Pub. L. 100–553, § 2(3), Oct. 28, 1988, 102 Stat. 2769; Pub. L. 100–607, title I, § 101(3), Nov. 4, 1988, 102 Stat. 3049; Pub. L. 100–690, title II, § 2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 101–93, § 5(a), Aug. 16, 1989, 103 Stat. 611.)

AMENDMENTS

1989—Pub. L. 101–93 substituted ''disease and'' for ''disease and and''.

1988—Pub. L. 100–553 and Pub. L. 100–607 made identical amendments, substituting ''Neurological Disorders'' for ''Neurological and Communicative Disorders'' and ''and disorder and stroke'' for ''disorder, stroke, and disorders of human communication''. Pub. L. 100–690 amended this section to read as if the amendments by Pub. L. 100–607 had not been enacted.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

§ 285j–1. Spinal cord regeneration research

The Director of the Institute shall conduct and support research into spinal cord regeneration.

(July 1, 1944, ch. 373, title IV, § 458, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 857.)

INTERAGENCY COMMITTEE ON SPINAL CORD INJURY

Section 7 of Pub. L. 99–158 provided that:

''(a) ESTABLISHMENT.—Within 90 days after the date of enactment of this Act [Nov. 20, 1985], the Secretary of Health and Human Services shall establish in the National Institute of Neurological and Communicative Diseases and Stroke an Interagency Committee on Spinal Cord Injury (hereafter in this section referred to as the 'Interagency Committee'). The Interagency Committee shall plan, develop, coordinate, and implement comprehensive Federal initiatives in research on spinal cord injury and regeneration.

''(b) COMMITTEE COMPOSITION AND MEETINGS.—(1) The Interagency Committee shall consist of representatives from—

''(A) the National Institute on Neurological and Communicative Disorders and Stroke;

''(B) the Department of Defense;

''(C) the Department of Education;

''(D) the Veterans' Administration;

''(E) the Office of Science and Technology Policy; and

''(F) the National Science Foundation;

designated by the heads of such entities.

''(2) The Interagency Committee shall meet at least four times. The Secretary of Health and Human Services shall select the Chairman of the Interagency Committee from the members of the Interagency Committee.

''(c) REPORT.—Within the 18 months after the date of enactment of this Act [Nov. 20, 1985], the Interagency Committee shall prepare and transmit to the Congress a report concerning its activities under this section. The report shall include a description of research projects on spinal cord injury and regeneration conducted or supported by Federal agencies during such 18-month period, the nature and purpose of each such project, the amounts expended for each such project, and an identification of the entity which conducted the research under each such project.

''(d) TERMINATION.—The Interagency Committee shall terminate 90 days after the date on which the Interagency Committee transmits the report required by subsection (c) to the Congress.''

§ 285j–2. Bioengineering research

The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

(July 1, 1944, ch. 373, title IV, § 459, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 857.)

§ 285j–3. Research on multiple sclerosis

The Director of the Institute shall conduct and support research on multiple sclerosis, especially research on effects of genetics and hormonal changes on the progress of the disease.

(July 1, 1944, ch. 373, title IV, § 460, as added Pub. L. 103–43, title XII, § 1201, June 10, 1993, 107 Stat. 169.)

SUBPART 11—NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

§ 285k. Purpose of Institute

The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

(July 1, 1944, ch. 373, title IV, § 461, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 857.)

SUBPART 12—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

§ 285*l*. Purpose of Institute

The general purpose of the National Institute of Environmental Health Sciences (in this subpart referred to as the ''Institute'') is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

(July 1, 1944, ch. 373, title IV, § 463, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 103–43, title XIII, § 1301(b), June 10, 1993, 107 Stat. 170.)

AMENDMENTS

1993—Pub. L. 103–43 inserted ''(in this subpart referred to as the 'Institute')'' after ''Sciences''.

§ 285*l*–1. Applied Toxicological Research and Testing Program

(a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

(b) In carrying out the program established under subsection (a) of this section, the Director of the Institute shall, with respect to toxicology, carry out activities—

(1) to expand knowledge of the health effects of environmental agents;

(2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;

(3) to develop and validate assays and protocols, including alternative methods that can

reduce or eliminate the use of animals in acute or chronic safety testing;

(4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;

(5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and

(6) to integrate related activities of the Department of Health and Human Services.

(July 1, 1944, ch. 373, title IV, § 463A, as added Pub. L. 103–43, title XIII, § 1301(a), June 10, 1993, 107 Stat. 169.)

§ 285*l*–2. Definitions

In sections 285*l*–2 to 285*l*–5 of this title:

(1) Alternative test method

The term ''alternative test method'' means a test method that—

(A) includes any new or revised test method; and

(B)(i) reduces the number of animals required;

(ii) refines procedures to lessen or eliminate pain or distress to animals, or enhances animal well-being; or

(iii) replaces animals with non-animal systems or one animal species with a phylogenetically lower animal species, such as replacing a mammal with an invertebrate.

(2) ICCVAM test recommendation

The term ''ICCVAM test recommendation'' means a summary report prepared by the ICCVAM characterizing the results of a scientific expert peer review of a test method.

