

103D CONGRESS
1ST SESSION

S. 1

AMENDMENT

In the House of Representatives, U. S.,

March 10, 1993.

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

AMENDMENT:

Strike out all after the enacting clause, and insert:

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

2 (a) *SHORT TITLE.*—*This Act may be cited as the “National*
3 *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. Nullification of moratorium.

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

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

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

PART II—OFFICE OF RESEARCH ON WOMEN'S HEALTH

- Sec. 141. Establishment.*

PART III—OFFICE OF RESEARCH ON MINORITY HEALTH

- Sec. 151. Establishment.*

Subtitle C—Research Integrity

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

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

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

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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

TITLE IV—NATIONAL CANCER INSTITUTE

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

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

- Sec. 501. Education and training.*

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

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

- Sec. 601. Provisions regarding nutritional disorders.*

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

- Sec. 701. Juvenile arthritis.*

TITLE VIII—NATIONAL INSTITUTE ON AGING

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

*TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS
DISEASES*

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

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

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

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

Subtitle B—Program Regarding Obstetrics and Gynecology

- Sec. 1011. Establishment of program.*

Subtitle C—Child Health Research Centers

- Sec. 1021. Establishment of centers.*

Subtitle D—Study Regarding Adolescent Health

- Sec. 1031. Prospective longitudinal study.*

TITLE XI—NATIONAL EYE INSTITUTE

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

*TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS
AND STROKE*

- Sec. 1201. Research on multiple sclerosis.*

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Sec. 1301. Applied Toxicological Research and Testing Program.

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

Sec. 1401. Additional authorities.

Sec. 1402. Authorization of appropriations.

Subtitle B—Financial Assistance

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

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

Sec. 1421. Establishment of Center.

Sec. 1422. Conforming provisions.

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF HEALTH

Subtitle A—Division of Research Resources

Sec. 1501. Redesignation of Division as National Center for Research Resources.

Sec. 1502. Biomedical and behavioral research facilities.

Sec. 1503. Construction program for national primate research center.

Subtitle B—National Center for Nursing Research

Sec. 1511. Redesignation of National Center for Nursing Research as National Institute of Nursing Research.

Sec. 1512. Study on adequacy of number of nurses.

Subtitle C—National Center for Human Genome Research

Sec. 1521. Purpose of Center.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

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

Subtitle B—Acquired Immune Deficiency Syndrome

Sec. 1611. Loan repayment program.

Subtitle C—Loan Repayment for Research Generally

Sec. 1621. Establishment of program.

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

Sec. 1631. Establishment of programs.

Sec. 1632. Funding.

Subtitle E—Funding for Awards and Training Generally

Sec. 1641. Authorization of appropriations.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

Sec. 1701. Date certain for appointment of Board members.

Sec. 1702. Miscellaneous provisions.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

Subtitle A—Office of AIDS Research

Sec. 1801. Establishment of Office.

Sec. 1802. Establishment of emergency discretionary fund.

Sec. 1803. General provisions.

Subtitle B—Certain Programs

Sec. 1811. Revision and extension of certain programs.

TITLE XIX—STUDIES

Sec. 1901. Acquired immune deficiency syndrome.

Sec. 1902. Malnutrition in the elderly.

Sec. 1903. Research activities on chronic fatigue syndrome.

Sec. 1904. Report on medical uses of biological agents in development of defenses against biological warfare.

Sec. 1905. Personnel study of recruitment, retention and turnover.

Sec. 1906. Procurement.

Sec. 1907. Chronic pain conditions.

Sec. 1908. Back injuries.

TITLE XX—MISCELLANEOUS PROVISIONS

Sec. 2001. Designation of Senior Biomedical Research Service in honor of Silvio O. Conte; limitation on number of members.

Sec. 2002. Master plan for physical infrastructure for research.

Sec. 2003. Certain authorization of appropriations.

Sec. 2004. Buy-American provisions.

Sec. 2005. Prohibition against further funding for Project Aries.

TITLE XXI—EFFECTIVE DATES

Sec. 2101. Effective dates.

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.—*

18 *“(1) PROTECTION OF HUMAN RESEARCH SUB-*
 19 *JECTS.—*

20 *“(A) In the case of any application submit-*
 21 *ted to the Secretary for financial assistance to*
 22 *conduct research, the Secretary may not approve*
 23 *or fund any application that is subject to review*
 24 *under section 491(a) by an Institutional Review*
 25 *Board unless the application has undergone re-*

1 view in accordance with such section and has
2 been recommended for approval by a majority of
3 the members of the Board conducting such re-
4 view.

5 “(B) In the case of research that is subject
6 to review under procedures established by the
7 Secretary for the protection of human subjects in
8 clinical research conducted by the National In-
9 stitutes of Health, the Secretary may not author-
10 ize the conduct of the research unless the research
11 has, pursuant to such procedures, been rec-
12 ommended for approval.

13 “(2) PEER REVIEW.—In the case of any applica-
14 tion submitted to the Secretary for financial assist-
15 ance to conduct research, the Secretary may not ap-
16 prove or fund any application that is subject to tech-
17 nical and scientific peer review under section 492(a)
18 unless the application has undergone peer review in
19 accordance with such section and has been rec-
20 ommended for approval by a majority of the members
21 of the entity conducting such review.

22 “(b) ETHICAL REVIEW OF RESEARCH.—

23 “(1) PROCEDURES REGARDING WITHHOLDING OF
24 FUNDS.—If research has been recommended for ap-
25 proval for purposes of subsection (a), the Secretary

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

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

6 *“(B)(i) the majority of the advisory board*
7 *recommends that, on ethical grounds, the Sec-*
8 *retary withhold funds for the research; or*

9 *(ii) the majority of such board recommends*
10 *that the Secretary not withhold funds for the re-*
11 *search on ethical grounds, but the Secretary*
12 *finds, on the basis of the report submitted under*
13 *paragraph (4)(B)(ii), that the recommendation*
14 *is arbitrary and capricious.*

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

21 *“(3) PRELIMINARY MATTERS REGARDING USE OF*
22 *PROCEDURES.—*

23 *“(A) If the Secretary makes a determina-*
24 *tion that an advisory board should be convened*
25 *for purposes of paragraph (1), the Secretary*

1 shall, through a statement published in the Fed-
2 eral Register, announce the intention of the Sec-
3 retary to convene such a board.

4 “(B) A statement issued under subpara-
5 graph (A) shall include a request that interested
6 individuals submit to the Secretary recommenda-
7 tions specifying the particular individuals who
8 should be appointed to the advisory board in-
9 volved. The Secretary shall consider such rec-
10 ommendations in making appointments to the
11 board.

12 “(C) The Secretary may not make appoint-
13 ments to an advisory board under paragraph (1)
14 until the expiration of the 30-day period begin-
15 ning on the date on which the statement required
16 in subparagraph (A) is made with respect to the
17 board.

18 “(4) ETHICS ADVISORY BOARDS.—

19 “(A) Any advisory board convened for pur-
20 poses of paragraph (1) shall be known as an eth-
21 ics advisory board (hereafter in this paragraph
22 referred to as an ‘ethics board’).

23 “(B)(i) An ethics board shall advise, consult
24 with, and make recommendations to the Sec-
25 retary regarding the ethics of the project of bio-

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

3 “(ii) Not later than 180 days after the date
4 on which the statement required in paragraph
5 (3)(A) is made with respect to an ethics board,
6 the board shall submit to the Secretary, and to
7 the Committee on Energy and Commerce of the
8 House of Representatives and the Committee on
9 Labor and Human Resources of the Senate, a re-
10 port describing the findings of the board regard-
11 ing the project of research involved and making
12 a recommendation under clause (i) of whether
13 the Secretary should or should not withhold
14 funds for the project. The report shall include the
15 information considered in making the findings.

16 “(C) An ethics board shall be composed of
17 no fewer than 14, and no more than 20, individ-
18 uals who are not officers or employees of the
19 United States. The Secretary shall make ap-
20 pointments to the board from among individuals
21 with special qualifications and competence to
22 provide advice and recommendations regarding
23 ethical matters in biomedical and behavioral re-
24 search. Of the members of the board—

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

3 “(ii) no fewer than 1 shall be an
4 ethicist;

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

7 “(iv) no fewer than 1 shall be a theolo-
8 gian; and

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

13 “(D) The term of service as a member of an
14 ethics board shall be for the life of the board. If
15 such a member does not serve the full term of
16 such service, the individual appointed to fill the
17 resulting vacancy shall be appointed for the re-
18 mainder of the term of the predecessor of the in-
19 dividual.

20 “(E) A member of an ethics board shall be
21 subject to removal from the board by the Sec-
22 retary for neglect of duty or malfeasance or for
23 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) In carrying out subparagraph (B)(i)
9 with respect to a project of research, an ethics
10 board shall have access to all relevant informa-
11 tion possessed by the Department of Health and
12 Human Services, or available to the Secretary
13 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 reasonable staff and
24 assistance to carry out the duties of the board.

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 a donation of the tis-*
22 *sue for use in such research;*

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; and*

3 “(iii) *the abortion was performed in*
4 *accordance with applicable State law;*

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 the*
8 *woman with regard to—*

9 “(i) *such physician’s interest, if any,*
10 *in the research to be conducted with the tis-*
11 *sue; 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 tissue*
15 *and that are in addition to risks of such*
16 *type that are associated with the woman’s*
17 *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 pur-
2 suant to a spontaneous or induced abortion or
3 pursuant 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 (b) (2)
22 and (c) will be available for audit by the Secretary.

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

1 *the privacy rights of the individuals and entities in-*
2 *volved in such research, including such individuals*
3 *and entities involved in the donation, transfer, re-*
4 *ceipt, or transplantation of human fetal tissue. With*
5 *respect to any material or information obtained pur-*
6 *suant to such audit, the Secretary shall—*

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

10 *“(B) not disclose or publish such material*
11 *or information, except where required by Federal*
12 *law, in which case such material or information*
13 *shall be coded in a manner such that the identi-*
14 *ties of such individuals and entities are pro-*
15 *TECTED; and*

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

19 *“(e) APPLICABILITY OF STATE AND LOCAL LAW.—*

20 *“(1) RESEARCH CONDUCTED BY RECIPIENTS OF*
21 *ASSISTANCE.—The Secretary may not provide sup-*
22 *port for research under subsection (a) unless the ap-*
23 *plicant for the financial assistance involved agrees to*
24 *conduct the research in accordance with applicable*
25 *State 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) *REPORT.*—*The Secretary shall annually submit to*
 6 *the Committee on Energy and Commerce of the House of*
 7 *Representatives, and to the Committee on Labor and*
 8 *Human Resources of the Senate, a report describing the ac-*
 9 *tivities carried out under this section during the preceding*
 10 *fiscal year, including a description of whether and to what*
 11 *extent research under subsection (a) has been conducted in*
 12 *accordance with this section.*

13 “(g) *DEFINITION.*—*For purposes of this section, the*
 14 *term ‘human fetal tissue’ means tissue or cells obtained*
 15 *from a dead human embryo or fetus after a spontaneous*
 16 *or induced abortion, or after a stillbirth.’.*

17 **SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITA-**
 18 **TION OR ACCEPTANCE OF TISSUE AS DI-**
 19 **RECTED DONATION FOR USE IN TRANSPLAN-**
 20 **TATION.**

21 *Part G of title IV of the Public Health Service Act,*
 22 *as amended by section 111 of this Act, is amended by insert-*
 23 *ing after section 498A the following new section:*

24 “*PROHIBITIONS REGARDING HUMAN FETAL TISSUE*

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

1 *otherwise transfer any human fetal tissue for valuable con-*
2 *sideration if the transfer affects interstate commerce.*

3 “(b) *SOLICITATION OR ACCEPTANCE OF TISSUE AS DI-*
4 *RECTED DONATION FOR USE IN TRANSPLANTATION.—It*
5 *shall be unlawful for any person to solicit or knowingly*
6 *acquire, receive, or accept a donation of human fetal tissue*
7 *for the purpose of transplantation of such tissue into an-*
8 *other person if the donation affects interstate commerce, the*
9 *tissue will be or is obtained pursuant to an induced abor-*
10 *tion, and—*

11 “(1) *the donation will be or is made pursuant to*
12 *a promise to the donating individual that the donated*
13 *tissue will be transplanted into a recipient specified*
14 *by such individual;*

15 “(2) *the donated tissue will be transplanted into*
16 *a relative of the donating individual; or*

17 “(3) *the person who solicits or knowingly ac-*
18 *quires, receives, or accepts the donation has provided*
19 *valuable consideration for the costs associated with*
20 *such abortion.*

21 “(c) *CRIMINAL PENALTIES FOR VIOLATIONS.—*

22 “(1) *IN GENERAL.—Any person who violates sub-*
23 *section (a) or (b) shall be fined in accordance with*
24 *title 18, United States Code, subject to paragraph (2),*
25 *or imprisoned for not more than 10 years, or both.*

