# Public Law 94-278
## 94th Congress
## An Act

To amend the Public Health Service Act to revise and extend the program under the National Heart and Lung Institute, to revise and extend the program of National Research Service Awards, and to establish a national program with respect to genetic diseases; and to require a study and report on the release of research information.

Apr. 22, 1976
[H.R. 7988]

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

Health Research and Health Services Amendments of 1976.
42 USC 201 note.

SECTION 1. (a) This Act may be cited as the "Health Research and Health Services Amendments of 1976".

(b) Whenever in this Act (other than in titles III, V, VI, VII, and XI) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

42 USC 201 note.

## TITLE I—REVISION OF NATIONAL HEART AND LUNG INSTITUTE PROGRAMS

42 USC 287 note.

SEC. 101. (a) Congress finds and declares that—

(1) diseases of the heart, blood, and blood vessels collectively cause more than half of all the deaths each year in the United States and the combined effect of the disabilities and deaths from such diseases is having a major social and economic impact on the Nation;

(2) elimination of heart and blood vessel diseases as significant causes of disability and death could increase the average American's life expectancy by about eleven years and could provide for annual savings to the economy in lost wages, productivity, and cost of medical care of more than $40,000,000,000 per year;

(3) chronic lung diseases have been gaining steadily in recent years as important causes of disability and death, with emphysema being among the fastest rising causes of death in the United States;

(4) chronic respiratory diseases affect an estimated ten million Americans, emphysema an estimated one million, chronic bronchitis an estimated four million, and asthma an estimated five million;

(5) thrombosis (the formation of blood clots in the vessels) may cause, directly or in combination with other problems, many deaths and disabilities from heart disease and stroke which can now be prevented;

(6) blood and blood products are essential human resources whose value in saving life and promoting health cannot be assessed in terms of dollars;

(7) the provision of prompt and effective emergency medical services utilizing to the fullest extent possible advances in transportation and communications and other electronic systems and specially trained professional and paraprofessional health care personnel can reduce substantially the number of fatalities and

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severe disabilities due to critical illnesses in connection with heart, blood vessel, lung, and blood diseases;

(8) blood diseases, including nutritional anemia, anemia due to inherited abnormalities (such as sickle cell anemia and Cooley's anemia (thalassemia), anemias resulting from failure of the bone marrow, hemorrhagic defects (a common cause of death in patients with leukemia and other malignancies, and of disability from inherited diseases such as hemophilia)), and malignancies of the lymph nodes and bone marrow, such as leukemia, have a devastating impact in spite of recent advances, and constitute an important category of illness that requires major attention; and

(9) the greatest potential for advancement against heart, blood vessel, lung, and blood diseases lies in the National Heart, Lung, and Blood Institute, but advancement against such diseases depends not only on the research programs of that Institute but also on the research programs of other research institutes of the National Institutes of Health.

(b) It is the purpose of this title to enlarge the authority of the National Heart, Lung, and Blood Institute in order to advance the national attack upon heart, blood vessel, lung, and blood diseases and to enlarge its authority with respect to blood resources.

National Heart, Lung, and Blood Institute.
42 USC 287, 287g, 287h.
42 USC 287a.

SEC. 102. Sections 411, 418(a)(6), and 419A(c) are each amended by striking out "National Heart and Lung Institute" and inserting in lieu thereof "National Heart, Lung, and Blood Institute".

SEC. 103. (a) Section 412 is amended—

(1) by inserting "and with respect to the use of blood and blood products and the management of blood resources" after "diseases" in the matter preceding paragraph (1);

(2) by inserting "and to the use of blood and blood products and the management of blood resources" before the semicolon at the end of paragraph (1);

(3) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (4);

(4) by inserting "and on the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (5);

(5) by striking out "heart diseases" in paragraph (6) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and the management of blood resources";

(6) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraph (7); and

(7) by inserting at the end of the section heading "AND IN THE MANAGEMENT OF BLOOD RESOURCES".

