

**(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.

**§ 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 2851-2 to 2851-5 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.

**§ 2851-6. 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];

“(B) part C of title IV [this part]; and  
 “(C) the heading for subpart 10 of such part C [42 U.S.C. prec. 285j].  
 “(3) Subsection (a)(2) of this section [set out below] is repealed.”

#### TRANSITIONAL AND SAVINGS PROVISIONS

Section 3 of Pub. L. 100-553 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.”

Section 2612(a)(2) of Pub. L. 100-690, 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 or<sup>1</sup> 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 determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Director of NIH.

(b) Activities under the Program shall include—

(1) investigation into the etiology, pathology, detection, treatment, and prevention of all forms of disorders of hearing and other communication processes, primarily through the support of basic research in such areas as anatomy, audiology, biochemistry, bioengineering, epidemiology, genetics, immunology, microbiology, molecular biology, the neurosciences, otolaryngology, psychology, phar-

macology, physiology, speech and language pathology, and any other scientific disciplines that can contribute important knowledge to the understanding and elimination of disorders of hearing and other communication processes;

(2) research into the evaluation of techniques (including surgical, medical, and behavioral approaches) and devices (including hearing aids, implanted auditory and nonauditory prosthetic devices and other communication aids) used in diagnosis, treatment, rehabilitation, and prevention of disorders of hearing and other communication processes;

(3) research into prevention, and early detection and diagnosis, of hearing loss and speech and language disturbances (including stuttering) and research into preventing the effects of such disorders on learning and learning disabilities with extension of programs for appropriate referral and rehabilitation;

(4) research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population with extension of rehabilitative programs to ensure continued effective communication skills in such population;

(5) research to expand knowledge of the effects of environmental agents that influence hearing or other communication processes; and

(6) developing and facilitating intramural programs on clinical and fundamental aspects of disorders of hearing and all other communication processes.

(July 1, 1944, ch. 373, title IV, §464A, 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.

#### 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.

#### § 285m-2. Data System and Information Clearinghouse

(a) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing or other communication processes, including where possible, data involving general populations for the purpose of identifying individuals at risk of developing such disorders.

(b) The Director of the Institute shall establish a National Deafness and Other Communica-

<sup>1</sup> So in original. Probably should be “of”.