RISKS

Section 313 of title III of Pub. L. 99-660 provided that:

"(a) STUDY.—

"(1) Not later than 3 years after the effective date of this title [see Effective Date note above], the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa-19 of this title]—

"(A) arrange for a broad study of the risks (other than the risks considered under section 102 [21

U.S.C. 382) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act [section 300aa-14 of this title], and

“(B) establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include—

“(i) the circumstances under which any such vaccine should not be administered,

“(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

“(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

“(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

“(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study.

“(C) The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa-19 of this title].

“(b) REVISION OF GUIDELINES.—The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

“(c) FACTORS AFFECTING GUIDELINES.—Guidelines under subsection (a) shall take into account—

“(1) the risk to potential recipients of the vaccines with respect to which the guidelines are established,

“(2) the medical and other characteristics of such potential recipients, and

“(3) the risks to the public of not having such vaccines administered.

“(d) DISSEMINATION.—The Secretary shall widely disseminate the guidelines established under subsection (a) to—

“(1) physicians and other health care providers,

“(2) professional health associations,

“(3) State and local governments and agencies, and

“(4) other relevant entities.”

REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION

Section 314 of title III of Pub. L. 99-660 directed Secretary of Health and Human Services, not later than 1 year after the effective date of this title (see Effective Date note above) and after consultation with Advisory Commission on Childhood Vaccines and with other appropriate entities, to review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 300aa-14 of this title and by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines, and, if any such warning, instruction, or information is determined to be inadequate for such purpose in any respect, require at the same time that the manufacturers revise and reissue such warning, instruction,

or information as expeditiously as practical, but not later than 18 months after the effective date of this title.

STUDY OF IMPACT ON SUPPLY OF VACCINES

Pub. L. 99-660, title III, §316, Nov. 14, 1986, 100 Stat. 3786, provided that: “On June 30, 1987, and on June 30 of each second year thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate—

“(1) an assessment of the impact of the amendments made by this title [enacting this subchapter, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa-15 of this title as sections 300cc to 300cc-15 of this title, and enacting provisions set out as notes under this section and sections 201 and 300aa-1 of this title] on the supply of vaccines listed in the Vaccine Injury Table under section 2114 of the Public Health Service Act [section 300aa-14 of this title], and

“(2) an assessment of the ability of the administrators of vaccines (including public clinics and private administrators) to provide such vaccines to children.”

WAIVER OF PAPERWORK REDUCTION

Section 321 of title III of Pub. L. 99-660 provided that: “Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this title and implementing the amendments made by this title [enacting this subchapter, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa-15 of this title as sections 300cc to 300cc-15 of this title, and enacting provisions set out as notes under sections 201, 300aa-1, and 300aa-4 of this title].”

§ 300aa-2. Program responsibilities

(a) The Director of the Program shall have the following responsibilities:

(1) Vaccine research

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) Vaccine development

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

(3) Safety and efficacy testing of vaccines

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of

Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(4) Licensing of vaccine manufacturers and vaccines

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 263a of this title.

(5) Production and procurement of vaccines

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) Distribution and use of vaccines

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction to the Centers for Disease Control and Prevention and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

(7) Evaluating the need for and the effectiveness and adverse effects of vaccines and immunization activities

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Centers for Medicare & Medicaid Services in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

(8) Coordinating governmental and non-governmental activities

The Director of the Program shall, through the plan issued under section 300aa-3 of this title, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

(9) Funding of Federal agencies

The Director of the Program shall make available to Federal agencies involved in the

implementation of the plan issued under section 300aa-3 of this title funds appropriated under section 300aa-6 of this title to supplement the funds otherwise available to such agencies for activities under the plan.

(b) In carrying out subsection (a) of this section and in preparing the plan under section 300aa-3 of this title, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

(July 1, 1944, ch. 373, title XXI, §2102, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756; amended Pub. L. 102-531, title III, §312(d)(13), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 108-173, title IX, §900(e)(2)(F), Dec. 8, 2003, 117 Stat. 2372.)

PRIOR PROVISIONS

A prior section 300aa-2, act July 1, 1944, §2103, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

A prior section 2102 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

AMENDMENTS

2003—Subsec. (a)(7). Pub. L. 108-173 substituted “Centers for Medicare & Medicaid Services” for “Health Care Financing Administration”.

1992—Subsec. (a)(1), (3), (6), (7). Pub. L. 102-531 substituted “Centers for Disease Control and Prevention” for “Centers for Disease Control”.

GRANTS FOR RESEARCH ON VACCINE AGAINST VALLEY FEVER

Pub. L. 109-432, div. B, title IV, §402, Dec. 20, 2006, 120 Stat. 2994, provided that:

“(a) IN GENERAL.—In supporting research on the development of vaccines against human diseases, the Secretary of Health and Human Services shall make grants for the purpose of conducting research toward the development of a vaccine against coccidioidomycosis (commonly known as Valley Fever).

“(b) SUNSET.—No grant may be made under subsection (a) on or after October 1, 2012. The preceding sentence does not have any legal effect on payments under grants for which amounts appropriated under subsection (c) were obligated prior to such date.

“(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making grants under subsection (a), there are authorized to be appropriated \$40,000,000 for the period of fiscal years 2007 through 2012.”

DEMONSTRATION PROJECTS FOR OUTREACH PROGRAMS

Pub. L. 101-502, §2(b), Nov. 3, 1990, 104 Stat. 1285, provided that:

“(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, may make grants to public and nonprofit private entities for the purpose of carrying out demonstration projects—

“(A) to provide, without charge, immunizations against vaccine-preventable diseases to children not more than 2 years of age who reside in communities whose population includes a significant number of low-income individuals; and

“(B) to provide outreach services to identify such children and to inform the parents (or other guardians) of the children of the availability from the entities of the immunizations specified in subparagraph (A).

