extent that such laws are inconsistent with this section, unless such laws provide greater protection from liability.

''(2) VOLUNTEER PROTECTION ACT.—Protections afforded by this section are in addition to those provided by the Volunteer Protection Act of 1997 (Public Law 105–19) [42 U.S.C. 14501 et seq.].

''(d) DEFINITIONS.—In this section—

''(1) the term 'harm' includes physical, nonphysical, economic, and noneconomic losses;

''(2) the term 'health care professional' means an individual who is licensed, registered, or certified under Federal or State law to provide health care services;

''(3) the term 'health care services' means any services provided by a health care professional, or by any individual working under the supervision of a health care professional that relate to—

''(A) the diagnosis, prevention, or treatment of COVID–19; or

''(B) the assessment or care of the health of a human being related to an actual or suspected case of COVID–19; and

''(4) the term 'volunteer' means a health care professional who, with respect to the health care services rendered, does not receive compensation or any other thing of value in lieu of compensation, which compensation—

''(A) includes a payment under any insurance policy or health plan, or under any Federal or State health benefits program; and

''(B) excludes—

''(i) receipt of items to be used exclusively for rendering health care services in the health care professional's capacity as a volunteer described in subsection (a)(1); and

''(ii) any reimbursement for travel to the site where the volunteer services are rendered and any payments in cash or kind to cover room and board, if services are being rendered more than 75 miles from the volunteer's principal place of residence.

''(e) EFFECTIVE DATE.—This section shall take effect upon the date of enactment of this Act [Mar. 27, 2020], and applies to a claim for harm only if the act or omission that caused such harm occurred on or after the date of enactment.

''(f) SUNSET.—This section shall be in effect only for the length of the public health emergency declared by the Secretary of Health and Human Services (referred to in this section as the 'Secretary') under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020 with respect to COVID–19.''

§ 235. Administration of grants in multigrant projects; promulgation of regulations

For the purpose of facilitating the administration of, and expediting the carrying out of the purposes of, the programs established by subchapters V, VI, and VII,[1] and sections 242b, 246(a), 246(b), 246(c), 246(d),[1] and 246(e)[1] of this title in situations in which grants are sought or made under two or more of such programs with respect to a single project, the Secretary is authorized to promulgate regulations—

(1) under which the administrative functions under such programs with respect to such project will be performed by a single administrative unit which is the administrative unit charged with the administration of any of such programs or is the administrative unit charged with the supervision of two or more of such programs;

(2) designed to reduce the number of applications, reports, and other materials required under such programs to be submitted with respect to such project, and otherwise to simplify, consolidate, and make uniform (to the extent feasible), the data and information required to be contained in such applications, reports, and other materials; and

(3) under which inconsistent or duplicative requirements imposed by such programs will be revised and made uniform with respect to such project;

except that nothing in this section shall be construed to authorize the Secretary to waive or suspend, with respect to any such project, any requirement with respect to any of such programs if such requirement is imposed by law or by any regulation required by law.

(July 1, 1944, ch. 373, title II, § 226, formerly title III, § 310A, as added Pub. L. 91–515, title II, § 270, Oct. 30, 1970, 84 Stat. 1306; amended Pub. L. 92–157, title II, § 201, Nov. 18, 1971, 85 Stat. 461; renumbered § 226, Pub. L. 93–353, title I, § 102(e), July 23, 1974, 88 Stat. 362.)

Editorial Notes

REFERENCES IN TEXT

Subchapters V and VI, referred to in text, are classified to sections 292 et seq. and 296 et seq., respectively, of this title.

Subchapter VII, referred to in text, which was classified to section 299 et seq. of this title, was repealed by Pub. L. 99–117, § 12(d), Oct. 7, 1985, 99 Stat. 495.

Section 246(d) of this title, referred to in text, was repealed by Pub. L. 97–35, title IX, § 902(b), Aug. 13, 1981, 95 Stat. 559.

Section 246(e) of this title, referred to in text, was repealed by Pub. L. 94–63, title V, § 501(b), July 29, 1975, 89 Stat. 346.

CODIFICATION

Section was formerly classified to section 242i of this title.

AMENDMENTS

1971—Pub. L. 92–157 provided for administration of programs established under subchapters V and VI of this chapter.

§ 236. Orphan Products Board

(a) Establishment; composition; chairman

There is established in the Department of Health and Human Services a board for the development of drugs (including biologics) and devices (including diagnostic products) for rare diseases or conditions to be known as the Orphan Products Board. The Board shall be comprised of the Assistant Secretary for Health of the Department of Health and Human Services and representatives, selected by the Secretary, of the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and any other Federal department or agency which the Secretary determines has activities relating to drugs and devices for rare diseases or conditions. The Assistant Secretary for Health shall chair the Board.

