Effective: December 22, 2006

United States Code Annotated Currentness
Title 42. The Public Health and Welfare
Chapter 6A. Public Health Service (Refs & Annos)
Subchapter II. General Powers and Duties
Part A. Research and Investigations (Refs & Annos)

➞ § 241. Research and investigations generally

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to--

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and orga-

nizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of Title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains--

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved--

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

(e) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery and infant mortality.

CREDIT(S)

(July 1, 1944, c. 373, Title III, § 301, 58 Stat. 691; July 3, 1946, c. 538, § 7(a),(b), 60 Stat. 423; June 16, 1948, c. 481, § 4(e),(f), 62 Stat. 467; June 24, 1948, c. 621, § 4(e),(f), 62 Stat. 601; June 25, 1948, c. 654, § 1, 62 Stat. 1017; July 3, 1956, c. 510, § 4, 70 Stat. 490; Sept. 15, 1960, Pub.L. 86-798, 74 Stat. 1053; Oct. 17, 1962, Pub.L. 87-838, § 2, 76 Stat. 1073; Aug. 9, 1965, Pub.L. 89-115, § 3, 79 Stat. 448; Dec. 5, 1967, Pub.L. 90-174, § 9, 81 Stat. 540; Oct. 27, 1970, Pub.L. 91-513, Title I, § 3(a), 84 Stat. 1241; Oct. 30, 1970, Pub.L. 91-515, Title II, § 292, 84 Stat. 1308; Dec. 23, 1971, Pub.L. 92-218, § 6(a)(2), 85 Stat. 785; Sept. 19, 1972, Pub.L. 92-423, § 7(b), 86 Stat. 687; May 14, 1974, Pub.L. 93-282, Title I, § 122(b), 88 Stat. 132; July 12, 1974, Pub.L. 93-348, Title I, § 104(a)(1), 88 Stat. 346; July 23, 1974, Pub.L. 93-352, Title I, § 111, 88 Stat. 360; Apr. 22, 1976, Pub.L. 94-278, Title I, § 111, 90 Stat. 405; Nov. 9, 1978, Pub.L. 95-622, Title II, §§ 261, 262, 92 Stat. 3434; Oct. 17, 1979, Pub.L. 96-88, Title V, § 509(b), 93 Stat. 695; Nov. 20, 1985, Pub.L. 99-158, § 3(a)(5), 99 Stat. 879; Oct. 27, 1986, Pub.L. 99-570, Title IV, § 4021(b)(2), 100 Stat. 3207-124; Nov. 14, 1986, Pub.L. 99-660, Title I, § 104, 100 Stat. 3751; Nov. 4, 1988, Pub.L. 100-607, Title I, § 163(1), (2), 102 Stat. 3062; June 10, 1993, Pub.L. 103-43, Title XX, § 2009, 107 Stat. 213; Dec. 22, 2006, Pub.L. 109-450, § 3(a), 120 Stat. 3341.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1946 Acts. Senate Report No. 1353, see 1946 U.S. Code Cong. Service, p. 1259.

1948 Acts. House Report No. 2144, see 1948 U.S. Code Cong. Service, p. 1814.

House Report No. 2158, see 1948 U.S. Code Cong. Service, p. 1974.

Senate Report No. 1578, see 1948 U.S. Code Cong. Service, p. 2063.

1956 Acts. House Report No. 2108, see 1956 U.S. Code Cong. and Adm. News, p. 2988.

1960 Acts. House Report No. 2174, see 1960 U.S. Code Cong. and Adm. News, p. 3845.

1962 Acts. Senate Report No. 2174, see 1962 U.S. Code Cong. and Adm. News, p. 3787.

1965 Acts. Senate Report No. 367 and Conference Report No. 677, see 1965 U.S. Code Cong. and Adm. News, p. 2591.

1967 Acts. Senate Report No. 724 and Conference Report No. 974, see 1967 U.S. Code Cong. and Adm. News, p. 2076.

1970 Acts. House Report No. 91-1297 and Conference Report No. 1590, see 1970 U.S. Code Cong. and Adm. News, p. 4678.

1971 Acts. House Report No. 92-659 andHouse Conference Report No. 92-722, see 1971 U.S. Code Cong. and Adm. News, p. 2337.

1972 Acts. Senate Report No. 92-733 and Senate Conference Report No. 92-1068, see 1972 U.S. Code Cong. and Adm. News, p. 3196.