National Heart, Lung, and Blood Advisory Council.
42 USC 287b.

(b) Section 412 is amended by striking out "National Heart and Lung Advisory Council" and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

SEC. 104 (a) Section 413(a) is amended—

(1) by striking out "Disease" in the first sentence and inserting in lieu thereof "Diseases and Blood Resources"; and

(2) by inserting "and blood resources" after "diseases" in such sentence and in paragraph (7).

(b) Section 413(b) is amended—

(1) by striking out "calendar" each place it occurs in paragraph (2) and inserting in lieu thereof "fiscal"; and

(2) by adding at the end of such paragraph the following: "Each such plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations to carry out the program during such five years".

(c) Section 413(c)(1) is amended by striking out "fifty" and inserting in lieu thereof "one hundred". 42 USC 287b.

(d) Section 413(c)(2) is amended—

(1) by striking out "operate" and inserting in lieu thereof "operate, alter, renovate"; and

(2) by inserting "and blood resource" after "disease".

(e) Section 413(d) is amended—

(1) by striking out "Assistant Director for Health Information Programs" each place it occurs and inserting in lieu thereof "Assistant Director for Prevention Education, and Control"; Assistant Director for Prevention Education, and Control.

(2) by striking out "and pulmonary" in the second sentence and inserting in lieu thereof ", blood, and pulmonary" and by inserting "and blood" after "pulmonary" in the third sentence; and

(3) by inserting "and blood resources" after "diseases" in the second sentence.

(f) The section heading of section 413 is amended by striking out "DISEASE" and inserting in lieu thereof "DISEASES AND BLOOD RESOURCES".

SEC. 105. Section 414(b) is amended (1) by striking out "and" after "1974,", and (2) by inserting before the period a comma and the following: "$10,000,000 for fiscal year 1976, and $30,000,000 for fiscal year 1977". 42 USC 287c.

SEC. 106. (a)(1) Subsection (a)(1)(A) of section 415 is amended by— National research and demonstration centers. 42 USC 287d.

(A) striking out "fifteen" and inserting in lieu thereof "ten", and

(B) striking out ", blood vessel, and blood diseases" and inserting in lieu thereof "diseases".

(2) Subsection (a)(1)(B) of such section is amended by striking out "fifteen" and inserting in lieu thereof "ten".

(3) Subsection (a)(1) of such section is amended—

(A) by striking out "and" at the end of subparagraph (A),

(B) by striking out the period at the end of subparagraph (B) and inserting in lieu thereof ", and", and

(C) by inserting after subparagraph (B) the following new subparagraph:

"(C) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood, blood vessel diseases, research in the use of blood products, and research in the management of blood resources.".

(b) Section 415(a) is further amended—

(1) by inserting "and for research in the use of blood and blood products and in the management of blood resources" after "diseases" in paragraph (1)(A);

(2) by striking out "chronic" in paragraph (1)(B);

(3) by striking out "paragraph (1)(A)" in paragraph (2) and inserting in lieu thereof "paragraph (1)";

(4) by inserting ", pulmonary, and blood" before "diseases" in paragraph (2);

(5) by striking out "cardiovascular disease" in paragraph (2) (A) and inserting in lieu thereof "cardiovascular, pulmonary, and blood diseases"; and

(6) by striking out "such disease" in subparagraphs (B), (C), and (D) of paragraph (2) and inserting in lieu thereof "such diseases".

42 USC 287d.

(c) Section 415(b) is amended—

(1) by inserting "the management of blood resources and" before "advanced"; and

Aggregate of payments, limitation.

(2) by amending the first sentence after paragraph (4) to read as follows: "The aggregate of payments (other than payments for construction) made to any center under such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed $5,000,000 in any year, except that the aggregate of such payments in any year may exceed such amount to the extent that the excess amount is attributable to increases in such year in appropriate costs as reflected in the Consumer Price Index published by the Bureau of Labor Statistics.".

(d) The section heading of section 415 is amended by inserting "AND BLOOD RESOURCES" after "DISEASES".