1 “(2) *PENALTIES APPLICABLE TO PERSONS RE-*
 2 *CEIVING CONSIDERATION.*—*With respect to the impo-*
 3 *sition of a fine under paragraph (1), if the person in-*
 4 *involved violates subsection (a) or (b)(3), a fine shall be*
 5 *imposed in an amount not less than twice the amount*
 6 *of the valuable consideration received.*

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

8 “(1) *The term ‘human fetal tissue’ has the mean-*
 9 *ing given such term in section 498A(f).*

10 “(2) *The term ‘interstate commerce’ has the*
 11 *meaning given such term in section 201(b) of the Fed-*
 12 *eral Food, Drug, and Cosmetic Act.*

13 “(3) *The term ‘valuable consideration’ does not*
 14 *include reasonable payments associated with the*
 15 *transportation, implantation, processing, preserva-*
 16 *tion, quality control, or storage of human fetal*
 17 *tissue.”.*

18 **SEC. 113. NULLIFICATION OF MORATORIUM.**

19 (a) *IN GENERAL.*—*Except as provided in subsection*
 20 *(c), no official of the executive branch may impose a policy*
 21 *that the Department of Health and Human Services is pro-*
 22 *hibited from conducting or supporting any research on the*
 23 *transplantation of human fetal tissue for therapeutic pur-*
 24 *poses. Such research shall be carried out in accordance with*
 25 *section 498A of the Public Health Service Act (as added*

1 *by section 111 of this Act), without regard to any such pol-*
2 *icy that may have been in effect prior to the date of the*
3 *enactment of this Act.*

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

6 *(1) IN GENERAL.—In the case of any proposal*
7 *for research on the transplantation of human fetal tis-*
8 *sue for therapeutic purposes, the Secretary of Health*
9 *and Human Services may not withhold funds for the*
10 *research if—*

11 *(A) the research has been approved for pur-*
12 *poses of section 492A(a) of the Public Health*
13 *Service Act (as added by section 101 of this Act);*

14 *(B) the research will be carried out in ac-*
15 *cordance with section 498A of such Act (as added*
16 *by section 111 of this Act); and*

17 *(C) there are reasonable assurances that the*
18 *research will not utilize any human fetal tissue*
19 *that has been obtained in violation of section*
20 *498B(a) of such Act (as added by section 112 of*
21 *this Act).*

22 *(2) STANDING APPROVAL REGARDING ETHICAL*
23 *STATUS.—In the case of any proposal for research on*
24 *the transplantation of human fetal tissue for thera-*
25 *peutic purposes, the issuance in December 1988 of the*

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

3 *(A) issued by an ethics advisory board pur-*
4 *suant to section 492A(b)(4)(B)(ii) of the Public*
5 *Health Service Act (as added by section 101 of*
6 *this Act); and*

7 *(B) finding, on a basis that is neither arbi-*
8 *trary nor capricious, that there are no ethical*
9 *grounds for withholding funds for the research.*

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

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

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

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

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

3 *(1) whether and to what extent such research*
 4 *conducted or supported by the Secretary of Health*
 5 *and Human Services has been conducted in accord-*
 6 *ance with section 498A of the Public Health Service*
 7 *Act (as added by section 111 of this Act); and*

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

11 *(b) REPORT.—Not later than May 19, 1995, the Comp-*
 12 *troller General of the United States shall complete the audit*
 13 *required in subsection (a) and submit to the Committee on*
 14 *Energy and Commerce of the House of Representatives, and*
 15 *to the Committee on Labor and Human Resources of the*
 16 *Senate, a report describing the findings made pursuant to*
 17 *the audit.*

18 **PART III—MISCELLANEOUS REPEALS**

19 **SEC. 121. REPEALS.**

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

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

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

1 “(B) members of minority groups are in-
2 cluded as subjects in such research.

3 “(2) *OUTREACH REGARDING PARTICIPATION AS*
4 *SUBJECTS.—The Director of NIH, in consultation*
5 *with the Director of the Office of Research on Wom-*
6 *en’s Health and the Director of the Office of Research*
7 *on Minority Health, shall conduct or support out-*
8 *reach programs for the recruitment of women and*
9 *members of minority groups as subjects in projects of*
10 *clinical research.*

11 “(b) *INAPPLICABILITY OF REQUIREMENT.—The re-*
12 *quirement established in subsection (a) regarding women*
13 *and members of minority groups shall not apply to a*
14 *project of clinical research if the inclusion, as subjects in*
15 *the project, of women and members of minority groups, re-*
16 *spectively—*

17 “(1) *is inappropriate with respect to the health*
18 *of the subjects;*

19 “(2) *is inappropriate with respect to the purpose*
20 *of the research; or*

21 “(3) *is inappropriate under such other cir-*
22 *cumstances as the Director of NIH may designate.*

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

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

6 “(d) *GUIDELINES.*—

7 “(1) *IN GENERAL.*—*Subject to paragraph (2), the*
8 *Director of NIH, in consultation with the Director of*
9 *the Office of Research on Women’s Health and the Di-*
10 *rector of the Office of Research on Minority Health,*
11 *shall establish guidelines regarding the requirements*
12 *of this section. The guidelines shall include guidelines*
13 *regarding—*

14 “(A) *the circumstances under which the in-*
15 *clusion of women and minorities as subjects in*
16 *projects of clinical research is inappropriate for*
17 *purposes of subsection (b);*

18 “(B) *the manner in which clinical trials*
19 *are required to be designed and carried out for*
20 *purposes of subsection (c); and*

21 “(C) *the operation of outreach programs*
22 *under subsection (a).*

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

1 *subjects in a project of clinical research is inappropriate*
2 *for purposes of subsection (b), the following ap-*
3 *plies to guidelines under paragraph (1):*

4 *“(A)(i) In the case of a clinical trial, the*
5 *guidelines shall provide that the costs of such in-*
6 *clusion in the trial is not a permissible consider-*
7 *ation in determining whether such inclusion is*
8 *inappropriate.*

9 *“(ii) In the case of other projects of clinical*
10 *research, the guidelines shall provide that the*
11 *costs of such inclusion in the project is not a per-*
12 *missible consideration in determining whether*
13 *such inclusion is inappropriate unless the data*
14 *regarding women or members of minority*
15 *groups, respectively, that would be obtained in*
16 *such project (in the event that such inclusion*
17 *were required) have been or will be obtained*
18 *through other means that provide data of com-*
19 *parable quality.*

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

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

4 “(ii) the effects that the variables have
5 on the individuals who would serve as sub-
6 jects in the trial in the event that such in-
7 clusion were not required.

8 “(e) *DATE CERTAIN FOR GUIDELINES; APPLICABIL-*
9 *ITY.*—

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

15 “(2) *APPLICABILITY.*—*For fiscal year 1995 and*
16 *subsequent fiscal years, the Director of NIH may not*
17 *approve any proposal of clinical research to be con-*
18 *ducted or supported by any agency of the National*
19 *Institutes of Health unless the proposal specifies the*
20 *manner in which the research will comply with this*
21 *section.*

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

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

3 “(g) *DEFINITIONS.*—*For purposes of this section:*

4 “(1) *The term ‘project of clinical research’ in-*
5 *cludes a clinical trial.*

6 “(2) *The term ‘minority group’ includes sub-*
7 *populations of minority groups. The Director of NIH*
8 *shall, through the guidelines established under sub-*
9 *section (d), define the terms ‘minority group’ and*
10 *‘subpopulation’ for purposes of the preceding sen-*
11 *tence.’.*

12 **SEC. 132. PEER REVIEW.**

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

16 “(c)(1) *In technical and scientific peer review under*
17 *this section of proposals for clinical research, the consider-*
18 *ation of any such proposal (including the initial consider-*
19 *ation) shall, except as provided in paragraph (2), include*
20 *an evaluation of the technical and scientific merit of the*
21 *proposal regarding compliance with section 492B.*

22 “(2) *Paragraph (1) shall not apply to any proposal*
23 *for clinical research that, pursuant to subsection (b) of sec-*
24 *tion 492B, is not subject to the requirement of subsection*
25 *(a) of such section regarding the inclusion of women and*

1 *members of minority groups as subjects in clinical re-*
 2 *search.”.*

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

4 *Section 492B of the Public Health Service Act, as*
 5 *added by section 131 of this Act, shall not apply with re-*
 6 *spect to projects of clinical research for which initial fund-*
 7 *ing was provided prior to the date of the enactment of this*
 8 *Act. With respect to the inclusion of women and minorities*
 9 *as subjects in clinical research conducted or supported by*
 10 *the National Institutes of Health, any policies of the Sec-*
 11 *retary of Health and Human Services regarding such inclu-*
 12 *sion that are in effect on the day before the date of the enact-*
 13 *ment of this Act shall continue to apply to the projects re-*
 14 *ferred to in the preceding sentence.*

15 **PART II—OFFICE OF RESEARCH ON WOMEN’S**

16 **HEALTH**

17 **SEC. 141. ESTABLISHMENT.**

18 *(a) IN GENERAL.—Title IV of the Public Health Serv-*
 19 *ice Act, as amended by the preceding provisions of this title,*
 20 *is amended—*

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

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

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

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) *The Advisory Committee shall be composed*
2 *of no fewer than 12, and not more than 18 individ-*
3 *uals, who are not officers or employees of the Federal*
4 *Government. The Director of the Office shall make ap-*
5 *pointments to the Advisory Committee from among*
6 *physicians, practitioners, scientists, and other health*
7 *professionals, whose clinical practice, research spe-*
8 *cialization, 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 “(3) *The Director of the Office shall serve as the*
13 *chair of the Advisory Committee.*

14 “(4) *The Advisory Committee shall—*

15 “(A) *advise the Director of the Office on ap-*
16 *propriate research activities to be undertaken by*
17 *the national research institutes with respect to—*

18 “(i) *research on women’s health;*

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

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

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

2
3
4 “(v) research on women’s health conditions which require a multidisciplinary approach;

5
6
7 “(B) report to the Director of the Office on such research;

8
9 “(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and

10
11
12
13
14 “(D) assist in monitoring compliance with section 492B regarding the inclusion of women in clinical research.

15
16
17
18 “(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

19
20
21 “(i) compliance with section 492B;

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

24
25

1 “(iii) the level of funding needed for such
2 research.

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

6 “(e) REPRESENTATION OF WOMEN AMONG RESEARCH-
7 ERS.—The Secretary, acting through the Assistant Sec-
8 retary for Personnel and in collaboration with the Director
9 of the Office, shall determine the extent to which women
10 are represented among senior physicians and scientists of
11 the national research institutes and among physicians and
12 scientists conducting research with funds provided by such
13 institutes, and as appropriate, carry out activities to in-
14 crease the extent of such representation.

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

16 “(1) The term ‘women’s health conditions’, with
17 respect to women of all age, ethnic, and racial groups,
18 means all diseases, disorders, and conditions (includ-
19 ing with respect to mental health)—

20 “(A) unique to, more serious, or more prev-
21 alent in women;

22 “(B) for which the factors of medical risk or
23 types of medical intervention are different for
24 women, or for which it is unknown whether such
25 factors or types are different for women; 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, includ-
6 ing research on preventing such conditions.

7 **“SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE**
8 **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 and the Director of the Na-
12 tional Library of Medicine, shall establish a data sys-
13 tem for the collection, storage, analysis, retrieval, and
14 dissemination of information regarding research on
15 women’s health that is conducted or supported by the
16 national research institutes. Information from the
17 data system shall be available through information
18 systems available to health care professionals and
19 providers, researchers, and members of the 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 for
23 research on women’s health. Such registry shall in-
24 clude information on subject eligibility criteria, sex,
25 age, ethnicity or race, and the location of the trial site

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

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

15 **“SEC. 486B. BIENNIAL REPORT.**

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

20 *“(1) describing and evaluating the progress made*
21 *during the preceding 2 fiscal years in research and*
22 *treatment conducted or supported by the National In-*
23 *stitutes of Health;*

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

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

3 *“(3) summarizing and analyzing expenditures*
4 *made by the agencies of such Institutes (and by such*
5 *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 re-*
11 *port prepared under subsection (a) to the Director of NIH*
12 *for inclusion in the report submitted to the President and*
13 *the Congress under section 403.”.*

14 *(b) REQUIREMENT OF SUFFICIENT ALLOCATION OF*
15 *RESOURCES OF INSTITUTES.—Section 402(b) of the Public*
16 *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 follow-*
22 *ing new paragraph:*

23 *“(12) after consultation with the Director of the*
24 *Office of Research on Women’s Health, shall ensure*
25 *that resources of the National Institutes of Health are*

1 “(4) encourage the conduct of such research by
2 entities receiving funds from the national research in-
3 stitutes;

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

6 “(6) promote the sufficient allocation of the re-
7 sources of the national research institutes for conduct-
8 ing and supporting such research; and

9 “(7) assist in the administration of section 492B
10 with respect to the inclusion of members of minority
11 groups as subjects in clinical research.”.