1974 Acts. Senate Report No. 93-381 and House Conference Report No. 93-1148, see 1974 U.S. Code Cong. and Adm. News, p. 3634.

Senate Report No. 93-736 and Conference Report No. 93-1164, see 1974 U.S. Code Cong. and Adm. News, p. 3730.

1976 Acts. House Report No. 94-498 andHouse Conference Report No. 94-1005, see 1976 U.S. Code Cong. and Adm. News, p. 709.

1978 Acts. Senate Report No. 95-838, see 1978 U.S. Code Cong. and Adm. News, p. 9042.

1979 Acts. Senate Report No. 96-49 and House Conference Report No. 96-459, see 1979 U.S. Code Cong. and Adm. News, p. 1514.

1985 Acts. House Report No. 99-158 andHouse Conference Report No. 99-309, see 1985 U.S. Code Cong. and Adm. News, p. 672.

1986 Acts. Statement by President, see 1986 U.S. Code Cong. and Adm. News, p. 5393.

Senate Report No. 99-380, Related Reports, and Statement by President, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

1988 Acts. House Report Nos. 100-761, 100-778, 100-70, Senate Report Nos. 100-133, 100-310, 100-552, 100-476, and House Conference Report No. 100-1055, see 1988 U.S. Code Cong. and Adm. News, p. 4167.

1993 Acts. Senate Report No. 103-2 and House Conference Report No. 103-100, see 1993 U.S. Code Cong. and Adm. News, p. 196.

2006 Acts. Senate Report No. 109-298, see 2006 U.S. Code Cong. and Adm. News, p. 1766.

Codifications

Amendment of subsec. (h) of this section by Pub.L. 93-352 was executed to subsec. (g) of this section in view of the redesignation of subsec. (h) as (g) by Pub.L. 93-348.

Amendments

2006 Amendments. Subsec. (e). Pub.L. 109-450, § 3(a), added subsec. (e).

1993 Amendments. Subsec. (b)(4). Pub.L. 103-43, § 2009, substituted “a biennial report” for “an annual report” in the provisions preceding subpar. (A).

1988 Amendments. Subsec. (d). Pub.L. 100-607 redesignated concluding provisions of subsec. (a) of section 242a of this title as subsec. (d) of this section, substituted “biomedical, behavioral, clinical, or other research (including research on mental health, including” for “research on mental health, including”, and substituted “drugs)” for “drugs,”.

Pub.L. 100-607, § 163(2), substituted “biomedical, behavioral, clinical, or other research (including research on mental health, including” for “research on mental health, including”, and “drugs)” for “drugs,”.

1986 Amendments. Subsec. (a)(3). Pub.L. 99-570, § 4021(b)(2), struck out “or, in the case of mental health projects, by the National Advisory Mental Health Council;” after “Department supporting such projects” and struck out “or the National Advisory Mental Health Council” after “appropriate entity of the Department”.

Subsec. (c). Pub.L. 99-660 added subsec. (c).

1985 Amendments. Subsec. (a)(3). Pub.L. 99-158, § 3(a)(5)(A), substituted following “as are recommended” text reading “by the advisory council to the entity of the Department supporting such projects or, in the case of mental

health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research" for "by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: Provided, That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year".

Subsec. (a)(8). Pub.L. 99-158, § 3(a)(5)(B), substituted "recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers" for "recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems".

1978 Amendments. Pub.L. 95-622 designated existing provisions as subsec. (a) and, in subsec. (a) as so designated, redesignated former pars. (a) to (h) as (1) to (8), substituted "Secretary" for "Surgeon General" wherever appearing, and added following par. (8) provisions relating to the authority of the Secretary to make available to individuals and entities substances and living organisms, and added subsec. (b).

1976 Amendments. Subsec. (c). Pub.L. 94-278 substituted "heart, blood vessel, lung, and blood diseases and blood resources" for "heart diseases" and "National Heart, Lung, and Blood Advisory Council" for "National Heart and Lung Advisory Council".

Subsec. (h). Pub.L. 94-278 substituted "heart, blood vessel, lung, and blood diseases and blood resources" for "heart diseases" and "National Heart, Lung, and Blood Advisory Council" for "National Heart and Lung Advisory Council".

