S. 1

One Hundred Third Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the fifth day of January, one thousand nine hundred and ninety-three

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.

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

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:

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 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 review 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 proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 492 unless the proposal has undergone such 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 funds for the research because of ethical considerations unless—

"(A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and

"(B)(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or

"(ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the report submitted under paragraph (5)(B)(ii), that the recommendation is arbitrary and capricious.

"(2) RULES OF CONSTRUCTION.—Paragraph (1) may not be construed as prohibiting the Secretary from withholding funds for research on the basis of—

"(A) the inadequacy of the qualifications of the entities that would be involved with the conduct of the research (including the entity that would directly receive the funds from the Secretary), subject to the condition that, with respect to the process of review through which the research was recommended for approval for purposes of subsection (a), all findings regarding such qualifications made in such process are conclusive; or

"(B) the priorities established by the Secretary for the allocation of funds among projects of research that have been so recommended.

"(3) APPLICABILITY.—The limitation established in paragraph (1) regarding the authority to withhold funds because of ethical considerations shall apply without regard to whether the withholding of funds on such basis is characterized as a disapproval, a moratorium, a prohibition, or other characterization.

"(4) 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.

"(5) ETHICS ADVISORY BOARDS.—

"(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (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 biomedical 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 (4)(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.

"(6) DEFINITION.—For purposes of this subsection, the term 'ethical considerations' means considerations as to whether the

nature of the research involved is such that it is unethical to conduct or support the research.''.

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 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 statement, 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 still-birth; 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 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.—Subject to subsection (b)(2) of section 492A of the Public Health Service Act (as added by section 101 of this Act), 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 subsection (a) of such section 492A;

(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)(5)(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 the nature of the research is such that it is not unethical to conduct or support 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 purposes, the Comptrol-

ler 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 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 are being 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 prepare biennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved for inclusion in the biennial report under section 403.

"(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 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. INAPPLICABILITY 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 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 (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 (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 Institutes, 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 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.

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) IN GENERAL.—

"(1) ESTABLISHMENT OF OFFICE.—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 (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) APPOINTMENT OF 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.

"(3) DEFINITIONS.—

"(A) The Secretary shall by regulation establish a definition for the term 'research misconduct' for purposes of this section.

"(B) For purposes of this section, the term 'financial assistance' means a grant, contract, or cooperative agreement.

"(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS CONDITION OF FUNDING FOR RESEARCH.—The Secretary shall by regulation

require that each entity that applies for financial assistance 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 assistance—

"(1) assurances satisfactory to the Secretary that such entity has established and has in effect (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;

"(2) an agreement that the entity 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; and

"(3) an agreement that the entity will comply with regulations issued under this section.

"(c) PROCESS FOR RESPONSE OF DIRECTOR.—The Secretary shall by regulation establish 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.".

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;

(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 paragraph (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 subsection:

"(e) 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 by regulation establish 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 retaliation 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.".

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.—The Secretary shall by regulation define 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 subsection (b), 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.

"(b) RELEVANT PROJECTS.—A project of research referred to in subsection (a) 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.

"(c) IDENTIFYING AND REPORTING TO SECRETARY.—The Secretary shall by regulation require that each entity described in subsection (a) that applies for assistance under this Act for any project described in subsection (b) submit in or with its application for such assistance—

"(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under subsection (a) to identify financial interests (as defined under subsection (a)) that exist regarding the project; and

"(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

"(3) an agreement that the entity will comply with regulations issued under this section.

"(d) MONITORING OF PROCESS.—The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a).

"(e) RESPONSE.—In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), the Secretary—

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

"(2) may take such other actions as the Secretary determines to be appropriate.

"(f) DEFINITIONS.—For purposes of this section:

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

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

SEC. 165. REGULATIONS.

(a) ISSUANCE OF FINAL RULES.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall, subject to paragraph (2), issue the final rule for each regulation required in section 493 or 493A of the Public Health Service Act.

(2) DEFINITION OF RESEARCH MISCONDUCT.—Not later than 90 days after the date on which the report required in section 162(e) is submitted to the Secretary, the Secretary shall issue the final rule for the regulations required in section 493 of the Public Health Service Act with respect to the definition of the term "research misconduct".

(b) APPLICABILITY TO ONGOING INVESTIGATIONS.—The final rule issued pursuant to subsection (a) for investigations under section 493 of the Public Health Service Act does not apply to investigations commenced before the date of the enactment of this Act under authority of such section as in effect before such date.

(c) DEFINITIONS.—For purposes of this section:

(1) The term "section 493 of the Public Health Service Act" means such section as amended by sections 161 and 163 of this Act, except as indicated otherwise in subsection (b).

(2) The term "section 493A of the Public Health Service Act" means such section as added by section 164 of this Act.

(3) The term "Secretary" means the Secretary of Health and Human Services.

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 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 preparation 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 AND SOCIAL SCIENCES RESEARCH.

(a) IN GENERAL.—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 section:

"OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES 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 and Social Sciences 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—

"(A) coordinate research conducted or supported by the agencies of the National Institutes of Health; and

"(B) identify projects of behavioral and social sciences research that should be conducted or supported by the national research institutes, and develop such projects in cooperation with such institutes.

"(2) Research authorized under paragraph (1) includes research on teen pregnancy, infant mortality, violent behavior, suicide, and homelessness. Such research does not include neurobiological research, or research in which the behavior of an organism is observed for the purpose of determining activity at the cellular or molecular level.".

(b) REPORT.—Not later than February 1, 1994, the Director of the Office of Behavioral and Social Sciences Research (established in section 404A of the Public Health Service Act, as added by

subsection (a) of this section) 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 extent to which the national research institutes of the National Institutes of Health conduct and support behavioral research and social sciences research. In preparing the report, such Director shall (subject to subsection (b)(2) of such section 404A) state the definitions used in the report for the terms "behavioral research" and "social sciences research", and shall apply the definitions uniformly to such institutes for purposes of the report.

(c) EFFECTIVE DATES.—The amendment described in subsection (a) is made upon the date of the enactment of this Act and takes effect July 1, 1993. Subsection (b) takes effect on such date.

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 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 contacts 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 $20,000,000 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 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 (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, which representatives shall include not less than one veterinarian with expertise in laboratory-animal medicine.''.

(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 subsection:

"(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) 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 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 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 alternative medical treatment modalities, including acupuncture and Oriental medicine, homeopathic medicine, and physical manipulation therapies.

"(c) The Secretary shall establish an advisory council for the purpose of providing advice to the Director of the Office on carrying out this section. Section 222 applies to such council to the same extent and in the same manner as such section applies to committees or councils established under such section.

"(d) 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)(A) prepare biennial reports on the activities carried out or to be carried out by the Office; and

"(B) submit each such report to the Director of NIH for inclusion in the biennial report under section 403.".