(Pub. L. 106–545, § 2, Dec. 19, 2000, 114 Stat. 2721.)

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§ 285*l*–3. Interagency Coordinating Committee on the Validation of Alternative Methods

(a) In general

With respect to the interagency coordinating committee that is known as the Interagency Coordinating Committee on the Validation of Alternative Methods (referred to in sections 285*l*–2 to 285*l*–5 of this title as ''ICCVAM'') and that was established by the Director of the National Institute of Environmental Health Sciences for purposes of section 285*l*–1(b) of this title, the Director of the Institute shall designate such committee as a permanent interagency coordinating committee of the Institute under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. Sections 285*l*–2 to 285*l*–5 of this title may not be construed as affecting the authorities of such Director regarding ICCVAM that were in effect on the day before December 19, 2000, except to the extent inconsistent with sections 285*l*–2 to 285*l*–5 of this title.

(b) Purposes

The purposes of the ICCVAM shall be to—

(1) increase the efficiency and effectiveness of Federal agency test method review;

(2) eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies;

(3) optimize utilization of scientific expertise outside the Federal Government;

(4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and

(5) reduce, refine, or replace the use of animals in testing, where feasible.

(c) Composition

The ICCVAM shall be composed of the heads of the following Federal agencies (or their designees):

(1) Agency for Toxic Substances and Disease Registry.

(2) Consumer Product Safety Commission.

(3) Department of Agriculture.

(4) Department of Defense.

(5) Department of Energy.

(6) Department of the Interior.

(7) Department of Transportation.

(8) Environmental Protection Agency.

(9) Food and Drug Administration.

(10) National Institute for Occupational Safety and Health.

(11) National Institutes of Health.

(12) National Cancer Institute.

(13) National Institute of Environmental Health Sciences.

(14) National Library of Medicine.

(15) Occupational Safety and Health Administration.

(16) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

(d) Scientific Advisory Committee

(1) Establishment

The Director of the National Institute of Environmental Health Sciences shall establish a Scientific Advisory Committee (referred to in sections 285*l*–2 to 285*l*–5 of this title as the ''SAC'') to advise ICCVAM and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods regarding ICCVAM activities. The activities of the SAC shall be subject to provisions of the Federal Advisory Committee Act.

(2) Membership

(A) In general

The SAC shall be composed of the following voting members:

(i) At least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of—

(I) the personal care, pharmaceutical, industrial chemicals, or agriculture industry;

(II) any other industry that is regulated by the Federal agencies specified in subsection (c) of this section; and

(III) a national animal protection organization established under section 501(c)(3) of title 26.

(ii) Representatives (selected by the Director of the National Institute of Environmental Health Sciences) from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories.

(B) Nonvoting ex officio members

The membership of the SAC shall, in addition to voting members under subparagraph (A), include as nonvoting ex officio members the agency heads specified in subsection (c) of this section (or their designees).

(e) Duties

The ICCVAM shall, consistent with the purposes described in subsection (b) of this section, carry out the following functions:

(1) Review and evaluate new or revised or alternative test methods, including batteries of tests and test screens, that may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised or alternative test methods of interagency interest.

(2) Facilitate appropriate interagency and international harmonization of acute or chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal test methods.

(3) Facilitate and provide guidance on the development of validation criteria, validation studies and processes for new or revised or alternative test methods and help facilitate the acceptance of such scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders.

(4) Submit ICCVAM test recommendations for the test method reviewed by the ICCVAM, through expeditious transmittal by the Secretary of Health and Human Services (or the designee of the Secretary), to each appropriate Federal agency, along with the identification of specific agency guidelines, recommendations, or regulations for a test method, including batteries of tests and test screens, for chemicals or class of chemicals within a regulatory framework that may be appropriate for scientific improvement, while seeking to reduce, refine, or replace animal test methods.

(5) Consider for review and evaluation, petitions received from the public that—

(A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and

(B) recommend new or revised or alternative test methods and provide valid scientific evidence of the potential of the test method.

(6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the responses from the agencies regarding such recommendations.

(7) Prepare reports to be made available to the public on its progress under sections 285*l*–2 to 285*l*–5 of this title. The first report shall be completed not later than 12 months after December 19, 2000, and subsequent reports shall be completed biennially thereafter.

(Pub. L. 106–545, § 3, Dec. 19, 2000, 114 Stat. 2721.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (d)(1), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

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.

§ 285*l*–4. Federal agency action

(a) Identification of tests

With respect to each Federal agency carrying out a program that requires or recommends acute or chronic toxicological testing, such agency shall, not later than 180 days after receiving an ICCVAM test recommendation, identify and forward to the ICCVAM any relevant test method specified in a regulation or industry-wide guideline which specifically, or in practice requires, recommends, or encourages the use of an animal acute or chronic toxicological test method for which the ICCVAM test recommendation may be added or substituted.

(b) Alternatives

Each Federal agency carrying out a program described in subsection (a) of this section shall promote and encourage the development and use of alternatives to animal test methods (including batteries of tests and test screens), where appropriate, for the purpose of complying with Federal statutes, regulations, guidelines, or recommendations (in each instance, and for each chemical class) if such test methods are found to be effective for generating data, in an amount and of a scientific value that is at least equivalent to the data generated from existing tests, for hazard identification, dose-response assessment, or risk assessment purposes.

