

Calendar No. 2

103D CONGRESS
1ST SESSION

S. 1

[Report No. 103-2]

A BILL

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

JANUARY 27 (legislative day, JANUARY 5), 1993

Reported with an amendment

Calendar No. 2103D CONGRESS
1ST SESSION**S. 1****[Report No. 103-2]**

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 21 (legislative day, JANUARY 5), 1993

Mr. KENNEDY (for himself, Mrs. BOXER, Mr. WELLSTONE, Mr. DODD, Mr. LAUTENBERG, Ms. MIKULSKI, Mr. PELL, Mr. SIMON, Mr. WOFFORD, Mr. INOUE, Mr. SARBANES, Ms. MOSELEY-BRAUN, Mr. LEAHY, Mr. RIEGLE, Mr. DURENBERGER, Mr. METZENBAUM, and Mr. LEVIN) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

JANUARY 27 (legislative day, JANUARY 5), 1993

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “National Institutes of Health Revitalization Act of
4 1993”.

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

Sec. 1. Short title; table of contents.

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

Subtitle A—Research Freedom

PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL
RESEARCH

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

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

Sec. 111. Establishment of authorities.

Sec. 112. Purchase of human fetal tissue; solicitation or acceptance of tissue
as directed donation for use in transplantation.

Sec. 113. Nullification of moratorium.

Sec. 114. Report by General Accounting Office on adequacy of requirements.

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

Sec. 131. Requirement of inclusion in research.

Sec. 132. Peer review.

Sec. 133. Applicability to current projects.

PART II—OFFICE OF RESEARCH ON WOMEN’S HEALTH

Sec. 141. Establishment.

PART III—OFFICE OF RESEARCH ON MINORITY HEALTH

Sec. 151. Establishment.

Subtitle C—Scientific Integrity

Sec. 161. Establishment of Office of Scientific Integrity.

Sec. 162. Commission on Scientific Integrity.

Sec. 163. Protection of whistleblowers.

- Sec. 164. Requirement of regulations regarding protection against financial conflicts of interest in certain projects of research.
- Sec. 165. Effective dates.

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

- Sec. 201. Health promotion research dissemination.
- Sec. 202. Programs for increased support regarding certain States and researchers.
- Sec. 203. Children's vaccine initiative.
- Sec. 204. Plan for use of animals in research.
- Sec. 205. Increased participation of women and members of underrepresented minorities in fields of biomedical and behavioral research.
- Sec. 206. Requirements regarding surveys of sexual behavior.
- Sec. 207. Discretionary fund of Director of National Institutes of Health.
- Sec. 208. Miscellaneous provisions.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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

TITLE IV—NATIONAL CANCER INSTITUTE

- Sec. 401. Expansion and intensification of activities regarding breast cancer.
- Sec. 402. Expansion and intensification of activities regarding prostate cancer.
- Sec. 403. Authorization of appropriations.

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

- Sec. 501. Education and training.
- Sec. 502. Centers for the study of pediatric cardiovascular diseases.
- Sec. 503. National Center on Sleep Disorders.
- Sec. 504. Authorization of appropriations.

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

- Sec. 601. Provisions regarding nutritional disorders.

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

- Sec. 701. Juvenile arthritis.

TITLE VIII—NATIONAL INSTITUTE ON AGING

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

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

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

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

Subtitle B—Program Regarding Obstetrics and Gynecology

- Sec. 1011. Establishment of program.

Subtitle C—Child Health Research Centers

- Sec. 1021. Establishment of centers.

Subtitle D—Study Regarding Adolescent Health

- Sec. 1031. Prospective longitudinal study.

TITLE XI—NATIONAL EYE INSTITUTE

- Sec. 1101. Clinical research on diabetes eye care.

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

- Sec. 1201. Research on multiple sclerosis.

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

- Sec. 1301. Applied Toxicological Research and Testing Program.

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

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

Subtitle B—Financial Assistance

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

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

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

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF HEALTH

Subtitle A—Division of Research Resources

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

Subtitle B—National Center for Nursing Research

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

Subtitle C—National Center for Human Genome Research

- Sec. 1521. Purpose of Center.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

- Sec. 1601. Requirement regarding women and individuals from disadvantaged backgrounds.
- Sec. 1602. Service payback requirements.

Subtitle B—Acquired Immune Deficiency Syndrome

- Sec. 1611. Loan repayment program.

Subtitle C—Loan Repayment for Research Generally

- Sec. 1621. Establishment of program.

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

- Sec. 1631. Establishment of programs.
- Sec. 1632. Funding.

Subtitle E—Funding for Awards and Training Generally

- Sec. 1641. Authorization of appropriations.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

- Sec. 1701. Establishment of Foundation.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

- Sec. 1801. Revision and extension of various programs.

TITLE XIX—STUDIES

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

- Sec. 1907. Report concerning leading causes of death.
 Sec. 1908. Relationship between the consumption of legal and illegal drugs.

TITLE XX—MISCELLANEOUS PROVISIONS

- Sec. 2001. Designation of Senior Biomedical Research Service in honor of Silvio Conte, and limitation on number of members.
 Sec. 2002. Technical corrections.
 Sec. 2003. Biennial report on carcinogens.
 Sec. 2004. Master plan for physical infrastructure for research.
 Sec. 2005. Transfer of provisions of title xxvii.
 Sec. 2006. Certain authorization of appropriations.
 Sec. 2007. Prohibition against SHARP adult sex survey and the American teenage sex survey.
 Sec. 2008. Support for bioengineering research.

TITLE XXI—EFFECTIVE DATES

- Sec. 2101. Effective dates.

1 **TITLE I—GENERAL PROVISIONS**
 2 **REGARDING TITLE IV OF PUB-**
 3 **LIC HEALTH SERVICE ACT**

4 **Subtitle A—Research Freedom**

5 **PART I—REVIEW OF PROPOSALS FOR**
 6 **BIOMEDICAL AND BEHAVIORAL RESEARCH**

7 **SEC. 101. ESTABLISHMENT OF CERTAIN PROVISIONS RE-**
 8 **GARDING RESEARCH CONDUCTED OR SUP-**
 9 **PORTED BY NATIONAL INSTITUTES OF**
 10 **HEALTH.**

11 Part G of title IV of the Public Health Service Act
 12 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
 13 tion 492 the following new section:

14 “CERTAIN PROVISIONS REGARDING REVIEW AND
 15 APPROVAL OF PROPOSALS FOR RESEARCH
 16 “SEC. 492A. (a) REVIEW AS PRECONDITION TO RE-
 17 SEARCH.—

1 ~~“(1) PROTECTION OF HUMAN RESEARCH SUB-~~
2 ~~JECTS.—~~

3 ~~“(A) In the case of any application submit-~~
4 ~~ted to the Secretary for financial assistance to~~
5 ~~conduct research, the Secretary may not ap-~~
6 ~~prove or fund any application that is subject to~~
7 ~~review under section 491(a) by an Institutional~~
8 ~~Review Board unless the application has under-~~
9 ~~gone review in accordance with such section and~~
10 ~~has been recommended for approval by a major-~~
11 ~~ity of the members of the Board conducting~~
12 ~~such review.~~

13 ~~“(B) In the case of research that is subject~~
14 ~~to review under procedures established by the~~
15 ~~Secretary for the protection of human subjects~~
16 ~~in clinical research conducted by the National~~
17 ~~Institutes of Health, the Secretary may not au-~~
18 ~~thorize the conduct of the research unless the~~
19 ~~research has, pursuant to such procedures, been~~
20 ~~recommended for approval.~~

21 ~~“(2) PEER REVIEW.—In the case of any appli-~~
22 ~~cation submitted to the Secretary for financial as-~~
23 ~~sistance to conduct research, the Secretary may not~~
24 ~~approve or fund any application that is subject to~~
25 ~~technical and scientific peer review under section~~

1 492(a) unless the application has undergone peer re-
2 view in accordance with such section and has been
3 recommended for approval by a majority of the
4 members of the entity conducting such review.

5 “(b) ETHICAL REVIEW OF RESEARCH.—

6 “(1) PROCEDURES REGARDING WITHHOLDING
7 OF FUNDS.—If research has been recommended for
8 approval for purposes of subsection (a), the Sec-
9 retary may not withhold funding for the research on
10 ethical grounds unless—

11 “(A) the Secretary convenes an advisory
12 board in accordance with paragraph (4) to
13 study the ethical implications of the research;
14 and

15 “(B) the majority of the advisory board
16 recommends that, on ethical grounds, the Sec-
17 retary withhold funds for the research.

18 “(2) APPLICABILITY.—The limitation estab-
19 lished in paragraph (1) regarding the authority to
20 withhold funds on ethical grounds shall apply with-
21 out regard to whether the withholding of funds is
22 characterized as a disapproval, a moratorium, a pro-
23 hibition, or other description.

24 “(3) PRELIMINARY MATTERS REGARDING USE
25 OF PROCEDURES.—

1 “(A) If the Secretary makes a determina-
2 tion that an advisory board should be convened
3 for purposes of paragraph (1), the Secretary
4 shall, through a statement published in the
5 Federal Register, announce the intention of the
6 Secretary to convene such a board.

7 “(B) A statement issued under subpara-
8 graph (A) shall include a request that inter-
9 ested individuals submit to the Secretary rec-
10 ommendations specifying the particular individ-
11 uals who should be appointed to the advisory
12 board involved. The Secretary shall consider
13 such recommendations in making appointments
14 to the board.

15 “(C) The Secretary may not make appoint-
16 ments to an advisory board under paragraph
17 (1) until the expiration of the 30-day period be-
18 ginning on the date on which the statement re-
19 quired in subparagraph (A) is made with re-
20 spect to the board.

21 “(4) ETHICS ADVISORY BOARDS.—

22 “(A) Any advisory board convened for pur-
23 poses of paragraph (1) shall be known as an
24 ethics advisory board (hereafter in this para-
25 graph referred to as an ‘ethics board’).

1 “(B)(i) An ethics board shall advise, con-
2 sult with, and make recommendations to the
3 Secretary regarding the ethics of the project of
4 biomedical or behavioral research with respect
5 to which the board has been convened.

6 “(ii) Not later than 180 days after the
7 date on which the statement required in para-
8 graph (3)(A) is made with respect to an ethics
9 board, the board shall submit to the Secretary,
10 and to the Committee on Energy and Com-
11 merce of the House of Representatives and the
12 Committee on Labor and Human Resources of
13 the Senate, a report describing the findings of
14 the board regarding the project of research in-
15 volved and making a recommendation under
16 clause (i) of whether the Secretary should or
17 should not withhold funds for the project. The
18 report shall include the information considered
19 in making the findings.

20 “(C) An ethics board shall be composed of
21 no fewer than 14, and no more than 20, indi-
22 viduals who are not officers or employees of the
23 United States. The Secretary shall make ap-
24 pointments to the board from among individ-
25 uals with special qualifications and competence

1 to provide advice and recommendations regard-
2 ing ethical matters in biomedical and behavioral
3 research. Of the members of the board—

4 “(i) no fewer than 1 shall be an attor-
5 ney;

6 “(ii) no fewer than 1 shall be an
7 ethicist;

8 “(iii) no fewer than 1 shall be a prac-
9 ticing physician;

10 “(iv) no fewer than 1 shall be a theo-
11 logian; and

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

16 “(D) The term of service as a member of
17 an ethics board shall be for the life of the
18 board. If such a member does not serve the full
19 term of such service, the individual appointed to
20 fill the resulting vacancy shall be appointed for
21 the remainder of the term of the predecessor of
22 the individual.

23 “(E) A member of an ethics board shall be
24 subject to removal from the board by the Sec-

1 retary for neglect of duty or malfeasance or for
2 other good cause shown.

3 “(F) The Secretary shall designate an indi-
4 vidual from among the members of an ethics
5 board to serve as the chair of the board.

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

10 “(H) With respect to information relevant
11 to the duties described in subparagraph (B)(i),
12 an ethics board shall have access to all such in-
13 formation possessed by the Department of
14 Health and Human Services, or available to the
15 Secretary from other agencies.

16 “(I) Members of an ethics board shall re-
17 ceive compensation for each day engaged in ear-
18 rying out the duties of the board, including
19 time engaged in traveling for purposes of such
20 duties. Such compensation may not be provided
21 in an amount in excess of the maximum rate of
22 basic pay payable for GS-18 of the General
23 Schedule.

24 “(J) The Secretary, acting through the Di-
25 rector of the National Institutes of Health,

1 shall provide to each ethics board such staff
 2 and other assistance as may be necessary to
 3 carry out the duties of the board.

4 “(K) An ethics board shall terminate 30
 5 days after the date on which the report required
 6 in subparagraph (B)(ii) is submitted to the Sec-
 7 retary and the congressional committees speci-
 8 fied in such subparagraph.”.

9 **PART II—RESEARCH ON TRANSPLANTATION OF**
 10 **FETAL TISSUE**

11 **SEC. 411. ESTABLISHMENT OF AUTHORITIES.**

12 Part G of title IV of the Public Health Service Act
 13 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
 14 tion 498 the following new section:

15 “RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

16 “SEC. 498A. (a) ESTABLISHMENT OF PROGRAM.—

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

20 “(2) SOURCE OF TISSUE.—Human fetal tissue
 21 may be used in research carried out under para-
 22 graph (1) regardless of whether the tissue is ob-
 23 tained pursuant to a spontaneous or induced abor-
 24 tion or pursuant to a stillbirth.

25 “(b) INFORMED CONSENT OF DONOR.—

1 “(1) IN GENERAL.—In research carried out
2 under subsection (a), human fetal tissue may be
3 used only if the woman providing the tissue makes
4 a statement, made in writing and signed by the
5 woman, declaring that—

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

8 “(B) the donation is made without any re-
9 striction regarding the identity of individuals
10 who may be the recipients of transplantations
11 of the tissue; and

12 “(C) the woman has not been informed of
13 the identity of any such individuals.

14 “(2) ADDITIONAL STATEMENT.—In research
15 carried out under subsection (a), human fetal tissue
16 may be used only if the attending physician with re-
17 spect to obtaining the tissue from the woman in-
18 volved makes a statement, made in writing and
19 signed by the physician, declaring that—

20 “(A) in the case of tissue obtained pursu-
21 ant to an induced abortion—

22 “(i) the consent of the woman for the
23 abortion was obtained prior to requesting
24 or obtaining consent for the tissue to be
25 used in such research; and

1 “(ii) no alteration of the timing,
2 method, or procedures used to terminate
3 the pregnancy was made solely for the pur-
4 poses of obtaining the tissue;

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

7 “(C) full disclosure has been provided to
8 the woman with regard to—

9 “(i) such physician’s interest, if any,
10 in the research to be conducted with the
11 tissue; and

12 “(ii) any known medical risks to the
13 woman or risks to her privacy that might
14 be associated with the donation of the tis-
15 sue and that are in addition to risks of
16 such type that are associated with the
17 woman’s medical care.

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

24 “(1) is aware that—

25 “(A) the tissue is human fetal tissue;

1 ~~“(B) the tissue may have been obtained~~
2 ~~pursuant to a spontaneous or induced abortion~~
3 ~~or subsequent to a stillbirth; and~~

4 ~~“(C) the tissue was donated for research~~
5 ~~purposes;~~

6 ~~“(2) has provided such information to other in-~~
7 ~~dividuals with responsibilities regarding the research;~~

8 ~~“(3) will require, prior to obtaining the consent~~
9 ~~of an individual to be a recipient of a transplan-~~
10 ~~tation of the tissue, written acknowledgment of re-~~
11 ~~ceipt of such information by such recipient; and~~

12 ~~“(4) has had no part in any decisions as to the~~
13 ~~timing, method, or procedures used to terminate the~~
14 ~~pregnancy made solely for the purposes of the re-~~
15 ~~search.~~

16 ~~“(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—~~

17 ~~“(1) IN GENERAL.—In research carried out~~
18 ~~under subsection (a), human fetal tissue may be~~
19 ~~used only if the head of the agency or other entity~~
20 ~~conducting the research involved certifies to the Sec-~~
21 ~~retary that the statements required under sub-~~
22 ~~sections (a)(3), (b)(2), and (c) will be available for~~
23 ~~audit by the Secretary.~~

24 ~~“(2) CONFIDENTIALITY OF AUDIT.—Any audit~~
25 ~~conducted by the Secretary pursuant to paragraph~~

1 ~~(1)~~ shall be conducted in a confidential manner to
2 protect the privacy rights of the individuals and enti-
3 ties involved in such research, including such indi-
4 viduals and entities involved in the donation, trans-
5 fer, receipt, or transplantation of human fetal tissue.
6 With respect to any material or information obtained
7 pursuant to such audit, the Secretary shall—

8 ~~“(A)~~ use such material or information only
9 for the purposes of verifying compliance with
10 the requirements of this section;

11 ~~“(B)~~ not disclose or publish such material
12 or information, except where required by Fed-
13 eral law, in which case such material or infor-
14 mation shall be coded in a manner such that
15 the identities of such individuals and entities
16 are protected; and

17 ~~“(C)~~ not maintain such material or infor-
18 mation after completion of such audit, except
19 where necessary for the purposes of such audit.

20 ~~“(e) APPLICABILITY OF STATE AND LOCAL LAW.—~~

21 ~~“(1) RESEARCH CONDUCTED BY RECIPIENTS~~
22 ~~OF ASSISTANCE.—~~The Secretary may not provide
23 support for research under subsection ~~(a)~~ conduct
24 the research in accordance with applicable State and
25 local law.

1 “(2) RESEARCH CONDUCTED BY SECRETARY.—

2 The Secretary may conduct research under sub-
3 section (a) only in accordance with applicable State
4 and local law.

5 “(f) DEFINITION.—For purposes of this section, the
6 term ‘human fetal tissue’ means tissue or cells obtained
7 from a dead human embryo or fetus after a spontaneous
8 or induced abortion, or after a stillbirth.”.

9 **SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITA-**
10 **TION OR ACCEPTANCE OF TISSUE AS DI-**
11 **RECTED DONATION FOR USE IN TRANSPLAN-**
12 **TATION.**

13 Part G of title IV of the Public Health Service Act,
14 as amended by section 111 of this Act, is amended by in-
15 serting after section 498A the following new section:

16 “PROHIBITIONS REGARDING HUMAN FETAL TISSUE

17 “SEC. 498B. (a) PURCHASE OF TISSUE.—It shall be
18 unlawful for any person to knowingly acquire, receive, or
19 otherwise transfer any human fetal tissue for valuable con-
20 sideration if the transfer affects interstate commerce.

21 “(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS
22 DIRECTED DONATION FOR USE IN TRANSPLANTATION.—
23 It shall be unlawful for any person to solicit or knowingly
24 acquire, receive, or accept a donation of human fetal tissue
25 for the purpose of transplantation of such tissue into an-
26 other person if the donation affects interstate commerce,

1 the tissue will be or is obtained pursuant to an induced
2 abortion, and—

3 “(1) the donation will be or is made pursuant
4 to a promise to the donating individual that the do-
5 nated tissue will be transplanted into a recipient
6 specified by such individual;

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

9 “(3) the person who solicits or knowingly ac-
10 quires, receives, or accepts the donation has provided
11 valuable consideration for the costs associated with
12 such abortion.

13 “(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

14 “(1) IN GENERAL.—Any person who violates
15 subsection (a) or (b) shall be fined in accordance
16 with title 18, United States Code, subject to para-
17 graph (2), or imprisoned for not more than 10
18 years, or both.

19 “(2) PENALTIES APPLICABLE TO PERSONS RE-
20 CEIVING CONSIDERATION.—With respect to the im-
21 position of a fine under paragraph (1), if the person
22 involved violates subsection (a) or (b)(3), a fine shall
23 be imposed in an amount not less than twice the
24 amount of the valuable consideration received.

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

1 “(1) The term ‘human fetal tissue’ has the
2 meaning given such term in section 498A(f).

3 “(2) The term ‘interstate commerce’ has the
4 meaning given such term in section 201(b) of the
5 Federal Food, Drug, and Cosmetic Act.

6 “(3) The term ‘valuable consideration’ does not
7 include reasonable payments associated with the
8 transportation, implantation, processing, preserva-
9 tion, quality control, or storage of human fetal tis-
10 sue.”.

11 **SEC. 113. NULLIFICATION OF MORATORIUM.**

12 (a) **IN GENERAL.**—Except as provided in subsection
13 (c), no official of the executive branch may impose a policy
14 that the Department of Health and Human Services is
15 prohibited from conducting or supporting any research on
16 the transplantation of human fetal tissue for therapeutic
17 purposes. Such research shall be carried out in accordance
18 with section 498A of the Public Health Service Act (as
19 added by section 111 of this Act), without regard to any
20 such policy that may have been in effect prior to the date
21 of the enactment of this Act.

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

24 (1) **IN GENERAL.**—In the case of any proposal
25 for research on the transplantation of human fetal

1 tissue for therapeutic purposes, the Secretary of
2 Health and Human Services may not withhold funds
3 for the research if—

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

8 (B) the research will be carried out in ac-
9 cordance with section 498A of such Act (as
10 added by section 111 of this Act); and

11 (C) there are reasonable assurances that
12 the research will not utilize any human fetal tis-
13 sue that has been obtained in violation of sec-
14 tion 498B(a) of such Act (as added by section
15 112 of this Act).

16 ~~(2) STANDING APPROVAL REGARDING ETHICAL~~
17 ~~STATUS.—~~In the case of any proposal for research
18 on the transplantation of human fetal tissue for
19 therapeutic purposes, the issuance in December
20 1988 of the Report of the Human Fetal Tissue
21 Transplantation Research Panel shall be deemed to
22 be a report—

23 (A) issued by an ethics advisory board pur-
24 suant to section 492A(b)(4)(B)(ii) of the Public

1 Health Service Act (as added by section 101 of
2 this Act); and

3 ~~(B) finding, on a basis that is neither arbi-~~
4 ~~trary nor capricious, that there are no ethical~~
5 ~~grounds for withholding funds for the research.~~

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

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

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

19 ~~(a) IN GENERAL.—With respect to research on the~~
20 ~~transplantation of human fetal tissue for therapeutic pur-~~
21 ~~poses, the Comptroller General of the United States shall~~
22 ~~conduct an audit for the purpose of determining—~~

23 ~~(1) whether and to what extent such research~~
24 ~~conducted or supported by the Secretary of Health~~
25 ~~and Human Services has been conducted in accord-~~

1 ance with section 498A of the Public Health Service
2 Act (as added by section 111 of this Act); and

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

6 (b) ~~REPORT.~~—Not later than May 19, 1995, the
7 Comptroller General of the United States shall complete
8 the audit required in subsection (a) and submit to the
9 Committee on Energy and Commerce of the House of
10 Representatives, and to the Committee on Labor and
11 Human Resources of the Senate, a report describing the
12 findings made pursuant to the audit.

13 **PART III—MISCELLANEOUS REPEALS**

14 **SEC. 121. REPEALS.**

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

18 (b) ~~OTHER REPEALS.~~—Part G of title IV of the Pub-
19 lic Health Service Act (42 U.S.C. 289 et seq.) is amend-
20 ed—

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

22 and

23 (2) by striking section 499; and

24 (3) by redesignating section 499A as section
25 499.

1 (c) NULLIFICATION OF CERTAIN REGULATION.—The
2 provisions of section 204(d) of part 46 of title 45 of the
3 Code of Federal Regulations (45 CFR 46.204(d)) shall
4 not have any legal effect.

5 **Subtitle B—Clinical Research Eq-**
6 **uity Regarding Women and Mi-**
7 **norities**

8 **PART I—WOMEN AND MINORITIES AS SUBJECTS**
9 **IN CLINICAL RESEARCH**

10 **SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.**

11 Part G of title IV of the Public Health Service Act,
12 as amended by section 101 of this Act, is amended by in-
13 sserting after section 492A the following new section:

14 “INCLUSION OF WOMEN AND MINORITIES IN CLINICAL
15 RESEARCH

16 “SEC. 492B. (a) In conducting or supporting clinical
17 research for purposes of this title, the Director of NIH
18 shall, subject to subsection (b), ensure that—

19 “(1) women are included as subjects in each
20 project of such research; and

21 “(2) members of minority groups are included
22 as subjects in such research.

23 “(b) The requirement established in subsection (a)
24 regarding women and members of minority groups shall
25 not apply to a project of clinical research if the inclusion,

1 as subjects in the project, of women and members of mi-
2 nority groups, respectively—

3 ~~“(1) is inappropriate with respect to the health~~
4 ~~of the subjects;~~

5 ~~“(2) is inappropriate with respect to the pur-~~
6 ~~pose of the research; or~~

7 ~~“(3) is inappropriate under such other cir-~~
8 ~~cumstances as the Director of NIH may designate.~~

9 ~~“(c) In the case of any project of clinical research~~
10 ~~in which women or members of minority groups will under~~
11 ~~subsection (a) be included as subjects in the research, the~~
12 ~~Director of NIH shall ensure that the project is designed~~
13 ~~and carried out in a manner sufficient to provide for a~~
14 ~~valid analysis of whether the variables being tested in the~~
15 ~~research affect women or members of minority groups, as~~
16 ~~the case may be, differently than other subjects in the re-~~
17 ~~search.~~

18 ~~“(d)(1) The Director of NIH, in consultation with the~~
19 ~~Director of the Office of Research on Women’s Health,~~
20 ~~shall establish guidelines regarding—~~

21 ~~“(A) the circumstances under which the inclu-~~
22 ~~sion of women and minorities in projects of clinical~~
23 ~~research is inappropriate for purposes of subsection~~
24 ~~(b);~~

1 “(B) the manner in which such projects are re-
2 quired to be designed and carried out for purposes
3 of subsection (c), including a specification of the cir-
4 cumstances in which the requirement of such sub-
5 section does not apply on the basis of impracticabil-
6 ity; and

7 “(C) the conduct of outreach programs for the
8 recruitment of women and members of minority
9 groups as subjects in such research.

10 “(2) With respect to the circumstances under which
11 the inclusion of women or members of minority groups (as
12 the case may be) as subjects in clinical research is inap-
13 propriate for purposes of subsection (b), the guidelines es-
14 tablished under paragraph (1)(A)—

15 “(A) shall provide that the costs of such inclu-
16 sion in a project of clinical research is not a permis-
17 sible consideration in determining whether such in-
18 clusion is inappropriate unless the data of com-
19 parable quality regarding women or members of mi-
20 nority groups, respectively, that would be obtained in
21 such project in the event that such inclusion were re-
22 quired will be obtained through other means; and

23 “(B) may provide that such inclusion in a
24 project of clinical research is not required if there is

1 substantial scientific data demonstrating that there
2 is no significant difference between—

3 “(i) the effects that the variables to be
4 studied in the project have on women or mem-
5 bers of minority groups, respectively; and

6 “(ii) the effects that the variables have on
7 the individuals who would serve as subjects in
8 the project in the event that such inclusion were
9 not required.

10 “(3) The guidelines required in paragraph (1) shall
11 be established and published in the Federal Register not
12 later than 120 days after the date of the enactment of
13 the National Institutes of Health Revitalization Act of
14 1993.

15 “(4) For fiscal year 1994 and subsequent fiscal years,
16 the Director of NIH may not approve any proposal of clin-
17 ical research to be conducted or supported by any agency
18 of the National Institutes of Health unless the proposal
19 specifies the manner in which the research will comply
20 with subsection (a).

21 “(e) The advisory council of each national research
22 institute shall annually submit to the Director of NIH and
23 the Director of the institute involved a report describing
24 the manner in which the agency has complied with sub-
25 section (a).”

1 **SEC. 132. PEER REVIEW.**

2 Section 492 of the Public Health Service Act (42
3 U.S.C. 289a) is amended by adding at the end the follow-
4 ing new subsection:

5 “(c)(1) In technical and scientific peer review under
6 this section of proposals for clinical research, the consider-
7 ation of any such proposal (including the initial consider-
8 ation) shall, except as provided in paragraph (2), include
9 an evaluation of the technical and scientific merit of the
10 proposal regarding compliance with section 492B(a).

11 “(2) Paragraph (1) shall not apply to any proposal
12 for clinical research that, pursuant to subsection (b) of
13 section 492B, is not subject to the requirement of sub-
14 section (a) of such section regarding the inclusion of
15 women and members of minority groups as subjects in
16 clinical research.”.

17 **SEC. 133. APPLICABILITY TO CURRENT PROJECTS.**

18 Section 492B of the Public Health Service Act, as
19 added by section 131 of this Act, shall not apply with re-
20 spect to projects of clinical research for which initial fund-
21 ing was provided prior to the date of the enactment of
22 this Act. With respect to the inclusion of women and mi-
23 norities as subjects in clinical research conducted or sup-
24 ported by the National Institutes of Health, any policies
25 of the Secretary of Health and Human Services regarding
26 such inclusion that are in effect on the day before the date

1 of the enactment of this Act shall continue to apply to
2 the projects referred to in the preceding sentence.

3 **PART II—OFFICE OF RESEARCH ON WOMEN'S**
4 **HEALTH**

5 **SEC. 141. ESTABLISHMENT.**

6 (a) ~~IN GENERAL.~~—Title IV of the Public Health
7 Service Act, as amended by section 2 of Public Law 101-
8 613, is amended—

9 (1) by redesignating section 486 as section
10 485A;

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

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

15 “PART F—RESEARCH ON WOMEN'S HEALTH

16 “SEC. 486. OFFICE OF RESEARCH ON WOMEN'S HEALTH.

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

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

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

1 “(2) identify multidisciplinary research relating
2 to research on women’s health that should be so con-
3 ducted or supported;

4 “(3) carry out paragraphs (1) and (2) with re-
5 spect to the aging process in women, with priority
6 given to menopause;

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

10 “(5) encourage the conduct of such research by
11 entities receiving funds from the national research
12 institutes;

13 “(6) recommend an agenda for conducting and
14 supporting such research;

15 “(7) promote the sufficient allocation of the re-
16 sources of the national research institutes for con-
17 ducting and supporting such research;

18 “(8) assist in the administration of section
19 492B with respect to the inclusion of women as sub-
20 jects in clinical research; and

21 “(9) prepare the report required in section
22 486B.

23 “(c) COORDINATING COMMITTEE.—

24 “(1) In carrying out subsection (b), the Direc-
25 tor of the Office shall establish a committee to be

1 known as the Coordinating Committee on Research
2 on Women's Health (hereafter in this subsection re-
3 ferred to as the 'Coordinating Committee').

4 ~~“(2) The Coordinating Committee shall be com-
5 posed of the Directors of the national research insti-
6 tutes (or the designees of the Directors).~~

7 ~~“(3) The Director of the Office shall serve as
8 the chair of the Coordinating Committee.~~

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

12 ~~“(A) identifying the need for such re-
13 search, and making an estimate each fiscal year
14 of the funds needed to adequately support the
15 research;~~

16 ~~“(B) identifying needs regarding the co-
17 ordination of research activities, including in-
18 tramural and extramural multidisciplinary ac-
19 tivities;~~

20 ~~“(C) supporting the development of meth-
21 odologies to determine the circumstances in
22 which obtaining data specific to women (includ-
23 ing data relating to the age of women and the
24 membership of women in ethnic or racial~~

1 groups) is an appropriate function of clinical
2 trials of treatments and therapies;

3 ~~“(D) supporting the development and ex-~~
4 ~~ansion of clinical trials of treatments and~~
5 ~~therapies for which obtaining such data has~~
6 ~~been determined to be an appropriate function;~~
7 ~~and~~

8 ~~“(E) encouraging the national research in-~~
9 ~~stitutes to conduct and support such research,~~
10 ~~including such clinical trials.~~

11 ~~“(d) ADVISORY COMMITTEE.—~~

12 ~~“(1) In carrying out subsection (b), the Direc-~~
13 ~~tor of the Office shall establish an advisory commit-~~
14 ~~tee to be known as the Advisory Committee on Re-~~
15 ~~search on Women’s Health (hereafter in this sub-~~
16 ~~section referred to as the ‘Advisory Committee’).~~

17 ~~“(2)(A) The Advisory Committee shall be com-~~
18 ~~posed of no fewer than 12, and not more than 18~~
19 ~~individuals, who are not officers or employees of the~~
20 ~~Federal Government. The Director of the Office~~
21 ~~shall make appointments to the Advisory Committee~~
22 ~~from among physicians, practitioners, scientists, and~~
23 ~~other health professionals, whose clinical practice,~~
24 ~~research specialization, or professional expertise in-~~
25 ~~cludes a significant focus on research on women’s~~

1 health. A majority of the members of the Advisory
2 Committee shall be women.

3 ~~“(B) Members of the Advisory Committee shall~~
4 ~~receive compensation for each day engaged in carry-~~
5 ~~ing out the duties of the Committee, including time~~
6 ~~engaged in traveling for purposes of such duties.~~
7 ~~Such compensation may not be provided in an~~
8 ~~amount in excess of the maximum rate of basic pay~~
9 ~~payable for GS-18 of the General Schedule.~~

10 ~~“(3) The Director of the Office shall serve as~~
11 ~~the chair of the Advisory Committee.~~

12 ~~“(4) The Advisory Committee shall—~~

13 ~~“(A) advise the Director of the Office on~~
14 ~~appropriate research activities to be undertaken~~
15 ~~by the national research institutes with respect~~
16 ~~to—~~

17 ~~“(i) research on women’s health;~~

18 ~~“(ii) research on gender differences in~~
19 ~~clinical drug trials, including responses to~~
20 ~~pharmacological drugs;~~

21 ~~“(iii) research on gender differences~~
22 ~~in disease etiology, course, and treatment;~~

23 ~~“(iv) research on obstetrical and gynecological~~
24 ~~health conditions, diseases, and~~
25 ~~treatments; and~~

1 ~~“(v) research on women’s health con-~~
2 ~~ditions which require a multidisciplinary~~
3 ~~approach;~~

4 ~~“(B) report to the Director of the Office~~
5 ~~on such research;~~

6 ~~“(C) provide recommendations to such Di-~~
7 ~~rector regarding activities of the Office (includ-~~
8 ~~ing recommendations on the development of the~~
9 ~~methodologies described in subsection (c)(4)(C)~~
10 ~~and recommendations on priorities in carrying~~
11 ~~out research described in subparagraph (A));~~
12 ~~and~~

13 ~~“(D) assist in monitoring compliance with~~
14 ~~section 492B regarding the inclusion of women~~
15 ~~in clinical research.~~

16 ~~“(5)(A) The Advisory Committee shall prepare~~
17 ~~a biennial report describing the activities of the~~
18 ~~Committee, including findings made by the Commit-~~
19 ~~tee regarding—~~

20 ~~“(i) compliance with section 492B;~~

21 ~~“(ii) the extent of expenditures made for~~
22 ~~research on women’s health by the agencies of~~
23 ~~the National Institutes of Health; and~~

24 ~~“(iii) the level of funding needed for such~~
25 ~~research.~~

1 ~~“(B) The report required in subparagraph (A)~~
2 ~~shall be submitted to the Director of NIH for inclu-~~
3 ~~sion in the report required in section 403.~~

4 ~~“(e) REPRESENTATION OF WOMEN AMONG RE-~~
5 ~~SEARCHERS.—The Secretary, acting through the Assist-~~
6 ~~ant Secretary for Personnel and in collaboration with the~~
7 ~~Director of the Office, shall determine the extent to which~~
8 ~~women are represented among senior physicians and sci-~~
9 ~~entists of the national research institutes and among phy-~~
10 ~~sicians and scientists conducting research with funds pro-~~
11 ~~vided by such institutes, and as appropriate, carry out ac-~~
12 ~~tivities to increase the extent of such representation.~~

13 ~~“(f) DEFINITIONS.—For purposes of this part:~~

14 ~~“(1) The term ‘women’s health conditions’, with~~
15 ~~respect to women of all age, ethnic, and racial~~
16 ~~groups, means all diseases, disorders, and conditions~~
17 ~~(including with respect to mental health)—~~

18 ~~“(A) unique to, more serious, or more~~
19 ~~prevalent in women;~~

20 ~~“(B) for which the factors of medical risk~~
21 ~~or types of medical intervention are different~~
22 ~~for women, or for which it is unknown whether~~
23 ~~such factors or types are different for women;~~
24 ~~or~~

1 ~~“(C) with respect to which there has been~~
2 ~~insufficient clinical research involving women as~~
3 ~~subjects or insufficient clinical data on women.~~

4 ~~“(2) The term ‘research on women’s health’~~
5 ~~means research on women’s health conditions, in-~~
6 ~~cluding research on preventing such conditions.~~

7 ~~“SEC. 486A. NATIONAL DATA SYSTEM AND CLEARING-~~
8 ~~HOUSE ON RESEARCH ON WOMEN’S HEALTH.~~

9 ~~“(a) DATA SYSTEM.—~~

10 ~~“(1) The Director of NIH, in consultation with~~
11 ~~the Director of the Office, shall establish a data sys-~~
12 ~~tem for the collection, storage, analysis, retrieval,~~
13 ~~and dissemination of information regarding research~~
14 ~~on women’s health that is conducted or supported by~~
15 ~~the national research institutes. Information from~~
16 ~~the data system shall be available through informa-~~
17 ~~tion systems available to health care professionals~~
18 ~~and providers, researchers, and members of the~~
19 ~~public.~~

20 ~~“(2) The data system established under para-~~
21 ~~graph (1) shall include a registry of clinical trials of~~
22 ~~experimental treatments that have been developed~~
23 ~~for research on women’s health. Such registry shall~~
24 ~~include information on subject eligibility criteria,~~
25 ~~sex, age, ethnicity or race, and the location of the~~

1 trial site or sites. Principal investigators of such
2 clinical trials shall provide this information to the
3 registry within 30 days after it is available. Once a
4 trial has been completed, the principal investigator
5 shall provide the registry with information pertain-
6 ing to the results, including potential toxicities or
7 adverse effects associated with the experimental
8 treatment or treatments evaluated.

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

15 **“SEC. 486B. BIENNIAL REPORT.**

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

20 ~~“(1) describing and evaluating the progress~~
21 ~~made during the preceding 2 fiscal years in research~~
22 ~~and treatment conducted or supported by the Na-~~
23 ~~tional Institutes of Health;~~

24 ~~“(2) describing and analyzing the professional~~
25 ~~status of women physicians and scientists of such~~

1 Institutes, including the identification of problems
2 and barriers regarding advancements;

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

6 ~~“(4) making such recommendations for legisla-~~
7 ~~tive and administrative initiatives as the Director of~~
8 ~~the Office determines to be appropriate.~~

9 ~~“(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR~~
10 ~~OF NIH.—The Director of the Office shall submit each~~
11 ~~report prepared under subsection (a) to the Director of~~
12 ~~NIH for inclusion in the report submitted to the President~~
13 ~~and the Congress under section 403.”.~~

14 ~~(b) REQUIREMENT OF SUFFICIENT ALLOCATION OF~~
15 ~~RESOURCES OF INSTITUTES.—Section 402(b) of the Pub-~~
16 ~~lie Health Service Act (42 U.S.C. 282(b)) is amended—~~

17 ~~(1) in paragraph (10), by striking “and” after~~
18 ~~the semicolon at the end;~~

19 ~~(2) in paragraph (11), by striking the period at~~
20 ~~the end and inserting “; and”; and~~

21 ~~(3) by inserting after paragraph (11) the fol-~~
22 ~~lowing new paragraph:~~

23 ~~“(12) after consultation with the Director of~~
24 ~~the Office of Research on Women’s Health, shall en-~~
25 ~~sure that resources of the National Institutes of~~

1 Health are sufficiently allocated for projects of re-
2 search on women's health that are identified under
3 section 486(b).”.

4 **PART III—OFFICE OF RESEARCH ON MINORITY**
5 **HEALTH**

6 **SEC. 451. ESTABLISHMENT.**

7 Part A of title IV of the Public Health Service Act
8 (42 U.S.C. 281 et seq.) is amended by adding at the end
9 the following new section:

10 “OFFICE OF RESEARCH ON MINORITY HEALTH

11 “SEC. 403A. (a) ESTABLISHMENT.—There is estab-
12 lished within the Office of the Director of NIH an office
13 to be known as the Office of Research on Minority Health
14 (in this section referred to as the ‘Office’). The Office shall
15 be headed by a director, who shall be appointed by the
16 Director of NIH.

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

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

21 “(2) identify multidisciplinary research relating
22 to research on minority health that should be so con-
23 ducted or supported;

24 “(3) promote coordination and collaboration
25 among entities conducting research identified under
26 paragraph (1) or (2);

1 ~~“(2) DIRECTOR.~~—The Office shall be headed by
2 a Director, who shall be appointed by the Secretary,
3 be experienced and specially trained in the conduct
4 of research, and have experience in the conduct of
5 investigations of scientific misconduct. The Sec-
6 retary shall carry out this section acting through the
7 Director of the Office. The Director shall report to
8 the Secretary.

9 ~~“(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS~~
10 ~~CONDITION OF FUNDING FOR RESEARCH.~~—The Secretary
11 shall by regulation require that each entity that applies
12 for a grant, contract, or cooperative agreement under this
13 Act for any project or program that involves the conduct
14 of biomedical or behavioral research submit in or with its
15 application for such grant, contract, or cooperative agree-
16 ment assurances satisfactory to the Secretary that such
17 entity—

18 ~~“(1) has established (in accordance with regula-~~
19 ~~tions which the Secretary shall prescribe) an admin-~~
20 ~~istrative process to review reports of scientific mis-~~
21 ~~conduct in connection with biomedical and behav-~~
22 ~~ioral research conducted at or sponsored by such en-~~
23 ~~tity; and~~

24 ~~“(2) will report to the Director any investiga-~~
25 ~~tion of alleged scientific misconduct in connection~~

1 with projects for which funds have been made avail-
2 able under this Act that appears substantial.

3 ~~“(c) PROCESS FOR RESPONSE OF DIRECTOR.—The~~
4 Secretary shall establish by regulation a process to be fol-
5 lowed by the Director for the prompt and appropriate—

6 ~~“(1) response to information provided to the~~
7 Director respecting scientific misconduct in connec-
8 tion with projects for which funds have been made
9 available under this Act;

10 ~~“(2) receipt of reports by the Director of such~~
11 information from recipients of funds under this Act;

12 ~~“(3) conduct of investigations, when appro-~~
13 piate; and

14 ~~“(4) taking of other actions, including appro-~~
15 piate remedies, with respect to such misconduct.

16 ~~“(d) MONITORING BY DIRECTOR.—The Secretary~~
17 shall by regulation establish procedures for the Director
18 to monitor administrative processes and investigations
19 that have been established or carried out under this sec-
20 tion.

21 ~~“(e) EFFECT ON PRESENT INVESTIGATIONS.—Noth-~~
22 ing in this section shall affect investigations which have
23 been or will be commenced prior to the promulgation of
24 final regulations under this section.”.

1 (b) ~~ESTABLISHMENT OF DEFINITION OF SCIENTIFIC~~
2 ~~MISCONDUCT.~~—Not later than 90 days after the date on
3 which the report required under section 152(d) is submit-
4 ted to the Secretary of Health and Human Services, such
5 Secretary shall by regulation establish a definition for the
6 term “scientific misconduct” for purposes of section 493
7 of the Public Health Service Act, as amended by sub-
8 section (a) of this section.

9 **SEC. 162. COMMISSION ON SCIENTIFIC INTEGRITY.**

10 (a) ~~IN GENERAL.~~—The Secretary of Health and
11 Human Services shall establish a commission to be known
12 as the Commission on Scientific Integrity (in this section
13 referred to as the “Commission”).

14 (b) ~~DUTIES.~~—The Commission shall develop rec-
15 ommendations for the Secretary of Health and Human
16 Services on the administration of section 493 of the Public
17 Health Service Act (as amended and added by section 161
18 of this Act).

19 (c) ~~COMPOSITION.~~—The Commission shall be com-
20 posed of 12 members to be appointed by the Secretary
21 of Health and Human Services from among individuals
22 who are not officers or employees of the United States.
23 Of the members appointed to the Commission—

24 (1) three shall be scientists with substantial ac-
25 complishments in biomedical or behavioral research;

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

4 (3) three shall be representatives of institutions
5 of higher education at which biomedical or behav-
6 ioral research is conducted; and

7 (4) three shall be individuals who are not de-
8 scribed in paragraphs (1), (2), or (3), at least one
9 of whom shall be an attorney and at least one of
10 whom shall be an ethicist.

11 (d) COMPENSATION.—Members of the Commission
12 shall receive compensation for each day engaged in carry-
13 ing out the duties of the Commission, including time en-
14 gaged in traveling for purposes of such duties. Such com-
15 pensation may not be provided in an amount in excess of
16 the maximum rate of basic pay payable for GS-18 of the
17 General Schedule.

18 (e) REPORT.—Not later than 120 days after the date
19 of enactment of this section, the Commission shall prepare
20 and submit to the Secretary of Health and Human Serv-
21 ices, the Committee on Energy and Commerce of the
22 House of Representatives, and the Committee on Labor
23 and Human Resources of the Senate, a report containing
24 the recommendations developed under subsection (b).

1 **SEC. 163. PROTECTION OF WHISTLEBLOWERS.**

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

5 ~~“(f) PROTECTION OF WHISTLEBLOWERS.—~~

6 ~~“(1) IN GENERAL.—In the case of any entity~~
7 ~~required to establish administrative processes under~~
8 ~~subsection (b), the Secretary shall by regulation es-~~
9 ~~tablish standards for preventing, and for responding~~
10 ~~to the occurrence of retaliation by such entity, its of-~~
11 ~~ficials or agents, against an employee in the terms~~
12 ~~and conditions of employment in response to the em-~~
13 ~~ployee having in good faith—~~

14 ~~“(A) made an allegation that the entity, its~~
15 ~~officials or agents, has engaged in or failed to~~
16 ~~adequately respond to an allegation of scientific~~
17 ~~misconduct; or~~

18 ~~“(B) cooperated with an investigation of~~
19 ~~such an allegation.~~

20 ~~“(2) MONITORING BY SECRETARY.—The Sec-~~
21 ~~retary shall establish by regulation procedures for~~
22 ~~the Director to monitor the implementation of the~~
23 ~~standards established by an entity under paragraph~~
24 ~~(1) for the purpose of determining whether the pro-~~
25 ~~cedures have been established, and are being uti-~~

1 lized, in accordance with the standards established
2 under such paragraph.

3 “(3) NONCOMPLIANCE.—The Secretary shall by
4 regulation establish remedies for noncompliance by
5 an entity, its officials or agents, which has engaged
6 in retaliation in violation of the standards estab-
7 lished under paragraph (1). Such remedies may in-
8 clude termination of funding provided by the Sec-
9 retary for such project or recovery of funding being
10 provided by the Secretary for such project, or other
11 actions as appropriate.

12 “(4) FINAL RULE FOR REGULATIONS.—The
13 Secretary shall issue a final rule for the regulations
14 required in paragraph (1) not later than 180 days
15 after the date of the enactment of the National In-
16 stitutes of Health Revitalization Act of 1993.

17 “(5) REQUIRED AGREEMENTS.—For any fiscal
18 year beginning after the date on which the regula-
19 tions required in paragraph (1) are issued, the Sec-
20 retary may not provide a grant, cooperative agree-
21 ment, or contract under this Act for biomedical or
22 behavioral research unless the entity seeking such fi-
23 nancial assistance agrees that the entity—

24 “(A) will maintain the procedures de-
25 scribed in the regulations; and

1 “(B) will otherwise be subject to the regu-
2 lations.”.

3 **SEC. 164. REQUIREMENT OF REGULATIONS REGARDING**
4 **PROTECTION AGAINST FINANCIAL CON-**
5 **FLICTS OF INTEREST IN CERTAIN PROJECTS**
6 **OF RESEARCH.**

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

10 “PROTECTION AGAINST FINANCIAL CONFLICTS OF
11 INTEREST IN CERTAIN PROJECTS OF RESEARCH

12 “SEC. 493A. (a) ISSUANCE OF REGULATIONS.—

13 “(1) IN GENERAL.—The Secretary shall define
14 by regulation, the specific circumstances that con-
15 stitute the existence of a financial interest in a
16 project on the part of an entity or individual that
17 will, or may be reasonably expected to, create a bias
18 in favor of obtaining results in such project that are
19 consistent with such financial interest. Such defini-
20 tion shall apply uniformly to each entity or individ-
21 ual conducting a research project under this Act. In
22 the case of any entity or individual receiving assist-
23 ance from the Secretary for a project of research de-
24 scribed in paragraph (2), the Secretary shall by reg-
25 ulation establish standards for responding to, includ-
26 ing managing, reducing, or eliminating, the existence

1 of such a financial interest. The entity may adopt
2 individualized procedures for implementing the
3 standards.

4 “(2) RELEVANT PROJECTS.—A project of re-
5 search referred to in paragraph (1) is a project of
6 clinical research whose purpose is to evaluate the
7 safety or effectiveness of a drug, medical device, or
8 treatment and for which such entity is receiving as-
9 sistance from the Secretary.

10 “(3) IDENTIFYING AND REPORTING TO THE DI-
11 RECTOR.—The Secretary shall ensure that the
12 standards established under paragraph (1) specify
13 that as a condition of receiving assistance from the
14 Secretary for the project involved, an entity de-
15 scribed in such subsection is required—

16 “(A) to have in effect at the time the en-
17 tity applies for the assistance and throughout
18 the period during which the assistance is re-
19 ceived, a process for identifying such financial
20 interests as defined in paragraph (1) that exist
21 regarding the project; and

22 “(B) to report to the Director such finan-
23 cial interest as defined in paragraph (1) identi-
24 fied by the entity and how any such financial
25 interest identified by the entity will be managed

1 or eliminated such that the project in question
2 will be protected from bias that may stem from
3 such financial interest.

4 ~~“(4) MONITORING OF PROCESS.—~~The Secretary
5 shall monitor the establishment and conduct of the
6 process established by an entity pursuant to para-
7 graph (1).

8 ~~“(5) RESPONSE.—~~In any case in which the Sec-
9 retary determines that an entity has failed to comply
10 with paragraph (3) regarding a project of research
11 described in paragraph (1), the Secretary—

12 ~~“(A) shall require that, as a condition of~~
13 ~~receiving assistance, the entity disclose the ex-~~
14 ~~istence of a financial interest as defined in~~
15 ~~paragraph (1) in each public presentation of the~~
16 ~~results of such project; and~~

17 ~~“(B) may take such other actions as the~~
18 ~~Secretary determines to be appropriate.~~

19 ~~“(6) DEFINITION.—~~As used in this section:

20 ~~“(A) The term ‘financial interest’ includes~~
21 ~~the receipt of consulting fees or honoraria and~~
22 ~~the ownership of stock or equity.~~

23 ~~“(B) The term ‘assistance’, with respect to~~
24 ~~conducting a project of research, means a~~
25 ~~grant, contract, or cooperative agreement.~~

1 “(b) FINAL RULE FOR REGULATIONS.—The Sec-
2 retary shall issue a final rule for the regulations required
3 in subsection (a) not later than 180 days after the date
4 of the enactment of the National Institutes of Health Re-
5 vitalization Act of 1993.”.