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 the following paragraph:

"(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded by the National Institutes of Health and intended for the general public are 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 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 subparagraph:

"(C) shall, subject to section 2353(d)(2), 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 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, the National Institute of Dental Research, and the National Institute of Diabetes and 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 related 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 (in this section referred to as the 'Director'), shall establish a comprehensive program of conducting basic and clinical research on trauma (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 December 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 (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 subsection:

"(k) The Director of NIH shall carry out the program established in part F 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 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 support 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 October 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 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 October 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 section:

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 417B. (a) ACTIVITIES GENERALLY.—For the purpose of carrying out this subpart, there are authorized to be appropriated $2,728,000,000 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)".

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 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 the following 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 RESEARCH.

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 section:

''NATIONAL CENTER ON SLEEP DISORDERS RESEARCH

''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 Research (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—

''(1) the conduct and support of research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep, chronobiological and other sleep related research; and

''(2) to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes of Health, and similar activities of other public entities and nonprofit entities.

''(c)(1) The Director of the National Institutes of Health shall establish a board to be known as the Sleep Disorders Research Advisory Board (in this section referred to as the 'Advisory Board').

''(2) The Advisory Board shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health, through the Director of the Institute, and the Director of the Center concerning matters relating to the scientific activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in subsection (c).

''(3)(A) The Director of the National Institutes of Health shall appoint to the Advisory Board 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, eight shall be representatives of health and scientific disciplines with respect to sleep disorders and four shall be individuals representing the interests of individuals with or undergoing treatment for sleep disorders.

''(B) The following officials shall serve as ex officio members of the Advisory Board:

''(i) The Director of the National Institutes of Health.

''(ii) The Director of the Center.

''(iii) The Director of the National Heart, Lung and Blood Institute.

''(iv) The Director of the National Institute of Mental Health.

''(v) The Director of the National Institute on Aging.

''(vi) The Director of the National Institute of Child Health and Human Development.

''(vii) The Director of the National Institute of Neurological Disorders and Stroke.

''(viii) The Assistant Secretary for Health.

''(ix) The Assistant Secretary of Defense (Health Affairs).

''(x) The Chief Medical Director of the Veterans' Administration.

"(4) The members of the Advisory Board shall, from among the members of the Advisory Board, designate an individual to serve as the chair of the Advisory Board.

"(5) Except as inconsistent with, or inapplicable to, this section, the provisions of section 406 shall apply to the advisory board established under this section in the same manner as such provisions apply to any advisory council established under such section.

"(d)(1) After consultation with the Director of the Center and the advisory board established under subsection (c), the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of sleep disorders research.

"(2) The plan developed under paragraph (1) shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

"(3) The Director of the National Institutes of Health (after consultation with the Director of the Center and the advisory board established under subsection (c)) shall revise the plan developed under paragraph (1) as appropriate.

"(e) The Director of the Center, in cooperation with the Centers for Disease Control and Prevention, is authorized to coordinate activities with the Department of Transportation, the Department of Defense, the Department of Education, the Department of Labor, and the Department of Commerce to collect data, conduct studies, and disseminate public information concerning the impact of sleep disorders and sleep deprivation.".

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.".

SEC. 505. PREVENTION AND CONTROL PROGRAMS.

Section 419 of the Public Health Service Act (42 U.S.C. 285b–1) is amended by striking "The Director of the Institute" and all that follows and inserting the following: "(a) The Director of the Institute shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

"(b) In carrying out programs under subsection (a), the Director of the Institute shall give special consideration to the prevention and control of heart, blood vessel, lung, and blood diseases in children, and in populations that are at increased risk with respect to such diseases.".

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 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 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 the following 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 the following subsection:

"(f) Not later than October 1, 1993, 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, control, 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 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 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 (in this section referred to as the 'Council')"; and

(2) by adding at the end the following 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 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 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 devices 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 contracts with qualified health professionals (including graduate students) under which such health professionals agree to conduct research with respect to contraception, 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, except as inconsistent with subsection (a) of this section, 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 available 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 made available.".

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 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 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 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 extent 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 compo-

nent 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 AND HEALTH SERVICES RESEARCH ON EYE CARE AND DIABETES.

(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 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 research grants to one or more Diabetes Eye Research Institutions for the support of programs in clinical or health services aimed at—

"(1) providing comprehensive eye care services for people with diabetes, including a full complement of preventive, diagnostic and treatment procedures;

"(2) developing new and improved techniques of patient care through basic and clinical research;

"(3) assisting in translation of the latest research advances into clinical practice; and

"(4) expanding the knowledge of the eye and diabetes through further research.

"(b) USE OF FUNDS.—Amounts received under a grant awarded under this section shall be used for the following:

"(1) Establishing the biochemical, cellular, and genetic mechanisms associated with diabetic eye disease and the earlier detection of pending eye abnormalities. The focus of work under this paragraph shall require that ophthalmologists have training in the most up-to-date molecular and cell biological methods.

"(2) Establishing new frontiers in technology, such as video-based diagnostic and research resources, to—

"(A) provide improved patient care;

"(B) provide for the evaluation of retinal physiology and its affect on diabetes; and

"(C) provide for the assessment of risks for the development and progression of diabetic eye disease and a more immediate evaluation of various therapies aimed at preventing diabetic eye disease.

Such technologies shall be designed to permit evaluations to be performed both in humans and in animal models.

"(3) The translation of the results of vision research into the improved care of patients with diabetic eye disease. Such translation shall require the application of institutional resources that encompass patient care, clinical research and basic laboratory research.

"(4) The conduct of research concerning the outcomes of eye care treatments and eye health education programs as they relate to patients with diabetic eye disease, including the evaluation of regional approaches to such research.

"(c) AUTHORIZED EXPENDITURES.—The purposes for which a grant under subsection (a) may be expended include equipment for the research described in such subsection.".

(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 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 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: ''(in this subpart referred to as the 'Institute')''.

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 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–5(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 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 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 (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 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 (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 paragraph (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 (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 Director 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 whose population includes a significant number of individuals with a health-status deficit, and the applicant provides health services to such individuals; 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 subsection (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 regulations, 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 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(h) $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 (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 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 18 months after the date of the enactment of this Act, 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 subparagraph:

"(D) The National Center for Human Genome Research."; and

(2) in part E, by adding at the end the following 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 (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 (including legal issues regarding patents).

"(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 (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.".

SEC. 1602. SERVICE PAYBACK REQUIREMENTS.

Section 487(c) of the Public Health Service Act (42 U.S.C. 288(c)) is amended by striking paragraphs (1) and (2) and inserting the following: "(1) Each individual who is awarded a National Research Service Award for postdoctoral research training shall, in accordance with paragraph (3), engage in research training, research, or teaching that is health-related (or any combination thereof) for the period specified in paragraph (2). Such period shall be served in accordance with the usual patterns of scientific employment.

