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 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

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 nongovernmental 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.

(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.)

Editorial Notes

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''.

Statutory Notes and Related Subsidiaries

ENCOURAGING VACCINE INNOVATION; MEETINGS

Pub. L. 114–255, div. A, title III, § 3093(a), Dec. 13, 2016, 130 Stat. 1151, provided that: ''The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and oth-

ers, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics.''

GRANTS FOR RESEARCH ON VACCINE AGAINST VALLEY FEVER

Pub. L. 109–432, div. B, title IV, § 402, Dec. 20, 2006, 120 Stat. 2994, authorized the Secretary of Health and Human Services to make grants for research on the development of a vaccine against coccidioidomycosis (commonly known as Valley Fever) before Oct. 1, 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.)

Editorial Notes

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–4[1] 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[1] of this title.

[1] See References in Text note below.