6 **SEC. 165. EFFECTIVE DATES.**

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

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

1 **TITLE II—NATIONAL INSTITUTES**
2 **OF HEALTH IN GENERAL**

3 **SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINA-**
4 **TION.**

5 Section 402(f) of the Public Health Service Act (42
6 U.S.C. 282(f)) is amended by striking “other public and
7 private entities.” and all that follows through the end and
8 inserting “other public and private entities, including ele-
9 mentary, secondary, and post-secondary schools. The As-
10 sociate Director shall—

11 “(1) annually review the efficacy of existing
12 policies and techniques used by the national research
13 institutes to disseminate the results of disease pre-
14 vention and behavioral research programs;

15 “(2) recommend, coordinate, and oversee the
16 modification or reconstruction of such policies and
17 techniques to ensure maximum dissemination, using
18 advanced technologies to the maximum extent prac-
19 ticable, of research results to such entities; and

20 “(3) annually prepare and submit to the Direc-
21 tor of NIH a report concerning the prevention and
22 dissemination activities undertaken by the Associate
23 Director, including—

24 “(A) a summary of the Associate Direc-
25 tor’s review of existing dissemination policies

1 and techniques together with a detailed state-
2 ment concerning any modification or restructur-
3 ing, or recommendations for modification or re-
4 structuring, of such policies and techniques;
5 and

6 “(B) a detailed statement of the expendi-
7 tures made for the prevention and dissemina-
8 tion activities reported on and the personnel
9 used in connection with such activities.”.

10 **SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARD-**
11 **ING CERTAIN STATES AND RESEARCHERS.**

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

15 “(g)(1)(A) In the case of entities described in sub-
16 paragraph (B), the Director of NIH, acting through the
17 Director of the National Center for Research Resources,
18 shall establish a program to enhance the competitiveness
19 of such entities in obtaining funds from the national re-
20 search institutes for conducting biomedical and behavioral
21 research.

22 “(B) The entities referred to in subparagraph (A) are
23 entities that conduct biomedical and behavioral research
24 and are located in a State in which the aggregate success
25 rate for applications to the national research institutes for

1 assistance for such research by the entities in the State
2 has historically constituted a low success rate of obtaining
3 such funds, relative to such aggregate rate for such enti-
4 ties in other States.

5 “(C) With respect to enhancing competitiveness for
6 purposes of subparagraph (A), the Director of NIH, in
7 carrying out the program established under such subpara-
8 graph, may—

9 “(i) provide technical assistance to the entities
10 involved, including technical assistance in the prepa-
11 ration of applications for obtaining funds from the
12 national research institutes;

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

15 “(iii) assist the entities in implementing such
16 plan.

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

22 **SEC. 203. CHILDREN’S VACCINE INITIATIVE.**

23 Part A of title IV of the Public Health Service Act
24 (42 U.S.C. 281 et seq.) is amended by adding at the end
25 the following new section:

1 “CHILDREN’S VACCINE INITIATIVE

2 “SEC. 404. (a) DEVELOPMENT OF NEW VAC-
3 CINES.—The Secretary, in consultation with the Director
4 of the National Vaccine Program under title XXI and act-
5 ing through the Directors of the National Institute for Al-
6 lergy and Infectious Diseases, the National Institute for
7 Child Health and Human Development, the National In-
8 stitute for Aging, and other public and private programs,
9 shall carry out activities, which shall be consistent with
10 the global Children’s Vaccine Initiative, to develop afford-
11 able new and improved vaccines to be used in the United
12 States and in the developing world that will increase the
13 efficacy and efficiency of the prevention of infectious dis-
14 eases. In carrying out such activities, the Secretary shall,
15 to the extent practicable, develop and make available vac-
16 cines that require fewer contacts to deliver, that can be
17 given early in life, that provide long lasting protection,
18 that obviate refrigeration, needles and syringes, and that
19 protect against a larger number of diseases.

20 “(b) REPORT.—In the report required in section
21 2104, the Secretary, acting through the Director of the
22 National Vaccine Program under title XXI, shall include
23 information with respect to activities and the progress
24 made in implementing the provisions of this section and
25 achieving its goals.

1 ~~“(c) AUTHORIZATION OF APPROPRIATIONS.—In ad-~~
 2 ~~dition to any other amounts authorized to be appropriated~~
 3 ~~for activities of the type described in this section, there~~
 4 ~~are authorized to be appropriated to carry out this section~~
 5 ~~\$20,000,000 for fiscal year 1994, and such sums as may~~
 6 ~~be necessary for each of the fiscal years 1995 and 1996.”.~~

7 **SEC. 204. PLAN FOR USE OF ANIMALS IN RESEARCH.**

8 ~~(a) IN GENERAL.—Part A of title IV of the Public~~
 9 ~~Health Service Act, as amended by section 203 of this Act,~~
 10 ~~is amended by adding at the end the following new section:~~

11 ~~“PLAN FOR USE OF ANIMALS IN RESEARCH~~

12 ~~“SEC. 404A. (a) The Director of NIH, after consulta-~~
 13 ~~tion with the committee established under subsection (e),~~
 14 ~~shall prepare a plan—~~

15 ~~“(1) for the National Institutes of Health to~~
 16 ~~conduct or support research into—~~

17 ~~“(A) methods of biomedical research and~~
 18 ~~experimentation that do not require the use of~~
 19 ~~animals;~~

20 ~~“(B) methods of such research and experi-~~
 21 ~~mentation that reduce the number of animals~~
 22 ~~used in such research; and~~

23 ~~“(C) methods of such research and experi-~~
 24 ~~mentation that produce less pain and distress in~~
 25 ~~such animals;~~

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

3 ~~“(3) for encouraging the acceptance by the sci-~~
4 ~~entific community of such methods that have been~~
5 ~~found to be valid and reliable; and~~

6 ~~“(4) for training scientists in the use of such~~
7 ~~methods that have been found to be valid and reli-~~
8 ~~able.~~

9 ~~“(b) Not later than October 1, 1993, the Director~~
10 ~~of NIH shall submit to the Committee on Energy and~~
11 ~~Commerce of the House of Representatives, and to the~~
12 ~~Committee on Labor and Human Resources of the Senate,~~
13 ~~the plan required in subsection (a) and shall begin imple-~~
14 ~~mentation of the plan.~~

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

21 ~~“(d) The Director of NIH shall take such actions as~~
22 ~~may be appropriate to convey to scientists and others who~~
23 ~~use animals in biomedical or behavioral research or experi-~~
24 ~~mentation information respecting the methods found to be~~
25 ~~valid and reliable under subsection (a)(2).~~

1 “(e)(1) The Director of NIH shall establish within
2 the National Institutes of Health a committee to be known
3 as the Interagency Coordinating Committee on the Use
4 of Animals in Research (hereafter in this subsection re-
5 ferred to as the ‘Committee’).

6 “(2) The Committee shall provide advice to the Direc-
7 tor of NIH on the preparation of the plan required in sub-
8 section (a).

9 “(3) The Committee shall be composed of—

10 “(A) the Directors of each of the national re-
11 search institutes and the Director of the Center for
12 Research Resources (or the designees of such Direc-
13 tors); and

14 “(B) representatives of the Environmental Pro-
15 tection Agency, the Food and Drug Administration,
16 the Consumer Product Safety Commission, the Na-
17 tional Science Foundation, and such additional agen-
18 cies as the Director of NIH determines to be appro-
19 priate.”.

20 (b) CONFORMING AMENDMENT.—Section 4 of the
21 Health Research Extension Act of 1985 (Public Law 99-
22 158; 99 Stat. 880) is repealed.

1 **SEC. 205. INCREASED PARTICIPATION OF WOMEN AND**
 2 **MEMBERS OF UNDERREPRESENTED MINORI-**
 3 **TIES IN FIELDS OF BIOMEDICAL AND BEHAV-**
 4 **IORAL RESEARCH.**

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

8 “(h) The Secretary, acting through the Director of
 9 NIH and the Directors of the agencies of the National
 10 Institutes of Health, may conduct and support programs
 11 for research, research training, recruitment, and other ac-
 12 tivities to provide for an increase in the number of women
 13 and members of underrepresented minority groups in the
 14 fields of biomedical and behavioral research.”.

15 **SEC. 206. REQUIREMENTS REGARDING SURVEYS OF SEX-**
 16 **UAL BEHAVIOR.**

17 Part A of title IV of the Public Health Service Act,
 18 as amended by section 204 of this Act, is amended by add-
 19 ing at the end the following new section:

20 “REQUIREMENTS REGARDING SURVEYS OF SEXUAL
 21 BEHAVIOR

22 “SEC. 404B. With respect to any survey of human
 23 sexual behavior proposed to be conducted or supported
 24 through the National Institutes of Health, the survey may
 25 not be carried out unless—

1 ~~“(1) the proposal has undergone review in ac-~~
2 ~~cordance with any applicable requirements of sec-~~
3 ~~tions 491 and 492; and~~

4 ~~“(2) the Secretary, in accordance with section~~
5 ~~492A, makes a determination that the information~~
6 ~~expected to be obtained through the survey will as-~~
7 ~~sist—~~

8 ~~“(A) in reducing the incidence of sexually~~
9 ~~transmitted diseases, the incidence of infection~~
10 ~~with the human immunodeficiency virus, or the~~
11 ~~incidence of any other infectious disease; or~~

12 ~~“(B) in improving reproductive health or~~
13 ~~other conditions of health.”.~~

14 **SEC. 207. DISCRETIONARY FUND OF DIRECTOR OF NA-**
15 **TIONAL INSTITUTES OF HEALTH.**

16 Section 402 of the Public Health Service Act, as
17 amended by section 205 of this Act, is amended by adding
18 at the end the following new subsection:

19 ~~“(i)(1) There is established a fund, consisting of~~
20 ~~amounts appropriated under paragraph (3) and made~~
21 ~~available for the fund, for use by the Director of NIH to~~
22 ~~carry out the activities authorized in this Act for the Na-~~
23 ~~tional Institutes of Health. The purposes for which such~~
24 ~~fund may be expended include—~~

1 ~~“(A) providing for research on matters that~~
2 ~~have not received significant funding relative to~~
3 ~~other matters, responding to new issues and sci-~~
4 ~~entific emergencies, and acting on research opportu-~~
5 ~~nities of high priority;~~

6 ~~“(B) supporting research that is not exclusively~~
7 ~~within the authority of any single agency of such In-~~
8 ~~stitutes; and~~

9 ~~“(C) purchasing or renting equipment and~~
10 ~~quarters for activities of such Institutes.~~

11 ~~“(2) Not later than February 10 of each fiscal year,~~
12 ~~the Secretary shall submit to the Committee on Energy~~
13 ~~and Commerce of the House of Representatives, and to~~
14 ~~the Committee on Labor and Human Resources of the~~
15 ~~Senate, a report describing the activities undertaken and~~
16 ~~expenditures made under this section during the preceding~~
17 ~~fiscal year. The report may contain such comments of the~~
18 ~~Secretary regarding this section as the Secretary deter-~~
19 ~~mines to be appropriate.~~

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

1 **SEC. 208. MISCELLANEOUS PROVISIONS.**

2 (a) ~~TERM OF OFFICE FOR MEMBERS OF ADVISORY~~
3 ~~COUNCILS.~~—Section 406(e) of the Public Health Service
4 Act (~~42 U.S.C. 284a(c)~~) is amended in the second sen-
5 tence by striking “until a successor has been appointed”
6 and inserting the following: “for 180 days after the date
7 of such expiration”.

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

11 (1) in paragraph (3), by striking “and” at the
12 end;

13 (2) in paragraph (4), by striking the period and
14 inserting “; and”; and

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

17 “~~(5)~~ ensure that, after January 1, 1994, at
18 least one-half of all new or revised health education
19 and promotion materials developed or funded by the
20 National Institutes of Health is in a form that does
21 not exceed a level of functional literacy, as defined
22 in the National Literacy Act of 1991 (Public Law
23 ~~102-73).~~”.

24 (c) ~~DAY CARE REGARDING CHILDREN OF EMPLOY-~~
25 ~~EES.~~—Section 402 of the Public Health Service Act, as

1 amended by section 207 of this Act, is amended by adding
 2 at the end the following new subsection:

3 “(i)(1) The Director of NIH may establish a program
 4 to provide day care service for the employees of the Na-
 5 tional Institutes of Health similar to those services pro-
 6 vided by other Federal agencies (including the availability
 7 of day care service on a 24-hour-a-day basis).”

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

11 “(3) For purposes regarding the provision of day care
 12 service, the Director of NIH may enter into rental or lease
 13 purchase agreements.”

14 **TITLE III—GENERAL PROVI-**
 15 **SIONS RESPECTING NA-**
 16 **TIONAL RESEARCH INSTI-**
 17 **TUTES**

18 **SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS**
 19 **OF NATIONAL RESEARCH INSTITUTES.**

20 (a) ESTABLISHMENT OF GENERAL AUTHORITY RE-
 21 GARDING DIRECT FUNDING.—

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

1 (A) in subparagraph (A), by striking
2 “and” after the semicolon at the end;

3 (B) in subparagraph (B), by striking the
4 period at the end and inserting “; and”; and

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

7 “(C) shall receive from the President and the
8 Office of Management and Budget directly all funds
9 appropriated by the Congress for obligation and ex-
10 penditure by the Institute.”.

11 (2) CONFORMING AMENDMENT.—Section
12 413(b)(9) of the Public Health Service Act (42
13 U.S.C. 285a-2(b)(9)) is amended—

14 (A) by striking “(A)” after “(9)”; and

15 (B) by striking “advisory council;” and all
16 that follows and inserting “advisory council.”.

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

21 (1) by amending paragraph (3) to read as fol-
22 lows:

23 “(3) may, in consultation with the advisory
24 council for the Institute and with the approval of the
25 Director of NIH—

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

4 “(B) appoint the members of peer review
5 groups established under subparagraph (A);
6 and”; and

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

9 “The Federal Advisory Committee Act shall not apply to
10 the duration of a peer review group appointed under para-
11 graph (3).”.

12 **SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS,**
13 **PAGET’S DISEASE, AND RELATED BONE DIS-**
14 **ORDERS.**

15 Part B of title IV of the Public Health Service Act
16 (42 U.S.C. 284 et seq.), as amended by section 121(b)
17 of Public Law 102-321 (106 Stat. 358), is amended by
18 adding at the end the following new section:

19 “RESEARCH ON OSTEOPOROSIS, PAGET’S DISEASE, AND
20 RELATED BONE DISORDERS

21 “SEC. 410. (a) ESTABLISHMENT.—The Directors of
22 the National Institute of Arthritis and Musculoskeletal
23 and Skin Diseases, the National Institute on Aging, and
24 the National Institute of Diabetes, Digestive and Kidney
25 Diseases, shall expand and intensify the programs of such
26 Institutes with respect to research and related activities

1 concerning osteoporosis, Paget's disease, and related bone
2 disorders.

3 ~~“(b) COORDINATION.—~~The Directors referred to in
4 subsection (a) shall jointly coordinate the programs re-
5 ferred to in such subsection and consult with the Arthritis
6 and Musculoskeletal Diseases Interagency Coordinating
7 Committee and the Interagency Task Force on Aging Re-
8 search.

9 ~~“(c) INFORMATION CLEARINGHOUSE.—~~

10 ~~“(1) IN GENERAL.—~~In order to assist in carry-
11 ing out the purpose described in subsection (a), the
12 Director of NIH shall provide for the establishment
13 of an information clearinghouse on osteoporosis and
14 related bone disorders to facilitate and enhance
15 knowledge and understanding on the part of health
16 professionals, patients, and the public through the
17 effective dissemination of information.

18 ~~“(2) ESTABLISHMENT THROUGH GRANT OR~~
19 ~~CONTRACT.—~~For the purpose of carrying out para-
20 graph (1), the Director of NIH shall enter into a
21 grant, cooperative agreement, or contract with a
22 nonprofit private entity involved in activities regard-
23 ing the prevention and control of osteoporosis and
24 related bone disorders.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated \$40,000,000 for fiscal year 1994, and
4 such sums as may be necessary for each of the fiscal years
5 1995 and 1996.”.

6 **SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM**
7 **FOR TRAUMA RESEARCH.**

8 (a) IN GENERAL.—Title XII of the Public Health
9 Service Act (42 U.S.C. 300d et seq.) is amended by adding
10 at the end the following part:

11 “PART E—INTERAGENCY PROGRAM FOR TRAUMA
12 RESEARCH

13 **“SEC. 1251. ESTABLISHMENT OF PROGRAM.**

14 “(a) IN GENERAL.—The Secretary, acting through
15 the Director of the National Institutes of Health (here-
16 after in this section referred to as the ‘Director’), shall
17 establish a comprehensive program of conducting basic
18 and clinical research on trauma (hereafter in this section
19 referred to as the ‘Program’). The Program shall include
20 research regarding the diagnosis, treatment, rehabilita-
21 tion, and general management of trauma.

22 (b) PLAN FOR PROGRAM.—

23 “(1) IN GENERAL.—The Director, in consulta-
24 tion with the Trauma Research Interagency Coordi-
25 nating Committee established under subsection (g),

1 shall establish and implement a plan for carrying
2 out the activities of the Program, including the ac-
3 tivities described in subsection (d). All such activities
4 shall be carried out in accordance with the plan. The
5 plan shall be periodically reviewed, and revised as
6 appropriate.

7 “(2) SUBMISSION TO CONGRESS.—Not later
8 than June 1, 1993, the Director shall submit the
9 plan required in paragraph (1) to the Committee on
10 Energy and Commerce of the House of Representa-
11 tives, and to the Committee on Labor and Human
12 Resources of the Senate, together with an estimate
13 of the funds needed for each of the fiscal years 1994
14 through 1996 to implement the plan.

15 “(c) PARTICIPATING AGENCIES; COORDINATION AND
16 COLLABORATION.—The Director—

17 “(1) shall provide for the conduct of activities
18 under the Program by the Directors of the agencies
19 of the National Institutes of Health involved in re-
20 search with respect to trauma;

21 “(2) shall ensure that the activities of the Pro-
22 gram are coordinated among such agencies; and

23 “(3) shall, as appropriate, provide for collabora-
24 tion among such agencies in carrying out such ac-
25 tivities.

1 “(d) CERTAIN ACTIVITIES OF PROGRAM.—The Pro-
2 gram shall include—

3 “(1) studies with respect to all phases of trau-
4 ma care, including prehospital, resuscitation, sur-
5 gical intervention, critical care, infection control,
6 wound healing, nutritional care and support, and
7 medical rehabilitation care;

8 “(2) basic and clinical research regarding the
9 response of the body to trauma and the acute treat-
10 ment and medical rehabilitation of individuals who
11 are the victims of trauma; and

12 “(3) basic and clinical research regarding trau-
13 ma care for pediatric and geriatric patients.

14 “(e) MECHANISMS OF SUPPORT.—In carrying out the
15 Program, the Director, acting through the Directors of the
16 agencies referred to in subsection (c)(1), may make grants
17 to public and nonprofit entities, including designated trau-
18 ma centers.

19 “(f) RESOURCES.—The Director shall assure the
20 availability of appropriate resources to carry out the Pro-
21 gram, including the plan established under subsection (b)
22 (including the activities described in subsection (d)).

23 “(g) COORDINATING COMMITTEE.—

24 “(1) IN GENERAL.—There shall be established
25 a Trauma Research Interagency Coordinating Com-

1 mittee (hereafter in this section referred to as the
2 ‘Coordinating Committee’).

3 ~~“(2) DUTIES.—The Coordinating Committee~~
4 ~~shall make recommendations regarding—~~

5 ~~“(A) the activities of the Program to be~~
6 ~~carried out by each of the agencies represented~~
7 ~~on the Committee and the amount of funds~~
8 ~~needed by each of the agencies for such activi-~~
9 ~~ties; and~~

10 ~~“(B) effective collaboration among the~~
11 ~~agencies in carrying out the activities.~~

12 ~~“(3) COMPOSITION.—The Coordinating Com-~~
13 ~~mittee shall be composed of the Directors of each of~~
14 ~~the agencies that, under subsection (c), have respon-~~
15 ~~sibilities under the Program, and any other individ-~~
16 ~~uals who are practitioners in the trauma field as~~
17 ~~designated by the Director of the National Institutes~~
18 ~~of Health.~~

19 ~~“(h) DEFINITIONS.—For purposes of this section:~~

20 ~~“(1) The term ‘designated trauma center’ has~~
21 ~~the meaning given such term in section 1231(1).~~

22 ~~“(2) The term ‘Director’ means the Director of~~
23 ~~the National Institutes of Health.~~

24 ~~“(3) The term ‘trauma’ means any serious in-~~
25 ~~jury that could result in loss of life or in significant~~

1 disability and that would meet pre-hospital triage
 2 criteria for transport to a designated trauma cen-
 3 ter.”.

4 (b) CONFORMING AMENDMENT.—Section 402 of the
 5 Public Health Service Act, as amended by section 208(c)
 6 of this Act, is amended by adding at the end the following
 7 new subsection:

8 “(k) The Director of NIH shall carry out the pro-
 9 gram established in part E of title XII (relating to inter-
 10 agency research on trauma).”.

11 **TITLE IV—NATIONAL CANCER** 12 **INSTITUTE**

13 **SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVI-** 14 **TIES REGARDING BREAST CANCER.**

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

18 “BREAST AND GYNECOLOGICAL CANCERS

19 “SEC. 417. (a) EXPANSION AND COORDINATION OF
 20 ACTIVITIES.—The Director of the Institute, in consulta-
 21 tion with the National Cancer Advisory Board, shall ex-
 22 pand, intensify, and coordinate the activities of the Insti-
 23 tute with respect to research on breast cancer, ovarian
 24 cancer, and other cancers of the reproductive system of
 25 women.

1 “(b) COORDINATION WITH OTHER INSTITUTES.—

2 The Director of the Institute shall coordinate the activities
3 of the Director under subsection (a) with similar activities
4 conducted by other national research institutes and agen-
5 cies of the National Institutes of Health to the extent that
6 such Institutes and agencies have responsibilities that are
7 related to breast cancer and other cancers of the reproduc-
8 tive system of women.

9 “(c) PROGRAMS FOR BREAST CANCER.—

10 “(1) IN GENERAL.—In carrying out subsection
11 (a), the Director of the Institute shall conduct or
12 support research to expand the understanding of the
13 cause of, and to find a cure for, breast cancer. Ac-
14 tivities under such subsection shall provide for an
15 expansion and intensification of the conduct and
16 support of—

17 “(A) basic research concerning the etiology
18 and causes of breast cancer;

19 “(B) clinical research and related activities
20 concerning the causes, prevention, detection and
21 treatment of breast cancer;

22 “(C) control programs with respect to
23 breast cancer in accordance with section 412;

1 ~~“(D) information and education programs~~
2 ~~with respect to breast cancer in accordance with~~
3 ~~section 413; and~~

4 ~~“(E) research and demonstration centers~~
5 ~~with respect to breast cancer in accordance with~~
6 ~~section 414, including the development and op-~~
7 ~~eration of centers for breast cancer research to~~
8 ~~bring together basic and clinical, biomedical and~~
9 ~~behavioral scientists to conduct basic, clinical,~~
10 ~~epidemiological, psychosocial, prevention and~~
11 ~~treatment research and related activities on~~
12 ~~breast cancer.~~

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

19 ~~“(2) IMPLEMENTATION OF PLAN FOR PRO-~~
20 ~~GRAMS.—~~

21 ~~“(A) The Director of the Institute shall en-~~
22 ~~sure that the research programs described in~~
23 ~~paragraph (1) are implemented in accordance~~
24 ~~with a plan for the programs. Such plan shall~~
25 ~~include comments and recommendations that~~

1 the Director of the Institute considers appro-
2 priate, with due consideration provided to the
3 professional judgment needs of the Institute as
4 expressed in the annual budget estimate pre-
5 pared in accordance with section 413(9). The
6 Director of the Institute, in consultation with
7 the National Cancer Advisory Board, shall peri-
8 odically review and revise such plan.

9 “(B) Not later than May 1, 1993, the Di-
10 rector of the Institute shall submit a copy of
11 the plan to the President’s Cancer Panel, the
12 Secretary and the Director of NIH.

13 “(C) The Director of the Institute shall
14 submit any revisions of the plan to the Presi-
15 dent’s Cancer Panel, the Secretary, and the Di-
16 rector of NIH.

17 “(D) The Secretary shall provide a copy of
18 the plan submitted under subparagraph (A),
19 and any revisions submitted under subpara-
20 graph (C), to the Committee on Energy and
21 Commerce of the House of Representatives and
22 the Committee on Labor and Human Resources
23 of the Senate.

24 “(d) OTHER CANCERS.—In carrying out subsection
25 (a), the Director of the Institute shall conduct or support

1 research on ovarian cancer and other cancers of the repro-
2 ductive system of women. Activities under such subsection
3 shall provide for the conduct and support of—

4 “(1) basic research concerning the etiology and
5 causes of ovarian cancer and other cancers of the re-
6 productive system of women;

7 “(2) clinical research and related activities into
8 the causes, prevention, detection and treatment of
9 ovarian cancer and other cancers of the reproductive
10 system of women;

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

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

18 “(5) research and demonstration centers with
19 respect to ovarian cancer and cancers of the repro-
20 ductive system in accordance with section 414.

21 “(e) REPORT.—The Director of the Institute shall
22 prepare, for inclusion in the biennial report submitted
23 under section 407, a report that describes the activities
24 of the National Cancer Institute under the research pro-
25 grams referred to in subsection (a), that shall include—

1 “(1) a description of the research plan with re-
2 spect to breast cancer prepared under subsection (c);

3 “(2) an assessment of the development, revi-
4 sion, and implementation of such plan;

5 “(3) a description and evaluation of the
6 progress made, during the period for which such re-
7 port is prepared, in the research programs on breast
8 cancer and cancers of the reproductive system of
9 women;

10 “(4) a summary and analysis of expenditures
11 made, during the period for which such report is
12 made, for activities with respect to breast cancer and
13 cancers of the reproductive system of women con-
14 ducted and supported by the National Institutes of
15 Health; and

16 “(5) such comments and recommendations as
17 the Director considers appropriate.”.

18 **SEC. 402. EXPANSION AND INTENSIFICATION OF ACTIVI-**
19 **TIES REGARDING PROSTATE CANCER.**

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

23 “PROSTATE CANCER

24 “SEC. 417A. (a) EXPANSION AND COORDINATION
25 OF ACTIVITIES.—The Director of the Institute, in con-
26 sultation with the National Cancer Advisory Board, shall

1 expand, intensify, and coordinate the activities of the In-
2 stitute with respect to research on prostate cancer.

3 “(b) COORDINATION WITH OTHER INSTITUTES.—

4 The Director of the Institute shall coordinate the activities
5 of the Director under subsection (a) with similar activities
6 conducted by other national research institutes and agen-
7 cies of the National Institutes of Health to the extent that
8 such Institutes and agencies have responsibilities that are
9 related to prostate cancer.

10 “(c) PROGRAMS.—

11 “(1) IN GENERAL.—In carryinf out subsection
12 (a), the Director of the Institute shall conduct or
13 support research to expand the understanding of the
14 cause of, and to find a cure for, prostate cancer. Ac-
15 tivities under such subsection shall provide for an
16 expansion and intensification of the conduct and
17 support of—

18 “(A) basic research concerning the etiology
19 and causes of prostate cancer;

20 “(B) clinical research and related activities
21 concerning the causes, prevention, detection and
22 treatment of prostate cancer;

23 “(C) prevention and control and early de-
24 tecton programs with respect to prostate can-
25 cer in accordance with section 412, particularly

1 as it relates to intensifying research on the role
2 of prostate specific antigen for the screening
3 and early detection of prostate cancer;

4 “(D) an Inter-Institute Task Force, under
5 the direction of the Director of the Institute, to
6 provide coordination between relevant National
7 Institutes of Health components of research ef-
8 forts on prostate cancer;

9 “(E) control programs with respect to
10 prostate cancer in accordance with section 412;

11 “(F) information and education programs
12 with respect to prostate cancer in accordance
13 with section 413; and

14 “(G) research and demonstration centers
15 with respect to prostate cancer in accordance
16 with section 414, including the development and
17 operation of centers for prostate cancer re-
18 search to bring together basic and clinical, bio-
19 medical and behavioral scientists to conduct
20 basic, clinical, epidemiological, psychosocial,
21 prevention and treatment research and related
22 activities on prostate cancer.

23 Not less than six centers shall be operated under
24 subparagraph (G). Activities of such centers should
25 include supporting new and innovative research and

1 training programs for new researchers. Such centers
2 shall give priority to expediting the transfer of re-
3 search advances to clinical applications.

4 ~~“(2) IMPLEMENTATION OF PLAN FOR PRO-~~
5 ~~GRAMS.—~~

6 ~~“(A) The Director of the Institute shall en-~~
7 ~~sure that the research programs described in~~
8 ~~paragraph (1) are implemented in accordance~~
9 ~~with a plan for the programs. Such plan shall~~
10 ~~include comments and recommendations that~~
11 ~~the Director of the Institute considers appro-~~
12 ~~priate, with due consideration provided to the~~
13 ~~professional judgment needs of the Institute as~~
14 ~~expressed in the annual budget estimate pre-~~
15 ~~pared in accordance with section 413(9). The~~
16 ~~Director of the Institute, in consultation with~~
17 ~~the National Cancer Advisory Board, shall peri-~~
18 ~~odically review and revise such plan.~~

19 ~~“(B) Not later than May 1, 1993, the Di-~~
20 ~~rector of the Institute shall submit a copy of~~
21 ~~the plan to the President’s Cancer Panel, the~~
22 ~~Secretary, and the Director of NIH.~~

23 ~~“(C) The Director of the Institute shall~~
24 ~~submit any revisions of the plan to the Presi-~~

1 dent's Cancer Panel, the Secretary, and the Di-
2 rector of NIH.

3 “(D) The Secretary shall provide a copy of
4 the plan submitted under subparagraph (A),
5 and any revisions submitted under subpara-
6 graph (C), to the Committee on Energy and
7 Commerce of the House of Representatives and
8 the Committee on Labor and Human Resources
9 of the Senate.”.

10 **SEC. 403. AUTHORIZATION OF APPROPRIATIONS.**

11 (a) IN GENERAL.—Subpart 1 of part C of title IV
12 of the Public Health Service Act, as amended by section
13 402 of this Act, is amended by adding at the end the fol-
14 lowing new section:

15 “AUTHORIZATION OF APPROPRIATIONS

16 “SEC. 417B. (a) ACTIVITIES GENERALLY.—For the
17 purpose of carrying out this subpart, there are authorized
18 to be appropriated \$2,200,000,000 for fiscal year 1994,
19 and such sums as may be necessary for each of the fiscal
20 years 1995 and 1996.

21 “(b) BREAST CANCER AND GYNECOLOGICAL CAN-
22 CERS.—

23 “(1) BREAST CANCER.—

24 “(A) For the purpose of carrying out sub-
25 paragraph (A) of section 417(c)(1), there are
26 authorized to be appropriated \$225,000,000 for

1 fiscal year 1994, and such sums as may be nec-
2 essary for each of the fiscal years 1995 and
3 1996. Such authorizations of appropriations are
4 in addition to the authorizations of appropria-
5 tions established in subsection (a) with respect
6 to such purpose.

7 “(B) For the purpose of carrying out sub-
8 paragraphs (B) through (E) of section
9 417(c)(1), there are authorized to be appro-
10 priated \$100,000,000 for fiscal year 1994, and
11 such sums as may be necessary for each of the
12 fiscal years 1995 and 1996. Such authoriza-
13 tions of appropriations are in addition to the
14 authorizations of appropriations established in
15 subsection (a) with respect to such purpose.

16 “(2) OTHER CANCERS.—For the purpose of
17 carrying out subsection (d) of section 417, there are
18 authorized to be appropriated \$75,000,000 for fiscal
19 year 1994, and such sums as are necessary for each
20 of the fiscal years 1995 and 1996. Such authoriza-
21 tions of appropriations are in addition to the author-
22 izations of appropriations established in subsection
23 (a) with respect to such purpose.

24 “(c) PROSTATE CANCER.—For the purpose of carry-
25 ing out section 417A, there are authorized to be appro-

1 priated \$72,000,000 for fiscal year 1994, and such sums
2 as may be necessary for each of the fiscal years 1995 and
3 1996. Such authorizations of appropriations are in addi-
4 tion to the authorizations of appropriations established in
5 subsection (a) with respect to such purpose.

6 “(d) ALLOCATION REGARDING CANCER CONTROL.—
7 Of the amounts appropriated for the National Cancer In-
8 stitute for a fiscal year, the Director of the Institute shall
9 make available not less than 10 percent for carrying out
10 the cancer control activities authorized in section 412 and
11 for which budget estimates are made under section
12 413(b)(9) for the fiscal year.”.

13 (b) SPECIAL RULE REGARDING FUNDS FOR SECTION
14 412 FOR FISCAL YEAR 1994.—Notwithstanding section
15 417B(d) of the Public Health Service Act, as added by
16 subsection (a) of this section, the amount made available
17 under such section for fiscal year 1994 for carrying out
18 section 412 of such Act shall be an amount not less than
19 an amount equal to 75 percent of the amount specified
20 for activities under such section 412 in the budget esti-
21 mate made under section 413(b)(9) of such Act for such
22 fiscal year.

23 (c) CONFORMING AMENDMENTS.—

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

1 (A) by striking subsection (a);

2 (B) by redesignating subsection (b) as sub-
3 section (a);

4 (C) by redesignating paragraph (5) of sub-
5 section (a) (as so redesignated) as subsection
6 (b); and

7 (D) by amending the heading for the sec-
8 tion to read as follows:

9 “CERTAIN USES OF FUNDS”.

10 (2) ~~CROSS-REFERENCE.~~—Section 464F of the
11 Public Health Service Act (42 U.S.C. 285m-6) is
12 amended by striking “section 408(b)(1)” and insert-
13 ing “section 408(a)(1)”.

14 **TITLE V—NATIONAL HEART,**
15 **LUNG, AND BLOOD INSTITUTE**

16 **SEC. 501. EDUCATION AND TRAINING.**

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

19 (1) in paragraph (3), by striking “and” after
20 the semicolon at the end;

21 (2) in paragraph (4), by striking the period at
22 the end and inserting “; and”; and

23 (3) by inserting after paragraph (4) the follow-
24 ing new paragraph:

25 “(5) shall, in consultation with the advisory
26 council for the Institute, conduct appropriate intra-

1 mural training and education programs, including
2 continuing education and laboratory and clinical re-
3 search training programs.”.

4 **SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CAR-**
5 **DIOVASCULAR DISEASES.**

6 Section 422(a)(1) of the Public Health Service Act
7 (~~42 U.S.C. 285b-4(a)(1)~~) is amended—

8 (1) in subparagraph (B), by striking “and” at
9 the end;

10 (2) in subparagraph (C), by striking the period
11 and inserting “; and”; and

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

14 “(D) three centers for basic and clinical re-
15 search into, training in, and demonstration of, ad-
16 vanced diagnostic, prevention, and treatment (in-
17 cluding genetic studies, intrauterine environment
18 studies, postnatal studies, heart arrhythmias, and
19 acquired heart disease and preventive cardiology) for
20 cardiovascular diseases in children.”.

21 **SEC. 503. NATIONAL CENTER ON SLEEP DISORDERS.**

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

1 ~~“NATIONAL CENTER ON SLEEP DISORDERS~~

2 ~~“SEC. 424. (a) Not later than 1 year after the date~~
 3 ~~of the enactment of the National Institutes of Health Re-~~
 4 ~~vitalization Act of 1993, the Director of the Institute shall~~
 5 ~~establish the National Center on Sleep Disorders (in this~~
 6 ~~section referred to as the ‘Center’). The Center shall head-~~
 7 ~~ed by a director, who shall be appointed by the Director~~
 8 ~~of the Institute.~~

9 ~~“(b) The general purpose of the Center is the conduct~~
 10 ~~and support of research, training, health information dis-~~
 11 ~~semination, and other activities with respect to sleep dis-~~
 12 ~~orders.”.~~

13 **SEC. 504. AUTHORIZATION OF APPROPRIATIONS.**

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

17 ~~“AUTHORIZATION OF APPROPRIATIONS~~

18 ~~“SEC. 425. (a) For the purpose of carrying out this~~
 19 ~~subpart, there are authorized to be appropriated~~
 20 ~~\$1,500,000,000 for fiscal year 1994, and such sums as~~
 21 ~~may be necessary for each of the fiscal years 1995 and~~
 22 ~~1996.~~

23 ~~“(b) Of the amounts appropriated under paragraph~~
 24 ~~(1) for a fiscal year, the Director of the Institute shall~~
 25 ~~make available not less than 10 percent for carrying out~~
 26 ~~community-based prevention and control activities that in-~~

1 clude clinical investigations, clinical trials, epidemiologic
 2 studies, and prevention demonstration and education
 3 projects.”.

4 **TITLE VI—NATIONAL INSTITUTE**
 5 **ON DIABETES AND DIGESTIVE**
 6 **AND KIDNEY DISEASES**

7 **SEC. 601. PROVISIONS REGARDING NUTRITIONAL DIS-**
 8 **ORDERS.**

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

12 “NUTRITIONAL DISORDERS PROGRAM

13 “SEC. 434. (a) The Director of the Institute shall es-
 14 tablish a program of conducting and supporting research,
 15 training, health information dissemination, and other ac-
 16 tivities with respect to nutritional disorders, including obe-
 17 sity.

18 “(b) In carrying out the program established under
 19 subsection (a), the Director of the Institute shall conduct
 20 and support each of the activities described in such sub-
 21 section. The Director of NIH shall ensure that, as appro-
 22 priate, the other national research institutes and agencies
 23 of the National Institutes of Health have responsibilities
 24 regarding such activities.

25 “(c) In carrying out the program established under
 26 subsection (a), the Director of the Institute shall carry out

1 activities to facilitate and enhance knowledge and under-
2 standing of nutritional disorders, including obesity, on the
3 part of health professionals, patients, and the public
4 through the effective dissemination of information.”.

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

8 (1) by redesignating subsection (d) as sub-
9 section (e); and

10 (2) by inserting after subsection (c) the follow-
11 ing new subsection:

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

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

22 “(3) Each center developed or expanded under para-
23 graph (1) shall—

24 “(A) utilize the facilities of a single institution,
25 or be formed from a consortium of cooperating insti-

1 tutions, meeting such research and training quali-
2 fications as may be prescribed by the Director;

3 “(B) conduct basic and clinical research into
4 the cause, diagnosis, early detection, prevention, con-
5 trol and treatment of nutritional disorders, including
6 obesity and the impact of nutrition and diet on child
7 development;

8 “(C) conduct training programs for physicians
9 and allied health professionals in current methods of
10 diagnosis and treatment of such diseases and com-
11 plications, and in research in such disorders; and

12 “(D) conduct information programs for physi-
13 cians and allied health professionals who provide pri-
14 mary care for patients with such disorders or com-
15 plications.”.

16 **TITLE VII—NATIONAL INSTI-**
17 **TUTE ON ARTHRITIS AND**
18 **MUSCULOSKELETAL AND**
19 **SKIN DISEASES**

20 **SEC. 701. JUVENILE ARTHRITIS.**

21 (a) **PURPOSE.**—Section 435 of the Public Health
22 Service Act (42 U.S.C. 285d) is amended by striking “and
23 other programs” and all that follows and inserting the fol-
24 lowing: “and other programs with respect to arthritis and
25 musculoskeletal and skin diseases (including sports-related

1 disorders), with particular attention to the effect of these
2 diseases on children.”.

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

5 (1) in subsection (a), by inserting after the sec-
6 ond sentence, the following: “The plan shall place
7 particular emphasis upon expanding research into
8 better understanding the causes and the develop-
9 ment of effective treatments for arthritis affecting
10 children.”; and

11 (2) in subsection (b)—

12 (A) by striking “and” at the end of para-
13 graph (3);

14 (B) by striking the period at the end of
15 paragraph (4) and inserting “; and”; and

16 (C) by adding at the end thereof the fol-
17 lowing new paragraph:

18 “(5) research into the causes of arthritis affect-
19 ing children and the development, trial, and evalua-
20 tion of techniques, drugs and devices used in the di-
21 agnosis, treatment (including medical rehabilitation),
22 and prevention of arthritis in children.”.

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

1 “(f) Not later than October 1, 1994, the Director
2 shall establish a multipurpose arthritis and musculo-
3 skeletal disease center for the purpose of expanding the
4 level of research into the cause, diagnosis, early detection,
5 prevention, control, and treatment of, and rehabilitation
6 of children with arthritis and musculoskeletal diseases.”.

7 (d) ADVISORY BOARD.—

8 (1) TITLE.—Section 442(a) of the Public
9 Health Service Act (42 U.S.C. 285d–7(a)) is amend-
10 ed by inserting after “Arthritis” the first place such
11 term appears the following: “and Musculoskeletal
12 and Skin Diseases”.

13 (2) COMPOSITION.—Section 442(b) of the Pub-
14 lic Health Service Act (42 U.S.C. 285d–7(b)) is
15 amended—Section 442(b) of the Public Health Serv-
16 ice Act (42 U.S.C. 285d–7(b)) is amended—

17 (A) in the matter preceding paragraph (1),
18 by striking “eighteen” and inserting “twenty”;
19 and

20 (B) in paragraph (1)(B)—

21 (i) by striking “six” and inserting
22 “eight”; and

23 (ii) by striking “including” and all
24 that follows and inserting the following:
25 “including one member who is a person

1 who has such a disease, one person who is
 2 the parent of an adult with such a disease,
 3 and two members who are parents of chil-
 4 dren with arthritis.”.

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

8 (1) by striking “and” at the end of paragraph
 9 (3);

10 (2) by striking the period at the end of para-
 11 graph (4) and inserting “; and”; and

12 (3) by adding at the end the following para-
 13 graph:

14 “~~(5)~~ contains recommendations for expanding
 15 the Institute’s funding of research directly applicable
 16 to the cause, diagnosis, early detection, prevention,
 17 control, and treatment of, and rehabilitation of chil-
 18 dren with arthritis and musculoskeletal diseases.”.

19 **TITLE VIII—NATIONAL**
 20 **INSTITUTE ON AGING**

21 **SEC. 801. ALZHEIMER’S DISEASE REGISTRY.**

22 (a) IN GENERAL.—Section 12 of Public Law 99-158
 23 (99 Stat. 885) is—

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

4 (2) redesignated as section 445G; and

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

6 (b) ~~TECHNICAL AND CONFORMING AMENDMENTS.—~~

7 Section 445G of the Public Health Service Act, as trans-
8 ferred and inserted by subsection (a) of this section, is
9 amended—

10 (1) by striking the section heading and all that
11 follows through “may make a grant” in subsection
12 (a) and inserting the following:

13 ~~“ALZHEIMER’S DISEASE REGISTRY~~

14 ~~“SEC. 445G. (a) IN GENERAL.—The Director of the~~
15 ~~Institute may make a grant”;~~ and

16 (2) by striking subsection (c).

17 **~~SEC. 802. AGING PROCESSES REGARDING WOMEN.~~**

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

21 ~~“AGING PROCESSES REGARDING WOMEN~~

22 ~~“SEC. 445H. The Director of the Institute, in addi-~~
23 ~~tion to other special functions specified in section 444 and~~
24 ~~in cooperation with the Directors of the other national re-~~
25 ~~search institutes and agencies of the National Institutes~~
26 ~~of Health, shall conduct research into the aging processes~~

1 of women, with particular emphasis given to the effects
 2 of menopause and the physiological and behavioral
 3 changes occurring during the transition from pre- to post-
 4 menopause, and into the diagnosis, disorders, and com-
 5 plications related to aging and loss of ovarian hormones
 6 in women.”.

7 **SEC. 803. AUTHORIZATION OF APPROPRIATIONS.**

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

11 “AUTHORIZATION OF APPROPRIATIONS

12 “SEC. 445I. For the purpose of carrying out this sub-
 13 part, there are authorized to be appropriated
 14 \$500,000,000 for fiscal year 1994, and such sums as may
 15 be necessary for each of the fiscal years 1995 and 1996.”.

16 **SEC. 804. CONFORMING AMENDMENT.**

17 Section 445C of the Public Health Service Act (42
 18 U.S.C. 285e-5(b)) is amended—

19 (1) in subsection (b)(1), in the first sentence,
 20 by inserting after “Council” the following: “on Alz-
 21 heimer’s Disease (hereafter in this section referred
 22 to as the ‘Council’)”; and

23 (2) by adding at the end the following new sub-
 24 section:

1 “(d) For purposes of this section, the term ‘Council
2 on Alzheimer’s Disease’ means the council established in
3 section 911(a) of Public Law 99–660.”.

4 **TITLE IX—NATIONAL INSTITUTE**
5 **OF ALLERGY AND INFEC-**
6 **TIOUS DISEASES**

7 **SEC. 901. TROPICAL DISEASES.**

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

11 **SEC. 902. CHRONIC FATIGUE SYNDROME.**

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

15 “RESEARCH CENTERS REGARDING CHRONIC FATIGUE
16 SYNDROME

17 “SEC. 447. (a) The Director of the Institute, after
18 consultation with the advisory council for the Institute,
19 may make grants to, or enter into contracts with, public
20 or nonprofit private entities for the development and oper-
21 ation of centers to conduct basic and clinical research on
22 chronic fatigue syndrome.

23 “(b) Each center assisted under this section shall use
24 the facilities of a single institution, or be formed from a
25 consortium of cooperating institutions, meeting such re-

1 requirements as may be prescribed by the Director of the
2 Institute.”.

3 (b) EXTRAMURAL STUDY SECTION.—Not later than
4 6 months after the date of enactment of this Act, the Sec-
5 retary of Health and Human Services shall establish an
6 extramural study section for chronic fatigue syndrome re-
7 search.

8 (c) REPRESENTATIVES.—The Secretary of Health
9 and Human Services, acting through the Director of the
10 National Institutes of Health, shall ensure that appro-
11 priate individuals with expertise in chronic fatigue syn-
12 drome or neuromuscular diseases and representative of a
13 variety of disciplines and fields within the research com-
14 munity are appointed to appropriate National Institutes
15 of Health advisory committees and boards.

1 **TITLE X—NATIONAL INSTITUTE**
 2 **OF CHILD HEALTH AND**
 3 **HUMAN DEVELOPMENT**

4 **Subtitle A—Research Centers With**
 5 **Respect to Contraception and**
 6 **Research Centers With Respect**
 7 **to Infertility**

8 **SEC. 1001. GRANTS AND CONTRACTS FOR RESEARCH CEN-**
 9 **TERS.**

10 Subpart 7 of part C of title IV of the Public Health
 11 Service Act, as amended by section 3 of Public Law 101–
 12 613, is amended by adding at the end the following new
 13 section:

14 “RESEARCH CENTERS WITH RESPECT TO
 15 CONTRACEPTION AND INFERTILITY

16 “SEC. 452A. (a) The Director of the Institute, after
 17 consultation with the advisory council for the Institute,
 18 shall make grants to, or enter into contracts with, public
 19 or nonprofit private entities for the development and oper-
 20 ation of centers to conduct activities for the purpose of
 21 improving methods of contraception and centers to con-
 22 duct activities for the purpose of improving methods of
 23 diagnosis and treatment of infertility.

24 “(b) In carrying out subsection (a), the Director of
 25 the Institute shall, subject to the extent of amounts made

1 available in appropriations Acts, provide for the establish-
2 ment of three centers with respect to contraception and
3 for two centers with respect to infertility.

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

6 “(A) conduct clinical and other applied re-
7 search, including—

8 “(i) for centers with respect to contracep-
9 tion, clinical trials of new or improved drugs
10 and devices for use by males and females (in-
11 cluding barrier methods); and

12 “(ii) for centers with respect to infertility,
13 clinical trials of new or improved drugs and de-
14 vices for the diagnosis and treatment of infertil-
15 ity in males and females;

16 “(B) develop protocols for training physicians,
17 scientists, nurses, and other health and allied health
18 professionals;

19 “(C) conduct training programs for such indi-
20 viduals;

21 “(D) develop model continuing education pro-
22 grams for such professionals; and

23 “(E) disseminate information to such profes-
24 sionals and the public.

1 “(2) A center may use funds provided under sub-
2 section (a) to provide stipends for health and allied health
3 professionals enrolled in programs described in subpara-
4 graph (C) of paragraph (1), and to provide fees to individ-
5 uals serving as subjects in clinical trials conducted under
6 such paragraph.

7 “(d) The Director of the Institute shall, as appro-
8 priate, provide for the coordination of information among
9 the centers assisted under this section.

10 “(e) Each center assisted under subsection (a) shall
11 use the facilities of a single institution, or be formed from
12 a consortium of cooperating institutions, meeting such re-
13 quirements as may be prescribed by the Director of the
14 Institute.

15 “(f) Support of a center under subsection (a) may
16 be for a period not exceeding 5 years. Such period may
17 be extended for one or more additional periods not exceed-
18 ing 5 years if the operations of such center have been re-
19 viewed by an appropriate technical and scientific peer re-
20 view group established by the Director and if such group
21 has recommended to the Director that such period should
22 be extended.

23 “(g) For the purpose of carrying out this section,
24 there are authorized to be appropriated \$30,000,000 for

1 fiscal year 1994, and such sums as may be necessary for
2 each of the fiscal years 1995 and 1996.”.

3 **SEC. 1002. LOAN REPAYMENT PROGRAM FOR RESEARCH**
4 **WITH RESPECT TO CONTRACEPTION AND IN-**
5 **FERTILITY.**

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

9 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
10 RESPECT TO CONTRACEPTION AND INFERTILITY

11 “SEC. 487B. (a) The Secretary, in consultation with
12 the Director of the National Institute of Child Health and
13 Human Development, shall establish a program of enter-
14 ing into agreements with qualified health professionals (in-
15 cluding graduate students) under which such health pro-
16 fessionals agree to conduct research with respect to con-
17 traception, or with respect to infertility, in consideration
18 of the Federal Government agreeing to repay, for each
19 year of such service, not more than \$20,000 of the prin-
20 cipal and interest of the educational loans of such health
21 professionals.

22 “(b) The provisions of sections 338B, 338C, and
23 338E shall apply to the program established in subsection
24 (a) to the same extent and in the same manner as such
25 provisions apply to the National Health Service Corps

1 Loan Repayment Program established in subpart III of
2 part D of title III.

3 “(c) Amounts appropriated for carrying out this sec-
4 tion shall remain available until the expiration of the sec-
5 ond fiscal year beginning after the fiscal year for which
6 the amounts were appropriated.”.

7 **Subtitle B—Program Regarding** 8 **Obstetrics and Gynecology**

9 **SEC. 1011. ESTABLISHMENT OF PROGRAM.**

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

13 “PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

14 “SEC. 452B. The Director of the Institute shall es-
15 tablish and maintain within the Institute an intramural
16 laboratory and clinical research program in obstetrics and
17 gynecology.”.

18 **Subtitle C—Child Health Research** 19 **Centers**

20 **SEC. 1021. ESTABLISHMENT OF CENTERS.**

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

24 “CHILD HEALTH RESEARCH CENTERS

25 “SEC. 452C. The Director of the Institute shall de-
26 velop and support centers for conducting research with re-

1 jects. With respect to the purpose described in such
2 subsection, the study shall monitor the subjects
3 throughout the period of the study to determine the
4 health status of the subjects and any change in such
5 status over time.