"(2)(A) The period referred to in paragraph (1) is 12 months, or one month for each month for which the individual involved receives a National Research Service Award for postdoctoral research training, whichever is less.

"(B) With respect to postdoctoral research training, in any case in which an individual receives a National Research Service Award for more than 12 months, the 13th month and each subsequent month of performing activities under the Award shall be considered to be activities engaged in toward satisfaction of the requirement established in paragraph (1) regarding a period of service.".

Subtitle B—Acquired Immune Deficiency Syndrome

SEC. 1611. LOAN REPAYMENT PROGRAM.

(a) IN GENERAL.—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.—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.

"(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, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.".

(b) APPLICABILITY.—The amendment made by subsection (a) does not apply to any agreement entered into under section 487A of the Public Health Service Act before the date of the enactment of this Act. Each such agreement continues to be subject to the terms of the agreement in effect on the day before such date.

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 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 contracts 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.".

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 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 appropriate 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 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. NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH.

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) by inserting ", acting through the Director of NIH," after "Secretary shall"; and

(B) by striking ", except for" and all that follows through "Transfer Act,";

(2) by redesignating subsections (c), (d), (e), (f), (g), (h), and (i) as subsections (d), (f), (g), (h), (i), (j), and (m), respectively;

(3) by striking subsection (b) and inserting the following subsections:

"(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to support the National Institutes of Health in its mission, and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

"(c) CERTAIN ACTIVITIES OF FOUNDATION.—

"(1) IN GENERAL.—In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in sup-

port of the following activities with respect to the purpose described in such subsection:

"(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

"(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

"(C) Supplementary programs to provide for—

"(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health officials in the United States to serve in such capacities in other countries, or both;

"(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

"(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

"(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

"(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

"(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

"(2) FEES.—The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

"(3) AUTHORITY OF FOUNDATION.—The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.";

(4) in subsection (d) (as so redesignated)—

(A) in paragraph (1)—

(i) by striking "members of the Foundation" in subparagraph (A) and inserting "appointed members of the Board";

(ii) by striking "Council" in subparagraph (B) and inserting "Board";

(iii) by striking "Council" in subparagraph (C) and inserting "Board"; and

(iv) by adding at the end the following subparagraphs:

"(D)(i) Not later than 30 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

"(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the Foundation; and

"(II) appoint the members of the Board in accordance with subparagraph (C).

"(ii) Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

"(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

"(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

"(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of members of the Board shall be greater than the number specified in subparagraph (C).";

(B) in paragraph (2)—

(i) by striking "The ex officio" and inserting the following:

"(A) The ex officio";

(ii) by striking "an appointed member of the Board to serve as the Chair" and inserting "an individual to serve as the initial Chair"; and

(iii) by adding at the end the following subparagraph:

"(B) Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chair of the Board.";

(C) in paragraph (3)(A), by striking "(2)(C)" and inserting "(1)(C)"; and

(D) by adding at the end the following paragraphs:

"(5) MEETINGS AND QUORUM.—A majority of the members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

"(6) CERTAIN BYLAWS.—

"(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

"(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

"(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

"(iii) Policies for the conduct of the general operations of the Foundation.

"(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

"(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

"(i) reflect unfavorably upon the ability of the Foundation or the National Institutes of Health to carry out its responsibilities or official duties in a fair and objective manner; or

"(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.";

(5) in subsection (i) (as so redesignated)—

(A) in paragraph (4), by inserting ", and define the duties of the officers and employees" before the semicolon at the end;

(B) by striking paragraph (5);

(C) by redesignating paragraphs (6) through (14), as paragraphs (5) through (13), respectively;

(D) in paragraph (7) (as so redesignated), by striking "this subtitle" and inserting "this part";

(E) by striking paragraph (8) (as so redesignated), and inserting the following paragraph:

"(8) establish a process for the selection of candidates for positions under subsection (c);"

(F) by inserting "solicit" after the paragraph designation in paragraph (11) (as so redesignated);

(G) by striking "and" at the end of paragraph (13) (as so redesignated);

(H) by inserting after paragraph (13) (as so redesignated), the following paragraph:

"(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and"; and

(I) in paragraph (15), by striking "this subtitle" and inserting "this part";

(6) by inserting after subsection (j) (as so redesignated), the following subsections:

"(k) GENERAL PROVISIONS.—

"(1) FOUNDATION INTEGRITY.—The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct (including those developed under subsection (d)(2)(B)(i)(II)), financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

"(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(2)(B)(i)(II)) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

"(3) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

"(A) provide for annual audits of the financial condition of the Foundation; and

"(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

"(4) REPORTS.—

"(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation.

"(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

"(C) The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

"(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

"(5) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying

out its function, so long as the employees do not direct or control Foundation activities.

"(6) RELATIONSHIP WITH EXISTING ENTITIES.—The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation, such as the Foundation for Advanced Education in the Sciences.

"(7) INTELLECTUAL PROPERTY RIGHTS.—The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

"(8) NATIONAL INSTITUTES OF HEALTH AMENDMENTS OF 1990.—The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101–613), and the amendments made by such Act, shall not be nullified by the enactment of this section.

"(9) LIMITATION OF ACTIVITIES.—The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

"(10) TRANSFER OF FUNDS.—The Foundation may not transfer funds to the National Institutes of Health.

"(l) DUTIES OF THE DIRECTOR.—

"(1) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of the National Institutes of Health, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of the National Institutes of Health determines is appropriate.

"(2) SUPPORT SERVICES.—The Director of the National Institutes of Health may provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health.";

(7) in subsection (m) (as so redesignated), by amending the subsection to read as follows:

"(m) FUNDING.—

"(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there is authorized to be appropriated an aggregate $200,000 for the fiscal years 1994 and 1995.

"(2) LIMITATION REGARDING OTHER FUNDS.—Amounts appropriated under any provision of law other than paragraph (1) may not be expended to establish or operate the Foundation."; and

(8) by adding at the end the following subsection:

"(n) REPORT ON ADEQUACY OF COMPLIANCE.—

"(1) IN GENERAL.—With respect to the mission and function of the Foundation, the Comptroller General of the United States shall conduct an audit to determine—

"(A) whether the Foundation is in compliance with the guidelines established under this section; and

"(B) whether the procedures utilized under this section are adequate to prevent conflicts of interest involving the Foundation, the employees of the Foundation or members of the Board of the Foundation.

"(2) REPORT.—Not later than 18 months after the date on which the Foundation is incorporated, the Comptroller General of the United States shall complete the audit required under paragraph (1) and 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 describing the findings made with respect to such audit.".