1974 Amendments. Subsec. (c). Pub.L. 93-348, § 104(a)(1)(A) to (C), struck authorization of Surgeon General to establish and maintain research fellowships in the Public Health Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and

promising research fellows from the United States and abroad, now covered in § 289l-1(b) of this title; substituted "research projects" for "research or research training projects" in two instances, "general support of their research" for "general support of their research and research training programs" and "research grants-in-aid" for "research and research training program grants-in-aid"; and redesignated former subsec. (d) as amended as subsec. (c).

Subsec. (d). Pub.L. 93-348, § 104(a)(1)(C), redesignated former subsec. (e) as (d). Former subsec. (d) redesignated (c).

Pub.L. 93-282 substituted "mental health, including research on the use and effect of alcohol and other psychoactive drugs" for "the use and effect of drugs" in former concluding provisions of section 242a(a) of this title. See 1988 Amendments note under this section.

Subsecs. (e), (f). Pub.L. 93-348, § 104(a)(1)(C), redesignated former subsecs. (f) and (g) as subsecs. (e) and (f), respectively. Formerly subsec. (e) redesignated (d).

Subsec. (g). Pub.L. 93-352 struck out "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years" following "Enter into contracts". See Codification Note under this section.

Pub.L. 93-348, § 104(a)(1)(C), redesignated former subsec. (h) as (g). Former subsec. (g) redesignated (f).

Subsec. (h). Pub.L. 93-348, § 104(a)(1)(C), redesignated former subsec. (i) as (h). Former subsec. (h) redesignated (g).

Subsec. (i). Pub.L. 93-348, § 104(a)(1)(C), redesignated former subsec. (i) as (h).

1972 Amendments. Subsecs. (d), (i). Pub.L. 92-423 substituted "National Heart and Lung Advisory Council" for "National Advisory Heart Council".

1971 Amendments. Subsecs. (d), (i). Pub.L. 92-218 substituted "National Cancer Advisory Board" for "National Advisory Cancer Council".

1970 Amendments. Subsec. (d). Pub.L. 91-513 added subsec. (d). See 1988 Amendment notes set out under this section.

Subsec. (h). Pub.L. 91-515 substituted "eight succeeding fiscal years" for "five succeeding fiscal years".

1967 Amendments. Subsec. (h). Pub.L. 90-174 substituted "five" for "two" succeeding fiscal years.

1965 Amendments. Subsec. (h). Pub.L. 89-115 added subsec. (h). Former Subsec. (h) redesignated (i).

Subsec. (i). Pub.L. 89-115 redesignated former subsec. (h) as (i).

1962 Amendments. Subsec. (d). Pub.L. 87-838 inserted “or research training” in two places.

1960 Amendments. Subsec. (d). Pub.L. 86-798 authorized the Surgeon General, upon recommendation of the National Advisory Health Council, to make grants to public or nonprofit universities, hospitals, laboratories, and other institutions to support research and research training programs, and to make available for such research and research training programs, up to 15 per centum of amounts provided for research grants through the appropriations for the National Institutes of Health.

1956 Amendments. Subsec. (g). Act July 3, 1956 added subsec. (g). Former subsec. (g) redesignated (h).

Subsec. (h). Act July 3, 1956 redesignated former subsec. (g) as (h).

1948 Amendments. Subsec. (d). Act June 25, 1948 continued in basic legislation and authority to purchase penicillin and other antibiotic compounds for use in research projects.

Acts June 16, 1948, § 4(e), and June 24, 1948, § 4(e), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

Subsec. (g). Acts June 16, 1948, § 4(f), and June 24, 1948, § 4(f), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

1946 Amendments. Subsec. (d). Act July 3, 1946 made the National Advisory Mental Health Council the body to make recommendations to the Surgeon General on awarding of grants-in-aid for research projects with respect to mental health.

Subsec. (g). Act July 3, 1946 gave the National Advisory Health Council the right to make recommendations to carry out the purposes of this section.

Effective and Applicability Provisions

1993 Acts. Amendment by Pub.L. 103-43 effective June 10, 1993, see section 2101 of Pub.L. 103-43, set out as a note under section 201 of this title.

1978 Acts. Section 261 of Pub.L. 95-622 provided in part that the amendment to subsec. (a) by section 261 of Pub.L. 95-622 is effective Oct. 1, 1978.

Section 262 of Pub.L. 95-622 provided in part that the amendment to this section by section 262 of Pub.L. 95-622 is effective Oct. 1, 1978.