12 ***Subtitle C—Research Integrity***

13 ***SEC. 161. ESTABLISHMENT OF OFFICE OF RESEARCH IN-*** 14 ***TEGRITY.***

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

17 “OFFICE OF RESEARCH INTEGRITY

18 “SEC. 493. (a) *ESTABLISHMENT.*—

19 “(1) *IN GENERAL.*—Not later than 90 days after
20 the date of enactment of this section, the Secretary
21 shall establish an office to be known as the Office of
22 Research Integrity (hereafter referred to in this sec-
23 tion as the ‘Office’), which shall be established as an
24 independent entity in the Department of Health and
25 Human Services.

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 of*
4 *research, and have experience in the conduct of inves-*
5 *tigations of research misconduct. The Secretary shall*
6 *carry out this section acting through the Director of*
7 *the Office. The Director shall report to the Secretary.*

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

16 “(1) *has established (in accordance with regula-*
17 *tions which the Secretary shall prescribe) an adminis-*
18 *trative process to review reports of research mis-*
19 *conduct in connection with biomedical and behavioral*
20 *research conducted at or sponsored by such entity;*
21 *and*

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

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

4 “(1) response to information provided to the Di-
5 rector respecting research misconduct in connection
6 with projects for which funds have been made avail-
7 able under this Act;

8 “(2) receipt of reports by the Director of such in-
9 formation from recipients of funds under this Act;

10 “(3) conduct of investigations, when appropriate;
11 and

12 “(4) taking of other actions, including appro-
13 priate remedies, with respect to such misconduct.

14 “(d) *MONITORING BY DIRECTOR.*—The Secretary shall
15 by regulation establish procedures for the Director to mon-
16 itor administrative processes and investigations that have
17 been established or carried out under this section.

18 “(e) *EFFECT ON PRESENT INVESTIGATIONS.*—Nothing
19 in this section shall affect investigations which have been
20 or will be commenced prior to the promulgation of final
21 regulations under this section.”.

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

1 *retary shall by regulation establish a definition for the term*
2 *“research misconduct” for purposes of section 493 of the*
3 *Public Health Service Act, as amended by subsection (a)*
4 *of this section.*

5 **SEC. 162. COMMISSION ON RESEARCH INTEGRITY.**

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

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

16 (c) *COMPOSITION.*—*The Commission shall be composed*
17 *of 12 members to be appointed by the Secretary of Health*
18 *and Human Services. Not more than 3 members of the Com-*
19 *mission may be officers or employees of the United States.*
20 *Of the members of the Commission—*

21 (1) *three shall be scientists with substantial ac-*
22 *complishments in biomedical or behavioral research;*

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

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

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

8 (d) *COMPENSATION.*—Members of the Commission
9 may not receive compensation for service on the Commis-
10 sion. Members may be reimbursed for travel, subsistence,
11 and other necessary expenses incurred in carrying out the
12 duties of the Commission.

13 (e) *REPORT.*—Not later than 120 days after the date
14 on which the Commission is established under subsection
15 (a), the Commission shall prepare and submit to the Sec-
16 retary of Health and Human Services, the Committee on
17 Energy and Commerce of the House of Representatives, and
18 the Committee on Labor and Human Resources of the Sen-
19 ate, a report containing the recommendations developed
20 under subsection (b).

21 **SEC. 163. PROTECTION OF WHISTLEBLOWERS.**

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

25 “(f) *PROTECTION OF WHISTLEBLOWERS.*—

1 “(1) *IN GENERAL.*—*In the case of any entity re-*
2 *quired to establish administrative processes under*
3 *subsection (b), the Secretary shall by regulation estab-*
4 *lish standards for preventing, and for responding to*
5 *the occurrence of retaliation by such entity, its offi-*
6 *cial or agents, against an employee in the terms and*
7 *conditions of employment in response to the employee*
8 *having in good faith—*

9 “(A) *made an allegation that the entity, its*
10 *officials or agents, has engaged in or failed to*
11 *adequately respond to an allegation of research*
12 *misconduct; or*

13 “(B) *cooperated with an investigation of*
14 *such an allegation.*

15 “(2) *MONITORING BY SECRETARY.*—*The Sec-*
16 *retary shall establish by regulation procedures for the*
17 *Director to monitor the implementation of the stand-*
18 *ards established by an entity under paragraph (1) for*
19 *the purpose of determining whether the procedures*
20 *have been established, and are being utilized, in ac-*
21 *cordance with the standards established under such*
22 *paragraph.*

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

1 *taliation in violation of the standards established*
2 *under paragraph (1). Such remedies may include ter-*
3 *mination of funding provided by the Secretary for*
4 *such project or recovery of funding being provided by*
5 *the Secretary for such project, or other actions as ap-*
6 *propriate.*

7 *“(4) FINAL RULE FOR REGULATIONS.—The Sec-*
8 *retary shall issue a final rule for the regulations re-*
9 *quired in paragraph (1) not later than 180 days after*
10 *the date of the enactment of the National Institutes of*
11 *Health Revitalization Act of 1993.*

12 *“(5) REQUIRED AGREEMENTS.—For any fiscal*
13 *year beginning after the date on which the regulations*
14 *required in paragraph (1) are issued, the Secretary*
15 *may not provide a grant, cooperative agreement, or*
16 *contract under this Act for biomedical or behavioral*
17 *research unless the entity seeking such financial as-*
18 *sistance agrees that the entity—*

19 *“(A) will maintain the procedures described*
20 *in the regulations; and*

21 *“(B) will otherwise be subject to the regula-*
22 *tions.”.*

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

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

8 *“PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST*
9 *IN CERTAIN PROJECTS OF RESEARCH*

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

11 *“(1) IN GENERAL.—The Secretary shall define by*
12 *regulation, the specific circumstances that constitute*
13 *the existence of a financial interest in a project on the*
14 *part of an entity or individual that will, or may be*
15 *reasonably expected to, create a bias in favor of ob-*
16 *taining results in such project that are consistent*
17 *with such financial interest. Such definition shall*
18 *apply uniformly to each entity or individual conduct-*
19 *ing a research project under this Act. In the case of*
20 *any entity or individual receiving assistance from the*
21 *Secretary for a project of research described in para-*
22 *graph (2), the Secretary shall by regulation establish*
23 *standards for responding to, including managing, re-*
24 *ducing, or eliminating, the existence of such a finan-*
25 *cial interest. The entity may adopt individualized*
26 *procedures for implementing the standards.*

1 “(2) *RELEVANT PROJECTS.*—A project of re-
2 search referred to in paragraph (1) is a project of
3 clinical research whose purpose is to evaluate the safe-
4 ty or effectiveness of a drug, medical device, or treat-
5 ment and for which such entity is receiving assistance
6 from the Secretary.

7 “(3) *IDENTIFYING AND REPORTING TO THE DI-*
8 *RECTOR.*—The Secretary shall ensure that the stand-
9 ards established under paragraph (1) specify that as
10 a condition of receiving assistance from the Secretary
11 for the project involved, an entity described in such
12 subsection is required—

13 “(A) to have in effect at the time the entity
14 applies for the assistance and throughout the pe-
15 riod during which the assistance is received, a
16 process for identifying such financial interests as
17 defined in paragraph (1) that exist regarding the
18 project; and

19 “(B) to report to the Director such financial
20 interest as defined in paragraph (1) identified
21 by the entity and how any such financial inter-
22 est identified by the entity will be managed or
23 eliminated such that the project in question will
24 be protected from bias that may stem from such
25 financial interest.

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

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

9 “(A) *shall require that, as a condition of re-*
10 *ceiving assistance, the entity disclose the exist-*
11 *ence of a financial interest as defined in para-*
12 *graph (1) in each public presentation of the re-*
13 *sults of such project; and*

14 “(B) *may take such other actions as the*
15 *Secretary determines to be appropriate.*

16 “(6) *DEFINITION.*—*As used in this section:*

17 “(A) *The term ‘financial interest’ includes*
18 *the receipt of consulting fees or honoraria and*
19 *the ownership of stock or equity.*

20 “(B) *The term ‘assistance’, with respect to*
21 *conducting a project of research, means a grant,*
22 *contract, or cooperative agreement.*

23 “(b) *FINAL RULE FOR REGULATIONS.*—*The Secretary*
24 *shall issue a final rule for the regulations required in sub-*
25 *section (a) not later than 180 days after the date of the*

1 *enactment of the National Institutes of Health Revitaliza-*
2 *tion Act of 1993.”.*

3 **SEC. 165. EFFECTIVE DATES.**

4 (a) *IN GENERAL.*—*The amendments made by this sub-*
5 *title shall become effective on the date that occurs 180 days*
6 *after the date on which the final rule required under section*
7 *493(f)(4) of the Public Health Service Act, as amended by*
8 *sections 161 and 163, is published in the Federal Register.*

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

17 **TITLE II—NATIONAL INSTITUTES**
18 **OF HEALTH IN GENERAL**

19 **SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINATION.**

20 *Section 402(f) of the Public Health Service Act (42*
21 *U.S.C. 282(f)) is amended by striking “other public and*
22 *private entities.” and all that follows through the end and*
23 *inserting “other public and private entities, including ele-*
24 *mentary, secondary, and post-secondary schools. The Asso-*
25 *ciate Director shall—*

1 “(1) annually review the efficacy of existing poli-
2 cies and techniques used by the national research in-
3 stitutes to disseminate the results of disease preven-
4 tion and behavioral research programs;

5 “(2) recommend, coordinate, and oversee the
6 modification or reconstruction of such policies and
7 techniques to ensure maximum dissemination, using
8 advanced technologies to the maximum extent prac-
9 ticable, of research results to such entities; and

10 “(3) annually prepare and submit to the Direc-
11 tor of NIH a report concerning the prevention and
12 dissemination activities undertaken by the Associate
13 Director, including—

14 “(A) a summary of the Associate Director’s
15 review of existing dissemination policies and
16 techniques together with a detailed statement
17 concerning any modification or restructuring, or
18 recommendations for modification or restructur-
19 ing, of such policies and techniques; and

20 “(B) a detailed statement of the expendi-
21 tures made for the prevention and dissemination
22 activities reported on and the personnel used in
23 connection with such activities.”.

1 **SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARD-**
2 **ING CERTAIN STATES AND RESEARCHERS.**

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

6 *“(g)(1)(A) In the case of entities described in subpara-*
7 *graph (B), the Director of NIH, acting through the Director*
8 *of the National Center for Research Resources, shall estab-*
9 *lish a program to enhance the competitiveness of such enti-*
10 *ties in obtaining funds from the national research institutes*
11 *for conducting biomedical and behavioral research.*

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

20 *“(C) With respect to enhancing competitiveness for*
21 *purposes of subparagraph (A), the Director of NIH, in car-*
22 *rying out the program established under such subpara-*
23 *graph, may—*

24 *“(i) provide technical assistance to the entities*
25 *involved, including technical assistance in the prepa-*

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

3 “(2) *Research authorized under paragraph (1) in-*
4 *cludes research on teen pregnancy, infant mortality, violent*
5 *behavior, suicide, and homelessness.*

6 “(3) *The sole responsibility of the Director of the Office*
7 *shall be carrying out paragraph (1).”.*

8 **SEC. 204. CHILDREN’S VACCINE INITIATIVE.**

9 *Part A of title IV of the Public Health Service Act,*
10 *as amended by section 203 of this Act, is amended by add-*
11 *ing at the end the following new section:*

12 “CHILDREN’S VACCINE INITIATIVE

13 “SEC. 404B. (a) DEVELOPMENT OF NEW VACCINES.—
14 *The Secretary, in consultation with the Director of the Na-*
15 *tional Vaccine Program under title XXI and acting through*
16 *the Directors of the National Institute for Allergy and Infec-*
17 *tious Diseases, the National Institute for Child Health and*
18 *Human Development, the National Institute for Aging, and*
19 *other public and private programs, shall carry out activi-*
20 *ties, which shall be consistent with the global Children’s*
21 *Vaccine Initiative, to develop affordable new and improved*
22 *vaccines to be used in the United States and in the develop-*
23 *ing world that will increase the efficacy and efficiency of*
24 *the prevention of infectious diseases. In carrying out such*
25 *activities, the Secretary shall, to the extent practicable, de-*
26 *velop and make available vaccines that require fewer con-*

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

5 “(b) *REPORT.*—*In the report required in section 2104,*
 6 *the Secretary, acting through the Director of the National*
 7 *Vaccine Program under title XXI, shall include information*
 8 *with respect to activities and the progress made in imple-*
 9 *menting the provisions of this section and achieving its*
 10 *goals.*

11 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—*In addi-*
 12 *tion to any other amounts authorized to be appropriated*
 13 *for activities of the type described in this section, there are*
 14 *authorized to be appropriated to carry out this section*
 15 *\$50,000,000 for fiscal year 1994, and such sums as may*
 16 *be necessary for each of the fiscal years 1995 and 1996.”.*

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

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

21 “*PLAN FOR USE OF ANIMALS IN RESEARCH*

22 “*SEC. 404C. (a) The Director of NIH, after consulta-*
 23 *tion with the committee established under subsection (e),*
 24 *shall prepare a plan—*

25 “(1) *for the National Institutes of Health to con-*
 26 *duct or support research into—*

1 “(A) *methods of biomedical research and ex-*
2 *perimentation that do not require the use of ani-*
3 *mals;*

4 “(B) *methods of such research and experi-*
5 *mentation that reduce the number of animals*
6 *used in such research;*

7 “(C) *methods of such research and experi-*
8 *mentation that produce less pain and distress in*
9 *such animals; and*

10 “(D) *methods of such research and experi-*
11 *mentation that involve the use of marine life*
12 *(other than marine mammals);*

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

15 “(3) *for encouraging the acceptance by the sci-*
16 *entific community of such methods that have been*
17 *found to be valid and reliable; and*

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

20 “(b) *Not later than October 1, 1993, the Director of*
21 *NIH shall submit to the Committee on Energy and Com-*
22 *merce of the House of Representatives, and to the Committee*
23 *on Labor and Human Resources of the Senate, the plan*
24 *required in subsection (a) and shall begin implementation*
25 *of the plan.*

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

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

12 “(e)(1) The Director of NIH shall establish within the
13 National Institutes of Health a committee to be known as
14 the Interagency Coordinating Committee on the Use of Ani-
15 mals in Research (hereafter in this subsection referred to
16 as the ‘Committee’).