42 USC 287f.

SEC. 107. (a) Section 417(a)(1) is amended by striking out "Director of the Office of Science and Technology" and inserting in lieu thereof "Director of the National Science Foundation".

(b) Section 417 is amended by striking out "National Heart and Lung Advisory Council" in subsection (a) and in subsection (b)(3) and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

(c) The section heading of section 417 is amended by striking out "AND LUNG" and inserting in lieu thereof ", LUNG, AND BLOOD".

42 USC 287g.

SEC. 108. Section 418 is amended—

(1) by inserting "and to the use of blood and blood products and the management of blood resources" after "diseases" in paragraphs (1), (2), (3), and (4) of subsection (a);

(2) by redesignating paragraphs (4), (5), and (6) of subsection (a) as paragraphs (5), (6), and (7), respectively, and by adding after paragraph (3) the following new paragraph:

"(4) recommend to the Secretary (A) areas of research in heart, blood vessels, lung, and blood diseases and in the use of blood and blood products and the management of blood resources which it determines should be supported by the awarding of contracts in order to best carry out the purposes of this part, and (B) the percentage of the budget of the Institute which should be expended for such contracts;"; and

(3)(A) by amending paragraph (2) of subsection (b) to read as follows:

Report to Secretary for transmittal to President and Congress.

"(2) The Council shall submit a report to the Secretary for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress on the progress of the Program toward the accomplishment of its objectives during the preceding fiscal year.".

42 USC 287g note.

(B) For purposes of section 418(b)(2) of the Public Health Service Act (as amended by subparagraph (A)), the period beginning July 1, 1975, and ending September 30, 1976, shall be considered a fiscal year.

Effective date. 42 USC 287g note.

(C) The amendment made by subparagraph (A) shall take effect as of January 1, 1976.

SEC. 109. Section 419A is amended— Administration. 42 USC 287h.

(1) by inserting "and projects with respect to the use of blood and blood products and the management of blood resources" after "training projects" in subsection (a);

(2) by inserting "and into the use of blood and blood products and the management of blood resources" after "diseases" in subsection (b);

(3) by inserting "and for research and training in the use of blood and blood products and the management of blood resources" after "diseases" in subsection (c);

(4) by striking out "in amounts not to exceed $35,000" in paragraph (1) of subsection (c) and inserting in lieu thereof "if the direct costs of such research and training do not exceed $35,000, but only"; and

(5) by striking out "in amounts exceeding $35,000" in paragraph (2) of subsection (c) and inserting in lieu thereof "if the direct costs of such research and training exceed $35,000, but only".

SEC. 110. Section 419B is amended— 42 USC 287i.

(1) by striking out "and" after "1974," and by inserting before the period at the end of the first sentence a comma and the following: "$339,000,000 for fiscal year 1976, and $373,000,000 for fiscal year 1977"; and

(2) by striking out "diseases of the blood" and inserting in lieu thereof "blood diseases and blood resources".

SEC. 111. (a) Section 301 is amended by striking out "heart diseases" in paragraphs (c) and (h) and inserting in lieu thereof "heart, blood vessel, lung, and blood diseases and blood resources". 42 USC 241.

(b) Section 301 is amended by striking out "National Heart and Lung Advisory Council" in paragraphs (c) and (h) and inserting in lieu thereof "National Heart, Lung, and Blood Advisory Council".

SEC. 112. The title of Part B of title IV is amended to read as follows:

"PART B—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE".

## TITLE II—NATIONAL RESEARCH SERVICE AWARDS

SEC. 201. (a) (1) Subsection (a) (1) (A) (i) of section 472 is amended (A) by striking out "in matters" and inserting in lieu thereof "or under programs administered by the Division of Nursing of the Health Resources Administration, in matters", and (ii) by inserting before "are directed" the following: "or Division of Nursing". 42 USC 289l-1.

(2) Subsections (a) (1) (A) (iii) and (a) (1) (B) of such section are each amended by striking out "non-Federal".