1974 Acts. Section 104(b) of Pub.L. 93-348 provided that: "The amendments made by subsection (a) [amending this section and sections 242a(a)(1), (b), 282(a)(3) to (7), 286a(b)(7), 286b(b)(3), 287a(7), 287b(a)(7), 287d(b), 288a(c) to (f), 289c(a), 289c, 289c-1(c)(2), 289g, 289k, and heading preceding section 289l of this title] shall not apply with respect to commitments made before the date of the enactment of this Act [July 12, 1974] by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a) [supra]."

1972 Acts. Amendment by Pub.L. 92-423 effective 60 days after Sept. 19, 1972, or on such prior date after Sept. 19, 1972, as the President shall prescribe and publish in the Federal Register, see section 9 of Pub.L. 92-423, set out as a note under section 218 of this title.

1971 Acts. Amendment by Pub.L. 92-218 effective 60 days after Dec. 23, 1971, or on such prior date after Dec. 23, 1971, as the President shall prescribe and publish in the Federal Register, see section 7 of Pub.L. 92-218, set out as a note under section 218 of this title.

Change of Name

"Secretary of Health and Human Services" was substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(7) and "Department of Health and Human Services" was substituted for "Department of Health, Education, and Welfare" in subsec. (b)(1), (3), and (4)(D)(I), (II) pursuant to section 509(b) of Pub.L. 96-88 which is classified to § 3508(b) of Title 20, Education.

Coordination of Data Surveys and Reports

Pub.L. 106-113, Div. B, § 1000(a)(6) [Title VII, § 703(e)], Nov. 29, 1999, 113 Stat. 1536, 1501A-402, provided that: "The Secretary of Health and Human Services, through the Assistant Secretary for Planning and Evaluation, shall establish a clearinghouse for the consolidation and coordination of all Federal databases and reports regarding children's health."

Analysis of Thyroid Cancer; Creation and Publication of Radioepidemiological Tables

Pub.L. 97-414, § 7, Jan. 4, 1983, 96 Stat. 2059, as amended Pub.L. 109-482, Title I, § 104(b)(3)(A), Jan. 15, 2007, 120 Stat. 3694, provided that:

"(a) In carrying out section 301 of the Public Health Service Act [this section], the Secretary of Health and Human Services shall--

"(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

"(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout; and

"(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests.

"(4) Repealed. Pub.L. 109-482, Title I, § 104(b)(3)(A)(i)(III), Jan. 15, 2007, 120 Stat. 3694

"(b)(1) Within one year after the date of enactment of this Act [Jan. 4, 1983], the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

"(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish--

"(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

"(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

"(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise.".

[Amendment of this note by Pub.L. 109-482, Title I, applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see Pub.L. 109-482, Title I, § 109, Jan. 15, 2007, 120 Stat. 3697, set out as an Effective and Applicability Provisions note under 42 U.S.C.A. § 281.]

Continuing Care for Psychiatric Patients in Former Clinical Research Center at National Institute on Drug Abuse

Pub.L. 99-117, § 10, Oct. 7, 1985, 99 Stat. 494, provided that: "In any fiscal year beginning after September 30, 1981, from funds appropriated for carrying out section 301 of the Public Health Service Act [this section] with respect to mental health, the Secretary of Health and Human Services may provide, by contract or otherwise, for the continuing care of psychiatric patients who were under active and continuous treatment at the National Institute on Drug Abuse Clinical Research Center on the date such Clinical Research Center ceased operations."

Female Genital Mutilation

Pub.L. 104-134, Title I, § 101(d) [Title V, § 520], Apr. 26, 1996, 110 Stat. 1321-250; renumbered Title I Pub.L. 104-140, § 1(a), May 2, 1996, 110 Stat. 1327, provided that:

"(a) Congress finds that--

"(1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and

"(2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved.

"(b) The Secretary of Health and Human Services shall do the following:

"(1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation.

"(2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice.

"(3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation. Such recommendations shall be disseminated to such schools.

"(c) For purposes of this section the term 'female genital mutilation' means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major.

"(d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act [Apr. 26, 1996]."

Fiscal Year Transition Period July 1, 1976, Through September 30, 1976, Deemed Part of Fiscal Year Beginning July 1, 1975

Fiscal year transition period of July 1, 1976, through Sept. 30, 1976, deemed part of fiscal year beginning July 1, 1975, for purposes of subsec. (c) of this section, see § 204(1) of Pub.L. 94-274, Apr. 21, 1976, 90 Stat. 392, set out as a note under § 390e of Title 7, Agriculture.