6 ~~“(2) POPULATION-SPECIFIC ANALYSES.—~~The
7 study required in subsection (a) shall be conducted
8 with respect to the population of adolescents who are
9 female, the population of adolescents who are male,
10 various socioeconomic populations of adolescents,
11 and various racial and ethnic populations of adoles-
12 cents. The study shall be designed and conducted in
13 a manner sufficient to provide for a valid analysis of
14 whether there are significant differences among such
15 populations in health status and whether and to
16 what extent any such differences are due to factors
17 particular to the populations involved.

18 ~~“(c) COORDINATION WITH WOMEN’S HEALTH INI-~~
19 ~~TIATIVE.—~~With respect to the national study of women
20 being conducted by the Secretary and known as the Wom-
21 en’s Health Initiative, the Secretary shall ensure that such
22 study is coordinated with the component of the study re-
23 quired in subsection (a) that concerns adolescent females,
24 including coordination in the design of the 2 studies.

1 “(d) ALLOCATION OF FUNDS FOR STUDY.—Of the
 2 amounts appropriated for each of the fiscal years 1994
 3 through 1996 for the National Institute of Child Health
 4 and Human Development, the Secretary of Health and
 5 Human Services, acting through the Director of such In-
 6 stitute, shall reserve \$3,000,000 to conduct the study re-
 7 quired in subsection (a). The amounts so reserved shall
 8 remain available until expended.”.

9 **TITLE XI—NATIONAL EYE**
 10 **INSTITUTE**

11 **SEC. 456. CLINICAL RESEARCH ON DIABETES EYE CARE.**

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

15 “CLINICAL RESEARCH ON EYE CARE AND DIABETES

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

21 “(b) AUTHORIZED EXPENDITURES.—The purposes
 22 for which a grant under subsection (a) may be expended
 23 include equipment for the research described in such sub-
 24 section and the construction and modernization of facili-
 25 ties for such research.”.

1 (b) CONFORMING AMENDMENT.—Section 455 of the
 2 Public Health Service Act (42 U.S.C. 285i) is amended
 3 in the second sentence by striking “The Director” and in-
 4 serting “Subject to section 456, the Director”.

5 **TITLE XII—NATIONAL INSTI-**
 6 **TUTE OF NEUROLOGICAL DIS-**
 7 **ORDERS AND STROKE**

8 **SEC. 1201. RESEARCH ON MULTIPLE SCLEROSIS.**

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

12 “RESEARCH ON MULTIPLE SCLEROSIS

13 “SEC. 460. The Director of the Institute shall con-
 14 duct and support research on multiple sclerosis, especially
 15 research on effects of genetics and hormonal changes on
 16 the progress of the disease.”.

17 **TITLE XIII—NATIONAL INSTI-**
 18 **TUTE OF ENVIRONMENTAL**
 19 **HEALTH SCIENCES**

20 **SEC. 1301. APPLIED TOXICOLOGICAL RESEARCH AND**
 21 **TESTING PROGRAM.**

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

1 ~~“(5) to communicate the results of research to~~
 2 ~~government agencies, to medical, scientific, and reg-~~
 3 ~~ulatory communities, and to the public; and~~

4 ~~“(6) to integrate related activities of the De-~~
 5 ~~partment of Health and Human Services.”.~~

6 ~~(b) TECHNICAL AMENDMENT.—Section 463 of the~~
 7 ~~Public Health Service Act (42 U.S.C. 2851) is amended~~
 8 ~~by inserting after “Sciences” the following: “(hereafter in~~
 9 ~~this subpart referred to as the ‘Institute’)”.~~

10 **TITLE XIV—NATIONAL LIBRARY**
 11 **OF MEDICINE**

12 **Subtitle A—General Provisions**

13 **SEC. 1401. ADDITIONAL AUTHORITIES.**

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

16 ~~(1) by striking “and” after the semicolon at the~~
 17 ~~end of paragraph (5);~~

18 ~~(2) by redesignating paragraph (6) as para-~~
 19 ~~graph (8); and~~

20 ~~(3) by inserting after paragraph (5) the follow-~~
 21 ~~ing new paragraphs:~~

22 ~~“(6) publicize the availability from the Library~~
 23 ~~of the products and services described in any of~~
 24 ~~paragraphs (1) through (5);~~

1 “(7) promote the use of computers and tele-
2 communications by health professionals (including
3 health professionals in rural areas) for the purpose
4 of improving access to biomedical information for
5 health care delivery and medical research; and”.

6 (b) LIMITATION REGARDING GRANTS.—Section
7 474(b)(2) of the Public Health Service Act (42 U.S.C.
8 286b-5(b)(2)) is amended by striking “\$750,000” and in-
9 serting “\$1,000,000”.

10 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

11 (1) REPEAL OF CERTAIN AUTHORITY.—Section
12 215 of the Department of Health and Human Serv-
13 ices Appropriations Act, 1988, as contained in sec-
14 tion 101(h) of Public Law 100-202 (101 Stat.
15 1329-275), is repealed.

16 (2) APPLICABILITY OF CERTAIN NEW AUTHOR-
17 ITY.—With respect to the authority established for
18 the National Library of Medicine in section
19 465(b)(6) of the Public Health Service Act, as added
20 by subsection (a) of this section, such authority shall
21 be effective as if the authority had been established
22 on December 22, 1987.

23 **SEC. 1402. AUTHORIZATION OF APPROPRIATIONS.**

24 (a) ESTABLISHMENT OF SINGLE AUTHORIZATION.—
25 Subpart 1 of part D of title IV of the Public Health Serv-

1 ice Act (42 U.S.C. 286 et seq.) is amended by adding at
2 the end the following section:

3 “AUTHORIZATION OF APPROPRIATIONS

4 “SEC. 468. (a) For the purpose of carrying out this
5 part, there are authorized to be appropriated
6 \$150,000,000 for fiscal year 1994, and such sums as may
7 be necessary for each of the fiscal years 1995 and 1996.

8 “(b) Amounts appropriated under subsection (a) and
9 made available for grants or contracts under any of sec-
10 tions 472 through 476 shall remain available until the end
11 of the fiscal year following the fiscal year for which the
12 amounts were appropriated.”.

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

16 **Subtitle B—Financial Assistance**

17 **SEC. 1411. ESTABLISHMENT OF PROGRAM OF GRANTS FOR**
18 **DEVELOPMENT OF EDUCATION TECH-**
19 **NOLOGIES.**

20 Section 473 of the Public Health Service Act (42
21 U.S.C. 286b-4) is amended by adding at the end the fol-
22 lowing new subsection:

23 “(c)(1) The Secretary shall make grants to public or
24 nonprofit private institutions for the purpose of carrying
25 out projects of research on, and development and dem-
26 onstration of, new education technologies.

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

3 “(A) computer-assisted teaching and testing of
4 clinical competence at health professions and re-
5 search institutions;

6 “(B) the effective transfer of new information
7 from research laboratories to appropriate clinical ap-
8 plications;

9 “(C) the expansion of the laboratory and clini-
10 cal uses of computer-stored research databases; and

11 “(D) the testing of new technologies for train-
12 ing health care professionals.

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

16 “(A) assisting in the training of health profes-
17 sions students; and

18 “(B) enhancing and improving the capabilities
19 of health professionals regarding research and teach-
20 ing.”.

1 **Subtitle C—National Information**
 2 **Center on Health Services Re-**
 3 **search and Health Care Tech-**
 4 **nology**

5 **SEC. 1421. ESTABLISHMENT OF CENTER.**

6 Part D of title IV of the Public Health Service Act
 7 (~~42 U.S.C. 286 et seq.~~) is amended by adding at the end
 8 the following new subpart:

9 “Subpart 4—National Information Center on Health
 10 Services Research and Health Care Technology

11 “NATIONAL INFORMATION CENTER

12 “SEC. 478A. (a) There is established within the Li-
 13 brary an entity to be known as the National Information
 14 Center on Health Services Research and Health Care
 15 Technology (in this section referred to as the ‘Center’).

16 “(b) The purpose of the Center is the collection, stor-
 17 age, analysis, retrieval, and dissemination of information
 18 on health services research, clinical practice guidelines,
 19 and on health care technology, including the assessment
 20 of such technology. Such purpose includes developing and
 21 maintaining data bases and developing and implementing
 22 methods of carrying out such purpose.

23 “(c) The Director of the Center shall ensure that in-
 24 formation under subsection (b) concerning clinical practice
 25 guidelines is collected and maintained electronically and

1 in a convenient format. Such Director shall develop and
2 publish criteria for the inclusion of practice guidelines and
3 technology assessments in the information center
4 database.

5 “(d) The Secretary, acting through the Center, shall
6 coordinate the activities carried out under this section
7 through the Center with related activities of the Adminis-
8 trator for Health Care Policy and Research.”.

9 **SEC. 1422. CONFORMING PROVISIONS.**

10 (a) **IN GENERAL.**—Section 903 of the Public Health
11 Service Act, as amended by section 3 of Public Law 102-
12 410 (106 Stat. 2094), is amended to read as follows:

13 “(e) **REQUIRED INTERAGENCY AGREEMENT.**—The
14 Administrator and the Director of the National Library
15 of Medicine shall enter into an agreement providing for
16 the implementation of section 478A.”.

17 (b) **RULE OF CONSTRUCTION.**—The amendments
18 made by section 3 of Public Law 102-410 (106 Stat.
19 2094), by section 1421 of this Act, and by subsection (a)
20 of this section may not be construed as terminating the
21 information center on health care technologies and health
22 care technology assessment established under section 904
23 of the Public Health Service Act, as in effect on the day
24 before the date of the enactment of Public Law 102-410.
25 Such center shall be considered to be the center estab-

1 lished in section 478A of the Public Health Service Act,
 2 as added by section 1421 of this Act, and shall be subject
 3 to the provisions of such section 478A.

4 **TITLE XV—OTHER AGENCIES OF**
 5 **NATIONAL INSTITUTES OF**
 6 **HEALTH**

7 **Subtitle A—Division of Research**
 8 **Resources**

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

11 Title IV of the Public Health Service Act (42 U.S.C.
 12 281 et seq.) is amended—

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

15 “(B) The National Center for Research Re-
 16 sources.”; and

17 (2) in part E—

18 (A) in the heading for subpart 1, by strik-
 19 ing “Division of” and inserting “National Cen-
 20 ter for”;

21 (B) in section 479, by striking “the Divi-
 22 sion of Research Resources” and inserting the
 23 following: “the National Center for Research
 24 Resources (hereafter in this subpart referred to
 25 as the ‘Center’)”;

1 (C) in sections 480 and 481, by striking
2 “the Division of Research Resources” each
3 place such term appears and inserting “the
4 Center”; and

5 (D) in sections 480 and 481, as amended
6 by subparagraph (C), by striking “the Division”
7 each place such term appears and inserting
8 “the Center”.

9 **SEC. 1502. BIOMEDICAL AND BEHAVIORAL RESEARCH FA-**
10 **CILITIES.**

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

14 “BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES
15 “SEC. 481A. (a) MODERNIZATION AND CONSTRU-
16 TION OF FACILITIES.—

17 “(1) IN GENERAL.—The Director of NIH, act-
18 ing through the Director of the Center, may make
19 grants to public and nonprofit private entities to ex-
20 pand, remodel, renovate, or alter existing research
21 facilities or construct new research facilities, subject
22 to the provisions of this section.

23 “(2) CONSTRUCTION AND COST OF CONSTRU-
24 TION.—For purposes of this section, the terms ‘con-
25 struction’ and ‘cost of construction’ include the con-
26 struction of new buildings and the expansion, ren-

1 ovation, remodeling, and alteration of existing build-
2 ings, including architects' fees, but do not include
3 the cost of acquisition of land or off-site improve-
4 ments.

5 “(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS
6 FOR MERIT BASED REVIEW OF PROPOSALS.—

7 “(1) IN GENERAL; APPROVAL AS PRECONDITION
8 TO GRANTS.—

9 “(A) There is established within the Center
10 a Scientific and Technical Review Board on
11 Biomedical and Behavioral Research Facilities
12 (hereafter referred to in this section as the
13 ‘Board’).

14 “(B) The Director of the Center may ap-
15 prove an application for a grant under sub-
16 section (a) only if the Board has under para-
17 graph (2) recommended the application for ap-
18 proval.

19 “(2) DUTIES.—

20 “(A) The Board shall provide advice to the
21 Director of the Center and the advisory council
22 established under section 480 (hereafter in this
23 section referred to as the ‘Advisory Council’) on
24 carrying out this section.

1 “(B) In carrying out subparagraph (A),
2 the Board shall make a determination of the
3 merit of each application submitted for a grant
4 under subsection (a), after consideration of the
5 requirements established in subsection (c), and
6 shall report the results of the determination to
7 the Director of the Center and the Advisory
8 Council. Such determinations shall be con-
9 ducted in a manner consistent with procedures
10 established under section 492.

11 “(C) In carrying out subparagraph (A),
12 the Board shall, in the case of applications rec-
13 ommended for approval, make recommendations
14 to the Director and the Advisory Council on the
15 amount that should be provided in the grant.

16 “(D) In carrying out subparagraph (A),
17 the Board shall prepare an annual report for
18 the Director of the Center and the Advisory
19 Council describing the activities of the Board in
20 the fiscal year for which the report is made.
21 Each such report shall be available to the pub-
22 lic, and shall—

23 “(i) summarize and analyze expendi-
24 tures made under this section;

1 ~~“(ii) provide a summary of the types,~~
2 ~~numbers, and amounts of applications that~~
3 ~~were recommended for grants under sub-~~
4 ~~section (a) but that were not approved by~~
5 ~~the Director of the Center; and~~

6 ~~“(iii) contain the recommendations of~~
7 ~~the Board for any changes in the adminis-~~
8 ~~tration of this section.~~

9 ~~“(3) MEMBERSHIP.—~~

10 ~~“(A) Subject to subparagraph (B), the~~
11 ~~Board shall be composed of such appointed and~~
12 ~~ex officio members as the Director of the Cen-~~
13 ~~ter may determine.~~

14 ~~“(B) Not more than 3 individuals who are~~
15 ~~officers or employees of the Federal Govern-~~
16 ~~ment may serve as members of the Board.~~

17 ~~“(C) Of the members of the Board—~~

18 ~~“(i) 12 shall be appointed by the Di-~~
19 ~~rector of the Center (without regard to the~~
20 ~~civil service laws); and~~

21 ~~“(ii) 1 shall be an official of the Na-~~
22 ~~tional Science Foundation designated by~~
23 ~~the National Science Board.~~

24 ~~“(4) CERTAIN REQUIREMENTS REGARDING~~
25 ~~MEMBERSHIP.—In selecting individuals for member-~~

1 ship on the Board, the Director of the Center shall
2 ensure that the members are individuals who, by the
3 virtue of their training or experience, are eminently
4 qualified to perform peer review functions. In select-
5 ing such individuals for such membership, the Direc-
6 tor of the Center shall ensure that the members of
7 the Board collectively—

8 “(A) are experienced in the planning, con-
9 struction, financing, and administration of enti-
10 ties that conduct biomedical or behavioral re-
11 search sciences;

12 “(B) are knowledgeable in making deter-
13 minations of the need of entities for biomedical
14 or behavioral research facilities, including such
15 facilities for the dentistry, nursing, pharmacy,
16 and allied health professions;

17 “(C) are knowledgeable in evaluating the
18 relative priorities for applications for grants
19 under subsection (a) in view of the overall re-
20 search needs of the United States; and

21 “(D) are experienced with emerging cen-
22 ters of excellence, as described in subsection
23 (c)(3).

24 “(5) CERTAIN AUTHORITIES.—

1 “(A) In carrying out paragraph (2), the
2 Board may establish subcommittees, convene
3 workshops and conferences, and collect data as
4 the Board considers appropriate.

5 “(B) In carrying out paragraph (2), the
6 Board may establish subcommittees within the
7 Board. Such subcommittees may hold meetings
8 as determined necessary to enable the sub-
9 committee to carry out its duties.

10 “(6) TERMS.—

11 “(A) Except as provided in subparagraph
12 (B), each appointed member of the Board shall
13 hold office for a term of 4 years. Any member
14 appointed to fill a vacancy occurring prior to
15 the expiration of the term for which such mem-
16 ber’s predecessor was appointed shall be ap-
17 pointed for the remainder of the term of the
18 predecessor.

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

22 “(i) 3 shall hold office for a term of
23 3 years;

24 “(ii) 3 shall hold office for a term of
25 2 years; and

1 ~~“(iii) 3 shall hold office for a term of~~
2 ~~1 year.~~

3 ~~“(C) No member is eligible for reappoint-~~
4 ~~ment to the Board until 1 year has elapsed~~
5 ~~after the end of the most recent term of the~~
6 ~~member.~~

7 ~~“(7) COMPENSATION.—Members of board who~~
8 ~~are not officers or employees of the United States~~
9 ~~shall receive compensation for each day engaged in~~
10 ~~carrying out the duties of the board, including time~~
11 ~~engaged in traveling for purposes of such duties.~~
12 ~~Such compensation may not be provided in an~~
13 ~~amount in excess of the maximum rate of basic pay~~
14 ~~payable for GS-18 of the General Schedule.~~

15 ~~“(c) REQUIREMENTS FOR GRANTS.—~~

16 ~~“(1) IN GENERAL.—The Director of the Center~~
17 ~~may make a grant under subsection (a) only if the~~
18 ~~applicant for the grant meets the following condi-~~
19 ~~tions:~~

20 ~~“(A) The applicant is determined by such~~
21 ~~Director to be competent to engage in the type~~
22 ~~of research for which the proposed facility is to~~
23 ~~be constructed.~~

24 ~~“(B) The applicant provides assurances~~
25 ~~satisfactory to the Director that—~~

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

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

8 “(iii) sufficient funds will be available,
9 when construction is completed, for the ef-
10 fective use of the facility for the research
11 for which it is being constructed; and

12 “(iv) the proposed construction will
13 expand the applicant’s capacity for re-
14 search, or is necessary to improve or main-
15 tain the quality of the applicant’s research.

16 “(C) The applicant meets reasonable quali-
17 fications established by the Director with re-
18 spect to—

19 “(i) the relative scientific and tech-
20 nical merit of the applications, and the rel-
21 ative effectiveness of the proposed facili-
22 ties, in expanding the capacity for bio-
23 medical or behavioral research and in im-
24 proving the quality of such research;

1 “(ii) the quality of the research or
2 training, or both, to be carried out in the
3 facilities involved;

4 “(iii) the need of the applicant for
5 such facilities in order to maintain or ex-
6 pand the applicant’s research and training
7 mission;

8 “(iv) the congruence of the research
9 activities to be carried out within the facil-
10 ity with the research and investigator man-
11 power needs of the United States; and

12 “(v) the age and condition of existing
13 research facilities and equipment.

14 “(D) The applicant has demonstrated a
15 commitment to enhancing and expanding the
16 research productivity of the applicant.

17 “(2) CONSIDERATION OF CERTAIN FACTORS.—

18 In making grants under subsection (a), the Director
19 of the Center may, in addition to the requirements
20 established in paragraph (1), consider the following
21 factors:

22 “(A) To what extent the applicant has the
23 capacity to broaden the scope of research and
24 research training programs of the applicant by
25 promoting—

1 “(i) interdisciplinary research;

2 “(ii) research on emerging tech-
3 nologies, including those involving novel
4 analytical techniques or computational
5 methods; or

6 “(iii) other novel research mechanisms
7 or programs.

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

14 “(3) INSTITUTIONS OF EMERGING EXCEL-
15 LENCE.—Of the amounts appropriated under sub-
16 section (i) for a fiscal year, the Director of the Cen-
17 ter shall make available 25 percent for grants under
18 subsection (a) to applicants that, in addition to
19 meeting the requirements established in paragraph
20 (1), have demonstrated emerging excellence in bio-
21 medical or behavioral research, as follows:

22 “(A) The applicant has a plan for research
23 or training advancement and possesses the abil-
24 ity to carry out the plan.

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

5 “(C) The applicant has been productive in
6 research or research development and training.

7 “(D) The applicant—

8 “(i) has been designated as a center
9 of excellence under section 739;

10 “(ii) is located in a geographic area a
11 significant percentage of whose population
12 has a health-status deficit, and the appli-
13 cant provides health services to such popu-
14 lation; or

15 “(iii) is located in a geographic area
16 in which a deficit in health care tech-
17 nology, services, or research resources may
18 adversely affect health status of the popu-
19 lation of the area in the future, and the
20 applicant is carrying out activities with re-
21 spect to protecting the health status of
22 such population.

23 “(d) REQUIREMENT OF APPLICATION.—The Director
24 of the Center may make a grant under subsection (a) only
25 if an application for the grant is submitted to the Director

1 and the application is in such form, is made in such man-
2 ner, and contains such agreements, assurances, and infor-
3 mation as the Director determines to be necessary to carry
4 out this section.

5 “(e) AMOUNT OF GRANT; PAYMENTS.—

6 “(1) AMOUNT.—The amount of any grant
7 awarded under subsection (a) shall be determined by
8 the Director of the Center, except that such amount
9 shall not exceed—

10 “(A) 50 percent of the necessary cost of
11 the construction of a proposed facility as deter-
12 mined by the Director; or

13 “(B) in the case of a multipurpose facility,
14 40 percent of that part of the necessary cost of
15 construction that the Director determines to be
16 proportionate to the contemplated use of the fa-
17 cility.

18 “(2) RESERVATION OF AMOUNTS.—On approval
19 of any application for a grant under subsection (a),
20 the Director of the Center shall reserve, from any
21 appropriation available therefore, the amount of
22 such grant, and shall pay such amount, in advance
23 or by way of reimbursement, and in such install-
24 ments consistent with the construction progress, as
25 the Director may determine appropriate. The res-

1 ervation of the Director of any amount by the Direc-
2 tor under this paragraph may be amended by the
3 Director, either on the approval of an amendment of
4 the application or on the revision of the estimated
5 cost of construction of the facility.

6 ~~“(3) EXCLUSION OF CERTAIN COSTS.—~~In deter-
7 mining the amount of any grant under this sub-
8 section (a), there shall be excluded from the cost of
9 construction an amount equal to the sum of—

10 ~~“(A) the amount of any other Federal~~
11 grant that the applicant has obtained, or is as-
12 sured of obtaining, with respect to construction
13 that is to be financed in part by a grant author-
14 ized under this section; and

15 ~~“(B) the amount of any non-Federal funds~~
16 required to be expended as a condition of such
17 other Federal grant.

18 ~~“(4) WAIVER OF LIMITATIONS.—~~The limita-
19 tions imposed by paragraph (1) may be waived at
20 the discretion of the Director for applicants meeting
21 the conditions described in paragraphs (1) and (2)
22 of subsection (c).

23 ~~“(f) RECAPTURE OF PAYMENTS.—~~If, not later than
24 20 years after the completion of construction for which
25 a grant has been awarded under subsection (a)—

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

4 ~~“(2) the facility shall cease to be used for the~~
5 ~~research purposes for which it was constructed (un-~~
6 ~~less the Director determines, in accordance with reg-~~
7 ~~ulations, that there is good cause for releasing the~~
8 ~~applicant or other owner from obligation to do so);~~
9 ~~the United States shall be entitled to recover from the ap-~~
10 ~~plicant or other owner of the facility the amount bearing~~
11 ~~the same ratio to the current value (as determined by an~~
12 ~~agreement between the parties or by action brought in the~~
13 ~~United States District Court for the district in which such~~
14 ~~facility is situated) of the facility as the amount of the~~
15 ~~Federal participation bore to the cost of the construction~~
16 ~~of such facility.~~

17 ~~“(g) NONINTERFERENCE WITH ADMINISTRATION OF~~
18 ~~ENTITIES.—Except as otherwise specifically provided in~~
19 ~~this section, nothing contained in this part shall be con-~~
20 ~~strued as authorizing any department, agency, officer, or~~
21 ~~employee of the United States to exercise any direction,~~
22 ~~supervision, or control over, or impose any requirement~~
23 ~~or condition with respect to the administration of any en-~~
24 ~~tity funded under this part.~~

1 year is subject to the availability of qualified applicants
2 for such awards.

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

12 **Subtitle B—National Center for** 13 **Nursing Research**

14 **SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR** 15 **NURSING RESEARCH AS NATIONAL INSTI-** 16 **TUTE OF NURSING RESEARCH.**

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

20 (1) in section 483—

21 (A) in the heading for the section, by strik-
22 ing “CENTER” and inserting “INSTITUTE”; and

23 (B) by striking “The general purpose” and
24 all that follows through “is” and inserting the
25 following: “The general purpose of the National

1 Institute of Nursing Research (hereafter in this
2 subpart referred to as the ‘Institute’) is”;

3 ~~(2)~~ in section 484, by striking “Center” each
4 place such term appears and inserting “Institute”;

5 ~~(3)~~ in section 485—

6 (A) in subsection (a), in each of para-
7 graphs (1) through (3), by striking “Center”
8 each place such term appears and inserting
9 “Institute”;

10 (B) in subsection (b)—

11 (i) in paragraph ~~(2)~~(A), by striking
12 “Center” and inserting “Institute”; and

13 (ii) in paragraph ~~(3)~~(A), in the first
14 sentence, by striking “Center” and insert-
15 ing “Institute”; and

16 (C) in subsections (d) through (g), by
17 striking “Center” each place such term appears
18 and inserting “Institute”; and

19 ~~(4)~~ in section 485A (as redesignated by section
20 141(a)(1) of this Act), by striking “Center” each
21 place such term appears and inserting “Institute”.

22 (b) CONFORMING AMENDMENTS.—

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

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

3 “(Q) The National Institute of Nursing
4 Research.”; and

5 (B) in paragraph (2), by striking subpara-
6 graph (D).

7 (2) TRANSFER OF STATUTORY PROVISIONS.—
8 Sections 483 through 485A of the Public Health
9 Service Act, as amended by subsection (a) of this
10 section—

11 (A) are transferred to part C of title IV of
12 such Act;

13 (B) are redesignated as sections 464V
14 through 464Y of such part; and

15 (C) are inserted, in the appropriate se-
16 quence, at the end of such part.

17 (3) HEADING FOR NEW SUBPART.—Title IV of
18 the Public Health Service Act, as amended by the
19 preceding provisions of this section, is amended—

20 (A) in part C, by inserting before section
21 464V the following new heading:

22 “Subpart 17—National Institute of Nursing Research”;

23 and

24 (B) by striking the heading for subpart 3
25 of part E.

1 (4) ~~CROSS-REFERENCES.~~—Title IV of the Pub-
2 lic Health Service Act, as amended by the preceding
3 provisions of this section, is amended in subpart 17
4 of part C—

5 (A) in section 464W, by striking “section
6 483” and inserting “section 464V”;

7 (B) in section 464X(g), by striking “sec-
8 tion 486” and inserting “section 464Y”; and

9 (C) in section 464Y, in the last sentence,
10 by striking “section 485(g)” and inserting “sec-
11 tion 464X(g)”.

12 **SEC. 1512. STUDY ON ADEQUACY OF NUMBER OF NURSES.**

13 (a) ~~IN GENERAL.~~—The Secretary of Health and
14 Human Services, acting through the Director of the Na-
15 tional Institute of Nursing Research, shall enter into a
16 contract with a public or nonprofit private entity to con-
17 duct a study for the purpose of determining whether and
18 to what extent there is a need for an increase in the num-
19 ber of nurses in hospitals and nursing homes in order to
20 promote the quality of patient care and reduce the inci-
21 dence among nurses of work-related injuries and stress.

22 (b) ~~NATIONAL ACADEMY OF SCIENCES.~~—The Sec-
23 retary shall request the National Academy of Sciences to
24 enter into the contract under subsection (a) to conduct
25 the study described in such subsection. If such Institute

1 declines to conduct the study, the Secretary shall carry
 2 out such subsection through another public or nonprofit
 3 private entity.

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

5 (1) The term “nurse” means a registered nurse,
 6 a licensed practical nurse, a licensed vocational
 7 nurse, and a nurse assistant.

8 (2) The term “Secretary” means the Secretary
 9 of Health and Human Services.

10 (d) REPORT.—The Secretary shall ensure that, not
 11 later than October 1, 1994, the study required in sub-
 12 section (a) is completed and a report describing the find-
 13 ings made as a result of the study is submitted to the
 14 Committee on Energy and Commerce of the House of
 15 Representatives, and to the Committee on Labor and
 16 Human Resources of the Senate.

17 **Subtitle C—National Center for**
 18 **Human Genome Research**

19 **SEC. 1521. PURPOSE OF CENTER.**

20 Title IV of the Public Health Service Act, as amended
 21 by sections 141(a)(1) and 1611(b)(1)(B) of this Act, is
 22 amended—

23 (1) in section 401(b)(2), by adding at the end
 24 the following new subparagraph:

1 ~~“(b)(1) Except as provided in paragraph (2), of the~~
 2 ~~amounts appropriated to carry out subsection (a) for a~~
 3 ~~fiscal year, the Director of the Center shall make available~~
 4 ~~not less than 5 percent for carrying out paragraph (6)~~
 5 ~~of such subsection.~~

6 ~~“(2) With respect to providing funds under sub-~~
 7 ~~section (a)(6) for proposals to address the ethical issues~~
 8 ~~associated with the genome project, paragraph (1) shall~~
 9 ~~not apply for a fiscal year if the Director of the Center~~
 10 ~~certifies to the Committee on Energy and Commerce of~~
 11 ~~the House of Representatives, and to the Committee on~~
 12 ~~Labor and Human Resources of the Senate, that the Di-~~
 13 ~~rector has determined that an insufficient number of such~~
 14 ~~proposals meet the applicable requirements of sections 491~~
 15 ~~and 492.”.~~

16 **TITLE XVI—AWARDS AND**
 17 **TRAINING**

18 **Subtitle A—National Research**
 19 **Service Awards**

20 **SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDI-**
 21 **VIDUALS FROM DISADVANTAGED BACK-**
 22 **GROUND.**

23 Section 487(a) of the Public Health Service Act (42
 24 U.S.C. 288(a)(4)) is amended by adding at the end the
 25 following paragraph:

1 “(4) The Secretary shall carry out paragraph (1) in
2 a manner that will result in the recruitment of women,
3 and members from underrepresented minority groups, into
4 fields of biomedical or behavioral research and in the pro-
5 vision of research training to women and such individ-
6 uals.”.

7 **SEC. 1602. SERVICE PAYBACK REQUIREMENTS.**

8 Paragraph (2) of section 487(c) of the Public Health
9 Service Act (~~42 U.S.C. 288(c)(2)~~) is amended to read as
10 follows:

11 “(2)(A) For the initial year for which an individual
12 receives a National Research Service Award for the con-
13 duct of postdoctoral training or research, such individual
14 shall engage in one year of health research or teaching
15 or any combination thereof which is in accordance with
16 the usual patterns of academic employment, or complete
17 a second year of training or research under such Award.

18 “(B) Service obligations for National Research Serv-
19 ice Awards that are less than 12 months may be satis-
20 fied—

21 “(i) by the conduct of health research or teach-
22 ing or any combination thereof which is in accord-
23 ance with the usual patterns of academic employ-
24 ment for a period of time equal to the amount of
25 time under the Award; or

1 “(ii) by reimbursing the Federal Government
2 for the amounts provided to such individual under
3 the Award.

4 **Subtitle B—Acquired Immune**
5 **Deficiency Syndrome**

6 **SEC. 1611. LOAN REPAYMENT PROGRAM.**

7 Section 487A of the Public Health Service Act (42
8 U.S.C. 288–1) is amended to read as follows:

9 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
10 RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

11 “SEC. 487A. (a) IN GENERAL.—

12 “(1) AUTHORITY FOR PROGRAM.—Subject to
13 paragraph (2), the Secretary shall carry out a pro-
14 gram of entering into agreements with appropriately
15 qualified health professionals under which such
16 health professionals agree to conduct, as employees
17 of the National Institutes of Health, research with
18 respect to acquired immune deficiency syndrome in
19 consideration of the Federal Government agreeing to
20 repay, for each year of such service, not more than
21 \$20,000 of the principal and interest of the edu-
22 cational loans of such health professionals.

23 “(2) LIMITATION.—The Secretary may not
24 enter into an agreement with a health professional
25 pursuant to paragraph (1) unless such profes-
26 sional—

1 “(A) has a substantial amount of edu-
2 cational loans relative to income; and

3 “(B)(i) was not employed at the National
4 Institutes of Health during the 1-year period
5 preceding the date of the enactment of the
6 Health Professions Reauthorization Act of
7 1988; or

8 “(ii) agrees to serve as an employee of
9 such Institutes for purposes of paragraph (1)
10 for a period of not less than 3 years.”.

11 “(b) APPLICABILITY OF CERTAIN PROVISIONS.—

12 With respect to the National Health Service Corps Loan
13 Repayment Program established in subpart III of part D
14 of title III, the provisions of such subpart shall, except
15 as inconsistent with subsection (a) of this section, apply
16 to the program established in such subsection (a) in the
17 same manner and to the same extent as such provisions
18 apply to the National Health Service Corps Loan Repay-
19 ment Program established in such subpart.

20 “(c) FUNDING; REIMBURSABLE TRANSFERS.—

21 “(1) AUTHORIZATION OF APPROPRIATIONS.—

22 For the purpose of carrying out this section, there
23 are authorized to be appropriated such sums as may
24 be necessary for each of the fiscal years 1994
25 through 1996.

1 “(2) TRANSFERS FOR RELATED PROGRAM.—
 2 The Commissioner of Food and Drugs may carry
 3 out for the Food and Drug Administration a pro-
 4 gram similar to the program established in sub-
 5 section (a), which program shall be carried out with
 6 respect to the review of applications concerning ac-
 7 quired immune deficiency syndrome that are submit-
 8 ted to such Commissioner. From the amounts appro-
 9 priated under paragraph (1) for a fiscal year, the
 10 Secretary may transfer amounts to the Commis-
 11 sioner for the purpose of carrying out such program.
 12 The Commissioner shall provide a reimbursement to
 13 the Secretary for the amount so transferred, and the
 14 reimbursement shall be available only for the pro-
 15 gram established in subsection (a). Any transfer and
 16 reimbursement made for purposes of this paragraph
 17 for a fiscal year shall be completed by April 1 of
 18 such year.”.

19 **Subtitle C—Loan Repayment for**
 20 **Research Generally**

21 **SEC. 1621. ESTABLISHMENT OF PROGRAM.**

22 Part G of title IV of the Public Health Service Act,
 23 as redesignated by section 141(a)(2) of this Act and as
 24 amended by section 1002 of this Act, is amended by in-
 25 serting after section 487B the following new section:

1 “(ii) agrees to serve as an employee of
2 such Institutes for purposes of paragraph (1)
3 for a period of not less than 3 years.”.

4 “(b) APPLICABILITY OF CERTAIN PROVISIONS.—
5 With respect to the National Health Service Corps Loan
6 Repayment Program established in subpart III of part D
7 of title III, the provisions of such subpart shall, except
8 as inconsistent with subsection (a) of this section, apply
9 to the program established in such subsection (a) in the
10 same manner and to the same extent as such provisions
11 apply to the National Health Service Corps Loan Repay-
12 ment Program established in such subpart.

13 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
14 purpose of carrying out this section other than with re-
15 spect to acquired immune deficiency syndrome, there are
16 authorized to be appropriated such sums as may be nec-
17 essary for each of the fiscal years 1994 through 1996.”.

18 **Subtitle D—Scholarship and Loan**
19 **Repayment Programs Regard-**
20 **ing Professional Skills Needed**
21 **by Certain Agencies**

22 **SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL**
23 **INSTITUTES OF HEALTH.**

24 Part G of title IV of the Public Health Service Act,
25 as redesignated by section 141(a)(2) of this Act and as

1 amended by section 1621 of this Act, is amended by in-
2 serting after section 487C the following new sections:

3 “UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING
4 PROFESSIONS NEEDED BY NATIONAL RESEARCH IN-
5 STITUTES

6 “SEC. 487D. (a) ESTABLISHMENT OF PROGRAM.—

7 “(1) IN GENERAL.—Subject to section
8 487(a)(1)(C), the Secretary, acting through the Di-
9 rector of NIH, may carry out a program of entering
10 into contracts with individuals described in para-
11 graph (2) under which—

12 “(A) the Director of NIH agrees to provide
13 to the individuals scholarships for pursuing, as
14 undergraduates at accredited institutions of
15 higher education, academic programs appro-
16 priate for careers in professions needed by the
17 National Institutes of Health; and

18 “(B) the individuals agree to serve as em-
19 ployees of the National Institutes of Health, for
20 the period described in subsection (c), in posi-
21 tions that are needed by the National Institutes
22 of Health and for which the individuals are
23 qualified.

24 “(2) INDIVIDUALS FROM DISADVANTAGED
25 BACKGROUNDS.—The individuals referred to in
26 paragraph (1) are individuals who—

1 ~~“(A) are enrolled or accepted for enroll-~~
2 ~~ment as full-time undergraduates at accredited~~
3 ~~institutions of higher education; and~~

4 ~~“(B) are from minority groups that are~~
5 ~~underrepresented in the fields of biomedical or~~
6 ~~behavioral research.~~

7 ~~“(b) FACILITATION OF INTEREST OF STUDENTS IN~~
8 ~~CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In~~
9 ~~providing employment to individuals pursuant to contracts~~
10 ~~under subsection (a)(1), the Director of NIH shall carry~~
11 ~~out activities to facilitate the interest of the individuals~~
12 ~~in pursuing careers as employees of the National Insti-~~
13 ~~tutes of Health.~~

14 ~~“(c) PERIOD OF OBLIGATED SERVICE.—~~

15 ~~“(1) DURATION OF SERVICE.—For purposes of~~
16 ~~subparagraph (B) of subsection (a)(1), the period of~~
17 ~~service for which an individual is obligated to serve~~
18 ~~as an employee of the National Institutes of Health~~
19 ~~is 12 months for each academic year for which the~~
20 ~~scholarship under such subsection is provided.~~

21 ~~“(2) SCHEDULE FOR SERVICE.—~~

22 ~~“(A) Subject to subparagraph (B), the Di-~~
23 ~~rector of NIH may not provide a scholarship~~
24 ~~under subsection (a) unless the individual ap-~~
25 ~~plying for the scholarship agrees that—~~

1 “(i) the individual will serve as an em-
2 ployee of the National Institutes of Health
3 full-time for not less than 10 consecutive
4 weeks of each year during which the indi-
5 vidual is attending the educational institu-
6 tion involved and receiving such a scholar-
7 ship;

8 “(ii) the period of service as such an
9 employee that the individual is obligated to
10 provide under clause (i) is in addition to
11 the period of service as such an employee
12 that the individual is obligated to provide
13 under subsection (a)(1)(B); and

14 “(iii) not later than 60 days after ob-
15 taining the educational degree involved, the
16 individual will begin serving full-time as
17 such an employee in satisfaction of the pe-
18 riod of service that the individual is obli-
19 gated to provide under subsection
20 (a)(1)(B).

21 “(B) The Director of NIH may defer the
22 obligation of an individual to provide a period
23 of service under subsection (a)(1)(B), if the Di-
24 rector determines that such a deferral is appro-
25 priate.

1 ~~“(3) APPLICABILITY OF CERTAIN PROVISIONS~~
2 ~~RELATING TO APPOINTMENT AND COMPENSATION.—~~
3 ~~For any period in which an individual provides serv-~~
4 ~~ice as an employee of the National Institutes of~~
5 ~~Health in satisfaction of the obligation of the indi-~~
6 ~~vidual under subsection (a)(1)(B) or paragraph~~
7 ~~(2)(A)(i), the individual may be appointed as such~~
8 ~~an employee without regard to the provisions of title~~
9 ~~5, United States Code, relating to appointment and~~
10 ~~compensation.~~

11 ~~“(d) PROVISIONS REGARDING SCHOLARSHIP.—~~

12 ~~“(1) APPROVAL OF ACADEMIC PROGRAM.—The~~
13 ~~Director of NIH may not provide a scholarship~~
14 ~~under subsection (a) for an academic year unless—~~

15 ~~“(A) the individual applying for the schol-~~
16 ~~arship has submitted to the Director a proposed~~
17 ~~academic program for the year and the Director~~
18 ~~has approved the program; and~~

19 ~~“(B) the individual agrees that the pro-~~
20 ~~gram will not be altered without the approval of~~
21 ~~the Director.~~

22 ~~“(2) ACADEMIC STANDING.—The Director of~~
23 ~~NIH may not provide a scholarship under subsection~~
24 ~~(a) for an academic year unless the individual apply-~~
25 ~~ing for the scholarship agrees to maintain an accept-~~

1 able level of academic standing, as determined by
2 the educational institution involved in accordance
3 with regulations issued by the Secretary.

4 “(3) LIMITATION ON AMOUNT.—The Director
5 of NIH may not provide a scholarship under sub-
6 section (a) for an academic year in an amount ex-
7 ceeding \$20,000.

8 “(4) AUTHORIZED USES.—A scholarship pro-
9 vided under subsection (a) may be expended only for
10 tuition expenses, other reasonable educational ex-
11 penses, and reasonable living expenses incurred in
12 attending the school involved.

13 “(5) CONTRACT REGARDING DIRECT PAYMENTS
14 TO INSTITUTION.—In the case of an institution of
15 higher education with respect to which a scholarship
16 under subsection (a) is provided, the Director of
17 NIH may enter into a contract with the institution
18 under which the amounts provided in the scholarship
19 for tuition and other educational expenses are paid
20 directly to the institution. Payments to the institu-
21 tion under the contract may be made without regard
22 to section 3324 of title 31, United States Code.

23 “(e) PENALTIES FOR BREACH OF SCHOLARSHIP
24 CONTRACT.—The provisions of section 338E shall apply
25 to the program established in subsection (a) to the same

1 extent and in the same manner as such provisions apply
2 to the National Health Service Corps Loan Repayment
3 Program established in section 338B.

4 “(f) REQUIREMENT OF APPLICATION.—The Director
5 of NIH may not provide a scholarship under subsection
6 (a) unless an application for the scholarship is submitted
7 to the Director and the application is in such form, is
8 made in such manner, and contains such agreements, as-
9 surances, and information as the Director determines to
10 be necessary to carry out this section.

11 “(g) AVAILABILITY OF AUTHORIZATION OF APPRO-
12 PRIATIONS.—Amounts appropriated for a fiscal year for
13 scholarships under this section shall remain available until
14 the expiration of the second fiscal year beginning after the
15 fiscal year for which the amounts were appropriated.

16 “LOAN REPAYMENT PROGRAM REGARDING CLINICAL
17 RESEARCHERS FROM DISADVANTAGED BACKGROUNDS

18 “SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—

19 “(1) IN GENERAL.—Subject to section
20 487(a)(1)(C), the Secretary, acting through the Di-
21 rector of NIH may, subject to paragraph (2), carry
22 out a program of entering into contracts with appro-
23 priately qualified health professionals who are from
24 disadvantaged backgrounds under which such health
25 professionals agree to conduct clinical research as
26 employees of the National Institutes of Health in

1 consideration of the Federal Government agreeing to
2 pay, for each year of such service, not more than
3 \$20,000 of the principal and interest of the edu-
4 cational loans of the health professionals.

5 “(2) LIMITATION.—The Director of NIH may
6 not enter into a contract with a health professional
7 pursuant to paragraph (1) unless such professional
8 has a substantial amount of education loans relative
9 to income.

10 “(3) APPLICABILITY OF CERTAIN PROVISIONS
11 REGARDING OBLIGATED SERVICE.—Except to the ex-
12 tent inconsistent with this section, the provisions of
13 sections 338C and 338E shall apply to the program
14 established in paragraph (1) to the same extent and
15 in the same manner as such provisions apply to the
16 National Health Service Corps Loan Repayment
17 Program established in section 338B.

18 “(b) AVAILABILITY OF AUTHORIZATION OF APPRO-
19 PRIATIONS.—Amounts appropriated for a fiscal year for
20 contracts under subsection (a) shall remain available until
21 the expiration of the second fiscal year beginning after the
22 fiscal year for which the amounts were appropriated.”.

23 **SEC. 1632. FUNDING.**

24 Section 487(a)(1) of the Public Health Service Act
25 (42 U.S.C. 288(a)(1)) is amended—

1 (1) in subparagraph (A), by striking “and”
2 after the semicolon at the end;

3 (2) in subparagraph (B), by striking the period
4 at the end and inserting “; and”; and

5 (3) by adding at the end the following new sub-
6 paragraph:

7 “(C) provide contracts for scholarships and loan
8 repayments in accordance with sections 487D and
9 487E, subject to providing not more than an aggre-
10 gate 50 such contracts during the fiscal years 1994
11 through 1996.”.

12 **Subtitle D—Funding**

13 **SEC. 1641. AUTHORIZATION OF APPROPRIATIONS.**

14 Section 487(d) of the Public Health Service Act (42
15 U.S.C. 288(d)) is amended—

16 (1) in the first sentence, by amending the sen-
17 tence to read as follows: “For the purpose of carry-
18 ing out this section, there are authorized to be ap-
19 propriated \$400,000,000 for fiscal year 1994, and
20 such sums as may be necessary for each of the fiscal
21 years 1995 and 1996.”; and

22 (2) in paragraph (3)—

23 (A) by striking “one-half of one percent”
24 each place such term appears and inserting “1
25 percent”; and

1 (B) by striking “780, 784, or 786” and in-
2 serting “747, 748, or 749”.

3 **TITLE XVII—NATIONAL FOUNDA-**
4 **TION FOR BIOMEDICAL RE-**
5 **SEARCH**

6 **SEC. 1701. ESTABLISHMENT OF FOUNDATION.**

7 Section 499 of the Public Health Service Act, as re-
8 designated by section 121(b), is amended to read as fol-
9 lows:

10 **“SEC. 499A. ESTABLISHMENT AND DUTIES OF FOUNDATION.**

11 “(a) IN GENERAL.—The Secretary shall establish a
12 nonprofit corporation to be known as the National Foun-
13 dation for Biomedical Research (hereafter in this section
14 referred to as the ‘Foundation’). The Foundation shall
15 not, except for the purposes of the Ethics in Government
16 Act and the Technology Transfer Act, be an agency or
17 instrumentality of the United States Government.

18 “(b) PURPOSE OF FOUNDATION.—The purpose of
19 the Foundation shall be to conduct and support research
20 with respect to any particular disease or groups of diseases
21 or any other aspect of human health.

22 “(c) ENDOWMENT FUND.—

23 “(1) IN GENERAL.—In carrying out subsection
24 (b), the Foundation shall establish a fund whose pri-
25 mary purpose shall be to provide endowments for po-

1 sitions at the National Institutes of Health to con-
2 duct biomedical research, and dedicated to the pur-
3 pose described in such subsection. Such positions
4 may be held by scientists without regard to whether
5 the scientists are employees of the Federal Govern-
6 ment. Subject to subsection (g)(1)(B), the fund shall
7 consist of such donations as may be provided by
8 non-Federal entities and such non-Federal assets of
9 the Foundation (including earnings of the Founda-
10 tion and the fund) as the Foundation may elect to
11 transfer to the fund.

12 ~~“(2) AUTHORIZED EXPENDITURES OF FUND.—~~

13 The provision of endowments under paragraph (1)
14 shall be the primary function of the fund established
15 under such paragraph. Such endowments may be ex-
16 pended only for the compensation of individuals
17 holding the positions, for staff, equipment, quarters,
18 travel, and other expenditures that are appropriate
19 in supporting the positions, and for recruiting indi-
20 viduals to hold the positions endowed by the fund.

21 ~~“(d) CERTAIN ACTIVITIES OF FOUNDATION.—~~In car-
22 rying out subsection (b), and subject to subsection (c), the
23 Foundation may provide for the following with respect to
24 the purpose described in such subsection:

1 “(1) Endowed chairs for distinguished senior
2 investigators.

3 “(2) Positions for support of visiting scientists
4 in mid-career who participate in the National Insti-
5 tutes of Health Scholars program.

6 “(3) Studies, projects, and research conducted
7 by scientists under paragraphs (1) and (2).

8 “(4) Forums for the exchange of information
9 between scientists. Participants in such forums may
10 include institutions of higher education and appro-
11 priate private and public organizations.

12 “(5) Meetings, conferences, courses, and train-
13 ing workshops.

14 “(6) Programs to improve the collection and
15 analysis of data.

16 “(7) Programs for writing, editing, printing,
17 and publishing of books and other materials.

18 “(8) Other activities to carry out the purpose
19 described in subsection (b).

20 “(e) POWERS.—In carrying out subsection (b), the
21 Foundation shall—

22 “(1) operate under the direction of its Board;

23 “(2) adopt, alter, and use a corporate seal,
24 which shall be judicially noticed;

1 ~~“(3) provide for 1 or more officers, employees,~~
2 ~~and agents, as may be necessary, define their duties,~~
3 ~~and require surety bonds or make other provisions~~
4 ~~against losses occasioned by acts of such persons;~~

5 ~~“(4) hire, promote, compensate, and discharge~~
6 ~~officers and employees of the Foundation;~~

7 ~~“(5) prescribe by its Board its bylaws, as de-~~
8 ~~scribed in subsection (g)(1)(A);~~

9 ~~“(6) with the consent of any executive depart-~~
10 ~~ment or independent agency, use the information,~~
11 ~~services, staff, and facilities of such in carrying out~~
12 ~~this section;~~

13 ~~“(7) sue and be sued in its corporate name, and~~
14 ~~complain and defend in courts of competent jurisdic-~~
15 ~~tion;~~

16 ~~“(8) modify or consent to the modification of~~
17 ~~any contract or agreement to which it is a party or~~
18 ~~in which it has an interest under this subtitle;~~

19 ~~“(9) establish a mechanism for the selection of~~
20 ~~candidates, subject to the approval of the Director of~~
21 ~~the National Institutes of Health for the endowed~~
22 ~~scientific positions within the organizational struc-~~
23 ~~ture of the intramural research programs of the Na-~~
24 ~~tional Institutes of Health and candidates for par-~~

1 participation in the National Institutes of Health Schol-
2 ars program;

3 ~~“(10) enter into contracts with public and pri-
4 vate organizations for the writing, editing, printing,
5 and publishing of books and other material;~~

6 ~~“(11) take such action as may be necessary to
7 obtain patents and licenses for devices and proce-
8 dures developed by the Foundation and its employ-
9 ees;~~

10 ~~“(12) accept, hold, administer, invest, and
11 spend any gift, devise, or bequest of real or personal
12 property made to the Foundation;~~

13 ~~“(13) enter into such other contracts, leases,
14 cooperative agreements, and other transactions as
15 the Executive Director considers appropriate to con-
16 duct the activities of the Foundation;~~

17 ~~“(14) appoint other groups of advisors as may
18 be determined necessary from time to time to carry
19 out the functions of the Foundation; and~~

20 ~~“(15) exercise other powers as set forth in this
21 section, and such other incidental powers as are nec-
22 essary to carry out its powers, duties, and functions
23 in accordance with this subtitle.~~

24 ~~“(f) GENERAL STRUCTURE OF FOUNDATION; NON-
25 PROFIT STATUS.—~~

1 “(1) BOARD OF DIRECTORS.—The Foundation
2 shall have a board of directors (in this part referred
3 to as the ‘Board’), which shall be established and
4 conducted in accordance with subsection (g). The
5 Board shall establish the general policies of the
6 Foundation for carrying out subsection (b), includ-
7 ing the establishment of the bylaws of the Founda-
8 tion.