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. In carrying out the preceding sentence, the Director of the Office shall evaluate the AIDS activities of each of such agencies and shall provide for the periodic reevaluation of such activities.

"(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.

"(3) COORDINATION.—The Director of the Office shall act as the primary Federal official with responsibility for overseeing all AIDS research conducted or supported by the National Institutes of Health, and

"(A) shall serve to represent the National Institutes of Health AIDS Research Program at all relevant Executive branch task forces and committees; and

"(B) shall maintain communications with all relevant Public Health Service agencies and with various other departments of the Federal Government, to ensure the timely transmission of information concerning advances in AIDS research and the clinical treatment of acquired immune deficiency syndrome and its related conditions, between these various agencies for dissemination to affected communities and health care providers.

"SEC. 2352. ADVISORY COUNCIL; COORDINATING COMMITTEES.

"(a) ADVISORY COUNCIL.—

"(1) 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 subsection as the 'Advisory Council'.)

"(2) 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—

"(A) in addition to the ex officio members specified in section 406(b)(2), there shall serve as such members of the Advisory Council a representative from the advisory council of each of the National Cancer Institute and the National Institute on Allergy and Infectious Diseases; and

"(B) with respect to the other national research institutes, there shall serve as ex officio members of such Council, in addition to such members specified in subparagraph (A), a representative from the advisory council of each of the 2 institutes that receive the greatest funding for AIDS activities.

"(b) INDIVIDUAL COORDINATING COMMITTEES REGARDING RESEARCH DISCIPLINES.—

"(1) IN GENERAL.—The Director of the Office shall establish, for each research discipline in which any activity under the plan required in section 2353 is carried out, a committee for the purpose of providing advice to the Director of the Office on carrying out this part with respect to such discipline. (Each such committee is referred to in this subsection as a 'coordinating committee'.)

"(2) COMPOSITION.—Each coordinating committee shall be composed of representatives of the agencies of the National Institutes of Health with significant responsibilities regarding the research discipline involved.

"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 Institutes 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) RECEIPT OF FUNDS.—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 Office 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) ALLOCATIONS FOR AGENCIES.—

"(A) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out the AIDS activities specified in subsection (c)(2)(B)(ii)(I) for such year. Such allocation shall, to the extent practicable, be made not later than 15 days after the date on which the Director receives amounts under paragraph (2).

"(B) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out AIDS

activities that are not referred to in subparagraph (A). Such allocation shall, to the extent practicable, be made not later than 30 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 AIDS activities, including projects of AIDS research, as may be authorized in this Act for the National Institutes of Health.

"(2) PRECONDITIONS TO USE OF FUND.—Amounts in the Fund may be expended only if—

"(A) the Director identifies the particular set of AIDS activities for which such amounts are to be expended;

"(B) the set of activities so identified constitutes either a new project or additional AIDS activities for an existing project;

"(C) the Director of the Office has made a determination that there is a significant need for such set of activities; and

"(D) 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 identified set of AIDS activities, obligations of amounts in the Fund may not be made for such set of activities after the expiration of the 2-year period beginning on the date on which the initial obligation of such amounts is made for such set.

"(b) PEER REVIEW.—With respect to an identified set of AIDS activities 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 identified set of AIDS activities, or a category of AIDS activities, 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 identified sets of AIDS activities 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 identified sets of AIDS activities carried out during the preceding fiscal year with amounts in the Fund. The report shall provide a description of each such set of activities and an explanation of the reasons underlying the use of the Fund for the set.

"(f) DEFINITIONS.—For purposes of this section:

"(1) The term 'Fund' means the fund established in subsection (a).

"(2) The term 'identified set of AIDS activities' means a particular set of AIDS activities identified under subsection (a)(2)(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 and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

"(b) EVALUATION AND REPORT.—

"(1) EVALUATION.—Not later than 5 years after the date of the enactment of National Institutes of Health Revitalization Act of 1993, the Secretary shall conduct an evaluation to—

"(A) determine the effect of this section on the planning and coordination of the AIDS research programs at the institutes, centers and divisions of the National Institutes of Health;

"(B) evaluate the extent to which this part has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

"(C) provide recommendations concerning future alterations with respect to this part.

"(2) REPORT.—Not later than 1 year after the date on which the evaluation is commenced under paragraph (1), the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of such evaluation.

"(c) 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. LIFE-THREATENING ILLNESSES.

(a) THIRD-PARTY PAYMENTS REGARDING CERTAIN CLINICAL TRIALS AND CERTAIN LIFE-THREATENING ILLNESSES.—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, cancer, and other life-threatening illnesses; and

(2) developing recommendations regarding such policies.

(b) 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 implement the plan developed under paragraph (1), including measures for the full participation of other Federal agencies currently conducting HIV vaccine studies.

(4) AUTHORIZATION OF APPROPRIATIONS.—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 and Related Research Program established by section 5311(a) of Public Law 101–445 (7 U.S.C. 5301 et seq.), 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 for each day engaged in carrying out the duties of the panel, 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.

(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 October 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 the Secretary of Defense and with the heads of 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 Secretary of Health and Human Services 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. Such Secretary shall submit the report not later than 12 months after the date of the enactment of this Act. The Secretary shall provide a copy of the report to the House and Senate Committees on Armed Services.

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 appropriate 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 agencies of such Institutes, shall conduct a study for the purpose of determining the incidence in the United States of cases of chronic pain (including chronic pain resulting from back injuries) 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 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. RELATIONSHIP BETWEEN THE CONSUMPTION OF LEGAL AND ILLEGAL DRUGS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall review and consider all existing relevant data and research concerning whether there is a relationship between an individual's receptivity to use or consume legal drugs and the consumption or abuse by the individual of illegal drugs. On the basis of such review, the Secretary shall determine whether additional research is necessary. If the Secretary determines additional research is required, the Secretary shall conduct a study of those subjects where the Secretary's review indicates additional research is needed, including, if necessary, a review of—

(1) the effect of advertising and marketing campaigns that promote the use of legal drugs on the public;

(2) the correlation of legal drug abuse with illegal drug abuse; and

(3) other matters that the Secretary determines appropriate.

(b) REPORT.—Not later than 12 months after the date of enactment of this Act, the Secretary shall prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and Committee on Labor and Human Resources of the Senate, a report containing the results of the review conducted under subsection (b). If the Secretary determines additional research is required, no later than 2 years after the date of enactment of this Act, the Secretary shall prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and Committee on Labor and Human Resources of the Senate, a report containing the results of the additional research conducted under subsection (b).

SEC. 1909. REDUCING ADMINISTRATIVE HEALTH CARE COSTS.