(b) Subsection (c) (1) (A) (i) of such section is amended by striking out "health research or teaching" and inserting in lieu thereof "health research or teaching or any combination thereof which is in accordance with usual patterns of academic employment".

(c) Subsection (c) (2) (A) of such section is amended by striking out "health research or teaching" and inserting in lieu thereof "health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment".

(d) The first sentence of subsection (d) of such section is amended by inserting a comma before the period and the following: "$165,000,000 for fiscal year 1976, and $185,000,000 for fiscal year 1977".

42 USC 289l-1.

SEC. 202. (a) Subsection (a)(1)(A)(i) of section 472 is amended by striking out "the disease or (diseases) or other health problems to which the activities of the Institutes and Administration are directed" and inserting in lieu thereof "diseases or other health problems".

(b) Subsection (b)(2) of section 472 is amended by striking out "to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration" and inserting in lieu thereof "within the Department of Health, Education, and Welfare".

42 USC 289l-1.

SEC. 203. (a)(1) Subparagraph (A) of the first paragraph (4) of subsection (c) of section 472 is amended by striking out "and the interest on such amount" down through and including "was made".

(2) The last sentence of subparagraph (B) of such paragraph is amended by striking out "at the same rate as that fixed by the Secretary of the Treasury under subparagraph (A) to determine the amount due the United States" and inserting in lieu thereof "at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount".

(b) The amendments made by subsection (a) shall apply with respect to National Research Awards under section 472 which are made from appropriations for fiscal years ending on or after June 30, 1975.

Biomedical and behavioral research personnel, studies.
42 USC 289l-2.

SEC. 204. Section 473(b) is amended by adding after paragraph (2) the following new paragraph:

"(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of the National Institutes of Health.".

Report to congressional committees.
42 USC 289l-2.

SEC. 205. Subsection (c) of section 473 is amended by striking out "March 31" and inserting in lieu thereof "September 30".

## TITLE III—DISCLOSURE OF RESEARCH INFORMATION

Investigations and study.
42 USC 289l-1 note.

SEC. 301. (a)(1) The President's Biomedical Research Panel (established by section 201(a) of the National Cancer Act Amendments of 1974 (Public Law 93-352)) and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by section 201 of the National Research Act (Public Law 93-348)) shall each conduct an investigation and study of the implication of the disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education, and Welfare (hereinafter in the subsection referred to as the "Secretary") in connection with an application or proposal submitted, during the period beginning January 1, 1975, and ending December 31, 1975, to the Secretary for a grant, fellowship, or contract under the Public Health Service Act. In making such investigation and study the Panel and the Commission shall each determine the following:

42 USC 289l-1 note.

42 USC 201 note.

(A) The number of requests made to the Secretary for the disclosure of information contained in such research protocols, hypotheses, and designs and the interests represented by the persons for whom such requests were made.

(B) The purposes for which information disclosed by the Secretary pursuant to such requests was used.

(C) The effect of the disclosure of such information on—

(i) proprietary interests in the research protocol, hypothesis, or design from which such information was disclosed and on patent rights;

(ii) the ability of peer review systems to insure high quality federally funded research; and

(iii) the (I) protection of the public against research which presents an unreasonable risk to human subjects of such research and (II) the adequacy of informed consent procedures.

(2) (A) Not later than May 31, 1976, the Panel shall complete the investigation and study required to be made by the Panel by paragraph (1), and, not later than June 30, 1976, the Panel shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Panel deems appropriate.

Report to congressional committees.

(B) Not later than November 30, 1976, the Commission shall complete the investigation and study required to be made by the Commission by paragraph (1), and, not later than December 31, 1976, the Commission shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Commission deems appropriate.

Report to congressional committees.

(b) Section 211(b) of the National Research Act (Public Law 93-348) is amended by striking out "July 1, 1976" and inserting in lieu thereof "January 1, 1977".

42 USC 218 note.

## TITLE IV—GENETIC DISEASES

SEC. 401. This title may be cited as the "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act".