National Commission on Sleep Disorders Research

Section 162 of Pub.L. 100-607 provided that:

"(a) Establishment.--Not later than 90 days after the date of enactment of this Act [Nov. 4, 1988], the Secretary of Health and Human Services (hereafter in this section referred to as the 'Secretary'), after consultation with the Director of the National Institutes of Health, shall establish a National Commission on Sleep Disorders Research (hereafter in this section referred to as the 'Commission').

"(b) Composition.--

"(1) Appointed members.--The Commission shall be composed of 10 members to be appointed as follows:

"(A) Six members shall be appointed by the Secretary from among scientists, physicians, and other health professionals who are not in the employment of the Federal Government, and who have primary expertise in sleep disorders research or medicine.

"(B) Two members shall be appointed by the Secretary from the general public, of whom one of which shall have personal or close family experience with sleep disorders.

"(C) Two members shall be appointed by the Secretary from among the personnel of the National Institutes of Health, and such members interest shall be in the field of sleep disorders research.

"(2) Ex officio members.--The Director of the National Institutes of Health, the Director of the National Institute of Neurological and Communicative Disorders and Stroke, the Directors of the National Heart, Lung and Blood Institute, the National Institute on Mental Health, the National Institute on Aging, the National Institute on Child Health and Human Development [Now, 'Eunice Kennedy Shriver National Institute of Child Health and Human Development'], the Director of the Center for Disease Control, the Chief Medical Director of the Veterans' Ad-

ministration [now, Under Secretary for Health of the Department of Veterans Affairs], and the Secretary of Defense shall be ex officio members of the Commission, or their designees.

"(c) Chairperson.--The members of the Commission shall select a Chairperson from among the appointed members of the Commission.

"(d) Meetings.--Not later than 60 days after the establishment of the Commission, the Commission shall meet as directed by the Secretary, and thereafter shall meet at the call of the Chairperson of the Commission, but in no event shall the Commission meet less often than three times during the life of the Commission. The Commission may hold such hearings, take such testimony, and sit and act at such time and places as the Commission considers appropriate.

"(e) Personnel.--

"(1) Executive Secretary.--

"(A) Appointment.--The Commission may appoint and fix the compensation of an executive secretary to effectively carry out the functions of the Commission.

"(B) Compensation.--The executive secretary shall be appointed subject to title 5, United States Code, governing appointments in the competitive service, and shall receive compensation in accordance with chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

"(2) Additional personnel.--The Secretary shall, to the extent practicable, provide the Commission with such additional professional and clerical staff, such information, and the services of such consultants as the Commission determines to be necessary to carry out its functions effectively.

"(f) Compensation.--

"(1) Officers or employees of the Federal Government.--Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment.

"(2) Non-Federal Government members.--Members of the Commission who are not officers or employees of the Federal Government shall receive compensation at a rate not to exceed the daily equivalent of the annual rate in effect for Grade GS-18 of the General Schedule for each day (including traveltime) that such members are engaged in the performance of their duties as members of the Commission.

"(3) Expenses.--All members of the Commission, while serving away from their homes or regular places of business in the performance of services for the Commission, shall be allowed travel expenses, including per diem in

lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for persons in Government Service employed intermittently.

"(g) Duties.--

"(1) Study.--The Commission shall--

"(A) conduct a comprehensive study of the present state of knowledge of the incidence, prevalence, morbidity, and mortality resulting from sleep disorders, and of the social and economic impact of such disorders;

"(B) evaluate the public and private facilities and resources (including trained personnel and research activities) available for the diagnosis, prevention, and treatment of, and research into, such disorders; and

"(C) identify programs (including biological, physiological, behavioral, environmental, and social programs) by which improvement in the management and research into sleep disorders can be accomplished.

"(2) Development of plan.--Based on the study conducted under paragraph (1), the Commission shall develop a long-range plan for the use and organization of national resources to effectively deal with sleep disorders research and medicine.

"(3) Cooperation.--Each Federal entity administering programs and activities related to sleep disorders shall, on request, assist the Commission in carrying out its duties under this subsection.

"(h) Development of estimates.--The Commission shall recommend, for each of the Institutes of the National Institutes of Health whose activities are to be affected by the long-range plan, estimates of the expenditures needed to carry out each Institute's part of the overall program. Such estimates shall be prepared for the fiscal year beginning immediately after completion of the plan under subsection (g)(2) and for each of the next 2 fiscal years.