9 “(2) EXECUTIVE DIRECTOR.—The Foundation
10 shall have an executive director (in this part referred
11 to as the ‘Director’), who shall be appointed by the
12 Board, who shall serve at the pleasure of the Board,
13 and for whom the Board shall establish the rate of
14 compensation. Subject to compliance with the poli-
15 cies and bylaws established by the Board pursuant
16 to paragraph (1), the Director shall be responsible
17 for the daily operations of the Foundation in carry-
18 ing out subsection (b).

19 “(3) NONPROFIT STATUS.—In carrying out
20 subsection (b), the Board shall establish such poli-
21 cies and bylaws under paragraph (1), and the Direc-
22 tor shall carry out such activities under paragraph
23 (2), as may be necessary to ensure that the Founda-
24 tion maintains status as an organization that—

1 “(A) is described in subsection (c)(3) of
2 section 501 of the Internal Revenue Code of
3 1986; and

4 “(B) is, under subsection (a) of such sec-
5 tion, exempt from taxation.

6 “(4) LIAISON.—The Director of the National
7 Institutes of Health shall serve as the liaison rep-
8 resentative of the National Institutes of Health to
9 the Board and the Foundation.

10 “(g) BOARD OF DIRECTORS.—

11 “(1) CERTAIN BYLAWS.—

12 “(A) In establishing bylaws under sub-
13 section (f)(1), the Board shall ensure that the
14 bylaws of the Foundation include bylaws for the
15 following:

16 “(i) Policies for the selection of the
17 officers, employees, agents, and contractors
18 of the Foundation.

19 “(ii) Policies for the acquisition, hold-
20 ing, and transfer of property.

21 “(iii) Policies, including ethical stand-
22 ards, for the acceptance and disposition of
23 donations to the Foundation and for the
24 disposition of the assets of the Foundation.

1 ~~“(iv) Policies for the conduct of the~~
2 ~~general operations of the Foundation.~~

3 ~~“(v) Policies for writing, editing,~~
4 ~~printing, and publishing of books and other~~
5 ~~materials, and the acquisition of patents~~
6 ~~and licenses for devices and procedures de-~~
7 ~~veloped by the Foundation.~~

8 ~~“(B) In establishing bylaws under sub-~~
9 ~~section (f)(1), the Board shall ensure that the~~
10 ~~bylaws of the Foundation (and activities carried~~
11 ~~out under the bylaws) do not—~~

12 ~~“(i) reflect unfavorably upon the abil-~~
13 ~~ity of the Foundation, or the National In-~~
14 ~~stitutes of Health, to carry out its respon-~~
15 ~~sibilities or official duties in a fair and ob-~~
16 ~~jective manner; or~~

17 ~~“(ii) compromise, or appear to com-~~
18 ~~promise, the integrity of any governmental~~
19 ~~program or any officer or employee in-~~
20 ~~volved in such program.~~

21 ~~“(2) COMPOSITION.—~~

22 ~~“(A) The Foundation shall have a Board~~
23 ~~of Directors (hereafter referred to in this sec-~~
24 ~~tion as the ‘Board’), which shall initially be~~
25 ~~composed of ex officio and appointed members~~

1 in accordance with this subsection until such
2 time as all the appointed members, including
3 the Chairperson, are fully appointed by the
4 Board under paragraph (4).

5 “(B) The ex officio members of the Coun-
6 cil shall be—

7 “(i) the Chairperson and ranking mi-
8 nority member of the Subcommittee on
9 Health and the Environment (Committee
10 on Energy and Commerce) or their des-
11 ignees, in the case of the House of Rep-
12 resentatives;

13 “(ii) the Chairperson and ranking mi-
14 nority member of the Committee on Labor
15 and Human Resources or their designees,
16 in the case of the Senate; and

17 “(iii) the Director of the National In-
18 stitutes of Health.

19 “(C) The ex officio members of the Board
20 under subparagraph (B) shall appoint to the
21 Council 9 individuals. Of such appointed mem-
22 bers—

23 “(i) 2 shall be representatives of the
24 general biomedical field;

1 “(ii) 2 shall be representatives of the
2 general biobehavioral field; and

3 “(iii) 3 shall be representatives of the
4 general public.

5 “(3) CHAIRPERSON.—The ex officio members of
6 the Board under paragraph (2)(B) shall designate
7 an appointed member of the Board to serve as the
8 first Chairperson of the Board. Subsequently, the
9 Chairperson of the Board shall be chosen by the
10 Board according to its bylaws.

11 “(4) APPOINTMENTS, VACANCIES, AND
12 TERMS.—The following shall apply to the Board:

13 “(A) Any vacancy in the membership of
14 the Board shall be filled by appointment by the
15 Board, after consideration of suggestions made
16 by the Chairperson and the Director regarding
17 the appointments. Any such vacancy shall be
18 filled not later than the expiration of the 180-
19 day period beginning on the date on which the
20 vacancy occurs.

21 “(B) The term of office of each member of
22 the Board appointed under subparagraph (A)
23 shall be 5 years, except that the terms of office
24 for the initial appointed members of the Board
25 shall expire as determined by the Chairperson

1 of the Board, in consultation with the Director
2 of the National Institutes of Health.

3 ~~“(C) A vacancy in the membership of the~~
4 ~~Board shall not affect the power of the Board~~
5 ~~to carry out the duties of the Board. If a mem-~~
6 ~~ber of the Board does not serve the full term~~
7 ~~applicable under subparagraph (B), the individ-~~
8 ~~ual appointed to fill the resulting vacancy shall~~
9 ~~be appointed for the remainder of the term of~~
10 ~~the predecessor of the individual.~~

11 ~~“(5) COMPENSATION.—Members of the Board~~
12 ~~may not receive compensation for service on the~~
13 ~~Board. Such members may be reimbursed for travel,~~
14 ~~subsistence, and other necessary expenses incurred~~
15 ~~in carrying out the duties of the Board, as set forth~~
16 ~~in the bylaws issued by the Board.~~

17 ~~“(h) INCORPORATION.—The initial members of the~~
18 ~~Board shall serve as incorporators and shall take whatever~~
19 ~~actions necessary to incorporate the Foundation.~~

20 ~~“(i) GENERAL PROVISIONS.—~~

21 ~~“(1) ADMINISTRATIVE CONTROL.—No officer,~~
22 ~~employee, or member of the Board of the Founda-~~
23 ~~tion may exercise any administrative or managerial~~
24 ~~control over any Federal employee.~~

1 ~~“(2) APPLICABILITY OF CERTAIN STANDARDS~~
2 ~~TO NON-FEDERAL EMPLOYEES.—~~In the case of any
3 individual who is not an employee of the Federal
4 Government and who serves with financial support
5 from the Foundation, the Foundation shall negotiate
6 a memorandum of understanding with the individual
7 and the Director of the National Institutes of Health
8 specifying that the individual—

9 ~~“(A) shall be subject to the ethical and~~
10 procedural standards regulating Federal em-
11 ployment, scientific investigation, and research
12 findings (including publications and patents)
13 that are required of individuals employed by the
14 National Institutes of Health, including stand-
15 ards under this Act, the Ethics in Government
16 Act, and the Technology Transfer Act; and

17 ~~“(B) shall be subject to such ethical and~~
18 procedural standards under chapter 11 of title
19 18, United States Code (relating to conflicts of
20 interest), as the Director of the National Insti-
21 tutes of Health determines is appropriate, ex-
22 cept such memorandum may not provide that
23 the individual shall be subject to the standards
24 of section 209 of such chapter.

1 ~~“(3) FINANCIAL CONFLICTS OF INTEREST.—~~
2 Any individual who is an officer, employee, or mem-
3 ber of the Board of the Foundation may not directly
4 or indirectly participate in the consideration or de-
5 termination by the Foundation of any question af-
6 fecting—

7 ~~“(A) any direct or indirect financial inter-~~
8 est of the individual; or

9 ~~“(B) any direct or indirect financial inter-~~
10 est of any business organization or other entity
11 of which the individual is an officer or employee
12 or in which the individual has a direct or indi-
13 rect financial interest.

14 ~~“(4) AUDITS; AVAILABILITY OF RECORDS.—The~~
15 Foundation shall—

16 ~~“(A) provide for biennial audits of the fi-~~
17 nancial condition of the Foundation; and

18 ~~“(B) make such audits, and all other~~
19 records, documents, and other papers of the
20 Foundation, available to the Secretary and the
21 Comptroller General of the United States for
22 examination or audit.

23 ~~“(5) REPORTS.—~~

24 ~~“(A) Not later than February 1 of each~~
25 fiscal year, the Foundation shall publish a re-

1 port describing the activities of the Foundation
2 during the preceding fiscal year. Each such re-
3 port shall include for the fiscal year involved a
4 comprehensive statement of the operations, ac-
5 tivities, financial condition, and accomplish-
6 ments of the Foundation.

7 “(B) With respect to the financial condi-
8 tion of the Foundation, each report under sub-
9 paragraph (A) shall include the source, and a
10 description of, all gifts to the Foundation of
11 real or personal property, and the source and
12 amount of all gifts to the Foundation of money.
13 Each such report shall include a specification of
14 any restrictions on the purposes for which gifts
15 to the Foundation may be used.

16 “(C) The Foundation shall make copies of
17 each report submitted under subparagraph (A)
18 available for public inspection, and shall upon
19 request provide a copy of the report to any indi-
20 vidual for a charge not exceeding the cost of
21 providing the copy.

22 “(j) FEDERAL FUNDING.—

23 “(1) AUTHORITY FOR ANNUAL GRANTS.—

24 “(A) The Secretary, acting through the Di-
25 rector of the National Institutes of Health,

1 shall for each of the fiscal years 1994 through
2 1996, make a grant to the Foundation.

3 “(B) A grant under subparagraph (A) may
4 be expended only for the purpose of the admin-
5 istrative expenses of the Foundation.

6 “(C) A grant under subparagraph (A) may
7 not be expended to provide amounts for the
8 fund established under subsection (c).

9 “(2) FUNDING FOR GRANTS.—

10 “(A) For the purpose of grants under
11 paragraph (1), there is authorized to be appro-
12 priated \$500,000 for each of the fiscal years
13 1994 through 1996.

14 “(B) For the purpose of grants under
15 paragraph (1), the Secretary may for each fis-
16 cal year make available not more than
17 \$500,000 from the amounts appropriated for
18 the fiscal year for the programs of the National
19 Institutes of Health. Such amounts may be
20 made available without regard to whether
21 amounts have been appropriated under sub-
22 paragraph (A).”

1 **TITLE XVIII—RESEARCH WITH**
2 **RESPECT TO ACQUIRED IM-**
3 **MUNE DEFICIENCY SYN-**
4 **DROME**

5 **SEC. 1801. REVISION AND EXTENSION OF VARIOUS PRO-**
6 **GRAMS.**

7 Title XXIII of the Public Health Service Act (42
8 U.S.C. 300ce et seq.) is amended—

9 (1) in section 2304(c)(1)—

10 (A) in the matter preceding subparagraph
11 (A), by inserting after “Director of such Insti-
12 tute” the following: “(and may provide advice
13 to the Directors of other agencies of the Na-
14 tional Institutes of Health, as appropriate)”;
15 and

16 (B) in subparagraph (A), by inserting be-
17 fore the semicolon the following: “, including
18 recommendations on the projects of research
19 with respect to diagnosing immune deficiency
20 and with respect to predicting, diagnosing, pre-
21 venting, and treating opportunistic cancers and
22 infectious diseases”;

23 (2) in section 2311(a)(1), by inserting before
24 the semicolon the following: “, including evaluations
25 of methods of diagnosing immune deficiency and

1 evaluations of methods of predicting, diagnosing,
2 preventing, and treating opportunistic cancers and
3 infectious diseases”;

4 (3) in section 2315—

5 (A) in subsection (a)(2), by striking “inter-
6 national research” and all that follows and in-
7 serting “international research and training
8 concerning the natural history and pathogenesis
9 of the human immunodeficiency virus and the
10 development and evaluation of vaccines and
11 treatments for acquired immune deficiency syn-
12 drome and opportunistic infections.”; and

13 (B) in subsection (f), by striking “and
14 1991” and inserting “through 1996”;

15 (4) in section 2318—

16 (A) in subsection (a)(1)—

17 (i) by inserting after “The Secretary”
18 the following: “, acting through the Direc-
19 tor of the National Institutes of Health
20 and after consultation with the Adminis-
21 trator for Health Care Policy and Re-
22 search,”; and

23 (ii) by striking “syndrome” and in-
24 serting “syndrome, including treatment

1 and prevention of HIV infection and relat-
2 ed conditions among women”; and

3 ~~(B)~~ in subsection (e), by striking “1991.”
4 and inserting the following: “1991, and such
5 sums as may be necessary for each of the fiscal
6 years 1994 through 1996.”;

7 (5) in section 2320(b)(1)(A), by striking “syn-
8 drome” and inserting “syndrome and the natural
9 history of such infection”;

10 (6) in the part heading for part D, by striking
11 “DIRECTOR OF THE NATIONAL INSTITUTES OF
12 HEALTH” and inserting “OFFICE OF AIDS RE-
13 SEARCH”;

14 (7) in section 2351—

15 (A) by redesignating subsections (a), (b)
16 and (c) as subsections (b), (d) and (e), respec-
17 tively;

18 ~~(B)~~ by striking subsection (a) and insert-
19 ing the following new subsection:

20 “(a) IN GENERAL.—In carrying out research with re-
21 spect to acquired immune deficiency syndrome, the Sec-
22 retary, acting through the Director of the National Insti-
23 tutes of Health—

1 ~~“(1) shall establish an office to be known as the~~
 2 ~~Office of AIDS Research, which Office shall be~~
 3 ~~headed by a Director who shall be—~~

4 ~~“(A) appointed by the Secretary;~~

5 ~~“(B) determined by the Secretary to be an~~
 6 ~~individual who is an outstanding scientist and a~~
 7 ~~highly skilled administrator; and~~

8 ~~“(C) the primary Federal official respon-~~
 9 ~~sible for the conduct of AIDS-related research~~
 10 ~~at the National Institutes of Health; and~~

11 ~~“(2) shall provide administrative support and~~
 12 ~~support services to the Director of such Office.”;~~

13 ~~(C) in subsection (b) (as so redesign-~~
 14 ~~ated)—~~

15 ~~(i) by striking the subsection designa-~~
 16 ~~tion and all that follows through paragraph~~
 17 ~~(1) and inserting in lieu thereof the follow-~~
 18 ~~ing:~~

19 ~~“(b) ACTIVITIES OF THE OFFICE OF AIDS RE-~~
 20 ~~SEARCH.—~~

21 ~~“(1) IN GENERAL.—The Secretary, acting~~
 22 ~~through the director of the Office of AIDS Research,~~
 23 ~~shall ensure that AIDS research activities are co-~~
 24 ~~ordinated across and throughout the institutes, cen-~~

1 ters, and divisions of the National Institutes of
2 Health.

3 ~~“(2) GENERAL DUTIES.—~~The Director of the
4 Office of AIDS Research shall, based upon a strate-
5 gic plan as defined in paragraph (3), develop and
6 implement a budget for AIDS-related research at
7 the National Institutes of Health and coordinate all
8 AIDS-related research activities conducted at the in-
9 stitutes, centers, and divisions of the National Insti-
10 tutes of Health, and conduct evaluations on all such
11 programs.

12 ~~“(3) STRATEGIC PLAN.—~~

13 ~~“(A) DEVELOPMENT.—~~The Director of the
14 Office of AIDS Research shall, with the advice
15 of the directors of the institutes, centers, and
16 divisions of the National Institutes of Health,
17 and in consultation with the advisory council es-
18 tablished in paragraph (5) and the coordinating
19 groups established in subparagraph (B), de-
20 velop and implement a comprehensive, long-
21 range plan for the conduct and support of such
22 research by the National Institutes of Health.
23 Such plan shall be updated annually, and
24 shall—

1 “(i) determine and prioritize among
2 critical scientific AIDS-related questions;

3 “(ii) based upon such determinations,
4 specify the range of objectives to be
5 achieved, the date the objectives are ex-
6 pected to be achieved, and provide an esti-
7 mate of the resources needed to achieve
8 the objectives by such date;

9 “(iii) evaluate the sufficiency of exist-
10 ing AIDS research programs to meet such
11 objectives, and establish standard evalua-
12 tion criteria, timelines and objectives for
13 future program evaluation activities; and

14 “(iv) make recommendations for
15 changes and necessary resource allocation
16 in and among such programs.

17 “(B) COORDINATING GROUPS.—The Direc-
18 tor of the Office of AIDS Research shall estab-
19 lish AIDS coordinating groups for each re-
20 search discipline within the AIDS research pro-
21 gram, composed of representatives of relevant
22 agencies of the National Institutes of Health
23 and qualified extramural scientists, to evaluate
24 and assess the efforts of the AIDS Research
25 Program at the National Institutes of Health,

1 to advise on the development of the strategic
2 plan described in subparagraph (A), and to de-
3 termine the extent to which such efforts are in
4 accordance with such strategic plan.

5 “(4) COORDINATION.—The Director of the Of-
6 fice of AIDS Research shall act as the primary Fed-
7 eral official with responsibility for overseeing all
8 AIDS-related research efforts undertaken by the Na-
9 tional Institutes of Health, and

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

14 “(B) shall maintain communications with
15 all relevant Public Health Service agencies and
16 with various other departments of the Federal
17 Government, to ensure the timely transmission
18 of information concerning advances in AIDS-re-
19 lated research and the clinical treatment of
20 AIDS and its related conditions, to these var-
21 ious agencies for dissemination to affected com-
22 munities and health care providers.

23 “(5) ADVISORY COUNCIL.—

24 “(A) ESTABLISHMENT.—The Director of
25 the Office of AIDS Research shall establish an

1 advisory council to be known as the Office of
2 AIDS Research Advisory Council (hereafter re-
3 ferred to as the “Council”), which shall serve to
4 replace the AIDS Program Advisory Committee
5 which is operating on the date of enactment of
6 this subsection.

7 “(B) COMPOSITION.—The Council shall be
8 composed of biomedical, behavioral, and social
9 scientists, and representatives of diverse HIV
10 affected communities, and shall be appointed by
11 the Director.

12 “(C) AUTHORITY.—The Council shall, con-
13 sistent with section 406—

14 “(i) advise the Director of the Office
15 of AIDS Research and make recommenda-
16 tions concerning the development of the
17 AIDS-related research budget, and the de-
18 velopment and implementation of the stra-
19 tegic plan for AIDS-related research at the
20 National Institutes of Health;

21 “(ii) provide the second level of peer
22 review for awards made directly to the Of-
23 fice of AIDS Research from the discre-
24 tionary fund described in paragraph (7);
25 and

1 ~~“(iii) carry out such other activities~~
2 determined appropriate by the Director of
3 the Office of AIDS Research.

4 ~~“(6) BUDGETARY AUTHORITY.—The Director~~
5 of the Office of AIDS Research shall—

6 ~~“(A) in consultation with the advisory~~
7 council established under paragraph (5) and
8 based upon budget requests and additional ad-
9 vice from the directors of the institutes, centers,
10 and divisions of the National Institutes of
11 Health, prepare and submit, directly to the
12 President for review and transmittal to Con-
13 gress, an annual budget estimate for the AIDS-
14 related research program conducted within the
15 agencies of the National Institutes of Health,
16 after reasonable opportunity for comment (but
17 without change) by the Secretary and the Di-
18 rector of the National Institutes of Health;

19 ~~“(B) receive from the President and the~~
20 Office of Management and Budget directly all
21 AIDS-related research funds appropriated by
22 Congress for obligation and expenditure by the
23 agencies of the National Institutes of Health in
24 accordance with the strategic plan developed
25 under paragraph (3)(A); and

1 “(C) distribute AIDS research funding to
2 the various institutes, centers, and divisions of
3 the National Institutes of Health in accordance
4 with the strategic plan.

5 “(7) DISCRETIONARY FUND.—

6 “(A) AVAILABILITY OF FUNDS.—The Sec-
7 retary shall ensure that not to exceed 25 per-
8 cent of the funds available in excess of the
9 amount of baseline AIDS research spending
10 during the previous fiscal year, but in no event
11 less than \$50,000,000 each fiscal year, be made
12 available to the Director of the Office of AIDS
13 Research for the establishment of an AIDS re-
14 search discretionary fund.

15 “(B) USE.—The Director of the Office of
16 AIDS Research, in consultation with the advi-
17 sory council established under paragraph (5),
18 shall use amounts in the AIDS research discre-
19 tionary fund to—

20 “(i) fund emergency AIDS research
21 programs;

22 “(ii) fund programs for the conduct of
23 research aimed at filling gaps that exist in
24 existing research programs;

1 ~~“(iii) conduct conferences, convene~~
2 ~~committees, hold meetings or carry out~~
3 ~~other activities determined appropriate by~~
4 ~~the Director.~~

5 ~~“(C) REDUCTION IN ADMINISTRATIVE IM-~~
6 ~~PEDIMENTS.—Notwithstanding any other provi-~~
7 ~~sion of law, with respect to the number of full-~~
8 ~~time equivalent individuals employed, the Direc-~~
9 ~~tor of the Office of AIDS Research shall be per-~~
10 ~~mitted to authorize the employment of such~~
11 ~~full-time equivalent individuals to perform~~
12 ~~AIDS-related research through the agencies of~~
13 ~~the National Institutes of Health.~~

14 ~~“(e) OTHER DUTIES.—The director of the office—~~
15 ~~”; and~~

16 (ii) by redesignating paragraphs (2)
17 through (8) (as such paragraphs existed
18 one day prior to the date of enactment of
19 this Act) as paragraphs (1) through (7),
20 respectively; and

21 (C) in subsection (e) (as added by the
22 amendment made by subparagraph (B)) by
23 striking “for the appropriate national research
24 institute of the National Institutes of Health”

1 in paragraph (4) (as so designated by the
2 amendments made by subparagraph (B));

3 (8) in section 2361, by striking “For purposes”
4 and all that follows and inserting the following:
5 “For purposes of this title:

6 “(1) The term ‘infection’, with respect to the
7 etiologic agent for acquired immune deficiency syn-
8 drome, includes opportunistic cancers and infectious
9 diseases and any other conditions arising from infec-
10 tion with such etiologic agent.

11 “(2) The term ‘treatment’, with respect to the
12 etiologic agent for acquired immune deficiency syn-
13 drome, includes primary and secondary prophylaxis.”;

14
15 (9) in section 2315(f), by striking “there are
16 authorized” and all that follows and inserting “there
17 are authorized to be appropriated such sums as may
18 be necessary for each fiscal year.”;

19 (10) in section 2320(e)(1), by striking “there
20 are authorized” and all that follows and inserting
21 “there are authorized to be appropriated such sums
22 as may be necessary for each fiscal year.”; and

23 (11) in section 2341(d), by striking “there are
24 authorized” and all that follows and inserting “there

1 are authorized to be appropriated such sums as may
2 be necessary for each fiscal year.”.

3 **TITLE XIX—STUDIES**

4 **SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.**

5 ~~(a) CERTAIN DRUG-RELEASE MECHANISMS.—~~

6 (1) The Secretary of Health and Human Serv-
7 ices shall, subject to paragraph (2), enter into a con-
8 tract with a public or nonprofit private entity to con-
9 duct a study for the purpose of determining, with re-
10 spect to acquired immune deficiency syndrome, the
11 impact of parallel-track drug-release mechanisms on
12 public and private clinical research, and on the ac-
13 tivities of the Commissioner of Food and Drugs re-
14 garding the approval of drugs.

15 (2) The Secretary of Health and Human Serv-
16 ices shall request the Institute of Medicine of the
17 National Academy of Sciences to enter into the con-
18 tract under paragraph (1) to conduct the study de-
19 scribed in such paragraph. If such Institute declines
20 to conduct the study, the Secretary shall carry out
21 paragraph (1) through another public or nonprofit
22 private entity.

23 ~~(b) THIRD-PARTY PAYMENTS REGARDING CERTAIN~~
24 ~~CLINICAL TRIALS.—~~The Secretary of Health and Human
25 Services shall conduct a study for the purpose of—

1 (1) determining the policies of third-party
2 payors regarding the payment of the costs of appro-
3 priate health services that are provided incident to
4 the participation of individuals as subjects in clinical
5 trials conducted in the development of drugs with re-
6 spect to acquired immune deficiency syndrome; and

7 (2) developing recommendations regarding such
8 policies.

9 (c) *ADVISORY COMMITTEES.*—The Secretary of
10 Health and Human Services, acting through the Director
11 of the National Institutes of Health, shall conduct a study
12 for the purpose of determining—

13 (1) whether the activities of the various advi-
14 sory committees established in the National Insti-
15 tutes of Health regarding acquired immune defi-
16 ciency syndrome are being coordinated sufficiently;
17 and

18 (2) whether the functions of any of such advi-
19 sory committees should be modified in order to
20 achieve greater efficiency.

21 (d) *VACCINES FOR HUMAN IMMUNODEFICIENCY*
22 *VIRUS.*—

23 (1) *IN GENERAL.*—The Secretary of Health and
24 Human Services, acting through the National Insti-
25 tutes of Health, shall develop a plan for the appro-

1 appropriate inclusion of HIV-infected women, including
2 pregnant women, HIV-infected infants, and HIV-in-
3 fected children in studies conducted by or through
4 the National Institutes of Health concerning the
5 safety and efficacy of HIV vaccines for the treat-
6 ment and prevention of HIV infection. Such plan
7 shall ensure the full participation of other Federal
8 agencies currently conducting HIV vaccine studies
9 and require that such studies conform fully to the
10 requirements of part 46 of title 45, Code of Federal
11 Regulations.

12 (2) REPORT.—Not later than 180 days after
13 the date of the enactment of this Act, the Secretary
14 of Health and Human Services shall prepare and
15 submit to the Committee on Energy and Commerce
16 of the House of Representatives, and the Committee
17 on Labor and Human Resources of the Senate, a re-
18 port concerning the plan developed under paragraph
19 (1).

20 (3) IMPLEMENTATION.—Not later than 12
21 months after the date of the enactment of this Act,
22 the Secretary of Health and Human Services shall
23 implement the plan developed under paragraph (1),
24 including measures for the full participation of other

1 Federal agencies currently conducting HIV vaccine
2 studies.

3 (4) For the purpose of carrying out this sub-
4 section, there are authorized to be appropriated such
5 sums as may be necessary for each of the fiscal
6 years 1994 through 1996.

7 **SEC. 1902. MALNUTRITION IN THE ELDERLY.**

8 (a) STUDY.—

9 (1) IN GENERAL.—The Secretary of Health and
10 Human Services (referred to in this section as the
11 “Secretary”), acting through the National Institute
12 on Aging, coordinating with the Agency for Health
13 Care Policy and Research and, to the degree pos-
14 sible, in consultation with the head of the National
15 Nutrition Monitoring System established under sec-
16 tion 1428 of the Food and Agriculture Act of 1977
17 (7 U.S.C. 3178), shall conduct a 3-year nutrition
18 screening and intervention activities study of the el-
19 derly.

20 (2) EFFICACY AND COST-EFFECTIVENESS OF
21 NUTRITION SCREENING AND INTERVENTION ACTIVI-
22 TIES.—In conducting the study, the Secretary shall
23 determine the efficacy and cost-effectiveness of nu-
24 trition screening and intervention activities con-
25 ducted in the elderly health and long-term care con-

1 tinuum, and of a program that would institutionalize
2 nutrition screening and intervention activities. In
3 evaluating such a program, the Secretary shall de-
4 termine—

5 (A) if health or quality of life is measur-
6 ably improved for elderly individuals who re-
7 ceive routine nutritional screening and treat-
8 ment;

9 (B) if federally subsidized home or institu-
10 tional care is reduced because of increased inde-
11 pendence of elderly individuals resulting from
12 improved nutritional status;

13 (C) if a multidisciplinary approach to nu-
14 tritional care is effective in addressing the nu-
15 tritional needs of elderly individuals; and

16 (D) if reimbursement for nutrition screen-
17 ing and intervention activities is a cost-effective
18 approach to improving the health status of el-
19 derly individuals.

20 (3) POPULATIONS.—The populations of elderly
21 individuals in which the study will be conducted
22 shall include populations of elderly individuals who
23 are—

24 (A) living independently, including—

1 (i) individuals who receive home and
2 community-based services or family sup-
3 port;

4 (ii) individuals who do not receive ad-
5 ditional services and support;

6 (iii) individuals with low incomes; and

7 (iv) individuals who are minorities;

8 (B) hospitalized, including individuals ad-
9 mitted from home and from institutions; and

10 (C) institutionalized in residential facilities
11 such as nursing homes and adult homes.

12 (b) MALNUTRITION STUDY.—The Secretary, acting
13 through the National Institute on Aging, shall conduct a
14 3-year study to determine the extent of malnutrition in
15 elderly individuals in hospitals and long-term care facili-
16 ties and in elderly individuals who are living independ-
17 ently.

18 (c) REPORT.—The Secretary shall submit a report to
19 the Committee on Labor and Human Resources of the
20 Senate and the Committee on Energy and Commerce of
21 the House of Representatives containing the findings re-
22 sulting from the studies described in subsections (a) and
23 (b), including a determination regarding whether a pro-
24 gram that would institutionalize nutrition screening and

1 intervention activities should be adopted, and the rationale
2 for the determination.

3 ~~(d) ADVISORY PANEL.—~~

4 ~~(1) ESTABLISHMENT.—~~The Secretary, acting
5 through the Director of the National Institute on
6 Aging, shall establish an advisory panel that shall
7 oversee the design, implementation, and evaluation
8 of the studies described in subsections (a) and (b).

9 ~~(2) COMPOSITION.—~~The advisory panel shall in-
10 clude representatives appointed for the life of the
11 panel by the Secretary from the Health Care Fi-
12 nancing Administration, the Social Security Admin-
13 istration, the National Center for Health Statistics,
14 the Administration on Aging, the National Council
15 on the Aging, the American Dietetic Association, the
16 American Academy of Family Physicians, and such
17 other agencies or organizations as the Secretary de-
18 termines to be appropriate.

19 ~~(3) COMPENSATION AND EXPENSES.—~~

20 ~~(A) COMPENSATION.—~~Each member of the
21 advisory panel who is not an employee of the
22 Federal Government shall receive compensation
23 for each day engaged in carrying out the duties
24 of the panel, including time engaged in travel-
25 ing for purposes of such duties. Such com-

1 pensation may not be provided in an amount in
2 excess of the maximum rate of basic pay pay-
3 able for GS-18 of the General Schedule.

4 (B) TRAVEL EXPENSES.—Each member of
5 the advisory panel shall receive travel expenses,
6 including per diem in lieu of subsistence, at
7 rates authorized for employees of agencies
8 under subchapter I of chapter 57 of title 5,
9 United States Code, for each day the member
10 is engaged in the performance of duties away
11 from the home or regular place of business of
12 the member.

13 (4) DETAIL OF FEDERAL EMPLOYEES.—On the
14 request of the advisory panel, the head of any Fed-
15 eral agency shall detail, without reimbursement, any
16 of the personnel of the agency to the advisory panel
17 to assist the advisory panel in carrying out its du-
18 ties. Any detail shall not interrupt or otherwise af-
19 fect the civil service status or privileges of the Fed-
20 eral employee.

21 (5) TECHNICAL ASSISTANCE.—On the request
22 of the advisory panel, the head of a Federal agency
23 shall provide such technical assistance to the advi-
24 sory panel as the advisory panel determines to be
25 necessary to carry out its duties.

1 (6) TERMINATION.—Notwithstanding section
2 15 of the Federal Advisory Committee Act (5 U.S.C.
3 App.), the advisory panel shall terminate 3 years
4 after the date of enactment of this Act.

5 **SEC. 1903. RESEARCH ACTIVITIES ON CHRONIC FATIGUE**
6 **SYNDROME.**

7 The Secretary of Health and Human Services shall,
8 not later than May 1, 1993, and annually thereafter for
9 the next 3 years, prepare and submit to the Committee
10 on Energy and Commerce of the House of Representatives
11 and the Committee on Labor and Human Resources of
12 the Senate, a report that summarizes the research activi-
13 ties conducted or supported by the National Institutes of
14 Health concerning chronic fatigue syndrome. Such report
15 should include information concerning grants made, coop-
16 erative agreements or contracts entered into, intramural
17 activities, research priorities and needs, and a plan to ad-
18 dress such priorities and needs.

19 **SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL**
20 **AGENTS IN DEVELOPMENT OF DEFENSES**
21 **AGAINST BIOLOGICAL WARFARE.**

22 The Secretary of Health and Human Services, in con-
23 sultation with other appropriate executive agencies, shall
24 report to the House Energy and Commerce Committee
25 and the Senate Labor and Human Resources Committee

1 on the appropriateness and impact of the National Insti-
2 tutes of Health assuming responsibility for the conduct of
3 all Federal research, development, testing, and evaluation
4 functions relating to medical countermeasures against
5 biowarfare threat agents. In preparing the report, the Sec-
6 retary shall identify the extent to which such activities are
7 carried out by agencies other than the National Institutes
8 of Health, and assess the impact (positive and negative)
9 of the National Institutes of Health assuming responsibil-
10 ity for such activities, including the impact under the
11 Budget Enforcement Act and the Omnibus Budget Rec-
12 onciliation Act of 1990 on existing National Institutes of
13 Health research programs as well as other programs with-
14 in the category of domestic discretionary spending. The
15 Secretary shall submit the report not later than 12 months
16 after the date of the enactment of this Act.

17 **SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETEN-**
18 **TION AND TURNOVER.**

19 (a) STUDY OF PERSONNEL SYSTEM.—Not later than
20 1 year after the date of the enactment of this Act, the
21 Secretary of Health and Human Services, acting through
22 the Director of the National Institutes of Health, shall
23 conduct a study to review the retention, recruitment, va-
24 cancy and turnover rates of support staff, including fire-
25 fighters, law enforcement, procurement officers, techni-

1 cians, nurses and clerical employees, to ensure that the
2 National Institutes of Health is adequately supporting the
3 conduct of efficient, effective and high quality research for
4 the American public. The Director of NIH shall work in
5 conjunction with appropriate employee organizations and
6 representatives in developing such a study.

7 (b) ~~SUBMISSION TO CONGRESS.~~—Not later than 1
8 year after the date of the enactment of this Act, the Sec-
9 retary of Health and Human Services shall prepare and
10 submit to the Committee on Energy and Commerce of the
11 House of Representatives, and to the Committee on Labor
12 and Human Resources of the Senate, a report containing
13 the study conducted under subsection (a) together with
14 the recommendations of the Secretary concerning the en-
15 actment of legislation to implement the results of such
16 study.

17 **SEC. 1906. PROCUREMENT.**

18 (a) ~~IN GENERAL.~~—The Director of the National In-
19 stitutes of Health and the Administrator of the General
20 Services Administration shall jointly conduct a study to
21 develop a streamlined procurement system for the Na-
22 tional Institutes of Health that complies with the require-
23 ments of Federal law.

24 (b) ~~REPORT.~~—Not later than March 1, 1994, the of-
25 ficials specified in subsection (a) shall complete the study

1 required in such subsection and shall submit to the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives, and the Committee on Labor and Human Re-
4 sources of the Senate, a report describing the findings
5 made as a result of the study.

6 **SEC. 1907. REPORT CONCERNING LEADING CAUSES OF**
7 **DEATH.**

8 (a) REPORT.—The Secretary of Health and Human
9 Services shall, not later than February 1, 1993, prepare
10 a report that lists—

11 (1) the 20 illnesses that, in terms of mortality,
12 number of years of expected life lost, and of number
13 of preventable years of life lost, are the leading
14 causes of death in the United States and the number
15 of deaths from each such cause, the age-specific and
16 age-adjusted death rates for each such cause, the
17 death rate per 100,000 population for each such
18 cause, the percentage of change in cause specific
19 death rates for each age group, and the percentage
20 of total deaths for each such cause;

21 (2) the amount expended by the Department of
22 Health and Human Services for research, preven-
23 tion, and education with respect to each of the 20
24 illnesses described in paragraph (1) for the most re-

1 cent year for which the actual expenditures are
2 known;

3 (3) an estimate by the Secretary of the amount
4 to be expended on research, prevention, and edu-
5 cation with respect to each of the 20 illnesses de-
6 scribed in paragraph (1) for the year for which the
7 report is prepared; and

8 (4) with respect to the years specified in para-
9 graphs (2) and (3), the percentage of the total of
10 the annual expenditures for research, prevention,
11 and education on the 20 illnesses described in para-
12 graph (1) that are attributable to each illness.

13 (b) ~~SUBMISSION TO CONGRESS.~~—The Secretary of
14 Health and Human Services shall submit the report re-
15 quired under subsection (a), together with relevant budget
16 information, to the Committee on Energy and Commerce
17 and the Committee on Appropriations of the House of
18 Representatives and the Committee on Labor and Human
19 Resources and the Committee on Appropriations of the
20 Senate.

21 **SEC. 1908. RELATIONSHIP BETWEEN THE CONSUMPTION**
22 **OF LEGAL AND ILLEGAL DRUGS.**

23 (a) ~~IN GENERAL.~~—The Secretary of Health and
24 Human Services, acting through the Commissioner of
25 Food and Drugs, shall review and consider all existing rel-

1 evant data and research concerning whether there is a re-
2 lationship between an individual's receptivity to use or
3 consume legal drugs and the consumption or abuse by the
4 individual of illegal drugs. On the basis of such review,
5 the Secretary shall determine whether additional research
6 is necessary. If the Secretary determines additional re-
7 search is required, the Secretary shall conduct a study of
8 those subjects where the Secretary's review indicates addi-
9 tional research is needed, including, if necessary, a review
10 of—

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

14 (2) the correlation of legal drug abuse with ille-
15 gal drug abuse; and

16 (3) other matters that the Secretary determines
17 appropriate.

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

1 of this Act, the Secretary shall prepare and submit, to the
 2 Committee on Energy and Commerce of the House of
 3 Representatives and Committee on Labor and Human Re-
 4 sources of the Senate, a report containing the results of
 5 the additional research conducted under subsection (b).

6 **TITLE XX—MISCELLANEOUS** 7 **PROVISIONS**

8 **SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RE-** 9 **SEARCH SERVICE IN HONOR OF SILVIO O.** 10 **CONTE, AND LIMITATION ON NUMBER OF** 11 **MEMBERS.**

12 (a) IN GENERAL.—Section 228(a) of the Public
 13 Health Service Act (42 U.S.C. 237(a)), as added by sec-
 14 tion 304 of Public Law 101–509, is amended to read as
 15 follows:

16 “(a)(1) There shall be in the Public Health Service
 17 a Silvio O. Conte Senior Biomedical Research Service, not
 18 to exceed 750 members.

19 “(2) The authority established in paragraph (1) re-
 20 garding the number of members in the Silvio O. Conte
 21 Senior Biomedical Research Service is in addition to any
 22 authority established regarding the number of members
 23 in the commissioned Regular Corps, in the Reserve Corps,
 24 and in the Senior Executive Service. Such paragraph may
 25 not be construed to require that the number of members

1 in the commissioned Regular Corps, in the Reserve Corps,
 2 or in the Senior Executive Service be reduced to offset
 3 the number of members serving in the Silvio O. Conte Sen-
 4 ior Biomedical Research Service (hereafter in this section
 5 referred to as the ‘Service’).”.

6 (b) CONFORMING AMENDMENT.—Section 228 of the
 7 Public Health Service Act (42 U.S.C. 237), as added by
 8 section 304 of Public Law 101–509, is amended in the
 9 heading for the section by amending the heading to read
 10 as follows:

11 “SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH
 12 SERVICE”.

13 **SEC. 2002. TECHNICAL CORRECTIONS.**

14 (a) TITLE III.—Subsection (c) of section 316 of the
 15 Public Health Service Act (42 U.S.C. 247a(c)) is repealed.

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

18 (1) in section 406—

19 (A) in subsection (b)(2)(A), by striking
 20 “Veterans’ Administration” each place such
 21 term appears and inserting “Department of
 22 Veterans Affairs”; and

23 (B) in subsection (h)(2)(A)(v), by striking
 24 “Veterans’ Administration” and inserting “De-
 25 partment of Veterans Affairs”;

1 (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”;

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

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

10 (5) in section 430(b)(2)(A)(i), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

13 (6) in section 439(b), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

16 (7) in section 442(b)(2)(A), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

19 (8) in section 464D(b)(2)(A), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

22 (9) in section 464E—

23 (A) in subsection (d), in the first sentence,
24 by inserting “Coordinating” before “Committee”;

25 and

1 (B) in subsection (e), by inserting “Coordi-
2 nating” before “Committee” the first place
3 such term appears;

4 (10) in section 464P(b)(6) (as added by section
5 123 of Public Law 102-321 (106 Stat. 362)), by
6 striking “Administration” and inserting “Institute”;

7 (11) in section 466(a)(1)(B), by striking “Vet-
8 erans’ Administration” and inserting “Department
9 of Veterans Affairs”;

10 (12) in section 480(b)(2)(A), by striking “Vet-
11 erans’ Administration” and inserting “Department
12 of Veterans Affairs”;

13 (13) in section 485(b)(2)(A), by striking “Vet-
14 erans’ Administration” and inserting “Department
15 of Veterans Affairs”;

16 (14) in section 487(d)(3), by striking “section
17 304(a)(3)” and inserting “section 304(a)”; and

18 (15) in section 496(a), by striking “Such ap-
19 propriations,” and inserting the following: “Appro-
20 priations to carry out the purposes of this title,”.

21 (c) TITLE XXIII.—Part A of title XXIII of the Pub-
22 lic Health Service Act (42 U.S.C. 300ce et seq.) is amend-
23 ed—

24 (1) in section 2304—

1 (A) in the heading for the section, by strik-
2 ing “**CLINICAL RESEARCH REVIEW COM-**
3 **MITTEE**” and inserting “**RESEARCH ADVI-**
4 **SORY COMMITTEE**”; and

5 (B) in subsection (a), by striking “AIDS
6 Clinical Research Review Committee” and in-
7 serting “AIDS Research Advisory Committee”;

8 (2) in section 2312(a)(2)(A), by striking “AIDS
9 Clinical Research Review Committee” and inserting
10 “AIDS Research Advisory Committee”;

11 (3) in section 2314(a)(1), in the matter preced-
12 ing subparagraph (A), by striking “Clinical Research
13 Review Committee” and inserting “AIDS Research
14 Advisory Committee”;

15 (4) in section 2317(d)(1), by striking “Clinical
16 Research Review Committee” and inserting “AIDS
17 Research Advisory Committee established under sec-
18 tion 2304”; and

19 (5) in section 2318(b)(3), by striking “Clinical
20 Research Review Committee” and inserting “AIDS
21 Research Advisory Committee”.

22 (d) SECRETARY.—Section 2(c) of the Public Health
23 Service Act (42 U.S.C. 201(c)) is amended by striking
24 “Health, Education, and Welfare” and inserting “Health
25 and Human Services”.

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

3 (1) by striking “Health, Education, and Wel-
4 fare” and inserting “Health and Human Services”;
5 and

6 (2) by striking “Surgeon General” and insert-
7 ing “Assistant Secretary for Health”.

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

10 (1) by striking “Health, Education, and Wel-
11 fare” and inserting “Health and Human Services”;

12 (2) by striking “Surgeon General” the second
13 and subsequent times that such term appears and
14 inserting “Secretary”; and

15 (3) by inserting “, and the Agency for Health
16 Care Policy and Research” before the first period.

17 (g) VOLUNTEER SERVICES.—Section 223 of the Pub-
18 lic Health Service Act (42 U.S.C. 217b) is amended by
19 striking “Health, Education, and Welfare” and inserting
20 “Health and Human Services”.

21 **SEC. 2003. BIENNIAL REPORT ON CARCINOGENS.**

22 Section 301(b)(4) of the Public Health Service Act
23 (42 U.S.C. 241(b)(4)) is amended by striking “an annual”
24 and inserting in lieu thereof “a biennial”.

1 **SEC. 2004. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE**
2 **FOR RESEARCH.**

3 Not later than 90 days after the date of the enact-
4 ment of this Act, the Secretary of Health and Human
5 Services, acting through the Director of the National In-
6 stitutes of Health, shall present to the Congress a master
7 plan to provide for the replacement or refurbishment of
8 less than adequate buildings, utility equipment and dis-
9 tribution systems (including the resources that provide
10 electrical and other utilities, chilled water, air handling,
11 and other services that the Secretary, acting through the
12 Director, deems necessary), roads, walkways, parking
13 areas, and grounds that underpin the laboratory and clini-
14 cal facilities of the National Institutes of Health. Such
15 plan may make recommendations for the undertaking of
16 new projects that are consistent with the objectives of this
17 section, such as encircling the National Institutes of
18 Health Federal enclave with an adequate chilled water
19 conduit.

20 **SEC. 2005. TRANSFER OF PROVISIONS OF TITLE XXVII.**

21 (a) IN GENERAL.—The Public Health Service Act
22 (42 U.S.C. 201 et seq.), as amended by section 101 of
23 Public Law 101–381 and section 304 of Public Law 101–
24 509, is amended—

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

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

3 (3) by inserting such sections, in the appro-
4 priate sequence, after section 228;

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

7 “PART A—ADMINISTRATION”; and

8 (5) by inserting before section 231 (as redesign-
9 nated by paragraph (2) of this subsection) the fol-
10 lowing new heading:

11 “Part B—Miscellaneous Provisions”.

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

14 (1) in the heading for title II, by inserting
15 “AND MISCELLANEOUS PROVISIONS” after
16 “ADMINISTRATION”;

17 (2) in section 406(a)(2), by striking “2701”
18 and inserting “231”;

19 (3) in section 465(f), by striking “2701” and
20 inserting “231”;

21 (4) in section 480(a)(2), by striking “2701”
22 and inserting “231”;

23 (5) in section 485(a)(2), by striking “2701”
24 and inserting “231”;

1 (6) in section 497, by striking “2701” and in-
2 serting “231”;

3 (7) in section 505(a)(2), by striking “2701”
4 and inserting “231”;

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

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

9 **SEC. 2006. CERTAIN AUTHORIZATION OF APPROPRIATIONS.**

10 Section 399L(a) of the Public Health Service Act (42
11 U.S.C. 280e-4(a)), as added by Public Law 102-515 (106
12 Stat. 3376), is amended—

13 (1) in the first sentence, by striking “the Sec-
14 retary” and all that follows and inserting the follow-
15 ing: “there are authorized to be appropriated
16 \$30,000,000 for fiscal year 1994, and such sums as
17 may be necessary for each of the fiscal years 1995
18 through 1997.”; and

19 (2) in the second sentence, by striking “Out of
20 any amounts used” and inserting “Of the amounts
21 appropriated under the preceding sentence”.

1 **SEC. 2007. PROHIBITION AGAINST SHARP ADULT SEX SUR-**
2 **VEY AND THE AMERICAN TEENAGE SEX SUR-**
3 **VEY.**

4 The Secretary of Health and Human Services may
5 not during fiscal year 1993 or any subsequent fiscal year
6 conduct or support the SHARP survey of adult sexual be-
7 havior or the American Teenage Study of adolescent sex-
8 ual behavior. This section becomes effective April 15,
9 1993.

10 **SEC. 2008. SUPPORT FOR BIOENGINEERING RESEARCH.**

11 (a) STUDY.—The Secretary of Health and Human
12 Services, acting through the Director of the National In-
13 stitutes of Health, shall conduct a study for the purpose
14 of—

15 (1) determining the sources and amounts of
16 public and private funding devoted to basic research
17 in bioengineering and biomaterials sciences;

18 (2) evaluating whether that commitment is suf-
19 ficient to maintain the innovative edge that the
20 United States has in these technologies; and

21 (3) evaluating the need to modify the structure
22 of the National Institutes of Health or any other
23 Federal agency to achieve a greater commitment to
24 innovation in bioengineering; and evaluating the
25 need for better coordination and collaboration among

1 Federal agencies and between the public and private
2 sectors.

3 In conducting such study, the Director shall work in con-
4 junction with appropriate organizations and representa-
5 tives including academics, industry leaders, bioengineering
6 societies, and public agencies (such as the National
7 Science Foundation, Veterans Administration, Depart-
8 ment of Defense, National Aeronautics and Space Admin-
9 istration, and the White House Office of Science and
10 Technology Policy).

11 (b) REPORT.—Not later than 1 year after the date
12 of enactment of this Act, the Secretary of Health and
13 Human Services shall prepare and submit to the Commit-
14 tee on Labor and Human Resources of the Senate, and
15 the Committee on Energy and Commerce of the House
16 of Representatives, a report containing the findings of the
17 study conducted under subsection (a) together with rec-
18 ommendations concerning the enactment of legislation to
19 implement the results of such study.

20 **TITLE XXI—EFFECTIVE DATES**

21 **SEC. 2101. EFFECTIVE DATES.**

22 Subject to section 155, this Act and the amendments
23 made by this Act take effect upon the date of the enact-
24 ment of this Act.

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) *SHORT TITLE.*—*This Act may be cited as the “Na-*
 3 *tional Institutes of Health Revitalization Act of 1993”.*

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

Sec. 1. Short title; table of contents.

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

Subtitle A—Research Freedom

*PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL
 RESEARCH*

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

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

Sec. 111. Establishment of authorities.

*Sec. 112. Purchase of human fetal tissue; solicitation or acceptance of tissue as
 directed donation for use in transplantation.*

Sec. 113. Report by General Accounting Office on adequacy of requirements.

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

Sec. 131. Requirement of inclusion in research.

Sec. 132. Peer review.

Sec. 133. Applicability to current projects.

PART II—OFFICE OF RESEARCH ON WOMEN’S HEALTH

Sec. 141. Establishment.

PART III—OFFICE OF RESEARCH ON MINORITY HEALTH

Sec. 151. Establishment.

Subtitle C—Scientific Integrity

Sec. 161. Establishment of Office of Scientific Integrity.

Sec. 162. Commission on Scientific Integrity.

Sec. 163. Protection of whistleblowers.

*Sec. 164. Requirement of regulations regarding protection against financial con-
 flicts of interest in certain projects of research.*

Sec. 165. Effective dates.

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

- Sec. 201. Health promotion research dissemination.*
Sec. 202. Programs for increased support regarding certain States and researchers.
Sec. 203. Children's vaccine initiative.
Sec. 204. Plan for use of animals in research.
Sec. 205. Increased participation of women and members of underrepresented minorities in fields of biomedical and behavioral research.
Sec. 206. Requirements regarding surveys of sexual behavior.
Sec. 207. Discretionary fund of Director of National Institutes of Health.
Sec. 208. Miscellaneous provisions.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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

TITLE IV—NATIONAL CANCER INSTITUTE

- Sec. 401. Expansion and intensification of activities regarding breast cancer.*
Sec. 402. Expansion and intensification of activities regarding prostate cancer.
Sec. 403. Authorization of appropriations.

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

- Sec. 501. Education and training.*
Sec. 502. Centers for the study of pediatric cardiovascular diseases.
Sec. 503. National Center on Sleep Disorders.
Sec. 504. Authorization of appropriations.

