ATTACHMENT 1

Section 301 of the Public Health Service Act
[42 U.S.C. 241]

(Includes provision originally outlined in
Public Law 102-515
Cancer Registries Amendment Act)

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Section 301 of the Public Health Service Act [42 U.S.C. 241]

TITLE 42 , CHAPTER 6A , SUBCHAPTER II , Part A , Sec. 241.
US CODE COLLECTION

TITLE 42 CHAPTER 6A SUBCHAPTER II Part A Sec. 241. Next
Sec. 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 organizations, 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.

Title 42. The Public Health and Welfare
Chapter 6a. The Public Health Service
National Program of Cancer Registries
42 U.S.C. § 280e (1998)
§ 280e. National program of cancer registries

(a) In general. The Secretary, acting through the Director of the Centers for Disease Control, [Director of the Centers for Disease Control and Prevention] may make grants to States, or may make grants or enter into contracts with academic or nonprofit organizations designated by the State to operate the State's cancer registry in lieu of making a grant directly to the State, to support the operation of population-based, statewide cancer registries in order to collect, for each form of in-situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin), data concerning--

(1) demographic information about each case of cancer;

(2) information on the industrial or occupational history of the individuals with the cancers, to the extent such information is available from the same record;

(3) administrative information, including date of diagnosis and source of information;

(4) pathological data characterizing the cancer, including the cancer site, stage of disease (pursuant to Staging Guide), incidence, and type of treatment; and

(5) other elements determined appropriate by the Secretary.

(b) Matching funds.

(1) In general. The Secretary may make a grant under subsection (a) only if the State, or the academic or nonprofit private organization designated by the State to Operate the cancer registry of the State, involved agrees, with respect to the costs of the program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs or $ 1 for every $ 3 of Federal funds provided in the grant.

(2) Determination of amount of non-federal contribution; maintenance of effort.

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) With respect to a State in which the purpose described in subsection

(a) is to be carried out, the Secretary, in making a determination of the amount of non-Federal contributions provided under paragraph (1), may include only such

contributions as are in excess of the amount of such contributions made by the State toward the collection of data on cancer for the fiscal year preceding the first year for which a grant under subsection (a) is made with respect to the State. The Secretary may decrease the amount of non-Federal contributions that otherwise would have been required by this subsection in those cases in which the State can demonstrate that decreasing such amount is appropriate because of financial hardship.

(c) Eligibility for grants.

(1) In general. No grant shall be made by the Secretary under subsection (a) unless an application has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such a manner, and be accompanied by such information, as the Secretary may specify. No such application may be approved unless it contains assurances that the applicant will use the funds provided only for the purposes specified in the approved application and in accordance with the requirements of this section, that the application will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the applicant under subsection (a) of this section, and that the applicant will comply with the peer review requirements under sections 491 and 492 [42 U.S.C. §§ 289 and 289a].

(2) Assurances. Each applicant, prior to receiving Federal funds under subsection (a), shall provide assurances satisfactory to the Secretary that the applicant will--

(A) provide for the establishment of a registry in accordance with subsection (a);

(B) comply with appropriate standards of completeness, timeliness, and quality of population-based cancer registry data;

(C) provide for the annual publication of reports of cancer data under subsection (a); and

(D) provide for the authorization under State law of the statewide cancer registry, including promulgation of regulations providing--

(i) a means to assure complete reporting of cancer cases (as described in subsection (a)) to the statewide cancer registry by hospitals or other facilities providing screening, diagnostic or therapeutic services to patients with respect to cancer;

(ii) a means to assure the complete reporting of cancer cases (as defined in subsection (a)) to the statewide cancer registry by physicians, surgeons, and all other health care

practitioners diagnosing or providing treatment for cancer patients, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities;

(iii) a means for the statewide cancer registry to access all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes, and all other facilities, individuals, or agencies providing such services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified patient;

(iv) for the reporting of cancer case data to the statewide cancer registry in such a format, with such data elements, and in accordance with such standards of quality timeliness and completeness, as may be established by the Secretary;

(v) for the protection of the confidentiality of all cancer case data reported to the statewide cancer registry, including a prohibition on disclosure to any person of information reported to the statewide cancer registry that identifies, or could lead to the identification of, an individual cancer patient, except for disclosure to other State cancer registries and local and State health officers;

(vi) for a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research; registry or other persons and organizations, of studies utilizing statewide cancer registry data, including studies of the sources and causes of cancer, evaluations of the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventative services and programs relating to cancer, and any other clinical, epidemiological, or other cancer research; and

(viii) for protection for individuals complying with the law, including provisions specifying that no person shall be held liable in any civil action with respect to a cancer case report provided to the statewide cancer registry, or with respect to access to cancer case information provided to the statewide cancer registry.