National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act.

SEC. 402. In order to preserve and protect the health and welfare of all citizens, it is the purpose of this title to establish a national program to provide for basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic diseases, including sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

42 USC 300b note.

SEC. 403. (a) Title XI is amended by striking out parts A and B and inserting in lieu thereof the following:

42 USC 300b note.

### "PART A—GENETIC DISEASES

#### "TESTING AND COUNSELING PROGRAMS AND INFORMATION AND EDUCATION PROGRAMS

"SEC. 1101. (a) (1) The Secretary, through an identifiable administrative unit within the Department of Health, Education, and Welfare, may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities, for projects to establish and operate voluntary genetic testing and counseling programs primarily in conjunction with other existing health programs, including programs assisted under title V of the Social Security Act.

42 USC 300b.

42 USC 701.

"(2) The Secretary shall carry out, through an identifiable administrative unit within the Department of Health, Education, and Welfare, a program to develop information and educational materials

relating to genetic diseases and to disseminate such information and materials to persons providing health care, to teachers and students, and to the public generally in order to most rapidly make available the latest advances in the testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. The Secretary may, under such program, make grants to public and nonprofit private entities and enter into contracts with public and private entities and individuals for the development and dissemination of such materials.

Appropriation authorization.

"(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $30,000,000 for fiscal year 1976, $30,000,000 for fiscal year 1977, and $30,000,000 for fiscal year 1978.

"RESEARCH PROJECT GRANTS AND CONTRACTS

42 USC 300b-1.
42 USC 241.

"SEC. 1102. In carrying out section 301, the Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals, and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases, and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

Sickle cell anemia and Cooley's anemia research, priority.

"VOLUNTARY PARTICIPATION

42 USC 300b-2.

"SEC. 1103. The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

"APPLICATIONS; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS

42 USC 300b-3.

"SEC. 1104. (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require. Each applicant shall—

"(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

"(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

"(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part;

"(4) in the case of an applicant for a grant or contract under section 1101(a)(1) for the delivery of services, provide assurances satisfactory to the Secretary that (A) the services for community-wide testing and counseling to be provided under the program for which the application is made (i) will take into consideration widely prevalent diseases with a genetic component and high-risk population groups in which certain genetic diseases occur, and (ii) where appropriate will be directed especially but not exclusively to persons who are entering their child-producing years, and (B) appropriate arrangements will be made to provide counseling to persons found to have a genetic disease and to persons found to carry a gene or chromosome which may cause a deleterious effect in their offspring; and

"(5) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

"(b) In making any grant or entering into any contract for testing and counseling programs under section 1101, the Secretary shall (1) take into account the number of persons to be served by the program supported by such grant or contract and the extent to which rapid and effective use will be made of funds under the grant or contract; and (2) give priority to programs operating in areas which the Secretary determines have the greatest number of persons who will benefit from and are in need of the services provided under such programs.

"(c) In making grants and entering into contracts for any fiscal year under section 301 for projects described in section 1102 or under section 1101 the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics. 42 USC 241.

"PUBLIC HEALTH SERVICE FACILITIES

"SEC. 1105. The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services. 42 USC 300b-4.

"REPORTS

"SEC. 1106. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part. Report to President for transmittal to Congress.

"(b) The report required by this section shall contain such recommendations for additional legislation as the Secretary deems necessary.". 42 USC 300b-5.

(b)(1) Section 1121(b)(5) is amended by striking out "ending June 30," each place it occurs. 42 USC 300c-11.

(2) Parts C and D are redesignated as parts B and C, respectively. 42 USC 300c-11, 300c-21.

(3) The heading of such title is amended to read as follows:

"TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME."

Effective date. 42 USC 300b note.

(c) The amendments made by subsections (a) and (b) shall take effect July 1, 1976.