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

- Sec. 601. Provisions regarding nutritional disorders.*

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

- Sec. 701. Juvenile arthritis.*

TITLE VIII—NATIONAL INSTITUTE ON AGING

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

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

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

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

Subtitle B—Program Regarding Obstetrics and Gynecology

- Sec. 1011. Establishment of program.*

Subtitle C—Child Health Research Centers

- Sec. 1021. Establishment of centers.*

Subtitle D—Study Regarding Adolescent Health.

- Sec. 1031. Prospective longitudinal study.*

TITLE XI—NATIONAL EYE INSTITUTE

- Sec. 1101. Clinical research on diabetes eye care.*

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

- Sec. 1201. Research on multiple sclerosis.*

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

- Sec. 1301. Applied Toxicological Research and Testing Program.*

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

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

Subtitle B—Financial Assistance

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

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

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

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF HEALTH

Subtitle A—Division of Research Resources

- Sec. 1501. Redesignation of Division as National Center for Research Resources.*
Sec. 1502. Biomedical and behavioral research facilities.

Sec. 1503. Construction program for national primate research center.

Subtitle B—National Center for Nursing Research

Sec. 1511. Redesignation of National Center for Nursing Research as National Institute of Nursing Research.

Sec. 1512. Study on adequacy of number of nurses.

Subtitle C—National Center for Human Genome Research

Sec. 1521. Purpose of Center.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

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

Sec. 1602. Service payback requirements.

Subtitle B—Acquired Immune Deficiency Syndrome

Sec. 1611. Loan repayment program.

Subtitle C—Loan Repayment for Research Generally

Sec. 1621. Establishment of program.

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

Sec. 1631. Establishment of programs.

Sec. 1632. Funding.

Subtitle E—Funding for Awards and Training Generally

Sec. 1641. Authorization of appropriations.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

Sec. 1701. Establishment of Foundation.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

Sec. 1801. Revision and extension of various programs.

TITLE XIX—STUDIES

Sec. 1901. Acquired immune deficiency syndrome.

Sec. 1902. Malnutrition in the elderly.

Sec. 1903. Research activities on chronic fatigue syndrome.

Sec. 1904. Report on medical uses of biological agents in development of defenses against biological warfare.

Sec. 1905. Personnel study of recruitment, retention and turnover.

Sec. 1906. Procurement.

Sec. 1907. Report concerning leading causes of death.

Sec. 1908. Relationship between the consumption of legal and illegal drugs.

Sec. 1909. Cost of care in last 6 months of life.

TITLE XX—MISCELLANEOUS PROVISIONS

- Sec. 2001. Designation of Senior Biomedical Research Service in honor of Silvio Conte, and limitation on number of members.
- Sec. 2002. Technical corrections.
- Sec. 2003. Biennial report on carcinogens.
- Sec. 2004. Master plan for physical infrastructure for research.
- Sec. 2005. Transfer of provisions of title xxvii.
- Sec. 2006. Certain authorization of appropriations.
- Sec. 2007. Prohibition against SHARP adult sex survey and the American teenage sex survey.
- Sec. 2008. Support for bioengineering research.

TITLE XXI—EFFECTIVE DATES

- Sec. 2101. Effective dates.

1 **TITLE I—GENERAL PROVISIONS**
 2 **REGARDING TITLE IV OF PUB-**
 3 **LIC HEALTH SERVICE ACT**

4 **Subtitle A—Research Freedom**

5 **PART I—REVIEW OF PROPOSALS FOR**
 6 **BIOMEDICAL AND BEHAVIORAL RESEARCH**

7 **SEC. 101. ESTABLISHMENT OF CERTAIN PROVISIONS RE-**
 8 **GARDING RESEARCH CONDUCTED OR SUP-**
 9 **PORTED BY NATIONAL INSTITUTES OF**
 10 **HEALTH.**

11 *Part G of title IV of the Public Health Service Act*
 12 *(42 U.S.C. 289 et seq.) is amended by inserting after section*
 13 *492 the following new section:*

14 *“CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL*
 15 *OF PROPOSALS FOR RESEARCH*

16 *“SEC. 492A. (a) REVIEW AS PRECONDITION TO RE-*
 17 *SEARCH.—*

1 “(1) *PROTECTION OF HUMAN RESEARCH SUB-*
2 *JECTS.—*

3 “(A) *In the case of any application submit-*
4 *ted to the Secretary for financial assistance to*
5 *conduct research, the Secretary may not approve*
6 *or fund any application that is subject to review*
7 *under section 491(a) by an Institutional Review*
8 *Board unless the application has undergone re-*
9 *view in accordance with such section and has*
10 *been recommended for approval by a majority of*
11 *the members of the Board conducting such re-*
12 *view.*

13 “(B) *In the case of research that is subject*
14 *to review under procedures established by the*
15 *Secretary for the protection of human subjects in*
16 *clinical research conducted by the National In-*
17 *stitutes of Health, the Secretary may not author-*
18 *ize the conduct of the research unless the research*
19 *has, pursuant to such procedures, been rec-*
20 *ommended for approval.*

21 “(2) *PEER REVIEW.—In the case of any applica-*
22 *tion submitted to the Secretary for financial assist-*
23 *ance to conduct research, the Secretary may not ap-*
24 *prove or fund any application that is subject to tech-*
25 *nic and scientific peer review under section 492(a)*

1 *unless the application has undergone peer review in*
2 *accordance with such section and has been rec-*
3 *ommended for approval by a majority of the members*
4 *of the entity conducting such review.*

5 *“(b) ETHICAL REVIEW OF RESEARCH.—*

6 *“(1) PROCEDURES REGARDING WITHHOLDING OF*
7 *FUNDS.—If research has been recommended for ap-*
8 *proval for purposes of subsection (a), the Secretary*
9 *may not withhold funding for the research on ethical*
10 *grounds unless—*

11 *“(A) the Secretary convenes an advisory*
12 *board in accordance with paragraph (4) to study*
13 *the ethical implications of the research; and*

14 *“(B) the majority of the advisory board rec-*
15 *ommends that, on ethical grounds, the Secretary*
16 *withhold funds for the research.*

17 *“(2) APPLICABILITY.—The limitation established*
18 *in paragraph (1) regarding the authority to withhold*
19 *funds on ethical grounds shall apply without regard*
20 *to whether the withholding of funds is characterized*
21 *as a disapproval, a moratorium, a prohibition, or*
22 *other description.*

23 *“(3) PRELIMINARY MATTERS REGARDING USE OF*
24 *PROCEDURES.—*

1 “(A) If the Secretary makes a determina-
2 tion that an advisory board should be convened
3 for purposes of paragraph (1), the Secretary
4 shall, through a statement published in the Fed-
5 eral Register, announce the intention of the Sec-
6 retary to convene such a board.

7 “(B) A statement issued under subpara-
8 graph (A) shall include a request that interested
9 individuals submit to the Secretary recommenda-
10 tions specifying the particular individuals who
11 should be appointed to the advisory board in-
12 volved. The Secretary shall consider such rec-
13 ommendations in making appointments to the
14 board.

15 “(C) The Secretary may not make appoint-
16 ments to an advisory board under paragraph (1)
17 until the expiration of the 30-day period begin-
18 ning on the date on which the statement required
19 in subparagraph (A) is made with respect to the
20 board.

21 “(4) ETHICS ADVISORY BOARDS.—

22 “(A) Any advisory board convened for pur-
23 poses of paragraph (1) shall be known as an eth-
24 ics advisory board (hereafter in this paragraph
25 referred to as an ‘ethics board’).

1 “(B)(i) An ethics board shall advise, consult
2 with, and make recommendations to the Sec-
3 retary regarding the ethics of the project of bio-
4 medical or behavioral research with respect to
5 which the board has been convened.

6 “(ii) Not later than 180 days after the date
7 on which the statement required in paragraph
8 (3)(A) is made with respect to an ethics board,
9 the board shall submit to the Secretary, and to
10 the Committee on Energy and Commerce of the
11 House of Representatives and the Committee on
12 Labor and Human Resources of the Senate, a re-
13 port describing the findings of the board regard-
14 ing the project of research involved and making
15 a recommendation under clause (i) of whether
16 the Secretary should or should not withhold
17 funds for the project. The report shall include the
18 information considered in making the findings.

19 “(C) An ethics board shall be composed of
20 no fewer than 14, and no more than 20, individ-
21 uals who are not officers or employees of the
22 United States. The Secretary shall make ap-
23 pointments to the board from among individuals
24 with special qualifications and competence to
25 provide advice and recommendations regarding

1 *ethical matters in biomedical and behavioral re-*
2 *search. Of the members of the board—*

3 “(i) *no fewer than 1 shall be an attor-*
4 *ney;*

5 “(ii) *no fewer than 1 shall be an*
6 *ethicist;*

7 “(iii) *no fewer than 1 shall be a prac-*
8 *ticing physician;*

9 “(iv) *no fewer than 1 shall be a theolo-*
10 *gian; and*

11 “(v) *no fewer than one-third, and no*
12 *more than one-half, shall be scientists with*
13 *substantial accomplishments in biomedical*
14 *or behavioral research.*

15 “(D) *The term of service as a member of an*
16 *ethics board shall be for the life of the board. If*
17 *such a member does not serve the full term of*
18 *such service, the individual appointed to fill the*
19 *resulting vacancy shall be appointed for the re-*
20 *mainder of the term of the predecessor of the in-*
21 *dividual.*

22 “(E) *A member of an ethics board shall be*
23 *subject to removal from the board by the Sec-*
24 *retary for neglect of duty or malfeasance or for*
25 *other good cause shown.*

1 “(F) The Secretary shall designate an indi-
2 vidual from among the members of an ethics
3 board to serve as the chair of the board.

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

8 “(H) With respect to information relevant
9 to the duties described in subparagraph (B)(i),
10 an ethics board shall have access to all such in-
11 formation possessed by the Department of Health
12 and Human Services, or available to the Sec-
13 retary from other agencies.

14 “(I) Members of an ethics board shall re-
15 ceive compensation for each day engaged in car-
16 rying out the duties of the board, including time
17 engaged in traveling for purposes of such duties.
18 Such compensation may not be provided in an
19 amount in excess of the maximum rate of basic
20 pay payable for GS-18 of the General Schedule.

21 “(J) The Secretary, acting through the Di-
22 rector of the National Institutes of Health, shall
23 provide to each ethics board such staff and other
24 assistance as may be necessary to carry out the
25 duties of the board.

1 “(K) An ethics board shall terminate 30
2 days after the date on which the report required
3 in subparagraph (B)(ii) is submitted to the Sec-
4 retary and the congressional committees specified
5 in such subparagraph.”.

6 **PART II—RESEARCH ON TRANSPLANTATION OF**
7 **FETAL TISSUE**

8 **SEC. 111. ESTABLISHMENT OF AUTHORITIES.**

9 Part G of title IV of the Public Health Service Act
10 (42 U.S.C. 289 et seq.) is amended by inserting after section
11 498 the following new section:

12 “RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

13 “SEC. 498A. (a) ESTABLISHMENT OF PROGRAM.—

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

17 “(2) SOURCE OF TISSUE.—Human fetal tissue
18 may be used in research carried out under paragraph
19 (1) regardless of whether the tissue is obtained pursu-
20 ant to a spontaneous or induced abortion or pursuant
21 to a stillbirth.

22 “(b) INFORMED CONSENT OF DONOR.—

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

1 *ment, made in writing and signed by the woman, de-*
2 *claring that—*

3 “(A) *the woman donates the fetal tissue for*
4 *use in research described in subsection (a);*

5 “(B) *the donation is made without any re-*
6 *striction regarding the identity of individuals*
7 *who may be the recipients of transplantations of*
8 *the tissue; and*

9 “(C) *the woman has not been informed of*
10 *the identity of any such individuals.*

11 “(2) *ADDITIONAL STATEMENT.—In research car-*
12 *ried out under subsection (a), human fetal tissue may*
13 *be used only if the attending physician with respect*
14 *to obtaining the tissue from the woman involved*
15 *makes a statement, made in writing and signed by*
16 *the physician, declaring that—*

17 “(A) *in the case of tissue obtained pursuant*
18 *to an induced abortion—*

19 “(i) *the consent of the woman for the*
20 *abortion was obtained prior to requesting or*
21 *obtaining consent for the tissue to be used*
22 *in such research; and*

23 “(ii) *no alteration of the timing, meth-*
24 *od, or procedures used to terminate the*

1 *pregnancy was made solely for the purposes*
2 *of obtaining the tissue;*

3 “(B) *the tissue has been donated by the*
4 *woman in accordance with paragraph (1); and*

5 “(C) *full disclosure has been provided to the*
6 *woman with regard to—*

7 “(i) *such physician’s interest, if any,*
8 *in the research to be conducted with the tis-*
9 *sue; and*

10 “(ii) *any known medical risks to the*
11 *woman or risks to her privacy that might*
12 *be associated with the donation of the tissue*
13 *and that are in addition to risks of such*
14 *type that are associated with the woman’s*
15 *medical care.*

16 “(c) *INFORMED CONSENT OF RESEARCHER AND*
17 *DONEE.—In research carried out under subsection (a),*
18 *human fetal tissue may be used only if the individual with*
19 *the principal responsibility for conducting the research in-*
20 *volved makes a statement, made in writing and signed by*
21 *the individual, declaring that the individual—*

22 “(1) *is aware that—*

23 “(A) *the tissue is human fetal tissue;*

1 “(B) the tissue may have been obtained pur-
2 suant to a spontaneous or induced abortion or
3 subsequent to a stillbirth; and

4 “(C) the tissue was donated for research
5 purposes;

6 “(2) has provided such information to other in-
7 dividuals with responsibilities regarding the research;

8 “(3) will require, prior to obtaining the consent
9 of an individual to be a recipient of a transplan-
10 tation of the tissue, written acknowledgment of receipt
11 of such information by such recipient; and

12 “(4) has had no part in any decisions as to the
13 timing, method, or procedures used to terminate the
14 pregnancy made solely for the purposes of the re-
15 search.

16 “(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

17 “(1) IN GENERAL.—In research carried out
18 under subsection (a), human fetal tissue may be used
19 only if the head of the agency or other entity conduct-
20 ing the research involved certifies to the Secretary
21 that the statements required under subsections (a)(3),
22 (b)(2), and (c) will be available for audit by the Sec-
23 retary.

24 “(2) CONFIDENTIALITY OF AUDIT.—Any audit
25 conducted by the Secretary pursuant to paragraph (1)

1 *shall be conducted in a confidential manner to protect*
2 *the privacy rights of the individuals and entities in-*
3 *involved in such research, including such individuals*
4 *and entities involved in the donation, transfer, re-*
5 *ceipt, or transplantation of human fetal tissue. With*
6 *respect to any material or information obtained pur-*
7 *suant to such audit, the Secretary shall—*

8 *“(A) use such material or information only*
9 *for the purposes of verifying compliance with the*
10 *requirements of this section;*

11 *“(B) not disclose or publish such material*
12 *or information, except where required by Federal*
13 *law, in which case such material or information*
14 *shall be coded in a manner such that the identi-*
15 *ties of such individuals and entities are pro-*
16 *tected; and*

17 *“(C) not maintain such material or infor-*
18 *mation after completion of such audit, except*
19 *where necessary for the purposes of such audit.*

20 *“(e) APPLICABILITY OF STATE AND LOCAL LAW.—*

21 *“(1) RESEARCH CONDUCTED BY RECIPIENTS OF*
22 *ASSISTANCE.—The Secretary may not provide sup-*
23 *port for research under subsection (a) unless the ap-*
24 *plicant agrees to conduct the research in accordance*
25 *with applicable State and local law.*

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

5 “(f) *DEFINITION.*—*For purposes of this section, the*
 6 *term ‘human fetal tissue’ means tissue or cells obtained*
 7 *from a dead human embryo or fetus after a spontaneous*
 8 *or induced abortion, or after a stillbirth.’.*

9 ***SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITA-***
 10 ***TION OR ACCEPTANCE OF TISSUE AS DI-***
 11 ***RECTED DONATION FOR USE IN TRANSPLAN-***
 12 ***TATION.***

13 *Part G of title IV of the Public Health Service Act,*
 14 *as amended by section 111 of this Act, is amended by insert-*
 15 *ing after section 498A the following new section:*

16 “*PROHIBITIONS REGARDING HUMAN FETAL TISSUE*

17 “*SEC. 498B. (a) PURCHASE OF TISSUE.*—*It shall be*
 18 *unlawful for any person to knowingly acquire, receive, or*
 19 *otherwise transfer any human fetal tissue for valuable con-*
 20 *sideration if the transfer affects interstate commerce.*

21 “(b) *SOLICITATION OR ACCEPTANCE OF TISSUE AS DI-*
 22 *RECTED DONATION FOR USE IN TRANSPLANTATION.*—*It*
 23 *shall be unlawful for any person to solicit or knowingly*
 24 *acquire, receive, or accept a donation of human fetal tissue*
 25 *for the purpose of transplantation of such tissue into an-*
 26 *other person if the donation affects interstate commerce, the*

1 *tissue will be or is obtained pursuant to an induced abor-*
2 *tion, and—*

3 “(1) *the donation will be or is made pursuant to*
4 *a promise to the donating individual that the donated*
5 *tissue will be transplanted into a recipient specified*
6 *by such individual;*

7 “(2) *the donated tissue will be transplanted into*
8 *a relative of the donating individual; or*

9 “(3) *the person who solicits or knowingly ac-*
10 *quires, receives, or accepts the donation has provided*
11 *valuable consideration for the costs associated with*
12 *such abortion.*

13 “(c) *CRIMINAL PENALTIES FOR VIOLATIONS.—*

14 “(1) *IN GENERAL.—Any person who violates sub-*
15 *section (a) or (b) shall be fined in accordance with*
16 *title 18, United States Code, subject to paragraph (2),*
17 *or imprisoned for not more than 10 years, or both.*

18 “(2) *PENALTIES APPLICABLE TO PERSONS RE-*
19 *CEIVING CONSIDERATION.—With respect to the impo-*
20 *sition of a fine under paragraph (1), if the person in-*
21 *volved violates subsection (a) or (b)(3), a fine shall be*
22 *imposed in an amount not less than twice the amount*
23 *of the valuable consideration received.*

24 “(d) *DEFINITIONS.—For purposes of this section:*

1 “(1) The term ‘human fetal tissue’ has the mean-
2 ing given such term in section 498A(e).

3 “(2) The term ‘interstate commerce’ has the
4 meaning given such term in section 201(b) of the Fed-
5 eral Food, Drug, and Cosmetic Act.

6 “(3) The term ‘valuable consideration’ does not
7 include reasonable payments associated with the
8 transportation, implantation, processing, preserva-
9 tion, quality control, or storage of human fetal tis-
10 sue.”

11 **SEC. 113. REPORT BY GENERAL ACCOUNTING OFFICE ON**
12 **ADEQUACY OF REQUIREMENTS.**

13 (a) *IN GENERAL.*—With respect to research on the
14 transplantation of human fetal tissue for therapeutic pur-
15 poses, the Comptroller General of the United States shall
16 conduct an audit for the purpose of determining—

17 (1) whether and to what extent such research
18 conducted or supported by the Secretary of Health
19 and Human Services has been conducted in accord-
20 ance with section 498A of the Public Health Service
21 Act (as added by section 111 of this Act); and

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

1 (b) *REPORT.*—Not later than May 19, 1995, the Comp-
2 troller General of the United States shall complete the audit
3 required in subsection (a) and submit to the Committee on
4 Energy and Commerce of the House of Representatives, and
5 to the Committee on Labor and Human Resources of the
6 Senate, a report describing the findings made pursuant to
7 the audit.

8 **PART III—MISCELLANEOUS REPEALS**

9 **SEC. 121. REPEALS.**

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

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

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

16 (2) by striking section 499; and

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

18 (c) *NULLIFICATION OF CERTAIN REGULATION.*—The
19 provisions of section 204(d) of part 46 of title 45 of the
20 Code of Federal Regulations (45 CFR 46.204(d)) shall not
21 have any legal effect.

1 ***Subtitle B—Clinical Research Eq-***
2 ***uity Regarding Women and Mi-***
3 ***norities***

4 ***PART I—WOMEN AND MINORITIES AS SUBJECTS***
5 ***IN CLINICAL RESEARCH***

6 ***SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.***

7 *Part G of title IV of the Public Health Service Act,*
8 *as amended by section 101 of this Act, is amended by insert-*
9 *ing after section 492A the following new section:*

10 *“INCLUSION OF WOMEN AND MINORITIES IN CLINICAL*
11 *RESEARCH*

12 *“SEC. 492B. (a) In conducting or supporting clinical*
13 *research for purposes of this title, the Director of NIH shall,*
14 *subject to subsection (b), ensure that—*

15 *“(1) women are included as subjects in each*
16 *project of such research; and*

17 *“(2) members of minority groups are included as*
18 *subjects in such research.*

19 *“(b) The requirement established in subsection (a) re-*
20 *garding women and members of minority groups shall not*
21 *apply to a project of clinical research if the inclusion, as*
22 *subjects in the project, of women and members of minority*
23 *groups, respectively—*

24 *“(1) is inappropriate with respect to the health*
25 *of the subjects;*

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

3 “(3) is inappropriate under such other cir-
4 cumstances as the Director of NIH may designate.

5 “(c) In the case of any project of clinical research in
6 which women or members of minority groups will under
7 subsection (a) be included as subjects in the research, the
8 Director of NIH shall ensure that the project is designed
9 and carried out in a manner sufficient to provide for a
10 valid analysis of whether the variables being tested in the
11 research affect women or members of minority groups, as
12 the case may be, differently than other subjects in the re-
13 search.

14 “(d)(1) The Director of NIH, in consultation with the
15 Director of the Office of Research on Women’s Health, shall
16 establish guidelines regarding—

17 “(A) the circumstances under which the inclu-
18 sion of women and minorities in projects of clinical
19 research is inappropriate for purposes of subsection
20 (b);

21 “(B) the manner in which such projects are re-
22 quired to be designed and carried out for purposes of
23 subsection (c), including a specification of the cir-
24 cumstances in which the requirement of such sub-

1 *section does not apply on the basis of impracticabil-*
2 *ity; and*

3 *“(C) the conduct of outreach programs for the re-*
4 *ruitment of women and members of minority groups*
5 *as subjects in such research.*

6 *“(2) The guidelines established under paragraph (1)—*

7 *“(A) may not provide that the cost of including*
8 *women and minorities in clinical research are a per-*
9 *missible consideration regarding the circumstances*
10 *described in subparagraph (A) of such paragraph;*
11 *and*

12 *“(B) may provide that such circumstances in-*
13 *clude circumstances in which there are scientific rea-*
14 *sons for believing that the variables proposed to be*
15 *studied do not affect women or minorities differently*
16 *than other subjects in the research.*

17 *“(3) The guidelines required in paragraph (1) shall*
18 *be established and published in the Federal Register not*
19 *later than 120 days after the date of the enactment of the*
20 *National Institutes of Health Revitalization Act of 1993.*

21 *“(4) For fiscal year 1994 and subsequent fiscal years,*
22 *the Director of NIH may not approve any proposal of clini-*
23 *cal research to be conducted or supported by any agency*
24 *of the National Institutes of Health unless the proposal*

1 *specifies the manner in which the research will comply with*
2 *subsection (a).*

3 *“(e) The advisory council of each national research in-*
4 *stitute shall annually submit to the Director of NIH and*
5 *the Director of the institute involved a report describing the*
6 *manner in which the agency has complied with subsection*
7 *(a).”.*

8 **SEC. 132. PEER REVIEW.**

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

12 *“(c)(1) In technical and scientific peer review under*
13 *this section of proposals for clinical research, the consider-*
14 *ation of any such proposal (including the initial consider-*
15 *ation) shall, except as provided in paragraph (2), include*
16 *an evaluation of the technical and scientific merit of the*
17 *proposal regarding compliance with section 492B(a).*

18 *“(2) Paragraph (1) shall not apply to any proposal*
19 *for clinical research that, pursuant to subsection (b) of sec-*
20 *tion 492B, is not subject to the requirement of subsection*
21 *(a) of such section regarding the inclusion of women and*
22 *members of minority groups as subjects in clinical re-*
23 *search.”.*

1 “PART F—RESEARCH ON WOMEN’S HEALTH

2 **“SEC. 486. OFFICE OF RESEARCH ON WOMEN’S HEALTH.**

3 “(a) *ESTABLISHMENT.*—There is established within
4 the Office of the Director of NIH an office to be known as
5 the Office of Research on Women’s Health (in this part re-
6 ferred to as the ‘Office’). The Office shall be headed by a
7 director, who shall be appointed by the Director of NIH.

8 “(b) *PURPOSE.*—The Director of the Office shall—

9 “(1) identify projects of research on women’s
10 health that should be conducted or supported by the
11 national research institutes;

12 “(2) identify multidisciplinary research relating
13 to research on women’s health that should be so con-
14 ducted or supported;

15 “(3) carry out paragraphs (1) and (2) with re-
16 spect to the aging process in women, with priority
17 given to menopause;

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

21 “(5) encourage the conduct of such research by
22 entities receiving funds from the national research in-
23 stitutes;

24 “(6) recommend an agenda for conducting and
25 supporting such research;

1 “(7) promote the sufficient allocation of the re-
2 sources of the national research institutes for conduct-
3 ing and supporting such research;

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

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

8 “(c) COORDINATING COMMITTEE.—

9 “(1) In carrying out subsection (b), the Director
10 of the Office shall establish a committee to be known
11 as the Coordinating Committee on Research on Wom-
12 en’s Health (hereafter in this subsection referred to as
13 the ‘Coordinating Committee’).

14 “(2) The Coordinating Committee shall be com-
15 posed of the Directors of the national research insti-
16 tutes (or the designees of the Directors).

17 “(3) The Director of the Office shall serve as the
18 chair of the Coordinating Committee.

19 “(4) With respect to research on women’s health,
20 the Coordinating Committee shall assist the Director
21 of the Office in—

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

1 “(B) identifying needs regarding the coordi-
2 nation of research activities, including intra-
3 mural and extramural multidisciplinary activi-
4 ties;

5 “(C) supporting the development of meth-
6 odologies to determine the circumstances in
7 which obtaining data specific to women (includ-
8 ing data relating to the age of women and the
9 membership of women in ethnic or racial
10 groups) is an appropriate function of clinical
11 trials of treatments and therapies;

12 “(D) supporting the development and ex-
13 pansion of clinical trials of treatments and
14 therapies for which obtaining such data has been
15 determined to be an appropriate function; and

16 “(E) encouraging the national research in-
17 stitutes to conduct and support such research, in-
18 cluding such clinical trials.

19 “(d) ADVISORY COMMITTEE.—

20 “(1) In carrying out subsection (b), the Director
21 of the Office shall establish an advisory committee to
22 be known as the Advisory Committee on Research on
23 Women’s Health (hereafter in this subsection referred
24 to as the ‘Advisory Committee’).

1 “(2)(A) *The Advisory Committee shall be com-*
2 *posed of no fewer than 12, and not more than 18 in-*
3 *dividuals, who are not officers or employees of the*
4 *Federal Government. The Director of the Office shall*
5 *make appointments to the Advisory Committee from*
6 *among physicians, practitioners, scientists, and other*
7 *health professionals, whose clinical practice, research*
8 *specialization, or professional expertise includes a sig-*
9 *nificant focus on research on women’s health. A ma-*
10 *jority of the members of the Advisory Committee shall*
11 *be women.*

12 “(B) *Members of the Advisory Committee shall*
13 *receive compensation for each day engaged in carry-*
14 *ing out the duties of the Committee, including time*
15 *engaged in traveling for purposes of such duties. Such*
16 *compensation may not be provided in an amount in*
17 *excess of the maximum rate of basic pay payable for*
18 *GS-18 of the General Schedule.*

19 “(3) *The Director of the Office shall serve as the*
20 *chair of the Advisory Committee.*

21 “(4) *The Advisory Committee shall—*

22 “(A) *advise the Director of the Office on ap-*
23 *propriate research activities to be undertaken by*
24 *the national research institutes with respect to—*

25 “(i) *research on women’s health;*

1 “(ii) research on gender differences in
2 clinical drug trials, including responses to
3 pharmacological drugs;

4 “(iii) research on gender differences in
5 disease etiology, course, and treatment;

6 “(iv) research on obstetrical and gyne-
7 cological health conditions, diseases, and
8 treatments; and

9 “(v) research on women’s health condi-
10 tions which require a multidisciplinary ap-
11 proach;

12 “(B) report to the Director of the Office on
13 such research;

14 “(C) provide recommendations to such Di-
15 rector regarding activities of the Office (includ-
16 ing recommendations on the development of the
17 methodologies described in subsection (c)(4)(C)
18 and recommendations on priorities in carrying
19 out research described in subparagraph (A)); and

20 “(D) assist in monitoring compliance with
21 section 492B regarding the inclusion of women
22 in clinical research.

23 “(5)(A) The Advisory Committee shall prepare a
24 biennial report describing the activities of the Com-

1 *mittee, including findings made by the Committee re-*
2 *garding—*

3 *“(i) compliance with section 492B;*

4 *“(ii) the extent of expenditures made for re-*
5 *search on women’s health by the agencies of the*
6 *National Institutes of Health; and*

7 *“(iii) the level of funding needed for such*
8 *research.*

9 *“(B) The report required in subparagraph (A)*
10 *shall be submitted to the Director of NIH for inclu-*
11 *sion in the report required in section 403.*

12 *“(e) REPRESENTATION OF WOMEN AMONG RESEARCH-*
13 *ERS.—The Secretary, acting through the Assistant Sec-*
14 *retary for Personnel and in collaboration with the Director*
15 *of the Office, shall determine the extent to which women*
16 *are represented among senior physicians and scientists of*
17 *the national research institutes and among physicians and*
18 *scientists conducting research with funds provided by such*
19 *institutes, and as appropriate, carry out activities to in-*
20 *crease the extent of such representation.*

21 *“(f) DEFINITIONS.—For purposes of this part:*

22 *“(1) The term ‘women’s health conditions’, with*
23 *respect to women of all age, ethnic, and racial groups,*
24 *means all diseases, disorders, and conditions (includ-*
25 *ing with respect to mental health)—*

1 “(A) unique to, more serious, or more prev-
2 alent in women;

3 “(B) for which the factors of medical risk or
4 types of medical intervention are different for
5 women, or for which it is unknown whether such
6 factors or types are different for women; or

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

10 “(2) The term ‘research on women’s health’
11 means research on women’s health conditions, includ-
12 ing research on preventing such conditions.

13 **“SEC. 486A. NATIONAL DATA SYSTEM AND CLEARING-**
14 **HOUSE ON RESEARCH ON WOMEN’S HEALTH.**

15 “(a) DATA SYSTEM.—

16 “(1) The Director of NIH, in consultation with
17 the Director of the Office, shall establish a data sys-
18 tem for the collection, storage, analysis, retrieval, and
19 dissemination of information regarding research on
20 women’s health that is conducted or supported by the
21 national research institutes. Information from the
22 data system shall be available through information
23 systems available to health care professionals and
24 providers, researchers, and members of the public.

1 “(2) *The data system established under para-*
2 *graph (1) shall include a registry of clinical trials of*
3 *experimental treatments that have been developed for*
4 *research on women’s health. Such registry shall in-*
5 *clude information on subject eligibility criteria, sex,*
6 *age, ethnicity or race, and the location of the trial site*
7 *or sites. Principal investigators of such clinical trials*
8 *shall provide this information to the registry within*
9 *30 days after it is available. Once a trial has been*
10 *completed, the principal investigator shall provide the*
11 *registry with information pertaining to the results,*
12 *including potential toxicities or adverse effects associ-*
13 *ated with the experimental treatment or treatments*
14 *evaluated.*

15 “(b) *CLEARINGHOUSE.*—*The Director of NIH, in con-*
16 *sultation with the Director of the Office and with the Na-*
17 *tional Library of Medicine, shall establish, maintain, and*
18 *operate a program to provide information on research and*
19 *prevention activities of the national research institutes that*
20 *relate to research on women’s health.*

21 “**SEC. 486B. BIENNIAL REPORT.**

22 “(a) *IN GENERAL.*—*With respect to research on wom-*
23 *en’s health, the Director of the Office shall, not later than*
24 *February 1, 1994, and biennially thereafter, prepare a re-*
25 *port—*

1 “(1) describing and evaluating the progress made
2 during the preceding 2 fiscal years in research and
3 treatment conducted or supported by the National In-
4 stitutes of Health;

5 “(2) describing and analyzing the professional
6 status of women physicians and scientists of such In-
7 stitutes, including the identification of problems and
8 barriers regarding advancements;

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

12 “(4) making such recommendations for legisla-
13 tive and administrative initiatives as the Director of
14 the Office determines to be appropriate.

15 “(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR
16 OF NIH.—The Director of the Office shall submit each re-
17 port prepared under subsection (a) to the Director of NIH
18 for inclusion in the report submitted to the President and
19 the Congress under section 403.”.

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

23 (1) in paragraph (10), by striking “and” after
24 the semicolon at the end;

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

3 (3) by inserting after paragraph (11) the follow-
4 ing new paragraph:

5 “(12) after consultation with the Director of the
6 Office of Research on Women’s Health, shall ensure
7 that resources of the National Institutes of Health are
8 sufficiently allocated for projects of research on wom-
9 en’s health that are identified under section 486(b).”.

10 **PART III—OFFICE OF RESEARCH ON MINORITY**

11 **HEALTH**

12 **SEC. 151. ESTABLISHMENT.**

13 Part A of title IV of the Public Health Service Act
14 (42 U.S.C. 281 et seq.) is amended by adding at the end
15 the following new section:

16 “OFFICE OF RESEARCH ON MINORITY HEALTH

17 “SEC. 403A. (a) ESTABLISHMENT.—There is estab-
18 lished within the Office of the Director of NIH an office
19 to be known as the Office of Research on Minority Health
20 (in this section referred to as the ‘Office’). The Office shall
21 be headed by a director, who shall be appointed by the Di-
22 rector of NIH.

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

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

1 “(2) identify multidisciplinary research relating
2 to research on minority health that should be so con-
3 ducted or supported;

4 “(3) promote coordination and collaboration
5 among entities conducting research identified under
6 paragraph (1) or (2);

7 “(4) encourage the conduct of such research by
8 entities receiving funds from the national research in-
9 stitutes;

10 “(5) recommend an agenda for conducting and
11 supporting such research;

12 “(6) promote the sufficient allocation of the re-
13 sources of the national research institutes for conduct-
14 ing and supporting such research; and

15 “(7) assist in the administration of section 492B
16 with respect to the inclusion of members of minority
17 groups as subjects in clinical research.”.

18 ***Subtitle C—Scientific Integrity***

19 ***SEC. 161. ESTABLISHMENT OF OFFICE OF SCIENTIFIC IN-***
20 ***TEGRITY.***

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

23 “OFFICE OF SCIENTIFIC INTEGRITY

24 “SEC. 493. (a) *ESTABLISHMENT.*—

25 “(1) *IN GENERAL.*—Not later than 90 days after
26 the date of enactment of this section, the Secretary

1 *shall establish an office to be known as the Office of*
2 *Scientific Integrity (hereafter referred to in this sec-*
3 *tion as the ‘Office’), which shall be established as an*
4 *independent entity in the Department of Health and*
5 *Human Services.*

6 “(2) *DIRECTOR.*—*The Office shall be headed by*
7 *a Director, who shall be appointed by the Secretary,*
8 *be experienced and specially trained in the conduct of*
9 *research, and have experience in the conduct of inves-*
10 *tigations of scientific misconduct. The Secretary shall*
11 *carry out this section acting through the Director of*
12 *the Office. The Director shall report to the Secretary.*

13 “(b) *EXISTENCE OF ADMINISTRATIVE PROCESSES AS*
14 *CONDITION OF FUNDING FOR RESEARCH.*—*The Secretary*
15 *shall by regulation require that each entity that applies for*
16 *a grant, contract, or cooperative agreement under this Act*
17 *for any project or program that involves the conduct of bio-*
18 *medical or behavioral research submit in or with its appli-*
19 *cation for such grant, contract, or cooperative agreement*
20 *assurances satisfactory to the Secretary that such entity—*

21 “(1) *has established (in accordance with regula-*
22 *tions which the Secretary shall prescribe) an adminis-*
23 *trative process to review reports of scientific mis-*
24 *conduct in connection with biomedical and behavioral*

1 *research conducted at or sponsored by such entity;*
2 *and*

3 “(2) *will report to the Director any investigation*
4 *of alleged scientific misconduct in connection with*
5 *projects for which funds have been made available*
6 *under this Act that appears substantial.*

7 “(c) *PROCESS FOR RESPONSE OF DIRECTOR.—The*
8 *Secretary shall establish by regulation a process to be fol-*
9 *lowed by the Director for the prompt and appropriate—*

10 “(1) *response to information provided to the Di-*
11 *rector respecting scientific misconduct in connection*
12 *with projects for which funds have been made avail-*
13 *able under this Act;*

14 “(2) *receipt of reports by the Director of such in-*
15 *formation from recipients of funds under this Act;*

16 “(3) *conduct of investigations, when appropriate;*
17 *and*

18 “(4) *taking of other actions, including appro-*
19 *priate remedies, with respect to such misconduct.*

20 “(d) *MONITORING BY DIRECTOR.—The Secretary shall*
21 *by regulation establish procedures for the Director to mon-*
22 *itor administrative processes and investigations that have*
23 *been established or carried out under this section.*

24 “(e) *EFFECT ON PRESENT INVESTIGATIONS.—Nothing*
25 *in this section shall affect investigations which have been*

1 *or will be commenced prior to the promulgation of final*
2 *regulations under this section.”.*

3 (b) *ESTABLISHMENT OF DEFINITION OF SCIENTIFIC*
4 *MISCONDUCT.—Not later than 90 days after the date on*
5 *which the report required under section 152(d) is submitted*
6 *to the Secretary of Health and Human Services, such Sec-*
7 *retary shall by regulation establish a definition for the term*
8 *“scientific misconduct” for purposes of section 493 of the*
9 *Public Health Service Act, as amended by subsection (a)*
10 *of this section.*

11 ***SEC. 162. COMMISSION ON SCIENTIFIC INTEGRITY.***

12 (a) *IN GENERAL.—The Secretary of Health and*
13 *Human Services shall establish a commission to be known*
14 *as the Commission on Scientific Integrity (in this section*
15 *referred to as the “Commission”).*

16 (b) *DUTIES.—The Commission shall develop rec-*
17 *ommendations for the Secretary of Health and Human*
18 *Services on the administration of section 493 of the Public*
19 *Health Service Act (as amended and added by section 161*
20 *of this Act).*

21 (c) *COMPOSITION.—The Commission shall be composed*
22 *of 12 members to be appointed by the Secretary of Health*
23 *and Human Services from among individuals who are not*
24 *officers or employees of the United States. Of the members*
25 *appointed to the Commission—*

1 (1) *three shall be scientists with substantial ac-*
2 *complishments in biomedical or behavioral research;*

3 (2) *three shall be individuals with experience in*
4 *investigating allegations of misconduct with respect to*
5 *scientific research;*

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

9 (4) *three shall be individuals who are not de-*
10 *scribed in paragraphs (1), (2), or (3), at least one of*
11 *whom shall be an attorney and at least one of whom*
12 *shall be an ethicist.*

13 (d) *COMPENSATION.—Members of the Commission*
14 *shall receive compensation for each day engaged in carrying*
15 *out the duties of the Commission, including time engaged*
16 *in traveling for purposes of such duties. Such compensation*
17 *may not be provided in an amount in excess of the maxi-*
18 *mum rate of basic pay payable for GS-18 of the General*
19 *Schedule.*

20 (e) *REPORT.—Not later than 120 days after the date*
21 *of enactment of this section, the Commission shall prepare*
22 *and submit to the Secretary of Health and Human Services,*
23 *the Committee on Energy and Commerce of the House of*
24 *Representatives, and the Committee on Labor and Human*

1 *Resources of the Senate, a report containing the rec-*
2 *ommendations developed under subsection (b).*

3 **SEC. 163. PROTECTION OF WHISTLEBLOWERS.**

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

7 *“(f) PROTECTION OF WHISTLEBLOWERS.—*

8 *“(1) IN GENERAL.—In the case of any entity re-*
9 *quired to establish administrative processes under*
10 *subsection (b), the Secretary shall by regulation estab-*
11 *lish standards for preventing, and for responding to*
12 *the occurrence of retaliation by such entity, its offi-*
13 *cial or agents, against an employee in the terms and*
14 *conditions of employment in response to the employee*
15 *having in good faith—*

16 *“(A) made an allegation that the entity, its*
17 *officials or agents, has engaged in or failed to*
18 *adequately respond to an allegation of scientific*
19 *misconduct; or*

20 *“(B) cooperated with an investigation of*
21 *such an allegation.*

22 *“(2) MONITORING BY SECRETARY.—The Sec-*
23 *retary shall establish by regulation procedures for the*
24 *Director to monitor the implementation of the stand-*
25 *ards established by an entity under paragraph (1) for*

1 *the purpose of determining whether the procedures*
2 *have been established, and are being utilized, in ac-*
3 *cordance with the standards established under such*
4 *paragraph.*

5 “(3) *NONCOMPLIANCE.*—*The Secretary shall by*
6 *regulation establish remedies for noncompliance by an*
7 *entity, its officials or agents, which has engaged in re-*
8 *taliation in violation of the standards established*
9 *under paragraph (1). Such remedies may include ter-*
10 *mination of funding provided by the Secretary for*
11 *such project or recovery of funding being provided by*
12 *the Secretary for such project, or other actions as ap-*
13 *propriate.*

14 “(4) *FINAL RULE FOR REGULATIONS.*—*The Sec-*
15 *retary shall issue a final rule for the regulations re-*
16 *quired in paragraph (1) not later than 180 days after*
17 *the date of the enactment of the National Institutes of*
18 *Health Revitalization Act of 1993.*

19 “(5) *REQUIRED AGREEMENTS.*—*For any fiscal*
20 *year beginning after the date on which the regulations*
21 *required in paragraph (1) are issued, the Secretary*
22 *may not provide a grant, cooperative agreement, or*
23 *contract under this Act for biomedical or behavioral*
24 *research unless the entity seeking such financial as-*
25 *sistance agrees that the entity—*

1 “(A) will maintain the procedures described
2 in the regulations; and

3 “(B) will otherwise be subject to the regula-
4 tions.”.

5 **SEC. 164. REQUIREMENT OF REGULATIONS REGARDING**
6 **PROTECTION AGAINST FINANCIAL CON-**
7 **FLICTS OF INTEREST IN CERTAIN PROJECTS**
8 **OF RESEARCH.**

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

12 “PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST
13 IN CERTAIN PROJECTS OF RESEARCH

14 “SEC. 493A. (a) ISSUANCE OF REGULATIONS.—

15 “(1) IN GENERAL.—The Secretary shall define by
16 regulation, the specific circumstances that constitute
17 the existence of a financial interest in a project on the
18 part of an entity or individual that will, or may be
19 reasonably expected to, create a bias in favor of ob-
20 taining results in such project that are consistent
21 with such financial interest. Such definition shall
22 apply uniformly to each entity or individual conduct-
23 ing a research project under this Act. In the case of
24 any entity or individual receiving assistance from the
25 Secretary for a project of research described in para-
26 graph (2), the Secretary shall by regulation establish

1 *standards for responding to, including managing, re-*
2 *ducing, or eliminating, the existence of such a finan-*
3 *cial interest. The entity may adopt individualized*
4 *procedures for implementing the standards.*

5 “(2) *RELEVANT PROJECTS.*—A project of re-
6 *search referred to in paragraph (1) is a project of*
7 *clinical research whose purpose is to evaluate the safe-*
8 *ty or effectiveness of a drug, medical device, or treat-*
9 *ment and for which such entity is receiving assistance*
10 *from the Secretary.*

11 “(3) *IDENTIFYING AND REPORTING TO THE DI-*
12 *RECTOR.*—The Secretary shall ensure that the stand-
13 *ards established under paragraph (1) specify that as*
14 *a condition of receiving assistance from the Secretary*
15 *for the project involved, an entity described in such*
16 *subsection is required—*

17 “(A) *to have in effect at the time the entity*
18 *applies for the assistance and throughout the pe-*
19 *riod during which the assistance is received, a*
20 *process for identifying such financial interests as*
21 *defined in paragraph (1) that exist regarding the*
22 *project; and*

23 “(B) *to report to the Director such financial*
24 *interest as defined in paragraph (1) identified*
25 *by the entity and how any such financial inter-*

1 *est identified by the entity will be managed or*
2 *eliminated such that the project in question will*
3 *be protected from bias that may stem from such*
4 *financial interest.*

5 “(4) *MONITORING OF PROCESS.*—*The Secretary*
6 *shall monitor the establishment and conduct of the*
7 *process established by an entity pursuant to para-*
8 *graph (1).*

9 “(5) *RESPONSE.*—*In any case in which the Sec-*
10 *retary determines that an entity has failed to comply*
11 *with paragraph (3) regarding a project of research*
12 *described in paragraph (1), the Secretary—*

13 “(A) *shall require that, as a condition of re-*
14 *ceiving assistance, the entity disclose the exist-*
15 *ence of a financial interest as defined in para-*
16 *graph (1) in each public presentation of the re-*
17 *sults of such project; and*

18 “(B) *may take such other actions as the*
19 *Secretary determines to be appropriate.*

20 “(6) *DEFINITION.*—*As used in this section:*

21 “(A) *The term ‘financial interest’ includes*
22 *the receipt of consulting fees or honoraria and*
23 *the ownership of stock or equity.*

1 “(B) The term ‘assistance’, with respect to
2 conducting a project of research, means a grant,
3 contract, or cooperative agreement.

4 “(b) FINAL RULE FOR REGULATIONS.—The Secretary
5 shall issue a final rule for the regulations required in sub-
6 section (a) not later than 180 days after the date of the
7 enactment of the National Institutes of Health Revitaliza-
8 tion Act of 1993.”.

9 **SEC. 165. EFFECTIVE DATES.**

10 (a) IN GENERAL.—The amendments made by this sub-
11 title shall become effective on the date that occurs 180 days
12 after the date on which the final rule required under section
13 493(f)(4) of the Public Health Service Act, as amended by
14 sections 161 and 163, is published in the Federal Register.

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

1 **TITLE II—NATIONAL INSTITUTES**
2 **OF HEALTH IN GENERAL**

3 **SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINA-**
4 **TION.**

5 *Section 402(f) of the Public Health Service Act (42*
6 *U.S.C. 282(f)) is amended by striking “other public and*
7 *private entities.” and all that follows through the end and*
8 *inserting “other public and private entities, including ele-*
9 *mentary, secondary, and post-secondary schools. The Asso-*
10 *ciate Director shall—*

11 *“(1) annually review the efficacy of existing poli-*
12 *cies and techniques used by the national research in-*
13 *stitutes to disseminate the results of disease preven-*
14 *tion and behavioral research programs;*

15 *“(2) recommend, coordinate, and oversee the*
16 *modification or reconstruction of such policies and*
17 *techniques to ensure maximum dissemination, using*
18 *advanced technologies to the maximum extent prac-*
19 *ticable, of research results to such entities; and*

20 *“(3) annually prepare and submit to the Direc-*
21 *tor of NIH a report concerning the prevention and*
22 *dissemination activities undertaken by the Associate*
23 *Director, including—*

24 *“(A) a summary of the Associate Director’s*
25 *review of existing dissemination policies and*

1 *techniques together with a detailed statement*
2 *concerning any modification or restructuring, or*
3 *recommendations for modification or restructur-*
4 *ing, of such policies and techniques; and*

5 *“(B) a detailed statement of the expendi-*
6 *tures made for the prevention and dissemination*
7 *activities reported on and the personnel used in*
8 *connection with such activities.”.*

9 **SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARD-**
10 **ING CERTAIN STATES AND RESEARCHERS.**

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

14 *“(g)(1)(A) In the case of entities described in subpara-*
15 *graph (B), the Director of NIH, acting through the Director*
16 *of the National Center for Research Resources, shall estab-*
17 *lish a program to enhance the competitiveness of such enti-*
18 *ties in obtaining funds from the national research institutes*
19 *for conducting biomedical and behavioral research.*

20 *“(B) The entities referred to in subparagraph (A) are*
21 *entities that conduct biomedical and behavioral research*
22 *and are located in a State in which the aggregate success*
23 *rate for applications to the national research institutes for*
24 *assistance for such research by the entities in the State has*
25 *historically constituted a low success rate of obtaining such*

1 *funds, relative to such aggregate rate for such entities in*
2 *other States.*

3 “(C) *With respect to enhancing competitiveness for*
4 *purposes of subparagraph (A), the Director of NIH, in car-*
5 *rying out the program established under such subpara-*
6 *graph, may—*

7 “(i) *provide technical assistance to the entities*
8 *involved, including technical assistance in the prepa-*
9 *ration of applications for obtaining funds from the*
10 *national research institutes;*

11 “(ii) *assist the entities in developing a plan for*
12 *biomedical or behavioral research proposals; and*

13 “(iii) *assist the entities in implementing such*
14 *plan.*

15 “(2) *The Director of NIH shall establish a program*
16 *of supporting projects of biomedical or behavioral research*
17 *whose principal researchers are individuals who have not*
18 *previously served as the principal researchers of such*
19 *projects supported by the Director.”.*

20 **SEC. 203. CHILDREN'S VACCINE INITIATIVE.**

21 *Part A of title IV of the Public Health Service Act*
22 *(42 U.S.C. 281 et seq.) is amended by adding at the end*
23 *the following new section:*

24 “CHILDREN'S VACCINE INITIATIVE

25 “SEC. 404. (a) *DEVELOPMENT OF NEW VACCINES.—*
26 *The Secretary, in consultation with the Director of the Na-*

1 *tional Vaccine Program under title XXI and acting through*
2 *the Directors of the National Institute for Allergy and Infec-*
3 *tious Diseases, the National Institute for Child Health and*
4 *Human Development, the National Institute for Aging, and*
5 *other public and private programs, shall carry out activi-*
6 *ties, which shall be consistent with the global Children’s*
7 *Vaccine Initiative, to develop affordable new and improved*
8 *vaccines to be used in the United States and in the develop-*
9 *ing world that will increase the efficacy and efficiency of*
10 *the prevention of infectious diseases. In carrying out such*
11 *activities, the Secretary shall, to the extent practicable, de-*
12 *velop and make available vaccines that require fewer con-*
13 *tacts to deliver, that can be given early in life, that provide*
14 *long lasting protection, that obviate refrigeration, needles*
15 *and syringes, and that protect against a larger number of*
16 *diseases.*

17 “(b) *REPORT.—In the report required in section 2104,*
18 *the Secretary, acting through the Director of the National*
19 *Vaccine Program under title XXI, shall include information*
20 *with respect to activities and the progress made in imple-*
21 *menting the provisions of this section and achieving its*
22 *goals.*

23 “(c) *AUTHORIZATION OF APPROPRIATIONS.—In addi-*
24 *tion to any other amounts authorized to be appropriated*
25 *for activities of the type described in this section, there are*

1 *authorized to be appropriated to carry out this section*
2 *\$20,000,000 for fiscal year 1994, and such sums as may*
3 *be necessary for each of the fiscal years 1995 and 1996.”.*

4 **SEC. 204. PLAN FOR USE OF ANIMALS IN RESEARCH.**

5 *(a) IN GENERAL.—Part A of title IV of the Public*
6 *Health Service Act, as amended by section 203 of this Act,*
7 *is amended by adding at the end the following new section:*

8 *“PLAN FOR USE OF ANIMALS IN RESEARCH*

9 *“SEC. 404A. (a) The Director of NIH, after consulta-*
10 *tion with the committee established under subsection (e),*
11 *shall prepare a plan—*

12 *“(1) for the National Institutes of Health to con-*
13 *duct or support research into—*

14 *“(A) methods of biomedical research and ex-*
15 *perimentation that do not require the use of ani-*
16 *mals;*

17 *“(B) methods of such research and experi-*
18 *mentation that reduce the number of animals*
19 *used in such research; and*

20 *“(C) methods of such research and experi-*
21 *mentation that produce less pain and distress in*
22 *such animals;*

23 *“(2) for establishing the validity and reliability*
24 *of the methods described in paragraph (1);*

1 “(3) for encouraging the acceptance by the sci-
2 entific community of such methods that have been
3 found to be valid and reliable; and

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

6 “(b) Not later than October 1, 1993, the Director of
7 NIH shall submit to the Committee on Energy and Com-
8 merce of the House of Representatives, and to the Committee
9 on Labor and Human Resources of the Senate, the plan
10 required in subsection (a) and shall begin implementation
11 of the plan.