The Secretary of Health and Human Services, acting through the Agency for Health Care Policy and Research and, to the extent possible, in consultation with the Health Care Financing Administration, may fund research to develop a text-based standardized billing process, through the utilization of text-based information retrieval and natural language processing techniques applied to automatic coding and analysis of textual patient discharge summaries and other text-based electronic medical records, within a parallel general purpose (shared memory) high performance computing environment. The Secretary shall determine whether such a standardized approach to medical billing, through the utilization of the text-based hospital discharge summary as well as electronic patient records can reduce the administrative billing costs of health care delivery.

SEC. 1910. SENTINEL DISEASE CONCEPT STUDY.

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

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

(c) REPORT.—Not later than 4 years after the date of enactment of this Act, the Director of the National Institutes of Health shall prepare and submit to the appropriate committees of Congress, a report concerning the results of the study conducted under subsection (a).

SEC. 1911. POTENTIAL 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-control study to assess biological markers of environmental and other potential 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, 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 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).

SEC. 1912. SUPPORT FOR BIOENGINEERING RESEARCH.

(a) STUDY.—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 sources and amounts of public and private funding devoted to basic research in bioengineering, including biomaterials sciences, cellular bioprocessing, tissue and rehabilitation engineering;

(2) evaluating whether that commitment is sufficient to maintain the innovative edge that the United States has in these technologies;

(3) evaluating the role of the National Institutes of Health or any other Federal agency to achieve a greater commitment to innovation in bioengineering; and

(4) evaluating the need for better coordination and collaboration among Federal agencies and between the public and private sectors.

In conducting such study, the Director shall work in conjunction with appropriate organizations and representatives including academics, industry leaders, bioengineering societies, and public agencies.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report containing the findings of the study conducted under subsection (a) together with recommendations concerning the enactment of legislation to implement the results of such study.

SEC. 1913. COST OF CARE IN LAST 6 MONTHS OF LIFE.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Agency for Health Care Policy and Research and, to the degree possible, in consultation with the Health Care Financing Administration, shall conduct a study, using the most recent National Medical Expenditure Survey database, to estimate the average amount of health care expenditures incurred during the last 6 months of life by—

(A) the population of individuals who are 65 years of age and older; and

(B) the total population, broken down based on noninstitutionalized and institutionalized populations.

(2) ELEMENTS OF STUDY.—The study conducted under paragraph (1) shall—

(A) be designed in a manner that will produce estimates of health care costs expended for health care provided to individuals during the last 6 months of life;

(B) be designed to produce estimates of such costs for the populations identified in subparagraphs (A) and (B) of paragraph (1);

(C) include a calculation of the estimated amount of total health care expenditures during such periods of time; and

(D) include a calculation of the estimate described in subparagraph (C)—

(i) as a percentage of the total national health care expenditures; and

(ii) for those age 65 years and over, as a percentage of the total Medicare expenditures for those age 65 years and over.

(b) REPORT.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report containing the findings resulting from the study described in subsection (a).

(c) 1996 NATIONAL MEDICAL EXPENDITURE SURVEY.—

(1) IN GENERAL.—The Secretary, acting through the Agency for Health Care Policy and Research, shall ensure that the 1996 National Medical Expenditure Survey is designed in a manner that will produce an estimate of the amount expended for health care provided to individuals during the last 6 months of life.

(2) POPULATIONS.—In designing the Survey under paragraph (1), the Secretary shall ensure that such Survey produces the data required under such paragraph for the population

of individuals who are 65 years of age or older, broken down based on noninstitutionalized and institutionalized populations.

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 500 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 (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 June 1, 1994, 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.

(a) COMPLIANCE WITH BUY AMERICAN ACT.—No funds appropriated pursuant to this Act for any of the fiscal years 1994 through 1996 may be expended by an entity unless the entity agrees that in expending the assistance the entity will comply with sections 2 through 4 of the Act of March 3, 1933 (41 U.S.C. 10a–10c, popularly known as the "Buy American Act").

(b) SENSE OF CONGRESS; REQUIREMENT REGARDING NOTICE.—

(1) PURCHASE OF AMERICAN-MADE EQUIPMENT AND PRODUCTS.—In the case of any equipment or product that may be authorized to be purchased with financial assistance provided pursuant to this Act for any of the fiscal years 1994 through 1996, it is the sense of the Congress that entities receiving such assistance should, in expending the assistance, purchase only American-made equipment and products.

(2) NOTICE TO RECIPIENTS OF ASSISTANCE.—In providing financial assistance pursuant to this Act, the Secretary of Health and Human Services shall provide to each recipient of the assistance a notice describing the statement made in paragraph (1) by the Congress.

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) unless—

(1) the proposal for funding for the project has undergone review in accordance with the applicable requirements of section 491 of the Public Health Service Act on restrictions regarding institutional review boards and ethics guidance;

(2) the proposal for funding for the project has undergone review in accordance with the applicable requirements of section 492 of such Act on restrictions regarding peer review;

(3) the Secretary of Health and Human Services, in accordance with section 492A of such Act (as added by section 101 of this Act), makes a determination that the project will assist—

(A) in reducing the incidence of infection with the human immunodeficiency virus;

(B) in reducing the incidence of sexually transmitted diseases; or

(C) in reducing the incidence of tuberculosis; and

(4) the data to be collected through the project cannot be obtained in any other manner.

SEC. 2006. LOAN REPAYMENT PROGRAM.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.), as amended by Public Law 101–635, is amended—

(1) by redesignating the second section 903 as section 904; and

(2) by adding at the end the following section:

"SEC. 905. LOAN REPAYMENT PROGRAM.

"(a) IN GENERAL.—

"(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the Food and Drug Administration, 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 Food and Drug Administration 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 of the Public Health Service Act, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

"(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.".

SEC. 2007. EXCLUSION OF ALIENS INFECTED WITH THE AGENT FOR ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) EXCLUSION OF ALIENS ON HEALTH-RELATED GROUNDS.—Section 212(a)(1)(A)(i) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(1)(A)(i)) is amended by adding at the end the following: "which shall include infection with the etiologic agent for acquired immune deficiency syndrome,".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 30 days after the date of the enactment of this Act.

SEC. 2008. TECHNICAL CORRECTIONS.

(a) TITLE III.—Section 316 of the Public Health Service Act (42 U.S.C. 247a(c)) is amended by striking subsection (c).

