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, §201, 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 (§300ccc et seq.) of this chapter, renumbered title XXV, §§2501 to 2514, of the Public Health Service Act, and transferred to subchapter XXV (§300aa et seq.) of this chapter, renumbered title XXVI, §§2701 to 2714, 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 I—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. 97-35, 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. 100-201, §302(a), Dec. 22, 1987, 101 Stat. 1330-221; Pub. L. 100-129, title IV, §402(a), Dec. 22, 1987, 101 Stat. 1330-221; Pub. L. 100-128, title II, §201(a), Nov. 26, 1989, 103 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. 26, 1989) 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 in prior sections 300aa-1 to 300aa-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 1967 (Dec. 22, 1987).”

SEVERABILITY


“(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, 1990, see section 5(c) of Pub. L. 101-502, set out as an Effective Date of 1990 Amendment note under section 300aa-11 of this title.]
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) DISSEMINATION.—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) REVIEW 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—

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

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

“(iii) 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.”

§ 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 to nontoxic vaccines and other forms of biological agents.

(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 to develop the techniques needed to produce safe and effective vaccines.
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 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.  


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  


GRANTS FOR RESEARCH ON VACCINE AGAINST VALLEY FEVER  


“(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 1999.”
SUPPLY OF VACCINES


"(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 1996."

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title II, § 300aa–2(9) of this title there are authorized to be appropriated $5,000,000 for fiscal year 1988, and such sums as may be necessary for each of the fiscal years 1989 and 1990.]

§ 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. 99–621, § 10(a), 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–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–4 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–4 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


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.


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.


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 sections 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 238c to 238g, respectively, of this title.

AMENDMENTS


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 Program for such injury or death.

(c) Publicity

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


PRIOR PROVISIONS

A prior section 300aa–10, act July 1, 1944, §2111, was successively renumbered by subsequent acts and transferred, see section 238d 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.

* * *

1So in original. Probably should be capitalized.