(b) Function

The function of the Board shall be to promote the development of drugs and devices for rare diseases or conditions and the coordination

[1] See References in Text note below.

among Federal, other public, and private agencies in carrying out their respective functions relating to the development of such articles for such diseases or conditions.

(c) Duties with respect to drugs for rare diseases or conditions

In the case of drugs for rare diseases or conditions the Board shall—

(1) evaluate—

(A) the effect of subchapter B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360aa et seq.] on the development of such drugs, and

(B) the implementation of such subchapter;[1]

(2) evaluate the activities of the National Institutes of Health for the development of drugs for such diseases or conditions,

(3) assure appropriate coordination among the Food and Drug Administration, the National Institutes of Health and the Centers for Disease Control and Prevention in the carrying out of their respective functions relating to the development of drugs for such diseases or conditions to assure that the activities of each agency are complementary,

(4) assure appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs,

(5) with the consent of the sponsor of a drug for a rare disease or condition exempt under section 505(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i)] or regulations issued under such section, inform physicians and the public respecting the availability of such drug for such disease or condition and inform physicians and the public respecting the availability of drugs approved under section 505(c) of such Act [21 U.S.C. 355(c)] or licensed under section 262 of this title for rare diseases or conditions,

(6) seek business entities and others to undertake the sponsorship of drugs for rare diseases or conditions, seek investigators to facilitate the development of such drugs, and seek business entities to participate in the distribution of such drugs, and

(7) recognize the efforts of public and private entities and individuals in seeking the development of drugs for rare diseases or conditions and in developing such drugs.

(d) Consultation

The Board shall consult with interested persons respecting the activities of the Board under this section and as part of such consultation shall provide the opportunity for the submission of oral views.

(e) Annual report; contents

The Board shall submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report—

(1) identifying the drugs which have been designated under section 526 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bb] for a rare disease or condition,

(2) describing the activities of the Board, and

(3) containing the results of the evaluations carried out by the Board.

The Director of the National Institutes of Health shall submit to the Board for inclusion in the annual report a report on the rare disease and condition research activities of the Institutes of the National Institutes of Health; the Secretary of the Treasury shall submit to the Board for inclusion in the annual report a report on the use of the credit against tax provided by section 44H[2] of title 26; and the Secretary of Health and Human Services shall submit to the Board for inclusion in the annual report a report on the program of assistance under section 360ee of title 21 for the development of drugs for rare diseases and conditions. Each annual report shall be submitted by June 1 of each year for the preceding calendar year.

(July 1, 1944, ch. 373, title II, §227, as added Pub. L. 97–414, §3, Jan. 4, 1983, 96 Stat. 2051; amended Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 102–321, title I, §163(b)(1), July 10, 1992, 106 Stat. 375; Pub. L. 102–531, title III, §312(d)(1), Oct. 27, 1992, 106 Stat. 3504.)

Editorial Notes

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(1)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended. Subchapter B of the Federal Food, Drug, and Cosmetic Act probably means subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act which is classified generally to part B (section 360aa et seq.) of subchapter V of chapter 9 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 44H of title 26, referred to in subsec. (e), was renumbered section 28 of title 26, by Pub. L. 98–369, div. A, title IV, §471(c)(1), July 18, 1984, 98 Stat. 826, and subsequently renumbered section 45C of title 26 by Pub. L. 104–188, title I, §1205(a)(1), Aug. 20, 1996, 110 Stat. 1775.

PRIOR PROVISIONS

A prior section 236, act July 1, 1944, ch. 373, title II, §227, formerly title III, §310B, as added Oct. 30, 1970, Pub. L. 91–515, title II, §280, 84 Stat. 1307; renumbered §227 and amended July 23, 1974, Pub. L. 93–353, title I, §102(f), 88 Stat. 362, related to an annual report by Secretary on activities related to health facilities and services and expenditure of funds, prior to repeal by Pub. L. 97–35, title XXI, §2193(b)(4), Aug. 13, 1981, 95 Stat. 827.

AMENDMENTS

1992—Subsec. (a). Pub. L. 102–531 substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control''.

Subsec. (c)(2). Pub. L. 102–321, §163(b)(1)(A), which directed the striking out of '', and the Alcohol, Drug Abuse, and Mental Health Administration'', was executed by striking ''and the Alcohol, Drug Abuse, and Mental Health Administration'' after ''National Institutes of Health'' to reflect the probable intent of Congress.

Subsec. (c)(3). Pub. L. 102–531 substituted ''Centers for Disease Control and Prevention'' for ''Centers for Disease Control''.

Pub. L. 102–321, §163(b)(1)(B), struck out '', the Alcohol, Drug Abuse, and Mental Health Administration,'' after ''National Institutes of Health''.

[1] So in original. The semicolon probably should be a comma.

[2] See References in Text note below.