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

(1) in section 406—

(A) in subsection (b)(2)(A), by striking "Veterans' Administration" each place such term appears and inserting "Department of Veterans Affairs"; and

(B) in subsection (h)(2)(A)(v), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(2) in section 408, in subsection (b) (as redesignated by section 501(c)(1)(C) of this Act), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(3) in section 421(b)(1), by inserting a comma after "may";

(4) in section 428(b), in the matter preceding paragraph (1), by striking "the the" and inserting "the";

(5) in section 430(b)(2)(A)(i), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(6) in section 439(b), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(7) in section 442(b)(2)(A), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(8) in section 464D(b)(2)(A), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(9) in section 464E—

(A) in subsection (d), in the first sentence, by inserting "Coordinating" before "Committee"; and

(B) in subsection (e), by inserting "Coordinating" before "Committee" the first place such term appears;

(10) in section 464P(b)(6) (as added by section 123 of Public Law 102–321 (106 Stat. 362)), by striking "Administration" and inserting "Institute";

(11) in section 466(a)(1)(B), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(12) in section 480(b)(2)(A), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(13) in section 485(b)(2)(A), by striking "Veterans' Administration" and inserting "Department of Veterans Affairs";

(14) in section 487(d)(3), by striking "section 304(a)(3)" and inserting "section 304(a)"; and

(15) in section 496(a), by striking "Such appropriations," and inserting the following: "Appropriations to carry out the purposes of this title,".

(c) TITLE XV.—

(1) LIMITED AUTHORITY REGARDING FOR-PROFIT ENTITIES.—Section 1501(b) of the Public Health Service Act (42 U.S.C. 300k(b)) is amended—

(A) by striking "STATES.—A State" and all that follows through "may expend" and inserting the following: "STATES.—

"(1) IN GENERAL.—A State receiving a grant under subsection (a) may, subject to paragraph (2), expend"; and

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

"(2) LIMITED AUTHORITY REGARDING OTHER ENTITIES.—In addition to the authority established in paragraph (1) for a State with respect to grants and contracts, the State may provide for screenings under subsection (a)(1) through entering into contracts with private entities. The amount paid by a State to a private entity under the preceding sentence for a screening procedure may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act if payment were made under such part for furnishing the procedure to a woman enrolled under such part.".

(2) CONFORMING AMENDMENT.—Section 1505(3) of the Public Health Service Act (42 U.S.C. 300n–1(3)) is amended by inserting before the semicolon the following: "(and additionally,

in the case of services and activities under section 1501(a)(1), with any similar services or activities of private entities)".

(d) TITLE XXIII.—Part A of title XXIII of the Public Health Service Act (42 U.S.C. 300cc et seq.) is amended—

(1) in section 2304—

(A) in the heading for the section, by striking "**CLINICAL RESEARCH REVIEW COMMITTEE**" and inserting "**RESEARCH ADVISORY COMMITTEE**"; and

(B) in subsection (a), by striking "AIDS Clinical Research Review Committee" and inserting "AIDS Research Advisory Committee";

(2) in section 2312(a)(2)(A), by striking "AIDS Clinical Research Review Committee" and inserting "AIDS Research Advisory Committee";

(3) in section 2314(a)(1), in the matter preceding subparagraph (A), by striking "Clinical Research Review Committee" and inserting "AIDS Research Advisory Committee";

(4) in section 2317(d)(1), by striking "Clinical Research Review Committee" and inserting "AIDS Research Advisory Committee established under section 2304"; and

(5) in section 2318(b)(3), by striking "Clinical Research Review Committee" and inserting "AIDS Research Advisory Committee".

(e) SECRETARY.—Section 2(c) of the Public Health Service Act (42 U.S.C. 201(c)) is amended by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

(f) DEPARTMENT.—Section 201 of the Public Health Service Act (42 U.S.C. 202) is amended—

(1) by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(2) by striking "Surgeon General" and inserting "Assistant Secretary for Health".

(g) DEPARTMENT.—Section 202 of the Public Health Service Act (42 U.S.C. 203) is amended—

(1) by striking "Surgeon General" the second and subsequent times that such term appears and inserting "Secretary"; and

(2) by inserting ", and the Agency for Health Care Policy and Research" before the first period.

(h) VOLUNTEER SERVICES.—Section 223 of the Public Health Service Act (42 U.S.C. 217b) is amended by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

(i) MISCELLANEOUS.—

(1) AMENDATORY INSTRUCTIONS.—

(A) Section 602(a) of Public Law 102–585 (106 Stat. 4967) is amended by striking "by adding the following subpart" and inserting "by adding at the end the following subpart".

(B) Public Law 102–531 is amended—

(i) in section 303(b) (106 Stat. 3488)—

(I) by striking "Part A of title III" and inserting "Part B of title III"; and

(II) by striking "241 et seq." and inserting "243 et seq.";

(ii) in section 304 (106 Stat. 3490)—

(I) by striking "Part A of title III" and inserting "Part B of title III"; and

(II) by striking "241 et seq." and inserting "243 et seq.";

(iii) in section 306 (106 Stat. 3494), by striking "Part A of title III" and inserting "Part B of title III"; and

(iv) in section 308 (106 Stat. 3495), by striking "Part A of title III" and inserting "Part B of title III";

(2) TITLE III OF PUBLIC HEALTH SERVICE ACT.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.), as amended by Public Law 102–321, Public Law 102–515, Public Law 102–531, and Public Law 102–585, by section 121(a) of this Act, and by paragraph (1) of this subsection, is amended—

(A) in part D—

(i) by transferring subpart VIII from the current placement of the subpart and inserting the subpart after subpart VII; and

(ii) by redesignating section 340B of subpart VIII as section 340C; and

(B)(i) by redesignating parts K and L as parts J and K, respectively; and

(ii) by redesignating the part M added by Public Law 102–321 as part L.

(3) TITLE VII OF PUBLIC HEALTH SERVICE ACT.—Section 746(i)(1) of the Public Health Service Act (42 U.S.C. 293j(i)(1)), as added by section 102 of Public Law 102–408 (106 Stat. 1994) and amended by section 313(a)(2)(B) of Public Law 102–531 (106 Stat. 3507), is amended to read as if the amendment made by such section 313(a)(2)(B) had not been enacted.

SEC. 2009. BIENNIAL REPORT ON CARCINOGENS.

Section 301(b)(4) of the Public Health Service Act (42 U.S.C. 241(b)(4)) is amended by striking "an annual" and inserting "a biennial".

SEC. 2010. TRANSFER OF PROVISIONS OF TITLE XXVII.

(a) IN GENERAL.—The Public Health Service Act (42 U.S.C. 201 et seq.), as amended by section 101 of Public Law 101–381 and section 304 of Public Law 101–509, is amended—

(1) by transferring sections 2701 through 2714 to title II;

(2) by redesignating such sections as sections 231 through 244, respectively;

(3) by inserting such sections, in the appropriate sequence, after section 228;

(4) by inserting before section 201 the following heading:

"PART A—ADMINISTRATION"; and

(5) by inserting before section 231 (as redesignated by paragraph (2) of this subsection) the following heading:

"PART B—MISCELLANEOUS PROVISIONS".

