

(3) in the case of an application for a research project, the panel established by subsection (e)(2) of this section has determined that the project is of scientific merit.

(d) Coordination with National Institutes of Health

The Secretary shall, where appropriate, coordinate research and dissemination activities carried out under this section with research and dissemination activities carried out by the National Institutes of Health.

(e) Review of applications for grants and contracts; establishment of review panel

(1) The Secretary shall establish a system for the review of applications for grants and contracts under this section. Such system shall be substantially similar to the system for scientific peer review of the National Institutes of Health and shall meet the requirements of paragraphs (2) and (3).

(2) In establishing the system required by paragraph (1), the Secretary shall establish a panel to review applications under this section. Not more than 25 per centum of the members of the panel shall be physicians. The panel shall meet as often as may be necessary to facilitate the expeditious review of applications under this section, but not less than once each year. The panel shall review each project for which an application is made under this section, evaluate the scientific merit of the project, determine whether the project is of scientific merit, and make recommendations to the Secretary concerning whether the application for the project should be approved.

(3) The Secretary shall make grants under this section from among the projects which the panel established by paragraph (2) has determined to be of scientific merit and may only approve an application for a project if the panel has made such determination with respect to such a project. The Secretary shall make a determination with respect to an application within one month after receiving the determinations and recommendations of such panel with respect to the application.

(f) Reports

(1)(A) The recipient of a grant or contract for a research project under this section shall prepare and transmit to the Secretary a report describing the results and conclusions of such research. Except as provided in subparagraph (B), such report shall be transmitted to the Secretary not later than eighteen months after the end of the year for which funds are provided under this section. The recipient may utilize reprints of articles published or accepted for publication in professional journals to supplement or replace such report if the research contained in such articles was supported under this section during the year for which the report is required.

(B) In the case of any research project for which assistance is provided under this section for two or more consecutive one-year periods, the recipient of such assistance shall prepare and transmit the report required by subparagraph (A) to the Secretary not later than twelve months after the end of each one-year period for which such funding is provided.

(2) Recipients of grants and contracts for dissemination under this section shall submit to the Secretary such reports as the Secretary determines appropriate.

(July 1, 1944, ch. 373, title XX, §2008, as added Pub. L. 97-35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 589; amended Pub. L. 98-512, §2(e), Oct. 19, 1984, 98 Stat. 2409.)

AMENDMENTS

1984—Subsec. (g). Pub. L. 98-512 struck out subsec. (g) which provided for collection of survey data used primarily for generation of national population estimates.

§ 300z-8. Evaluation and administration

(a) Of the funds appropriated under this subchapter, the Secretary shall reserve not less than 1 per centum and not more than 3 per centum for the evaluation of activities carried out under this subchapter. The Secretary shall submit to the appropriate committees of the Congress a summary of each evaluation conducted under this section.

(b) The officer or employee of the Department of Health and Human Services designated by the Secretary to carry out the provisions of this subchapter shall report directly to the Assistant Secretary for Health with respect to the activities of such officer or employee in carrying out such provisions.

(July 1, 1944, ch. 373, title XX, §2009, as added Pub. L. 97-35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 591.)

§ 300z-9. Authorization of appropriations

(a) For the purpose of carrying out this subchapter, there are authorized to be appropriated \$30,000,000 for the fiscal year ending September 30, 1982, \$30,000,000 for the fiscal year ending September 30, 1983, \$30,000,000 for the fiscal year ending September 30, 1984, and \$30,000,000 for the fiscal year ending September 30, 1985.

(b) At least two-thirds of the amounts appropriated to carry out this subchapter shall be used to make grants for demonstration projects for services.

(c) Not more than one-third of the amounts specified under subsection (b) of this section for use for grants for demonstration projects for services shall be used for grants for demonstration projects for prevention services.

(July 1, 1944, ch. 373, title XX, §2010, as added Pub. L. 97-35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 591; amended Pub. L. 98-512, §2(a), Oct. 19, 1984, 98 Stat. 2409.)

AMENDMENTS

1984—Subsec. (a). Pub. L. 98-509 inserted provisions authorizing appropriations for fiscal year ending Sept. 30, 1985.

§ 300z-10. Restrictions

(a) Grants or payments may be made only to programs or projects which do not provide abortions or abortion counseling or referral, or which do not subcontract with or make any payment to any person who provides abortions or abortion counseling or referral, except that any such program or project may provide referral for

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

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