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

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

21 “(A) the Directors of each of the national re-
22 search institutes and the Director of the Center for
23 Research Resources (or the designees of such Direc-
24 tors); and

1 “(B) representatives of the Environmental Pro-
2 tection Agency, the Food and Drug Administration,
3 the Consumer Product Safety Commission, the Na-
4 tional Science Foundation, and such additional agen-
5 cies as the Director of NIH determines to be appro-
6 priate.”.

7 (b) *CONFORMING AMENDMENT.*—Section 4 of the
8 Health Research Extension Act of 1985 (Public Law 99–
9 158; 99 Stat. 880) is repealed.

10 **SEC. 206. INCREASED PARTICIPATION OF WOMEN AND DIS-**
11 **ADVANTAGED INDIVIDUALS IN FIELDS OF**
12 **BIOMEDICAL AND BEHAVIORAL RESEARCH.**

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

16 “(h) The Secretary, acting through the Director of NIH
17 and the Directors of the agencies of the National Institutes
18 of Health, may conduct and support programs for research,
19 research training, recruitment, and other activities to pro-
20 vide for an increase in the number of women and individ-
21 uals from disadvantaged backgrounds in the fields of bio-
22 medical and behavioral research.”.

1 **SEC. 207. REQUIREMENTS REGARDING SURVEYS OF SEXUAL**
2 **BEHAVIOR.**

3 *Part A of title IV of the Public Health Service Act,*
4 *as amended by section 205 of this Act, is amended by add-*
5 *ing at the end the following new section:*

6 *“REQUIREMENTS REGARDING SURVEYS OF SEXUAL*
7 *BEHAVIOR*

8 *“SEC. 404D. With respect to any survey of human sex-*
9 *ual behavior proposed to be conducted or supported through*
10 *the National Institutes of Health, the survey may not be*
11 *carried out unless—*

12 *“(1) the proposal has undergone review in ac-*
13 *cordance with any applicable requirements of sections*
14 *491 and 492; and*

15 *“(2) the Secretary, in accordance with section*
16 *492A, makes a determination that the information ex-*
17 *pected to be obtained through the survey will assist—*

18 *“(A) in reducing the incidence of sexually*
19 *transmitted diseases, the incidence of infection*
20 *with the human immunodeficiency virus, or the*
21 *incidence of any other infectious disease; or*

22 *“(B) in improving reproductive health or*
23 *other conditions of health.”.*

1 **SEC. 208. DISCRETIONARY FUND OF DIRECTOR OF NA-**
2 **TIONAL INSTITUTES OF HEALTH.**

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

6 *“(i)(1) There is established a fund, consisting of*
7 *amounts appropriated under paragraph (3) and made*
8 *available for the fund, for use by the Director of NIH to*
9 *carry out the activities authorized in this Act for the Na-*
10 *tional Institutes of Health. The purposes for which such*
11 *fund may be expended include—*

12 *“(A) providing for research on matters that have*
13 *not received significant funding relative to other mat-*
14 *ters, responding to new issues and scientific emer-*
15 *gencies, and acting on research opportunities of high*
16 *priority;*

17 *“(B) supporting research that is not exclusively*
18 *within the authority of any single agency of such In-*
19 *stitutes; and*

20 *“(C) purchasing or renting equipment and quar-*
21 *ters for activities of such Institutes.*

22 *“(2) Not later than February 10 of each fiscal year,*
23 *the Secretary shall submit to the Committee on Energy and*
24 *Commerce of the House of Representatives, and to the Com-*
25 *mittee on Labor and Human Resources of the Senate, a*
26 *report describing the activities undertaken and expenditures*

1 *made under this section during the preceding fiscal year.*
 2 *The report may contain such comments of the Secretary re-*
 3 *garding this section as the Secretary determines to be ap-*
 4 *propriate.*

5 “(3) *For the purpose of carrying out this subsection,*
 6 *there are authorized to be appropriated \$25,000,000 for fis-*
 7 *cal year 1994, and such sums as may be necessary for each*
 8 *of the fiscal years 1995 and 1996.”*

9 **SEC. 209. ESTABLISHMENT OF OFFICE OF ALTERNATIVE**
 10 **MEDICINE.**

11 *Part A of title IV of the Public Health Service Act,*
 12 *as amended by section 207 of this Act, is amended by add-*
 13 *ing at the end the following section:*

14 “OFFICE OF ALTERNATIVE MEDICINE

15 “SEC. 404E. (a) *There is established within the Office*
 16 *of the Director of NIH an office to be known as the Office*
 17 *of Alternative Medicine (in this section referred to as the*
 18 *‘Office’), which shall be headed by a director appointed by*
 19 *the Director of NIH.*

20 “(b) *The purpose of the Office is to facilitate the eval-*
 21 *uation of various alternative medicine treatment modali-*
 22 *ties, including acupuncture and Oriental medicine, homeo-*
 23 *pathic medicine, and physical manipulation therapies.*

24 “(c) *In carrying out subsection (b), the Director of the*
 25 *Office shall—*

1 “(1) establish an information clearinghouse to
2 exchange information with the public about alter-
3 native medicine;

4 “(2) support research training—

5 “(A) for which fellowship support is not
6 provided under section 487; and

7 “(B) that is not residency training of physi-
8 cians or other health professionals; and

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

14 **SEC. 210. MISCELLANEOUS PROVISIONS.**

15 (a) *TERM OF OFFICE FOR MEMBERS OF ADVISORY*
16 *COUNCILS.*—Section 406(c) of the Public Health Service
17 Act (42 U.S.C. 284a(c)) is amended in the second sentence
18 by striking “until a successor has taken office” and insert-
19 ing the following: “for 180 days after the date of such expi-
20 ration”.

21 (b) *LITERACY REQUIREMENTS.*—Section 402(e) of the
22 Public Health Service Act (42 U.S.C. 282(e)) is amended—
23 (1) in paragraph (3), by striking “and” at the
24 end;

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

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

5 “(5) ensure that, after January 1, 1994, at least
6 one-half of all new or revised health education and
7 promotion materials developed or funded by the Na-
8 tional Institutes of Health is in a form that does not
9 exceed a level of functional literacy, as defined in the
10 National Literacy Act of 1991 (Public Law 102-
11 73).”.

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

16 “(j)(1) The Director of NIH may establish a program
17 to provide day care services for the employees of the Na-
18 tional Institutes of Health similar to those services provided
19 by other Federal agencies (including the availability of day
20 care service on a 24-hour-a-day basis).

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

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

4 **TITLE III—GENERAL PROVI-**
5 **SIONS RESPECTING NA-**
6 **TIONAL RESEARCH INSTI-**
7 **TUTES**

8 **SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS**
9 **OF NATIONAL RESEARCH INSTITUTES.**

10 (a) *ESTABLISHMENT OF GENERAL AUTHORITY RE-*
11 *GARDING DIRECT FUNDING.—*

12 (1) *IN GENERAL.—Section 405(b)(2) of the Pub-*
13 *lic Health Service Act (42 U.S.C. 284(b)(2)) is*
14 *amended—*

15 (A) *in subparagraph (A), by striking “and”*
16 *after the semicolon at the end;*

17 (B) *in subparagraph (B), by striking the*
18 *period at the end and inserting “; and”; and*

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

21 “(C) *shall receive from the President and the Of-*
22 *ice of Management and Budget directly all funds ap-*
23 *propriated by the Congress for obligation and expend-*
24 *iture by the Institute.”.*

1 (2) *CONFORMING AMENDMENT.*—Section
2 413(b)(9) of the Public Health Service Act (42 U.S.C.
3 285a–2(b)(9)) is amended—

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

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

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

10 (1) by amending paragraph (3) to read as fol-
11 lows:

12 “(3) may, in consultation with the advisory
13 council for the Institute and with the approval of the
14 Director of NIH—

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

18 “(B) appoint the members of peer review
19 groups established under subparagraph (A);
20 and”; and

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

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

1 **SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS,**
2 **PAGET'S DISEASE, AND RELATED BONE DIS-**
3 **ORDERS.**

4 *Part B of title IV of the Public Health Service Act*
5 *(42 U.S.C. 284 et seq.), as amended by section 121(b) of*
6 *Public Law 102–321 (106 Stat. 358), is amended by adding*
7 *at the end the following new section:*

8 *“RESEARCH ON OSTEOPOROSIS, PAGET’S DISEASE, AND*
9 *RELATED BONE DISORDERS*

10 *“SEC. 409A. (a) ESTABLISHMENT.—The Directors of*
11 *the National Institute of Arthritis and Musculoskeletal and*
12 *Skin Diseases, the National Institute on Aging, and the Na-*
13 *tional Institute of Diabetes, Digestive and Kidney Diseases,*
14 *shall expand and intensify the programs of such Institutes*
15 *with respect to research and related activities concerning*
16 *osteoporosis, Paget’s disease, and related bone disorders.*

17 *“(b) COORDINATION.—The Directors referred to in sub-*
18 *section (a) shall jointly coordinate the programs referred*
19 *to in such subsection and consult with the Arthritis and*
20 *Musculoskeletal Diseases Interagency Coordinating Com-*
21 *mittee and the Interagency Task Force on Aging Research.*

22 *“(c) INFORMATION CLEARINGHOUSE.—*

23 *“(1) IN GENERAL.—In order to assist in carry-*
24 *ing out the purpose described in subsection (a), the*
25 *Director of NIH shall provide for the establishment of*
26 *an information clearinghouse on osteoporosis and re-*

1 *lated bone disorders to facilitate and enhance knowl-*
2 *edge and understanding on the part of health profes-*
3 *sionals, patients, and the public through the effective*
4 *dissemination of information.*

5 *“(2) ESTABLISHMENT THROUGH GRANT OR CON-*
6 *TRACT.—For the purpose of carrying out paragraph*
7 *(1), the Director of NIH shall enter into a grant, co-*
8 *operative agreement, or contract with a nonprofit pri-*
9 *vate entity involved in activities regarding the pre-*
10 *vention and control of osteoporosis and related bone*
11 *disorders.*

12 *“(d) AUTHORIZATION OF APPROPRIATIONS.—For the*
13 *purpose of carrying out this section, there are authorized*
14 *to be appropriated \$40,000,000 for fiscal year 1994, and*
15 *such sums as may be necessary for each of the fiscal years*
16 *1995 and 1996.”.*

17 **SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM**
18 **FOR TRAUMA RESEARCH.**

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

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

5 *“(c) PARTICIPATING AGENCIES; COORDINATION AND*
6 *COLLABORATION.—The Director—*

7 *“(1) shall provide for the conduct of activities*
8 *under the Program by the Directors of the agencies of*
9 *the National Institutes of Health involved in research*
10 *with respect to trauma;*

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

13 *“(3) shall, as appropriate, provide for collabora-*
14 *tion among such agencies in carrying out such activi-*
15 *ties.*

16 *“(d) CERTAIN ACTIVITIES OF PROGRAM.—The Pro-*
17 *gram shall include—*

18 *“(1) studies with respect to all phases of trauma*
19 *care, including prehospital, resuscitation, surgical*
20 *intervention, critical care, infection control, wound*
21 *healing, nutritional care and support, and medical*
22 *rehabilitation care;*

23 *“(2) basic and clinical research regarding the re-*
24 *sponse of the body to trauma and the acute treatment*

1 *and medical rehabilitation of individuals who are the*
2 *victims of trauma; and*

3 “(3) *basic and clinical research regarding trauma*
4 *care for pediatric and geriatric patients.*

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

10 “(f) *RESOURCES.*—*The Director shall assure the avail-*
11 *ability of appropriate resources to carry out the Program,*
12 *including the plan established under subsection (b) (includ-*
13 *ing the activities described in subsection (d)).*

14 “(g) *COORDINATING COMMITTEE.*—

15 “(1) *IN GENERAL.*—*There shall be established a*
16 *Trauma Research Interagency Coordinating Commit-*
17 *tee (hereafter in this section referred to as the ‘Coordi-*
18 *nating Committee’).*

19 “(2) *DUTIES.*—*The Coordinating Committee*
20 *shall make recommendations regarding—*

21 “(A) *the activities of the Program to be car-*
22 *ried out by each of the agencies represented on*
23 *the Committee and the amount of funds needed*
24 *by each of the agencies for such activities; and*

1 “(B) effective collaboration among the agen-
2 cies in carrying out the activities.

