

“(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 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.

(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.)

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”.

GRANTS FOR RESEARCH ON VACCINE AGAINST VALLEY FEVER

Pub. L. 109-432, div. B, title IV, §402, Dec. 20, 2006, 120 Stat. 2994, provided that:

“(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 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, distribu-