"(i) Report.--Not later than 18 months after the initial meeting of the Commission (as prescribed by subsection (d)), the Commission shall prepare and submit to the appropriate Committees of Congress, a final report describing--

"(1) the long-range plan developed under subsection (g);

"(2) the expenditure estimates required under subsection (h); and

"(3) any recommendations of the Commission for legislation.

"(j) Termination.--The Commission shall cease to exist on the 30th day following the date of the submission of the final report under subsection (i)."

[Any reference in any law, regulation, order, document, paper, or other record of the United States to the National Institute of Child Health and Human Development shall be deemed to be a reference to the Eunice Kennedy Shriver National Institute of Child Health and Human Development, see Pub.L. 110-154, § 1(d), Dec. 21, 2007, 121 Stat. 1828, set out as a note under 42 U.S.C.A. § 285g.]

Research With Respect to Health Resources and Services Administration

Section 632 of Pub.L. 100-607 provided that with respect to any program of research pursuant to the Public Health Service Act, any such program carried out in fiscal year 1987 by an agency other than the Health Resources and Services Administration (or appropriate to be carried out by such an agency) could not, for each of the fiscal years 1989 through 1991, be carried out by such Administration.

Sentinel Disease Concept Study

Pub.L. 103-43, Title XIX, § 1910, June 10, 1993, 107 Stat. 205, provided that:

"(a) In general.--The Secretary of Health and Human Services, in cooperation with the Agency for Toxic Substances and Disease Registry and the Centers for Disease Control and Prevention, shall design and implement a pilot sentinel disease surveillance system, and as appropriate, a follow-up system.

"(b) Purpose.--The purpose of the study conducted under subsection (a) shall be to determine the applicability of and the difficulties associated with the implementation of the sentinel disease concept for identifying the relationship between the occupation of household members and the incidence of subsequent conditions or diseases in other members of the household.

"(c) Report.--Not later than 4 years after the date of enactment of this Act [June 10, 1993], the Director of the National Institutes of Health shall prepare and submit to the appropriate committees of Congress, a report concerning the results of the study conducted under subsection (a)."

Study of Thyroid Morbidity for Hanford, Washington

Pub.L. 100-607, Title I, § 161, Nov. 4, 1988, 102 Stat. 3059, as amended Pub.L. 102-531, Title III, § 312(e)(1), Oct. 27, 1992, 106 Stat. 3506, directed the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to conduct a study of thyroid morbidity of the population, including Indian tribes and tribal organizations, in the vicinity of Hanford, in the State of Washington, authorized the Director to contract out portions of the study, and required the Director, not later than 42 months after Nov. 4, 1988, to transmit a report, including such study, to the Congress, the chief executive officers of the States of Oregon and Washington, and the governing officials of the Indian tribes in the vicinity of Hanford, Washington. For termination of reporting

provisions pertaining to the thyroid morbidity study in Hanford, Washington, effective May 15, 2000, see Pub.L. 104-66, § 3003, as amended, set out as a note under 31 U.S.C.A. § 1113, and the 4th item on page 100 of House Document No. 103-7

Termination of Advisory Committees

Pub.L. 93-641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under § 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act (this chapter) shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

EXECUTIVE ORDERS

EXECUTIVE ORDER NO. 13435

Ex. Ord. No. 13435, June 20, 2007, 72 F.R. 34591, relating to expanding approved stem cell lines in ethically responsible ways, was revoked by section 5(b) of Ex. Ord. No. 13505, Mar. 9, 2009, 74 F.R. 10667.

EXECUTIVE ORDER NO. 13505

<Mar. 9, 2009, 74 F.R. 10667>

REMOVING BARRIERS TO RESPONSIBLE SCIENTIFIC RESEARCH INVOLVING HUMAN STEM CELLS

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.

For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.

Sec. 2. Research. The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell

research, to the extent permitted by law.

Sec. 3. Guidance. Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order. The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

Sec. 4. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 5. Revocations. (a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as a statement of governmental policy.

(b) Executive Order 13435 of June 20, 2007, which supplements the August 9, 2001, statement on human embryonic stem cell research, is revoked.

BARACK OBAMA

MEMORANDA OF PRESIDENT

PRESIDENTIAL MEMORANDUM OF JANUARY 22, 1993

Presidential Memorandum of Jan. 22, 1993, 58 FR 7457, relating to federal funding of fetal tissue transplantation research, is set out as a note under 42 U.S.C.A. § 289g.