## TITLE V—FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

SEC. 501 (a) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 410 (21 U.S.C. 349) the following new section:

"VITAMINS AND MINERALS

21 USC 350.
21 USC 321, 341, 343.

"SEC. 411. (a)(1) Except as provided in paragraph (2)—

"(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

"(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

"(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of any synthetic or natural—

"(i) vitamin,

"(ii) mineral, or

"(iii) other ingredient of food,

within a food to which this section applies.

"(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term 'children' means individuals who are under the age of twelve years.

"Children."

Food labeling.

"(b)(1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403(i)(2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

"(2)(A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 403. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

"(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

"(i) vitamins,

"(ii) minerals, or

"(iii) represented as a source of vitamins or minerals.

"Food to which this section applies."

"(c)(1) For purposes of this section, the term 'food to which this section applies' means a food for humans which is a food for special dietary use—

"(A) which is or contains any natural or synthetic vitamin or mineral, and

"(B) which—

"(i) is intended for ingestion in tablet, capsule, or liquid form, or

"(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

"(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

"(3) For purposes of paragraph (1) and of section 403(j) insofar as that section is applicable to food to which this section applies, the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

"Special dietary use."
21 USC 343.

"(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

"(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

"(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.".

(b) The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 411 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.

21 USC 350 note.
21 USC 301.
*Ante*, p. 410.

SEC. 502. (a)(1) Section 403(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(a)) is amended (A) by inserting "(1)" after "If", and (B) by inserting before the period at the end a comma and the following: "or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2)".

(2)(A) Section 201(n) of such Act is amended by inserting "or advertising" after "labeling" each time it occurs.

21 USC 321.

(B) Section 303 of such Act is amended by adding at the end the following new subsection:

21 USC 333.

"(d) No person shall be subject to the penalties of subsection (a) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising, and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead.".

Misbranded food, penalties, exemption.
21 USC 331.

(C) Section 304(a) of such Act (21 U.S.C. 334(a)) is amended by adding after paragraph (2) the following new paragraph:

"(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

Libel for condemnation.

"(i) is misbranded under section 403(a)(2) because of its advertising, and

*Supra.*

"(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

"(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

"(i) (I) the food's advertising which resulted in the food being misbranded under section 403(a)(2) was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

*Ante*, p. 411.

"(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

"(III) all or part of the cost of such advertising was paid by such owner or operator; and

"(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.".

(b) Chapter VII of such Act is amended by adding after section 706 (21 U.S.C. 376) the following new section:

"ADVERTISING OF CERTAIN FOODS

21 USC 378.
21 USC 331.

"SEC. 707. (a)(1) Except as provided in subsection (c), before the Secretary may initiate any action under chapter III—

"(A) with respect to any food which the Secretary determines is misbranded under section 403(a)(2) because of its advertising, or

*Ante*, p. 411.

Notice to FTC.

"(B) with respect to a food's advertising which the Secretary determines causes the food to be so misbranded,

the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

"(2) The notice required by paragraph (1) shall—

"(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary's determination that such advertising has caused such food to be misbranded, and

"(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

"(b)(1) If the Secretary notifies the Federal Trade Commission under subsection (a) of action proposed to be taken under chapter III with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

15 USC 58.

"(A) it has initiated under the Federal Trade Commission Act an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

15 USC 45, 53, 57b.

"(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 with respect to such advertising,

"(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act respecting such advertising, or

15 USC 56.

"(D) pursuant to section 16(b) of such Act it has made a certification to the Attorney General respecting such advertising,

the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice to the Federal Trade Commission.

"(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a)—

"(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary's notice,

"(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

"(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a). The Commission shall promptly notify the Secretary of the commencement by the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

"(c) The requirements of subsections (a) and (b) do not apply with respect to action under chapter III with respect to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health. 21 USC 331.

"(d) For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under chapter III because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act with respect to such advertising." 15 USC 58.

(c) The amendments made by subsection (a) shall take effect 180 days after the date of the enactment of this Act. Effective date. 21 USC 334 note.

