103D CONGRESS
1ST SESSION

S. 1

AMENDMENT

In the House of Representatives, U. S.,

March 10, 1993.

Resolved, That the bill from the Senate (S. 1) entitled ''An Act to amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes'', do pass with the following

AMENDMENT:

Strike out all after the enacting clause, and insert:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''National Institutes of Health Revitalization Act of 1993''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—GENERAL PROVISIONS REGARDING TITLE IV OF PUBLIC HEALTH SERVICE ACT

Subtitle A—Research Freedom

PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL RESEARCH

Sec. 101. Establishment of certain provisions regarding research conducted or supported by National Institutes of Health.

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

Sec. 111. Establishment of authorities.
Sec. 112. Purchase of human fetal tissue; solicitation or acceptance of tissue as directed donation for use in transplantation.
Sec. 113. Nullification of moratorium.
Sec. 114. Report by General Accounting Office on adequacy of requirements.

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

Sec. 131. Requirement of inclusion in research.
Sec. 132. Peer review.
Sec. 133. Applicability to current projects.

PART II—OFFICE OF RESEARCH ON WOMEN'S HEALTH

Sec. 141. Establishment.

PART III—OFFICE OF RESEARCH ON MINORITY HEALTH

Sec. 151. Establishment.

Subtitle C—Research Integrity

Sec. 161. Establishment of Office of Research Integrity.
Sec. 162. Commission on Research Integrity.
Sec. 163. Protection of whistleblowers.
Sec. 164. Requirement of regulations regarding protection against financial conflicts of interest in certain projects of research.
Sec. 165. Effective dates.

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

Sec. 201. Health promotion research dissemination.
Sec. 202. Programs for increased support regarding certain States and researchers.
Sec. 203. Establishment of Office of Behavioral Research.
Sec. 204. Children's vaccine initiative.
Sec. 205. Plan for use of animals in research.
Sec. 206. Increased participation of women and disadvantaged individuals in fields of biomedical and behavioral research.
Sec. 207. Requirements regarding surveys of sexual behavior.
Sec. 208. Discretionary fund of Director of National Institutes of Health.
Sec. 209. Establishment of Office of Alternative Medicine.
Sec. 210. Miscellaneous provisions.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Sec. 301. Appointment and authority of Directors of national research institutes.
Sec. 302. Program of research on osteoporosis, Paget's disease, and related disorders.
Sec. 303. Establishment of interagency program for trauma research.

TITLE IV—NATIONAL CANCER INSTITUTE

Sec. 401. Expansion and intensification of activities regarding breast cancer.
Sec. 402. Expansion and intensification of activities regarding prostate cancer.
Sec. 403. Authorization of appropriations.
Sec. 404. Study of environmental and other risks contributing to incidence of breast cancer.

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Sec. 501. Education and training.

Sec. 502. Centers for the study of pediatric cardiovascular diseases.
Sec. 503. National Center on Sleep Disorders.
Sec. 504. Authorization of appropriations.

TITLE VI—NATIONAL INSTITUTE ON DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Sec. 601. Provisions regarding nutritional disorders.

TITLE VII—NATIONAL INSTITUTE ON ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Sec. 701. Juvenile arthritis.

TITLE VIII—NATIONAL INSTITUTE ON AGING

Sec. 801. Alzheimer's disease registry.
Sec. 802. Aging processes regarding women.
Sec. 803. Authorization of appropriations.
Sec. 804. Conforming amendment.

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Sec. 901. Tropical diseases.
Sec. 902. Chronic fatigue syndrome.

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Subtitle A—Research Centers With Respect to Contraception and Research Centers With Respect to Infertility

Sec. 1001. Grants and contracts for research centers.
Sec. 1002. Loan repayment program for research with respect to contraception and infertility.

Subtitle B—Program Regarding Obstetrics and Gynecology

Sec. 1011. Establishment of program.

Subtitle C—Child Health Research Centers

Sec. 1021. Establishment of centers.

Subtitle D—Study Regarding Adolescent Health

Sec. 1031. Prospective longitudinal study.

TITLE XI—NATIONAL EYE INSTITUTE

Sec. 1101. Clinical research on diabetes eye care.

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Sec. 1201. Research on multiple sclerosis.

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Sec. 1301. Applied Toxicological Research and Testing Program.

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

Sec. 1401. Additional authorities.
Sec. 1402. Authorization of appropriations.

Subtitle B—Financial Assistance

Sec. 1411. Establishment of program of grants for development of education technologies.

Subtitle C—National Information Center on Health Services Research and Health Care Technology

Sec. 1421. Establishment of Center.
Sec. 1422. Conforming provisions.

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF HEALTH

Subtitle A—Division of Research Resources

Sec. 1501. Redesignation of Division as National Center for Research Resources.
Sec. 1502. Biomedical and behavioral research facilities.
Sec. 1503. Construction program for national primate research center.

Subtitle B—National Center for Nursing Research

Sec. 1511. Redesignation of National Center for Nursing Research as National Institute of Nursing Research.
Sec. 1512. Study on adequacy of number of nurses.

Subtitle C—National Center for Human Genome Research

Sec. 1521. Purpose of Center.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

Sec. 1601. Requirement regarding women and individuals from disadvantaged backgrounds.

Subtitle B—Acquired Immune Deficiency Syndrome

Sec. 1611. Loan repayment program.

Subtitle C—Loan Repayment for Research Generally

Sec. 1621. Establishment of program.

Subtitle D—Scholarship and Loan Repayment Programs Regarding Professional Skills Needed by National Institutes of Health

Sec. 1631. Establishment of programs.

Sec. 1632. Funding.

Subtitle E—Funding for Awards and Training Generally

Sec. 1641. Authorization of appropriations.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

Sec. 1701. Date certain for appointment of Board members.
Sec. 1702. Miscellaneous provisions.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

Subtitle A—Office of AIDS Research

Sec. 1801. Establishment of Office.
Sec. 1802. Establishment of emergency discretionary fund.
Sec. 1803. General provisions.

Subtitle B—Certain Programs

Sec. 1811. Revision and extension of certain programs.

TITLE XIX—STUDIES

Sec. 1901. Acquired immune deficiency syndrome.
Sec. 1902. Malnutrition in the elderly.
Sec. 1903. Research activities on chronic fatigue syndrome.
Sec. 1904. Report on medical uses of biological agents in development of defenses against biological warfare.
Sec. 1905. Personnel study of recruitment, retention and turnover.
Sec. 1906. Procurement.
Sec. 1907. Chronic pain conditions.
Sec. 1908. Back injuries.

TITLE XX—MISCELLANEOUS PROVISIONS

Sec. 2001. Designation of Senior Biomedical Research Service in honor of Silvio O. Conte; limitation on number of members.
Sec. 2002. Master plan for physical infrastructure for research.
Sec. 2003. Certain authorization of appropriations.
Sec. 2004. Buy-American provisions.
Sec. 2005. Prohibition against further funding for Project Aries.

TITLE XXI—EFFECTIVE DATES

Sec. 2101. Effective dates.

TITLE I—GENERAL PROVISIONS REGARDING TITLE IV OF PUBLIC HEALTH SERVICE ACT

Subtitle A—Research Freedom

PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL RESEARCH

SEC. 101. ESTABLISHMENT OF CERTAIN PROVISIONS REGARDING RESEARCH CONDUCTED OR SUPPORTED BY NATIONAL INSTITUTES OF HEALTH.

Part G of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 492 the following new section:

''CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH

''SEC. 492A. (a) REVIEW AS PRECONDITION TO RESEARCH.—

''(1) PROTECTION OF HUMAN RESEARCH SUBJECTS.—

''(A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 491(a) by an Institutional Review Board unless the application has undergone re-

view in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

''(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

''(2) PEER REVIEW.—In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to technical and scientific peer review under section 492(a) unless the application has undergone peer review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review.

''(b) ETHICAL REVIEW OF RESEARCH.—

''(1) PROCEDURES REGARDING WITHHOLDING OF FUNDS.—If research has been recommended for approval for purposes of subsection (a), the Secretary

may not withhold funding for the research on ethical grounds unless—

''(A) the Secretary convenes an advisory board in accordance with paragraph (4) to study the ethical implications of the research; and

''(B)(i) the majority of the advisory board recommends that, on ethical grounds, the Secretary withhold funds for the research; or

(ii) the majority of such board recommends that the Secretary not withhold funds for the research on ethical grounds, but the Secretary finds, on the basis of the report submitted under paragraph (4)(B)(ii), that the recommendation is arbitrary and capricious.

''(2) APPLICABILITY.—The limitation established in paragraph (1) regarding the authority to withhold funds on ethical grounds shall apply without regard to whether the withholding of funds on such grounds is characterized as a disapproval, a moratorium, a prohibition, or other description.

''(3) PRELIMINARY MATTERS REGARDING USE OF PROCEDURES.—

''(A) If the Secretary makes a determination that an advisory board should be convened for purposes of paragraph (1), the Secretary

shall, through a statement published in the Federal Register, announce the intention of the Secretary to convene such a board.

''(B) A statement issued under subparagraph (A) shall include a request that interested individuals submit to the Secretary recommendations specifying the particular individuals who should be appointed to the advisory board involved. The Secretary shall consider such recommendations in making appointments to the board.

''(C) The Secretary may not make appointments to an advisory board under paragraph (1) until the expiration of the 30-day period beginning on the date on which the statement required in subparagraph (A) is made with respect to the board.

''(4) ETHICS ADVISORY BOARDS.—

''(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (hereafter in this paragraph referred to as an 'ethics board').

''(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of bio-

medical or behavioral research with respect to which the board has been convened.

''(ii) Not later than 180 days after the date on which the statement required in paragraph (3)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

''(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

''(i) no fewer than 1 shall be an attorney;

''(ii) no fewer than 1 shall be an ethicist;

''(iii) no fewer than 1 shall be a practicing physician;

''(iv) no fewer than 1 shall be a theologian; and

''(v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

''(D) The term of service as a member of an ethics board shall be for the life of the board. If such a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(E) A member of an ethics board shall be subject to removal from the board by the Secretary for neglect of duty or malfeasance or for other good cause shown.

''(F) The Secretary shall designate an individual from among the members of an ethics board to serve as the chair of the board.

''(G) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall conduct inquiries and hold public hearings.

''(H) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall have access to all relevant information possessed by the Department of Health and Human Services, or available to the Secretary from other agencies.

''(I) Members of an ethics board shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

''(J) The Secretary, acting through the Director of the National Institutes of Health, shall provide to each ethics board reasonable staff and assistance to carry out the duties of the board.

''(K) An ethics board shall terminate 30 days after the date on which the report required in subparagraph (B)(ii) is submitted to the Secretary and the congressional committees specified in such subparagraph.''.

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

SEC. 111. ESTABLISHMENT OF AUTHORITIES.

Part G of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 498 the following new section:

''RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

''SEC. 498A. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

''(2) SOURCE OF TISSUE.—Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

''(b) INFORMED CONSENT OF DONOR.—

''(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a state-

ment, made in writing and signed by the woman, declaring that—

''(A) the woman donates the fetal tissue for use in research described in subsection (a);

''(B) the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and

''(C) the woman has not been informed of the identity of any such individuals.

''(2) ADDITIONAL STATEMENT.—In research carried out under subsection (a), human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

''(A) in the case of tissue obtained pursuant to an induced abortion—

''(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research;

''(ii) no alteration of the timing, method, or procedures used to terminate the

pregnancy was made solely for the purposes of obtaining the tissue; and

''(iii) the abortion was performed in accordance with applicable State law;

''(B) the tissue has been donated by the woman in accordance with paragraph (1); and

''(C) full disclosure has been provided to the woman with regard to—

''(i) such physician's interest, if any, in the research to be conducted with the tissue; and

''(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman's medical care.

''(c) INFORMED CONSENT OF RESEARCHER AND DONEE.—In research carried out under subsection (a), human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

''(1) is aware that—

''(A) the tissue is human fetal tissue;

''(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

''(C) the tissue was donated for research purposes;

''(2) has provided such information to other individuals with responsibilities regarding the research;

''(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

''(4) has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research.

''(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

''(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the head of the agency or other entity conducting the research involved certifies to the Secretary that the statements required under subsections (b) (2) and (c) will be available for audit by the Secretary.

''(2) CONFIDENTIALITY OF AUDIT.—Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect

the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

''(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

''(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

''(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

''(e) APPLICABILITY OF STATE AND LOCAL LAW.—

''(1) RESEARCH CONDUCTED BY RECIPIENTS OF ASSISTANCE.—The Secretary may not provide support for research under subsection (a) unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

''(2) RESEARCH CONDUCTED BY SECRETARY.—The Secretary may conduct research under subsection (a) only in accordance with applicable State and local law.

''(f) REPORT.—The Secretary shall annually 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 activities carried out under this section during the preceding fiscal year, including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.

''(g) DEFINITION.—For purposes of this section, the term 'human fetal tissue' means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.''.

SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION.

Part G of title IV of the Public Health Service Act, as amended by section 111 of this Act, is amended by inserting after section 498A the following new section:

''PROHIBITIONS REGARDING HUMAN FETAL TISSUE

''SEC. 498B. (a) PURCHASE OF TISSUE.—It shall be unlawful for any person to knowingly acquire, receive, or

otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

''(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION.—It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and—

''(1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;

''(2) the donated tissue will be transplanted into a relative of the donating individual; or

''(3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

''(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

''(1) IN GENERAL.—Any person who violates subsection (a) or (b) shall be fined in accordance with title 18, United States Code, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

''(2) PENALTIES APPLICABLE TO PERSONS RECEIVING CONSIDERATION.—With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

''(d) DEFINITIONS.—For purposes of this section:

''(1) The term 'human fetal tissue' has the meaning given such term in section 498A(f).

''(2) The term 'interstate commerce' has the meaning given such term in section 201(b) of the Federal Food, Drug, and Cosmetic Act.

''(3) The term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.''.

SEC. 113. NULLIFICATION OF MORATORIUM.

(a) IN GENERAL.—Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with section 498A of the Public Health Service Act (as added

by section 111 of this Act), without regard to any such policy that may have been in effect prior to the date of the enactment of this Act.

(b) PROHIBITION AGAINST WITHHOLDING OF FUNDS IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

(1) IN GENERAL.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if—

(A) the research has been approved for purposes of section 492A(a) of the Public Health Service Act (as added by section 101 of this Act);

(B) the research will be carried out in accordance with section 498A of such Act (as added by section 111 of this Act); and

(C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act (as added by section 112 of this Act).

(2) STANDING APPROVAL REGARDING ETHICAL STATUS.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the issuance in December 1988 of the

Report of the Human Fetal Tissue Transplantation Research Panel shall be deemed to be a report—

(A) issued by an ethics advisory board pursuant to section 492A(b)(4)(B)(ii) of the Public Health Service Act (as added by section 101 of this Act); and

(B) finding, on a basis that is neither arbitrary nor capricious, that there are no ethical grounds for withholding funds for the research.

(c) AUTHORITY FOR WITHHOLDING FUNDS FROM RESEARCH.—In the case of any research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may withhold funds for the research if any of the conditions specified in any of subparagraphs (A) through (C) of subsection (b)(1) are not met with respect to the research.

(d) DEFINITION.—For purposes of this section, the term ''human fetal tissue'' has the meaning given such term in section 498A(f) of the Public Health Service Act (as added by section 111 of this Act).

SEC. 114. REPORT BY GENERAL ACCOUNTING OFFICE ON ADEQUACY OF REQUIREMENTS.

(a) IN GENERAL.—With respect to research on the transplantation of human fetal tissue for therapeutic pur-

poses, the Comptroller General of the United States shall conduct an audit for the purpose of determining—

(1) whether and to what extent such research conducted or supported by the Secretary of Health and Human Services has been conducted in accordance with section 498A of the Public Health Service Act (as added by section 111 of this Act); and

(2) whether and to what extent there have been violations of section 498B of such Act (as added by section 112 of this Act).