(b) CONFORMING AMENDMENTS.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in the heading for title II, by inserting "AND MISCELLANEOUS PROVISIONS" after "ADMINISTRATION";

(2) in section 406(a)(2), by striking "2701" and inserting "231";

(3) in section 465(f), by striking "2701" and inserting "231";

(4) in section 480(a)(2), by striking "2701" and inserting "231";

(5) in section 485(a)(2), by striking "2701" and inserting "231";

(6) in section 497, by striking "2701" and inserting "231";

(7) in section 505(a)(2), by striking "2701" and inserting "231";

(8) in section 926(b), by striking "2711" each place such term appears and inserting "241"; and

(9) in title XXVII, by striking the heading for such title.

SEC. 2011. AUTHORIZATION OF APPROPRIATIONS.

Section 2602 of the Low-Income Home Energy Assistance Act of 1981 (42 U.S.C. 8621) is amended—

(1) in the first sentence of subsection (b), by striking "1993 and 1994" and inserting "1993, 1994, and 1995"; and

(2) in subsection (d), by striking "in each of the fiscal years 1993 and 1994" and inserting "for each of the fiscal years 1993, 1994, and 1995".

SEC. 2012. VACCINE INJURY COMPENSATION PROGRAM.

Section 2111(a) of the Public Health Service Act (42 U.S.C. 300aa–11(a)) is amended by adding at the end the following paragraph:

"(10) The Clerk of the United States Claims Court is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.".

SEC. 2013. TECHNICAL CORRECTIONS WITH RESPECT TO THE AGENCY FOR HEALTH CARE POLICY AND RESEARCH.

Title IX of the Public Health Service Act is amended—

(1) in section 904(d) (42 U.S.C. 299a–2(d))—

(A) by striking "IN GENERAL" in paragraph (1) and inserting "ADDITIONAL ASSESSMENTS";

(B) by redesignating paragraphs (1) and (2) as paragraphs (3) and (4), respectively;

(C) by inserting after the subsection designation the following paragraphs:

"(1) RECOMMENDATIONS WITH RESPECT TO HEALTH CARE TECHNOLOGY.—The Administrator shall make recommendations to the Secretary with respect to whether specific health care technologies should be reimbursable under federally financed health programs, including recommendations with respect to any conditions and requirements under which any such reimbursements should be made.

"(2) CONSIDERATIONS OF CERTAIN FACTORS.—In making recommendations respecting health care technologies, the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the appropriate uses of such technologies. The Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable."; and

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

"(5) CONSULTATIONS.—In carrying out this subsection, the Administrator shall cooperate and consult with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency."; and

(2) in section 914(a)(2)(C), by striking "904(c)(2)" and inserting "904(d)(2)".

SEC. 2014. TECHNICAL CORRECTIONS WITH RESPECT TO THE HEALTH PROFESSIONS EDUCATION EXTENSION AMENDMENTS OF 1992.

(a) INSURED HEALTH EDUCATION ASSISTANCE LOANS TO GRADUATE STUDENTS.—Subpart I of part A of title VII of the Public Health Service Act (42 U.S.C. 292 et seq.), as added by section 102 of Public Law 102–408 (106 Stat. 1994), is amended—

(1) in section 705(a)(2)—

(A) in subparagraph (G), by inserting "and" after the semicolon at the end;

(B) by striking subparagraph (H); and

(C) by redesignating subparagraph (I) as subparagraph (H); and

(2) in section 707—

(A) in subsection (g), by amending paragraph (1) to read as follows:

"(1) after the expiration of the seven-year period beginning on the first date when repayment of such loan is required, exclusive of any period after such date in which the obligation to pay installments on the loan is suspended;"; and

(B) by adding at the end the following subsection:

"(j) SCHOOL COLLECTION ASSISTANCE.—An institution or postgraduate training program attended by a borrower may assist in the collection of any loan of that borrower made under this subpart which becomes delinquent, including providing information concerning the borrower to the Secretary and to past and present lenders and holders of the borrower's loans, contacting the borrower in order to encourage repayment, and withholding services in accordance with regulations issued by the Secretary under section 715(a)(7). The institution or postgraduate training program shall not be subject to section 809 of the Fair Debt Collection Practices Act for purposes of carrying out activities authorized by this section.".

(b) LOAN PROVISIONS.—Section 722 of the Public Health Service Act (42 U.S.C. 292r), as added by section 102 of Public Law 102–408 (106 Stat. 1994), is amended—

(1) in subsection (a), by amending the subsection to read as follows:

"(a) AMOUNT OF LOAN.—

"(1) IN GENERAL.—Loans from a student loan fund (established under an agreement with a school under section 721) may not, subject to paragraph (2), exceed for any student for a school year (or its equivalent) the sum of—

"(A) the cost of tuition for such year at such school, and

"(B) $2,500.

"(2) THIRD AND FOURTH YEARS OF MEDICAL SCHOOL.—For purposes of paragraph (1), the amount $2,500 may, in the case of the third or fourth year of a student at school of

medicine or osteopathic medicine, be increased to the extent necessary (including such $2,500) to pay the balances of loans that, from sources other than the student loan fund under section 721, were made to the individual for attendance at the school. The authority to make such an increase is subject to the school and the student agreeing that such amount (as increased) will be expended to pay such balances."; and

(2) in subsection (b)—

(A) in paragraph (1), by adding "and" after the semicolon at the end;

(B) by striking paragraph (2); and

(C) by redesignating paragraph (3) as paragraph (2).

(c) MEDICAL SCHOOLS AND PRIMARY HEALTH CARE.—

(1) REQUIREMENTS FOR STUDENTS.—Section 723(a) of the Public Health Service Act (42 U.S.C. 292s(a)), as added by section 102 of Public Law 102–408 (106 Stat. 1994), is amended by adding at the end the following paragraph:

"(4) WAIVERS.—

"(A) With respect to the obligation of an individual under an agreement made under paragraph (1) as a student, the Secretary shall provide for the partial or total waiver or suspension of the obligation whenever compliance by the individual is impossible, or would involve extreme hardship to the individual, and if enforcement of the obligation with respect to the individual would be unconscionable.

"(B) For purposes of subparagraph (A), the obligation of an individual shall be waived if—

"(i) the status of the individual as a student of the school involved is terminated before graduation from the school, whether voluntarily or involuntarily; and

"(ii) the individual does not, after such termination, resume attendance at the school or begin attendance at any other school of medicine or osteopathic medicine.

"(C) If an individual resumes or begins attendance for purposes of subparagraph (B), the obligation of the individual under the agreement under paragraph (1) shall be considered to have been suspended for the period in which the individual was not in attendance.

"(D) This paragraph may not be construed as authorizing the waiver or suspension of the obligation of a student to repay, in accordance with section 722, loans from student loan funds under section 721.".

