cant number of patients with acquired immune deficiency syndrome.

(c) Duties

The Committee shall—

(1) advise the Director of such Institute (and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate) on appropriate research activities to be undertaken with respect to clinical treatment of such syndrome, including advice with respect to—

(A) research on drugs for preventing or minimizing the development of symptoms or conditions arising from infection with the etiologic agent for such syndrome, including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(B) research on the effectiveness of treating such symptoms or conditions with drugs that—

(i) are not approved by the Commissioner of Food and Drugs for the purpose of treating such symptoms or conditions; and

(ii) are being utilized for such purpose by individuals infected with such etiologic agent;

(2)(A) review ongoing publicly and privately supported research on clinical treatment for acquired immune deficiency syndrome, including research on drugs described in paragraph (1); and

(B) periodically issue, and make available to health care professionals, reports describing and evaluating such research;

(3) conduct studies and convene meetings for the purpose of determining the recommendations among physicians in clinical practice on clinical treatment of acquired immune deficiency syndrome, including treatment with the drugs described in paragraph (1); and

(4) conduct a study for the purpose of developing, with respect to individuals infected with the etiologic agent for acquired immune deficiency syndrome, a consensus among health care professionals on clinical treatments for preventing or minimizing the development of symptoms or conditions arising from infection with such etiologic agent.

(July 1, 1944, ch. 373, title XXIII, § 2304, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3065; amended Pub. L. 100–690, title II, § 2617(a), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 103–43, title XVIII, § 1811(1), title XX, § 2008(d)(1), June 10, 1993, 107 Stat. 199, 212.)

Editorial Notes

PRIOR PROVISIONS

A prior section 300cc–3, acts July 1, 1944, ch. 373, title XXIII, § 2304, formerly title V, § 504, 58 Stat. 710; June 25, 1948, ch. 654, § 6, 62 Stat. 1018; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; renumbered title XXI, § 2104, Apr. 26, 1983, Pub. L. 98–24, § 2(a)(1), 97 Stat. 176; renumbered title XXIII, § 2304, Nov. 14, 1986, Pub. L. 99–660, title III, § 311(a), 100 Stat. 3755, related to care of Service patients at Saint Elizabeths Hospital, prior to repeal by Pub. L. 98–621, § 10(s), Nov. 8, 1984, 98 Stat. 3381, effective Oct. 1, 1987. Subsequent to repeal, section 2104 of title XXI of act July 1, 1944, was renumbered section 2304 of title XXIII of that act by section 311(a) of Pub. L. 99–660.

A prior section 300cc–4, acts July 1, 1944, ch. 373, title XXI, § 2105, formerly title V, § 505, 58 Stat. 710; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; renumbered title XXI, § 2105, Apr. 26, 1983, Pub. L. 98–24, § 2(a)(1), 97 Stat. 176, provided procedures under which the Secretary could settle claims for damages from collisions or incident to the operation of vessels within a year of the accrual of such claims and not to exceed $3,000, prior to repeal by Pub. L. 99–117, § 12(f), Oct. 7, 1985, 99 Stat. 495. Subsequent to repeal, section 2105 of title XXI of act July 1, 1944, was renumbered section 2305 of title XXIII of that act by Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3755.

Prior sections 300cc–5 to 300cc–10, act July 1, 1944, §§ 2306 to 2311, respectively, were successively renumbered by subsequent acts and transferred, see sections 238c to 238h of this title.

AMENDMENTS

1993—Pub. L. 103–43, § 2008(d)(1)(A), substituted ''Research Advisory Committee'' for ''Clinical Research Review Committee'' in section catchline.

Subsec. (a). Pub. L. 103–43, § 2008(d)(1)(B), substituted ''AIDS Research Advisory Committee'' for ''AIDS Clinical Research Review Committee''.

Subsec. (c)(1). Pub. L. 103–43, § 1811(1), in introductory provisions inserted ''(and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate)'' after ''Director of such Institute'' and in subpar. (A) inserted before semicolon at end '', including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases''.