(b) REPORT.—Not later than May 19, 1995, the Comptroller General of the United States shall complete the audit 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 made pursuant to the audit.

PART III—MISCELLANEOUS REPEALS

SEC. 121. REPEALS.

(a) CERTAIN BIOMEDICAL ETHICS BOARD.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by striking part J.

(b) OTHER REPEALS.—Part G of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended—

(1) in section 498, by striking subsection (c); and

(2) by striking section 499; and

(3) by redesignating section 499A as section 499.

(c) NULLIFICATION OF CERTAIN PROVISIONS.—The provisions of Executive Order 12806 (57 Fed. Reg. 21589 (May 21, 1992)) shall not have any legal effect. The provisions of section 204(d) of part 46 of title 45 of the Code of Federal Regulations (45 CFR 46.204(d)) shall not have any legal effect.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.

Part G of title IV of the Public Health Service Act, as amended by section 101 of this Act, is amended by inserting after section 492A the following new section:

''INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

''SEC. 492B. (a) REQUIREMENT OF INCLUSION.—

''(1) IN GENERAL.—In conducting or supporting clinical research for purposes of this title, the Director of NIH shall, subject to subsection (b), ensure that—

''(A) women are included as subjects in each project of such research; and

''(B) members of minority groups are included as subjects in such research.

''(2) OUTREACH REGARDING PARTICIPATION AS SUBJECTS.—The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

''(b) INAPPLICABILITY OF REQUIREMENT.—The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

''(1) is inappropriate with respect to the health of the subjects;

''(2) is inappropriate with respect to the purpose of the research; or

''(3) is inappropriate under such other circumstances as the Director of NIH may designate.

''(c) DESIGN OF CLINICAL TRIALS.—In the case of any clinical trial in which women or members of minority groups will under subsection (a) be included as subjects, the

Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

''(d) GUIDELINES.—

''(1) IN GENERAL.—Subject to paragraph (2), the Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding the requirements of this section. The guidelines shall include guidelines regarding—

''(A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate for purposes of subsection (b);

''(B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c); and

''(C) the operation of outreach programs under subsection (a).

''(2) CERTAIN PROVISIONS.—With respect to the circumstances under which the inclusion of women or members of minority groups (as the case may be) as

subjects in a project of clinical research is inappropriate for purposes of subsection (b), the following applies to guidelines under paragraph (1):

''(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.

''(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or will be obtained through other means that provide data of comparable quality.

''(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

''(i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

''(ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required.

''(e) DATE CERTAIN FOR GUIDELINES; APPLICABILITY.—

''(1) DATE CERTAIN.—The guidelines required in subsection (d) shall be established and published in the Federal Register not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

''(2) APPLICABILITY.—For fiscal year 1995 and subsequent fiscal years, the Director of NIH may not approve any proposal of clinical research to be conducted or supported by any agency of the National Institutes of Health unless the proposal specifies the manner in which the research will comply with this section.

''(f) REPORTS BY ADVISORY COUNCILS.—The advisory council of each national research institute shall annually submit to the Director of NIH and the Director of the insti-

tute involved a report describing the manner in which the agency has complied with this section.

''(g) DEFINITIONS.—For purposes of this section:

''(1) The term 'project of clinical research' includes a clinical trial.

''(2) The term 'minority group' includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established under subsection (d), define the terms 'minority group' and 'subpopulation' for purposes of the preceding sentence.''.

SEC. 132. PEER REVIEW.

Section 492 of the Public Health Service Act (42 U.S.C. 289a) is amended by adding at the end the following new subsection:

''(c)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 492B.

''(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 492B, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and

members of minority groups as subjects in clinical research.''.

SEC. 133. APPLICABILITY TO CURRENT PROJECTS.

Section 492B of the Public Health Service Act, as added by section 131 of this Act, shall not apply with respect to projects of clinical research for which initial funding was provided prior to the date of the enactment of this Act. With respect to the inclusion of women and minorities as subjects in clinical research conducted or supported by the National Institutes of Health, any policies of the Secretary of Health and Human Services regarding such inclusion that are in effect on the day before the date of the enactment of this Act shall continue to apply to the projects referred to in the preceding sentence.

PART II—OFFICE OF RESEARCH ON WOMEN'S HEALTH

SEC. 141. ESTABLISHMENT.

(a) IN GENERAL.—Title IV of the Public Health Service Act, as amended by the preceding provisions of this title, is amended—

(1) by redesignating section 486 as section 485A;

(2) by redesignating parts F through H as parts G through I, respectively; and

(3) by inserting after part E the following new part:

''PART F—RESEARCH ON WOMEN'S HEALTH

"SEC. 486. OFFICE OF RESEARCH ON WOMEN'S HEALTH.

''(a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women's Health (in this part referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

''(b) PURPOSE.—The Director of the Office shall—

''(1) identify projects of research on women's health that should be conducted or supported by the national research institutes;

''(2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;

''(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;

''(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);

''(5) encourage the conduct of such research by entities receiving funds from the national research institutes;

''(6) recommend an agenda for conducting and supporting such research;

''(7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;

''(8) assist in the administration of section 492B with respect to the inclusion of women as subjects in clinical research; and

''(9) prepare the report required in section 486B.

''(c) COORDINATING COMMITTEE.—

''(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (hereafter in this subsection referred to as the 'Coordinating Committee').

''(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the designees of the Directors).

''(3) The Director of the Office shall serve as the chair of the Coordinating Committee.

''(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

''(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;

''(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;

''(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;

''(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and

''(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.

''(d) ADVISORY COMMITTEE.—

''(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Research on Women's Health (hereafter in this subsection referred to as the 'Advisory Committee').

''(2) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of the Office shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on research on women's health. A majority of the members of the Advisory Committee shall be women.

''(3) The Director of the Office shall serve as the chair of the Advisory Committee.

''(4) The Advisory Committee shall—

''(A) advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to—

''(i) research on women's health;

''(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;

''(iii) research on gender differences in disease etiology, course, and treatment;

''(iv) research on obstetrical and gynecological health conditions, diseases, and treatments; and

''(v) research on women's health conditions which require a multidisciplinary approach;

''(B) report to the Director of the Office on such research;

''(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and

''(D) assist in monitoring compliance with section 492B regarding the inclusion of women in clinical research.

''(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

''(i) compliance with section 492B;

''(ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and

''(iii) the level of funding needed for such research.

''(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 403.

''(e) REPRESENTATION OF WOMEN AMONG RESEARCHERS.—The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.

''(f) DEFINITIONS.—For purposes of this part:

''(1) The term 'women's health conditions', with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

''(A) unique to, more serious, or more prevalent in women;

''(B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or

''(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

''(2) The term 'research on women's health' means research on women's health conditions, including research on preventing such conditions.

''SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE ON RESEARCH ON WOMEN'S HEALTH.

''(a) DATA SYSTEM.—

''(1) The Director of NIH, in consultation with the Director of the Office and the Director of the National Library of Medicine, shall establish a data system for the collection, storage, analysis, retrieval, and dissemination of information regarding research on women's health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.

''(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments that have been developed for research on women's health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site

or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results, including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.

''(b) CLEARINGHOUSE.—The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women's health.

''SEC. 486B. BIENNIAL REPORT.

''(a) IN GENERAL.—With respect to research on women's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report—

''(1) describing and evaluating the progress made during the preceding 2 fiscal years in research and treatment conducted or supported by the National Institutes of Health;

''(2) describing and analyzing the professional status of women physicians and scientists of such In-

stitutes, including the identification of problems and barriers regarding advancements;

''(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and

''(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.

''(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR OF NIH.—The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH for inclusion in the report submitted to the President and the Congress under section 403.''.

(b) REQUIREMENT OF SUFFICIENT ALLOCATION OF RESOURCES OF INSTITUTES.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (10), by striking ''and'' after the semicolon at the end;

(2) in paragraph (11), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (11) the following new paragraph:

''(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are

sufficiently allocated for projects of research on women's health that are identified under section 486(b).''.

PART III—OFFICE OF RESEARCH ON MINORITY HEALTH

SEC. 151. ESTABLISHMENT.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following section:

''OFFICE OF RESEARCH ON MINORITY HEALTH

''SEC. 404. (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Research on Minority Health (in this section referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

''(b) PURPOSE.—The Director of the Office shall—

''(1) identify projects of research on minority health that should be conducted or supported by the national research institutes;

''(2) identify multidisciplinary research relating to research on minority health that should be so conducted or supported;

''(3) promote coordination and collaboration among entities conducting research identified under paragraph (1) or (2);

''(4) encourage the conduct of such research by entities receiving funds from the national research institutes;

''(5) recommend an agenda for conducting and supporting such research;

''(6) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research; and

''(7) assist in the administration of section 492B with respect to the inclusion of members of minority groups as subjects in clinical research.''.

Subtitle C—Research Integrity

SEC. 161. ESTABLISHMENT OF OFFICE OF RESEARCH INTEGRITY.

(a) IN GENERAL.—Section 493 of the Public Health Service Act (42 U.S.C. 289b) is amended to read as follows:

''OFFICE OF RESEARCH INTEGRITY

''SEC. 493. (a) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 90 days after the date of enactment of this section, the Secretary shall establish an office to be known as the Office of Research Integrity (hereafter referred to in this section as the 'Office'), which shall be established as an independent entity in the Department of Health and Human Services.

''(2) DIRECTOR.—The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

''(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS CONDITION OF FUNDING FOR RESEARCH.—The Secretary shall by regulation require that each entity that applies for a grant, contract, or cooperative agreement under this Act for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

''(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

''(2) will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this Act that appears substantial.

''(c) PROCESS FOR RESPONSE OF DIRECTOR.—The Secretary shall establish by regulation a process to be followed by the Director for the prompt and appropriate—

''(1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this Act;

''(2) receipt of reports by the Director of such information from recipients of funds under this Act;

''(3) conduct of investigations, when appropriate; and

''(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

''(d) MONITORING BY DIRECTOR.—The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

''(e) EFFECT ON PRESENT INVESTIGATIONS.—Nothing in this section shall affect investigations which have been or will be commenced prior to the promulgation of final regulations under this section.''.

(b) ESTABLISHMENT OF DEFINITION OF RESEARCH MISCONDUCT.—Not later than 90 days after the date on which the report required under section 162(d) is submitted to the Secretary of Health and Human Services, such Sec-

retary shall by regulation establish a definition for the term ''research misconduct'' for purposes of section 493 of the Public Health Service Act, as amended by subsection (a) of this section.

SEC. 162. COMMISSION ON RESEARCH INTEGRITY.

(a) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish a commission to be known as the Commission on Research Integrity (in this section referred to as the ''Commission'').

(b) DUTIES.—The Commission shall develop recommendations for the Secretary of Health and Human Services on the administration of section 493 of the Public Health Service Act (as amended and added by section 161 of this Act).

(c) COMPOSITION.—The Commission shall be composed of 12 members to be appointed by the Secretary of Health and Human Services. Not more than 3 members of the Commission may be officers or employees of the United States. Of the members of the Commission—

(1) three shall be scientists with substantial accomplishments in biomedical or behavioral research;

(2) three shall be individuals with experience in investigating allegations of misconduct with respect to research research;

(3) three shall be representatives of institutions of higher education at which biomedical or behavioral research is conducted; and

(4) three shall be individuals who are not described in paragraphs (1), (2), or (3), at least one of whom shall be an attorney and at least one of whom shall be an ethicist.

(d) COMPENSATION.—Members of the Commission may not receive compensation for service on the Commission. Members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Commission.

(e) REPORT.—Not later than 120 days after the date on which the Commission is established under subsection (a), the Commission shall prepare and submit to the Secretary of Health and Human Services, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report containing the recommendations developed under subsection (b).

SEC. 163. PROTECTION OF WHISTLEBLOWERS.

Section 493 of the Public Health Service Act, as amended by section 161 of this Act, is amended by adding at the end the following new subsection:

''(f) PROTECTION OF WHISTLEBLOWERS.—

''(1) IN GENERAL.—In the case of any entity required to establish administrative processes under subsection (b), the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

''(A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of research misconduct; or

''(B) cooperated with an investigation of such an allegation.

''(2) MONITORING BY SECRETARY.—The Secretary shall establish by regulation procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

''(3) NONCOMPLIANCE.—The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in re-

taliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.

''(4) FINAL RULE FOR REGULATIONS.—The Secretary shall issue a final rule for the regulations required in paragraph (1) not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

''(5) REQUIRED AGREEMENTS.—For any fiscal year beginning after the date on which the regulations required in paragraph (1) are issued, the Secretary may not provide a grant, cooperative agreement, or contract under this Act for biomedical or behavioral research unless the entity seeking such financial assistance agrees that the entity—

''(A) will maintain the procedures described in the regulations; and

''(B) will otherwise be subject to the regulations.''.

SEC. 164. REQUIREMENT OF REGULATIONS REGARDING PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST IN CERTAIN PROJECTS OF RESEARCH.

Part H of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 493 the following new section:

''PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST IN CERTAIN PROJECTS OF RESEARCH

''SEC. 493A. (a) ISSUANCE OF REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall define by regulation, the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this Act. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in paragraph (2), the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

''(2) RELEVANT PROJECTS.—A project of research referred to in paragraph (1) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

''(3) IDENTIFYING AND REPORTING TO THE DIRECTOR.—The Secretary shall ensure that the standards established under paragraph (1) specify that as a condition of receiving assistance from the Secretary for the project involved, an entity described in such subsection is required—

''(A) to have in effect at the time the entity applies for the assistance and throughout the period during which the assistance is received, a process for identifying such financial interests as defined in paragraph (1) that exist regarding the project; and

''(B) to report to the Director such financial interest as defined in paragraph (1) identified by the entity and how any such financial interest identified by the entity will be managed or eliminated such that the project in question will be protected from bias that may stem from such financial interest.

''(4) MONITORING OF PROCESS.—The Secretary shall monitor the establishment and conduct of the process established by an entity pursuant to paragraph (1).

''(5) RESPONSE.—In any case in which the Secretary determines that an entity has failed to comply with paragraph (3) regarding a project of research described in paragraph (1), the Secretary—

''(A) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest as defined in paragraph (1) in each public presentation of the results of such project; and

''(B) may take such other actions as the Secretary determines to be appropriate.

''(6) DEFINITION.—As used in this section:

''(A) The term 'financial interest' includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

''(B) The term 'assistance', with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

''(b) FINAL RULE FOR REGULATIONS.—The Secretary shall issue a final rule for the regulations required in subsection (a) not later than 180 days after the date of the

enactment of the National Institutes of Health Revitalization Act of 1993.''.

SEC. 165. EFFECTIVE DATES.

(a) IN GENERAL.—The amendments made by this subtitle shall become effective on the date that occurs 180 days after the date on which the final rule required under section 493(f)(4) of the Public Health Service Act, as amended by sections 161 and 163, is published in the Federal Register.

(b) AGREEMENTS AS A CONDITION OF FUNDING.—The requirements of subsection (f)(5) of section 493 of the Public Health Service Act, as amended by sections 161 and 163, with respect to agreements as a condition of funding shall not be effective in the case of projects of research for which initial funding under the Public Health Service Act was provided prior to the effective date described in subsection (a).

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINATION.

Section 402(f) of the Public Health Service Act (42 U.S.C. 282(f)) is amended by striking ''other public and private entities.'' and all that follows through the end and inserting ''other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

''(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs;

''(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities; and

''(3) annually prepare and submit to the Director of NIH a report concerning the prevention and dissemination activities undertaken by the Associate Director, including—

''(A) a summary of the Associate Director's review of existing dissemination policies and techniques together with a detailed statement concerning any modification or restructuring, or recommendations for modification or restructuring, of such policies and techniques; and

''(B) a detailed statement of the expenditures made for the prevention and dissemination activities reported on and the personnel used in connection with such activities.''.

SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARDING CERTAIN STATES AND RESEARCHERS.

Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by adding at the end the following new subsection:

''(g)(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Center for Research Resources, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

''(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

''(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

''(i) provide technical assistance to the entities involved, including technical assistance in the prepa-

ration of applications for obtaining funds from the national research institutes;

''(ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and

''(iii) assist the entities in implementing such plan.

''(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the principal researchers of such projects supported by the Director.''.

SEC. 203. ESTABLISHMENT OF OFFICE OF BEHAVIORAL RESEARCH.

Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by adding at the end the following new section:

''OFFICE OF BEHAVIORAL RESEARCH

''SEC. 404A. (a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral Research (in this section referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

''(b)(1) With respect to research on the relationship between human behavior and the development, treatment, and prevention of medical conditions, the Director of the Office

shall coordinate research conducted or supported by the agencies of the National Institutes of Health.

''(2) Research authorized under paragraph (1) includes research on teen pregnancy, infant mortality, violent behavior, suicide, and homelessness.

''(3) The sole responsibility of the Director of the Office shall be carrying out paragraph (1).''.

SEC. 204. CHILDREN'S VACCINE INITIATIVE.

Part A of title IV of the Public Health Service Act, as amended by section 203 of this Act, is amended by adding at the end the following new section:

''CHILDREN'S VACCINE INITIATIVE

''SEC. 404B. (a) DEVELOPMENT OF NEW VACCINES.—The Secretary, in consultation with the Director of the National Vaccine Program under title XXI and acting through the Directors of the National Institute for Allergy and Infectious Diseases, the National Institute for Child Health and Human Development, the National Institute for Aging, and other public and private programs, shall carry out activities, which shall be consistent with the global Children's Vaccine Initiative, to develop affordable new and improved vaccines to be used in the United States and in the developing world that will increase the efficacy and efficiency of the prevention of infectious diseases. In carrying out such activities, the Secretary shall, to the extent practicable, develop and make available vaccines that require fewer con-

tacts to deliver, that can be given early in life, that provide long lasting protection, that obviate refrigeration, needles and syringes, and that protect against a larger number of diseases.

''(b) REPORT.—In the report required in section 2104, the Secretary, acting through the Director of the National Vaccine Program under title XXI, shall include information with respect to activities and the progress made in implementing the provisions of this section and achieving its goals.

''(c) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other amounts authorized to be appropriated for activities of the type described in this section, there are authorized to be appropriated to carry out this section $50,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 205. PLAN FOR USE OF ANIMALS IN RESEARCH.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act, as amended by section 204 of this Act, is amended by adding at the end the following new section:

''PLAN FOR USE OF ANIMALS IN RESEARCH

''SEC. 404C. (a) The Director of NIH, after consultation with the committee established under subsection (e), shall prepare a plan—

''(1) for the National Institutes of Health to conduct or support research into—

''(A) methods of biomedical research and experimentation that do not require the use of animals;

''(B) methods of such research and experimentation that reduce the number of animals used in such research;

''(C) methods of such research and experimentation that produce less pain and distress in such animals; and

''(D) methods of such research and experimentation that involve the use of marine life (other than marine mammals);

''(2) for establishing the validity and reliability of the methods described in paragraph (1);

''(3) for encouraging the acceptance by the scientific community of such methods that have been found to be valid and reliable; and

''(4) for training scientists in the use of such methods that have been found to be valid and reliable.

''(b) Not later than October 1, 1993, the Director of NIH shall 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, the plan required in subsection (a) and shall begin implementation of the plan.

''(c) The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be included in the first biennial report under section 403 that is submitted after the revision is made.

''(d) The Director of NIH shall take such actions as may be appropriate to convey to scientists and others who use animals in biomedical or behavioral research or experimentation information respecting the methods found to be valid and reliable under subsection (a)(2).

''(e)(1) The Director of NIH shall establish within the National Institutes of Health a committee to be known as the Interagency Coordinating Committee on the Use of Animals in Research (hereafter in this subsection referred to as the 'Committee').

''(2) The Committee shall provide advice to the Director of NIH on the preparation of the plan required in subsection (a).

''(3) The Committee shall be composed of—

''(A) the Directors of each of the national research institutes and the Director of the Center for Research Resources (or the designees of such Directors); and

''(B) representatives of the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, the National Science Foundation, and such additional agencies as the Director of NIH determines to be appropriate.''.

(b) CONFORMING AMENDMENT.—Section 4 of the Health Research Extension Act of 1985 (Public Law 99–158; 99 Stat. 880) is repealed.

SEC. 206. INCREASED PARTICIPATION OF WOMEN AND DISADVANTAGED INDIVIDUALS IN FIELDS OF BIOMEDICAL AND BEHAVIORAL RESEARCH.

Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding at the end the following new subsection:

''(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, may conduct and support programs for research, research training, recruitment, and other activities to provide for an increase in the number of women and individuals from disadvantaged backgrounds in the fields of biomedical and behavioral research.''.

SEC. 207. REQUIREMENTS REGARDING SURVEYS OF SEXUAL BEHAVIOR.

Part A of title IV of the Public Health Service Act, as amended by section 205 of this Act, is amended by adding at the end the following new section:

''REQUIREMENTS REGARDING SURVEYS OF SEXUAL BEHAVIOR

''SEC. 404D. With respect to any survey of human sexual behavior proposed to be conducted or supported through the National Institutes of Health, the survey may not be carried out unless—

''(1) the proposal has undergone review in accordance with any applicable requirements of sections 491 and 492; and

''(2) the Secretary, in accordance with section 492A, makes a determination that the information expected to be obtained through the survey will assist—

''(A) in reducing the incidence of sexually transmitted diseases, the incidence of infection with the human immunodeficiency virus, or the incidence of any other infectious disease; or

''(B) in improving reproductive health or other conditions of health.''.

SEC. 208. DISCRETIONARY FUND OF DIRECTOR OF NATIONAL INSTITUTES OF HEALTH.

Section 402 of the Public Health Service Act, as amended by section 206 of this Act, is amended by adding at the end the following new subsection:

''(i)(1) There is established a fund, consisting of amounts appropriated under paragraph (3) and made available for the fund, for use by the Director of NIH to carry out the activities authorized in this Act for the National Institutes of Health. The purposes for which such fund may be expended include—

''(A) providing for research on matters that have not received significant funding relative to other matters, responding to new issues and scientific emergencies, and acting on research opportunities of high priority;

''(B) supporting research that is not exclusively within the authority of any single agency of such Institutes; and

''(C) purchasing or renting equipment and quarters for activities of such Institutes.

''(2) Not later than February 10 of each fiscal year, the Secretary shall 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 activities undertaken and expenditures

made under this section during the preceding fiscal year. The report may contain such comments of the Secretary regarding this section as the Secretary determines to be appropriate.

''(3) For the purpose of carrying out this subsection, there are authorized to be appropriated $25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 209. ESTABLISHMENT OF OFFICE OF ALTERNATIVE MEDICINE.

Part A of title IV of the Public Health Service Act, as amended by section 207 of this Act, is amended by adding at the end the following section:

''OFFICE OF ALTERNATIVE MEDICINE

''SEC. 404E. (a) There is established within the Office of the Director of NIH an office to be known as the Office of Alternative Medicine (in this section referred to as the 'Office'), which shall be headed by a director appointed by the Director of NIH.

''(b) The purpose of the Office is to facilitate the evaluation of various alternative medicine treatment modalities, including acupuncture and Oriental medicine, homeopathic medicine, and physical manipulation therapies.

''(c) In carrying out subsection (b), the Director of the Office shall—

''(1) establish an information clearinghouse to exchange information with the public about alternative medicine;

''(2) support research training—

''(A) for which fellowship support is not provided under section 487; and

''(B) that is not residency training of physicians or other health professionals; and

''(3) submit an annual report on past and future activities of the Office, each of which reports shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.''.

SEC. 210. MISCELLANEOUS PROVISIONS.

(a) TERM OF OFFICE FOR MEMBERS OF ADVISORY COUNCILS.—Section 406(c) of the Public Health Service Act (42 U.S.C. 284a(c)) is amended in the second sentence by striking ''until a successor has taken office'' and inserting the following: ''for 180 days after the date of such expiration''.

(b) LITERACY REQUIREMENTS.—Section 402(e) of the Public Health Service Act (42 U.S.C. 282(e)) is amended—

(1) in paragraph (3), by striking ''and'' at the end;

(2) in paragraph (4), by striking the period and inserting ''; and''; and

(3) by adding at the end thereof the following new paragraph:

''(5) ensure that, after January 1, 1994, at least one-half of all new or revised health education and promotion materials developed or funded by the National Institutes of Health is in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102–73).''.

(c) DAY CARE REGARDING CHILDREN OF EMPLOYEES.—Section 402 of the Public Health Service Act, as amended by section 208 of this Act, is amended by adding at the end the following new subsection:

''(j)(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

''(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

''(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.''.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS OF NATIONAL RESEARCH INSTITUTES.

(a) ESTABLISHMENT OF GENERAL AUTHORITY REGARDING DIRECT FUNDING.—

(1) IN GENERAL.—Section 405(b)(2) of the Public Health Service Act (42 U.S.C. 284(b)(2)) is amended—

(A) in subparagraph (A), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following new subparagraph:

''(C) shall receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.''.

(2) CONFORMING AMENDMENT.—Section 413(b)(9) of the Public Health Service Act (42 U.S.C. 285a–2(b)(9)) is amended—

(A) by striking ''(A)'' after ''(9)''; and

(B) by striking ''advisory council;'' and all that follows and inserting ''advisory council.''.

(b) APPOINTMENT AND DURATION OF TECHNICAL AND SCIENTIFIC PEER REVIEW GROUPS.—Section 405(c) of the Public Health Service Act (42 U.S.C. 284(c)) is amended—

(1) by amending paragraph (3) to read as follows:

''(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

''(A) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(6); and

''(B) appoint the members of peer review groups established under subparagraph (A); and''; and

(2) by adding after and below paragraph (4) the following:

''The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (3).''.

SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND RELATED BONE DISORDERS.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.), as amended by section 121(b) of Public Law 102–321 (106 Stat. 358), is amended by adding at the end the following new section:

''RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND RELATED BONE DISORDERS

''SEC. 409A. (a) ESTABLISHMENT.—The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, and the National Institute of Diabetes, Digestive and Kidney Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

''(b) COORDINATION.—The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

''(c) INFORMATION CLEARINGHOUSE.—

''(1) IN GENERAL.—In order to assist in carrying out the purpose described in subsection (a), the Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and re-

lated bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information.

''(2) ESTABLISHMENT THROUGH GRANT OR CONTRACT.—For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM FOR TRAUMA RESEARCH.

(a) IN GENERAL.—Title XII of the Public Health Service Act (42 U.S.C. 300d et seq.), as amended by title VI of Public Law 102–321 (106 Stat. 433) and section 304 of Public Law 102–408 (106 Stat. 2084), is amended by adding at the end the following part:

''PART F—INTERAGENCY PROGRAM FOR TRAUMA RESEARCH

''SEC. 1261. ESTABLISHMENT OF PROGRAM.

''(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health (hereafter in this section referred to as the 'Director'), shall establish a comprehensive program of conducting basic and clinical research on trauma (hereafter in this section referred to as the 'Program'). The Program shall include research regarding the diagnosis, treatment, rehabilitation, and general management of trauma.

''(b) PLAN FOR PROGRAM.—

''(1) IN GENERAL.—The Director, in consultation with the Trauma Research Interagency Coordinating Committee established under subsection (g), shall establish and implement a plan for carrying out the activities of the Program, including the activities described in subsection (d). All such activities shall be carried out in accordance with the plan. The plan shall be periodically reviewed, and revised as appropriate.

''(2) SUBMISSION TO CONGRESS.—Not later than June 1, 1993, the Director shall submit the plan required in paragraph (1) to the Committee on Energy and Commerce of the House of Representatives, and

to the Committee on Labor and Human Resources of the Senate, together with an estimate of the funds needed for each of the fiscal years 1994 through 1996 to implement the plan.

''(c) PARTICIPATING AGENCIES; COORDINATION AND COLLABORATION.—The Director—

''(1) shall provide for the conduct of activities under the Program by the Directors of the agencies of the National Institutes of Health involved in research with respect to trauma;

''(2) shall ensure that the activities of the Program are coordinated among such agencies; and

''(3) shall, as appropriate, provide for collaboration among such agencies in carrying out such activities.

''(d) CERTAIN ACTIVITIES OF PROGRAM.—The Program shall include—

''(1) studies with respect to all phases of trauma care, including prehospital, resuscitation, surgical intervention, critical care, infection control, wound healing, nutritional care and support, and medical rehabilitation care;

''(2) basic and clinical research regarding the response of the body to trauma and the acute treatment

and medical rehabilitation of individuals who are the victims of trauma; and

''(3) basic and clinical research regarding trauma care for pediatric and geriatric patients.

''(e) MECHANISMS OF SUPPORT.—In carrying out the Program, the Director, acting through the Directors of the agencies referred to in subsection (c)(1), may make grants to public and nonprofit entities, including designated trauma centers.

''(f) RESOURCES.—The Director shall assure the availability of appropriate resources to carry out the Program, including the plan established under subsection (b) (including the activities described in subsection (d)).

''(g) COORDINATING COMMITTEE.—

''(1) IN GENERAL.—There shall be established a Trauma Research Interagency Coordinating Committee (hereafter in this section referred to as the 'Coordinating Committee').

''(2) DUTIES.—The Coordinating Committee shall make recommendations regarding—

''(A) the activities of the Program to be carried out by each of the agencies represented on the Committee and the amount of funds needed by each of the agencies for such activities; and

''(B) effective collaboration among the agencies in carrying out the activities.

''(3) COMPOSITION.—The Coordinating Committee shall be composed of the Directors of each of the agencies that, under subsection (c), have responsibilities under the Program, and any other individuals who are practitioners in the trauma field as designated by the Director of the National Institutes of Health.

''(h) DEFINITIONS.—For purposes of this section:

''(1) The term 'designated trauma center' has the meaning given such term in section 1231(1).

''(2) The term 'Director' means the Director of the National Institutes of Health.

''(3) The term 'trauma' means any serious injury that could result in loss of life or in significant disability and that would meet pre-hospital triage criteria for transport to a designated trauma center.''.

(b) CONFORMING AMENDMENT.—Section 402 of the Public Health Service Act, as amended by section 210(c) of this Act, is amended by adding at the end the following new subsection:

''(k) The Director of NIH shall carry out the program established in part E of title XII (relating to interagency research on trauma).''.

TITLE IV—NATIONAL CANCER INSTITUTE

SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVITIES REGARDING BREAST CANCER.

Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following new section:

''BREAST AND GYNECOLOGICAL CANCERS

''SEC. 417. (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on breast cancer, ovarian cancer, and other cancers of the reproductive system of women.

''(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to breast cancer and other cancers of the reproductive system of women.

''(c) PROGRAMS FOR BREAST CANCER.—

''(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or sup-

port research to expand the understanding of the cause of, and to find a cure for, breast cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

''(A) basic research concerning the etiology and causes of breast cancer;

''(B) clinical research and related activities concerning the causes, prevention, detection and treatment of breast cancer;

''(C) control programs with respect to breast cancer in accordance with section 412, including community-based programs designed to assist women who are members of medically underserved populations, low-income populations, or minority groups;

''(D) information and education programs with respect to breast cancer in accordance with section 413; and

''(E) research and demonstration centers with respect to breast cancer in accordance with section 414, including the development and operation of centers for breast cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical,

epidemiological, psychosocial, prevention and treatment research and related activities on breast cancer.