3 “(3) COMPOSITION.—The Coordinating Commit-
4 tee shall be composed of the Directors of each of the
5 agencies that, under subsection (c), have responsibil-
6 ities under the Program, and any other individuals
7 who are practitioners in the trauma field as des-
8 ignated by the Director of the National Institutes of
9 Health.

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

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

13 “(2) The term ‘Director’ means the Director of
14 the National Institutes of Health.

15 “(3) The term ‘trauma’ means any serious in-
16 jury that could result in loss of life or in significant
17 disability and that would meet pre-hospital triage
18 criteria for transport to a designated trauma center.”.

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

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

1 **TITLE IV—NATIONAL CANCER**
2 **INSTITUTE**

3 **SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVI-**
4 **TIES REGARDING BREAST CANCER.**

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

8 *“BREAST AND GYNECOLOGICAL CANCERS*

9 *“SEC. 417. (a) EXPANSION AND COORDINATION OF AC-*
10 *TIVITIES.—The Director of the Institute, in consultation*
11 *with the National Cancer Advisory Board, shall expand,*
12 *intensify, and coordinate the activities of the Institute with*
13 *respect to research on breast cancer, ovarian cancer, and*
14 *other cancers of the reproductive system of women.*

15 *“(b) COORDINATION WITH OTHER INSTITUTES.—The*
16 *Director of the Institute shall coordinate the activities of*
17 *the Director under subsection (a) with similar activities*
18 *conducted by other national research institutes and agencies*
19 *of the National Institutes of Health to the extent that such*
20 *Institutes and agencies have responsibilities that are related*
21 *to breast cancer and other cancers of the reproductive sys-*
22 *tem of women.*

23 *“(c) PROGRAMS FOR BREAST CANCER.—*

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

1 *port research to expand the understanding of the*
2 *cause of, and to find a cure for, breast cancer. Activi-*
3 *ties under such subsection shall provide for an expan-*
4 *sion and intensification of the conduct and support*
5 *of—*

6 *“(A) basic research concerning the etiology*
7 *and causes of breast cancer;*

8 *“(B) clinical research and related activities*
9 *concerning the causes, prevention, detection and*
10 *treatment of breast cancer;*

11 *“(C) control programs with respect to breast*
12 *cancer in accordance with section 412, including*
13 *community-based programs designed to assist*
14 *women who are members of medically under-*
15 *served populations, low-income populations, or*
16 *minority groups;*

17 *“(D) information and education programs*
18 *with respect to breast cancer in accordance with*
19 *section 413; and*

20 *“(E) research and demonstration centers*
21 *with respect to breast cancer in accordance with*
22 *section 414, including the development and oper-*
23 *ation of centers for breast cancer research to*
24 *bring together basic and clinical, biomedical and*
25 *behavioral scientists to conduct basic, clinical,*

1 *epidemiological, psychosocial, prevention and*
2 *treatment research and related activities on*
3 *breast cancer.*

4 *Not less than six centers shall be operated under sub-*
5 *paragraph (E). Activities of such centers should in-*
6 *clude supporting new and innovative research and*
7 *training programs for new researchers. Such centers*
8 *shall give priority to expediting the transfer of re-*
9 *search advances to clinical applications.*

10 “(2) IMPLEMENTATION OF PLAN FOR PRO-
11 GRAMS.—

12 “(A) The Director of the Institute shall en-
13 sure that the research programs described in
14 paragraph (1) are implemented in accordance
15 with a plan for the programs. Such plan shall
16 include comments and recommendations that the
17 Director of the Institute considers appropriate,
18 with due consideration provided to the profes-
19 sional judgment needs of the Institute as ex-
20 pressed in the annual budget estimate prepared
21 in accordance with section 413(9). The Director
22 of the Institute, in consultation with the Na-
23 tional Cancer Advisory Board, shall periodically
24 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 control, treatment, research, and related ac-
14 tivities on 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 \$3,200,000,000 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.*—

23 “(1) *IN GENERAL.*—*Of the amounts appro-*
24 *priated for the National Cancer Institute for a fiscal*
25 *year, the Director of the Institute shall make available*

1 *not less than the applicable percentage specified in*
 2 *paragraph (2) for carrying out the cancer control ac-*
 3 *tivities authorized in section 412 and for which budg-*
 4 *et estimates are made under section 413(b)(9) for the*
 5 *fiscal year.*

6 “(2) *APPLICABLE PERCENTAGE.*—*The percentage*
 7 *referred to in paragraph (1) is—*

8 “(A) *7 percent, in the case of fiscal year*
 9 *1994;*

10 “(B) *9 percent, in the case of fiscal year*
 11 *1995; and*

12 “(C) *10 percent, in the case of fiscal year*
 13 *1996 and each subsequent fiscal year.”.*

14 *(b) CONFORMING AMENDMENTS.—*

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

17 *(A) by striking subsection (a);*

18 *(B) by redesignating subsection (b) as sub-*
 19 *section (a);*

20 *(C) by redesignating paragraph (5) of sub-*
 21 *section (a) (as so redesignated) as subsection (b);*

22 *and*

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

1 “CERTAIN USES OF FUNDS”.

2 (2) *CROSS-REFERENCE.*—Section 464F of the
3 Public Health Service Act (42 U.S.C. 285m–6) is
4 amended by striking “section 408(b)(1)” and insert-
5 ing “section 408(a)(1)”.

6 **SEC. 404. STUDY OF ENVIRONMENTAL AND OTHER RISKS**
7 **CONTRIBUTING TO INCIDENCE OF BREAST**
8 **CANCER.**

9 (a) *REQUIREMENT OF STUDY.*—

10 (1) *IN GENERAL.*—The Director of the National
11 Cancer Institute (in this section referred to as the
12 “Director”), in collaboration with the Director of the
13 National Institute of Environmental Health Sciences,
14 shall conduct a case-controlled study to assess biologi-
15 cal markers of environmental and other risk factors
16 contributing to the incidence of breast cancer in—

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

19 (B) the 2 counties in the northeastern Unit-
20 ed States that, as identified in the report speci-
21 fied in paragraph (2), had the highest age-ad-
22 justed mortality rate of such cancer that reflected
23 not less than 30 deaths during the 5-year period
24 for which findings are made in the report.

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

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

11 (1) contaminated drinking water;

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

14 (3) electromagnetic fields;

15 (4) pesticides and other toxic chemicals;

16 (5) hazardous and municipal waste; and

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

19 (c) *REPORT.*—Not later than 30 months after the date
20 of the enactment of this Act, the Director shall complete the
21 study required in subsection (a) and submit to the Commit-
22 tee on Energy and Commerce of the House of Representa-
23 tives, and to the Committee on Labor and Human Re-
24 sources of the Senate, a report describing the findings made
25 as a result of the study.

1 (d) *FUNDING.*—Of the amounts appropriated for fiscal
2 years 1994 and 1995 for the National Institute of Environ-
3 mental Health Sciences and the National Cancer Institute,
4 the Director of the National Institutes of Health shall make
5 available amounts for carrying out the study required in
6 subsection (a).

7 **TITLE V—NATIONAL HEART,**
8 **LUNG, AND BLOOD INSTITUTE**

9 **SEC. 501. EDUCATION AND TRAINING.**

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

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

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

16 (3) by inserting after paragraph (4) the follow-
17 ing new paragraph:

18 “(5) shall, in consultation with the advisory
19 council for the Institute, conduct appropriate intra-
20 mural training and education programs, including
21 continuing education and laboratory and clinical re-
22 search training programs.”.

1 **SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CARDIO-**
2 **VASCULAR DISEASES.**

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

5 *(1) in subparagraph (B), by striking “and” at*
6 *the end;*

7 *(2) in subparagraph (C), by striking the period*
8 *and inserting “; and”; and*

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

11 *“(D) three centers for basic and clinical research*
12 *into, training in, and demonstration of, advanced di-*
13 *agnostic, prevention, and treatment (including genetic*
14 *studies, intrauterine environment studies, postnatal*
15 *studies, heart arrhythmias, and acquired heart dis-*
16 *ease and preventive cardiology) for cardiovascular*
17 *diseases in children.”.*

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

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

22 *“NATIONAL CENTER ON SLEEP DISORDERS*

23 *“SEC. 424. (a) Not later than 1 year after the date*
24 *of the enactment of the National Institutes of Health Revi-*
25 *talization Act of 1993, the Director of the Institute shall*
26 *establish the National Center on Sleep Disorders (in this*

1 *section referred to as the 'Center'). The Center shall be head-*
2 *ed by a director, who shall be appointed by the Director*
3 *of the Institute.*

4 “(b) *The general purpose of the Center is the conduct*
5 *and support of research, training, health information dis-*
6 *semination, and other activities with respect to sleep dis-*
7 *orders.*”

8 “(c) *The Director of the Center may coordinate the ac-*
9 *tivities of the Center with similar activities of other agen-*
10 *cies of the Federal Government, including the other agencies*
11 *of the National Institutes of Health, and with similar ac-*
12 *tivities of other public entities and of private entities.*”

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. *For the purpose of carrying out this sub-*
19 *part, there are authorized to be appropriated*
20 *\$1,500,000,000 for fiscal year 1994, and such sums as may*
21 *be necessary for each of the fiscal years 1995 and 1996.*”

1 **TITLE VI—NATIONAL INSTITUTE**
2 **ON DIABETES AND DIGESTIVE**
3 **AND KIDNEY DISEASES**

4 **SEC. 601. PROVISIONS REGARDING NUTRITIONAL DIS-**
5 **ORDERS.**

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

9 *“NUTRITIONAL DISORDERS PROGRAM*

10 *“SEC. 434. (a) The Director of the Institute, in con-*
11 *sultation with the Director of NIH, shall establish a pro-*
12 *gram of conducting and supporting research, training,*
13 *health information dissemination, and other activities with*
14 *respect to nutritional disorders, including obesity.*

15 *“(b) In carrying out the program established under*
16 *subsection (a), the Director of the Institute shall conduct*
17 *and support each of the activities described in such sub-*
18 *section.*

19 *“(c) In carrying out the program established under*
20 *subsection (a), the Director of the Institute shall carry out*
21 *activities to facilitate and enhance knowledge and under-*
22 *standing of nutritional disorders, including obesity, on the*
23 *part of health professionals, patients, and the public*
24 *through the effective dissemination of information.”.*

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

4 (1) *by redesignating subsection (d) as subsection*
5 *(e); and*

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

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

13 “(2) *The Director of the Institute shall carry out para-*
14 *graph (1) in collaboration with the Director of the National*
15 *Cancer Institute and with the Directors of such other agen-*
16 *cies of the National Institutes of Health as the Director of*
17 *NIH determines to be appropriate.*

18 “(3) *Each center developed or expanded under para-*
19 *graph (1) shall—*

20 “(A) *utilize the facilities of a single institution,*
21 *or be formed from a consortium of cooperating insti-*
22 *tutions, meeting such research and training qualifica-*
23 *tions as may be prescribed by the Director;*

24 “(B) *conduct basic and clinical research into the*
25 *cause, diagnosis, early detection, prevention, control*

1 *and treatment of nutritional disorders, including obe-*
2 *sity and the impact of nutrition and diet on child de-*
3 *velopment;*

4 “(C) *conduct training programs for physicians*
5 *and allied health professionals in current methods of*
6 *diagnosis and treatment of such diseases and com-*
7 *plications, and in research in such disorders; and*

8 “(D) *conduct information programs for physi-*
9 *cians and allied health professionals who provide pri-*
10 *mary care for patients with such disorders or com-*
11 *plications.”.*

12 **TITLE VII—NATIONAL INSTITUTE ON ARTHRITIS AND**
13 **MUSCULOSKELETAL AND**
14 **SKIN DISEASES**

16 **SEC. 701. JUVENILE ARTHRITIS.**

17 (a) *PURPOSE.*—Section 435 of the Public Health Serv-
18 *ice Act (42 U.S.C. 285d) is amended by striking “and other*
19 *programs” and all that follows and inserting the following:*
20 *“and other programs with respect to arthritis and musculo-*
21 *skeletal and skin diseases (including sports-related dis-*
22 *orders), with particular attention to the effect of these dis-*
23 *eases on children.”.*

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

1 (1) in subsection (a), by inserting after the sec-
2 ond sentence, the following: “The plan shall place
3 particular emphasis upon expanding research into
4 better understanding the causes and the development
5 of effective treatments for arthritis affecting chil-
6 dren.”; and

7 (2) in subsection (b)—

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

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

12 (C) by adding at the end thereof the follow-
13 ing new paragraph:

14 “(5) research into the causes of arthritis affecting
15 children and the development, trial, and evaluation of
16 techniques, drugs and devices used in the diagnosis,
17 treatment (including medical rehabilitation), and
18 prevention of arthritis in children.”.