## TITLE VI—ARTHRITIS ACT AMENDMENTS

SEC. 601. This title may be cited as the "National Arthritis Act Technical Amendments of 1976". National Arthritis Act Technical Amendments of 1976.

SEC. 602. (a) Section 2 of the National Arthritis Act of 1974 (Public Law 93-640) (hereinafter in this section referred to as the "Act") is amended by— 42 USC 289c-1 note.

(1) inserting "(a)" after "SEC. 2."; 42 USC 289c-1 note.

(2) inserting a comma and "including $2,500,000,000 in medical expenses," after "$9,200,000,000" in paragraph (3); and

(3) inserting a new subsection (b) at the end thereof as follows:

"(b) It is therefore the purpose of this Act to provide for—

"(1) the formulation of a long-range plan—

"(A) to expand and coordinate the national research, treatment, and control effort against arthritis;

"(B) to advance educational activities for patients, professional and allied health personnel, and the public which will alert the citizens of the United States to the early indications of arthritis; and

"(C) to emphasize the significance of early detection and proper control of these diseases and of the complications which may evolve from them;

"(2) the establishment and support of programs to develop new and improved methods of arthritis screening, detection, prevention, and referral;

"(3) the establishment of a central arthritis screening and detection data bank; and

"(4) the development, modernization, and operation of centers for arthritis screening, detection, diagnosis, prevention, control, treatment, education, rehabilitation, and research and training programs.".

42 USC 289c-1 note.

(b) Section 3 of the Act is amended by striking out "chief medical officer" and inserting in lieu thereof "Chief Medical Director" in subsection (b)(4).

(c) The section heading for section 4 of the Act is amended by striking out "DEMONSTRATION" after "COMMITTEE,".

42 USC 289a.

SEC. 603. (a)(1) Section 431(c) of the Public Health Service Act is amended by inserting "(hereinafter in this part collectively referred to as 'arthritis')" after "musculoskeletal diseases".

42 USC 289c-1

(2) The fourth sentence of section 434(b) of such Act is amended by striking out "and related musculoskeletal diseases".

(3) Section 434(e) of such Act is amended by striking out "and related musculoskeletal diseases (hereinafter in this part collectively referred to as 'arthritis')".

42 USC 289c-5.

(b) Section 438 of such Act is amended by—

(1) inserting "the" before "health" the first time it appears in the first sentence of subsection (a); and

(2) inserting "established" after "bank" in the second sentence of subsection (a).

42 USC 289c-6.

(c) Section 439 of such Act is amended by—

(1) inserting "new and existing" before "centers" in the first sentence of subsection (a);

(2) striking out "$13,000,000" and inserting in lieu thereof "$8,000,000", and striking out "$15,000,000" and inserting in lieu thereof "$20,000,000" in subsection (h); and

(3) redesignating subsections (e), (f), (g), and (h) as subsections (d), (e), (f), and (g), respectively.

## TITLE VII—DIABETES PLAN

42 USC 289c-2 note.

SEC. 701. Section 3(i)(2) of the National Diabetes Mellitus Research and Education Act (42 U.S.C. 289c-2) is amended to read as follows:

"(2) The Commission shall cease to exist after September 30, 1976.".

## TITLE VIII—HEALTH SERVICES

### AMBULATORY SURGICAL SERVICES

42 USC 247d.

SEC. 801. (a) Section 319(a)(7) is amended by—

(1) inserting after subparagraph (K) the following new subparagraph:

"(L) ambulatory surgical services;" and

(2) redesignating subparagraphs (L) and (M) as subparagraphs (M) and (N), respectively.

(b) Section 330(b)(2) is amended by— 42 USC 254c.

(1) inserting after subparagraph (K) the following new subparagraph:

"(L) ambulatory surgical services;" and

(2) redesignating subparagraphs (L) and (M) as subparagraphs (M) and (N), respectively.

## TITLE IX—INDIAN HEALTH SERVICE

SEC. 901. Section 225 is amended by adding at the end thereof the following new subsection— 42 USC 234.

