

cember 19, 2000, and subsequent reports shall be completed biennially thereafter.

(Pub. L. 106–545, §3, Dec. 19, 2000, 114 Stat. 2721; Pub. L. 117–286, §4(a)(235), Dec. 27, 2022, 136 Stat. 4331.)

Editorial Notes

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.

AMENDMENTS

2022—Subsec. (d)(1). Pub. L. 117–286 substituted “chapter 10 of title 5.” for “the Federal Advisory Committee Act.”

Statutory Notes and Related Subsidiaries

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 1013 of 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.

§ 2851–4. 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) 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) 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) 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), 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.)

Editorial Notes

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.

§ 2851–5. Application

(a) Application

Sections 2851–2 to 2851–5 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 2851–2 to 2851–5 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 2851–2 to 2851–5 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 2851–2 to 2851–5 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 285I-2 to 285I-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.)

Editorial Notes**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.

§ 285I-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.)

Editorial Notes**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.

Statutory Notes and Related Subsidiaries**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

Pub. L. 100-690, title II, § 2613(b), Nov. 18, 1988, 102 Stat. 4238, 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 [42 U.S.C. 281(b)(1), 285j];

“(B) part C of title IV [42 U.S.C. 285 et seq.]; and

“(C) the heading for subpart 10 of such part C [42 U.S.C. prec. 285j].

“(3) Subsection (a)(2) of this section [formerly set out below] is repealed.”

TRANSITIONAL AND SAVINGS PROVISIONS

Pub. L. 100-553, § 3, Oct. 28, 1988, 102 Stat. 2774, provided that:

“(a) TRANSFER OF PERSONNEL, ASSETS, AND LIABILITIES.—Personnel employed by the National Institutes of Health in connection with the functions vested under section 2 [enacting this subpart and amending sections 281 and 285j of this title] in the Director of the National Institute on Deafness and Other Communication Disorders, and assets, property, contracts, liabilities, records, unexpended balances of appropriations, authorizations, allocations, and other funds of the National Institutes of Health, arising from or employed, held, used, available to, or to be made available, in connection with such functions shall be transferred to the Director for appropriate allocation. Unexpended funds transferred under this subsection shall be used only for the purposes for which the funds were originally authorized and appropriated.

“(b) SAVINGS PROVISIONS.—With respect to functions vested under section 1 [probably means section 2, enacting this subpart and amending sections 281 and 285j of this title] in the Director of the National Institute on Deafness and Other Communication Disorders, all orders, rules, regulations, grants, contracts, certificates, licenses, privileges, and other determinations, actions, or official documents, that have been issued, made, granted, or allowed to become effective, and that are effective on the date of the enactment of this Act [Oct. 28, 1988], shall continue in effect according to their terms unless changed pursuant to law.”

Pub. L. 100-690, title II, § 2613(a)(2), Nov. 18, 1988, 102 Stat. 4238, which enacted provisions that were substantially identical to the transitional and savings provisions above, was repealed by section 2613(b)(3) of Pub. L. 100-690.

§ 285m-1. National Deafness and Other Communication Disorders Program

(a) The Director of the Institute, with the advice of the Institute’s advisory council, shall establish a National Deafness and Other Communication Disorders Program (hereafter in this section referred to as the “Program”). The Director or¹ the Institute shall, with respect to the Program, prepare and transmit to the Director of NIH a plan to initiate, expand, intensify and coordinate activities of the Institute respecting disorders of hearing (including tinnitus) and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell. The plan shall include such comments and recommendations as the Director of the Institute

¹ So in original. Probably should be “of”.