

of this title regarding the conduct and support of research on, and development of, a microbicide to prevent the transmission of the human immunodeficiency virus; and

(2) review and, as appropriate, revise such plan to prioritize funding and activities relative to their scientific urgency and potential market readiness.

(b) Coordination

In implementing, reviewing, and prioritizing elements of the plan described in subsection (a), the Director of the Office shall consult, as appropriate, with—

(1) representatives of other Federal agencies involved in microbicide research, including the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the Director of the Centers for Disease Control and Prevention, and the Administrator of the United States Agency for International Development;

(2) the microbicide research and development community; and

(3) health advocates.

(July 1, 1944, ch. 373, title XXIII, §2351A, as added Pub. L. 110-293, title II, §203(b), July 30, 2008, 122 Stat. 2940.)

PRIOR PROVISIONS

A prior section 300cc-40a, act July 1, 1944, ch. 373, title XXIII, §2352, as added Pub. L. 103-43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 193, which required the establishment of an advisory council and coordinating committees, was transferred to section 300cc-40b of this title.

SENSE OF CONGRESS

Pub. L. 110-293, title II, §203(a), July 30, 2008, 122 Stat. 2940, provided that: “Congress recognizes the need and urgency to expand the range of interventions for preventing the transmission of human immunodeficiency virus (HIV), including nonvaccine prevention methods that can be controlled by women.”

§ 300cc-40b. Advisory Council; coordinating committees

(a) Advisory Council

(1) In general

The Secretary shall establish an advisory council for the purpose of providing advice to the Director of the Office on carrying out this part. (Such council is referred to in this subsection as the “Advisory Council”.)

(2) Composition, compensation, terms, chair, etc.

Subsections (b) through (g) of section 284a of this title apply to the Advisory Council to the same extent and in the same manner as such subsections apply to advisory councils for the national research institutes, except that—

(A) in addition to the ex officio members specified in section 284a(b)(2) of this title, there shall serve as such members of the Advisory Council a representative from the advisory council of each of the National Cancer Institute and the National Institute on Allergy and Infectious Diseases; and

(B) with respect to the other national research institutes, there shall serve as ex officio members of such Council, in addition to

such members specified in subparagraph (A), a representative from the advisory council of each of the 2 institutes that receive the greatest funding for AIDS activities.

(b) Individual coordinating committees regarding research disciplines

(1) In general

The Director of the Office shall establish, for each research discipline in which any activity under the plan required in section 300cc-40c of this title is carried out, a committee for the purpose of providing advice to the Director of the Office on carrying out this part with respect to such discipline. (Each such committee is referred to in this subsection as a “coordinating committee”.)

(2) Composition

Each coordinating committee shall be composed of representatives of the agencies of the National Institutes of Health with significant responsibilities regarding the research discipline involved.

(July 1, 1944, ch. 373, title XXIII, §2352, as added Pub. L. 103-43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 193.)

CODIFICATION

Section was formerly classified to section 300cc-40a of this title.

PRIOR PROVISIONS

A prior section 300cc-40b, act July 1, 1944, ch. 373, title XXIII, §2353, as added Pub. L. 103-43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 194, which required the establishment of a comprehensive plan, was transferred to section 300cc-40c of this title.

TERMINATION OF ADVISORY COUNCILS

Advisory councils 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 council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 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.

§ 300cc-40c. Comprehensive plan for expenditure of appropriations

(a) In general

Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 300cc-40 of this title, shall—

(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health (which plan shall be first established under this paragraph not later than 12 months after June 10, 1993);

(2) ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out;

(3) ensure that the Plan establishes objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(4) ensure that all amounts appropriated for such activities are expended in accordance with the Plan;

(5) review the Plan not less than annually, and revise the Plan as appropriate; and

(6) ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the Plan.

(b) Certain components of Plan

With respect to AIDS activities of the agencies of the National Institutes of Health, the Director of the Office shall ensure that the Plan—

(1) provides for basic research;

(2) provides for applied research;

(3) provides for research that is conducted by the agencies;

(4) provides for research that is supported by the agencies;

(5) provides for proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

(6) provides for behavioral research and social sciences research.