(c) Test method validation

Each Federal agency carrying out a program described in subsection (a) of this section shall ensure that any new or revised acute or chronic toxicity test method, including animal test methods and alternatives, is determined to be valid for its proposed use prior to requiring, recommending, or encouraging the application of such test method.

(d) Review

Not later than 180 days after receipt of an ICCVAM test recommendation, a Federal agency carrying out a program described in subsection (a) of this section shall review such recommendation and notify the ICCVAM in writing of its findings.

(e) Recommendation adoption

Each Federal agency carrying out a program described in subsection (a) of this section, or its specific regulatory unit or units, shall adopt the ICCVAM test recommendation unless such Federal agency determines that—

(1) the ICCVAM test recommendation is not adequate in terms of biological relevance for the regulatory goal authorized by that agency, or mandated by Congress;

(2) the ICCVAM test recommendation does not generate data, in an amount and of a scientific value that is at least equivalent to the data generated prior to such recommendation, for the appropriate hazard identification, dose-response assessment, or risk assessment purposes as the current test method recommended or required by that agency;

(3) the agency does not employ, recommend, or require testing for that class of chemical or for the recommended test endpoint; or

(4) the ICCVAM test recommendation is unacceptable for satisfactorily fulfilling the test needs for that particular agency and its respective congressional mandate.

(Pub. L. 106–545, § 4, Dec. 19, 2000, 114 Stat. 2723.)

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§ 285*l*–5. Application

(a) Application

Sections 285*l*–2 to 285*l*–5 of this title shall not apply to research, including research performed using biotechnology techniques, or research related to the causes, diagnosis, treatment, control, or prevention of physical or mental diseases or impairments of humans or animals.

(b) Use of test methods

Nothing in sections 285*l*–2 to 285*l*–5 of this title shall prevent a Federal agency from retaining final authority for incorporating the test methods recommended by the ICCVAM in the manner determined to be appropriate by such Federal agency or regulatory body.

(c) Limitation

Nothing in sections 285*l*–2 to 285*l*–5 of this title shall be construed to require a manufacturer that is currently not required to perform animal testing to perform such tests. Nothing in sections 285*l*–2 to 285*l*–5 of this title shall be construed to require a manufacturer to perform redundant endpoint specific testing.

(d) Submission of tests and data

Nothing in sections 285*l*–2 to 285*l*–5 of this title precludes a party from submitting a test method or scientific data directly to a Federal agency for use in a regulatory program.

(Pub. L. 106–545, § 5, Dec. 19, 2000, 114 Stat. 2724.)

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§ 285*l*–6. Methods of controlling certain insect and vermin populations

The Director of the Institute shall conduct or support research to identify or develop methods of controlling insect and vermin populations that transmit to humans diseases that have significant adverse health consequences.

(July 1, 1944, ch. 373, title IV, § 463B, as added Pub. L. 108–75, § 3, Aug. 15, 2003, 117 Stat. 902.)

SUBPART 13—NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

§ 285m. Purpose of Institute

The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the ''Institute'') is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell.

(July 1, 1944, ch. 373, title IV, § 464, as added Pub. L. 100–553, § 2(4), Oct. 28, 1988, 102 Stat. 2769, and Pub. L. 100–607, title I, § 101(4), Nov. 4, 1988, 102 Stat. 3049; amended Pub. L. 100–690, title II, § 2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

CODIFICATION

Pub. L. 100–553 and Pub. L. 100–607 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

1988—Pub. L. 100–690 amended this section to read as if the amendments made by Pub. L. 100–607, which enacted this section, had not been enacted. See Codification note above.

SHORT TITLE OF 1988 AMENDMENT

For short title of Pub. L. 100–553 which enacted this subpart and amended sections 281 and 285j of this title as the ''National Deafness and Other Communication Disorders Act of 1988'', see section 1 of Pub. L. 100–553, set out as a note under section 201 of this title.

EFFECT OF ENACTMENT OF SIMILAR PROVISIONS

Section 2613(b) of Pub. L. 100–690 provided that:

''(1) Paragraphs (2) and (3) shall take effect immediately after the enactment of both the bill, S. 1727, of the One Hundredth Congress [Pub. L. 100–553, approved Oct. 28, 1988], and the Health Omnibus Programs Extension of 1988 [Pub. L. 100–607, approved Nov. 4, 1988].

''(2)(A) The provisions of the Public Health Service Act referred to in subparagraph (B), as similarly amended by the enactment of the bill, S. 1727, of the One Hundredth Congress, by subtitle A of title I of the Health Omnibus Programs Extension of 1988, and by subsection (a)(1) of this section, are amended to read as if the amendments made by such subtitle A and such subsection (a)(1) had not been enacted.

''(B) The provisions of the Public Health Service Act referred to in subparagraph (A) are—

''(A) sections 401(b)(1) and 457 [sections 281(b)(1) and 285j of this title];