“(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.”

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102-531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.]

SUPPLY OF VACCINES

Pub. L. 101-502, § 3, Nov. 3, 1990, 104 Stat. 1285, provided that:

“(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period. Any proceeds received by the Secretary from the sale of vaccines from such supply shall be available to the Secretary for the purpose of purchasing vaccines for the supply. Such proceeds shall remain available for such purpose until expended.

“(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (a), there are authorized to be appropriated \$5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995.”

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102-531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.]

Pub. L. 100-177, title I, § 110(b), Dec. 1, 1987, 101 Stat. 991, provided that:

“(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period.

“(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out paragraph (1) \$5,000,000 for fiscal year 1988, and such sums as may be necessary for each of the fiscal years 1989 and 1990.”

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102-531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.]

§ 300aa-3. Plan

The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 300aa-2 of this title. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

(July 1, 1944, ch. 373, title XXI, § 2103, as added Pub. L. 99-660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3757.)

PRIOR PROVISIONS

A prior section 300aa-3, act July 1, 1944, § 2104, which was renumbered section 2304 by Pub. L. 99-660, was transferred to section 300cc-3 of this title, prior to repeal by Pub. L. 98-621, § 10(s), Nov. 8, 1984, 98 Stat. 3381.

A prior section 2103 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

§ 300aa-4. Repealed. Pub. L. 105-362, title VI, § 601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285

Section, act July 1, 1944, ch. 373, title XXI, § 2104, as added Pub. L. 99-660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3757, related to national vaccine program report.

A prior section 300aa-4, act July 1, 1944, § 2105, was repealed by Pub. L. 99-117, § 12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc-4 of this title.

A prior section 2104 of act July 1, 1944, was renumbered section 2304 by Pub. L. 99-660 and classified to section 300cc-3 of this title, and was repealed by Pub. L. 98-621, § 10(s), Nov. 8, 1984, 98 Stat. 3381.

§ 300aa-5. National Vaccine Advisory Committee

(a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

(b) The Committee shall—

(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States.

(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines.

(3) advise the Director of the Program in the implementation of sections 300aa-2, 300aa-3, and 300aa-4¹ of this title, and

(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 300aa-2, 300aa-3, and 300aa-4¹ of this title.

(July 1, 1944, ch. 373, title XXI, § 2105, as added Pub. L. 99-660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3758.)

REFERENCES IN TEXT

Section 300aa-4 of this title, referred to in subsec. (b)(3), (4), was repealed by Pub. L. 105-362, title VI, § 601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285.

PRIOR PROVISIONS

A prior section 300aa-5, act July 1, 1944, § 2106, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

A prior section 2105 of act July 1, 1944, was repealed by Pub. L. 99-117, § 12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc-4 of this title.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees 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 committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 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.

§ 300aa-6. Authorization of appropriations

(a) To carry out this part other than section 300aa-2(9) of this title there are authorized to be

¹ See References in Text note below.

appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(b) To carry out section 300aa-2(9) of this title there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(July 1, 1944, ch. 373, title XXI, §2106, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101-502, §4, Nov. 3, 1990, 104 Stat. 1286; Pub. L. 108-276, §2(c), July 21, 2004, 118 Stat. 842.)

PRIOR PROVISIONS

A prior section 300aa-6, act July 1, 1944, §2107, was successively renumbered by subsequent acts and transferred, see section 238d of this title.

A prior section 2106 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

Prior sections 300aa-7 to 300aa-9, act July 1, 1944, §§2108-2110, respectively, were successively renumbered by subsequent acts and transferred, see sections 238e to 238g, respectively, of this title.

AMENDMENTS

2004—Pub. L. 108-276 substituted provisions authorizing appropriations for fiscal years 2004 and 2005 for provisions authorizing appropriations for fiscal years 1991 through 1995 in subssecs. (a) and (b).

1990—Pub. L. 101-502 substituted provisions authorizing appropriations for fiscal years 1991 through 1995 for provisions authorizing appropriations for fiscal years 1987 through 1991 in subssecs. (a) and (b).

PART 2—NATIONAL VACCINE INJURY COMPENSATION PROGRAM

SUBPART A—PROGRAM REQUIREMENTS

§ 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 program¹ for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

(July 1, 1944, ch. 373, title XXI, §2110, as added Pub. L. 99-660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101-239, title VI, §6601(b), Dec. 19, 1989, 103 Stat. 2285.)

PRIOR PROVISIONS

A prior section 300aa-10, act July 1, 1944, §2111, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

A prior section 2110 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

¹ So in original. Probably should be capitalized.

AMENDMENTS

1989—Subsec. (c). Pub. L. 101-239 added subsec. (c).

EFFECTIVE DATE OF 1989 AMENDMENT

Section 6601(s) of Pub. L. 101-239, as amended by Pub. L. 102-572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that:

“(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa-11 to 300aa-17, 300aa-21, 300aa-23, 300aa-26, and 300aa-27 of this title] shall apply as follows:

“(A) Petitions filed after the date of enactment of this section [Dec. 19, 1989] shall proceed under the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [this subchapter] 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 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 U.S.C. 300aa-12(d)], as amended by this section, or the 420-day period prescribed by section 2121(b) of such Act [42 U.S.C. 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 U.S.C. 300aa-15] shall apply to all pending and subsequently filed petitions.”

EFFECTIVE DATE

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

§ 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) of this section with the United States Court of Federal Claims. The clerk of the 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 300aa-12(d)(1) of this title.

(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 October 1, 1988, 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 300aa-16 of this title, for compensation