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

18 “(d) The Director of NIH shall take such actions as
19 may be appropriate to convey to scientists and others who
20 use animals in biomedical or behavioral research or experi-
21 mentation information respecting the methods found to be
22 valid and reliable under subsection (a)(2).

23 “(e)(1) The Director of NIH shall establish within the
24 National Institutes of Health a committee to be known as
25 the Interagency Coordinating Committee on the Use of Ani-

1 *mals in Research (hereafter in this subsection referred to*
2 *as the ‘Committee’).*

3 “(2) *The Committee shall provide advice to the Direc-*
4 *tor of NIH on the preparation of the plan required in sub-*
5 *section (a).*

6 “(3) *The Committee shall be composed of—*

7 “(A) *the Directors of each of the national re-*
8 *search institutes and the Director of the Center for*
9 *Research Resources (or the designees of such Direc-*
10 *tors); and*

11 “(B) *representatives of the Environmental Pro-*
12 *tection Agency, the Food and Drug Administration,*
13 *the Consumer Product Safety Commission, the Na-*
14 *tional Science Foundation, and such additional agen-*
15 *cies as the Director of NIH determines to be appro-*
16 *priate.”.*

17 (b) *CONFORMING AMENDMENT.—Section 4 of the*
18 *Health Research Extension Act of 1985 (Public Law 99-*
19 *158; 99 Stat. 880) is repealed.*

1 **SEC. 205. INCREASED PARTICIPATION OF WOMEN AND MEM-**
 2 **BERS OF UNDERREPRESENTED MINORITIES**
 3 **IN FIELDS OF BIOMEDICAL AND BEHAVIORAL**
 4 **RESEARCH.**

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

8 *“(h) The Secretary, acting through the Director of NIH*
 9 *and the Directors of the agencies of the National Institutes*
 10 *of Health, may conduct and support programs for research,*
 11 *research training, recruitment, and other activities to pro-*
 12 *vide for an increase in the number of women and members*
 13 *of underrepresented minority groups in the fields of bio-*
 14 *medical and behavioral research.”.*

15 **SEC. 206. REQUIREMENTS REGARDING SURVEYS OF SEX-**
 16 **UAL BEHAVIOR.**

17 *Part A of title IV of the Public Health Service Act,*
 18 *as amended by section 204 of this Act, is amended by add-*
 19 *ing at the end the following new section:*

20 *“REQUIREMENTS REGARDING SURVEYS OF SEXUAL*
 21 *BEHAVIOR*

22 *“SEC. 404B. With respect to any survey of human*
 23 *sexual behavior proposed to be conducted or supported*
 24 *through the National Institutes of Health, the survey may*
 25 *not be carried out unless—*

1 “(1) the proposal has undergone review in ac-
2 cordance with any applicable requirements of sections
3 491 and 492; and

4 “(2) the Secretary, in accordance with section
5 492A, makes a determination that the information ex-
6 pected to be obtained through the survey will assist—

7 “(A) in reducing the incidence of sexually
8 transmitted diseases, the incidence of infection
9 with the human immunodeficiency virus, or the
10 incidence of any other infectious disease; or

11 “(B) in improving reproductive health or
12 other conditions of health.”.

13 **SEC. 207. DISCRETIONARY FUND OF DIRECTOR OF NA-**
14 **TIONAL INSTITUTES OF HEALTH.**

15 Section 402 of the Public Health Service Act, as
16 amended by section 205 of this Act, is amended by adding
17 at the end the following new subsection:

18 “(i)(1) There is established a fund, consisting of
19 amounts appropriated under paragraph (3) and made
20 available for the fund, for use by the Director of NIH to
21 carry out the activities authorized in this Act for the Na-
22 tional Institutes of Health. The purposes for which such
23 fund may be expended include—

24 “(A) providing for research on matters that have
25 not received significant funding relative to other mat-

1 *ters, responding to new issues and scientific emer-*
2 *gencies, and acting on research opportunities of high*
3 *priority;*

4 *“(B) supporting research that is not exclusively*
5 *within the authority of any single agency of such In-*
6 *stitutes; and*

7 *“(C) purchasing or renting equipment and quar-*
8 *ters for activities of such Institutes.*

9 *“(2) Not later than February 10 of each fiscal year,*
10 *the Secretary shall submit to the Committee on Energy and*
11 *Commerce of the House of Representatives, and to the Com-*
12 *mittee on Labor and Human Resources of the Senate, a*
13 *report describing the activities undertaken and expenditures*
14 *made under this section during the preceding fiscal year.*
15 *The report may contain such comments of the Secretary re-*
16 *garding this section as the Secretary determines to be ap-*
17 *propriate.*

18 *“(3) For the purpose of carrying out this subsection,*
19 *there are authorized to be appropriated \$25,000,000 for fis-*
20 *cal year 1994, and such sums as may be necessary for each*
21 *of the fiscal years 1995 and 1996.”.*

22 **SEC. 208. MISCELLANEOUS PROVISIONS.**

23 *(a) TERM OF OFFICE FOR MEMBERS OF ADVISORY*
24 *COUNCILS.—Section 406(c) of the Public Health Service*
25 *Act (42 U.S.C. 284a(c)) is amended in the second sentence*

1 *by striking “until a successor has been appointed” and in-*
2 *serting the following: “for 180 days after the date of such*
3 *expiration”.*

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

6 (1) *in paragraph (3), by striking “and” at the*
7 *end;*

8 (2) *in paragraph (4), by striking the period and*
9 *inserting “; and”; and*

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

12 “(5) *ensure that, after January 1, 1994, at least*
13 *one-half of all new or revised health education and*
14 *promotion materials developed or funded by the Na-*
15 *tional Institutes of Health is in a form that does not*
16 *exceed a level of functional literacy, as defined in the*
17 *National Literacy Act of 1991 (Public Law 102-*
18 *73).”.*

19 (c) *DAY CARE REGARDING CHILDREN OF EMPLOY-*
20 *EES.—Section 402 of the Public Health Service Act, as*
21 *amended by section 207 of this Act, is amended by adding*
22 *at the end the following new subsection:*

23 “(i)(1) *The Director of NIH may establish a program*
24 *to provide day care service for the employees of the National*
25 *Institutes of Health similar to those services provided by*

1 *other Federal agencies (including the availability of day*
 2 *care service on a 24-hour-a-day basis).*

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

6 *“(3) For purposes regarding the provision of day care*
 7 *service, the Director of NIH may enter into rental or lease*
 8 *purchase agreements.”.*

9 **TITLE III—GENERAL PROVI-**
 10 **SIONS RESPECTING NA-**
 11 **TIONAL RESEARCH INSTI-**
 12 **TUTES**

13 **SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS**
 14 **OF NATIONAL RESEARCH INSTITUTES.**

15 (a) *ESTABLISHMENT OF GENERAL AUTHORITY RE-*
 16 *GARDING DIRECT FUNDING.—*

17 (1) *IN GENERAL.—Section 405(b)(2) of the Pub-*
 18 *lic Health Service Act (42 U.S.C. 284(b)(2)) is*
 19 *amended—*

20 (A) *in subparagraph (A), by striking “and”*
 21 *after the semicolon at the end;*

22 (B) *in subparagraph (B), by striking the*
 23 *period at the end and inserting “; and”; and*

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

1 “(C) shall receive from the President and the Of-
2 fice of Management and Budget directly all funds ap-
3 propriated by the Congress for obligation and expend-
4 iture by the Institute.”.

5 (2) CONFORMING AMENDMENT.—Section
6 413(b)(9) of the Public Health Service Act (42 U.S.C.
7 285a–2(b)(9)) is amended—

8 (A) by striking “(A)” after “(9)”; and

9 (B) by striking “advisory council;” and all
10 that follows and inserting “advisory council.”.

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

14 (1) by amending paragraph (3) to read as fol-
15 lows:

16 “(3) may, in consultation with the advisory
17 council for the Institute and with the approval of the
18 Director of NIH—

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

22 “(B) appoint the members of peer review
23 groups established under subparagraph (A);
24 and”; and

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

3 “The Federal Advisory Committee Act shall not apply to
4 the duration of a peer review group appointed under para-
5 graph (3).”.

6 **SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS,**
7 **PAGET’S DISEASE, AND RELATED BONE DIS-**
8 **ORDERS.**

9 Part B of title IV of the Public Health Service Act
10 (42 U.S.C. 284 et seq.), as amended by section 121(b) of
11 Public Law 102–321 (106 Stat. 358), is amended by adding
12 at the end the following new section:

13 “RESEARCH ON OSTEOPOROSIS, PAGET’S DISEASE, AND
14 RELATED BONE DISORDERS

15 “SEC. 410. (a) ESTABLISHMENT.—The Directors of the
16 National Institute of Arthritis and Musculoskeletal and
17 Skin Diseases, the National Institute on Aging, and the Na-
18 tional Institute of Diabetes, Digestive and Kidney Diseases,
19 shall expand and intensify the programs of such Institutes
20 with respect to research and related activities concerning
21 osteoporosis, Paget’s disease, and related bone disorders.

22 “(b) COORDINATION.—The Directors referred to in sub-
23 section (a) shall jointly coordinate the programs referred
24 to in such subsection and consult with the Arthritis and
25 Musculoskeletal Diseases Interagency Coordinating Com-
26 mittee and the Interagency Task Force on Aging Research.

1 “(c) *INFORMATION CLEARINGHOUSE.*—

2 “(1) *IN GENERAL.*—In order to assist in carry-
3 ing out the purpose described in subsection (a), the
4 Director of NIH shall provide for the establishment of
5 an information clearinghouse on osteoporosis and re-
6 lated bone disorders to facilitate and enhance knowl-
7 edge and understanding on the part of health profes-
8 sionals, patients, and the public through the effective
9 dissemination of information.

10 “(2) *ESTABLISHMENT THROUGH GRANT OR CON-*
11 *TRACT.*—For the purpose of carrying out paragraph
12 (1), the Director of NIH shall enter into a grant, co-
13 operative agreement, or contract with a nonprofit pri-
14 vate entity involved in activities regarding the pre-
15 vention and control of osteoporosis and related bone
16 disorders.

17 “(d) *AUTHORIZATION OF APPROPRIATIONS.*—For the
18 purpose of carrying out this section, there are authorized
19 to be appropriated \$40,000,000 for fiscal year 1994, and
20 such sums as may be necessary for each of the fiscal years
21 1995 and 1996.”.

1 **SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM**
2 **FOR TRAUMA RESEARCH.**

3 (a) *IN GENERAL.*—Title XII of the Public Health Serv-
4 ice Act (42 U.S.C. 300d et seq.) is amended by adding at
5 the end the following part:

6 “PART E—INTERAGENCY PROGRAM FOR TRAUMA
7 RESEARCH

8 **“SEC. 1251. ESTABLISHMENT OF PROGRAM.**

9 “(a) *IN GENERAL.*—The Secretary, acting through the
10 Director of the National Institutes of Health (hereafter in
11 this section referred to as the ‘Director’), shall establish a
12 comprehensive program of conducting basic and clinical re-
13 search on trauma (hereafter in this section referred to as
14 the ‘Program’). The Program shall include research regard-
15 ing the diagnosis, treatment, rehabilitation, and general
16 management of trauma.

17 (b) *PLAN FOR PROGRAM.*—

18 “(1) *IN GENERAL.*—The Director, in consultation
19 with the Trauma Research Interagency Coordinating
20 Committee established under subsection (g), shall es-
21 tablish and implement a plan for carrying out the ac-
22 tivities of the Program, including the activities de-
23 scribed in subsection (d). All such activities shall be
24 carried out in accordance with the plan. The plan
25 shall be periodically reviewed, and revised as appro-
26 priate.

1 “(2) *SUBMISSION TO CONGRESS.*—Not later than
2 *June 1, 1993, the Director shall submit the plan re-*
3 *quired in paragraph (1) to the Committee on Energy*
4 *and Commerce of the House of Representatives, and*
5 *to the Committee on Labor and Human Resources of*
6 *the Senate, together with an estimate of the funds*
7 *needed for each of the fiscal years 1994 through 1996*
8 *to implement the plan.*

9 “(c) *PARTICIPATING AGENCIES; COORDINATION AND*
10 *COLLABORATION.*—*The Director—*

11 “(1) *shall provide for the conduct of activities*
12 *under the Program by the Directors of the agencies of*
13 *the National Institutes of Health involved in research*
14 *with respect to trauma;*

15 “(2) *shall ensure that the activities of the Pro-*
16 *gram are coordinated among such agencies; and*

17 “(3) *shall, as appropriate, provide for collabora-*
18 *tion among such agencies in carrying out such activi-*
19 *ties.*

20 “(d) *CERTAIN ACTIVITIES OF PROGRAM.*—*The Pro-*
21 *gram shall include—*

22 “(1) *studies with respect to all phases of trauma*
23 *care, including prehospital, resuscitation, surgical*
24 *intervention, critical care, infection control, wound*

1 *healing, nutritional care and support, and medical*
2 *rehabilitation care;*

3 “(2) *basic and clinical research regarding the re-*
4 *sponse of the body to trauma and the acute treatment*
5 *and medical rehabilitation of individuals who are the*
6 *victims of trauma; and*

7 “(3) *basic and clinical research regarding trau-*
8 *ma care for pediatric and geriatric patients.*

9 “(e) *MECHANISMS OF SUPPORT.—In carrying out the*
10 *Program, the Director, acting through the Directors of the*
11 *agencies referred to in subsection (c)(1), may make grants*
12 *to public and nonprofit entities, including designated trau-*
13 *ma centers.*

14 “(f) *RESOURCES.—The Director shall assure the avail-*
15 *ability of appropriate resources to carry out the Program,*
16 *including the plan established under subsection (b) (includ-*
17 *ing the activities described in subsection (d)).*

18 “(g) *COORDINATING COMMITTEE.—*

19 “(1) *IN GENERAL.—There shall be established a*
20 *Trauma Research Interagency Coordinating Commit-*
21 *tee (hereafter in this section referred to as the ‘Coordi-*
22 *nating Committee’).*

23 “(2) *DUTIES.—The Coordinating Committee*
24 *shall make recommendations regarding—*

1 “(A) the activities of the Program to be car-
2 ried out by each of the agencies represented on
3 the Committee and the amount of funds needed
4 by each of the agencies for such activities; and

5 “(B) effective collaboration among the agen-
6 cies in carrying out the activities.

7 “(3) COMPOSITION.—The Coordinating Commit-
8 tee shall be composed of the Directors of each of the
9 agencies that, under subsection (c), have responsibil-
10 ities under the Program, and any other individuals
11 who are practitioners in the trauma field as des-
12 ignated by the Director of the National Institutes of
13 Health.

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

15 “(1) The term ‘designated trauma center’ has the
16 meaning given such term in section 1231(1).

17 “(2) The term ‘Director’ means the Director of
18 the National Institutes of Health.

19 “(3) The term ‘trauma’ means any serious in-
20 jury that could result in loss of life or in significant
21 disability and that would meet pre-hospital triage
22 criteria for transport to a designated trauma center.”.

23 (b) CONFORMING AMENDMENT.—Section 402 of the
24 Public Health Service Act, as amended by section 208(c)

1 *of this Act, is amended by adding at the end the following*
 2 *new subsection:*

3 “(k) *The Director of NIH shall carry out the program*
 4 *established in part E of title XII (relating to interagency*
 5 *research on trauma).”.*

6 ***TITLE IV—NATIONAL CANCER***
 7 ***INSTITUTE***

8 ***SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVI-***
 9 ***TIES REGARDING BREAST CANCER.***

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

13 “*BREAST AND GYNECOLOGICAL CANCERS*

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

20 “*(b) COORDINATION WITH OTHER INSTITUTES.—The*
 21 *Director of the Institute shall coordinate the activities of*
 22 *the Director under subsection (a) with similar activities*
 23 *conducted by other national research institutes and agencies*
 24 *of the National Institutes of Health to the extent that such*
 25 *Institutes and agencies have responsibilities that are related*

1 *to breast cancer and other cancers of the reproductive sys-*
2 *tem of women.*

3 *“(c) PROGRAMS FOR BREAST CANCER.—*

4 *“(1) IN GENERAL.—In carrying out subsection*
5 *(a), the Director of the Institute shall conduct or sup-*
6 *port research to expand the understanding of the*
7 *cause of, and to find a cure for, breast cancer. Activi-*
8 *ties under such subsection shall provide for an expan-*
9 *sion and intensification of the conduct and support*
10 *of—*

11 *“(A) basic research concerning the etiology*
12 *and causes of breast cancer;*

13 *“(B) clinical research and related activities*
14 *concerning the causes, prevention, detection and*
15 *treatment of breast cancer;*

16 *“(C) control programs with respect to breast*
17 *cancer in accordance with section 412;*

18 *“(D) information and education programs*
19 *with respect to breast cancer in accordance with*
20 *section 413; and*

21 *“(E) research and demonstration centers*
22 *with respect to breast cancer in accordance with*
23 *section 414, including the development and oper-*
24 *ation of centers for breast cancer research to*
25 *bring together basic and clinical, biomedical and*

1 *behavioral scientists to conduct basic, clinical,*
2 *epidemiological, psychosocial, prevention and*
3 *treatment research and related activities on*
4 *breast cancer.*

5 *Not less than six centers shall be operated under sub-*
6 *paragraph (E). Activities of such centers should in-*
7 *clude supporting new and innovative research and*
8 *training programs for new researchers. Such centers*
9 *shall give priority to expediting the transfer of re-*
10 *search advances to clinical applications.*

11 “(2) IMPLEMENTATION OF PLAN FOR PRO-
12 GRAMS.—

13 “(A) *The Director of the Institute shall en-*
14 *sure that the research programs described in*
15 *paragraph (1) are implemented in accordance*
16 *with a plan for the programs. Such plan shall*
17 *include comments and recommendations that the*
18 *Director of the Institute considers appropriate,*
19 *with due consideration provided to the profes-*
20 *sional judgment needs of the Institute as ex-*
21 *pressed in the annual budget estimate prepared*
22 *in accordance with section 413(9). The Director*
23 *of the Institute, in consultation with the Na-*
24 *tional Cancer Advisory Board, shall periodically*
25 *review and revise such plan.*

1 “(B) Not later than May 1, 1993, the Direc-
2 tor of the Institute shall submit a copy of the
3 plan to the President’s Cancer Panel, the Sec-
4 retary and the Director of NIH.

5 “(C) The Director of the Institute shall sub-
6 mit any revisions of the plan to the President’s
7 Cancer Panel, the Secretary, and the Director of
8 NIH.

9 “(D) The Secretary shall provide a copy of
10 the plan submitted under subparagraph (A), and
11 any revisions submitted under subparagraph
12 (C), to the Committee on Energy and Commerce
13 of the House of Representatives and the Commit-
14 tee on Labor and Human Resources of the Sen-
15 ate.

16 “(d) OTHER CANCERS.—In carrying out subsection
17 (a), the Director of the Institute shall conduct or support
18 research on ovarian cancer and other cancers of the repro-
19 ductive system of women. Activities under such subsection
20 shall provide for the conduct and support of—

21 “(1) basic research concerning the etiology and
22 causes of ovarian cancer and other cancers of the re-
23 productive system of women;

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

1 *ovarian cancer and other cancers of the reproductive*
2 *system of women;*

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

6 “(4) *information and education programs with*
7 *respect to ovarian cancer and other cancers of the re-*
8 *productive system of women in accordance with sec-*
9 *tion 413; and*

10 “(5) *research and demonstration centers with re-*
11 *spect to ovarian cancer and cancers of the reproduc-*
12 *tive system in accordance with section 414.*

13 “(e) *REPORT.—The Director of the Institute shall pre-*
14 *pare, for inclusion in the biennial report submitted under*
15 *section 407, a report that describes the activities of the Na-*
16 *tional Cancer Institute under the research programs re-*
17 *ferred to in subsection (a), that shall include—*

18 “(1) *a description of the research plan with re-*
19 *spect to breast cancer prepared under subsection (c);*

20 “(2) *an assessment of the development, revision,*
21 *and implementation of such plan;*

22 “(3) *a description and evaluation of the progress*
23 *made, during the period for which such report is pre-*
24 *pared, in the research programs on breast cancer and*
25 *cancers of the reproductive system of women;*

1 “(4) a summary and analysis of expenditures
2 made, during the period for which such report is
3 made, for activities with respect to breast cancer and
4 cancers of the reproductive system of women con-
5 ducted and supported by the National Institutes of
6 Health; and

7 “(5) such comments and recommendations as the
8 Director considers appropriate.”.

9 **SEC. 402. EXPANSION AND INTENSIFICATION OF ACTIVI-**
10 **TIES REGARDING PROSTATE CANCER.**

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

14 “PROSTATE CANCER

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

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

1 “(c) *PROGRAMS.*—

2 “(1) *IN GENERAL.*—*In carrying out subsection*
3 *(a), the Director of the Institute shall conduct or sup-*
4 *port research to expand the understanding of the*
5 *cause of, and to find a cure for, prostate cancer. Ac-*
6 *tivities under such subsection shall provide for an ex-*
7 *pansion and intensification of the conduct and sup-*
8 *port of—*

9 “(A) *basic research concerning the etiology*
10 *and causes of prostate cancer;*

11 “(B) *clinical research and related activities*
12 *concerning the causes, prevention, detection and*
13 *treatment of prostate cancer;*

14 “(C) *prevention and control and early de-*
15 *tection programs with respect to prostate cancer*
16 *in accordance with section 412, particularly as*
17 *it relates to intensifying research on the role of*
18 *prostate specific antigen for the screening and*
19 *early detection of prostate cancer;*

20 “(D) *an Inter-Institute Task Force, under*
21 *the direction of the Director of the Institute, to*
22 *provide coordination between relevant National*
23 *Institutes of Health components of research ef-*
24 *forts on prostate cancer;*

1 “(E) control programs with respect to pros-
2 tate cancer in accordance with section 412;

3 “(F) information and education programs
4 with respect to prostate cancer in accordance
5 with section 413; and

6 “(G) research and demonstration centers
7 with respect to prostate cancer in accordance
8 with section 414, including the development and
9 operation of centers for prostate cancer research
10 to bring together basic and clinical, biomedical
11 and behavioral scientists to conduct basic, clini-
12 cal, epidemiological, psychosocial, prevention
13 and treatment research and related activities on
14 prostate cancer.

15 Not less than six centers shall be operated under sub-
16 paragraph (G). Activities of such centers should in-
17 clude supporting new and innovative research and
18 training programs for new researchers. Such centers
19 shall give priority to expediting the transfer of re-
20 search advances to clinical applications.

21 “(2) IMPLEMENTATION OF PLAN FOR PRO-
22 GRAMS.—

23 “(A) The Director of the Institute shall en-
24 sure that the research programs described in
25 paragraph (1) are implemented in accordance

1 with a plan for the programs. Such plan shall
2 include comments and recommendations that the
3 Director of the Institute considers appropriate,
4 with due consideration provided to the profes-
5 sional judgment needs of the Institute as ex-
6 pressed in the annual budget estimate prepared
7 in accordance with section 413(9). The Director
8 of the Institute, in consultation with the Na-
9 tional Cancer Advisory Board, shall periodically
10 review and revise such plan.

11 “(B) Not later than May 1, 1993, the Direc-
12 tor of the Institute shall submit a copy of the
13 plan to the President’s Cancer Panel, the Sec-
14 retary and the Director of NIH.

15 “(C) The Director of the Institute shall sub-
16 mit any revisions of the plan to the President’s
17 Cancer Panel, the Secretary, and the Director of
18 NIH.

19 “(D) The Secretary shall provide a copy of
20 the plan submitted under subparagraph (A), and
21 any revisions submitted under subparagraph
22 (C), to the Committee on Energy and Commerce
23 of the House of Representatives and the Commit-
24 tee on Labor and Human Resources of the Sen-
25 ate.”.

1 **SEC. 403. AUTHORIZATION OF APPROPRIATIONS.**

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

6 “AUTHORIZATION OF APPROPRIATIONS

7 “SEC. 417B. (a) *ACTIVITIES GENERALLY.*—For the
8 purpose of carrying out this subpart, there are authorized
9 to be appropriated \$2,200,000,000 for fiscal year 1994, and
10 such sums as may be necessary for each of the fiscal years
11 1995 and 1996.

12 “(b) *BREAST CANCER AND GYNECOLOGICAL CAN-*
13 *CERS.*—

14 “(1) *BREAST CANCER.*—

15 “(A) For the purpose of carrying out sub-
16 paragraph (A) of section 417(c)(1), there are au-
17 thorized to be appropriated \$225,000,000 for fis-
18 cal year 1994, and such sums as may be nec-
19 essary for each of the fiscal years 1995 and 1996.
20 Such authorizations of appropriations are in ad-
21 dition to the authorizations of appropriations es-
22 tablished in subsection (a) with respect to such
23 purpose.

24 “(B) For the purpose of carrying out sub-
25 paragraphs (B) through (E) of section 417(c)(1),
26 there are authorized to be appropriated

1 \$100,000,000 for fiscal year 1994, and such sums
2 as may be necessary for each of the fiscal years
3 1995 and 1996. Such authorizations of appro-
4 priations are in addition to the authorizations of
5 appropriations established in subsection (a) with
6 respect to such purpose.

7 “(2) OTHER CANCERS.—For the purpose of car-
8 rying out subsection (d) of section 417, there are au-
9 thorized to be appropriated \$75,000,000 for fiscal
10 year 1994, and such sums as are necessary for each
11 of the fiscal years 1995 and 1996. Such authoriza-
12 tions of appropriations are in addition to the author-
13 izations of appropriations established in subsection
14 (a) with respect to such purpose.

15 “(c) PROSTATE CANCER.—For the purpose of carrying
16 out section 417A, there are authorized to be appropriated
17 \$72,000,000 for fiscal year 1994, and such sums as may
18 be necessary for each of the fiscal years 1995 and 1996.
19 Such authorizations of appropriations are in addition to
20 the authorizations of appropriations established in sub-
21 section (a) with respect to such purpose.

22 “(d) ALLOCATION REGARDING CANCER CONTROL.—Of
23 the amounts appropriated for the National Cancer Institute
24 for a fiscal year, the Director of the Institute shall make
25 available not less than 10 percent for carrying out the can-

1 *cer control activities authorized in section 412 and for*
 2 *which budget estimates are made under section 413(b)(9)*
 3 *for the fiscal year.”.*

4 (b) *SPECIAL RULE REGARDING FUNDS FOR SECTION*
 5 *412 FOR FISCAL YEAR 1994.*—*Notwithstanding section*
 6 *417B(d) of the Public Health Service Act, as added by sub-*
 7 *section (a) of this section, the amount made available under*
 8 *such section for fiscal year 1994 for carrying out section*
 9 *412 of such Act shall be an amount not less than an amount*
 10 *equal to 75 percent of the amount specified for activities*
 11 *under such section 412 in the budget estimate made under*
 12 *section 413(b)(9) of such Act for such fiscal year.*

13 (c) *CONFORMING AMENDMENTS.*—

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

16 (A) *by striking subsection (a);*

17 (B) *by redesignating subsection (b) as sub-*
 18 *section (a);*

19 (C) *by redesignating paragraph (5) of sub-*
 20 *section (a) (as so redesignated) as subsection (b);*

21 *and*

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

24 “*CERTAIN USES OF FUNDS*”.

25 (2) *CROSS-REFERENCE.*—*Section 464F of the*
 26 *Public Health Service Act (42 U.S.C. 285m–6) is*

1 amended by striking “section 408(b)(1)” and insert-
2 ing “section 408(a)(1)”.

3 **TITLE V—NATIONAL HEART,**
4 **LUNG, AND BLOOD INSTITUTE**

5 **SEC. 501. EDUCATION AND TRAINING.**

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

8 (1) in paragraph (3), by striking “and” after the
9 semicolon at the end;

10 (2) in paragraph (4), by striking the period at
11 the end and inserting “; and”; and

12 (3) by inserting after paragraph (4) the follow-
13 ing new paragraph:

14 “(5) shall, in consultation with the advisory
15 council for the Institute, conduct appropriate intra-
16 mural training and education programs, including
17 continuing education and laboratory and clinical re-
18 search training programs.”.

19 **SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CARDIO-**
20 **VASCULAR DISEASES.**

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

23 (1) in subparagraph (B), by striking “and” at
24 the end;

1 (2) in subparagraph (C), by striking the period
2 and inserting “; and”; and

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

5 “(D) three centers for basic and clinical research
6 into, training in, and demonstration of, advanced di-
7 agnostic, prevention, and treatment (including genetic
8 studies, intrauterine environment studies, postnatal
9 studies, heart arrhythmias, and acquired heart dis-
10 ease and preventive cardiology) for cardiovascular
11 diseases in children.”.

12 **SEC. 503. NATIONAL CENTER ON SLEEP DISORDERS.**

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

16 “NATIONAL CENTER ON SLEEP DISORDERS

17 “SEC. 424. (a) Not later than 1 year after the date
18 of the enactment of the National Institutes of Health Revi-
19 talization Act of 1993, the Director of the Institute shall
20 establish the National Center on Sleep Disorders (in this
21 section referred to as the ‘Center’). The Center shall be head-
22 ed by a director, who shall be appointed by the Director
23 of the Institute.

24 “(b) The general purpose of the Center is the conduct
25 and support of research, training, health information dis-

1 *semination, and other activities with respect to sleep dis-*
 2 *orders.”.*

3 **SEC. 504. AUTHORIZATION OF APPROPRIATIONS.**

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

7 *“AUTHORIZATION OF APPROPRIATIONS*

8 *“SEC. 425. (a) For the purpose of carrying out this*
 9 *subpart, there are authorized to be appropriated*
 10 *\$1,500,000,000 for fiscal year 1994, and such sums as may*
 11 *be necessary for each of the fiscal years 1995 and 1996.*

12 *“(b) Of the amounts appropriated under paragraph*
 13 *(1) for a fiscal year, the Director of the Institute shall make*
 14 *available not less than 10 percent for carrying out commu-*
 15 *nity-based prevention and control activities that include*
 16 *clinical investigations, clinical trials, epidemiologic studies,*
 17 *and prevention demonstration and education projects.”.*

18 **TITLE VI—NATIONAL INSTITUTE**
 19 **ON DIABETES AND DIGESTIVE**
 20 **AND KIDNEY DISEASES**

21 **SEC. 601. PROVISIONS REGARDING NUTRITIONAL DIS-**
 22 **ORDERS.**

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

1 “NUTRITIONAL DISORDERS PROGRAM

2 “SEC. 434. (a) *The Director of the Institute shall estab-*
3 *lish a program of conducting and supporting research,*
4 *training, health information dissemination, and other ac-*
5 *tivities with respect to nutritional disorders, including obe-*
6 *sity.*

7 “(b) *In carrying out the program established under*
8 *subsection (a), the Director of the Institute shall conduct*
9 *and support each of the activities described in such sub-*
10 *section. The Director of NIH shall ensure that, as appro-*
11 *priate, the other national research institutes and agencies*
12 *of the National Institutes of Health have responsibilities re-*
13 *garding such activities.*

14 “(c) *In carrying out the program established under*
15 *subsection (a), the Director of the Institute shall carry out*
16 *activities to facilitate and enhance knowledge and under-*
17 *standing of nutritional disorders, including obesity, on the*
18 *part of health professionals, patients, and the public*
19 *through the effective dissemination of information.”.*

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

23 (1) *by redesignating subsection (d) as subsection*
24 *(e); and*

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

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

8 “(2) The Director of the Institute shall carry out para-
9 graph (1) in collaboration with the Director of the National
10 Cancer Institute and with the Directors of such other agen-
11 cies of the National Institutes of Health as the Director of
12 NIH determines to be appropriate.

13 “(3) Each center developed or expanded under para-
14 graph (1) shall—

15 “(A) utilize the facilities of a single institution,
16 or be formed from a consortium of cooperating insti-
17 tutions, meeting such research and training qualifica-
18 tions as may be prescribed by the Director;

19 “(B) conduct basic and clinical research into the
20 cause, diagnosis, early detection, prevention, control
21 and treatment of nutritional disorders, including obe-
22 sity and the impact of nutrition and diet on child de-
23 velopment;

24 “(C) conduct training programs for physicians
25 and allied health professionals in current methods of

1 *diagnosis and treatment of such diseases and com-*
 2 *plications, and in research in such disorders; and*

3 *“(D) conduct information programs for physi-*
 4 *cians and allied health professionals who provide pri-*
 5 *mary care for patients with such disorders or com-*
 6 *plications.”.*

7 **TITLE VII—NATIONAL INSTI-**
 8 **TUTE ON ARTHRITIS AND**
 9 **MUSCULOSKELETAL AND**
 10 **SKIN DISEASES**

11 **SEC. 701. JUVENILE ARTHRITIS.**

12 *(a) PURPOSE.—Section 435 of the Public Health Serv-*
 13 *ice Act (42 U.S.C. 285d) is amended by striking “and other*
 14 *programs” and all that follows and inserting the following:*
 15 *“and other programs with respect to arthritis and musculo-*
 16 *skeletal and skin diseases (including sports-related dis-*
 17 *orders), with particular attention to the effect of these dis-*
 18 *eases on children.”.*

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

21 *(1) in subsection (a), by inserting after the sec-*
 22 *ond sentence, the following: “The plan shall place*
 23 *particular emphasis upon expanding research into*
 24 *better understanding the causes and the development*

1 *of effective treatments for arthritis affecting chil-*
2 *dren.”; and*

3 *(2) in subsection (b)—*

4 *(A) by striking “and” at the end of para-*
5 *graph (3);*

6 *(B) by striking the period at the end of*
7 *paragraph (4) and inserting “; and”; and*

8 *(C) by adding at the end thereof the follow-*
9 *ing new paragraph:*

10 *“(5) research into the causes of arthritis affecting*
11 *children and the development, trial, and evaluation of*
12 *techniques, drugs and devices used in the diagnosis,*
13 *treatment (including medical rehabilitation), and*
14 *prevention of arthritis in children.”.*

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

18 *“(f) Not later than October 1, 1994, the Director shall*
19 *establish a multipurpose arthritis and musculoskeletal dis-*
20 *ease center for the purpose of expanding the level of research*
21 *into the cause, diagnosis, early detection, prevention, con-*
22 *trol, and treatment of, and rehabilitation of children with*
23 *arthritis and musculoskeletal diseases.”.*

24 *(d) ADVISORY BOARD.—*

1 (1) *TITLE.*—Section 442(a) of the Public Health
2 Service Act (42 U.S.C. 285d-7(a)) is amended by in-
3 serting after “Arthritis” the the first place such term
4 appears the following: “and Musculoskeletal and Skin
5 Diseases”.

6 (2) *COMPOSITION.*—Section 442(b) of the Public
7 Health Service Act (42 U.S.C. 285d-7(b)) is amend-
8 ed—Section 442(b) of the Public Health Service Act
9 (42 U.S.C. 285d-7(b)) is amended—

10 (A) in the matter preceding paragraph (1),
11 by striking “eighteen” and inserting “twenty”;
12 and

13 (B) in paragraph (1)(B)—

14 (i) by striking “six” and inserting
15 “eight”; and

16 (ii) by striking “including” and all
17 that follows and inserting the following:
18 “including one member who is a person who
19 has such a disease, one person who is the
20 parent of an adult with such a disease, and
21 two members who are parents of children
22 with arthritis.”.

23 (3) *ANNUAL REPORT.*—Section 442(j) of the Pub-
24 lic Health Service Act (42 U.S.C. 285d-7(j)) is
25 amended—

1 (1) by striking “and” at the end of paragraph
2 (3);

3 (2) by striking the period at the end of para-
4 graph (4) and inserting “; and”; and

5 (3) by adding at the end the following para-
6 graph:

7 “(5) contains recommendations for expanding
8 the Institute’s funding of research directly applicable
9 to the cause, diagnosis, early detection, prevention,
10 control, and treatment of, and rehabilitation of chil-
11 dren with arthritis and musculoskeletal diseases.”.

12 **TITLE VIII—NATIONAL**
13 **INSTITUTE ON AGING**

14 **SEC. 801. ALZHEIMER’S DISEASE REGISTRY.**

15 (a) *IN GENERAL.*—Section 12 of Public Law 99–158
16 (99 Stat. 885) is—

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

20 (2) redesignated as section 445G; and

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

22 (b) *TECHNICAL AND CONFORMING AMENDMENTS.*—
23 Section 445G of the Public Health Service Act, as trans-
24 ferred and inserted by subsection (a) of this section, is
25 amended—

1 (1) *by striking the section heading and all that*
2 *follows through “may make a grant” in subsection (a)*
3 *and inserting the following:*

4 “ALZHEIMER’S DISEASE REGISTRY

5 “SEC. 445G. (a) *IN GENERAL.*—*The Director of the*
6 *Institute may make a grant”;* and

7 (2) *by striking subsection (c).*

8 **SEC. 802. AGING PROCESSES REGARDING WOMEN.**

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

12 “AGING PROCESSES REGARDING WOMEN

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

23 **SEC. 803. AUTHORIZATION OF APPROPRIATIONS.**

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

1 “AUTHORIZATION OF APPROPRIATIONS

2 “SEC. 445I. For the purpose of carrying out this sub-
3 part, there are authorized to be appropriated \$500,000,000
4 for fiscal year 1994, and such sums as may be necessary
5 for each of the fiscal years 1995 and 1996.”.

6 **SEC. 804. CONFORMING AMENDMENT.**

7 Section 445C of the Public Health Service Act (42
8 U.S.C. 285e-5(b)) is amended—

9 (1) in subsection (b)(1), in the first sentence, by
10 inserting after “Council” the following: “on Alz-
11 heimer’s Disease (hereafter in this section referred to
12 as the ‘Council’)”; and

13 (2) by adding at the end the following new sub-
14 section:

15 “(d) For purposes of this section, the term ‘Council on
16 Alzheimer’s Disease’ means the council established in sec-
17 tion 911(a) of Public Law 99-660.”.

18 **TITLE IX—NATIONAL INSTITUTE**
19 **OF ALLERGY AND INFEC-**
20 **TIOUS DISEASES**

21 **SEC. 901. TROPICAL DISEASES.**

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

1 **SEC. 902. CHRONIC FATIGUE SYNDROME.**

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

5 “RESEARCH CENTERS REGARDING CHRONIC FATIGUE
6 SYNDROME

7 “SEC. 447. (a) The Director of the Institute, after con-
8 sultation with the advisory council for the Institute, may
9 make grants to, or enter into contracts with, public or non-
10 profit private entities for the development and operation of
11 centers to conduct basic and clinical research on chronic
12 fatigue syndrome.

13 “(b) Each center assisted under this section shall use
14 the facilities of a single institution, or be formed from a
15 consortium of cooperating institutions, meeting such re-
16 quirements as may be prescribed by the Director of the In-
17 stitute.”.

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

22 (c) *REPRESENTATIVES.*—The Secretary of Health and
23 Human Services, acting through the Director of the Na-
24 tional Institutes of Health, shall ensure that appropriate
25 individuals with expertise in chronic fatigue syndrome or
26 neuromuscular diseases and representative of a variety of

1 *disciplines and fields within the research community are*
 2 *appointed to appropriate National Institutes of Health ad-*
 3 *visory committees and boards.*

4 ***TITLE X—NATIONAL INSTITUTE***
 5 ***OF CHILD HEALTH AND***
 6 ***HUMAN DEVELOPMENT***

7 ***Subtitle A—Research Centers With***
 8 ***Respect to Contraception and***
 9 ***Research Centers With Respect***
 10 ***to Infertility***

11 ***SEC. 1001. GRANTS AND CONTRACTS FOR RESEARCH CEN-***
 12 ***TERS.***

13 *Subpart 7 of part C of title IV of the Public Health*
 14 *Service Act, as amended by section 3 of Public Law 101–*
 15 *613, is amended by adding at the end the following new*
 16 *section:*

17 *“RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION*
 18 *AND INFERTILITY*

19 *“SEC. 452A. (a) The Director of the Institute, after*
 20 *consultation with the advisory council for the Institute,*
 21 *shall make grants to, or enter into contracts with, public*
 22 *or nonprofit private entities for the development and oper-*
 23 *ation of centers to conduct activities for the purpose of im-*
 24 *proving methods of contraception and centers to conduct ac-*
 25 *tivities for the purpose of improving methods of diagnosis*
 26 *and treatment of infertility.*

1 “(b) In carrying out subsection (a), the Director of the
2 Institute shall, subject to the extent of amounts made avail-
3 able in appropriations Acts, provide for the establishment
4 of three centers with respect to contraception and for two
5 centers with respect to infertility.

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

8 “(A) conduct clinical and other applied research,
9 including—

10 “(i) for centers with respect to contracep-
11 tion, clinical trials of new or improved drugs
12 and devices for use by males and females (in-
13 cluding barrier methods); and

14 “(ii) for centers with respect to infertility,
15 clinical trials of new or improved drugs and de-
16 vices for the diagnosis and treatment of infertil-
17 ity in males and females;

18 “(B) develop protocols for training physicians,
19 scientists, nurses, and other health and allied health
20 professionals;

21 “(C) conduct training programs for such indi-
22 viduals;

23 “(D) develop model continuing education pro-
24 grams for such professionals; and

1 “(E) disseminate information to such profes-
2 sionals and the public.

3 “(2) A center may use funds provided under subsection
4 (a) to provide stipends for health and allied health profes-
5 sionals enrolled in programs described in subparagraph (C)
6 of paragraph (1), and to provide fees to individuals serving
7 as subjects in clinical trials conducted under such para-
8 graph.

9 “(d) The Director of the Institute shall, as appropriate,
10 provide for the coordination of information among the cen-
11 ters assisted under this section.

12 “(e) Each center assisted under subsection (a) shall use
13 the facilities of a single institution, or be formed from a
14 consortium of cooperating institutions, meeting such re-
15 quirements as may be prescribed by the Director of the In-
16 stitute.

17 “(f) Support of a center under subsection (a) may be
18 for a period not exceeding 5 years. Such period may be ex-
19 tended for one or more additional periods not exceeding 5
20 years if the operations of such center have been reviewed
21 by an appropriate technical and scientific peer review
22 group established by the Director and if such group has rec-
23 ommended to the Director that such period should be ex-
24 tended.

1 “(g) For the purpose of carrying out this section, there
2 are authorized to be appropriated \$30,000,000 for fiscal
3 year 1994, and such sums as may be necessary for each
4 of the fiscal years 1995 and 1996.”.

5 **SEC. 1002. LOAN REPAYMENT PROGRAM FOR RESEARCH**
6 **WITH RESPECT TO CONTRACEPTION AND IN-**
7 **FERTILITY.**

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

11 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
12 RESPECT TO CONTRACEPTION AND INFERTILITY

13 “SEC. 487B. (a) The Secretary, in consultation with
14 the Director of the National Institute of Child Health and
15 Human Development, shall establish a program of entering
16 into agreements with qualified health professionals (includ-
17 ing graduate students) under which such health profes-
18 sionals agree to conduct research with respect to contracep-
19 tion, or with respect to infertility, in consideration of the
20 Federal Government agreeing to repay, for each year of such
21 service, not more than \$20,000 of the principal and interest
22 of the educational loans of such health professionals.

23 “(b) The provisions of sections 338B, 338C, and 338E
24 shall apply to the program established in subsection (a) to
25 the same extent and in the same manner as such provisions
26 apply to the National Health Service Corps Loan Repay-

1 *ment Program established in subpart III of part D of title*
 2 *III.*

3 “(c) Amounts appropriated for carrying out this sec-
 4 *tion shall remain available until the expiration of the sec-*
 5 *ond fiscal year beginning after the fiscal year for which*
 6 *the amounts were appropriated.”.*

7 ***Subtitle B—Program Regarding***
 8 ***Obstetrics and Gynecology***

9 ***SEC. 1011. ESTABLISHMENT OF PROGRAM.***

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

13 “PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

14 “SEC. 452B. The Director of the Institute shall estab-
 15 *lish and maintain within the Institute an intramural lab-*
 16 *oratory and clinical research program in obstetrics and*
 17 *gynecology.”.*

18 ***Subtitle C—Child Health Research***
 19 ***Centers***

20 ***SEC. 1021. ESTABLISHMENT OF CENTERS.***

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

24 “CHILD HEALTH RESEARCH CENTERS

25 “SEC. 452C. The Director of the Institute shall develop
 26 *and support centers for conducting research with respect to*

1 *child health. Such centers shall give priority to the expedi-*
 2 *tious transfer of advances from basic science to clinical ap-*
 3 *plications and improving the care of infants and children.”.*

4 ***Subtitle D—Study Regarding***
 5 ***Adolescent Health***

6 ***SEC. 1031. PROSPECTIVE LONGITUDINAL STUDY.***

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

10 *“PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT*
 11 *HEALTH*

12 *“SEC. 452D. (a) IN GENERAL.—The Director of the*
 13 *Institute shall conduct a study for the purpose of providing*
 14 *information on the general health and well-being of adoles-*
 15 *cents in the United States, including, with respect to such*
 16 *adolescents, information on—*

17 *“(1) the behaviors that promote health and the*
 18 *behaviors that are detrimental to health; and*

19 *“(2) the influence on health of factors particular*
 20 *to the communities in which the adolescents reside.*

21 *“(b) DESIGN OF STUDY.—*

22 *“(1) IN GENERAL.—The study required in sub-*
 23 *section (a) shall be a longitudinal study in which a*
 24 *substantial number of adolescents participate as sub-*
 25 *jects. With respect to the purpose described in such*
 26 *subsection, the study shall monitor the subjects*

1 *throughout the period of the study to determine the*
2 *health status of the subjects and any change in such*
3 *status over time.*

4 “(2) *POPULATION-SPECIFIC ANALYSES.*—*The*
5 *study required in subsection (a) shall be conducted*
6 *with respect to the population of adolescents who are*
7 *female, the population of adolescents who are male,*
8 *various socioeconomic populations of adolescents, and*
9 *various racial and ethnic populations of adolescents.*
10 *The study shall be designed and conducted in a man-*
11 *ner sufficient to provide for a valid analysis of wheth-*
12 *er there are significant differences among such popu-*
13 *lations in health status and whether and to what ex-*
14 *tent any such differences are due to factors particular*
15 *to the populations involved.*

16 “(c) *COORDINATION WITH WOMEN’S HEALTH INITIA-*
17 *TIVE.*—*With respect to the national study of women being*
18 *conducted by the Secretary and known as the Women’s*
19 *Health Initiative, the Secretary shall ensure that such study*
20 *is coordinated with the component of the study required in*
21 *subsection (a) that concerns adolescent females, including*
22 *coordination in the design of the 2 studies.*

23 “(d) *ALLOCATION OF FUNDS FOR STUDY.*—*Of the*
24 *amounts appropriated for each of the fiscal years 1994*
25 *through 1996 for the National Institute of Child Health and*

1 *Human Development, the Secretary of Health and Human*
 2 *Services, acting through the Director of such Institute, shall*
 3 *reserve \$3,000,000 to conduct the study required in sub-*
 4 *section (a). The amounts so reserved shall remain available*
 5 *until expended.”.*

6 **TITLE XI—NATIONAL EYE**
 7 **INSTITUTE**

8 **SEC. 1101. CLINICAL RESEARCH ON DIABETES EYE CARE.**

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

12 “*CLINICAL RESEARCH ON EYE CARE AND DIABETES*

13 “*SEC. 456. (a) PROGRAM OF GRANTS.*—The Director
 14 *of the Institute, in consultation with the advisory council*
 15 *for the Institute, may award not more than three grants*
 16 *for the establishment and support of centers for clinical re-*
 17 *search on eye care for individuals with diabetes.*

18 “(b) *AUTHORIZED EXPENDITURES.*—The purposes for
 19 *which a grant under subsection (a) may be expended in-*
 20 *clude equipment for the research described in such sub-*
 21 *section and the construction and modernization of facilities*
 22 *for such research.”.*

23 (b) *CONFORMING AMENDMENT.*—Section 455 of the
 24 *Public Health Service Act (42 U.S.C. 285i) is amended in*
 25 *the second sentence by striking “The Director” and insert-*
 26 *ing “Subject to section 456, the Director”.*

1 **TITLE XII—NATIONAL INSTI-**
 2 **TUTE OF NEUROLOGICAL DIS-**
 3 **ORDERS AND STROKE**

4 **SEC. 1201. RESEARCH ON MULTIPLE SCLEROSIS.**

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

8 *“RESEARCH ON MULTIPLE SCLEROSIS*

9 *“SEC. 460. The Director of the Institute shall conduct*
 10 *and support research on multiple sclerosis, especially re-*
 11 *search on effects of genetics and hormonal changes on the*
 12 *progress of the disease.”.*

13 **TITLE XIII—NATIONAL INSTI-**
 14 **TUTE OF ENVIRONMENTAL**
 15 **HEALTH SCIENCES**

16 **SEC. 1301. APPLIED TOXICOLOGICAL RESEARCH AND TEST-**
 17 **ING PROGRAM.**

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

21 *“APPLIED TOXICOLOGICAL RESEARCH AND TESTING*

22 *PROGRAM*

23 *“SEC. 463A. (a) There is established within the Insti-*
 24 *tute a program for conducting applied research and testing*

1 *regarding toxicology, which program shall be known as the*
2 *Applied Toxicological Research and Testing Program.*

3 “(b) *In carrying out the program established under*
4 *subsection (a), the Director of the Institute shall, with re-*
5 *spect to toxicology, carry out activities—*

6 “(1) *to expand knowledge of the health effects of*
7 *environmental agents;*

8 “(2) *to broaden the spectrum of toxicology infor-*
9 *mation that is obtained on selected chemicals;*

10 “(3) *to develop and validate assays and proto-*
11 *cols, including alternative methods that can reduce or*
12 *eliminate the use of animals in acute or chronic safe-*
13 *ty testing;*

14 “(4) *to establish criteria for the validation and*
15 *regulatory acceptance of alternative testing and to*
16 *recommend a process through which scientifically*
17 *validated alternative methods can be accepted for reg-*
18 *ulatory use;*

19 “(5) *to communicate the results of research to*
20 *government agencies, to medical, scientific, and regu-*
21 *latory communities, and to the public; and*

22 “(6) *to integrate related activities of the Depart-*
23 *ment of Health and Human Services.”.*

24 (b) *TECHNICAL AMENDMENT.—Section 463 of the Pub-*
25 *lic Health Service Act (42 U.S.C. 285l) is amended by in-*

1 *serting after “Sciences” the following: “(hereafter in this*
2 *subpart referred to as the ‘Institute’)”.*

3 ***TITLE XIV—NATIONAL LIBRARY***
4 ***OF MEDICINE***

5 ***Subtitle A—General Provisions***

6 ***SEC. 1401. ADDITIONAL AUTHORITIES.***

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

9 *(1) by striking “and” after the semicolon at the*
10 *end of paragraph (5);*

11 *(2) by redesignating paragraph (6) as para-*
12 *graph (8); and*

13 *(3) by inserting after paragraph (5) the follow-*
14 *ing new paragraphs:*

15 *“(6) publicize the availability from the Library*
16 *of the products and services described in any of para-*
17 *graphs (1) through (5);*

18 *“(7) promote the use of computers and tele-*
19 *communications by health professionals (including*
20 *health professionals in rural areas) for the purpose of*
21 *improving access to biomedical information for health*
22 *care delivery and medical research; and”.*

23 *(b) LIMITATION REGARDING GRANTS.—Section*
24 *474(b)(2) of the Public Health Service Act (42 U.S.C. 286b—*

1 *S(b)(2)* is amended by striking “\$750,000” and inserting
2 “\$1,000,000”.