Not less than six centers shall be operated under subparagraph (E). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

''(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

''(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9). The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

''(B) Not later than May 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary and the Director of NIH.

''(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

''(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

''(d) OTHER CANCERS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research on ovarian cancer and other cancers of the reproductive system of women. Activities under such subsection shall provide for the conduct and support of—

''(1) basic research concerning the etiology and causes of ovarian cancer and other cancers of the reproductive system of women;

''(2) clinical research and related activities into the causes, prevention, detection and treatment of

ovarian cancer and other cancers of the reproductive system of women;

''(3) control programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 412;

''(4) information and education programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 413; and

''(5) research and demonstration centers with respect to ovarian cancer and cancers of the reproductive system in accordance with section 414.

''(e) REPORT.—The Director of the Institute shall prepare, for inclusion in the biennial report submitted under section 407, a report that describes the activities of the National Cancer Institute under the research programs referred to in subsection (a), that shall include—

''(1) a description of the research plan with respect to breast cancer prepared under subsection (c);

''(2) an assessment of the development, revision, and implementation of such plan;

''(3) a description and evaluation of the progress made, during the period for which such report is prepared, in the research programs on breast cancer and cancers of the reproductive system of women;

''(4) a summary and analysis of expenditures made, during the period for which such report is made, for activities with respect to breast cancer and cancers of the reproductive system of women conducted and supported by the National Institutes of Health; and

''(5) such comments and recommendations as the Director considers appropriate.''.

SEC. 402. EXPANSION AND INTENSIFICATION OF ACTIVITIES REGARDING PROSTATE CANCER.

Subpart 1 of part C of title IV of the Public Health Service Act, as amended by section 401 of this Act, is amended by adding at the end the following new section:

''PROSTATE CANCER

''SEC. 417A. (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on prostate cancer.

''(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to prostate cancer.

''(c) PROGRAMS.—

''(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, prostate cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

''(A) basic research concerning the etiology and causes of prostate cancer;

''(B) clinical research and related activities concerning the causes, prevention, detection and treatment of prostate cancer;

''(C) prevention and control and early detection programs with respect to prostate cancer in accordance with section 412, particularly as it relates to intensifying research on the role of prostate specific antigen for the screening and early detection of prostate cancer;

''(D) an Inter-Institute Task Force, under the direction of the Director of the Institute, to provide coordination between relevant National Institutes of Health components of research efforts on prostate cancer;

''(E) control programs with respect to prostate cancer in accordance with section 412;

''(F) information and education programs with respect to prostate cancer in accordance with section 413; and

''(G) research and demonstration centers with respect to prostate cancer in accordance with section 414, including the development and operation of centers for prostate cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer.

Not less than six centers shall be operated under subparagraph (G). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

''(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

''(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance

with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9). The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

''(B) Not later than May 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary and the Director of NIH.

''(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

''(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.''.

SEC. 403. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Subpart 1 of part C of title IV of the Public Health Service Act, as amended by section 402 of this Act, is amended by adding at the end the following new section:

''AUTHORIZATION OF APPROPRIATIONS

''SEC. 417B. (a) ACTIVITIES GENERALLY.—For the purpose of carrying out this subpart, there are authorized to be appropriated $3,200,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

''(b) BREAST CANCER AND GYNECOLOGICAL CANCERS.—

''(1) BREAST CANCER.—

''(A) For the purpose of carrying out subparagraph (A) of section 417(c)(1), there are authorized to be appropriated $225,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

''(B) For the purpose of carrying out subparagraphs (B) through (E) of section 417(c)(1), there are authorized to be appropriated

$100,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

''(2) OTHER CANCERS.—For the purpose of carrying out subsection (d) of section 417, there are authorized to be appropriated $75,000,000 for fiscal year 1994, and such sums as are necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

''(c) PROSTATE CANCER.—For the purpose of carrying out section 417A, there are authorized to be appropriated $72,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

''(d) ALLOCATION REGARDING CANCER CONTROL.—

''(1) IN GENERAL.—Of the amounts appropriated for the National Cancer Institute for a fiscal year, the Director of the Institute shall make available

not less than the applicable percentage specified in paragraph (2) for carrying out the cancer control activities authorized in section 412 and for which budget estimates are made under section 413(b)(9) for the fiscal year.

''(2) APPLICABLE PERCENTAGE.—The percentage referred to in paragraph (1) is—

''(A) 7 percent, in the case of fiscal year 1994;

''(B) 9 percent, in the case of fiscal year 1995; and

''(C) 10 percent, in the case of fiscal year 1996 and each subsequent fiscal year.''.

(b) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 408 of the Public Health Service Act (42 U.S.C. 284c) is amended—

(A) by striking subsection (a);

(B) by redesignating subsection (b) as subsection (a);

(C) by redesignating paragraph (5) of subsection (a) (as so redesignated) as subsection (b); and

(D) by amending the heading for the section to read as follows:

''CERTAIN USES OF FUNDS''.

(2) CROSS-REFERENCE.—Section 464F of the Public Health Service Act (42 U.S.C. 285m–6) is amended by striking ''section 408(b)(1)'' and inserting ''section 408(a)(1)''.

SEC. 404. STUDY OF ENVIRONMENTAL AND OTHER RISKS CONTRIBUTING TO INCIDENCE OF BREAST CANCER.

(a) REQUIREMENT OF STUDY.—

(1) IN GENERAL.—The Director of the National Cancer Institute (in this section referred to as the ''Director''), in collaboration with the Director of the National Institute of Environmental Health Sciences, shall conduct a case-controlled study to assess biological markers of environmental and other risk factors contributing to the incidence of breast cancer in—

(A) the Counties of Nassau and Suffolk, in the State of New York; and

(B) the 2 counties in the northeastern United States that, as identified in the report specified in paragraph (2), had the highest age-adjusted mortality rate of such cancer that reflected not less than 30 deaths during the 5-year period for which findings are made in the report.

(2) RELEVANT REPORT.—The report referred to in paragraph (1)(B) is the report of the findings made in the study entitled ''Survival, Epidemiology, and End Results'', relating to cases of cancer during the years 1983 through 1987.

(b) CERTAIN ELEMENTS OF STUDY.—Activities of the Director in carrying out the study under subsection (a) shall include the use of a geographic system to evaluate the current and past exposure of individuals, incuding direct monitoring and cumulative estimates of exposure, to—

(1) contaminated drinking water;

(2) sources of indoor and ambient air pollution, including emissions from aircraft;

(3) electromagnetic fields;

(4) pesticides and other toxic chemicals;

(5) hazardous and municipal waste; and

(6) such other factors as the Director determines to be appropriate.

(c) REPORT.—Not later than 30 months after the date of the enactment of this Act, the Director 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 made as a result of the study.

(d) FUNDING.—Of the amounts appropriated for fiscal years 1994 and 1995 for the National Institute of Environmental Health Sciences and the National Cancer Institute, the Director of the National Institutes of Health shall make available amounts for carrying out the study required in subsection (a).

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

SEC. 501. EDUCATION AND TRAINING.

Section 421(b) of the Public Health Service Act (42 U.S.C. 285b–3(b)) is amended—

(1) in paragraph (3), by striking ''and'' after the semicolon at the end;

(2) in paragraph (4), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (4) the following new paragraph:

''(5) shall, in consultation with the advisory council for the Institute, conduct appropriate intramural training and education programs, including continuing education and laboratory and clinical research training programs.''.

SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CARDIOVASCULAR DISEASES.

Section 422(a)(1) of the Public Health Service Act (42 U.S.C. 285b–4(a)(1)) is amended—

(1) in subparagraph (B), by striking ''and'' at the end;

(2) in subparagraph (C), by striking the period and inserting ''; and''; and

(3) by adding at the end thereof the following new subparagraph:

''(D) three centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment (including genetic studies, intrauterine environment studies, postnatal studies, heart arrhythmias, and acquired heart disease and preventive cardiology) for cardiovascular diseases in children.''.

SEC. 503. NATIONAL CENTER ON SLEEP DISORDERS.

Subpart 2 of part C of title IV of the Public Health Service Act (42 U.S.C. 285b et seq.) is amended by adding at the end the following new section:

''NATIONAL CENTER ON SLEEP DISORDERS

''SEC. 424. (a) Not later than 1 year after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the Institute shall establish the National Center on Sleep Disorders (in this

section referred to as the 'Center'). The Center shall be headed by a director, who shall be appointed by the Director of the Institute.

''(b) The general purpose of the Center is the conduct and support of research, training, health information dissemination, and other activities with respect to sleep disorders.

''(c) The Director of the Center may coordinate the activities of the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities.''.

SEC. 504. AUTHORIZATION OF APPROPRIATIONS.

Subpart 2 of part C of title IV of the Public Health Service Act, as amended by section 503 of this Act, is amended by adding at the end the following section:

''AUTHORIZATION OF APPROPRIATIONS

''SEC. 425. For the purpose of carrying out this subpart, there are authorized to be appropriated $1,500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

TITLE VI—NATIONAL INSTITUTE ON DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SEC. 601. PROVISIONS REGARDING NUTRITIONAL DISORDERS.

Subpart 3 of part C of title IV of the Public Health Service Act (42 U.S.C. 285c et seq.) is amended by adding at the end the following new section:

''NUTRITIONAL DISORDERS PROGRAM

''SEC. 434. (a) The Director of the Institute, in consultation with the Director of NIH, shall establish a program of conducting and supporting research, training, health information dissemination, and other activities with respect to nutritional disorders, including obesity.

''(b) In carrying out the program established under subsection (a), the Director of the Institute shall conduct and support each of the activities described in such subsection.

''(c) In carrying out the program established under subsection (a), the Director of the Institute shall carry out activities to facilitate and enhance knowledge and understanding of nutritional disorders, including obesity, on the part of health professionals, patients, and the public through the effective dissemination of information.''.

(b) DEVELOPMENT AND EXPANSION OF RESEARCH AND TRAINING CENTERS.—Section 431 of the Public Health Service Act (42 U.S.C. 285c–5) is amended—

(1) by redesignating subsection (d) as subsection (e); and

(2) by inserting after subsection (c) the following new subsection:

''(d)(1) The Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the development or substantial expansion of centers for research and training regarding nutritional disorders, including obesity.

''(2) The Director of the Institute shall carry out paragraph (1) in collaboration with the Director of the National Cancer Institute and with the Directors of such other agencies of the National Institutes of Health as the Director of NIH determines to be appropriate.

''(3) Each center developed or expanded under paragraph (1) shall—

''(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director;

''(B) conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control

and treatment of nutritional disorders, including obesity and the impact of nutrition and diet on child development;

''(C) conduct training programs for physicians and allied health professionals in current methods of diagnosis and treatment of such diseases and complications, and in research in such disorders; and

''(D) conduct information programs for physicians and allied health professionals who provide primary care for patients with such disorders or complications.''.

TITLE VII—NATIONAL INSTITUTE ON ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

SEC. 701. JUVENILE ARTHRITIS.

(a) PURPOSE.—Section 435 of the Public Health Service Act (42 U.S.C. 285d) is amended by striking ''and other programs'' and all that follows and inserting the following: ''and other programs with respect to arthritis and musculoskeletal and skin diseases (including sports-related disorders), with particular attention to the effect of these diseases on children.''.

(b) PROGRAMS.—Section 436 (42 U.S.C. 285d–1) is amended—

(1) in subsection (a), by inserting after the second sentence, the following: ''The plan shall place particular emphasis upon expanding research into better understanding the causes and the development of effective treatments for arthritis affecting children.''; and

(2) in subsection (b)—

(A) by striking ''and'' at the end of paragraph (3);

(B) by striking the period at the end of paragraph (4) and inserting ''; and''; and

(C) by adding at the end thereof the following new paragraph:

''(5) research into the causes of arthritis affecting children and the development, trial, and evaluation of techniques, drugs and devices used in the diagnosis, treatment (including medical rehabilitation), and prevention of arthritis in children.''.

(c) CENTERS.—Section 441 of the Public Health Service Act (42 U.S.C. 286d–6) is amended by adding at the end thereof the following new subsection:

''(f) Not later than October 1, 1994, the Director shall establish a multipurpose arthritis and musculoskeletal disease center for the purpose of expanding the level of research into the cause, diagnosis, early detection, prevention, con-

trol, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.''.

(d) ADVISORY BOARD.—

(1) TITLE.—Section 442(a) of the Public Health Service Act (42 U.S.C. 285d–7(a)) is amended by inserting after ''Arthritis'' the following: ''and Musculoskeletal and Skin Diseases''.

(2) COMPOSITION.—Section 442(b) of the Public Health Service Act (42 U.S.C. 285d–7(b)) is amended—

(A) in the matter preceding paragraph (1), by striking ''eighteen'' and inserting ''twenty''; and

(B) in paragraph (1)(B)—

(i) by striking ''six'' and inserting ''eight''; and

(ii) by striking ''including'' and all that follows and inserting the following: ''including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease, and two members who are parents of children with arthritis.''.

(3) ANNUAL REPORT.—Section 442(j) of the Public Health Service Act (42 U.S.C. 285d–7(j)) is amended—

(1) by striking ''and'' at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting ''; and''; and

(3) by adding at the end the following paragraph:

''(5) contains recommendations for expanding the Institute's funding of research directly applicable to the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.''.

TITLE VIII—NATIONAL INSTITUTE ON AGING

SEC. 801. ALZHEIMER'S DISEASE REGISTRY.

(a) IN GENERAL.—Section 12 of Public Law 99–158 (99 Stat. 885) is—

(1) transferred to subpart 5 of part C of title IV of the Public Health Service Act (42 U.S.C. 285e et seq.);

(2) redesignated as section 445G; and

(3) inserted after section 445F of such Act.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—Section 445G of the Public Health Service Act, as transferred and inserted by subsection (a) of this section, is amended—

(1) by striking the section heading and all that follows through ''may make a grant'' in subsection (a) and inserting the following:

''ALZHEIMER'S DISEASE REGISTRY

''SEC. 445G. (a) IN GENERAL.—The Director of the Institute may make a grant''; and

(2) by striking subsection (c).

SEC. 802. AGING PROCESSES REGARDING WOMEN.

Subpart 5 of part C of title IV of the Public Health Service Act, as amended by section 801 of this Act, is amended by adding at the end the following new section:

''AGING PROCESSES REGARDING WOMEN

''SEC. 445H. The Director of the Institute, in addition to other special functions specified in section 444 and in cooperation with the Directors of the other national research institutes and agencies of the National Institutes of Health, shall conduct research into the aging processes of women, with particular emphasis given to the effects of menopause and the physiological and behavioral changes occurring during the transition from pre- to post-menopause, and into the diagnosis, disorders, and complications related to aging and loss of ovarian hormones in women.''.

SEC. 803. AUTHORIZATION OF APPROPRIATIONS.

Subpart 5 of part C of title IV of the Public Health Service Act, as amended by section 802 of this Act, is amended by adding at the end the following new section:

''AUTHORIZATION OF APPROPRIATIONS

''SEC. 445I. For the purpose of carrying out this subpart, there are authorized to be appropriated $500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 804. CONFORMING AMENDMENT.

Section 445C of the Public Health Service Act (42 U.S.C. 285e–5), as amended by section 9 of Public Law 102–507 (106 Stat. 3287), is amended—

(1) in subsection (b)(1), in the first sentence, by inserting after ''Council'' the following: ''on Alzheimer's Disease (hereafter in this section referred to as the 'Council')''; and

(2) by adding at the end the following new subsection:

''(e) For purposes of this section, the term 'Council on Alzheimer's Disease' means the council established in section 911(a) of Public Law 99–660.''.

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SEC. 901. TROPICAL DISEASES.

