“(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 219 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. 3762, 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


“(1) an assessment of the impact of the amendment added 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
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) 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.

“(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 sufficient funds for each of fiscal years 1989 and 1990.

“(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. 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. 3504.)

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(e), 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 228b 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. 3504.)

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, § 300aa–3. 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.

PRIOR PROVISIONS

A prior section 300aa–5, act July 1, 1944, § 2105, 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 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. 3504.)

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.


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.


1 See References in Text note below.