"(j) Notwithstanding any other provision of law, the Secretary may, where he deems advisable, allow the Indian Health Service to utilize nonprofit recruitment agencies to assist in obtaining personnel for the Public Health Service.".

## TITLE X—APPOINTMENT OF ADVISORY COMMITTEES

SEC. 1001. All appointments to advisory committees established to assist in implementing the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, shall be made without regard to political affiliation. 42 USC 217a-1. 42 USC 201 note. 42 USC 2661 note. 42 USC 4551 note.

## TITLE XI—MISCELLANEOUS PROVISIONS

SEC. 1101. Section 212 of the Public Health Service Act is amended by adding after subsection (d) the following new subsection: 42 USC 213.

"(e) Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Soldiers' and Sailors' Civil Relief Act of 1940 (50 App. U.S.C. 501 et seq.).".

SEC. 1102. (a) The second paragraph (4) of subsection (c) of section 472 of the Public Health Service Act is redesignated as paragraph (5). 42 USC 289l-1.

(b) Section 507 of the Public Health Service Act is amended by striking out "hospitals of the Service, of the Veterans' Administration, or of the Bureau of Prisons of the Department of Justice, and to Saint Elizabeths Hospital, except that grants to such" and insert in lieu thereof "Federal institutions, except that grants to". 42 USC 225a.

SEC. 1103. Title IV of the Public Health Service Act is amended by adding after section 475 the following new section:

"VISITING SCIENTIST AWARDS

"SEC. 476. (a) The Secretary may make awards (referred to as 'Visiting Scientist Awards') to outstanding scientists who agree to serve as visiting scientists at institutions of post-secondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate. 42 USC 289l-5.

"(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe."

Eligibility requirements.

42 USC 295g-23.

SEC. 1104. Section 786 of the Public Health Service Act is amended by inserting before the period at the end of the first sentence "and $3,500,000 for the fiscal year ending June 30, 1975 and $2,000,000 for the fiscal year ending June 30, 1976".

42 USC 294b.

SEC. 1105. (a) Section 742(a) of the Public Health Service Act is amended by striking out "and" after "1974," and by inserting after "1975" the following: ", and $60,000,000 for the fiscal year ending June 30, 1976".

42 USC 294.

(b) Section 740(b)(4) of such Act is amended by striking out "1975" and inserting in lieu thereof "1976".

42 USC 300*l*.

SEC. 1106. Section 1511(b)(5) of the Public Health Service Act is amended by striking out "1535" and inserting in lieu thereof "1536".

42 USC 300p-3.

(b) Section 1613 of such Act is amended by striking out "1510" and inserting in lieu thereof "1610".

Repeal.

(c) The last sentence of section 1631 of such Act is repealed.

42 USC 300s-1.

SEC. 1107. (a) Section 132(a)(1)(A) of the Developmental Disabilities Services and Facilities Construction Act (42 U.S.C. 6062) (hereinafter in this section referred to as the "Act") is amended by striking out "134" and inserting in lieu thereof "133".

42 USC 6064.

(b) Section 134(b)(1) of the Act is amended by striking out "134" and inserting in lieu thereof "133".

(c) Section 134(b)(1) of the Act is amended by striking out "136" and inserting in lieu thereof "135".

42 USC 6001 note.

(d) Section 301(a) of the Developmentally Disabled Assistance and Bill of Rights Act is amended by striking out "101(7)" and inserting in lieu thereof "102(7)".

Approved April 22, 1976.

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LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 94-498 (Comm. on Interstate and Foreign Commerce) and No. 94-1005 (Comm. of Conference).

SENATE REPORTS: No. 94-509 accompanying S. 988 (Comm. on Labor and Public Welfare) and No. 94-743 (Comm. of Conference).

CONGRESSIONAL RECORD:

Vol. 121 (1975): Oct. 20, considered and passed House.

Dec. 11, considered and passed Senate, amended, in lieu of S. 988.

Vol. 122 (1976): Apr. 12, House and Senate agreed to conference report.