(c) Budget estimates

(1) Full-funding budget

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit directly to the President, for review and transmittal to the Congress, a budget estimate for carrying out the Plan for the fiscal year, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the advisory council established under section 300cc-40b of this title. The budget estimate shall include an estimate of the number and type of personnel needs for the Office.

(B) The budget estimate submitted under subparagraph (A) shall estimate the amounts necessary for the agencies of the National Institutes of Health to carry out all AIDS activities determined by the Director of the Office to be appropriate, without regard to the probability that such amounts will be appropriated.

(2) Alternative budgets

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit to the Secretary and the Director of the National Institutes of Health the budget estimates described in subparagraph (B) for carrying out the Plan for the fiscal year. The Secretary and such Director shall consider each of such estimates in making recommendations to the President regarding a budget for the Plan for such year.

(B) With respect to the fiscal year involved, the budget estimates referred to in subparagraph (A) for the Plan are as follows:

(i) The budget estimate submitted under paragraph (1).

(ii) A budget estimate developed on the assumption that the amounts appropriated will be sufficient only for—

(I) continuing the conduct by the agencies of the National Institutes of Health of existing AIDS activities (if approved for continuation), and continuing the support of such activities by the agencies in the case of projects or programs for which the agencies have made a commitment of continued support; and

(II) carrying out, of activities that are in addition to activities specified in subclause (I), only such activities for which the Director determines there is the most substantial need.

(iii) Such other budget estimates as the Director of the Office determines to be appropriate.

(d) Funding

(1) Authorization of appropriations

For the purpose of carrying out AIDS activities under the Plan, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

(2) Receipt of funds

For the first fiscal year beginning after the date on which the Plan first established under subsection (a)(1) has been in effect for 12 months, and for each subsequent fiscal year, the Director of the Office shall receive directly from the President and the Director of the Office of Management and Budget all funds available for AIDS activities of the National Institutes of Health.

(3) Allocations for agencies

(A) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out the AIDS activities specified in subsection (c)(2)(B)(ii)(I) for such year. Such allocation shall, to the extent practicable, be made not later than 15 days after the date on which the Director receives amounts under paragraph (2).

(B) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out AIDS activities that are not referred to in subparagraph (A). Such allocation shall, to the extent practicable, be made not later than 30 days after the date on which the Director receives amounts under paragraph (2).

(July 1, 1944, ch. 373, title XXIII, §2353, as added Pub. L. 103-43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 194.)

CODIFICATION

Section was formerly classified to section 300cc-40b of this title.

§ 300cc-41. Additional authorities**(a) In general**

In carrying out AIDS research, the Director of the Office—

(1) shall develop and expand clinical trials of treatments and therapies for infection with the etiologic agent for acquired immune deficiency syndrome, including such clinical trials for women, infants, children, hemophiliacs, and minorities;

(2) may establish or support the large-scale development and preclinical screening, production, or distribution of specialized biological materials and other therapeutic substances for AIDS research and set standards of safety and care for persons using such materials;

(3) may support—

(A) AIDS research conducted outside the United States by qualified foreign professionals if such research can reasonably be expected to benefit the people of the United States;

(B) collaborative research involving American and foreign participants; and

(C) the training of American scientists abroad and foreign scientists in the United States;

(4) may encourage and coordinate AIDS research conducted by any industrial concern that evidences a particular capability for the conduct of such research;

(5)(A) may acquire, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director of the Office determines necessary;

(B) may make grants for the construction or renovation of facilities; and

(C) may acquire, without regard to section 8141 of title 40 by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the National Institutes of Health for a period not to exceed ten years; and

(6) subject to section 284(b)(2) of this title and without regard to section 3324 of title 31 and section 6101 of title 41, may enter into such contracts and cooperative agreements with any public agency, or with any person, firm, association, corporation, or educational institution, as may be necessary to expedite and coordinate research relating to acquired immune deficiency syndrome.

