

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

Pub. L. 99-660, title III, § 323, Nov. 14, 1986, 100 Stat. 3784, 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 [42 U.S.C. 300aa-1 et seq.] 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 [42 U.S.C. 300aa-10 et seq., 300aa-21 et seq.] shall take effect on October 1, 1988 and parts C and D of such title [42 U.S.C. 300aa-25 et seq., 300aa-31 et seq.] 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

Pub. L. 99-660, title III, § 322, Nov. 14, 1986, 100 Stat. 3783, 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 [42 U.S.C. 300aa-10 et seq., 300aa-21 et seq.], 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 [42 U.S.C. 300aa-1 et seq.] 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

Pub. L. 99-660, title III, § 312, Nov. 14, 1986, 100 Stat. 3779, 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 non-profit 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

Pub. L. 99-660, title III, § 313, Nov. 14, 1986, 100 Stat. 3781, 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 [42 U.S.C. 300aa-19]—

"(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 [42 U.S.C. 300aa-14], 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 [42 U.S.C. 300aa-19].

“(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

Pub. L. 99-660, title III, §314, Nov. 14, 1986, 100 Stat. 3782, 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 [42 U.S.C. 300aa-14], 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

Pub. L. 99-660, title III, §321, Nov. 14, 1986, 100 Stat. 3783, 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