3 (c) *TECHNICAL AND CONFORMING AMENDMENTS.*—

4 (1) *REPEAL OF CERTAIN AUTHORITY.*—Section
5 215 of the Department of Health and Human Serv-
6 ices Appropriations Act, 1988, as contained in section
7 101(h) of Public Law 100–202 (101 Stat. 1329–275),
8 is repealed.

9 (2) *APPLICABILITY OF CERTAIN NEW AUTHOR-*
10 *ITY.*—With respect to the authority established for the
11 National Library of Medicine in section 465(b)(6) of
12 the Public Health Service Act, as added by subsection
13 (a) of this section, such authority shall be effective as
14 if the authority had been established on December 22,
15 1987.

16 **SEC. 1402. AUTHORIZATION OF APPROPRIATIONS.**

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

21 “AUTHORIZATION OF APPROPRIATIONS

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

1 “(b) Amounts appropriated under subsection (a) and
 2 made available for grants or contracts under any of sections
 3 472 through 476 shall remain available until the end of
 4 the fiscal year following the fiscal year for which the
 5 amounts were appropriated.”

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

9 ***Subtitle B—Financial Assistance***

10 ***SEC. 1411. ESTABLISHMENT OF PROGRAM OF GRANTS FOR***

11 ***DEVELOPMENT OF EDUCATION TECH-***

12 ***NOLOGIES.***

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

16 “(c)(1) The Secretary shall make grants to public or
 17 nonprofit private institutions for the purpose of carrying
 18 out projects of research on, and development and dem-
 19 onstration of, new education technologies.

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

22 “(A) computer-assisted teaching and testing of
 23 clinical competence at health professions and research
 24 institutions;

1 “(B) the effective transfer of new information
2 from research laboratories to appropriate clinical ap-
3 plications;

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

6 “(D) the testing of new technologies for training
7 health care professionals.

8 “(3) The Secretary may not make a grant under para-
9 graph (1) unless the applicant for the grant agrees to make
10 the projects available with respect to—

11 “(A) assisting in the training of health profes-
12 sions students; and

13 “(B) enhancing and improving the capabilities
14 of health professionals regarding research and teach-
15 ing.”.

16 ***Subtitle C—National Information***
17 ***Center on Health Services Re-***
18 ***search and Health Care Tech-***
19 ***nology***

20 ***SEC. 1421. ESTABLISHMENT OF CENTER.***

21 *Part D of title IV of the Public Health Service Act*
22 *(42 U.S.C. 286 et seq.) is amended by adding at the end*
23 *the following new subpart:*

1 *“Subpart 4—National Information Center on Health*
2 *Services Research and Health Care Technology*

3 *“NATIONAL INFORMATION CENTER*

4 *“SEC. 478A. (a) There is established within the Li-*
5 *brary an entity to be known as the National Information*
6 *Center on Health Services Research and Health Care Tech-*
7 *nology (in this section referred to as the ‘Center’).*

8 *“(b) The purpose of the Center is the collection, storage,*
9 *analysis, retrieval, and dissemination of information on*
10 *health services research, clinical practice guidelines, and on*
11 *health care technology, including the assessment of such*
12 *technology. Such purpose includes developing and main-*
13 *taining data bases and developing and implementing meth-*
14 *ods of carrying out such purpose.*

15 *“(c) The Director of the Center shall ensure that infor-*
16 *mation under subsection (b) concerning clinical practice*
17 *guidelines is collected and maintained electronically and in*
18 *a convenient format. Such Director shall develop and pub-*
19 *lish criteria for the inclusion of practice guidelines and*
20 *technology assessments in the information center database.*

21 *“(d) The Secretary, acting through the Center, shall*
22 *coordinate the activities carried out under this section*
23 *through the Center with related activities of the Adminis-*
24 *trator for Health Care Policy and Research.”.*

1 **SEC. 1422. CONFORMING PROVISIONS.**

2 (a) *IN GENERAL.*—Section 903 of the Public Health
3 Service Act, as amended by section 3 of Public Law 102–
4 410 (106 Stat. 2094), is amended to read as follows:

5 “(e) *REQUIRED INTERAGENCY AGREEMENT.*—The Ad-
6 ministrator and the Director of the National Library of
7 Medicine shall enter into an agreement providing for the
8 implementation of section 478A.”.

9 (b) *RULE OF CONSTRUCTION.*—The amendments made
10 by section 3 of Public Law 102–410 (106 Stat. 2094), by
11 section 1421 of this Act, and by subsection (a) of this section
12 may not be construed as terminating the information center
13 on health care technologies and health care technology as-
14 sessment established under section 904 of the Public Health
15 Service Act, as in effect on the day before the date of the
16 enactment of Public Law 102–410. Such center shall be con-
17 sidered to be the center established in section 478A of the
18 Public Health Service Act, as added by section 1421 of this
19 Act, and shall be subject to the provisions of such section
20 478A.

1 **TITLE XV—OTHER AGENCIES OF**
2 **NATIONAL INSTITUTES OF**
3 **HEALTH**

4 **Subtitle A—Division of Research**
5 **Resources**

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

8 *Title IV of the Public Health Service Act (42 U.S.C.*
9 *281 et seq.) is amended—*

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

12 *“(B) The National Center for Research Re-*
13 *sources.”; and*

14 *(2) in part E—*

15 *(A) in the heading for subpart 1, by strik-*
16 *ing “Division of” and inserting “National Cen-*
17 *ter for”;*

18 *(B) in section 479, by striking “the Divi-*
19 *sion of Research Resources” and inserting the*
20 *following: “the National Center for Research Re-*
21 *sources (hereafter in this subpart referred to as*
22 *the ‘Center’)”;*

23 *(C) in sections 480 and 481, by striking*
24 *“the Division of Research Resources” each place*

1 *such term appears and inserting “the Center”;*
 2 *and*

3 *(D) in sections 480 and 481, as amended by*
 4 *subparagraph (C), by striking “the Division”*
 5 *each place such term appears and inserting “the*
 6 *Center”.*

7 ***SEC. 1502. BIOMEDICAL AND BEHAVIORAL RESEARCH FA-***
 8 ***CILITIES.***

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

12 *“BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES*
 13 *“SEC. 481A. (a) MODERNIZATION AND CONSTRUCTION*
 14 *OF FACILITIES.—*

15 *“(1) IN GENERAL.—The Director of NIH, acting*
 16 *through the Director of the Center, may make grants*
 17 *to public and nonprofit private entities to expand, re-*
 18 *model, renovate, or alter existing research facilities or*
 19 *construct new research facilities, subject to the provi-*
 20 *sions of this section.*

21 *“(2) CONSTRUCTION AND COST OF CONSTRU-*
 22 *CTION.—For purposes of this section, the terms ‘con-*
 23 *struction’ and ‘cost of construction’ include the con-*
 24 *struction of new buildings and the expansion, renova-*
 25 *tion, remodeling, and alteration of existing buildings,*

1 *including architects' fees, but do not include the cost*
2 *of acquisition of land or off-site improvements.*

3 *“(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS*
4 *FOR MERIT-BASED REVIEW OF PROPOSALS.—*

5 *“(1) IN GENERAL; APPROVAL AS PRECONDITION*
6 *TO GRANTS.—*

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

12 *“(B) The Director of the Center may ap-*
13 *prove an application for a grant under sub-*
14 *section (a) only if the Board has under para-*
15 *graph (2) recommended the application for ap-*
16 *proval.*

17 *“(2) DUTIES.—*

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

23 *“(B) In carrying out subparagraph (A), the*
24 *Board shall make a determination of the merit*
25 *of each application submitted for a grant under*

1 *subsection (a), after consideration of the require-*
2 *ments established in subsection (c), and shall re-*
3 *port the results of the determination to the Direc-*
4 *tor of the Center and the Advisory Council. Such*
5 *determinations shall be conducted in a manner*
6 *consistent with procedures established under sec-*
7 *tion 492.*

8 *“(C) In carrying out subparagraph (A), the*
9 *Board shall, in the case of applications rec-*
10 *ommended for approval, make recommendations*
11 *to the Director and the Advisory Council on the*
12 *amount that should be provided in the grant.*

13 *“(D) In carrying out subparagraph (A), the*
14 *Board shall prepare an annual report for the Di-*
15 *rector of the Center and the Advisory Council de-*
16 *scribing the activities of the Board in the fiscal*
17 *year for which the report is made. Each such re-*
18 *port shall be available to the public, and shall—*

19 *“(i) summarize and analyze expendi-*
20 *tures made under this section;*

21 *“(ii) provide a summary of the types,*
22 *numbers, and amounts of applications that*
23 *were recommended for grants under sub-*
24 *section (a) but that were not approved by*
25 *the Director of the Center; and*

1 “(iii) contain the recommendations of
2 the Board for any changes in the adminis-
3 tration of this section.

4 “(3) MEMBERSHIP.—

5 “(A) Subject to subparagraph (B), the
6 Board shall be composed of such appointed and
7 ex officio members as the Director of the Center
8 may determine.

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

12 “(C) Of the members of the Board—

13 “(i) 12 shall be appointed by the Di-
14 rector of the Center (without regard to the
15 civil service laws); and

16 “(ii) 1 shall be an official of the Na-
17 tional Science Foundation designated by the
18 National Science Board.

19 “(4) CERTAIN REQUIREMENTS REGARDING MEM-
20 BERSHIP.—In selecting individuals for membership
21 on the Board, the Director of the Center shall ensure
22 that the members are individuals who, by the virtue
23 of their training or experience, are eminently quali-
24 fied to perform peer review functions. In selecting
25 such individuals for such membership, the Director of

1 *the Center shall ensure that the members of the Board*
2 *collectively—*

3 “(A) *are experienced in the planning, con-*
4 *struction, financing, and administration of enti-*
5 *ties that conduct biomedical or behavioral re-*
6 *search sciences;*

7 “(B) *are knowledgeable in making deter-*
8 *minations of the need of entities for biomedical*
9 *or behavioral research facilities, including such*
10 *facilities for the dentistry, nursing, pharmacy,*
11 *and allied health professions;*

12 “(C) *are knowledgeable in evaluating the*
13 *relative priorities for applications for grants*
14 *under subsection (a) in view of the overall re-*
15 *search needs of the United States; and*

16 “(D) *are experienced with emerging centers*
17 *of excellence, as described in subsection (c)(3).*

18 “(5) *CERTAIN AUTHORITIES.—*

19 “(A) *In carrying out paragraph (2), the*
20 *Board may establish subcommittees, convene*
21 *workshops and conferences, and collect data as*
22 *the Board considers appropriate.*

23 “(B) *In carrying out paragraph (2), the*
24 *Board may establish subcommittees within the*
25 *Board. Such subcommittees may hold meetings*

1 *as determined necessary to enable the sub-*
2 *committee to carry out its duties.*

3 “(6) *TERMS.—*

4 “(A) *Except as provided in subparagraph*
5 *(B), each appointed member of the Board shall*
6 *hold office for a term of 4 years. Any member*
7 *appointed to fill a vacancy occurring prior to*
8 *the expiration of the term for which such mem-*
9 *ber’s predecessor was appointed shall be ap-*
10 *pointed for the remainder of the term of the*
11 *predecessor.*

12 “(B) *Of the initial members appointed to*
13 *the Board (as specified by the Director of the*
14 *Center when making the appointments)—*

15 “(i) *3 shall hold office for a term of 3*
16 *years;*

17 “(ii) *3 shall hold office for a term of 2*
18 *years; and*

19 “(iii) *3 shall hold office for a term of*
20 *1 year.*

21 “(C) *No member is eligible for reappoint-*
22 *ment to the Board until 1 year has elapsed after*
23 *the end of the most recent term of the member.*

24 “(7) *COMPENSATION.—Members of board who*
25 *are not officers or employees of the United States*

1 *shall receive compensation for each day engaged in*
2 *carrying out the duties of the board, including time*
3 *engaged in traveling for purposes of such duties. Such*
4 *compensation may not be provided in an amount in*
5 *excess of the maximum rate of basic pay payable for*
6 *GS-18 of the General Schedule.*

7 *“(c) REQUIREMENTS FOR GRANTS.—*

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

11 *“(A) The applicant is determined by such*
12 *Director to be competent to engage in the type of*
13 *research for which the proposed facility is to be*
14 *constructed.*

15 *“(B) The applicant provides assurances sat-*
16 *isfactory to the Director that—*

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

21 *“(ii) sufficient funds will be available*
22 *to meet the non-Federal share of the cost of*
23 *constructing the facility;*

24 *“(iii) sufficient funds will be available,*
25 *when construction is completed, for the ef-*

1 *fective use of the facility for the research for*
2 *which it is being constructed; and*

3 *“(iv) the proposed construction will ex-*
4 *pend the applicant’s capacity for research,*
5 *or is necessary to improve or maintain the*
6 *quality of the applicant’s research.*

7 *“(C) The applicant meets reasonable quali-*
8 *fications established by the Director with respect*
9 *to—*

10 *“(i) the relative scientific and technical*
11 *merit of the applications, and the relative*
12 *effectiveness of the proposed facilities, in ex-*
13 *anding the capacity for biomedical or be-*
14 *havioral research and in improving the*
15 *quality of such research;*

16 *“(ii) the quality of the research or*
17 *training, or both, to be carried out in the*
18 *facilities involved;*

19 *“(iii) the need of the applicant for such*
20 *facilities in order to maintain or expand*
21 *the applicant’s research and training mis-*
22 *sion;*

23 *“(iv) the congruence of the research ac-*
24 *tivities to be carried out within the facility*

1 with the research and investigator man-
2 power needs of the United States; and

3 “(v) the age and condition of existing
4 research facilities and equipment.

5 “(D) The applicant has demonstrated a
6 commitment to enhancing and expanding the re-
7 search productivity of the applicant.

8 “(2) CONSIDERATION OF CERTAIN FACTORS.—In
9 making grants under subsection (a), the Director of
10 the Center may, in addition to the requirements es-
11 tablished in paragraph (1), consider the following fac-
12 tors:

13 “(A) To what extent the applicant has the
14 capacity to broaden the scope of research and re-
15 search training programs of the applicant by
16 promoting—

17 “(i) interdisciplinary research;

18 “(ii) research on emerging technologies,
19 including those involving novel analytical
20 techniques or computational methods; or

21 “(iii) other novel research mechanisms
22 or programs.

23 “(B) To what extent the applicant has
24 broadened the scope of research and research
25 training programs of qualified institutions by

1 *promoting genomic research with an emphasis*
2 *on interdisciplinary research, including research*
3 *related to pediatric investigations.*

4 “(3) *INSTITUTIONS OF EMERGING EXCEL-*
5 *LLENCE.—Of the amounts appropriated under sub-*
6 *section (i) for a fiscal year, the Director of the Center*
7 *shall make available 25 percent for grants under sub-*
8 *section (a) to applicants that, in addition to meeting*
9 *the requirements established in paragraph (1), have*
10 *demonstrated emerging excellence in biomedical or be-*
11 *havioral research, as follows:*

12 “(A) *The applicant has a plan for research*
13 *or training advancement and possesses the abil-*
14 *ity to carry out the plan.*

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

19 “(C) *The applicant has been productive in*
20 *research or research development and training.*

21 “(D) *The applicant—*

22 “(i) *has been designated as a center of*
23 *excellence under section 739;*

24 “(ii) *is located in a geographic area a*
25 *significant percentage of whose population*

1 *has a health-status deficit, and the appli-*
2 *cant provides health services to such popu-*
3 *lation; or*

4 “(iii) *is located in a geographic area*
5 *in which a deficit in health care technology,*
6 *services, or research resources may adversely*
7 *affect health status of the population of the*
8 *area in the future, and the applicant is car-*
9 *rying out activities with respect to protect-*
10 *ing the health status of such population.*

11 “(d) *REQUIREMENT OF APPLICATION.—The Director*
12 *of the Center may make a grant under subsection (a) only*
13 *if an application for the grant is submitted to the Director*
14 *and the application is in such form, is made in such man-*
15 *ner, and contains such agreements, assurances, and infor-*
16 *mation as the Director determines to be necessary to carry*
17 *out this section.*

18 “(e) *AMOUNT OF GRANT; PAYMENTS.—*

19 “(1) *AMOUNT.—The amount of any grant*
20 *awarded under subsection (a) shall be determined by*
21 *the Director of the Center, except that such amount*
22 *shall not exceed—*

23 “(A) *50 percent of the necessary cost of the*
24 *construction of a proposed facility as determined*
25 *by the Director; or*

1 “(B) *in the case of a multipurpose facility,*
2 *40 percent of that part of the necessary cost of*
3 *construction that the Director determines to be*
4 *proportionate to the contemplated use of the fa-*
5 *cility.*

6 “(2) *RESERVATION OF AMOUNTS.—On approval*
7 *of any application for a grant under subsection (a),*
8 *the Director of the Center shall reserve, from any ap-*
9 *propriation available therefore, the amount of such*
10 *grant, and shall pay such amount, in advance or by*
11 *way of reimbursement, and in such installments con-*
12 *sistent with the construction progress, as the Director*
13 *may determine appropriate. The reservation of the*
14 *Director of any amount by the Director under this*
15 *paragraph may be amended by the Director, either on*
16 *the approval of an amendment of the application or*
17 *on the revision of the estimated cost of construction*
18 *of the facility.*

19 “(3) *EXCLUSION OF CERTAIN COSTS.—In deter-*
20 *mining the amount of any grant under this sub-*
21 *section (a), there shall be excluded from the cost of*
22 *construction an amount equal to the sum of—*

23 “(A) *the amount of any other Federal grant*
24 *that the applicant has obtained, or is assured of*
25 *obtaining, with respect to construction that is to*

1 *be financed in part by a grant authorized under*
2 *this section; and*

3 “(B) *the amount of any non-Federal funds*
4 *required to be expended as a condition of such*
5 *other Federal grant.*

6 “(4) *WAIVER OF LIMITATIONS.—The limitations*
7 *imposed by paragraph (1) may be waived at the dis-*
8 *cretion of the Director for applicants meeting the con-*
9 *ditions described in paragraphs (1) and (2) of sub-*
10 *section (c).*

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

14 “(1) *the applicant or other owner of the facility*
15 *shall cease to be a public or nonprofit private entity;*
16 *or*

17 “(2) *the facility shall cease to be used for the re-*
18 *search purposes for which it was constructed (unless*
19 *the Director determines, in accordance with regula-*
20 *tions, that there is good cause for releasing the appli-*
21 *cant or other owner from obligation to do so);*

22 *the United States shall be entitled to recover from the appli-*
23 *cant or other owner of the facility the amount bearing the*
24 *same ratio to the current value (as determined by an agree-*
25 *ment between the parties or by action brought in the United*

1 *States District Court for the district in which such facility*
2 *is situated) of the facility as the amount of the Federal par-*
3 *ticipation bore to the cost of the construction of such*
4 *facility.*

5 “(g) *NONINTERFERENCE WITH ADMINISTRATION OF*
6 *ENTITIES.—Except as otherwise specifically provided in*
7 *this section, nothing contained in this part shall be con-*
8 *strued as authorizing any department, agency, officer, or*
9 *employee of the United States to exercise any direction, su-*
10 *pervision, or control over, or impose any requirement or*
11 *condition with respect to the administration of any entity*
12 *funded under this part.*

13 “(h) *GUIDELINES.—Not later than 6 months after the*
14 *date of the enactment of this section, the Director of the*
15 *Center, after consultation with the Advisory Council, shall*
16 *issue guidelines with respect to grants under subsection (a).*

17 “(i) *AUTHORIZATION OF APPROPRIATIONS.—For the*
18 *purpose of carrying out this section, there are authorized*
19 *to be appropriated \$150,000,000 for fiscal year 1994, and*
20 *such sums as may be necessary for each of the fiscal years*
21 *1995 and 1996.”.*

1 **SEC. 1503. CONSTRUCTION PROGRAM FOR NATIONAL PRI-**
2 **MATE RESEARCH CENTER.**

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

6 *“CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH*
7 *ON PRIMATES*

8 *“SEC. 481B. (a) With respect to activities carried out*
9 *by the National Center for Research Resources to support*
10 *regional centers for research on primates, the Director of*
11 *NIH shall, for each of the fiscal years 1994 through 1996,*
12 *reserve from the amounts appropriated under section*
13 *481A(i) \$7,000,000 for the purpose of making awards of*
14 *grants and contracts to public or nonprofit private entities*
15 *to construct, renovate, or otherwise improve such regional*
16 *centers. The reservation of such amounts for any fiscal year*
17 *is subject to the availability of qualified applicants for such*
18 *awards.*

19 *“(b) The Director of NIH may not make a grant or*
20 *enter into a contract under subsection (a) unless the appli-*
21 *cant for such assistance agrees, with respect to the costs to*
22 *be incurred by the applicant in carrying out the purpose*
23 *described in such subsection, to make available (directly or*
24 *through donations from public or private entities) non-Fed-*
25 *eral contributions in cash toward such costs in an amount*

1 *equal to not less than \$1 for each \$4 of Federal funds pro-*
 2 *vided in such assistance.”.*

3 ***Subtitle B—National Center for***
 4 ***Nursing Research***

5 ***SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR***
 6 ***NURSING RESEARCH AS NATIONAL INSTI-***
 7 ***TUTE OF NURSING RESEARCH.***

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

11 (1) *in section 483—*

12 (A) *in the heading for the section, by strik-*
 13 *ing “CENTER” and inserting “INSTITUTE”; and*

14 (B) *by striking “The general purpose” and*
 15 *all that follows through “is” and inserting the*
 16 *following: “The general purpose of the National*
 17 *Institute of Nursing Research (hereafter in this*
 18 *subpart referred to as the ‘Institute’) is”;*

19 (2) *in section 484, by striking “Center” each*
 20 *place such term appears and inserting “Institute”;*

21 (3) *in section 485—*

22 (A) *in subsection (a), in each of paragraphs*
 23 *(1) through (3), by striking “Center” each place*
 24 *such term appears and inserting “Institute”;*

25 (B) *in subsection (b)—*

1 (i) in paragraph (2)(A), by striking
2 “Center” and inserting “Institute”; and

3 (ii) in paragraph (3)(A), in the first
4 sentence, by striking “Center” and inserting
5 “Institute”; and

6 (C) in subsections (d) through (g), by strik-
7 ing “Center” each place such term appears and
8 inserting “Institute”; and

9 (4) in section 485A (as redesignated by section
10 141(a)(1) of this Act), by striking “Center” each place
11 such term appears and inserting “Institute”.

12 (b) CONFORMING AMENDMENTS.—

13 (1) ORGANIZATION OF NATIONAL INSTITUTE OF
14 HEALTH.—Section 401(b) of the Public Health Serv-
15 ice Act (42 U.S.C. 281(b)) is amended—

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

18 “(Q) The National Institute of Nursing Re-
19 search.”; and

20 (B) in paragraph (2), by striking subpara-
21 graph (D).

22 (2) TRANSFER OF STATUTORY PROVISIONS.—Sec-
23 tions 483 through 485A of the Public Health Service
24 Act, as amended by subsection (a) of this section—

1 (C) in section 464Y, in the last sentence, by
2 striking “section 485(g)” and inserting “section
3 464X(g)”.

4 **SEC. 1512. STUDY ON ADEQUACY OF NUMBER OF NURSES.**

5 (a) *IN GENERAL.*—The Secretary of Health and
6 Human Services, acting through the Director of the Na-
7 tional Institute of Nursing Research, shall enter into a con-
8 tract with a public or nonprofit private entity to conduct
9 a study for the purpose of determining whether and to what
10 extent there is a need for an increase in the number of
11 nurses in hospitals and nursing homes in order to promote
12 the quality of patient care and reduce the incidence among
13 nurses of work-related injuries and stress.

14 (b) *NATIONAL ACADEMY OF SCIENCES.*—The Secretary
15 shall request the National Academy of Sciences to enter into
16 the contract under subsection (a) to conduct the study de-
17 scribed in such subsection. If such Institute declines to con-
18 duct the study, the Secretary shall carry out such subsection
19 through another public or nonprofit private entity.

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

21 (1) The term “nurse” means a registered nurse,
22 a licensed practical nurse, a licensed vocational
23 nurse, and a nurse assistant.

24 (2) The term “Secretary” means the Secretary of
25 Health and Human Services.

1 *ture and function of the human genome, including the map-*
2 *ping and sequencing of individual genes. Such purpose in-*
3 *cludes—*

4 “(1) *planning and coordinating the research goal*
5 *of the genome project;*

6 “(2) *reviewing and funding research proposals;*

7 “(3) *developing training programs;*

8 “(4) *coordinating international genome research;*

9 “(5) *communicating advances in genome science*
10 *to the public; and*

11 “(6) *reviewing and funding proposals to address*
12 *the ethical issues associated with the genome project.*

13 “(b)(1) *Except as provided in paragraph (2), of the*
14 *amounts appropriated to carry out subsection (a) for a fis-*
15 *cal year, the Director of the Center shall make available*
16 *not less than 5 percent for carrying out paragraph (6) of*
17 *such subsection.*

18 “(2) *With respect to providing funds under subsection*
19 *(a)(6) for proposals to address the ethical issues associated*
20 *with the genome project, paragraph (1) shall not apply for*
21 *a fiscal year if the Director of the Center certifies to the*
22 *Committee on Energy and Commerce of the House of Rep-*
23 *resentatives, and to the Committee on Labor and Human*
24 *Resources of the Senate, that the Director has determined*

1 *that an insufficient number of such proposals meet the ap-*
2 *plicable requirements of sections 491 and 492.”.*

3 **TITLE XVI—AWARDS AND**
4 **TRAINING**
5 **Subtitle A—National Research**
6 **Service Awards**

7 **SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDI-**
8 **VIDUALS FROM DISADVANTAGED BACK-**
9 **GROUNDS.**

10 *Section 487(a) of the Public Health Service Act (42*
11 *U.S.C. 288(a)(4)) is amended by adding at the end the fol-*
12 *lowing paragraph:*

13 “(4) *The Secretary shall carry out paragraph (1) in*
14 *a manner that will result in the recruitment of women, and*
15 *members from underrepresented minority groups, into fields*
16 *of biomedical or behavioral research and in the provision*
17 *of research training to women and such individuals.”.*

18 **SEC. 1602. SERVICE PAYBACK REQUIREMENTS.**

19 *Paragraph (2) of section 487(c) of the Public Health*
20 *Service Act (42 U.S.C. 288(c)(2)) is amended to read as*
21 *follows:*

22 “(2)(A) *For the initial year for which an individual*
23 *receives a National Research Service Award for the conduct*
24 *of postdoctoral training or research, such individual shall*
25 *engage in one year of health research or teaching or any*

1 combination thereof which is in accordance with the usual
 2 patterns of academic employment, or complete a second
 3 year of training or research under such Award.

4 “(B) Service obligations for National Research Service
 5 Awards that are less than 12 months may be satisfied—

6 “(i) by the conduct of health research or teaching
 7 or any combination thereof which is in accordance
 8 with the usual patterns of academic employment for
 9 a period of time equal to the amount of time under
 10 the Award; or

11 “(ii) by reimbursing the Federal Government for
 12 the amounts provided to such individual under the
 13 Award.”.

14 **Subtitle B—Acquired Immune**
 15 **Deficiency Syndrome**

16 **SEC. 1611. LOAN REPAYMENT PROGRAM.**

17 Section 487A of the Public Health Service Act (42
 18 U.S.C. 288–1) is amended to read as follows:

19 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
 20 RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

21 “SEC. 487A. (a) IN GENERAL.—

22 “(1) AUTHORITY FOR PROGRAM.—Subject to
 23 paragraph (2), the Secretary shall carry out a pro-
 24 gram of entering into agreements with appropriately
 25 qualified health professionals under which such health
 26 professionals agree to conduct, as employees of the Na-

1 *tional Institutes of Health, research with respect to*
2 *acquired immune deficiency syndrome in consider-*
3 *ation of the Federal Government agreeing to repay,*
4 *for each year of such service, not more than \$20,000*
5 *of the principal and interest of the educational loans*
6 *of such health professionals.*

7 “(2) *LIMITATION.—The Secretary may not enter*
8 *into an agreement with a health professional pursu-*
9 *ant to paragraph (1) unless such professional—*

10 “(A) *has a substantial amount of edu-*
11 *cational loans relative to income; and*

12 “(B)(i) *was not employed at the National*
13 *Institutes of Health during the 1-year period*
14 *preceding the date of the enactment of the Health*
15 *Professions Reauthorization Act of 1988; or*

16 “(ii) *agrees to serve as an employee of such*
17 *Institutes for purposes of paragraph (1) for a pe-*
18 *riod of not less than 3 years.”.*

19 “(b) *APPLICABILITY OF CERTAIN PROVISIONS.—With*
20 *respect to the National Health Service Corps Loan Repay-*
21 *ment Program established in subpart III of part D of title*
22 *III, the provisions of such subpart shall, except as inconsis-*
23 *tent with subsection (a) of this section, apply to the program*
24 *established in such subsection (a) in the same manner and*
25 *to the same extent as such provisions apply to the National*

1 *Health Service Corps Loan Repayment Program established*
2 *in such subpart.*

3 “(c) *FUNDING; REIMBURSABLE TRANSFERS.*—

4 “(1) *AUTHORIZATION OF APPROPRIATIONS.*—*For*
5 *the purpose of carrying out this section, there are au-*
6 *thorized to be appropriated such sums as may be nec-*
7 *essary for each of the fiscal years 1994 through 1996.*

8 “(2) *TRANSFERS FOR RELATED PROGRAM.*—*The*
9 *Commissioner of Food and Drugs may carry out for*
10 *the Food and Drug Administration a program simi-*
11 *lar to the program established in subsection (a),*
12 *which program shall be carried out with respect to the*
13 *review of applications concerning acquired immune*
14 *deficiency syndrome that are submitted to such Com-*
15 *missioner. From the amounts appropriated under*
16 *paragraph (1) for a fiscal year, the Secretary may*
17 *transfer amounts to the Commissioner for the purpose*
18 *of carrying out such program. The Commissioner*
19 *shall provide a reimbursement to the Secretary for the*
20 *amount so transferred, and the reimbursement shall*
21 *be available only for the program established in sub-*
22 *section (a). Any transfer and reimbursement made for*
23 *purposes of this paragraph for a fiscal year shall be*
24 *completed by April 1 of such year.”.*

1 **Subtitle C—Loan Repayment for**
2 **Research Generally**

3 **SEC. 1621. ESTABLISHMENT OF PROGRAM.**

4 *Part G of title IV of the Public Health Service Act,*
5 *as redesignated by section 141(a)(2) of this Act and as*
6 *amended by section 1002 of this Act, is amended by insert-*
7 *ing after section 487B the following new section:*

8 “*LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY*

9 “*SEC. 487C. (a) IN GENERAL.—*

10 “(1) *AUTHORITY FOR PROGRAM.—Subject to*
11 *paragraph (2), the Secretary shall carry out a pro-*
12 *gram of entering into agreements with appropriately*
13 *qualified health professionals under which such health*
14 *professionals agree to conduct research, as employees*
15 *of the National Institutes of Health, in consideration*
16 *of the Federal Government agreeing to repay, for each*
17 *year of such service, not more than \$20,000 of the*
18 *principal and interest of the educational loans of such*
19 *health professionals.*

20 “(2) *LIMITATION.—The Secretary may not enter*
21 *into an agreement with a health professional pursu-*
22 *ant to paragraph (1) unless such professional—*

23 “(A) *has a substantial amount of edu-*
24 *cational loans relative to income; and*

1 “(B)(i) was not employed at the National
2 Institutes of Health during the 1-year period
3 preceding the date of the enactment of the Health
4 Professions Reauthorization Act of 1988; or

5 “(ii) agrees to serve as an employee of such
6 Institutes for purposes of paragraph (1) for a pe-
7 riod of not less than 3 years.”.

8 “(b) *APPLICABILITY OF CERTAIN PROVISIONS.*—With
9 respect to the National Health Service Corps Loan Repay-
10 ment Program established in subpart III of part D of title
11 III, the provisions of such subpart shall, except as inconsis-
12 tent with subsection (a) of this section, apply to the program
13 established in such subsection (a) in the same manner and
14 to the same extent as such provisions apply to the National
15 Health Service Corps Loan Repayment Program established
16 in such subpart.

17 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—For the
18 purpose of carrying out this section other than with respect
19 to acquired immune deficiency syndrome, there are author-
20 ized to be appropriated such sums as may be necessary for
21 each of the fiscal years 1994 through 1996.”.

1 ***Subtitle D—Scholarship and Loan***
2 ***Repayment Programs Regarding***
3 ***Professional Skills Needed by***
4 ***Certain Agencies***

5 ***SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL***
6 ***INSTITUTES OF HEALTH.***

7 *Part G of title IV of the Public Health Service Act,*
8 *as redesignated by section 141(a)(2) of this Act and as*
9 *amended by section 1621 of this Act, is amended by insert-*
10 *ing after section 487C the following new sections:*

11 *“UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING*
12 *PROFESSIONS NEEDED BY NATIONAL RESEARCH IN-*
13 *STITUTES*

14 *“SEC. 487D. (a) ESTABLISHMENT OF PROGRAM.—*

15 *“(1) IN GENERAL.—Subject to section*
16 *487(a)(1)(C), the Secretary, acting through the Direc-*
17 *tor of NIH, may carry out a program of entering into*
18 *contracts with individuals described in paragraph (2)*
19 *under which—*

20 *“(A) the Director of NIH agrees to provide*
21 *to the individuals scholarships for pursuing, as*
22 *undergraduates at accredited institutions of*
23 *higher education, academic programs appro-*
24 *priate for careers in professions needed by the*
25 *National Institutes of Health; and*

1 “(B) the individuals agree to serve as em-
2 ployees of the National Institutes of Health, for
3 the period described in subsection (c), in posi-
4 tions that are needed by the National Institutes
5 of Health and for which the individuals are
6 qualified.

7 “(2) INDIVIDUALS FROM DISADVANTAGED BACK-
8 GROUND^S.—The individuals referred to in paragraph
9 (1) are individuals who—

10 “(A) are enrolled or accepted for enrollment
11 as full-time undergraduates at accredited institu-
12 tions of higher education; and

13 “(B) are from minority groups that are
14 underrepresented in the fields of biomedical or
15 behavioral research.

16 “(b) FACILITATION OF INTEREST OF STUDENTS IN CA-
17 REERS AT NATIONAL INSTITUTES OF HEALTH.—In provid-
18 ing employment to individuals pursuant to contracts under
19 subsection (a)(1), the Director of NIH shall carry out ac-
20 tivities to facilitate the interest of the individuals in pursu-
21 ing careers as employees of the National Institutes of
22 Health.

23 “(c) PERIOD OF OBLIGATED SERVICE.—

24 “(1) DURATION OF SERVICE.—For purposes of
25 subparagraph (B) of subsection (a)(1), the period of

1 *service for which an individual is obligated to serve*
2 *as an employee of the National Institutes of Health*
3 *is 12 months for each academic year for which the*
4 *scholarship under such subsection is provided.*

5 *“(2) SCHEDULE FOR SERVICE.—*

6 *“(A) Subject to subparagraph (B), the Di-*
7 *rector of NIH may not provide a scholarship*
8 *under subsection (a) unless the individual apply-*
9 *ing for the scholarship agrees that—*

10 *“(i) the individual will serve as an em-*
11 *ployee of the National Institutes of Health*
12 *full-time for not less than 10 consecutive*
13 *weeks of each year during which the indi-*
14 *vidual is attending the educational institu-*
15 *tion involved and receiving such a scholar-*
16 *ship;*

17 *“(ii) the period of service as such an*
18 *employee that the individual is obligated to*
19 *provide under clause (i) is in addition to*
20 *the period of service as such an employee*
21 *that the individual is obligated to provide*
22 *under subsection (a)(1)(B); and*

23 *“(iii) not later than 60 days after ob-*
24 *taining the educational degree involved, the*
25 *individual will begin serving full-time as*

1 *such an employee in satisfaction of the pe-*
2 *riod of service that the individual is obli-*
3 *gated to provide under subsection (a)(1)(B).*

4 *“(B) The Director of NIH may defer the ob-*
5 *ligation of an individual to provide a period of*
6 *service under subsection (a)(1)(B), if the Direc-*
7 *tor determines that such a deferral is appro-*
8 *priate.*

9 *“(3) APPLICABILITY OF CERTAIN PROVISIONS RE-*
10 *LATING TO APPOINTMENT AND COMPENSATION.—For*
11 *any period in which an individual provides service as*
12 *an employee of the National Institutes of Health in*
13 *satisfaction of the obligation of the individual under*
14 *subsection (a)(1)(B) or paragraph (2)(A)(i), the indi-*
15 *vidual may be appointed as such an employee with-*
16 *out regard to the provisions of title 5, United States*
17 *Code, relating to appointment and compensation.*

18 *“(d) PROVISIONS REGARDING SCHOLARSHIP.—*

19 *“(1) APPROVAL OF ACADEMIC PROGRAM.—The*
20 *Director of NIH may not provide a scholarship under*
21 *subsection (a) for an academic year unless—*

22 *“(A) the individual applying for the schol-*
23 *arship has submitted to the Director a proposed*
24 *academic program for the year and the Director*
25 *has approved the program; and*

1 “(B) the individual agrees that the program
2 will not be altered without the approval of the
3 Director.

4 “(2) *ACADEMIC STANDING.*—The Director of
5 NIH may not provide a scholarship under subsection
6 (a) for an academic year unless the individual apply-
7 ing for the scholarship agrees to maintain an accept-
8 able level of academic standing, as determined by the
9 educational institution involved in accordance with
10 regulations issued by the Secretary.

11 “(3) *LIMITATION ON AMOUNT.*—The Director of
12 NIH may not provide a scholarship under subsection
13 (a) for an academic year in an amount exceeding
14 \$20,000.

15 “(4) *AUTHORIZED USES.*—A scholarship pro-
16 vided under subsection (a) may be expended only for
17 tuition expenses, other reasonable educational ex-
18 penses, and reasonable living expenses incurred in at-
19 tending the school involved.

20 “(5) *CONTRACT REGARDING DIRECT PAYMENTS*
21 *TO INSTITUTION.*—In the case of an institution of
22 higher education with respect to which a scholarship
23 under subsection (a) is provided, the Director of NIH
24 may enter into a contract with the institution under
25 which the amounts provided in the scholarship for

1 *tuition and other educational expenses are paid di-*
2 *rectly to the institution. Payments to the institution*
3 *under the contract may be made without regard to*
4 *section 3324 of title 31, United States Code.*

5 “(e) *PENALTIES FOR BREACH OF SCHOLARSHIP CON-*
6 *TRACT.—The provisions of section 338E shall apply to the*
7 *program established in subsection (a) to the same extent*
8 *and in the same manner as such provisions apply to the*
9 *National Health Service Corps Loan Repayment Program*
10 *established in section 338B.*

11 “(f) *REQUIREMENT OF APPLICATION.—The Director of*
12 *NIH may not provide a scholarship under subsection (a)*
13 *unless an application for the scholarship is submitted to*
14 *the Director and the application is in such form, is made*
15 *in such manner, and contains such agreements, assurances,*
16 *and information as the Director determines to be necessary*
17 *to carry out this section.*

18 “(g) *AVAILABILITY OF AUTHORIZATION OF APPRO-*
19 *PRIATIONS.—Amounts appropriated for a fiscal year for*
20 *scholarships under this section shall remain available until*
21 *the expiration of the second fiscal year beginning after the*
22 *fiscal year for which the amounts were appropriated.*

23 “*LOAN REPAYMENT PROGRAM REGARDING CLINICAL*
24 *RESEARCHERS FROM DISADVANTAGED BACKGROUNDS*

25 “*SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—*

1 “(1) *IN GENERAL.*—Subject to section
2 487(a)(1)(C), the Secretary, acting through the Direc-
3 tor of NIH may, subject to paragraph (2), carry out
4 a program of entering into contracts with appro-
5 priately qualified health professionals who are from
6 disadvantaged backgrounds under which such health
7 professionals agree to conduct clinical research as em-
8 ployees of the National Institutes of Health in consid-
9 eration of the Federal Government agreeing to pay,
10 for each year of such service, not more than \$20,000
11 of the principal and interest of the educational loans
12 of the health professionals.

13 “(2) *LIMITATION.*—The Director of NIH may
14 not enter into a contract with a health professional
15 pursuant to paragraph (1) unless such professional
16 has a substantial amount of education loans relative
17 to income.

18 “(3) *APPLICABILITY OF CERTAIN PROVISIONS RE-*
19 *GARDING OBLIGATED SERVICE.*—Except to the extent
20 inconsistent with this section, the provisions of sec-
21 tions 338C and 338E shall apply to the program es-
22 tablished in paragraph (1) to the same extent and in
23 the same manner as such provisions apply to the Na-
24 tional Health Service Corps Loan Repayment Pro-
25 gram established in section 338B.

1 *out this section, there are authorized to be appro-*
 2 *propriated \$400,000,000 for fiscal year 1994, and such*
 3 *sums as may be necessary for each of the fiscal years*
 4 *1995 and 1996.”; and*

5 *(2) in paragraph (3)—*

6 *(A) by striking “one-half of one percent”*
 7 *each place such term appears and inserting “1*
 8 *percent”;* and

9 *(B) by striking “780, 784, or 786” and in-*
 10 *serting “747, 748, or 749”.*

11 ***TITLE XVII—NATIONAL FOUNDA-***
 12 ***TION FOR BIOMEDICAL RE-***
 13 ***SEARCH***

14 ***SEC. 1701. ESTABLISHMENT OF FOUNDATION.***

15 *Section 499 of the Public Health Service Act, as reded-*
 16 *ignated by section 121(b), is amended to read as follows:*

17 ***“SEC. 499A. ESTABLISHMENT AND DUTIES OF FOUNDATION.***

18 *“(a) IN GENERAL.—The Secretary shall establish a*
 19 *nonprofit corporation to be known as the National Founda-*
 20 *tion for Biomedical Research (hereafter in this section re-*
 21 *ferred to as the ‘Foundation’). The Foundation shall not,*
 22 *except for the purposes of the Ethics in Government Act*
 23 *and the Technology Transfer Act, be an agency or instru-*
 24 *mentality of the United States Government.*

1 “(b) *PURPOSE OF FOUNDATION.*—The purpose of the
2 *Foundation shall be to conduct and support research with*
3 *respect to any particular disease or groups of diseases or*
4 *any other aspect of human health.*

5 “(c) *ENDOWMENT FUND.*—

6 “(1) *IN GENERAL.*—In carrying out subsection
7 *(b), the Foundation shall establish a fund whose pri-*
8 *mary purpose shall be to provide endowments for po-*
9 *sitions at the National Institutes of Health to conduct*
10 *biomedical research, and dedicated to the purpose de-*
11 *scribed in such subsection. Such positions may be held*
12 *by scientists without regard to whether the scientists*
13 *are employees of the Federal Government. Subject to*
14 *subsection (g)(1)(B), the fund shall consist of such do-*
15 *nations as may be provided by non-Federal entities*
16 *and such non-Federal assets of the Foundation (in-*
17 *cluding earnings of the Foundation and the fund) as*
18 *the Foundation may elect to transfer to the fund.*

19 “(2) *AUTHORIZED EXPENDITURES OF FUND.*—
20 *The provision of endowments under paragraph (1)*
21 *shall be the primary function of the fund established*
22 *under such paragraph. Such endowments may be ex-*
23 *pended only for the compensation of individuals hold-*
24 *ing the positions, for staff, equipment, quarters, trav-*
25 *el, and other expenditures that are appropriate in*

1 *supporting the positions, and for recruiting individ-*
2 *uals to hold the positions endowed by the fund.*

3 “(d) *CERTAIN ACTIVITIES OF FOUNDATION.*—*In car-*
4 *rying out subsection (b), and subject to subsection (c), the*
5 *Foundation may provide for the following with respect to*
6 *the purpose described in such subsection:*

7 “(1) *Endowed chairs for distinguished senior in-*
8 *vestigators.*

9 “(2) *Positions for support of visiting scientists*
10 *in mid-career who participate in the National Insti-*
11 *tutes of Health Scholars program.*

12 “(3) *Studies, projects, and research conducted by*
13 *scientists under paragraphs (1) and (2).*

14 “(4) *Forums for the exchange of information be-*
15 *tween scientists. Participants in such forums may in-*
16 *clude institutions of higher education and appro-*
17 *priate private and public organizations.*

18 “(5) *Meetings, conferences, courses, and training*
19 *workshops.*

20 “(6) *Programs to improve the collection and*
21 *analysis of data.*

22 “(7) *Programs for writing, editing, printing,*
23 *and publishing of books and other materials.*

24 “(8) *Other activities to carry out the purpose de-*
25 *scribed in subsection (b).*

1 “(e) *POWERS.*—*In carrying out subsection (b), the*
2 *Foundation shall—*

3 “(1) *operate under the direction of its Board;*

4 “(2) *adopt, alter, and use a corporate seal, which*
5 *shall be judicially noticed;*

6 “(3) *provide for 1 or more officers, employees,*
7 *and agents, as may be necessary, define their duties,*
8 *and require surety bonds or make other provisions*
9 *against losses occasioned by acts of such persons;*

10 “(4) *hire, promote, compensate, and discharge of-*
11 *ficers and employees of the Foundation;*

12 “(5) *prescribe by its Board its bylaws, as de-*
13 *scribed in subsection (g)(1)(A);*

14 “(6) *with the consent of any executive depart-*
15 *ment or independent agency, use the information,*
16 *services, staff, and facilities of such in carrying out*
17 *this section;*

18 “(7) *sue and be sued in its corporate name, and*
19 *complain and defend in courts of competent*
20 *jurisdiction;*

21 “(8) *modify or consent to the modification of*
22 *any contract or agreement to which it is a party or*
23 *in which it has an interest under this subtitle;*

24 “(9) *establish a mechanism for the selection of*
25 *candidates, subject to the approval of the Director of*

1 *the National Institutes of Health for the endowed sci-*
2 *entific positions within the organizational structure*
3 *of the intramural research programs of the National*
4 *Institutes of Health and candidates for participation*
5 *in the National Institutes of Health Scholars*
6 *program;*

7 “(10) enter into contracts with public and pri-
8 *vate organizations for the writing, editing, printing,*
9 *and publishing of books and other material;*

10 “(11) take such action as may be necessary to
11 *obtain patents and licenses for devices and procedures*
12 *developed by the Foundation and its employees;*

13 “(12) accept, hold, administer, invest, and spend
14 *any gift, devise, or bequest of real or personal prop-*
15 *erty made to the Foundation;*

16 “(13) enter into such other contracts, leases, co-
17 *operative agreements, and other transactions as the*
18 *Executive Director considers appropriate to conduct*
19 *the activities of the Foundation;*

20 “(14) appoint other groups of advisors as may be
21 *determined necessary from time to time to carry out*
22 *the functions of the Foundation; and*

23 “(15) exercise other powers as set forth in this
24 *section, and such other incidental powers as are nec-*

1 *essary to carry out its powers, duties, and functions*
2 *in accordance with this subtitle.*

3 “(f) *GENERAL STRUCTURE OF FOUNDATION; NON-*
4 *PROFIT STATUS.—*

5 “(1) *BOARD OF DIRECTORS.—The Foundation*
6 *shall have a board of directors (in this part referred*
7 *to as the ‘Board’), which shall be established and con-*
8 *ducted in accordance with subsection (g). The Board*
9 *shall establish the general policies of the Foundation*
10 *for carrying out subsection (b), including the estab-*
11 *lishment of the bylaws of the Foundation.*

12 “(2) *EXECUTIVE DIRECTOR.—The Foundation*
13 *shall have an executive director (in this part referred*
14 *to as the ‘Director’), who shall be appointed by the*
15 *Board, who shall serve at the pleasure of the Board,*
16 *and for whom the Board shall establish the rate of*
17 *compensation. Subject to compliance with the policies*
18 *and bylaws established by the Board pursuant to*
19 *paragraph (1), the Director shall be responsible for*
20 *the daily operations of the Foundation in carrying*
21 *out subsection (b).*

22 “(3) *NONPROFIT STATUS.—In carrying out sub-*
23 *section (b), the Board shall establish such policies and*
24 *bylaws under paragraph (1), and the Director shall*
25 *carry out such activities under paragraph (2), as*

1 *may be necessary to ensure that the Foundation*
2 *maintains status as an organization that—*

3 *“(A) is described in subsection (c)(3) of sec-*
4 *tion 501 of the Internal Revenue Code of 1986;*
5 *and*

6 *“(B) is, under subsection (a) of such section,*
7 *exempt from taxation.*

8 *“(4) LIAISON.—The Director of the National In-*
9 *stitutes of Health shall serve as the liaison representa-*
10 *tive of the National Institutes of Health to the Board*
11 *and the Foundation.*

12 *“(g) BOARD OF DIRECTORS.—*

13 *“(1) CERTAIN BYLAWS.—*

14 *“(A) In establishing bylaws under sub-*
15 *section (f)(1), the Board shall ensure that the by-*
16 *laws of the Foundation include bylaws for the*
17 *following:*

18 *“(i) Policies for the selection of the offi-*
19 *cers, employees, agents, and contractors of*
20 *the Foundation.*

21 *“(ii) Policies for the acquisition, hold-*
22 *ing, and transfer of property.*

23 *“(iii) Policies, including ethical stand-*
24 *ards, for the acceptance and disposition of*

1 *donations to the Foundation and for the*
2 *disposition of the assets of the Foundation.*

3 “(iv) *Policies for the conduct of the*
4 *general operations of the Foundation.*

5 “(v) *Policies for writing, editing,*
6 *printing, and publishing of books and other*
7 *materials, and the acquisition of patents*
8 *and licenses for devices and procedures de-*
9 *veloped by the Foundation.*

10 “(B) *In establishing bylaws under sub-*
11 *section (f)(1), the Board shall ensure that the by-*
12 *laws of the Foundation (and activities carried*
13 *out under the bylaws) do not—*

14 “(i) *reflect unfavorably upon the abil-*
15 *ity of the Foundation, or the National In-*
16 *stitutes of Health, to carry out its respon-*
17 *sibilities or official duties in a fair and ob-*
18 *jective manner; or*

19 “(ii) *compromise, or appear to com-*
20 *promise, the integrity of any governmental*
21 *program or any officer or employee involved*
22 *in such program.*

23 “(2) *COMPOSITION.—*

24 “(A) *The Foundation shall have a Board of*
25 *Directors (hereafter referred to in this section as*

1 the ‘Board’), which shall initially be composed of
2 ex officio and appointed members in accordance
3 with this subsection until such time as all the
4 appointed members, including the Chairperson,
5 are fully appointed by the Board under para-
6 graph (4).