(2) REQUIREMENTS FOR SCHOOLS.—Section 723(b) of the Public Health Service Act (42 U.S.C. 292s(b)), as added by section 102 of Public Law 102–408 (106 Stat. 1994), is amended—

(A) in paragraph (1)—

(i) by striking "1994," and inserting "1997;"; and

(ii) by striking "4 years before" and inserting "3 years before";

(B) in paragraph (2)(B), by striking "15 percent" and inserting "25 percent"; and

(C) in paragraph (4)(B)—

(i) in clause (i), by striking "1994," and inserting "1997,"; and

(ii) in clause (ii), by striking "1995," and inserting "1998,".

(d) AUTHORIZATION OF APPROPRIATIONS REGARDING MEDICAL SCHOOLS.—Section 735 of the Public Health Service Act (42 U.S.C. 292y), as added by section 102 of Public Law 102–408 (106 Stat. 1994), is amended by adding at the end the following subsection:

"(f) FUNDING FOR CERTAIN MEDICAL SCHOOLS.—

"(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making Federal capital contributions to student loan funds established under section 721 by schools of medicine or osteopathic medicine, there is authorized to be appropriated $10,000,000 for each of the fiscal years 1994 through 1996.

"(2) MINIMUM REQUIREMENTS.—

"(A) Subject to subparagraph (B), the Secretary may make a Federal capital contribution pursuant to paragraph (1) only if the school of medicine or osteopathic medicine involved meets the conditions described in subparagraph (A) of section 723(b)(2) or the conditions described in subparagraph (C) of such section.

"(B) For purposes of subparagraph (A), the conditions referred to in such subparagraph shall be applied with respect to graduates of the school involved whose date of graduation occurred approximately 3 years before June 30 of the fiscal year preceding the fiscal year for which the Federal capital contribution involved is made.

(e) PUBLIC HEALTH TRAINEESHIPS.—Section 761(b)(3) of the Public Health Service Act (42 U.S.C. 294(b)(3)), as added by section 102 of Public Law 102–408 (106 Stat. 1994), is amended by striking "and nutrition" and inserting "nutrition, and maternal and child health".

(f) TRAINEESHIPS FOR ADVANCED NURSE EDUCATION.—Section 830(a) of the Public Health Service Act, as added by section 206 of Public Law 102–408 (106 Stat. 2073), is amended—

(1) by striking "meet the cost of traineeships for individuals" and inserting the following: "meet the costs of—

"(1) traineeships for individuals";

(2) by striking the period at the end and inserting "; and"; and

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

"(2) traineeships for participation in certificate nurse midwifery programs that conform to guidelines established by the Secretary under section 822(b).".

(g) CERTAIN GENERALLY APPLICABLE PROVISIONS.—Section 860(d) of the Public Health Service Act (42 U.S.C. 298b–7(d)), as added by section 209 of Public Law 102–408 (106 Stat. 2075), is amended in the first sentence by striking "821, 822, 830, and 831" and inserting "821, 822, and 827".

SEC. 2015. PROHIBITION AGAINST SHARP ADULT SEX SURVEY AND THE AMERICAN TEENAGE SEX SURVEY.

The Secretary of Health and Human Services may not during fiscal year 1993 or any subsequent fiscal year conduct or support the SHARP survey of adult sexual behavior or the American Teenage Study of adolescent sexual behavior. This section becomes effective on the date of the enactment of this Act.

SEC. 2016. HEALTH SERVICES RESEARCH.

(a) DEFINITION.—Section 409 of the Public Health Service Act (42 U.S.C. 284d), as added by section 121(b) of Public Law 102–321 (106 Stat. 358), is amended by adding at the end the following sentence: "Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.".

(b) REQUIRED ALLOCATIONS.—

(1) IN GENERAL.—With respect to the allocation for health services research required in each of the provisions of law specified in paragraph (2), the term "15 percent" appearing in each of such provisions is, in the case of allocations for fiscal year 1993, deemed to be 12 percent.

(2) RELEVANT PROVISIONS OF LAW.—The provisions of law referred to in paragraph (1) are—

(A) section 464H(d)(2) of the Public Health Service Act, as added by section 122 of Public Law 102–321 (106 Stat. 358);

(B) section 464L(d)(2) of the Public Health Service Act, as added by section 123 of Public Law 102–321 (106 Stat. 360); and

(C) section 464R(f)(2) of the Public Health Service Act, as added by section 124 of Public Law 102–321 (106 Stat. 364).

(c) REPORT.—Section 494A(b) of the Public Health Service Act (42 U.S.C. 289c–1(b)), as added by section 125 of Public Law 102–321 (106 Stat. 366), is amended by striking "May 3, 1993," and inserting "September 30, 1993,".

SEC. 2017. CHILDHOOD MENTAL HEALTH.

Part E of title V of the Public Health Service Act (42 U.S.C. 290ff et seq.), as added by section 119 of Public Law 102–321 (106 Stat. 349), is amended—

(1) in section 561—

(A) in subsection (a)(2), by striking "this subpart" and inserting "this part"; and

(B) in subsection (b)(1), by striking "is receiving such payments" each place such term appears and inserting "is such a grantee"; and

(2) in section 565—

(A) in subsection (c)(1), by striking "this subpart" and inserting "this part";

(B) in subsection (d), by striking "this subpart" and inserting "this part"; and

(C) in subsection (f)—

(i) in paragraph (1), by striking "this subpart" and inserting "this part"; and

(ii) by amending paragraph (2) to read as follows:

"(2) LIMITATION REGARDING TECHNICAL ASSISTANCE.—Not more than 10 percent of the amounts appropriated under paragraph (1) for a fiscal year may be expended for carrying out subsection (b).".

SEC. 2018. EXPENDITURES FROM CERTAIN ACCOUNT.

With respect to amounts appropriated in title II of Public Law 102–394 for buildings and facilities of the National Institutes of Health, the purposes for which such amounts may be expended include repairing, improving, or constructing (or any combination

thereof) roads on non-Federal property in close proximity to the main campus of the National Institutes of Health in Bethesda, Maryland, subject to the agreement of the appropriate officials of Montgomery County, Maryland, or the appropriate officials of the State of Maryland, or both, as the case may be. None of such amounts may be used for the non-Federal share of the cost of any project or activity under title 23, United States Code, the Intermodal Surface Transportation Efficiency Act of 1991, or any law amended by such Act.

TITLE XXI—EFFECTIVE DATES

SEC. 2101. EFFECTIVE DATES.

Subject to section 203(c), this Act and the amendments made by this Act take effect upon the date of the enactment of this Act.

Speaker of the House of Representatives.

Vice President of the United States and
President of the Senate.