PRESIDENTIAL MEMORANDUM

GUIDELINES FOR HUMAN STEM CELL RESEARCH

<July 30, 2009, 74 F.R. 38885>

Memorandum for the Heads of Executive Departments and Agencies

As outlined in Executive Order 13505 of March 9, 2009, my Administration is committed to supporting and conducting ethically responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law. Pursuant to that order, the National Institutes of Health (NIH) published final 'National Institutes of Health Guidelines for Human Stem Cell Research' (Guidelines), effective July 7, 2009. These Guidelines apply to the expenditure of NIH funds for research using human embryonic stem cells and certain uses of human induced pluripotent stem cells. The Guidelines are based on the principles that responsible research with human embryonic stem cells has the potential to improve our understanding of human biology and aid in the discovery of new ways to prevent and treat illness, and that individuals donating embryos for research purposes should do so freely, with voluntary and informed consent. These Guidelines will ensure that NIH-funded research adheres to the highest ethical standards.

In order to ensure that all federally funded human stem cell research is conducted according to these same principles and to promote a uniform Federal policy across the executive branch, I hereby direct the heads of executive departments and agencies that support and conduct stem cell research to adopt these Guidelines, to the fullest extent practicable in light of legal authorities and obligations. I also direct those departments and agencies to submit to the Director of the Office of Management and Budget (OMB), within 90 days, proposed additions or revisions to any other guidance, policies, or procedures related to human stem cell research, consistent with Executive Order 13505 and this memorandum. The Director of the OMB shall, in coordination with the Director of NIH, review these proposals to ensure consistent implementation of Executive Order 13505 and this memorandum.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

The Director of the OMB is hereby authorized and directed to publish this memorandum in the **Federal Register**.

BARACK OBAMA

CROSS REFERENCES

For purposes of carrying out this section--
Director of National Institutes of Health's duties and authority, see 42 USCA § 282.
Directors of national research institutes' duties and authority, see 42 USCA § 284.

Preparation of biological products by service, see 42 USCA § 263.
Nonduplication of appropriations, see 42 USCA § 7610.

CODE OF FEDERAL REGULATIONS

For purposes of carrying out this section--

Administration and application of fellowships, internships and training, see 42 CFR § 61.1 et seq.

Administration of National Institutes of Health and National Library of Medicine traineeships, see 42 CFR § 63.1 et seq.

Delegations of authority, see 21 CFR § 5.10 et seq.

Enforcement policies, see 21 CFR § 7.1 et seq.

Exemptions for investigational devices, see 21 CFR § 812.1 et seq.

Institutional Review Boards, see 21 CFR § 56.101 et seq.

Minority biomedical support program, see 42 CFR § 52c.1 et seq.

Research projects, grants for, see 40 CFR § 40.100 et seq.

Training assistance, see 40 CFR § 45.100 et seq.

LIBRARY REFERENCES

American Digest System

United States 40, 41.
Key Number System Topic No. 393.

RESEARCH REFERENCES

Encyclopedias

14 Am. Jur. Proof of Facts 3d 85, Radiation Injuries--Ionizing Radiation.

Treatises and Practice Aids

Federal Evidence § 5:48, Researchers and Academics.

West's Federal Administrative Practice § 3802, Significant Food, Drug and Cosmetic Laws.

NOTES OF DECISIONS

1. Classification of carcinogens

Decision of National Toxicology Program (NTP) to list sulfuric acid mist in biennial report on carcinogenicity did not constitute substantive rulemaking, and thus was not subject to formal notice and comment requirements of Administrative Procedure Act (APA); Public Health Service Act mandated publication of report, summary of report was published in Federal Register, publication was product of congressional mandate, and report was not amendment to prior substantive rule. Fertilizer Institute v. U.S. Dept. of Health and Human Services, D.D.C.2004, 355 F.Supp.2d 123. Environmental Law 453

Criteria for classifying chemicals as known or reasonably anticipated carcinogens were not arbitrary or capricious and did not conflict with Public Health Service Act; Act did not require Secretary of Health and Human Services to conduct complete hazard identification, risk assessment, or weight of the evidence approach in preparing annual reports on carcinogens; and Secretary reasonably determined that pharmacokinetics and mechanisms of action data were not relevant to function of reports. Synthetic Organic Chemical Mfrs. Ass'n v. Secretary, Dept. of Health and Human Services, W.D.La.1989, 720 F.Supp. 1244. Health 372; Health 382