7 “(B) The ex officio members of the Council
8 shall be—

9 “(i) the Chairperson and ranking mi-
10 nority member of the Subcommittee on
11 Health and the Environment (Committee on
12 Energy and Commerce) or their designees,
13 in the case of the House of Representatives;

14 “(ii) the Chairperson and ranking mi-
15 nority member of the Committee on Labor
16 and Human Resources or their designees, in
17 the case of the Senate; and

18 “(iii) the Director of the National In-
19 stitutes of Health.

20 “(C) The ex officio members of the Board
21 under subparagraph (B) shall appoint to the
22 Council 9 individuals. Of such appointed mem-
23 bers—

24 “(i) 4 shall be representative of the
25 general biomedical field;

1 “(ii) 2 shall be representatives of the
2 general biobehavioral field; and

3 “(iii) 3 shall be representatives of the
4 general public.

5 “(3) CHAIRPERSON.—The *ex officio* members of
6 the Board under paragraph (2)(B) shall designate an
7 appointed member of the Board to serve as the first
8 Chairperson of the Board. Subsequently, the Chair-
9 person of the Board shall be chosen by the Board ac-
10 cording to its bylaws.

11 “(4) APPOINTMENTS, VACANCIES, AND TERMS.—
12 The following shall apply to the Board:

13 “(A) Any vacancy in the membership of the
14 Board shall be filled by appointment by the
15 Board, after consideration of suggestions made
16 by the Chairperson and the Director regarding
17 the appointments. Any such vacancy shall be
18 filled not later than the expiration of the 180-
19 day period beginning on the date on which the
20 vacancy occurs.

21 “(B) The term of office of each member of
22 the Board appointed under subparagraph (A)
23 shall be 5 years, except that the terms of office
24 for the initial appointed members of the Board
25 shall expire as determined by the Chairperson of

1 *the Board, in consultation with the Director of*
2 *the National Institutes of Health.*

3 “(C) A vacancy in the membership of the
4 Board shall not affect the power of the Board to
5 carry out the duties of the Board. If a member
6 of the Board does not serve the full term applica-
7 ble under subparagraph (B), the individual ap-
8 pointed to fill the resulting vacancy shall be ap-
9 pointed for the remainder of the term of the
10 predecessor of the individual.

11 “(5) COMPENSATION.—Members of the Board
12 may not receive compensation for service on the
13 Board. Such members may be reimbursed for travel,
14 subsistence, and other necessary expenses incurred in
15 carrying out the duties of the Board, as set forth in
16 the bylaws issued by the Board.

17 “(h) INCORPORATION.—The initial members of the
18 Board shall serve as incorporators and shall take whatever
19 actions necessary to incorporate the Foundation.

20 “(i) GENERAL PROVISIONS.—

21 “(1) ADMINISTRATIVE CONTROL.—No officer, em-
22 ployee, or member of the Board of the Foundation
23 may exercise any administrative or managerial con-
24 trol over any Federal employee.

1 “(2) *APPLICABILITY OF CERTAIN STANDARDS TO*
2 *NON-FEDERAL EMPLOYEES.*—*In the case of any indi-*
3 *vidual who is not an employee of the Federal Govern-*
4 *ment and who serves with financial support from the*
5 *Foundation, the Foundation shall negotiate a memo-*
6 *randum of understanding with the individual and the*
7 *Director of the National Institutes of Health specify-*
8 *ing that the individual—*

9 “(A) *shall be subject to the ethical and pro-*
10 *cedural standards regulating Federal employ-*
11 *ment, scientific investigation, and research find-*
12 *ings (including publications and patents) that*
13 *are required of individuals employed by the Na-*
14 *tional Institutes of Health, including standards*
15 *under this Act, the Ethics in Government Act,*
16 *and the Technology Transfer Act; and*

17 “(B) *shall be subject to such ethical and*
18 *procedural standards under chapter 11 of title*
19 *18, United States Code (relating to conflicts of*
20 *interest), as the Director of the National Insti-*
21 *tutes of Health determines is appropriate, except*
22 *such memorandum may not provide that the in-*
23 *dividual shall be subject to the standards of sec-*
24 *tion 209 of such chapter.*

1 “(3) *FINANCIAL CONFLICTS OF INTEREST.*—Any
2 *individual who is an officer, employee, or member of*
3 *the Board of the Foundation may not directly or in-*
4 *directly participate in the consideration or deter-*
5 *mination by the Foundation of any question affect-*
6 *ing—*

7 “(A) *any direct or indirect financial inter-*
8 *est of the individual; or*

9 “(B) *any direct or indirect financial inter-*
10 *est of any business organization or other entity*
11 *of which the individual is an officer or employee*
12 *or in which the individual has a direct or indi-*
13 *rect financial interest.*

14 “(4) *AUDITS; AVAILABILITY OF RECORDS.*—*The*
15 *Foundation shall—*

16 “(A) *provide for biennial audits of the fi-*
17 *nancial condition of the Foundation; and*

18 “(B) *make such audits, and all other*
19 *records, documents, and other papers of the*
20 *Foundation, available to the Secretary and the*
21 *Comptroller General of the United States for ex-*
22 *amination or audit.*

23 “(5) *REPORTS.*—

24 “(A) *Not later than February 1 of each fis-*
25 *cal year, the Foundation shall publish a report*

1 *describing the activities of the Foundation dur-*
2 *ing the preceding fiscal year. Each such report*
3 *shall include for the fiscal year involved a com-*
4 *prehensive statement of the operations, activities,*
5 *financial condition, and accomplishments of the*
6 *Foundation.*

7 “(B) *With respect to the financial condition*
8 *of the Foundation, each report under subpara-*
9 *graph (A) shall include the source, and a de-*
10 *scription of, all gifts to the Foundation of real*
11 *or personal property, and the source and amount*
12 *of all gifts to the Foundation of money. Each*
13 *such report shall include a specification of any*
14 *restrictions on the purposes for which gifts to the*
15 *Foundation may be used.*

16 “(C) *The Foundation shall make copies of*
17 *each report submitted under subparagraph (A)*
18 *available for public inspection, and shall upon*
19 *request provide a copy of the report to any indi-*
20 *vidual for a charge not exceeding the cost of pro-*
21 *viding the copy.*

22 “(j) *FEDERAL FUNDING.—*

23 “(1) *AUTHORITY FOR ANNUAL GRANTS.—*

24 “(A) *The Secretary, acting through the Di-*
25 *rector of the National Institutes of Health, shall*

1 *for each of the fiscal years 1994 through 1996,*
2 *make a grant to the Foundation.*

3 “(B) A grant under subparagraph (A) may
4 *be expended only for the purpose of the adminis-*
5 *trative expenses of the Foundation.*

6 “(C) A grant under subparagraph (A) may
7 *not be expended to provide amounts for the fund*
8 *established under subsection (c).*

9 “(2) FUNDING FOR GRANTS.—

10 “(A) For the purpose of grants under para-
11 *graph (1), there is authorized to be appropriated*
12 *\$500,000 for each of the fiscal years 1994*
13 *through 1996.*

14 “(B) For the purpose of grants under para-
15 *graph (1), the Secretary may for each fiscal year*
16 *make available not more than \$500,000 from the*
17 *amounts appropriated for the fiscal year for the*
18 *programs of the National Institutes of Health.*
19 *Such amounts may be made available without*
20 *regard to whether amounts have been appro-*
21 *priated under subparagraph (A).”.*

1 **TITLE XVIII—RESEARCH WITH**
2 **RESPECT TO ACQUIRED IM-**
3 **MUNE DEFICIENCY SYN-**
4 **DROME**

5 **SEC. 1801. REVISION AND EXTENSION OF VARIOUS PRO-**
6 **GRAMS.**

7 (a) *AMENDMENTS.*—Title XXIII of the Public Health
8 Service Act (42 U.S.C. 300cc et seq.) is amended—

9 (1) in section 2304(c)(1)—

10 (A) in the matter preceding subparagraph
11 (A), by inserting after “Director of such Insti-
12 tute” the following: “(and may provide advice to
13 the Directors of other agencies of the National
14 Institutes of Health, as appropriate)”; and

15 (B) in subparagraph (A), by inserting be-
16 fore the semicolon the following: “, including rec-
17 ommendations on the projects of research with
18 respect to diagnosing immune deficiency and
19 with respect to predicting, diagnosing, prevent-
20 ing, and treating cancers, opportunistic infec-
21 tions, and infectious diseases”;

22 (2) in section 2311(a)(1), by inserting before the
23 semicolon the following: “, including evaluations of
24 methods of diagnosing immune deficiency and evalua-
25 tions of methods of predicting, diagnosing, preventing,

1 *and treating cancers, opportunistic infections, and*
2 *infectious diseases”;*

3 (3) *in section 2315(a)(2), by striking “inter-*
4 *national research” and all that follows and inserting*
5 *“international research and training concerning the*
6 *natural history and pathogenesis of the human*
7 *immunodeficiency virus and the development and*
8 *evaluation of vaccines and treatments for acquired*
9 *immune deficiency syndrome and opportunistic infec-*
10 *tions.”;*

11 (4) *in section 2318—*

12 (A) *in subsection (a)(1)—*

13 (i) *by inserting after “The Secretary”*
14 *the following: “, acting through the Director*
15 *of the National Institutes of Health and*
16 *after consultation with the Administrator*
17 *for Health Care Policy and Research,”; and*

18 (ii) *by striking “syndrome” and insert-*
19 *ing “syndrome, including treatment and*
20 *prevention of HIV infection and related*
21 *conditions among women”;* and

22 (B) *in subsection (e), by striking “1991.”*
23 *and inserting the following: “1991, and such*
24 *sums as may be necessary for each of the fiscal*
25 *years 1994 through 1996.”;*

1 (5) in section 2320(b)(1)(A), by striking “syn-
2 drome” and inserting “syndrome and the natural his-
3 tory of such infection”;

4 (6) in the part heading for part D, by striking
5 “DIRECTOR OF THE NATIONAL INSTITUTES OF
6 HEALTH” and inserting “OFFICE OF AIDS RE-
7 SEARCH”;

8 (7) in section 2351—

9 (A) by redesignating subsections (a), (b)
10 and (c) as subsections (c), (d) and (e), respec-
11 tively;

12 (B) by inserting after the section heading
13 the following new subsections:

14 “(a) *IN GENERAL.*—In carrying out research with re-
15 spect to acquired immune deficiency syndrome, the Sec-
16 retary, acting through the Director of the National Insti-
17 tutes of Health—

18 “(1) shall establish an office to be known as the
19 Office of AIDS Research, which Office shall be headed
20 by a Director who shall—

21 “(A) be appointed by the Secretary;

22 “(B) be determined by the Secretary to be
23 an individual who is an outstanding scientist
24 and a highly skilled administrator;

1 “(C) report directly to the Director of the
2 National Institutes of Health; and

3 “(D) be the primary Federal official respon-
4 sible for the conduct of AIDS-related research at
5 the National Institutes of Health; and

6 “(2) shall provide administrative support and
7 support services to the Director of such Office and
8 shall ensure that such support takes maximum advan-
9 tage of existing administrative structures at the insti-
10 tutes, centers and divisions of the National Institutes
11 of Health to the fullest extent practicable.

12 “(b) ACTIVITIES OF THE OFFICE OF AIDS RE-
13 SEARCH.—

14 “(1) IN GENERAL.—The Secretary, acting
15 through the director of the Office of AIDS Research,
16 shall ensure that AIDS research activities are coordi-
17 nated across and throughout the institutes, centers,
18 and divisions of the National Institutes of Health.

19 “(2) GENERAL DUTIES.—The Director of the Of-
20 fice of AIDS Research shall, based upon a strategic
21 plan as defined in paragraph (3), develop and oversee
22 the implementation of a scientifically justified budget
23 for AIDS-related research at the National Institutes
24 of Health and coordinate all AIDS-related research
25 activities conducted at the institutes, centers, and di-

1 *visions of the National Institutes of Health, and con-*
2 *duct evaluations on all such programs.*

3 *“(3) STRATEGIC PLAN.—*

4 *“(A) DEVELOPMENT.—The Director of the*
5 *Office of AIDS Research shall, based on the ad-*
6 *vice of the directors of the institutes, centers, and*
7 *divisions of the National Institutes of Health,*
8 *and in consultation with the advisory council es-*
9 *tablished in paragraph (5) and the coordinating*
10 *groups established in subparagraph (B), develop*
11 *and oversee the implementation of a comprehen-*
12 *sive, long-range plan for the conduct and support*
13 *of such research by the institutes, centers and di-*
14 *visions of the National Institutes of Health. Such*
15 *plan shall be updated annually, and shall—*

16 *“(i) determine the appropriate overall*
17 *balance between basic and applied research*
18 *and between intramural and extramural re-*
19 *search;*

20 *“(ii) determine and prioritize among*
21 *critical scientific AIDS-related questions;*

22 *“(iii) based upon such determinations,*
23 *specify the broad short and long range ob-*
24 *jectives to be achieved, and provide an esti-*

1 *mate of the resources needed to achieve such*
2 *objectives;*

3 “(iv) *evaluate the sufficiency of exist-*
4 *ing AIDS research programs to meet such*
5 *objectives, and establish evaluation criteria,*
6 *timelines and objectives for future program*
7 *evaluation activities; and*

8 “(v) *make recommendations for*
9 *changes and necessary resource allocation in*
10 *and among such programs.*

11 “(B) *COORDINATING GROUPS.—The Direc-*
12 *tor of the Office of AIDS Research shall establish*
13 *AIDS coordinating groups for each research dis-*
14 *cipline within the AIDS research program, com-*
15 *posed of representatives of relevant agencies of*
16 *the National Institutes of Health and qualified*
17 *extramural scientists, to evaluate and assess the*
18 *efforts of the AIDS Research Program at the Na-*
19 *tional Institutes of Health, to advise on the de-*
20 *velopment of the strategic plan described in sub-*
21 *paragraph (A), and to determine the extent to*
22 *which such efforts are in accordance with such*
23 *strategic plan.*

24 “(4) *COORDINATION.—The Director of the Office*
25 *of AIDS Research shall act as the primary Federal*

1 *official with responsibility for overseeing all AIDS-re-*
2 *lated research efforts undertaken by the National In-*
3 *stitutes of Health, and*

4 “(A) shall serve to represent the National
5 *Institutes of Health AIDS Research Program at*
6 *all relevant Executive branch task forces and*
7 *committees; and*

8 “(B) shall maintain communications with
9 *all relevant Public Health Service agencies and*
10 *with various other departments of the Federal*
11 *Government, to ensure the timely transmission of*
12 *information concerning advances in AIDS-relat-*
13 *ed research and the clinical treatment of AIDS*
14 *and its related conditions, between these various*
15 *agencies for dissemination to affected commu-*
16 *nities and health care providers.*

17 “(5) *ADVISORY COUNCIL.*—

18 “(A) *ESTABLISHMENT.*—*The Secretary*
19 *shall, consistent with section 406, establish an*
20 *advisory council to be known as the Office of*
21 *AIDS Research Advisory Council (hereafter re-*
22 *ferred to as the ‘Council’), which shall serve to*
23 *replace the AIDS Program Advisory Committee*
24 *which is operating on the date of enactment of*
25 *this subsection.*

1 “(B) *COMPOSITION.*—*The Council shall be*
2 *composed of biomedical, behavioral, and social*
3 *scientists, and representatives of diverse HIV af-*
4 *ected communities, and shall be appointed by*
5 *the Secretary.*

6 “(C) *AUTHORITY.*—*The Council shall—*

7 “(i) *advise the Director of the Office of*
8 *AIDS Research and make recommendations*
9 *concerning the development of the AIDS-re-*
10 *lated research budget, and the development*
11 *and implementation of the strategic plan*
12 *for AIDS-related research at the National*
13 *Institutes of Health;*

14 “(ii) *provide the second level of peer re-*
15 *view for awards made directly from the Of-*
16 *ice of AIDS Research from the discre-*
17 *tionary fund described in paragraph (7);*
18 *and*

19 “(iii) *carry out such other activities*
20 *determined appropriate by the Director of*
21 *the Office of AIDS Research.*

22 “(6) *BUDGETARY AUTHORITY.*—*The Director of*
23 *the Office of AIDS Research shall—*

24 “(A) *in accordance with the strategic plan*
25 *established under paragraph (3), in consultation*

1 with the Council, and based on budget requests
2 and additional advice from the directors of the
3 institutes, centers and divisions of the National
4 Institutes of Health, prepare and submit directly
5 to the President for review and transmittal to
6 Congress, an annual, scientifically justified
7 budget estimate for AIDS-related research con-
8 ducted within the agencies of the National Insti-
9 tutes of Health, after reasonable opportunity for
10 comment (but without change) by the Secretary
11 and the Director of the National Institutes of
12 Health, which shall include the amount of funds
13 required (as requested by the directors of such in-
14 stitutes, centers and divisions) for—

15 “(i) the continued funding of the com-
16 mitment base (ongoing program initiatives)
17 at the sole discretion of the directors of such
18 institutes, centers and divisions; and

19 “(ii) the funding of new and competing
20 program initiatives through such institutes,
21 centers and divisions, at the discretion of
22 the Director of the Office of AIDS Research;

23 “(B) receive from the President and the Of-
24 fice of Management and Budget directly all
25 AIDS-related research funds appropriated by

1 Congress for transfer to, and obligation and ex-
2 penditure by, the institutes, centers and divisions
3 of the National Institutes of Health in accord-
4 ance with the budget delineated under clauses (i)
5 and (ii) of subparagraph (A); and

6 “(C) distribute AIDS research funding to
7 the various institutes, centers, and divisions of
8 the National Institutes of Health in accordance
9 with the budget delineated under clauses (i) and
10 (ii) of subparagraph (A).

11 The provisions of this paragraph shall become effec-
12 tive in the fiscal year following the submission of the
13 consolidated AIDS budget.

14 “(7) DISCRETIONARY FUND.—

15 “(A) AVAILABILITY OF FUNDS.—The Sec-
16 retary shall ensure that not to exceed 25 percent
17 of the funds available in excess of the amount of
18 baseline AIDS research spending during the pre-
19 vious fiscal year, be made available to the Direc-
20 tor of the Office of AIDS Research for the estab-
21 lishment of an AIDS research discretionary
22 fund.

23 “(B) USE.—The Director of the Office of
24 AIDS Research, in consultation with the advi-
25 sory council established under paragraph (5),

1 *shall use amounts in the AIDS research discre-*
2 *tionary fund, either through the institutes, cen-*
3 *ters and divisions of the National Institutes of*
4 *Health or grants made directly by the Office of*
5 *AIDS Research, to—*

6 “(i) *fund emergency AIDS research*
7 *programs;*

8 “(ii) *fund programs for the conduct of*
9 *research aimed at filling gaps that exist in*
10 *existing research programs;*

11 “(iii) *conduct conferences, convene*
12 *committees, hold meetings or carry out*
13 *other activities determined appropriate by*
14 *the Director.*

15 “(C) *REDUCTION IN ADMINISTRATIVE IM-*
16 *PEDIMENTS.—Notwithstanding any other provi-*
17 *sion of law relating to the number of individuals*
18 *who may be employed as full-time equivalent in-*
19 *dividuals, with respect to the number of full-time*
20 *equivalent individuals so employed, the Director*
21 *of the Office of AIDS Research shall be permitted*
22 *to authorize the employment of such full-time*
23 *equivalent individuals to perform AIDS-related*
24 *research through the institutes, centers and divi-*
25 *sions of the National Institutes of Health as de-*

1 scribed in clauses (i) and (ii) of subparagraph
2 (B) and subject to appropriations.”;

3 (C) in subsection (c) (as so redesignated)—

4 (i) by striking the subsection designa-
5 tion and all that follows through paragraph
6 (1) and inserting the following:

7 “(c) OTHER DUTIES.—The director of the office—”;

8 (ii) by redesignating paragraphs (2)
9 through (8) as paragraphs (1) through (7),
10 respectively;

11 (iii) by striking “for the appropriate
12 national research institute of the National
13 Institutes of Health” in paragraph (4) (as
14 so redesignated); and

15 (iv) by inserting “cannot reasonably be
16 accomplished within the United States and”
17 after “if such research” in paragraph (4)(A)
18 (as so redesignated); and

19 (D) by adding at the end thereof the follow-
20 ing new subsection:

21 “(f) EVALUATION AND REPORT.—

22 “(1) EVALUATION.—Not later than 5 years after
23 the date of enactment of this Act, the Secretary shall
24 conduct an evaluation to—

1 “(A) determine the effect of this section on
2 the planning and coordination of the AIDS re-
3 search programs at the institutes, centers and di-
4 visions of the National Institutes of Health;

5 “(B) evaluate the extent to which this sec-
6 tion has eliminated the duplication of adminis-
7 trative resources among such institutes, centers
8 and divisions; and

9 “(C) provide recommendations concerning
10 future alterations with respect to this section.

11 “(2) REPORT.—Not later than 1 year after the
12 date on which the evaluation is commenced under
13 paragraph (1), the Secretary shall prepare and sub-
14 mit to the Committee on Labor and Human Re-
15 sources of the Senate and the Committee on Energy
16 and Commerce of the House of Representatives, a re-
17 port concerning the results of such evaluation.”;

18 (8) in section 2361, by striking “For purposes”
19 and all that follows and inserting the following:

20 “For purposes of this title:

21 “(1) The term ‘infection’, with respect to the etio-
22 logic agent for acquired immune deficiency syndrome,
23 includes cancers, opportunistic infections, and infec-
24 tious diseases and any other conditions arising from
25 infection with such etiologic agent.

1 *public and private clinical research, and on the ac-*
2 *tivities of the Commissioner of Food and Drugs re-*
3 *garding the approval of drugs.*

4 *(2) The Secretary of Health and Human Serv-*
5 *ices shall request the Institute of Medicine of the Na-*
6 *tional Academy of Sciences to enter into the contract*
7 *under paragraph (1) to conduct the study described*
8 *in such paragraph. If such Institute declines to con-*
9 *duct the study, the Secretary shall carry out para-*
10 *graph (1) through another public or nonprofit private*
11 *entity.*

12 *(b) THIRD-PARTY PAYMENTS REGARDING CERTAIN*
13 *CLINICAL TRIALS.—The Secretary of Health and Human*
14 *Services shall conduct a study for the purpose of—*

15 *(1) determining the policies of third-party*
16 *payors regarding the payment of the costs of appro-*
17 *priate health services that are provided incident to*
18 *the participation of individuals as subjects in clinical*
19 *trials conducted in the development of drugs with re-*
20 *spect to acquired immune deficiency syndrome; and*

21 *(2) developing recommendations regarding such*
22 *policies.*

1 (c) *ADVISORY COMMITTEES.*—*The Secretary of Health*
2 *and Human Services, acting through the Director of the Na-*
3 *tional Institutes of Health, shall conduct a study for the*
4 *purpose of determining—*

5 (1) *whether the activities of the various advisory*
6 *committees established in the National Institutes of*
7 *Health regarding acquired immune deficiency syn-*
8 *drome are being coordinated sufficiently; and*

9 (2) *whether the functions of any of such advisory*
10 *committees should be modified in order to achieve*
11 *greater efficiency.*

12 (d) *VACCINES FOR HUMAN IMMUNODEFICIENCY*
13 *VIRUS.*—

14 (1) *IN GENERAL.*—*The Secretary of Health and*
15 *Human Services, acting through the National Insti-*
16 *tutes of Health, shall develop a plan for the appro-*
17 *prate inclusion of HIV-infected women, including*
18 *pregnant women, HIV-infected infants, and HIV-in-*
19 *fected children in studies conducted by or through the*
20 *National Institutes of Health concerning the safety*
21 *and efficacy of HIV vaccines for the treatment and*
22 *prevention of HIV infection. Such plan shall ensure*
23 *the full participation of other Federal agencies cur-*
24 *rently conducting HIV vaccine studies and require*

1 *that such studies conform fully to the requirements of*
2 *part 46 of title 45, Code of Federal Regulations.*

3 (2) *REPORT.*—*Not later than 180 days after the*
4 *date of the enactment of this Act, the Secretary of*
5 *Health and Human Services shall prepare and sub-*
6 *mit to the Committee on Energy and Commerce of the*
7 *House of Representatives, and the Committee on*
8 *Labor and Human Resources of the Senate, a report*
9 *concerning the plan developed under paragraph (1).*

10 (3) *IMPLEMENTATION.*—*Not later than 12*
11 *months after the date of the enactment of this Act, the*
12 *Secretary of Health and Human Services shall imple-*
13 *ment the plan developed under paragraph (1), includ-*
14 *ing measures for the full participation of other Fed-*
15 *eral agencies currently conducting HIV vaccine*
16 *studies.*

17 (4) *For the purpose of carrying out this sub-*
18 *section, there are authorized to be appropriated such*
19 *sums as may be necessary for each of the fiscal years*
20 *1994 through 1996.*

21 **SEC. 1902. MALNUTRITION IN THE ELDERLY.**

22 (a) *STUDY.*—

23 (1) *IN GENERAL.*—*The Secretary of Health and*
24 *Human Services (referred to in this section as the*
25 *“Secretary”), acting through the National Institute*

1 *on Aging, coordinating with the Agency for Health*
2 *Care Policy and Research and, to the degree possible,*
3 *in consultation with the head of the National Nutri-*
4 *tion Monitoring System established under section*
5 *1428 of the Food and Agriculture Act of 1977 (7*
6 *U.S.C. 3178), shall conduct a 3-year nutrition screen-*
7 *ing and intervention activities study of the elderly.*

8 (2) *EFFICACY AND COST-EFFECTIVENESS OF NU-*
9 *TRITION SCREENING AND INTERVENTION ACTIVI-*
10 *TIES.—In conducting the study, the Secretary shall*
11 *determine the efficacy and cost-effectiveness of nutri-*
12 *tion screening and intervention activities conducted*
13 *in the elderly health and long-term care continuum,*
14 *and of a program that would institutionalize nutri-*
15 *tion screening and intervention activities. In evaluat-*
16 *ing such a program, the Secretary shall determine—*

17 (A) *if health or quality of life is measurably*
18 *improved for elderly individuals who receive rou-*
19 *tine nutritional screening and treatment;*

20 (B) *if federally subsidized home or institu-*
21 *tional care is reduced because of increased inde-*
22 *pendence of elderly individuals resulting from*
23 *improved nutritional status;*

1 (C) if a multidisciplinary approach to nu-
2 tritional care is effective in addressing the nutri-
3 tional needs of elderly individuals; and

4 (D) if reimbursement for nutrition screen-
5 ing and intervention activities is a cost-effective
6 approach to improving the health status of elder-
7 ly individuals.

8 (3) *POPULATIONS.*—The populations of elderly
9 individuals in which the study will be conducted shall
10 include populations of elderly individuals who are—

11 (A) living independently, including—

12 (i) individuals who receive home and
13 community-based services or family sup-
14 port;

15 (ii) individuals who do not receive ad-
16 ditional services and support;

17 (iii) individuals with low incomes; and

18 (iv) individuals who are minorities;

19 (B) hospitalized, including individuals ad-
20 mitted from home and from institutions; and

21 (C) institutionalized in residential facilities
22 such as nursing homes and adult homes.

23 (b) *MALNUTRITION STUDY.*—The Secretary, acting
24 through the National Institute on Aging, shall conduct a
25 3-year study to determine the extent of malnutrition in el-

1 *derly individuals in hospitals and long-term care facilities*
2 *and in elderly individuals who are living independently.*

3 *(c) REPORT.—The Secretary shall submit a report to*
4 *the Committee on Labor and Human Resources of the Sen-*
5 *ate and the Committee on Energy and Commerce of the*
6 *House of Representatives containing the findings resulting*
7 *from the studies described in subsections (a) and (b), in-*
8 *cluding a determination regarding whether a program that*
9 *would institutionalize nutrition screening and intervention*
10 *activities should be adopted, and the rationale for the deter-*
11 *mination.*

12 *(d) ADVISORY PANEL.—*

13 *(1) ESTABLISHMENT.—The Secretary, acting*
14 *through the Director of the National Institute on*
15 *Aging, shall establish an advisory panel that shall*
16 *oversee the design, implementation, and evaluation of*
17 *the studies described in subsections (a) and (b).*

18 *(2) COMPOSITION.—The advisory panel shall in-*
19 *clude representatives appointed for the life of the*
20 *panel by the Secretary from the Health Care Financ-*
21 *ing Administration, the Social Security Administra-*
22 *tion, the National Center for Health Statistics, the*
23 *Administration on Aging, the National Council on*
24 *the Aging, the American Dietetic Association, the*
25 *American Academy of Family Physicians, and such*

1 *other agencies or organizations as the Secretary deter-*
2 *mines to be appropriate.*

3 (3) *COMPENSATION AND EXPENSES.—*

4 (A) *COMPENSATION.—Each member of the*
5 *advisory panel who is not an employee of the*
6 *Federal Government shall receive compensation*
7 *for each day engaged in carrying out the duties*
8 *of the panel, including time engaged in traveling*
9 *for purposes of such duties. Such compensation*
10 *may not be provided in an amount in excess of*
11 *the maximum rate of basic pay payable for GS-*
12 *18 of the General Schedule.*

13 (B) *TRAVEL EXPENSES.—Each member of*
14 *the advisory panel shall receive travel expenses,*
15 *including per diem in lieu of subsistence, at*
16 *rates authorized for employees of agencies under*
17 *subchapter I of chapter 57 of title 5, United*
18 *States Code, for each day the member is engaged*
19 *in the performance of duties away from the home*
20 *or regular place of business of the member.*

21 (4) *DETAIL OF FEDERAL EMPLOYEES.—On the*
22 *request of the advisory panel, the head of any Federal*
23 *agency shall detail, without reimbursement, any of*
24 *the personnel of the agency to the advisory panel to*
25 *assist the advisory panel in carrying out its duties.*

1 *Any detail shall not interrupt or otherwise affect the*
2 *civil service status or privileges of the Federal em-*
3 *ployee.*

4 (5) *TECHNICAL ASSISTANCE.*—*On the request of*
5 *the advisory panel, the head of a Federal agency shall*
6 *provide such technical assistance to the advisory*
7 *panel as the advisory panel determines to be nec-*
8 *essary to carry out its duties.*

9 (6) *TERMINATION.*—*Notwithstanding section 15*
10 *of the Federal Advisory Committee Act (5 U.S.C.*
11 *App.), the advisory panel shall terminate 3 years*
12 *after the date of enactment of this Act.*

13 ***SEC. 1903. RESEARCH ACTIVITIES ON CHRONIC FATIGUE***
14 ***SYNDROME.***

15 *The Secretary of Health and Human Services shall,*
16 *not later than May 1, 1993, and annually thereafter for*
17 *the next 3 years, prepare and submit to the Committee on*
18 *Energy and Commerce of the House of Representatives and*
19 *the Committee on Labor and Human Resources of the Sen-*
20 *ate, a report that summarizes the research activities con-*
21 *ducted or supported by the National Institutes of Health*
22 *concerning chronic fatigue syndrome. Such report should*
23 *include information concerning grants made, cooperative*
24 *agreements or contracts entered into, intramural activities,*

1 *research priorities and needs, and a plan to address such*
2 *priorities and needs.*

3 **SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL**
4 **AGENTS IN DEVELOPMENT OF DEFENSES**
5 **AGAINST BIOLOGICAL WARFARE.**

6 *The Secretary of Health and Human Services, in con-*
7 *sultation with other appropriate executive agencies, shall*
8 *report to the House Energy and Commerce Committee and*
9 *the Senate Labor and Human Resources Committee on the*
10 *appropriateness and impact of the National Institutes of*
11 *Health assuming responsibility for the conduct of all Fed-*
12 *eral research, development, testing, and evaluation func-*
13 *tions relating to medical countermeasures against*
14 *biowarfare threat agents. In preparing the report, the Sec-*
15 *retary shall identify the extent to which such activities are*
16 *carried out by agencies other than the National Institutes*
17 *of Health, and assess the impact (positive and negative) of*
18 *the National Institutes of Health assuming responsibility*
19 *for such activities, including the impact under the Budget*
20 *Enforcement Act and the Omnibus Budget Reconciliation*
21 *Act of 1990 on existing National Institutes of Health re-*
22 *search programs as well as other programs within the cat-*
23 *egory of domestic discretionary spending. The Secretary*
24 *shall submit the report not later than 12 months after the*
25 *date of the enactment of this Act.*

1 **SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETEN-**
2 **TION AND TURNOVER.**

3 (a) *STUDY OF PERSONNEL SYSTEM.*—Not later than
4 1 year after the date of the enactment of this Act, the Sec-
5 retary of Health and Human Services, acting through the
6 Director of the National Institutes of Health, shall conduct
7 a study to review the retention, recruitment, vacancy and
8 turnover rates of support staff, including firefighters, law
9 enforcement, procurement officers, technicians, nurses and
10 clerical employees, to ensure that the National Institutes of
11 Health is adequately supporting the conduct of efficient, ef-
12 fective and high quality research for the American public.
13 The Director of NIH shall work in conjunction with appro-
14 priate employee organizations and representatives in devel-
15 oping such a study.

16 (b) *SUBMISSION TO CONGRESS.*—Not later than 1 year
17 after the date of the enactment of this Act, the Secretary
18 of Health and Human Services shall prepare and submit
19 to the Committee on Energy and Commerce of the House
20 of Representatives, and to the Committee on Labor and
21 Human Resources of the Senate, a report containing the
22 study conducted under subsection (a) together with the rec-
23 ommendations of the Secretary concerning the enactment
24 of legislation to implement the results of such study.

1 **SEC. 1906. PROCUREMENT.**

2 (a) *IN GENERAL.*—The Director of the National Insti-
3 tutes of Health and the Administrator of the General Serv-
4 ices Administration shall jointly conduct a study to develop
5 a streamlined procurement system for the National Insti-
6 tutes of Health that complies with the requirements of Fed-
7 eral law.

8 (b) *REPORT.*—Not later than March 1, 1994, the offi-
9 cials specified in subsection (a) shall complete the study re-
10 quired in such subsection and shall submit to the Committee
11 on Energy and Commerce of the House of Representatives,
12 and the Committee on Labor and Human Resources of the
13 Senate, a report describing the findings made as a result
14 of the study.

15 **SEC. 1907. REPORT CONCERNING LEADING CAUSES OF**
16 **DEATH.**

17 (a) *REPORT.*—The Secretary of Health and Human
18 Services shall, not later than October 1, 1993, prepare a
19 report that lists—

20 (1) the 20 illnesses that, in terms of mortality,
21 number of years of expected life lost, and of number
22 of preventable years of life lost, are the leading causes
23 of death in the United States and the number of
24 deaths from each such cause, the age-specific and age-
25 adjusted death rates for each such cause, the death
26 rate per 100,000 population for each such cause, the

1 *percentage of change in cause specific death rates for*
2 *each age group, and the percentage of total deaths for*
3 *each such cause;*

4 *(2) the amount expended by the Department of*
5 *Health and Human Services for research, prevention,*
6 *and education with respect to each of the 20 illnesses*
7 *described in paragraph (1) for the most recent year*
8 *for which the actual expenditures are known;*

9 *(3) an estimate by the Secretary of the amount*
10 *to be expended on research, prevention, and education*
11 *with respect to each of the 20 illnesses described in*
12 *paragraph (1) for the year for which the report is*
13 *prepared; and*

14 *(4) with respect to the years specified in para-*
15 *graphs (2) and (3), the percentage of the total of the*
16 *annual expenditures for research, prevention, and*
17 *education on the 20 illnesses described in paragraph*
18 *(1) that are attributable to each illness.*

19 *(b) SUBMISSION TO CONGRESS.—The Secretary of*
20 *Health and Human Services shall submit the report re-*
21 *quired under subsection (a), together with relevant budget*
22 *information, to the Committee on Energy and Commerce*
23 *and the Committee on Appropriations of the House of Rep-*
24 *resentatives and the Committee on Labor and Human Re-*
25 *sources and the Committee on Appropriations of the Senate.*

1 **SEC. 1908. RELATIONSHIP BETWEEN THE CONSUMPTION OF**
2 **LEGAL AND ILLEGAL DRUGS.**

3 (a) *IN GENERAL.*—The Secretary of Health and
4 Human Services, acting through the Commissioner of Food
5 and Drugs, shall review and consider all existing relevant
6 data and research concerning whether there is a relation-
7 ship between an individual's receptivity to use or consume
8 legal drugs and the consumption or abuse by the individual
9 of illegal drugs. On the basis of such review, the Secretary
10 shall determine whether additional research is necessary. If
11 the Secretary determines additional research is required,
12 the Secretary shall conduct a study of those subjects where
13 the Secretary's review indicates additional research is need-
14 ed, including, if necessary, a review of—

15 (1) the effect of advertising and marketing cam-
16 paigns that promote the use of legal drugs on the
17 public;

18 (2) the correlation of legal drug abuse with ille-
19 gal drug abuse; and

20 (3) other matters that the Secretary determines
21 appropriate.

22 (b) *REPORT.*—Not later than 12 months after the date
23 of enactment of this Act, the Secretary shall prepare and
24 submit, to the Committee on Energy and Commerce of the
25 House of Representatives and Committee on Labor and
26 Human Resources of the Senate, a report containing the

1 *results of the review conducted under subsection (b). If the*
2 *Secretary determines additional research is required, no*
3 *later than 2 years after the date of enactment of this Act,*
4 *the Secretary shall prepare and submit, to the Committee*
5 *on Energy and Commerce of the House of Representatives*
6 *and Committee on Labor and Human Resources of the Sen-*
7 *ate, a report containing the results of the additional re-*
8 *search conducted under subsection (b).*

9 **SEC. 1909. COST OF CARE IN LAST 6 MONTHS OF LIFE.**

10 (a) *STUDY.*—

11 (1) *IN GENERAL.*—*The Secretary of Health and*
12 *Human Services (referred to in this section as the*
13 *“Secretary”), acting through the Agency for Health*
14 *Care Policy and Research and, to the degree possible,*
15 *in consultation with the Health Care Financing Ad-*
16 *ministration, shall conduct a study, using the most*
17 *recent National Medical Expenditure Survey*
18 *database, to estimate the average amount of health*
19 *care expenditures incurred during the last 6 months*
20 *of life and during the last 3 months of life by—*

21 (A) *the population of individuals who are*
22 *65 years of age and older; and*

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

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

3 (A) *be designed in a manner that will*
4 *produce estimates of health care costs expended*
5 *for health care provided to individuals during*
6 *the last 3 and 6 months of life;*

7 (B) *be designed to produce estimates of such*
8 *costs for the populations identified in subpara-*
9 *graphs (A) and (B) of paragraph (1);*

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

13 (D) *include a calculation of the estimate de-*
14 *scribed in subparagraph (C)—*

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

17 (ii) *for those age 65 years and over, as*
18 *a percentage of the total Medicare expendi-*
19 *tures for those age 65 years and over.*

20 (b) *REPORT.*—*Not later than 6 months after the date*
21 *of enactment of this section, the Secretary shall prepare and*
22 *submit to the Committee on Labor and Human Resources*
23 *of the Senate and the Committee on Energy and Commerce*
24 *of the House of Representatives, a report containing the*

1 *findings resulting from the study described in subsection*
2 *(a).*

3 *(c) 1996 NATIONAL MEDICAL EXPENDITURE SUR-*
4 *VEY.—*

5 *(1) IN GENERAL.—The Secretary, acting through*
6 *the Agency for Health Care Policy and Research,*
7 *shall ensure that the 1996 National Medical Expendi-*
8 *ture Survey is designed in a manner that will*
9 *produce an estimate of the amount expended for*
10 *health care provided to individuals during the last 3*
11 *and 6 months of life.*

12 *(2) POPULATIONS.—In designing the Survey*
13 *under paragraph (1), the Secretary shall ensure that*
14 *such Survey produces the data required under such*
15 *paragraph for—*

16 *(A) the population of individuals who are*
17 *65 years of age and older; and*

18 *(B) the population of individuals who are 1*
19 *year of age and younger;*

20 *broken down based on noninstitutionalized and insti-*
21 *tutionalized populations.*

1 **TITLE XX—MISCELLANEOUS**
2 **PROVISIONS**

3 **SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RE-**
4 **SEARCH SERVICE IN HONOR OF SILVIO O.**
5 **CONTE, AND LIMITATION ON NUMBER OF**
6 **MEMBERS.**

7 (a) *IN GENERAL.*—Section 228(a) of the Public Health
8 Service Act (42 U.S.C. 237(a)), as added by section 304
9 of Public Law 101–509, is amended to read as follows:

10 “(a)(1) There shall be in the Public Health Service a
11 Silvio O. Conte Senior Biomedical Research Service, not
12 to exceed 750 members.

13 “(2) The authority established in paragraph (1) re-
14 garding the number of members in the Silvio O. Conte Sen-
15 ior Biomedical Research Service is in addition to any au-
16 thority established regarding the number of members in the
17 commissioned Regular Corps, in the Reserve Corps, and in
18 the Senior Executive Service. Such paragraph may not be
19 construed to require that the number of members in the com-
20 missioned Regular Corps, in the Reserve Corps, or in the
21 Senior Executive Service be reduced to offset the number
22 of members serving in the Silvio O. Conte Senior Bio-
23 medical Research Service (hereafter in this section referred
24 to as the ‘Service’).”.

1 (4) in section 428(b), in the matter preceding
2 paragraph (1), by striking “the the” and inserting
3 “the”;

4 (5) in section 430(b)(2)(A)(i), by striking “Veter-
5 ans’ Administration” and inserting “Department of
6 Veterans Affairs”;

7 (6) in section 439(b), by striking “Veterans’ Ad-
8 ministration” and inserting “Department of Veterans
9 Affairs”;

10 (7) in section 442(b)(2)(A), by striking “Veter-
11 ans’ Administration” and inserting “Department of
12 Veterans Affairs”;

13 (8) in section 464D(b)(2)(A), by striking “Veter-
14 ans’ Administration” and inserting “Department of
15 Veterans Affairs”;

16 (9) in section 464E—

17 (A) in subsection (d), in the first sentence,
18 by inserting “Coordinating” before “Committee”;
19 and

20 (B) in subsection (e), by inserting “Coordi-
21 nating” before “Committee” the first place such
22 term appears;

23 (10) in section 464P(b)(6) (as added by section
24 123 of Public Law 102-321 (106 Stat. 362)), by strik-
25 ing “Administration” and inserting “Institute”;

1 (11) in section 466(a)(1)(B), by striking “Veter-
2 ans’ Administration” and inserting “Department of
3 Veterans Affairs”;

4 (12) in section 480(b)(2)(A), by striking “Veter-
5 ans’ Administration” and inserting “Department of
6 Veterans Affairs”;

7 (13) in section 485(b)(2)(A), by striking “Veter-
8 ans’ Administration” and inserting “Department of
9 Veterans Affairs”;

10 (14) in section 487(d)(3), by striking “section
11 304(a)(3)” and inserting “section 304(a)”; and

12 (15) in section 496(a), by striking “Such appro-
13 priations,” and inserting the following: “Appropria-
14 tions to carry out the purposes of this title.”.

15 (c) TITLE XV.—Title XV of the Public Health Service
16 Act is amended—

17 (1) in section 1501(b) (42 U.S.C. 300k(b)), by
18 striking “nonprofit”; and

19 (2) in section 1505(3) (42 U.S.C. 300n-1(3)), by
20 striking “nonprivate” and inserting “private”.

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

23 (1) in section 2304—

24 (A) in the heading for the section, by strik-
25 ing “**CLINICAL RESEARCH REVIEW COMMIT-**

1 **TEE**” and inserting “**RESEARCH ADVISORY**
2 **COMMITTEE**”; and

3 (B) in subsection (a), by striking “AIDS
4 Clinical Research Review Committee” and in-
5 serting “AIDS Research Advisory Committee”;

6 (2) in section 2312(a)(2)(A), by striking “AIDS
7 Clinical Research Review Committee” and inserting
8 “AIDS Research Advisory Committee”;

9 (3) in section 2314(a)(1), in the matter preced-
10 ing subparagraph (A), by striking “Clinical Research
11 Review Committee” and inserting “AIDS Research
12 Advisory Committee”;

13 (4) in section 2317(d)(1), by striking “Clinical
14 Research Review Committee” and inserting “AIDS
15 Research Advisory Committee established under sec-
16 tion 2304”; and

17 (5) in section 2318(b)(3), by striking “Clinical
18 Research Review Committee” and inserting “AIDS
19 Research Advisory Committee”.

20 (e) *SECRETARY*.—Section 2(c) of the Public Health
21 Service Act (42 U.S.C. 201(c)) is amended by striking
22 “Health, Education, and Welfare” and inserting “Health
23 and Human Services”.

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

1 (1) *by striking “Health, Education, and Wel-*
2 *fare” and inserting “Health and Human Services”;*
3 *and*

4 (2) *by striking “Surgeon General” and inserting*
5 *“Assistant Secretary for Health”.*

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

8 (1) *by striking “Surgeon General” the second*
9 *and subsequent times that such term appears and in-*
10 *serting “Secretary”; and*

11 (2) *by inserting “, and the Agency for Health*
12 *Care Policy and Research” before the first period.*

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

17 **SEC. 2003. BIENNIAL REPORT ON CARCINOGENS.**

18 *Section 301(b)(4) of the Public Health Service Act (42*
19 *U.S.C. 241(b)(4)) is amended by striking “an annual” and*
20 *inserting in lieu thereof “a biennial”.*

21 **SEC. 2004. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE**
22 **FOR RESEARCH.**

23 *Not later than 90 days after the date of the enactment*
24 *of this Act, the Secretary of Health and Human Services,*
25 *acting through the Director of the National Institutes of*

1 *Health, shall present to the Congress a master plan to pro-*
2 *vide for the replacement or refurbishment of less than ade-*
3 *quate buildings, utility equipment and distribution systems*
4 *(including the resources that provide electrical and other*
5 *utilities, chilled water, air handling, and other services that*
6 *the Secretary, acting through the Director, deems nec-*
7 *essary), roads, walkways, parking areas, and grounds that*
8 *underpin the laboratory and clinical facilities of the Na-*
9 *tional Institutes of Health. Such plan may make rec-*
10 *ommendations for the undertaking of new projects that are*
11 *consistent with the objectives of this section, such as encir-*
12 *cling the National Institutes of Health Federal enclave with*
13 *an adequate chilled water conduit.*

14 **SEC. 2005. TRANSFER OF PROVISIONS OF TITLE XXVII.**

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

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

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

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

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

3 “PART A—ADMINISTRATION”; and

4 (5) by inserting before section 231 (as redesign-
5 nated by paragraph (2) of this subsection) the follow-
6 ing new heading:

7 “PART B—MISCELLANEOUS PROVISIONS”.

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

10 (1) in the heading for title II, by inserting
11 “AND MISCELLANEOUS PROVISIONS” after
12 “ADMINISTRATION”;

13 (2) in section 406(a)(2), by striking “2701” and
14 inserting “231”;

15 (3) in section 465(f), by striking “2701” and in-
16 serting “231”;

17 (4) in section 480(a)(2), by striking “2701” and
18 inserting “231”;

19 (5) in section 485(a)(2), by striking “2701” and
20 inserting “231”;

21 (6) in section 497, by striking “2701” and in-
22 serting “231”;

23 (7) in section 505(a)(2), by striking “2701” and
24 inserting “231”;

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

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

5 **SEC. 2006. CERTAIN AUTHORIZATION OF APPROPRIATIONS.**

6 Section 399L(a) of the Public Health Service Act (42
7 U.S.C. 280e-4(a)), as added by Public Law 102-515 (106
8 Stat. 3376), is amended—

9 (1) in the first sentence, by striking “the Sec-
10 retary” and all that follows and inserting the follow-
11 ing: “there are authorized to be appropriated
12 \$30,000,000 for fiscal year 1994, and such sums as
13 may be necessary for each of the fiscal years 1995
14 through 1997.”; and

15 (2) in the second sentence, by striking “Out of
16 any amounts used” and inserting “Of the amounts
17 appropriated under the preceding sentence”.

18 **SEC. 2007. PROHIBITION AGAINST SHARP ADULT SEX SUR-**
19 **VEY AND THE AMERICAN TEENAGE SEX SUR-**
20 **VEY.**

21 The Secretary of Health and Human Services may not
22 during fiscal year 1993 or any subsequent fiscal year con-
23 duct or support the SHARP survey of adult sexual behavior
24 or the American Teenage Study of adolescent sexual behav-

1 *ior. This section becomes effective on the date of enactment*
2 *of this Act.*

3 **SEC. 2008. SUPPORT FOR BIOENGINEERING RESEARCH.**

4 (a) *STUDY.*—*The Secretary of Health and Human*
5 *Services, acting through the Director of the National Insti-*
6 *tutes of Health, shall conduct a study for the purpose of—*

7 (1) *determining the sources and amounts of pub-*
8 *lic and private funding devoted to basic research in*
9 *bioengineering and biomaterials sciences;*

10 (2) *evaluating whether that commitment is suffi-*
11 *cient to maintain the innovative edge that the United*
12 *States has in these technologies; and*

13 (3) *evaluating the need to modify the structure*
14 *of the National Institutes of Health or any other Fed-*
15 *eral agency to achieve a greater commitment to inno-*
16 *vation in bioengineering, and evaluating the need for*
17 *better coordination and collaboration among Federal*
18 *agencies and between the public and private sectors.*

19 *In conducting such study, the Director shall work in con-*
20 *junction with appropriate organizations and representa-*
21 *tives including academics, industry leaders, bioengineering*
22 *societies, and public agencies (such as the National Science*
23 *Foundation, Veterans Administration, Department of De-*
24 *fense, National Aeronautics and Space Administration, and*
25 *the White House Office of Science and Technology Policy).*

1 (b) *REPORT.*—Not later than 1 year after the date of
 2 enactment of this Act, the Secretary of Health and Human
 3 Services shall prepare and submit to the Committee on
 4 Labor and Human Resources of the Senate, and the Com-
 5 mittee on Energy and Commerce of the House of Represent-
 6 atives, a report containing the findings of the study con-
 7 ducted under subsection (a) together with recommendations
 8 concerning the enactment of legislation to implement the
 9 results of such study.

10 **TITLE XXI—EFFECTIVE DATES**

11 **SEC. 2101. EFFECTIVE DATES.**

12 Subject to section 155, this Act and the amendments
 13 made by this Act take effect upon the date of the enactment
 14 of this Act.

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