Section 446 of the Public Health Service Act (42 U.S.C. 285f) is amended by inserting before the period the following: '', *including tropical diseases''*.

SEC. 902. CHRONIC FATIGUE SYNDROME.

(a) RESEARCH CENTERS.—Subpart 6 of part C of title IV of the Public Health Service Act (42 U.S.C. 285f) is amended by adding at the end the following new section:

''RESEARCH CENTERS REGARDING CHRONIC FATIGUE SYNDROME

''SEC. 447. (a) The Director of the Institute, after consultation with the advisory council for the Institute, may make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct basic and clinical research on chronic fatigue syndrome.

''(b) Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.''.

(b) EXTRAMURAL STUDY SECTION.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall establish an extramural study section for chronic fatigue syndrome research.

(c) REPRESENTATIVES.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall ensure that appropriate individuals with expertise in chronic fatigue syndrome or neuromuscular diseases and representative of a variety of disciplines and fields within the research community are appointed to appropriate National Institutes of Health advisory committees and boards.

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Subtitle A—Research Centers With Respect to Contraception and Research Centers With Respect to Infertility

SEC. 1001. GRANTS AND CONTRACTS FOR RESEARCH CENTERS.

Subpart 7 of part C of title IV of the Public Health Service Act, as amended by section 3 of Public Law 101–613, is amended by adding at the end the following new section:

''RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND INFERTILITY

''SEC. 452A. (a) The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the purpose of improving methods of contraception and centers to conduct activities for the purpose of improving methods of diagnosis and treatment of infertility.

''(b) In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with respect to contraception and for two centers with respect to infertility.

''(c)(1) Each center assisted under this section shall, in carrying out the purpose of the center involved—

''(A) conduct clinical and other applied research, including—

''(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and females (including barrier methods); and

''(ii) for centers with respect to infertility, clinical trials of new or improved drugs and de-

vices for the diagnosis and treatment of infertility in males and females;

''(B) develop protocols for training physicians, scientists, nurses, and other health and allied health professionals;

''(C) conduct training programs for such individuals;

''(D) develop model continuing education programs for such professionals; and

''(E) disseminate information to such professionals and the public.

''(2) A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (1), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

''(d) The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

''(e) Each center assisted under subsection (a) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

''(f) Support of a center under subsection (a) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

''(g) For the purpose of carrying out this section, 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 and 1996.''.

SEC. 1002. LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY.

Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 487A the following section:

''LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY

''SEC. 487B. (a) The Secretary, in consultation with the Director of the National Institute of Child Health and Human Development, shall establish a program of entering into agreements with qualified health professionals (including graduate students) under which such health professionals agree to conduct research with respect to contracep-

tion, or with respect to infertility, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of such health professionals.

''(b) The provisions of sections 338B, 338C, and 338E shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

''(c) Amounts appropriated for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.''.

Subtitle B—Program Regarding Obstetrics and Gynecology

SEC. 1011. ESTABLISHMENT OF PROGRAM.

Subpart 7 of part C of title IV of the Public Health Service Act, as amended by section 1001 of this Act, is amended by adding at the end the following new section:

''PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

''SEC. 452B. The Director of the Institute shall establish and maintain within the Institute an intramural laboratory and clinical research program in obstetrics and gynecology.''.

Subtitle C—Child Health Research Centers

SEC. 1021. ESTABLISHMENT OF CENTERS.

Subpart 7 of part C of title IV of the Public Health Service Act, as amended by section 1011 of this Act, is amended by adding at the end the following new section:

''CHILD HEALTH RESEARCH CENTERS

''SEC. 452C. The Director of the Institute shall develop and support centers for conducting research with respect to child health. Such centers shall give priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children.''.

Subtitle D—Study Regarding Adolescent Health

SEC. 1031. PROSPECTIVE LONGITUDINAL STUDY.

Subpart 7 of part C of title IV of the Public Health Service Act, as amended by section 1021 of this Act, is amended by adding at the end the following new section:

''PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT HEALTH

''SEC. 452D. (a) IN GENERAL.—Not later than October 1, 1993, the Director of the Institute shall commence a study for the purpose of providing information on the general health and well-being of adolescents in the United States,

including, with respect to such adolescents, information on—

''(1) the behaviors that promote health and the behaviors that are detrimental to health; and

''(2) the influence on health of factors particular to the communities in which the adolescents reside.

''(b) DESIGN OF STUDY.—

''(1) IN GENERAL.—The study required in subsection (a) shall be a longitudinal study in which a substantial number of adolescents participate as subjects. With respect to the purpose described in such subsection, the study shall monitor the subjects throughout the period of the study to determine the health status of the subjects and any change in such status over time.

''(2) POPULATION-SPECIFIC ANALYSES.—The study required in subsection (a) shall be conducted with respect to the population of adolescents who are female, the population of adolescents who are male, various socioeconomic populations of adolescents, and various racial and ethnic populations of adolescents. The study shall be designed and conducted in a manner sufficient to provide for a valid analysis of whether there are significant differences among such populations in health status and whether and to what ex-

tent any such differences are due to factors particular to the populations involved.

''(c) COORDINATION WITH WOMEN'S HEALTH INITIATIVE.—With respect to the national study of women being conducted by the Secretary and known as the Women's Health Initiative, the Secretary shall ensure that such study is coordinated with the component of the study required in subsection (a) that concerns adolescent females, including coordination in the design of the 2 studies.''.

TITLE XI—NATIONAL EYE INSTITUTE

SEC. 1101. CLINICAL RESEARCH ON DIABETES EYE CARE.

(a) IN GENERAL.—Subpart 9 of part C of title IV of the Public Health Service Act (42 U.S.C. 285i) is amended by adding at the end the following new section:

''CLINICAL RESEARCH ON EYE CARE AND DIABETES

''SEC. 456. (a) PROGRAM OF GRANTS.—The Director of the Institute, in consultation with the advisory council for the Institute, may award not more than three grants for the establishment and support of centers for clinical research on eye care for individuals with diabetes.

''(b) AUTHORIZED EXPENDITURES.—The purposes for which a grant under subsection (a) may be expended include equipment for the research described in such subsection and the construction and modernization of facilities for such research.''.

(b) CONFORMING AMENDMENT.—Section 455 of the Public Health Service Act (42 U.S.C. 285i) is amended in the second sentence by striking ''The Director'' and inserting ''Subject to section 456, the Director''.

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

SEC. 1201. RESEARCH ON MULTIPLE SCLEROSIS.

Subpart 10 of part C of title IV of the Public Health Service Act (42 U.S.C. 285j et seq.) is amended by adding at the end the following new section:

''RESEARCH ON MULTIPLE SCLEROSIS

''SEC. 460. The Director of the Institute shall conduct and support research on multiple sclerosis, especially research on effects of genetics and hormonal changes on the progress of the disease.''.

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

SEC. 1301. APPLIED TOXICOLOGICAL RESEARCH AND TESTING PROGRAM.

(a) IN GENERAL.—Subpart 12 of part C of title IV of the Public Health Service Act (42 U.S.C. 285l) is amended by adding at the end the following new section:

''APPLIED TOXICOLOGICAL RESEARCH AND TESTING PROGRAM

''SEC. 463A. (a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

''(b) In carrying out the program established under subsection (a), the Director of the Institute shall, with respect to toxicology, carry out activities—

''(1) to expand knowledge of the health effects of environmental agents;

''(2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;

''(3) to develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing;

''(4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;

''(5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and

''(6) to integrate related activities of the Department of Health and Human Services.''.

(b) TECHNICAL AMENDMENT.—Section 463 of the Public Health Service Act (42 U.S.C. 285l) is amended by inserting after ''Sciences'' the following: ''(hereafter in this subpart referred to as the 'Institute')''.

SEC. 1302. STUDY OF ENVIRONMENTAL AND OTHER RISKS CONTRIBUTING TO INCIDENCE OF BREAST AND PROSTATE CANCER.

(a) IN GENERAL.—The Director of the National Institute of Environmental Health Sciences (in this section referred to as the ''Director''), in collaboration with the Director of the National Cancer Institute, shall conduct a case-controlled study to assess biological markers of environmental and other risk factors contributing to the incidence of breast and prostate cancer in the Counties of Nassau and Suffolk, in the State of New York.

(b) CERTAIN ELEMENTS OF STUDY.—Activities of the Director in carrying out the study under subsection (a) shall include the use of a geographic system to evaluate the current and past exposure of individuals, including direct monitoring and cumulative estimates of exposure, to—

(1) contaminated drinking water;

(2) sources of indoor and ambient air pollution, including emissions from aircraft;

(3) electromagnetic fields;

(4) pesticides and other toxic chemicals;

(5) hazardous and municipal waste; and

(6) such other factors as the Director determines to be appropriate.

(c) REPORT.—Not later than 24 months after the date of the enactment of this Act, the Director 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 made as a result of the study.

(d) FUNDING.—Of the amounts appropriated for fiscal years 1994 and 1995 for the National Institute of Environmental Health Sciences and the National Cancer Institute, the Director of the National Institutes of Health shall make available amounts for carrying out the study required in subsection (a).

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

SEC. 1401. ADDITIONAL AUTHORITIES.

(a) IN GENERAL.—Section 465(b) of the Public Health Service Act (42 U.S.C. 286(b)) is amended—

(1) by striking ''and'' after the semicolon at the end of paragraph (5);

(2) by redesignating paragraph (6) as paragraph (8); and

(3) by inserting after paragraph (5) the following new paragraphs:

''(6) publicize the availability from the Library of the products and services described in any of paragraphs (1) through (5);

''(7) promote the use of computers and telecommunications by health professionals (including health professionals in rural areas) for the purpose of improving access to biomedical information for health care delivery and medical research; and''.

(b) LIMITATION REGARDING GRANTS.—Section 474(b)(2) of the Public Health Service Act (42 U.S.C. 286b–S(b)(2)) is amended by striking ''$750,000'' and inserting ''$1,000,000''.

(c) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) REPEAL OF CERTAIN AUTHORITY.—Section 215 of the Department of Health and Human Services Appropriations Act, 1988, as contained in section 101(h) of Public Law 100–202 (101 Stat. 1329–275), is repealed.

(2) APPLICABILITY OF CERTAIN NEW AUTHORITY.—With respect to the authority established for the National Library of Medicine in section 465(b)(6) of the Public Health Service Act, as added by subsection (a) of this section, such authority shall be effective as if the authority had been established on December 22, 1987.

SEC. 1402. AUTHORIZATION OF APPROPRIATIONS.

(a) ESTABLISHMENT OF SINGLE AUTHORIZATION.—Subpart 1 of part D of title IV of the Public Health Service Act (42 U.S.C. 286 et seq.) is amended by adding at the end the following section:

''AUTHORIZATION OF APPROPRIATIONS

''SEC. 468. (a) For the purpose of carrying out this part, there are authorized to be appropriated $150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

''(b) Amounts appropriated under subsection (a) and made available for grants or contracts under any of sections 472 through 476 shall remain available until the end of the fiscal year following the fiscal year for which the amounts were appropriated.''.

(b) CONFORMING AMENDMENTS.—Part D of title IV of the Public Health Service Act (42 U.S.C. 286 et seq.) is amended by striking section 469 and section 478(c).

Subtitle B—Financial Assistance

SEC. 1411. ESTABLISHMENT OF PROGRAM OF GRANTS FOR DEVELOPMENT OF EDUCATION TECHNOLOGIES.

Section 473 of the Public Health Service Act (42 U.S.C. 286b–4) is amended by adding at the end the following new subsection:

''(c)(1) The Secretary shall make grants to public or nonprofit private institutions for the purpose of carrying out projects of research on, and development and demonstration of, new education technologies.

''(2) The purposes for which a grant under paragraph (1) may be made include projects concerning—

''(A) computer-assisted teaching and testing of clinical competence at health professions and research institutions;

''(B) the effective transfer of new information from research laboratories to appropriate clinical applications;

''(C) the expansion of the laboratory and clinical uses of computer-stored research databases; and

''(D) the testing of new technologies for training health care professionals.

''(3) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to make the projects available with respect to—

''(A) assisting in the training of health professions students; and

''(B) enhancing and improving the capabilities of health professionals regarding research and teaching.''.

Subtitle C—National Information Center on Health Services Research and Health Care Technology

SEC. 1421. ESTABLISHMENT OF CENTER.

Part D of title IV of the Public Health Service Act (42 U.S.C. 286 et seq.) is amended by adding at the end the following new subpart:

''Subpart 4—National Information Center on Health Services Research and Health Care Technology

''NATIONAL INFORMATION CENTER

''SEC. 478A. (a) There is established within the Library an entity to be known as the National Information Center on Health Services Research and Health Care Technology (in this section referred to as the 'Center').

''(b) The purpose of the Center is the collection, storage, analysis, retrieval, and dissemination of information on

health services research, clinical practice guidelines, and on health care technology, including the assessment of such technology. Such purpose includes developing and maintaining data bases and developing and implementing methods of carrying out such purpose.

''(c) The Director of the Center shall ensure that information under subsection (b) concerning clinical practice guidelines is collected and maintained electronically and in a convenient format. Such Director shall develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database.

''(d) The Secretary, acting through the Center, shall coordinate the activities carried out under this section through the Center with related activities of the Administrator for Health Care Policy and Research.''.

SEC. 1422. CONFORMING PROVISIONS.

(a) IN GENERAL.—Section 903 of the Public Health Service Act, as amended by section 3 of Public Law 102–410 (106 Stat. 2094), is amended by amending subsection (e) to read as follows:

''(e) REQUIRED INTERAGENCY AGREEMENT.—The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of section 478A.''.

(b) RULE OF CONSTRUCTION.—The amendments made by section 3 of Public Law 102–410 (106 Stat. 2094), by section 1421 of this Act, and by subsection (a) of this section may not be construed as terminating the information center on health care technologies and health care technology assessment established under section 904 of the Public Health Service Act, as in effect on the day before the date of the enactment of Public Law 102–410. Such center shall be considered to be the center established in section 478A of the Public Health Service Act, as added by section 1421 of this Act, and shall be subject to the provisions of such section 478A.

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF HEALTH

Subtitle A—Division of Research Resources

SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL CENTER FOR RESEARCH RESOURCES.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 401(b)(2)(B), by amending such subparagraph to read as follows:

''(B) The National Center for Research Resources.''; and

(2) in part E—

(A) in the heading for subpart 1, by striking ''Division of'' and inserting ''National Center for'';

(B) in section 479, by striking ''the Division of Research Resources'' and inserting the following: ''the National Center for Research Resources (hereafter in this subpart referred to as the 'Center')'';

(C) in sections 480 and 481, by striking ''the Division of Research Resources'' each place such term appears and inserting ''the Center''; and

(D) in sections 480 and 481, as amended by subparagraph (C), by striking ''the Division'' each place such term appears and inserting ''the Center''.

SEC. 1502. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

Subpart 1 of part E of title IV of the Public Health Service Act (42 U.S.C. 287 et seq.) is amended by adding at the end the following new section:

''BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

''SEC. 481A. (a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

''(1) IN GENERAL.—The Director of NIH, acting through the Director of the Center, may make grants to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.

''(2) CONSTRUCTION AND COST OF CONSTRUCTION.—For purposes of this section, the terms 'construction' and 'cost of construction' include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects' fees, but do not include the cost of acquisition of land or off-site improvements.

''(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS FOR MERIT-BASED REVIEW OF PROPOSALS.—

''(1) IN GENERAL; APPROVAL AS PRECONDITION TO GRANTS.—

''(A) There is established within the Center a Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (hereafter referred to in this section as the 'Board').

''(B) The Director of the Center may approve an application for a grant under subsection (a) only if the Board has under para-

graph (2) recommended the application for approval.