Subsec. (e). Pub. L. 102–321, § 163(b)(1)(C), (D), in concluding provisions, struck out ''and the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration'' after ''National Institutes of Health'' the first place appearing and ''and the Alcohol, Drug Abuse, and Mental Health Administration'' after ''National Institutes of Health'' the second place appearing.

1986—Subsec. (e). Pub. L. 99–514 substituted ''Internal Revenue Code of 1986'' for ''Internal Revenue Code of 1954'', which for purposes of codification was translated as ''title 26'' thus requiring no change in text.

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102–321, title VIII, § 801, July 10, 1992, 106 Stat. 441, provided that:

''(a) IN GENERAL.—This Act [See Tables for classification] takes effect on the date of the enactment of this Act [July 10, 1992], subject to subsections (b) through (d).

''(b) AMENDMENTS.—The amendments described in this Act are made on the date of the enactment of this Act and take effect on such date, except as provided in subsections (c) and (d).

''(c) REORGANIZATION UNDER TITLE I.—Title I [§§ 101–171] takes effect on October 1, 1992. The amendments described in such title are made on such date and take effect on such date.

''(d) PROGRAMS PROVIDING FINANCIAL ASSISTANCE.—

''(1) FISCAL YEAR 1993 AND SUBSEQUENT YEARS.—In the case of any program making awards of grants, cooperative agreements, or contracts, the amendments made by this Act are effective for awards made on or after October 1, 1992.

''(2) PRIOR FISCAL YEARS.—

''(A) Except as provided in subparagraph (B), in the case of any program making awards of grants, cooperative agreements, or contracts, if the program began operation prior to the date of the enactment of this Act [July 10, 1992] and the program is amended by this Act, awards made prior to October 1, 1992, shall continue to be subject to the terms and conditions upon which such awards were made, notwithstanding the amendments made by this Act.

''(B) Subparagraph (A) does not apply with respect to the amendments made by this Act to part B of title XIX of the Public Health Service Act [42 U.S.C. 300x et seq.]. Section 205(a) [42 U.S.C. 300x note] applies with respect to the program established in such part.''

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (e) of this section relating to the requirement to submit an annual report to certain committees of Congress, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 101 of House Document No. 103–7.

USE OF ''CDC'' AS ACRONYM FOR CENTERS FOR DISEASE CONTROL AND PREVENTION

Pub. L. 102–531, title III, § 312(i), Oct. 27, 1992, 106 Stat. 3506, provided that: ''The amendments made by this section [amending this section, sections 247d, 280b to 280b–2, 285c–4, 285d–7, 285m–4, 289c, 290aa–9, 290bb–1, 300u–5, 300aa–2, 300aa–19, 300aa–26, 300cc, 300cc–2, 300cc–15, 300cc–17, 300cc–20, 300cc–31, 300ee–1, 300ee–2, 300ee–31, 300ee–32, 300ee–34, 300ff–11 to 300ff–13, 300ff–17, 300ff–27, 300ff–28, 300ff–41, 300ff–43, 300ff–49, 300ff–75, 4841, and 9604 of this title, section 1341 of Title 15, Commerce and Trade, section 2001 of Title 25, Indians, and provisions set out as notes under sections 241 and 281 of this title and section 303 of Title 38, Veterans' Benefits] may not be construed as prohibiting the Director of the Centers for Disease Control and Prevention from utilizing for official purposes the term 'CDC' as an acronym for such Centers.''

NATIONAL COMMISSION ON ORPHAN DISEASES

Pub. L. 99–91, § 4, Aug. 15, 1985, 99 Stat. 388, as amended by Pub. L. 100–290, § 4, Apr. 18, 1988, 102 Stat. 92; Pub. L. 102–321, title I, § 163(c)(1), July 10, 1992, 106 Stat. 376, provided that:

''(a) ESTABLISHMENT.—There is established the National Commission on Orphan Diseases (hereinafter referred to as the 'Commission').

''(b) DUTY.—The Commission shall assess the activities of the National Institutes of Health, the Food and Drug Administration, other public agencies, and private entities in connection with—

''(1) basic research conducted on rare diseases;

''(2) the use in research on rare diseases of knowledge developed in other research;

''(3) applied and clinical research on the prevention, diagnosis, and treatment of rare diseases; and

''(4) the dissemination to the public, health care professionals, researchers, and drug and medical device manufacturers of knowledge developed in research on rare diseases and other diseases which can be used in the prevention, diagnosis, and treatment of rare diseases.