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

22 “(f) Not later than October 1, 1994, the Director shall
23 establish a multipurpose arthritis and musculoskeletal dis-
24 ease center for the purpose of expanding the level of research
25 into the cause, diagnosis, early detection, prevention, con-

1 *trol, and treatment of, and rehabilitation of children with*
2 *arthritis and musculoskeletal diseases.”.*

3 *(d) ADVISORY BOARD.—*

4 *(1) TITLE.—Section 442(a) of the Public Health*
5 *Service Act (42 U.S.C. 285d–7(a)) is amended by in-*
6 *serting after “Arthritis” the following: “and Musculo-*
7 *skeletal and Skin Diseases”.*

8 *(2) COMPOSITION.—Section 442(b) of the Public*
9 *Health Service Act (42 U.S.C. 285d–7(b)) is amend-*
10 *ed—*

11 *(A) in the matter preceding paragraph (1),*
12 *by striking “eighteen” and inserting “twenty”;*
13 *and*

14 *(B) in paragraph (1)(B)—*

15 *(i) by striking “six” and inserting*
16 *“eight”; and*

17 *(ii) by striking “including” and all*
18 *that follows and inserting the following:*
19 *“including one member who is a person who*
20 *has such a disease, one person who is the*
21 *parent of an adult with such a disease, and*
22 *two members who are parents of children*
23 *with arthritis.”.*

1 (3) *ANNUAL REPORT*.—Section 442(j) of the Pub-
 2 lic Health Service Act (42 U.S.C. 285d–7(j)) is
 3 amended—

4 (1) by striking “and” at the end of paragraph
 5 (3);

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

8 (3) by adding at the end the following para-
 9 graph:

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

15 **TITLE VIII—NATIONAL**
 16 **INSTITUTE ON AGING**

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

18 (a) *IN GENERAL*.—Section 12 of Public Law 99–158
 19 (99 Stat. 885) is—

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

23 (2) redesignated as section 445G; and

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

1 (b) *TECHNICAL AND CONFORMING AMENDMENTS.*—
 2 *Section 445G of the Public Health Service Act, as trans-*
 3 *ferred and inserted by subsection (a) of this section, is*
 4 *amended—*

5 (1) *by striking the section heading and all that*
 6 *follows through “may make a grant” in subsection (a)*
 7 *and inserting the following:*

8 “ALZHEIMER’S DISEASE REGISTRY
 9 “*SEC. 445G. (a) IN GENERAL.*—*The Director of the*
 10 *Institute may make a grant”;* and

11 (2) *by striking subsection (c).*

12 ***SEC. 802. AGING PROCESSES REGARDING WOMEN.***

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

16 “AGING PROCESSES REGARDING WOMEN
 17 “*SEC. 445H. The Director of the Institute, in addition*
 18 *to other special functions specified in section 444 and in*
 19 *cooperation with the Directors of the other national research*
 20 *institutes and agencies of the National Institutes of Health,*
 21 *shall conduct research into the aging processes of women,*
 22 *with particular emphasis given to the effects of menopause*
 23 *and the physiological and behavioral changes occurring*
 24 *during the transition from pre- to post-menopause, and into*
 25 *the diagnosis, disorders, and complications related to aging*
 26 *and loss of ovarian hormones in women.”.*

1 **SEC. 803. AUTHORIZATION OF APPROPRIATIONS.**

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

5 *“AUTHORIZATION OF APPROPRIATIONS*

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

10 **SEC. 804. CONFORMING AMENDMENT.**

11 *Section 445C of the Public Health Service Act (42*
12 *U.S.C. 285e-5), as amended by section 9 of Public Law*
13 *102-507 (106 Stat. 3287), is amended—*

14 *(1) in subsection (b)(1), in the first sentence, by*
15 *inserting after “Council” the following: “on Alz-*
16 *heimer’s Disease (hereafter in this section referred to*
17 *as the ‘Council’)”; and*

18 *(2) by adding at the end the following new sub-*
19 *section:*

20 *“(e) For purposes of this section, the term ‘Council on*
21 *Alzheimer’s Disease’ means the council established in sec-*
22 *tion 911(a) of Public Law 99-660.”.*

1 **TITLE IX—NATIONAL INSTITUTE**
2 **OF ALLERGY AND INFEC-**
3 **TIOUS DISEASES**

4 **SEC. 901. TROPICAL DISEASES.**

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

8 **SEC. 902. CHRONIC FATIGUE SYNDROME.**

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

12 *“RESEARCH CENTERS REGARDING CHRONIC FATIGUE*
13 *SYNDROME*

14 *“SEC. 447. (a) The Director of the Institute, after con-*
15 *sultation with the advisory council for the Institute, may*
16 *make grants to, or enter into contracts with, public or non-*
17 *profit private entities for the development and operation of*
18 *centers to conduct basic and clinical research on chronic*
19 *fatigue syndrome.*

20 *“(b) Each center assisted under this section shall use*
21 *the facilities of a single institution, or be formed from a*
22 *consortium of cooperating institutions, meeting such re-*
23 *quirements as may be prescribed by the Director of the In-*
24 *stitute.”.*

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

5 (c) *REPRESENTATIVES.*—The Secretary of Health and
 6 Human Services, acting through the Director of the Na-
 7 tional Institutes of Health, shall ensure that appropriate
 8 individuals with expertise in chronic fatigue syndrome or
 9 neuromuscular diseases and representative of a variety of
 10 disciplines and fields within the research community are
 11 appointed to appropriate National Institutes of Health ad-
 12 visory committees and boards.

13 **TITLE X—NATIONAL INSTITUTE**
 14 **OF CHILD HEALTH AND**
 15 **HUMAN DEVELOPMENT**

16 **Subtitle A—Research Centers With**
 17 **Respect to Contraception and**
 18 **Research Centers With Respect**
 19 **to Infertility**

20 **SEC. 1001. GRANTS AND CONTRACTS FOR RESEARCH CEN-**
 21 **TERS.**

22 Subpart 7 of part C of title IV of the Public Health
 23 Service Act, as amended by section 3 of Public Law 101-
 24 613, is amended by adding at the end the following new
 25 section:

1 *“RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION*
2 *AND INFERTILITY*

3 *“SEC. 452A. (a) The Director of the Institute, after*
4 *consultation with the advisory council for the Institute,*
5 *shall make grants to, or enter into contracts with, public*
6 *or nonprofit private entities for the development and oper-*
7 *ation of centers to conduct activities for the purpose of im-*
8 *proving methods of contraception and centers to conduct ac-*
9 *tivities for the purpose of improving methods of diagnosis*
10 *and treatment of infertility.*

11 *“(b) In carrying out subsection (a), the Director of the*
12 *Institute shall, subject to the extent of amounts made avail-*
13 *able in appropriations Acts, provide for the establishment*
14 *of three centers with respect to contraception and for two*
15 *centers with respect to infertility.*

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

18 *“(A) conduct clinical and other applied research,*
19 *including—*

20 *“(i) for centers with respect to contracep-*
21 *tion, clinical trials of new or improved drugs*
22 *and devices for use by males and females (in-*
23 *cluding barrier methods); and*

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

1 *vices for the diagnosis and treatment of infertil-*
2 *ity in males and females;*

3 “(B) *develop protocols for training physicians,*
4 *scientists, nurses, and other health and allied health*
5 *professionals;*

6 “(C) *conduct training programs for such indi-*
7 *viduals;*

8 “(D) *develop model continuing education pro-*
9 *grams for such professionals; and*

10 “(E) *disseminate information to such profes-*
11 *sionals and the public.*

12 “(2) *A center may use funds provided under subsection*
13 *(a) to provide stipends for health and allied health profes-*
14 *sionals enrolled in programs described in subparagraph (C)*
15 *of paragraph (1), and to provide fees to individuals serving*
16 *as subjects in clinical trials conducted under such para-*
17 *graph.*

18 “(d) *The Director of the Institute shall, as appropriate,*
19 *provide for the coordination of information among the cen-*
20 *ters assisted under this section.*

21 “(e) *Each center assisted under subsection (a) shall use*
22 *the facilities of a single institution, or be formed from a*
23 *consortium of cooperating institutions, meeting such re-*
24 *quirements as may be prescribed by the Director of the In-*
25 *stitute.*

1 “(f) Support of a center under subsection (a) may be
 2 for a period not exceeding 5 years. Such period may be ex-
 3 tended for one or more additional periods not exceeding 5
 4 years if the operations of such center have been reviewed
 5 by an appropriate technical and scientific peer review
 6 group established by the Director and if such group has rec-
 7 ommended to the Director that such period should be ex-
 8 tended.

9 “(g) For the purpose of carrying out this section, there
 10 are authorized to be appropriated \$30,000,000 for fiscal
 11 year 1994, and such sums as may be necessary for each
 12 of the fiscal years 1995 and 1996.”.

13 **SEC. 1002. LOAN REPAYMENT PROGRAM FOR RESEARCH**
 14 **WITH RESPECT TO CONTRACEPTION AND IN-**
 15 **FERTILITY.**

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

19 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
 20 RESPECT TO CONTRACEPTION AND INFERTILITY

21 “SEC. 487B. (a) The Secretary, in consultation with
 22 the Director of the National Institute of Child Health and
 23 Human Development, shall establish a program of entering
 24 into agreements with qualified health professionals (includ-
 25 ing graduate students) under which such health profes-
 26 sionals agree to conduct research with respect to contracep-

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

5 “(b) *The provisions of sections 338B, 338C, and 338E*
6 *shall apply to the program established in subsection (a) to*
7 *the same extent and in the same manner as such provisions*
8 *apply to the National Health Service Corps Loan Repay-*
9 *ment Program established in subpart III of part D of title*
10 *III.*

11 “(c) *Amounts appropriated for carrying out this sec-*
12 *tion shall remain available until the expiration of the sec-*
13 *ond fiscal year beginning after the fiscal year for which*
14 *the amounts were appropriated.”.*

15 ***Subtitle B—Program Regarding***
16 ***Obstetrics and Gynecology***

17 ***SEC. 1011. ESTABLISHMENT OF PROGRAM.***

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

21 “PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

22 “SEC. 452B. *The Director of the Institute shall estab-*
23 *lish and maintain within the Institute an intramural lab-*
24 *oratory and clinical research program in obstetrics and*
25 *gynecology.”.*

1 **Subtitle C—Child Health Research**
2 **Centers**

3 **SEC. 1021. ESTABLISHMENT OF CENTERS.**

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

7 “CHILD HEALTH RESEARCH CENTERS

8 “SEC. 452C. *The Director of the Institute shall develop*
9 *and support centers for conducting research with respect to*
10 *child health. Such centers shall give priority to the expedi-*
11 *tious transfer of advances from basic science to clinical ap-*
12 *plications and improving the care of infants and children.”.*

13 **Subtitle D—Study Regarding**
14 **Adolescent Health**

15 **SEC. 1031. PROSPECTIVE LONGITUDINAL STUDY.**

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

19 “PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT
20 HEALTH

21 “SEC. 452D. (a) *IN GENERAL.*—*Not later than October*
22 *1, 1993, the Director of the Institute shall commence a study*
23 *for the purpose of providing information on the general*
24 *health and well-being of adolescents in the United States,*

1 *including, with respect to such adolescents, information*
2 *on—*

3 *“(1) the behaviors that promote health and the*
4 *behaviors that are detrimental to health; and*

5 *“(2) the influence on health of factors particular*
6 *to the communities in which the adolescents reside.*

7 *“(b) DESIGN OF STUDY.—*

8 *“(1) IN GENERAL.—The study required in sub-*
9 *section (a) shall be a longitudinal study in which a*
10 *substantial number of adolescents participate as sub-*
11 *jects. With respect to the purpose described in such*
12 *subsection, the study shall monitor the subjects*
13 *throughout the period of the study to determine the*
14 *health status of the subjects and any change in such*
15 *status over time.*

16 *“(2) POPULATION-SPECIFIC ANALYSES.—The*
17 *study required in subsection (a) shall be conducted*
18 *with respect to the population of adolescents who are*
19 *female, the population of adolescents who are male,*
20 *various socioeconomic populations of adolescents, and*
21 *various racial and ethnic populations of adolescents.*
22 *The study shall be designed and conducted in a man-*
23 *ner sufficient to provide for a valid analysis of wheth-*
24 *er there are significant differences among such popu-*
25 *lations in health status and whether and to what ex-*

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

3 *“(c) COORDINATION WITH WOMEN’S HEALTH INITIA-*
 4 *TIVE.—With respect to the national study of women being*
 5 *conducted by the Secretary and known as the Women’s*
 6 *Health Initiative, the Secretary shall ensure that such study*
 7 *is coordinated with the component of the study required in*
 8 *subsection (a) that concerns adolescent females, including*
 9 *coordination in the design of the 2 studies.”.*

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

12 **SEC. 1101. CLINICAL RESEARCH ON DIABETES EYE CARE.**

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

16 *“CLINICAL RESEARCH ON EYE CARE AND DIABETES*

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

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

1 (b) *CONFORMING AMENDMENT.*—Section 455 of the
 2 *Public Health Service Act (42 U.S.C. 285i)* is amended in
 3 *the second sentence by striking “The Director” and insert-*
 4 *ing “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 conduct*
 14 *and support research on multiple sclerosis, especially re-*
 15 *search on effects of genetics and hormonal changes on the*
 16 *progress of the disease.”.*

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

20 **SEC. 1301. APPLIED TOXICOLOGICAL RESEARCH AND TEST-**
 21 **ING 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 amend-
 24 *ed by adding at the end the following new section:*

1 “(6) to integrate related activities of the Depart-
2 ment of Health and Human Services.”.