''(2) DUTIES.—

''(A) The Board shall provide advice to the Director of the Center and the advisory council established under section 480 (hereafter in this section referred to as the 'Advisory Council') on carrying out this section.

''(B) In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of the Center and the Advisory Council. Such determinations shall be conducted in a manner consistent with procedures established under section 492.

''(C) In carrying out subparagraph (A), the Board shall, in the case of applications recommended for approval, make recommendations to the Director and the Advisory Council on the amount that should be provided in the grant.

''(D) In carrying out subparagraph (A), the Board shall prepare an annual report for the Di-

rector of the Center and the Advisory Council describing the activities of the Board in the fiscal year for which the report is made. Each such report shall be available to the public, and shall—

''(i) summarize and analyze expenditures made under this section;

''(ii) provide a summary of the types, numbers, and amounts of applications that were recommended for grants under subsection (a) but that were not approved by the Director of the Center; and

''(iii) contain the recommendations of the Board for any changes in the administration of this section.

''(3) MEMBERSHIP.—

''(A) Subject to subparagraph (B), the Board shall be composed of 9 appointed members, and such ex officio members as the Director of the Center determines to be appropriate.

''(B) Not more than 3 individuals who are officers or employees of the Federal Government may serve as members of the Board.

''(4) CERTAIN REQUIREMENTS REGARDING MEMBERSHIP.—In selecting individuals for membership on the Board, the Director of the Center shall ensure

that the members are individuals who, by virtue of their training or experience, are eminently qualified to perform peer review functions. In selecting such individuals for such membership, the Director of the Center shall ensure that the members of the Board collectively—

''(A) are experienced in the planning, construction, financing, and administration of entities that conduct biomedical or behavioral research sciences;

''(B) are knowledgeable in making determinations of the need of entities for biomedical or behavioral research facilities, including such facilities for the dentistry, nursing, pharmacy, and allied health professions;

''(C) are knowledgeable in evaluating the relative priorities for applications for grants under subsection (a) in view of the overall research needs of the United States; and

''(D) are experienced with emerging centers of excellence, as described in subsection (c)(3).

''(5) CERTAIN AUTHORITIES.—

''(A) In carrying out paragraph (2), the Board may convene workshops and conferences,

and collect data as the Board considers appropriate.

''(B) In carrying out paragraph (2), the Board may establish subcommittees within the Board. Such subcommittees may hold meetings as determined necessary to enable the subcommittee to carry out its duties.

''(6) TERMS.—

''(A) Except as provided in subparagraph (B), each appointed member of the Board shall hold office for a term of 4 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of the term of the predecessor.

''(B) Of the initial members appointed to the Board (as specified by the Director of the Center when making the appointments)—

''(i) 3 shall hold office for a term of 3 years;

''(ii) 3 shall hold office for a term of 2 years; and

''(iii) 3 shall hold office for a term of 1 year.

''(C) No member is eligible for reappointment to the Board until 1 year has elapsed after the end of the most recent term of the member.

''(7) COMPENSATION.—Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this title.

''(c) REQUIREMENTS FOR GRANTS.—

''(1) IN GENERAL.—The Director of the Center may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

''(A) The applicant is determined by such Director to be competent to engage in the type of research for which the proposed facility is to be constructed.

''(B) The applicant provides assurances satisfactory to the Director that—

''(i) for not less than 20 years after completion of the construction, the facility will be used for the purposes of research for which it is to be constructed;

''(ii) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;

''(iii) sufficient funds will be available, when construction is completed, for the effective use of the facility for the research for which it is being constructed; and

''(iv) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

''(C) The applicant meets reasonable qualifications established by the Director with respect to—

''(i) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding the capacity for biomedical or behavioral research and in improving the quality of such research;

''(ii) the quality of the research or training, or both, to be carried out in the facilities involved;

''(iii) the need of the applicant for such facilities in order to maintain or expand

the applicant's research and training mission;

''(iv) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

''(v) the age and condition of existing research facilities and equipment.

''(D) The applicant has demonstrated a commitment to enhancing and expanding the research productivity of the applicant.

''(2) CONSIDERATION OF CERTAIN FACTORS.—In making grants under subsection (a), the Director of the Center may, in addition to the requirements established in paragraph (1), consider the following factors:

''(A) To what extent the applicant has the capacity to broaden the scope of research and research training programs of the applicant by promoting—

''(i) interdisciplinary research;

''(ii) research on emerging technologies, including those involving novel analytical techniques or computational methods; or

''(iii) other novel research mechanisms or programs.

''(B) To what extent the applicant has broadened the scope of research and research training programs of qualified institutions by promoting genomic research with an emphasis on interdisciplinary research, including research related to pediatric investigations.

''(3) INSTITUTIONS OF EMERGING EXCELLENCE.—Of the amounts appropriated under subsection (h) for a fiscal year, the Director of the Center shall make available 25 percent for grants under subsection (a) to applicants that, in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

''(A) The applicant has a plan for research or training advancement and possesses the ability to carry out the plan.

''(B) The applicant carries out research and research training programs that have a special relevance to a problem, concern, or unmet health need of the United States.

''(C) The applicant has been productive in research or research development and training.

''(D) The applicant—

''(i) has been designated as a center of excellence under section 739;

''(ii) is located in a geographic area a significant percentage of whose population has a health-status deficit, and the applicant provides health services to such population; or

''(iii) is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such population.

''(d) REQUIREMENT OF APPLICATION.—The Director of the Center may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

''(e) AMOUNT OF GRANT; PAYMENTS.—

''(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by

the Director of the Center, except that such amount shall not exceed—

''(A) 50 percent of the necessary cost of the construction of a proposed facility as determined by the Director; or

''(B) in the case of a multipurpose facility, 40 percent of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

''(2) RESERVATION OF AMOUNTS.—On approval of any application for a grant under subsection (a), the Director of the Center shall reserve, from any appropriation available therefore, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of the Director of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of the application or on the revision of the estimated cost of construction of the facility.

''(3) EXCLUSION OF CERTAIN COSTS.—In determining the amount of any grant under this sub-

section (a), there shall be excluded from the cost of construction an amount equal to the sum of—

''(A) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by a grant authorized under this section; and

''(B) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

''(4) WAIVER OF LIMITATIONS.—The limitations imposed by paragraph (1) may be waived at the discretion of the Director for applicants meeting the conditions described in paragraphs (1) and (2) of subsection (c).

''(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

''(1) the applicant or other owner of the facility shall cease to be a public or nonprofit private entity; or

''(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director determines, in accordance with regula-

tions, that there is good cause for releasing the applicant or other owner from obligation to do so);

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

''(g) GUIDELINES.—Not later than 6 months after the date of the enactment of this section, the Director of the Center, after consultation with the Advisory Council, shall issue guidelines with respect to grants under subsection (a).

''(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 1503. CONSTRUCTION PROGRAM FOR NATIONAL PRIMATE RESEARCH CENTER.

Subpart 1 of part E of title IV of the Public Health Service Act, as amended by section 1502 of this Act, is amended by adding at the end the following new section:

''CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH ON PRIMATES

''SEC. 481B. (a) With respect to activities carried out by the National Center for Research Resources to support regional centers for research on primates, the Director of NIH shall, for each of the fiscal years 1994 through 1996, reserve from the amounts appropriated under section 481A(i) $5,000,000 for the purpose of making awards of grants and contracts to public or nonprofit private entities to construct, renovate, or otherwise improve such regional centers. The reservation of such amounts for any fiscal year is subject to the availability of qualified applicants for such awards.

''(b) The Director of NIH may not make a grant or enter into a contract under subsection (a) unless the applicant for such assistance agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $4 of Federal funds provided in such assistance.''.

Subtitle B—National Center for Nursing Research

SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR NURSING RESEARCH AS NATIONAL INSTITUTE OF NURSING RESEARCH.

(a) IN GENERAL.—Subpart 3 of part E of title IV of the Public Health Service Act (42 U.S.C. 287c et seq.) is amended—

(1) in section 483—

(A) in the heading for the section, by striking ''CENTER'' and inserting ''INSTITUTE''; and

(B) by striking ''The general purpose'' and all that follows through ''is'' and inserting the following: ''The general purpose of the National Institute of Nursing Research (hereafter in this subpart referred to as the 'Institute') is'';

(2) in section 484, by striking ''Center'' each place such term appears and inserting ''Institute'';

(3) in section 485—

(A) in subsection (a), in each of paragraphs (1) through (3), by striking ''Center'' each place such term appears and inserting ''Institute'';

(B) in subsection (b)—

(i) in paragraph (2)(A), by striking ''Center'' and inserting ''Institute''; and

(ii) in paragraph (3)(A), in the first sentence, by striking ''Center'' and inserting ''Institute''; and

(C) in subsections (d) through (g), by striking ''Center'' each place such term appears and inserting ''Institute''; and

(4) in section 485A (as redesignated by section 141(a)(1) of this Act), by striking ''Center'' each place such term appears and inserting ''Institute''.

(b) CONFORMING AMENDMENTS.—

(1) ORGANIZATION OF NATIONAL INSTITUTES OF HEALTH.—Section 401(b) of the Public Health Service Act (42 U.S.C. 281(b)) is amended—

(A) in paragraph (1), by adding at the end the following new subparagraph:

''(Q) The National Institute of Nursing Research.''; and

(B) in paragraph (2), by striking subparagraph (D).

(2) TRANSFER OF STATUTORY PROVISIONS.—The Public Health Service Act, as amended by subsection (a) of this section and by section 124 of Public Law 102–321 (106 Stat. 364), is amended—

(A) by transferring sections 483 through 485A to part C of title IV;

(B) by redesignating such sections as sections 464V through 464Y of such part; and

(C) by adding such sections, in the appropriate sequence, at the end of such part.

(3) HEADING FOR NEW SUBPART.—Title IV of the Public Health Service Act, as amended by the preceding provisions of this section, is amended—

(A) in part C, by inserting before section 464V the following:

''Subpart 17—National Institute of Nursing Research'';

and

(B) by striking the subpart designation and heading for subpart 3 of part E.

(4) CROSS-REFERENCES.—Title IV of the Public Health Service Act, as amended by the preceding provisions of this section, is amended in subpart 17 of part C—

(A) in section 464W, by striking ''section 483'' and inserting ''section 464V'';

(B) in section 464X(g), by striking ''section 486'' and inserting ''section 464Y''; and

(C) in section 464Y, in the last sentence, by striking ''section 485(g)'' and inserting ''section 464X(g)''.

SEC. 1512. STUDY ON ADEQUACY OF NUMBER OF NURSES.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the National Institute of Nursing Research, shall enter into a contract with a public or nonprofit private entity to conduct a study for the purpose of determining whether and to what extent there is a need for an increase in the number of nurses in hospitals and nursing homes in order to promote the quality of patient care and reduce the incidence among nurses of work-related injuries and stress.

(b) NATIONAL ACADEMY OF SCIENCES.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to enter into the contract under subsection (a) to conduct the study described in such subsection. If such Institute declines to conduct the study, the Secretary shall carry out such subsection through another public or nonprofit private entity.

(c) DEFINITIONS.—For purposes of this section:

(1) The term ''nurse'' means a registered nurse, a licensed practical nurse, a licensed vocational nurse, and a nurse assistant.

(2) The term ''Secretary'' means the Secretary of Health and Human Services.

(d) REPORT.—The Secretary shall ensure that, not later than October 1, 1994, the study required in subsection (a) is completed and a report describing the findings made

as a result of the study is submitted to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate.

Subtitle C—National Center for Human Genome Research

SEC. 1521. PURPOSE OF CENTER.

Title IV of the Public Health Service Act, as amended by section 141(a)(1) of this Act and by paragraphs (1)(B) and (3)(B) of section 1511(b) of this Act, is amended—

(1) in section 401(b)(2), by adding at the end the following new subparagraph:

''(D) The National Center for Human Genome Research.''; and

(2) in part E, by adding at the end the following new subpart:

''Subpart 3—National Center for Human Genome Research

''PURPOSE OF THE CENTER

''SEC. 485B. (a) The general purpose of the National Center for Human Genome Research (hereafter in this subpart referred to as the 'Center') is to characterize the structure and function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

''(1) planning and coordinating the research goal of the genome project;

''(2) reviewing and funding research proposals;

''(3) developing training programs;

''(4) coordinating international genome research;

''(5) communicating advances in genome science to the public; and

''(6) reviewing and funding proposals to address the ethical and legal issues associated with the genome project.

''(b) The Director of the Center may conduct and support research training—

''(1) for which fellowship support is not provided under section 487; and

''(2) that is not residency training of physicians or other health professionals.

''(c)(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Center shall make available not less than 5 percent for carrying out paragraph (6) of such subsection.

''(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Center certifies to the

Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 491 and 492.''.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.

Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)(4)) is amended by adding at the end the following paragraph:

''(4) The Secretary shall carry out paragraph (1) in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds, into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.''.

Subtitle B—Acquired Immune Deficiency Syndrome

SEC. 1611. LOAN REPAYMENT PROGRAM.

Section 487A of the Public Health Service Act (42 U.S.C. 288–1) is amended to read as follows:

''LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

''SEC. 487A. (a) IN GENERAL.—

''(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct, as employees of the National Institutes of Health, research with respect to acquired immune deficiency syndrome in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of such health professionals.

''(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

''(A) has a substantial amount of educational loans relative to income; and

''(B) agrees to serve as an employee of the National Institutes of Health for purposes of paragraph (1) for a period of not less than 3 years.

''(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repay-

ment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

''(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.''.

Subtitle C—Loan Repayment for Research Generally

SEC. 1621. ESTABLISHMENT OF PROGRAM.

Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by inserting after section 487B the following new section:

''LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY

''SEC. 487C. (a) IN GENERAL.—

''(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration

of the Federal Government agreeing to repay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of such health professionals.

''(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

''(A) has a substantial amount of educational loans relative to income; and

''(B) agrees to serve as an employee of the National Institutes of Health for purposes of paragraph (1) for a period of not less than 3 years.

''(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

''(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section other than with respect to acquired immune deficiency syndrome, there are author-

ized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.''.

Subtitle D—Scholarship and Loan Repayment Programs Regarding Professional Skills Needed by Certain Agencies

SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL INSTITUTES OF HEALTH.

Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1621 of this Act, is amended by inserting after section 487C the following new sections:

''UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY NATIONAL RESEARCH INSTITUTES

''SEC. 487D. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH, may carry out a program of entering into contracts with individuals described in paragraph (2) under which—

''(A) the Director of NIH agrees to provide to the individuals scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appro-

priate for careers in professions needed by the National Institutes of Health; and

''(B) the individuals agree to serve as employees of the National Institutes of Health, for the period described in subsection (c), in positions that are needed by the National Institutes of Health and for which the individuals are qualified.

''(2) INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.—The individuals referred to in paragraph (1) are individuals who—

''(A) are enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education; and

''(B) are from disadvantaged backgrounds.

''(b) FACILITATION OF INTEREST OF STUDENTS IN CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In providing employment to individuals pursuant to contracts under subsection (a)(1), the Director of NIH shall carry out activities to facilitate the interest of the individuals in pursuing careers as employees of the National Institutes of Health.

''(c) PERIOD OF OBLIGATED SERVICE.—

''(1) DURATION OF SERVICE.—For purposes of subparagraph (B) of subsection (a)(1), the period of

service for which an individual is obligated to serve as an employee of the National Institutes of Health is, subject to paragraph (2)(A), 12 months for each academic year for which the scholarship under such subsection is provided.