1988—Subsec. (c)(2)(B). Pub. L. 100–690 substituted semicolon for period.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m 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.

PART B—RESEARCH AUTHORITY

§ 300cc–11. Clinical evaluation units at National Institutes of Health

(a) In general

The Secretary, acting through the Director of the National Cancer Institute and the Director of the National Institute of Allergy and Infec-

tious Diseases, shall for each such Institute establish a clinical evaluation unit at the Clinical Center at the National Institutes of Health. Each of the clinical evaluation units—

(1) shall conduct clinical evaluations of experimental treatments for acquired immune deficiency syndrome developed within the preclinical drug development program, including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(2) may conduct clinical evaluations of experimental treatments for such syndrome that are developed by any other national research institute of the National Institutes of Health or by any other entity.

(b) Personnel and administrative support

(1) For the purposes described in subsection (a), the Secretary, acting through the Director of the National Institutes of Health, shall provide each of the clinical evaluation units required in such subsection—

(A)(i) with not less than 50 beds; or

(ii) with an outpatient clinical capacity equal to not less than twice the outpatient clinical capacity, with respect to acquired immune deficiency syndrome, possessed by the Clinical Center of the National Institutes of Health on June 1, 1988; and

(B) with such personnel, such administrative support, and such other support services as may be necessary.

(2) Facilities, personnel, administrative support, and other support services provided pursuant to paragraph (1) shall be in addition to the number or level of facilities, personnel, administrative support, and other support services that otherwise would be available at the Clinical Center at the National Institutes of Health for the provision of clinical care for individuals with diseases or disorders.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(July 1, 1944, ch. 373, title XXIII, § 2311, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3066; amended Pub. L. 103–43, title XVIII, § 1811(2), June 10, 1993,107 Stat. 199.)

Editorial Notes

PRIOR PROVISIONS

A prior section 300cc–11, act July 1, 1944, § 2312, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–43 inserted before semicolon at end ", including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases".

§ 300cc–12. Use of investigational new drugs with respect to acquired immune deficiency syndrome

(a) Encouragement of applications with respect to clinical trials

(1) If, in the determination of the Secretary, there is preliminary evidence that a new drug has effectiveness in humans with respect to the prevention or treatment of acquired immune deficiency syndrome, the Secretary shall, through statements published in the Federal Register—

(A) announce the fact of such determination; and

(B) with respect to the new drug involved, encourage an application for an exemption for investigational use of the new drug under regulations issued under section 355(i) of title 21.

(2)(A) The AIDS Research Advisory Committee established pursuant to section 300cc–3 of this title shall make recommendations to the Secretary with respect to new drugs appropriate for determinations described in paragraph (1).

(B) The Secretary shall, as soon as is practicable, determine the merits of recommendations received by the Secretary pursuant to subparagraph (A).

(b) Encouragement of applications with respect to treatment use in circumstances other than clinical trials

(1) In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) and with respect to which an exemption is in effect for purposes of section 355(i) of title 21, the Secretary shall—

(A) as appropriate, encourage the sponsor of the investigation of the new drug to submit to the Secretary, in accordance with regulations issued under such section, an application to use the drug in the treatment of individuals—

(i) who are infected with the etiologic agent for acquired immune deficiency syndrome; and

(ii) who are not participating in the clinical trials conducted pursuant to such exemption; and

(B) if such an application is approved, encourage, as appropriate, licensed medical practitioners to obtain, in accordance with such regulations, the new drug from such sponsor for the purpose of treating such individuals.

(2) If the sponsor of the investigation of a new drug described in paragraph (1) does not submit to the Secretary an application described in such paragraph (relating to treatment use), the Secretary shall, through statements published in the Federal Register, encourage, as appropriate, licensed medical practitioners to submit to the Secretary such applications in accordance with regulations described in such paragraph.

(c) Technical assistance with respect to treatment use

In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a), the Secretary may, directly or through grants or contracts, provide technical assistance with respect to the process of—