3 (b) *TECHNICAL AMENDMENT.*—Section 463 of the Pub-
4 lic Health Service Act (42 U.S.C. 2851) is amended by in-
5 serting after “Sciences” the following: “(hereafter in this
6 subpart referred to as the ‘Institute’)”.

7 **SEC. 1302. STUDY OF ENVIRONMENTAL AND OTHER RISKS**
8 **CONTRIBUTING TO INCIDENCE OF BREAST**
9 **AND PROSTATE CANCER.**

10 (a) *IN GENERAL.*—The Director of the National Insti-
11 tute of Environmental Health Sciences (in this section re-
12 ferred to as the “Director”), in collaboration with the Direc-
13 tor of the National Cancer Institute, shall conduct a case-
14 controlled study to assess biological markers of environ-
15 mental and other risk factors contributing to the incidence
16 of breast and prostate cancer in the Counties of Nassau and
17 Suffolk, in the State of New York.

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

23 (1) contaminated drinking water;

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

1 (3) *electromagnetic fields;*
2 (4) *pesticides and other toxic chemicals;*
3 (5) *hazardous and municipal waste; and*
4 (6) *such other factors as the Director determines*
5 *to be appropriate.*

6 (c) *REPORT.*—*Not later than 24 months after the date*
7 *of the enactment of this Act, the Director shall complete the*
8 *study required in subsection (a) and submit to the Commit-*
9 *tee on Energy and Commerce of the House of Representa-*
10 *tives, and to the Committee on Labor and Human Re-*
11 *sources of the Senate, a report describing the findings made*
12 *as a result of the study.*

13 (d) *FUNDING.*—*Of the amounts appropriated for fiscal*
14 *years 1994 and 1995 for the National Institute of Environ-*
15 *mental Health Sciences and the National Cancer Institute,*
16 *the Director of the National Institutes of Health shall make*
17 *available amounts for carrying out the study required in*
18 *subsection (a).*

19 ***TITLE XIV—NATIONAL LIBRARY***
20 ***OF MEDICINE***

21 ***Subtitle A—General Provisions***

22 ***SEC. 1401. ADDITIONAL AUTHORITIES.***

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

1 (1) *by striking “and” after the semicolon at the*
2 *end of paragraph (5);*

3 (2) *by redesignating paragraph (6) as para-*
4 *graph (8); and*

5 (3) *by inserting after paragraph (5) the follow-*
6 *ing new paragraphs:*

7 “(6) *publicize the availability from the Library*
8 *of the products and services described in any of para-*
9 *graphs (1) through (5);*

10 “(7) *promote the use of computers and tele-*
11 *communications by health professionals (including*
12 *health professionals in rural areas) for the purpose of*
13 *improving access to biomedical information for health*
14 *care delivery and medical research; and”.*

15 (b) *LIMITATION REGARDING GRANTS.*—Section
16 *474(b)(2) of the Public Health Service Act (42 U.S.C. 286b–*
17 *S(b)(2)) is amended by striking “\$750,000” and inserting*
18 *“\$1,000,000”.*

19 (c) *TECHNICAL AND CONFORMING AMENDMENTS.*—

20 (1) *REPEAL OF CERTAIN AUTHORITY.*—Section
21 *215 of the Department of Health and Human Serv-*
22 *ices Appropriations Act, 1988, as contained in section*
23 *101(h) of Public Law 100–202 (101 Stat. 1329–275),*
24 *is repealed.*

1 (2) *APPLICABILITY OF CERTAIN NEW AUTHOR-*
2 *ITY.*—*With respect to the authority established for the*
3 *National Library of Medicine in section 465(b)(6) of*
4 *the Public Health Service Act, as added by subsection*
5 *(a) of this section, such authority shall be effective as*
6 *if the authority had been established on December 22,*
7 *1987.*

8 **SEC. 1402. AUTHORIZATION OF APPROPRIATIONS.**

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

13 “*AUTHORIZATION OF APPROPRIATIONS*

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

18 “*(b) Amounts appropriated under subsection (a) and*
19 *made available for grants or contracts under any of sections*
20 *472 through 476 shall remain available until the end of*
21 *the fiscal year following the fiscal year for which the*
22 *amounts were appropriated.*”.

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

1 **Subtitle B—Financial Assistance**

2 **SEC. 1411. ESTABLISHMENT OF PROGRAM OF GRANTS FOR**
3 **DEVELOPMENT OF EDUCATION TECH-**
4 **NOLOGIES.**

5 *Section 473 of the Public Health Service Act (42*
6 *U.S.C. 286b-4) is amended by adding at the end the follow-*
7 *ing new subsection:*

8 “(c)(1) *The Secretary shall make grants to public or*
9 *nonprofit private institutions for the purpose of carrying*
10 *out projects of research on, and development and dem-*
11 *onstration of, new education technologies.*

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

14 “(A) *computer-assisted teaching and testing of*
15 *clinical competence at health professions and research*
16 *institutions;*

17 “(B) *the effective transfer of new information*
18 *from research laboratories to appropriate clinical ap-*
19 *plications;*

20 “(C) *the expansion of the laboratory and clinical*
21 *uses of computer-stored research databases; and*

22 “(D) *the testing of new technologies for training*
23 *health care professionals.*

1 “(3) The Secretary may not make a grant under para-
2 graph (1) unless the applicant for the grant agrees to make
3 the projects available with respect to—

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

6 “(B) enhancing and improving the capabilities
7 of health professionals regarding research and teach-
8 ing.”.

9 **Subtitle C—National Information**
10 **Center on Health Services Re-**
11 **search and Health Care Tech-**
12 **nology**

13 **SEC. 1421. ESTABLISHMENT OF CENTER.**

14 Part D of title IV of the Public Health Service Act
15 (42 U.S.C. 286 et seq.) is amended by adding at the end
16 the following new subpart:

17 “Subpart 4—National Information Center on Health
18 Services Research and Health Care Technology

19 “NATIONAL INFORMATION CENTER

20 “SEC. 478A. (a) There is established within the Li-
21 brary an entity to be known as the National Information
22 Center on Health Services Research and Health Care Tech-
23 nology (in this section referred to as the ‘Center’).

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

1 *health services research, clinical practice guidelines, and on*
2 *health care technology, including the assessment of such*
3 *technology. Such purpose includes developing and main-*
4 *taining data bases and developing and implementing meth-*
5 *ods of carrying out such purpose.*

6 “(c) *The Director of the Center shall ensure that infor-*
7 *mation under subsection (b) concerning clinical practice*
8 *guidelines is collected and maintained electronically and in*
9 *a convenient format. Such Director shall develop and pub-*
10 *lish criteria for the inclusion of practice guidelines and*
11 *technology assessments in the information center database.*

12 “(d) *The Secretary, acting through the Center, shall*
13 *coordinate the activities carried out under this section*
14 *through the Center with related activities of the Adminis-*
15 *trator for Health Care Policy and Research.”.*

16 **SEC. 1422. CONFORMING PROVISIONS.**

17 (a) *IN GENERAL.*—*Section 903 of the Public Health*
18 *Service Act, as amended by section 3 of Public Law 102-*
19 *410 (106 Stat. 2094), is amended by amending subsection*
20 *(e) to read as follows:*

21 “(e) *REQUIRED INTERAGENCY AGREEMENT.*—*The Ad-*
22 *ministrators and the Director of the National Library of*
23 *Medicine shall enter into an agreement providing for the*
24 *implementation of section 478A.”.*

1 (b) *RULE OF CONSTRUCTION.*—*The amendments made*
 2 *by section 3 of Public Law 102–410 (106 Stat. 2094), by*
 3 *section 1421 of this Act, and by subsection (a) of this section*
 4 *may not be construed as terminating the information center*
 5 *on health care technologies and health care technology as-*
 6 *essment established under section 904 of the Public Health*
 7 *Service Act, as in effect on the day before the date of the*
 8 *enactment of Public Law 102–410. Such center shall be con-*
 9 *sidered to be the center established in section 478A of the*
 10 *Public Health Service Act, as added by section 1421 of this*
 11 *Act, and shall be subject to the provisions of such section*
 12 *478A.*

13 ***TITLE XV—OTHER AGENCIES OF***
 14 ***NATIONAL INSTITUTES OF***
 15 ***HEALTH***

16 ***Subtitle A—Division of Research***
 17 ***Resources***

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

20 *Title IV of the Public Health Service Act (42 U.S.C.*
 21 *281 et seq.) is amended—*

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

24 “(B) *The National Center for Research Re-*
 25 *sources.”; and*

1 (2) *in part E—*

2 (A) *in the heading for subpart 1, by strik-*
3 *ing “Division of” and inserting “National Cen-*
4 *ter for”;*

5 (B) *in section 479, by striking “the Divi-*
6 *sion of Research Resources” and inserting the*
7 *following: “the National Center for Research Re-*
8 *sources (hereafter in this subpart referred to as*
9 *the ‘Center’)”;*

10 (C) *in sections 480 and 481, by striking*
11 *“the Division of Research Resources” each place*
12 *such term appears and inserting “the Center”;*
13 *and*

14 (D) *in sections 480 and 481, as amended by*
15 *subparagraph (C), by striking “the Division”*
16 *each place such term appears and inserting “the*
17 *Center”.*

18 **SEC. 1502. BIOMEDICAL AND BEHAVIORAL RESEARCH FA-**
19 **CILITIES.**

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

23 “*BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES*

24 “*SEC. 481A. (a) MODERNIZATION AND CONSTRUCTION*
25 *OF FACILITIES.—*

1 “(1) *IN GENERAL.*—*The Director of NIH, acting*
2 *through the Director of the Center, may make grants*
3 *to public and nonprofit private entities to expand, re-*
4 *model, renovate, or alter existing research facilities or*
5 *construct new research facilities, subject to the provi-*
6 *sions of this section.*

7 “(2) *CONSTRUCTION AND COST OF CONSTRU-*
8 *CTION.*—*For purposes of this section, the terms*
9 *‘construction’ and ‘cost of construction’ include the*
10 *construction of new buildings and the expansion, ren-*
11 *ovation, remodeling, and alteration of existing build-*
12 *ings, including architects’ fees, but do not include the*
13 *cost of acquisition of land or off-site improvements.*

14 “(b) *SCIENTIFIC AND TECHNICAL REVIEW BOARDS*
15 *FOR MERIT-BASED REVIEW OF PROPOSALS.*—

16 “(1) *IN GENERAL; APPROVAL AS PRECONDITION*
17 *TO GRANTS.*—

18 “(A) *There is established within the Center*
19 *a Scientific and Technical Review Board on*
20 *Biomedical and Behavioral Research Facilities*
21 *(hereafter referred to in this section as the*
22 *‘Board’).*

23 “(B) *The Director of the Center may ap-*
24 *prove an application for a grant under*
25 *subsection (a) only if the Board has under para-*

1 *graph (2) recommended the application for ap-*
2 *proval.*

3 “(2) DUTIES.—

4 “(A) *The Board shall provide advice to the*
5 *Director of the Center and the advisory council*
6 *established under section 480 (hereafter in this*
7 *section referred to as the ‘Advisory Council’) on*
8 *carrying out this section.*

9 “(B) *In carrying out subparagraph (A), the*
10 *Board shall make a determination of the merit*
11 *of each application submitted for a grant under*
12 *subsection (a), after consideration of the require-*
13 *ments established in subsection (c), and shall re-*
14 *port the results of the determination to the Direc-*
15 *tor of the Center and the Advisory Council. Such*
16 *determinations shall be conducted in a manner*
17 *consistent with procedures established under sec-*
18 *tion 492.*

19 “(C) *In carrying out subparagraph (A), the*
20 *Board shall, in the case of applications rec-*
21 *ommended for approval, make recommendations*
22 *to the Director and the Advisory Council on the*
23 *amount that should be provided in the grant.*

24 “(D) *In carrying out subparagraph (A), the*
25 *Board shall prepare an annual report for the Di-*