(b) Projects for cooperation among public and private health entities

In carrying out subsection (a), the Director of the Office shall establish projects to promote cooperation among Federal agencies, State, local, and regional public health agencies, and private entities, in research concerning the diagnosis, prevention, and treatment of acquired immune deficiency syndrome.

(July 1, 1944, ch. 373, title XXIII, § 2354, formerly § 2351, as added Pub. L. 100-607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3076; renumbered § 2354 and amended Pub. L. 103-43, title XVIII, § 1801(a)(2),

(b), June 10, 1993, 107 Stat. 192, 196; Pub. L. 109-482, title I, § 104(b)(2)(D), Jan. 15, 2007, 120 Stat. 3693.)

CODIFICATION

In subsec. (a)(5)(C), “section 8141 of title 40” substituted for “the Act of March 3, 1877 (40 U.S.C. 34)” on authority of Pub. L. 107-217, § 5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

In subsec. (a)(6), “section 6101 of title 41” substituted for “section 3709 of the Revised Statutes (41 U.S.C. 5)” on authority of Pub. L. 111-350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2007—Subsecs. (b), (c). Pub. L. 109-482 redesignated subsec. (c) as (b) and struck out former subsec. (b). Subsec. (b) text read as follows: “The Director of the Office shall each fiscal year prepare and submit to the Secretary, for inclusion in the comprehensive report required in section 300cc(a) of this title, a report—

“(1) describing and evaluating the progress made in such fiscal year in research, treatment, and training with respect to acquired immune deficiency syndrome conducted or supported by the Institutes;

“(2) summarizing and analyzing expenditures made in such fiscal year for activities with respect to acquired immune deficiency syndrome conducted or supported by the National Institutes of Health; and

“(3) containing such recommendations as the Director considers appropriate.”

1993—Pub. L. 103-43, § 1801(b)(1), substituted “Additional” for “Establishment of” in section catchline.

Subsec. (a). Pub. L. 103-43, § 1801(b)(2)(A), in introductory provisions substituted “AIDS research, the Director of the Office” for “research with respect to acquired immune deficiency syndrome, the Secretary, acting through the Director of the National Institutes of Health”.

Subsec. (a)(1). Pub. L. 103-43, § 1801(b)(2)(B), redesignated par. (3) as (1) and struck out former par. (1) which read as follows:

“(A) shall establish an office to be known as the Office of AIDS Research, which Office shall be headed by a Director appointed by the Director of the National Institutes of Health; and

“(B) shall provide administrative support and support services to the Director of such Office;”.

Subsec. (a)(2). Pub. L. 103-43, § 1801(b)(2)(B), (E), redesignated par. (4) as (2), substituted “AIDS research” for “research relating to acquired immune deficiency syndrome”, and struck out former par. (2) which read as follows: “shall coordinate activities relating to acquired immune deficiency syndrome conducted by the national research institutes and the agencies of the National Institutes of Health;”.

Subsec. (a)(3). Pub. L. 103-43, § 1801(b)(2)(B), (C), (E), redesignated par. (5) as (3), struck out “, in consultation with the advisory council for the appropriate national research institute of the National Institutes of Health,” after “may” in introductory provisions, and substituted “AIDS research” for “research relating to acquired immune deficiency syndrome” in subpar. (A). Former par. (3) redesignated (1).

Subsec. (a)(4). Pub. L. 103-43, § 1801(b)(2)(B), (E), redesignated par. (6) as (4) and substituted “AIDS research” for “research relating to acquired immune deficiency syndrome”. Former par. (4) redesignated (2).

Subsec. (a)(5). Pub. L. 103-43, § 1801(b)(2)(B), (D), redesignated par. (7) as (5), in subpar. (A) struck out “, in consultation with such advisory council,” after “may” and substituted “Director of the Office determines” for “Director of the National Institutes of Health determines”, and in subpars. (B) and (C) struck out “, in consultation with such advisory council,” after “may”. Former par. (5) redesignated (3).

Subsec. (a)(6) to (8). Pub. L. 103-43, § 1801(b)(2)(B), redesignated pars. (6) to (8) as (4) to (6), respectively.