''(c) REVIEW REQUIREMENTS.—In assessing the activities of the National Institutes of Health, and the Food and Drug Administration in connection with research on rare diseases, the Commission shall review—

''(1) the appropriateness of the priorities currently placed on research on rare diseases;

''(2) the relative effectiveness of grants and contracts when used to fund research on rare diseases;

''(3) the appropriateness of specific requirements applicable to applications for funds for research on rare diseases taking into consideration the reasonable capacity of applicants to meet such requirements;

''(4) the adequacy of the scientific basis for such research, including the adequacy of the research facilities and research resources used in such research and the appropriateness of the scientific training of the personnel engaged in such research;

''(5) the effectiveness of activities undertaken to encourage such research;

''(6) the organization of the peer review process applicable to applications for funds for such research to determine if the organization of the peer review process could be revised to improve the effectiveness of the review provided to proposals for research on rare diseases;

''(7) the effectiveness of the coordination between the national research institutes of the National Institutes of Health, the Food and Drug Administration, and private entities in supporting such research; and

''(8) the effectiveness of activities undertaken to assure that knowledge developed in research on nonrare diseases is, when appropriate, used in research on rare diseases.

''(d) COMPOSITION.—The Commission shall be composed of twenty members appointed by the Secretary of Health and Human Services as follows:

''(1) Ten members shall be appointed from individuals who are not officers or employees of the Government and who by virtue of their training or experience in research on rare diseases or in the treatment of rare diseases are qualified to serve on the Commission.

''(2) Five members shall be appointed from individuals who are not officers or employees of the Government and who have a rare disease or are employed to represent or are members of an organization concerned about rare disease.

''(3) Four nonvoting members shall be appointed for the directors of the national research institutes of the National Institutes of Health which the Secretary determines are involved with rare diseases.

''(4) One nonvoting member shall be appointed from officers or employees of the Food and Drug Administration who the Secretary determines are involved with rare diseases.

A vacancy in the Commission shall be filled in the manner in which the original appointment was made. If any member of the Commission who was appointed to the Commission as a director of a national research institute or as an officer or employee of the Food and Drug Administration leaves that office or position, or if any member of the Commission who was appointed from persons who are not officers or employees of the Government becomes an officer or employee of the Government, such member may continue as a member of the Commission for not longer than the ninety-day period beginning on the date such member leaves that office or position or becomes such an officer or employee, as the case may be.

''(e) TERM.—Members shall be appointed for the life of the Commission.

''(f) COMPENSATION.—

''(1) Except as provided in paragraph (2), members of the Commission shall each be entitled to receive compensation at a rate not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Commission.

''(2) Members of the Commission who are full-time officers or employees of the Government shall receive no additional pay by reason of their service on the Commission.

''(g) CHAIRMAN.—The Chairman of the Commission shall be designated by the members of the Commission.

''(h) STAFF.—Subject to such rules as may be prescribed by the Commission, the Commission may appoint and fix the pay of such personnel as it determines are necessary to enable the Commission to carry out its functions. Personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

''(i) EXPERTS AND CONSULTANTS.—Subject to such rules as may be prescribed by the Commission, the Commission may procure temporary and intermittent services under section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the basic pay payable for grade GS–15 of the General Schedule.

''(j) DETAIL OF PERSONNEL.—Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist the Commission in carrying out its functions.

''(k) ADMINISTRATIVE SUPPORT SERVICES.—The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

''(*l*) GENERAL AUTHORITY.—The Commission may, for the purpose of carrying out this section, hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission considers appropriate.

''(m) INFORMATION.—The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this section. Upon request of the Chairman, the head of such department or agency shall furnish such information to the Commission.

''(n) REPORT.—The Commission shall transmit to the Secretary and to each House of the Congress a report not later than February 1, 1989, on the activities of the Commission. The report shall contain a detailed statement of the findings and conclusions of the Commission, together with its recommendations for—

''(1) a long range plan for the use of public and private resources to improve research into rare diseases and to assist in the prevention, diagnosis, and treatment of rare diseases; and

''(2) such legislation or administrative actions as it considers appropriate.

''(*o*) TERMINATION.—The Commission shall terminate 90 days after the date of the submittal of its report under subsection (n).

''(p) FUNDS.—The Director of the National Institutes of Health shall make available $1,000,000 to the Commission from appropriations for fiscal year 1986 for the National Institutes of Health.''

§ 237. Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service

(a) Creation; number of members

(1) There shall be in the Public Health Service a Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the ''Service''), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment.

(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service.

(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.

(b) Appointments; qualifications; provisions inapplicable to members

The Service shall be appointed by the Secretary without regard to the provisions of title 5 regarding appointment, and shall consist of individuals outstanding in the field of biomedical research, clinical research evaluation, or biomedical product assessment. No individual may be appointed to the Service unless such individual (1) has earned a doctoral level degree in biomedicine or a related field, or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field, and (2) meets the qualification standards prescribed by the Office of Personnel Management for appointment to a position at GS–15 of the General Schedule. Notwithstanding any previous applicability to an individual who is a member of the Service, the provisions of subchapter I of chapter 35 (relating to retention preference), chapter 43 (relating to performance appraisal and performance actions), chapter 51 (relating to classification), subchapter III of