''(2) SCHEDULE FOR SERVICE.—

''(A) Subject to subparagraph (B), the Director of NIH may not provide a scholarship under subsection (a) unless the individual applying for the scholarship agrees that—

''(i) the individual will serve as an employee of the National Institutes of Health full-time for not less than 10 consecutive weeks of each year during which the individual is attending the educational institution involved and receiving such a scholarship;

''(ii) the period of service as such an employee that the individual is obligated to provide under clause (i) is in addition to the period of service as such an employee that the individual is obligated to provide under subsection (a)(1)(B); and

''(iii) not later than 60 days after obtaining the educational degree involved, the

individual will begin serving full-time as such an employee in satisfaction of the period of service that the individual is obligated to provide under subsection (a)(1)(B).

''(B) The Director of NIH may defer the obligation of an individual to provide a period of service under subsection (a)(1)(B), if the Director determines that such a deferral is appropriate.

''(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO APPOINTMENT AND COMPENSATION.—For any period in which an individual provides service as an employee of the National Institutes of Health in satisfaction of the obligation of the individual under subsection (a)(1)(B) or paragraph (2)(A)(i), the individual may be appointed as such an employee without regard to the provisions of title 5, United States Code, relating to appointment and compensation.

''(d) PROVISIONS REGARDING SCHOLARSHIP.—

''(1) APPROVAL OF ACADEMIC PROGRAM.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless—

''(A) the individual applying for the scholarship has submitted to the Director a proposed

academic program for the year and the Director has approved the program; and

''(B) the individual agrees that the program will not be altered without the approval of the Director.

''(2) ACADEMIC STANDING.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless the individual applying for the scholarship agrees to maintain an acceptable level of academic standing, as determined by the educational institution involved in accordance with regulations issued by the Secretary.

''(3) LIMITATION ON AMOUNT.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year in an amount exceeding $20,000.

''(4) AUTHORIZED USES.—A scholarship provided under subsection (a) may be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in attending the school involved.

''(5) CONTRACT REGARDING DIRECT PAYMENTS TO INSTITUTION.—In the case of an institution of higher education with respect to which a scholarship under subsection (a) is provided, the Director of NIH

may enter into a contract with the institution under which the amounts provided in the scholarship for tuition and other educational expenses are paid directly to the institution.

''(e) PENALTIES FOR BREACH OF SCHOLARSHIP CONTRACT.—The provisions of section 338E shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

''(f) REQUIREMENT OF APPLICATION.—The Director of NIH may not provide a scholarship under subsection (a) unless an application for the scholarship is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

''(g) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for scholarships under this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

''LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS FROM DISADVANTAGED BACKGROUNDS

''SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—

"(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals who are from disadvantaged backgrounds under which such health professionals agree to conduct clinical research as employees of the National Institutes of Health in consideration of the Federal Government agreeing to pay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of the health professionals.

"(2) LIMITATION.—The Director of NIH may not enter into a contract with a health professional pursuant to paragraph (1) unless such professional has a substantial amount of education loans relative to income.

"(3) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338C and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

''(b) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.''.

SEC. 1632. FUNDING.

Section 487(a)(1) of the Public Health Service Act (42 U.S.C. 288(a)(1)) is amended—

(1) in subparagraph (A), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

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

''(C) provide contracts for scholarships and loan repayments in accordance with sections 487D and 487E, subject to providing not more than an aggregate 50 such contracts during the fiscal years 1994 through 1996.''.

Subtitle E—Funding

SEC. 1641. AUTHORIZATION OF APPROPRIATIONS.

Section 487(d) of the Public Health Service Act (42 U.S.C. 288(d)) is amended—

(1) in the first sentence, by amending the sentence to read as follows: ''For the purpose of carrying

out this section, there are authorized to be appropriated $400,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''; and

(2) in paragraph (3)—

(A) by striking ''one-half of one percent'' each place such term appears and inserting ''1 percent''; and

(B) by striking ''780, 784, or 786,'' and inserting ''747, 748, or 749,''.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD MEMBERS.

Section 499 of the Public Health Service Act, as redesignated by section 121(b)(3) of this Act, is amended in subsection (c)(1)(C) by inserting after and below clause (iii) the following:

''Not later than April 1, 1993, the Secretary shall convene a meeting of the ex officio members of the Board for the purpose of making the appointments required in this subparagraph.''.

SEC. 1702. MISCELLANEOUS PROVISIONS.

Section 499 of the Public Health Service Act, as redesignated by section 121(b)(3) of this Act, is amended—

(1) in subsection (a)—

(A) in the first sentence, by inserting after ''Secretary'' the following: '', acting through the Director of NIH,''; and

(B) in the second sentence, by striking ''the purposes of'' and all that follows through ''Transfer Act,'' and inserting the following: ''the purposes of the Ethics in Government Act of 1978 and the Stevenson-Wydler Technology Innovation Act of 1980,'';

(2) in subsection (b)(2), by striking ''Ethics'' and all that follows and inserting the following: ''Ethics in Government Act of 1978, and the Stevenson-Wydler Technology Innovation Act of 1980.'';

(3) in subsection (c)—

(A) in paragraph (1)—

(i) in subparagraph (A), in the second sentence, by inserting '', except the ex officio members,'' after ''Foundation'';

(ii) in subparagraph (B), in the matter preceding clause (i), by striking ''Council'' and inserting ''Board''; and

(iii) in subparagraph (C), in the first sentence, by striking ''Council'' and inserting ''Board''; and

(B) in paragraph (3)(A), by striking ''paragraph (2)(C)'' and inserting ''paragraph (1)(C)'';

(4) in subsection (g)(8), by striking ''subtitle'' and inserting ''part''; and

(5) in subsection (i)(1), by striking ''1995'' and inserting ''1996''.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

Subtitle A—Office of AIDS Research

SEC. 1801. ESTABLISHMENT OF OFFICE.

(a) IN GENERAL.—Part D of title XXIII of the Public Health Service Act (42 U.S.C. 300cc–41 et seq.) is amended—

(1) by striking the part designation and the heading for the part;

(2) by redesignating section 2351 as section 2354; and

(3) by inserting before section 2354 (as so redesignated) the following:

''PART D—OFFICE OF AIDS RESEARCH

''Subpart I—Interagency Coordination of Activities

''SEC. 2351. ESTABLISHMENT OF OFFICE.

''(a) IN GENERAL.—There is established within the National Institutes of Health an office to be known as the Office of AIDS Research. The Office shall be headed by a director, who shall be appointed by the Secretary.

''(b) DUTIES.—

''(1) INTERAGENCY COORDINATION OF AIDS ACTIVITIES.—With respect to acquired immune deficiency syndrome, the Director of the Office shall plan, coordinate, and evaluate research and other activities conducted or supported by the agencies of the National Institutes of Health.

''(2) CONSULTATIONS.—The Director of the Office shall carry out this subpart (including developing and revising the plan required in section 2353) in consultation with the heads of the agencies of the National Institutes of Health, with the advisory councils of the agencies, and with the advisory council established under section 2352.

''SEC. 2352. ADVISORY COUNCIL.

''(a) IN GENERAL.—The Secretary shall establish an advisory council for the purpose of providing advice to the

Director of the Office on carrying out this part. (Such council is referred to in this section as the 'Advisory Council'.)

''(b) COMPOSITION, COMPENSATION, TERMS, CHAIR, ETC.—Subsections (b) through (g) of section 406 apply to the Advisory Council to the same extent and in the same manner as such subsections apply to advisory councils for the national research institutes, except that, in addition to the ex officio members specified in section 406(b)(2), there shall serve as ex officio members of the Advisory Council the chairs of the advisory councils for each of the National Cancer Institute, the National Institute on Allergy and Infectious Diseases, the National Institute on Drug Abuse, and the National Institute on Mental Health.

''SEC. 2353. COMPREHENSIVE PLAN FOR EXPENDITURE OF APPROPRIATIONS.

''(a) IN GENERAL.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall—

''(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health (which plan shall be first established under this paragraph not later than 12 months after the date of the enactment of the National Institutes of Health Revitalization Act of 1993);

''(2) ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out;

''(3) ensure that the Plan establishes objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

''(4) ensure that all amounts appropriated for such activities are expended in accordance with the Plan;

''(5) review the Plan not less than annually, and revise the Plan as appropriate; and

''(6) ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the Plan.

''(b) CERTAIN COMPONENTS OF PLAN.—With respect to AIDS activities of the agencies of the National Institutes of Health, the Director of the Office shall ensure that the Plan—

''(1) provides for basic research;

''(2) provides for applied research;

''(3) provides for research that is conducted by the agencies;

''(4) provides for research that is supported by the agencies;

''(5) provides for proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

''(6) provides for behavioral research and social sciences research.

''(c) BUDGET ESTIMATES.—

''(1) FULL-FUNDING BUDGET.—

''(A) With respect to a fiscal year, the Director of the Office shall prepare and submit directly to the President, for review and transmittal to the Congress, a budget estimate for carrying out the Plan for the fiscal year, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the advisory council established under section 2352. The budget estimate shall include an estimate of the number and type of personnel needs for the Office.

''(B) The budget estimate submitted under subparagraph (A) shall estimate the amounts necessary for the agencies of the National Insti-

tutes of Health to carry out all AIDS activities determined by the Director of the Office to be appropriate, without regard to the probability that such amounts will be appropriated.

''(2) ALTERNATIVE BUDGETS.—

''(A) With respect to a fiscal year, the Director of the Office shall prepare and submit to the Secretary and the Director of the National Institutes of Health the budget estimates described in subparagraph (B) for carrying out the Plan for the fiscal year. The Secretary and such Director shall consider each of such estimates in making recommendations to the President regarding a budget for the Plan for such year.

''(B) With respect to the fiscal year involved, the budget estimates referred to in subparagraph (A) for the Plan are as follows:

''(i) The budget estimate submitted under paragraph (1).

''(ii) A budget estimate developed on the assumption that the amounts appropriated will be sufficient only for—

''(I) continuing the conduct by the agencies of the National Institutes of Health of existing AIDS activities (if

approved for continuation), and continuing the support of such activities by the agencies in the case of projects or programs for which the agencies have made a commitment of continued support; and

''(II) carrying out, of activities that are in addition to activities specified in subclause (I), only such activities for which the Director determines there is the most substantial need.

''(iii) Such other budget estimates as the Director of the Office determines to be appropriate.

''(d) FUNDING.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out AIDS activities under the Plan, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

''(2) DIRECT RECEIPT BY DIRECTOR OF NATIONAL INSTITUTES OF HEALTH.—For the first fiscal year beginning after the date on which the Plan first established under section 2353(a)(1) has been in effect for 12 months, and for each subsequent fiscal year, the

Director of the National Institutes of Health shall receive directly from the President and the Director of the Office of Management and Budget all funds available for AIDS activities of the National Institutes of Health.

''(3) DISBURSEMENT TO AGENCIES.—

''(A) With respect to the disbursement by the Director of the National Institutes of Health of amounts for carrying out AIDS activities specified in subsection (c)(2)(B)(ii)(I) for the fiscal year involved, the Director shall, to the extent practicable, disburse all of such amounts to the agencies of such Institutes not later than 30 days after the date on which the Director receives amounts under paragraph (2).

''(B) With respect to the disbursement by the Director of the National Institutes of Health of amounts for carrying out AIDS activities of the National Institutes of Health in addition to the activities specified in subparagraph (A) for the fiscal year, the Director shall, to the extent practicable, disburse all of such amounts to the agencies of the National Institutes of Health not later than 90 days after the date on which the

Director receives amounts under paragraph (2).''.

(b) CONFORMING AMENDMENTS.—Section 2354 of the Public Health Service Act, as redesignated by subsection (a)(2) of this section, is amended—

*(1) in the heading for the section, by striking ''**ESTABLISHMENT OF**'' and inserting ''**ADDITIONAL**'';*

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''In carrying out'' and all that follows and inserting the following: ''In carrying out AIDS research, the Director of the Office—'';

(B) by striking paragraphs (1) and (2) and redesignating paragraphs (3) through (8) as paragraphs (1) through (6);

(C) in paragraph (3) (as so redesignated), by striking ''may'' and all that follows in the matter preceding subparagraph (A) and inserting the following: ''may support—'';

(D) in paragraph (5) (as so redesignated)—

(i) in subparagraph (A)—

''(I) by striking ''may'' and all that follows through ''acquire,'' and inserting ''may acquire,''; and

''(II) by striking ''Director'' and all that follows through ''determines'' and inserting ''Director of the Office determines'';

(ii) in subparagraph (B), by striking ''may'' and all that follows through ''make grants'' and inserting ''may make grants''; and

(iii) in subparagraph (C), by striking ''may'' and all that follows through ''acquire,'' and inserting ''may acquire,''; and

(E) in each of paragraphs (2), (3)(A), and (4) (as so redesignated), by striking ''research relating to acquired immune deficiency syndrome'' and inserting ''AIDS research'';

(3) in subsection (b), in the matter preceding paragraph (1), by striking ''The Director'' and all that follows through ''shall'' and inserting ''The Director of the Office shall''; and

(4) in subsection (c), by striking ''the Director'' and all that follows through ''shall'' and inserting ''the Director of the Office shall''.

SEC. 1802. ESTABLISHMENT OF EMERGENCY DISCRETIONARY FUND.

Part D of title XXIII of the Public Health Service Act, as amended by section 1801 of this Act, is amended by adding at the end the following subpart:

''Subpart II—Emergency Discretionary Fund

''SEC. 2356. EMERGENCY DISCRETIONARY FUND.

''(a) IN GENERAL.—

''(1) ESTABLISHMENT.—There is established a fund consisting of such amounts as may be appropriated under subsection (g). Subject to the provisions of this section, the Director of the Office, after consultation with the advisory council established under section 2352, may expend amounts in the Fund for the purpose of conducting and supporting such projects of AIDS research and other AIDS activities as may be authorized in this Act for the National Institutes Health.

''(2) PRECONDITIONS TO USE OF FUND.—Amounts in the Fund may be expended for an AIDS project only if—

''(A) the Director of the Office has made a determination that there is a significant need for the project; and

''(B) as of June 30 of the fiscal year preceding the fiscal year in which the determination is

made, such need was not provided for in any appropriations Act passed by the House of Representatives to make appropriations for the Departments of Labor, Health and Human Services (including the National Institutes of Health), Education, and related agencies for the fiscal year in which the determination is made.

''(3) TWO-YEAR USE OF FUND FOR PROJECT INVOLVED.—In the case of an AIDS project, obligations of amounts in the Fund may not be made for the project after the expiration of the 2-year period beginning on the date on which the initial obligation of such amounts is made for the project.

''(b) PEER REVIEW.—With respect to an AIDS project carried out with amounts in the Fund, this section may not be construed as waiving applicable requirements for peer review.

''(c) LIMITATIONS ON USE OF FUND.—

''(1) CONSTRUCTION OF FACILITIES.—Amounts in the Fund may not be used for the construction, renovation, or relocation of facilities, or for the acquisition of land.

''(2) CONGRESSIONAL DISAPPROVAL OF PROJECTS.—

''(A) Amounts in the Fund may not be expended for the fiscal year involved for an AIDS project, or category of such projects, for which—

''(i)(I) amounts were made available in an appropriations Act for the preceding fiscal year; and

''(II) amounts are not made available in any appropriations Act for the fiscal year involved; or

''(ii) amounts are by law prohibited from being expended.

''(B) A determination under subparagraph (A)(i) of whether amounts have been made available in appropriations Acts for a fiscal year shall be made without regard to whether such Acts make available amounts for the Fund.

''(3) INVESTMENT OF FUND AMOUNTS.—Amounts in the Fund may not be invested.

''(d) APPLICABILITY OF LIMITATION REGARDING NUMBER OF EMPLOYEES.—The purposes for which amounts in the Fund may be expended include the employment of individuals necessary to carry out AIDS projects approved under subsection (a). Any individual employed under the preceding sentence may not be included in any determination of the number of full-time equivalent employees for the

Department of Health and Human Services for the purpose of any limitation on the number of such employees established by law prior to, on, or after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

''(e) REPORT TO CONGRESS.—Not later than February 1 of each fiscal year, the Director of the Office shall 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 on the AIDS projects carried out during the preceding fiscal year with amounts in the Fund. The report shall provide a description of each such project and an explanation of the reasons underlying the use of the Fund for the project.