(d) Relationship to certain programs.

(1) In general. This section may not be construed to act as a replacement for or diminishment of the program carried out by the Director of the National Cancer Institute and designated by such Director as the Surveillance, Epidemiology, and End Results Program (SEER).

(2) Supplanting of activities. In areas where both such programs exist, the Secretary shall ensure that SEER support is not supplanted and that any additional activities are consistent with the guidelines provided for in subsection (c)(2) (C) and (D) and are appropriately coordinated with the existing SEER program.

(3) Transfer of responsibility. The Secretary may not transfer administration responsibility for such SEER program from such Director.

(4) Coordination. To encourage the greatest possible efficiency and effectiveness of Federally supported efforts with respect to the activities described in this subsection, the Secretary shall take steps to assure the appropriate coordination of programs supported under this part [42 U.S.C. §§ 280e et seq.] with existing Federally supported cancer registry programs.

(e) Requirement regarding certain study on breast cancer. In the case of a grant under subsection (a) to any State specified in section 399K(b) [42 U.S.C. § 280e-3(b)], the Secretary may establish such conditions regarding the receipt of the grant as the Secretary determines are necessary to facilitate the collection of data for the study carried out under section 399C [*probably 42 U.S.C. § 280e-3*].

§ 280e-1. Planning grants regarding registries

(a) In general.

(1) States. The Secretary, acting through the Director of the Centers for Disease Control [Director of the Centers for Disease Control and Prevention], may make grants to States for the purpose of developing plans that meet the assurances required by the Secretary under section 399B(c)(2) [*probably 42 U.S.C. § 280e(c)(2)*].

(2) Other entities. For the purpose described in paragraph (1), the Secretary may make grants to public entities other than States and to nonprofit private entities.

Such a grant may be made to an entity only if the State in which the purpose is to be carried out has certified that the State approves the entity as qualified to carry out the purpose.

(b) Application. The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the certification required in subsection (a)(2) (if the application is for a grant under such subsection), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as

the Secretary determines to be necessary to carry out this section.

§ 280e-2. Technical assistance in operations of statewide cancer registries

The Secretary, acting through the Director of the Centers for Disease Control [Director of the Centers for Disease Control and Prevention], may, directly or through grants and contracts, or both, provide technical assistance to the States in the establishment and operation of statewide registries, including assistance in the development of model legislation for statewide cancer registries and assistance in establishing a computerized reporting and data processing system.

§ 280e-3. Study in certain States to determine the factors contributing to the elevated breast cancer mortality rates

(a) In general. Subject to subsections (c) and (d), the Secretary, acting through the Director of the National Cancer Institute, shall conduct a study for the purpose of determining the factors contributing to the fact that breast cancer mortality rates in the States specified in subsection (b) are elevated compared to rates in other States.

(b) Relevant States. The States referred to in subsection (a) are Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, and the District of Columbia.

(c) Cooperation of State. The Secretary may conduct the study required in subsection (a) in a State only if the State agrees to cooperate with the Secretary in the conduct of the study, including providing information from any registry operated by the State pursuant to section 399H(a) [42 U.S.C. § 280e(a)].

(d) Planning, commencement, and duration. The Secretary shall, during each of the fiscal years 1993 and 1994, develop a plan for conducting the study required in subsection (a). The study shall be initiated by the Secretary not later than fiscal year 1994, and the collection of data under the study may continue through fiscal year 1998.

(e) Report. Not later than September 30, 1999, the Secretary shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings and recommendations made as a result of the study.

§ 280e-4. Authorization of appropriations

(a) Registries. For the purpose of carrying out this part [42 U.S.C. §§ 280e et seq.], there are authorized to be appropriated $ 30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 ***through 2003***[1]***.*** Of the amounts appropriated under the preceding sentence for any such fiscal year, the Secretary may obligate not more than 25 percent for carrying out section 399I [42 U.S.C. § 280e-1], and not more than 10 percent may be expended for assessing the accuracy, completeness and quality of data collected, and not more than 10 percent of which is to be expended under subsection [section] 399J [42 U.S.C. § 280e-2].

(b) Breast cancer study. Of the amounts appropriated for the National Cancer Institute under subpart 1 of part C of title IV [42 U.S.C. §§ 285a et seq.] for any fiscal year in which the study required in section 399K [42 U.S.C. § 280e-3] is being carried out, the Secretary shall expend not less than $ 1,000,000 for the study.

[1]Italicized text shows changes made by the Women's Health Research and Prevention

Amendments of 1998, Public Law 105-340, signed October 31, 1998.