2. Distribution of grants

Purpose of this chapter to encourage and render assistance to scientific institutions can only be fulfilled by protecting interest of medical research personnel and medical faculties in fair and objective distribution of government grants. Apter v. Richardson, C.A.7 (Ill.) 1975, 510 F.2d 351. Colleges And Universities 4

3. Persons entitled to maintain action

Plaintiff alleged sufficient economic and noneconomic harm to show injury in fact and, thus, had standing to bring action challenging denial of application for a medical training grant by the Department of Health, Education and Welfare [now Department of Health and Human Services], even though application was merely filed by plaintiff on behalf of medical center where she worked, where plaintiff not only alleged that grant was denied because of her exercise of U.S.C.A.Const. Amend. 1 rights to testify before a senate subcommittee and to participate in feminist associations, but also alleged that she had been deprived of economic and professional benefits which she anticipated in return for some 800 hours spent in preparation of application. Apter v. Richardson, C.A.7 (Ill.) 1975, 510 F.2d 351. United States 135

Medical professor was not entitled to sue as a third-party beneficiary for alleged breach of a contract based upon medical school's deprivation of his rights under grant award by the Public Health Service through National Institutes of Health; measure of professor's rights was the statute and regulations thereunder, not principles of contract, and professor had shown nothing in the applicable statute and regulations that gave rise to any right to relief. Tavoloni v. Mount Sinai Medical Center, S.D.N.Y.1998, 26 F.Supp.2d 678, affirmed 198 F.3d 235. Colleges And Universities 8.1(6.1)

Chemical manufacturers and sellers and associations for producers of chlorobenzenes had standing to challenge inclusion in Fifth Annual Report on Carcinogens of chemicals produced by manufacturers; consumer reaction study showed that significant reduction in usage of mothballs and toilet deodorizers would result from Government's identification or labeling of those products as carcinogens; and listing of paradichlorobenzene, methylene chloride, tetracholroethylene, ethyl acrylate, and chlorinated paraffin in report would require manufacturers to label those products as carcinogens. Synthetic Organic Chemical Mfrs. Ass'n v. Secretary, Dept. of Health and Human Services, W.D.La.1989, 720 F.Supp. 1244. Environmental Law 656; Environmental Law 652

4. Pleadings

Complaint challenging denial of application for medical training grant by Department of Health, Education and Welfare [now Department of Health and Human Services] was properly treated as if application was merely filed by plaintiff on behalf of medical center where she worked even though there were ambiguous references in complaint to effect that plaintiff rather than medical center was “the applicant.” Apter v. Richardson, C.A.7 (Ill.) 1975, 510 F.2d 351. United States 135

5. Judicial review

Inasmuch as this chapter confers broad discretion in funding of training programs upon the National Institutes of Health (NIH), medical merits of NIH decisions on training grants may be committed to unreviewable discretion of agency, but this does not mean that such decisions wholly escape judicial scrutiny, and where it is alleged that agency has transgressed a constitutional guarantee or violated an express statutory or procedural directive, the otherwise nonreviewable agency action should be examined to the extent necessary to determine merits of allegation. Apter v. Richardson, C.A.7 (Ill.) 1975, 510 F.2d 351. Colleges And Universities 4

Decision of National Toxicology Program (NTP) to list sulfuric acid mist in biennial report on carcinogenicity was reasonably based on reliable evidence, as required under Public Health Service Act; NTP's finding of sufficient evidence of carcinogenicity was based on studies indicating causal relationship between exposure to mist and cancer, and NTP determined that significant number of persons were exposed to mist. Fertilizer Institute v. U.S. Dept. of Health and Human Services, D.D.C.2004, 355 F.Supp.2d 123. Environmental Law 415

Federal agency had broad discretion to determine manner in which it conducted research, and therefore discretionary function exception under Federal Tort Claims Act (FTCA) barred agency's liability to inmate for alleged negligence in manner in which agency structured study of hepatitis outbreak at inmate's prison. Williams v. Centers for Disease Control and Prevention, C.A.7 (Ill.) 2004, 96 Fed.Appx. 399, 2004 WL 422653, Unreported. United States 78(12)

42 U.S.C.A. § 241, 42 USCA § 241

Current through P.L. 112-3 (excluding P.L. 111-296, 111-314, 111-320, 111-350, 111-377, and 111-383) approved 2-25-11

END OF DOCUMENT