''(f) DEFINITIONS.—For purposes of this section:

''(1) The term 'AIDS project' means a project described in subsection (a).

''(2) The term 'Fund' means the fund established in subsection (a).

''(g) FUNDING.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing amounts for the Fund, there is authorized to be appropriated $100,000,000 for each of the fiscal years 1994 through 1996.

''(2) AVAILABILITY.—Amounts appropriated for the Fund are available until expended.''.

SEC. 1803. GENERAL PROVISIONS.

Part D of title XXIII of the Public Health Service Act, as amended by section 1802 of this Act, is amended by adding at the end the following subpart:

''Subpart III—General Provisions

''SEC. 2359. GENERAL PROVISIONS REGARDING THE OFFICE.

''(a) ADMINISTRATIVE SUPPORT FOR OFFICE.—The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Office.

''(b) DEFINITIONS.—For purposes of this part:

''(1) The term 'AIDS activities' means AIDS research and other activities that relate to acquired immune deficiency syndrome.

''(2) The term 'AIDS research' means research with respect to acquired immune deficiency syndrome.

''(3) The term 'Office' means the Office of AIDS Research.

''(4) The term 'Plan' means the plan required in section 2353(a)(1).''.

Subtitle B—Certain Programs

SEC. 1811. REVISION AND EXTENSION OF CERTAIN PROGRAMS.

Title XXIII of the Public Health Service Act (42 U.S.C. 300cc et seq.) is amended—

(1) in section 2304(c)(1)—

(A) in the matter preceding subparagraph (A), by inserting after ''Director of such Institute'' the following: ''(and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate)''; and

(B) in subparagraph (A), by inserting before the semicolon the following: '', including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases'';

(2) in section 2311(a)(1), by inserting before the semicolon the following: '', including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases'';

(3) in section 2315—

(A) in subsection (a)(2), by striking ''international research'' and all that follows and inserting ''international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections.''; and

(B) in subsection (f), by striking ''there are authorized'' and all that follows and inserting ''there are authorized to be appropriated such sums as may be necessary for each fiscal year.'';

(4) in section 2318—

(A) in subsection (a)(1)—

(i) by inserting after ''The Secretary'' the following: '', acting through the Director of the National Institutes of Health and after consultation with the Administrator for Health Care Policy and Research,''; and

(ii) by striking ''syndrome'' and inserting ''syndrome, including treatment and prevention of HIV infection and related conditions among women''; and

(B) in subsection (e), by striking ''1991.'' and inserting the following: ''1991, and such

sums as may be necessary for each of the fiscal years 1994 through 1996.'';

(5) in section 2320(b)(1)(A), by striking ''syndrome'' and inserting ''syndrome and the natural history of such infection'';

(6) in section 2320(e)(1), by striking ''there are authorized'' and all that follows and inserting ''there are authorized to be appropriated such sums as may be necessary for each fiscal year.'';

(7) in section 2341(d), by striking ''there are authorized'' and all that follows and inserting ''there are authorized to be appropriated such sums as may be necessary for each fiscal year.''; and

(8) in section 2361, by striking ''For purposes'' and all that follows and inserting the following:

''For purposes of this title:

''(1) The term 'infection', with respect to the etiologic agent for acquired immune deficiency syndrome, includes opportunistic cancers and infectious diseases and any other conditions arising from infection with such etiologic agent.

''(2) The term 'treatment', with respect to the etiologic agent for acquired immune deficiency syndrome, includes primary and secondary prophylaxis.''.

TITLE XIX—STUDIES

SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) THIRD-PARTY PAYMENTS REGARDING CERTAIN CLINICAL TRIALS.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of—

(1) determining the policies of third-party payors regarding the payment of the costs of appropriate health services that are provided incident to the participation of individuals as subjects in clinical trials conducted in the development of drugs with respect to acquired immune deficiency syndrome; and

(2) developing recommendations regarding such policies.

(b) ADVISORY COMMITTEES.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of determining—

(1) whether the activities of the various advisory committees established in the National Institutes of Health regarding acquired immune deficiency syndrome are being coordinated sufficiently; and

(2) whether the functions of any of such advisory committees should be modified in order to achieve greater efficiency.

(c) VACCINES FOR HUMAN IMMUNODEFICIENCY VIRUS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the National Institutes of Health, shall develop a plan for the appropriate inclusion of HIV-infected women, including pregnant women, HIV-infected infants, and HIV-infected children in studies conducted by or through the National Institutes of Health concerning the safety and efficacy of HIV vaccines for the treatment and prevention of HIV infection. Such plan shall ensure the full participation of other Federal agencies currently conducting HIV vaccine studies and require that such studies conform fully to the requirements of part 46 of title 45, Code of Federal Regulations.

(2) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report concerning the plan developed under paragraph (1).

(3) IMPLEMENTATION.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall imple-

ment the plan developed under paragraph (1), including measures for the full participation of other Federal agencies currently conducting HIV vaccine studies.

(4) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

SEC. 1902. MALNUTRITION IN THE ELDERLY.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the National Institute on Aging, coordinating with the Agency for Health Care Policy and Research and, to the degree possible, in consultation with the head of the National Nutrition Monitoring System established under section 1428 of the Food and Agriculture Act of 1977 (7 U.S.C. 3178), shall conduct a 3-year nutrition screening and intervention activities study of the elderly.

(2) EFFICACY AND COST-EFFECTIVENESS OF NUTRITION SCREENING AND INTERVENTION ACTIVITIES.—In conducting the study, the Secretary shall determine the efficacy and cost-effectiveness of nutrition screening and intervention activities conducted

in the elderly health and long-term care continuum, and of a program that would institutionalize nutrition screening and intervention activities. In evaluating such a program, the Secretary shall determine—

(A) if health or quality of life is measurably improved for elderly individuals who receive routine nutritional screening and treatment;

(B) if federally subsidized home or institutional care is reduced because of increased independence of elderly individuals resulting from improved nutritional status;

(C) if a multidisciplinary approach to nutritional care is effective in addressing the nutritional needs of elderly individuals; and

(D) if reimbursement for nutrition screening and intervention activities is a cost-effective approach to improving the health status of elderly individuals.

(3) POPULATIONS.—The populations of elderly individuals in which the study will be conducted shall include populations of elderly individuals who are—

(A) living independently, including—

(i) individuals who receive home and community-based services or family support;

(ii) individuals who do not receive additional services and support;

(iii) individuals with low incomes; and

(iv) individuals who are minorities;

(B) hospitalized, including individuals admitted from home and from institutions; and

(C) institutionalized in residential facilities such as nursing homes and adult homes.

(b) MALNUTRITION STUDY.—The Secretary, acting through the National Institute on Aging, shall conduct a 3-year study to determine the extent of malnutrition in elderly individuals in hospitals and long-term care facilities and in elderly individuals who are living independently.

(c) REPORT.—The Secretary shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives containing the findings resulting from the studies described in subsections (a) and (b), including a determination regarding whether a program that would institutionalize nutrition screening and intervention activities should be adopted, and the rationale for the determination.

(d) ADVISORY PANEL.—

(1) ESTABLISHMENT.—The Secretary, acting through the Director of the National Institute on

Aging, shall establish an advisory panel that shall oversee the design, implementation, and evaluation of the studies described in subsections (a) and (b).

(2) COMPOSITION.—The advisory panel shall include representatives appointed for the life of the panel by the Secretary from the Health Care Financing Administration, the Social Security Administration, the National Center for Health Statistics, the Administration on Aging, the National Council on the Aging, the American Dietetic Association, the American Academy of Family Physicians, and such other agencies or organizations as the Secretary determines to be appropriate.

(3) COMPENSATION AND EXPENSES.—

(A) COMPENSATION.—Each member of the advisory panel who is not an employee of the Federal Government shall receive compensation at the daily equivalent of the rate specified for level V of the Executive Schedule under section 5316 of title 5, United States Code, for each day the member is engaged in the performance of duties for the advisory panel, including attendance at meetings and conferences of the panel, and travel to conduct the duties of the panel.

(B) TRAVEL EXPENSES.—Each member of the advisory panel shall receive travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, for each day the member is engaged in the performance of duties away from the home or regular place of business of the member.

(4) DETAIL OF FEDERAL EMPLOYEES.—On the request of the advisory panel, the head of any Federal agency shall detail, without reimbursement, any of the personnel of the agency to the advisory panel to assist the advisory panel in carrying out its duties. Any detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

(5) TECHNICAL ASSISTANCE.—On the request of the advisory panel, the head of a Federal agency shall provide such technical assistance to the advisory panel as the advisory panel determines to be necessary to carry out its duties.

(6) TERMINATION.—Notwithstanding section 15 of the Federal Advisory Committee Act (5 U.S.C. App.), the advisory panel shall terminate 3 years after the date of enactment of this Act.

SEC. 1903. RESEARCH ACTIVITIES ON CHRONIC FATIGUE SYNDROME.

The Secretary of Health and Human Services shall, not later than May 1, 1993, and annually thereafter for the next 3 years, prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report that summarizes the research activities conducted or supported by the National Institutes of Health concerning chronic fatigue syndrome. Such report should include information concerning grants made, cooperative agreements or contracts entered into, intramural activities, research priorities and needs, and a plan to address such priorities and needs.

SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL AGENTS IN DEVELOPMENT OF DEFENSES AGAINST BIOLOGICAL WARFARE.

The Secretary of Health and Human Services, in consultation with other appropriate executive agencies, shall report to the House Energy and Commerce Committee and the Senate Labor and Human Resources Committee on the appropriateness and impact of the National Institutes of Health assuming responsibility for the conduct of all Federal research, development, testing, and evaluation functions relating to medical countermeasures against biowarfare threat agents. In preparing the report, the Sec-

retary shall identify the extent to which such activities are carried out by agencies other than the National Institutes of Health, and assess the impact (positive and negative) of the National Institutes of Health assuming responsibility for such activities, including the impact under the Budget Enforcement Act and the Omnibus Budget Reconciliation Act of 1990 on existing National Institutes of Health research programs as well as other programs within the category of domestic discretionary spending. The Secretary shall submit the report not later than 12 months after the date of the enactment of this Act.

SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETENTION AND TURNOVER.

(a) STUDY OF PERSONNEL SYSTEM.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study to review the retention, recruitment, vacancy and turnover rates of support staff, including firefighters, law enforcement, procurement officers, technicians, nurses and clerical employees, to ensure that the National Institutes of Health is adequately supporting the conduct of efficient, effective and high quality research for the American public. The Director of NIH shall work in conjunction with appro-

priate employee organizations and representatives in developing such a study.

(b) SUBMISSION TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare 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 containing the study conducted under subsection (a) together with the recommendations of the Secretary concerning the enactment of legislation to implement the results of such study.

SEC. 1906. PROCUREMENT.

(a) IN GENERAL.—The Director of the National Institutes of Health and the Administrator of the General Services Administration shall jointly conduct a study to develop a streamlined procurement system for the National Institutes of Health that complies with the requirements of Federal law.

(b) REPORT.—Not later than March 1, 1994, the officials specified in subsection (a) shall complete the study required in such subsection and shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.

SEC. 1907. CHRONIC PAIN CONDITIONS.

(a) IN GENERAL.—The Director of the National Institutes of Health (in this section referred to as the 'Director'), acting through the Director of the National Institute of Dental Research and as appropriate through the heads of other agenices of such Institutes, shall conduct a study for the purpose of determining the incidence in the United States of cases of chronic pain and the effect of such cases on the costs of health care in the United States.

(b) CERTAIN ELEMENTS OF STUDY.—The cases of chronic pain with respect to which the study required in subsection (a) is conducted shall include reflex sympathetic dystrophy syndrome, temporomandibular joint disorder, post-herpetic neuropathy, painful diabetic neuropathy, phantom pain, and post-stroke pain.

(c) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Director shall complete the study required in subsection (a) and submit to the 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 made as a result of the study.

SEC. 1908. BACK INJURIES.

(a) IN GENERAL.—The Director of the National Institutes of Health, acting through the appropriate national re-

search institute, shall conduct a study of back injuries, with consideration of the following:

(1) Accurate diagnosis, and the appropriate form of treatment.

(2) Providing for return to employment as soon as is practicable.

(3) Minimizing the probability of recurrence.

(4) A comparison of conventional treatments and alternative treatments.

(5) Costs to the health care system.

(6) Costs to the economy generally.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Director of the National Institute of Health 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 made as a result of the study.

TITLE XX—MISCELLANEOUS PROVISIONS

SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RESEARCH SERVICE IN HONOR OF SILVIO O. CONTE; LIMITATION ON NUMBER OF MEMBERS.

(a) IN GENERAL.—Section 228(a) of the Public Health Service Act (42 U.S.C. 237(a)), as added by section 304 of Public Law 101–509, is amended to read as follows:

''(a)(1) There shall be in the Public Health Service a Silvio O. Conte Senior Biomedical Research Service, not to exceed 750 members.

''(2) The authority established in paragraph (1) regarding the number of members in the Silvio O. Conte Senior Biomedical Research Service is in addition to any authority established regarding the number of members in the commissioned Regular Corps, in the Reserve Corps, and in the Senior Executive Service. Such paragraph may not be construed to require that the number of members in the commissioned Regular Corps, in the Reserve Corps, or in the Senior Executive Service be reduced to offset the number of members serving in the Silvio O. Conte Senior Biomedical Research Service (hereafter in this section referred to as the 'Service').''.

(b) CONFORMING AMENDMENT.—Section 228 of the Public Health Service Act (42 U.S.C. 237), as added by section 304 of Public Law 101–509, is amended in the heading for the section by amending the heading to read as follows:

''SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH SERVICE''.

SEC. 2002. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE FOR RESEARCH.

Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall present to the Congress a master plan to provide for the replacement or refurbishment of less than adequate buildings, utility equipment and distribution systems (including the resources that provide electrical and other utilities, chilled water, air handling, and other services that the Secretary, acting through the Director, deems necessary), roads, walkways, parking areas, and grounds that underpin the laboratory and clinical facilities of the National Institutes of Health. Such plan may make recommendations for the undertaking of new projects that are consistent with the objectives of this section, such as encircling the National Institutes of Health Federal enclave with an adequate chilled water conduit.

SEC. 2003. CERTAIN AUTHORIZATION OF APPROPRIATIONS.

Section 399L(a) of the Public Health Service Act (42 U.S.C. 280e–4(a)), as added by Public Law 102–515 (106 Stat. 3376), is amended—

(1) in the first sentence, by striking ''the Secretary'' and all that follows and inserting the following: ''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 1996.''; and

(2) in the second sentence, by striking ''Out of any amounts used'' and inserting ''Of the amounts appropriated under the preceding sentence''.

SEC. 2004. BUY-AMERICAN PROVISIONS.

No funds appropriated pursuant to this Act may be used to fund a grant or contract unless the recipient agrees that substantially all goods and services acquired with such grant or contract assistance will be produced in the United States.

TITLE XXI—EFFECTIVE DATES

SEC. 2101. EFFECTIVE DATES.

Subject to section 165, this Act and the amendments made by this Act take effect upon the date of the enactment of this Act.

SEC. 2005. PROHIBITION AGAINST FURTHER FUNDING FOR PROJECT ARIES.

For fiscal year 1994 and each subsequent fiscal year, the project administered by the University of Washington at Seattle and known as Project Aries may not receive any funding from any agency of the National Institutes of Health, other than payments under awards made for fiscal year 1993 or prior fiscal years.

Attest:

Clerk.

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S 1 EAH——3

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