1 *rector of the Center and the Advisory Council de-*
2 *scribing the activities of the Board in the fiscal*
3 *year for which the report is made. Each such re-*
4 *port shall be available to the public, and shall—*

5 *“(i) summarize and analyze expendi-*
6 *tures made under this section;*

7 *“(ii) provide a summary of the types,*
8 *numbers, and amounts of applications that*
9 *were recommended for grants under sub-*
10 *section (a) but that were not approved by*
11 *the Director of the Center; and*

12 *“(iii) contain the recommendations of*
13 *the Board for any changes in the adminis-*
14 *tration of this section.*

15 *“(3) MEMBERSHIP.—*

16 *“(A) Subject to subparagraph (B), the*
17 *Board shall be composed of 9 appointed mem-*
18 *bers, and such ex officio members as the Director*
19 *of the Center determines to be appropriate.*

20 *“(B) Not more than 3 individuals who are*
21 *officers or employees of the Federal Government*
22 *may serve as members of the Board.*

23 *“(4) CERTAIN REQUIREMENTS REGARDING MEM-*
24 *BERSHIP.—In selecting individuals for membership*
25 *on the Board, the Director of the Center shall ensure*

1 *that the members are individuals who, by virtue of*
2 *their training or experience, are eminently qualified*
3 *to perform peer review functions. In selecting such in-*
4 *dividuals for such membership, the Director of the*
5 *Center shall ensure that the members of the Board col-*
6 *lectively—*

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

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

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

20 *“(D) are experienced with emerging centers*
21 *of excellence, as described in subsection (c)(3).*

22 *“(5) CERTAIN AUTHORITIES.—*

23 *“(A) In carrying out paragraph (2), the*
24 *Board may convene workshops and conferences,*

1 *and collect data as the Board considers appro-*
2 *priate.*

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

8 “(6) *TERMS.—*

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

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

20 “(i) *3 shall hold office for a term of 3*
21 *years;*

22 “(ii) *3 shall hold office for a term of 2*
23 *years; and*

24 “(iii) *3 shall hold office for a term of*
25 *1 year.*

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

4 “(7) COMPENSATION.—Members of the Board
5 who are not officers or employees of the United States
6 shall receive for each day the members are engaged in
7 the performance of the functions of the Board com-
8 pensation at the same rate received by members of
9 other national advisory councils established under
10 this title.

11 “(c) REQUIREMENTS FOR GRANTS.—

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

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

19 “(B) The applicant provides assurances sat-
20 isfactory to the Director that—

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

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

4 “(iii) sufficient funds will be available,
5 when construction is completed, for the ef-
6 fective use of the facility for the research for
7 which it is being constructed; and

8 “(iv) the proposed construction will ex-
9 pand the applicant’s capacity for research,
10 or is necessary to improve or maintain the
11 quality of the applicant’s research.

12 “(C) The applicant meets reasonable quali-
13 fications established by the Director with respect
14 to—

15 “(i) the relative scientific and technical
16 merit of the applications, and the relative
17 effectiveness of the proposed facilities, in ex-
18 panding the capacity for biomedical or be-
19 havioral research and in improving the
20 quality of such research;

21 “(ii) the quality of the research or
22 training, or both, to be carried out in the
23 facilities involved;

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

1 *the applicant's research and training mis-*
2 *sion;*

3 “(iv) *the congruence of the research ac-*
4 *tivities to be carried out within the facility*
5 *with the research and investigator man-*
6 *power needs of the United States; and*

7 “(v) *the age and condition of existing*
8 *research facilities and equipment.*

9 “(D) *The applicant has demonstrated a*
10 *commitment to enhancing and expanding the re-*
11 *search productivity of the applicant.*

12 “(2) *CONSIDERATION OF CERTAIN FACTORS.—In*
13 *making grants under subsection (a), the Director of*
14 *the Center may, in addition to the requirements es-*
15 *tablished in paragraph (1), consider the following fac-*
16 *tors:*

17 “(A) *To what extent the applicant has the*
18 *capacity to broaden the scope of research and re-*
19 *search training programs of the applicant by*
20 *promoting—*

21 “(i) *interdisciplinary research;*

22 “(ii) *research on emerging technologies,*
23 *including those involving novel analytical*
24 *techniques or computational methods; or*

1 “(iii) other novel research mechanisms
2 or programs.

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

9 “(3) INSTITUTIONS OF EMERGING EXCEL-
10 LENCE.—Of the amounts appropriated under sub-
11 section (h) for a fiscal year, the Director of the Center
12 shall make available 25 percent for grants under sub-
13 section (a) to applicants that, in addition to meeting
14 the requirements established in paragraph (1), have
15 demonstrated emerging excellence in biomedical or be-
16 havioral research, as follows:

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

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

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

1 “(D) *The applicant—*

2 “(i) *has been designated as a center of*
3 *excellence under section 739;*

4 “(ii) *is located in a geographic area a*
5 *significant percentage of whose population*
6 *has a health-status deficit, and the appli-*
7 *cant provides health services to such popu-*
8 *lation; or*

9 “(iii) *is located in a geographic area*
10 *in which a deficit in health care technology,*
11 *services, or research resources may adversely*
12 *affect health status of the population of the*
13 *area in the future, and the applicant is car-*
14 *rying out activities with respect to protect-*
15 *ing the health status of such population.*

16 “(d) *REQUIREMENT OF APPLICATION.—The Director*
17 *of the Center may make a grant under subsection (a) only*
18 *if an application for the grant is submitted to the Director*
19 *and the application is in such form, is made in such man-*
20 *ner, and contains such agreements, assurances, and infor-*
21 *mation as the Director determines to be necessary to carry*
22 *out this section.*

23 “(e) *AMOUNT OF GRANT; PAYMENTS.—*

24 “(1) *AMOUNT.—The amount of any grant*
25 *awarded under subsection (a) shall be determined by*

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

3 “(A) 50 percent of the necessary cost of the
4 *construction of a proposed facility as determined*
5 *by the Director; or*

6 “(B) *in the case of a multipurpose facility,*
7 *40 percent of that part of the necessary cost of*
8 *construction that the Director determines to be*
9 *proportionate to the contemplated use of the fa-*
10 *cility.*

11 “(2) *RESERVATION OF AMOUNTS.—On approval*
12 *of any application for a grant under subsection (a),*
13 *the Director of the Center shall reserve, from any ap-*
14 *propriation available therefore, the amount of such*
15 *grant, and shall pay such amount, in advance or by*
16 *way of reimbursement, and in such installments con-*
17 *sistent with the construction progress, as the Director*
18 *may determine appropriate. The reservation of the*
19 *Director of any amount by the Director under this*
20 *paragraph may be amended by the Director, either on*
21 *the approval of an amendment of the application or*
22 *on the revision of the estimated cost of construction*
23 *of the facility.*

24 “(3) *EXCLUSION OF CERTAIN COSTS.—In deter-*
25 *mining the amount of any grant under this sub-*

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

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

8 *“(B) the amount of any non-Federal funds*
9 *required to be expended as a condition of such*
10 *other Federal grant.*

11 *“(4) WAIVER OF LIMITATIONS.—The limitations*
12 *imposed by paragraph (1) may be waived at the dis-*
13 *cretion of the Director for applicants meeting the con-*
14 *ditions described in paragraphs (1) and (2) of sub-*
15 *section (c).*

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

19 *“(1) the applicant or other owner of the facility*
20 *shall cease to be a public or nonprofit private entity;*
21 *or*

22 *“(2) the facility shall cease to be used for the re-*
23 *search purposes for which it was constructed (unless*
24 *the Director determines, in accordance with regula-*

1 *tions, that there is good cause for releasing the appli-*
 2 *cant or other owner from obligation to do so);*
 3 *the United States shall be entitled to recover from the appli-*
 4 *cant or other owner of the facility the amount bearing the*
 5 *same ratio to the current value (as determined by an agree-*
 6 *ment between the parties or by action brought in the United*
 7 *States District Court for the district in which such facility*
 8 *is situated) of the facility as the amount of the Federal*
 9 *participation bore to the cost of the construction of such*
 10 *facility.*

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

15 *“(h) AUTHORIZATION OF APPROPRIATIONS.—For the*
 16 *purpose of carrying out this section, there are authorized*
 17 *to be appropriated \$150,000,000 for fiscal year 1994, and*
 18 *such sums as may be necessary for each of the fiscal years*
 19 *1995 and 1996.”.*

20 **SEC. 1503. CONSTRUCTION PROGRAM FOR NATIONAL PRI-**
 21 **MATE RESEARCH CENTER.**

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

1 *“CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH*
2 *ON PRIMATES*

3 *“SEC. 481B. (a) With respect to activities carried out*
4 *by the National Center for Research Resources to support*
5 *regional centers for research on primates, the Director of*
6 *NIH shall, for each of the fiscal years 1994 through 1996,*
7 *reserve from the amounts appropriated under section*
8 *481A(i) \$5,000,000 for the purpose of making awards of*
9 *grants and contracts to public or nonprofit private entities*
10 *to construct, renovate, or otherwise improve such regional*
11 *centers. The reservation of such amounts for any fiscal year*
12 *is subject to the availability of qualified applicants for such*
13 *awards.*

14 *“(b) The Director of NIH may not make a grant or*
15 *enter into a contract under subsection (a) unless the appli-*
16 *cant for such assistance agrees, with respect to the costs to*
17 *be incurred by the applicant in carrying out the purpose*
18 *described in such subsection, to make available (directly or*
19 *through donations from public or private entities) non-Fed-*
20 *eral contributions in cash toward such costs in an amount*
21 *equal to not less than \$1 for each \$4 of Federal funds pro-*
22 *vided in such assistance.”.*

1 ***Subtitle B—National Center for***
2 ***Nursing Research***

3 ***SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR***
4 ***NURSING RESEARCH AS NATIONAL INSTI-***
5 ***TUTE OF NURSING RESEARCH.***

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

9 (1) *in section 483—*

10 (A) *in the heading for the section, by strik-*
11 *ing “CENTER” and inserting “INSTITUTE”; and*

12 (B) *by striking “The general purpose” and*
13 *all that follows through “is” and inserting the*
14 *following: “The general purpose of the National*
15 *Institute of Nursing Research (hereafter in this*
16 *subpart referred to as the ‘Institute’) is”;*

17 (2) *in section 484, by striking “Center” each*
18 *place such term appears and inserting “Institute”;*

19 (3) *in section 485—*

20 (A) *in subsection (a), in each of paragraphs*
21 *(1) through (3), by striking “Center” each place*
22 *such term appears and inserting “Institute”;*

23 (B) *in subsection (b)—*

24 (i) *in paragraph (2)(A), by striking*
25 *“Center” and inserting “Institute”; and*

1 (ii) in paragraph (3)(A), in the first
2 sentence, by striking “Center” and inserting
3 “*Institute*”; and

4 (C) in subsections (d) through (g), by strik-
5 ing “Center” each place such term appears and
6 inserting “*Institute*”; and

7 (4) in section 485A (as redesignated by section
8 141(a)(1) of this Act), by striking “Center” each place
9 such term appears and inserting “*Institute*”.

10 (b) *CONFORMING AMENDMENTS.*—

11 (1) *ORGANIZATION OF NATIONAL INSTITUTES OF*
12 *HEALTH.*—Section 401(b) of the Public Health Serv-
13 ice Act (42 U.S.C. 281(b)) is amended—

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

16 “(Q) *The National Institute of Nursing Re-*
17 *search.*”; and

18 (B) in paragraph (2), by striking subpara-
19 graph (D).

20 (2) *TRANSFER OF STATUTORY PROVISIONS.*—The
21 Public Health Service Act, as amended by subsection
22 (a) of this section and by section 124 of Public Law
23 102–321 (106 Stat. 364), is amended—

24 (A) by transferring sections 483 through
25 485A to part C of title IV;

1 **SEC. 1512. STUDY ON ADEQUACY OF NUMBER OF NURSES.**

2 (a) *IN GENERAL.*—The Secretary of Health and
3 Human Services, acting through the Director of the Na-
4 tional Institute of Nursing Research, shall enter into a con-
5 tract with a public or nonprofit private entity to conduct
6 a study for the purpose of determining whether and to what
7 extent there is a need for an increase in the number of
8 nurses in hospitals and nursing homes in order to promote
9 the quality of patient care and reduce the incidence among
10 nurses of work-related injuries and stress.

11 (b) *NATIONAL ACADEMY OF SCIENCES.*—The Secretary
12 shall request the Institute of Medicine of the National Acad-
13 emy of Sciences to enter into the contract under subsection
14 (a) to conduct the study described in such subsection. If such
15 Institute declines to conduct the study, the Secretary shall
16 carry out such subsection through another public or non-
17 profit private entity.

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

19 (1) The term “nurse” means a registered nurse,
20 a licensed practical nurse, a licensed vocational
21 nurse, and a nurse assistant.

22 (2) The term “Secretary” means the Secretary of
23 Health and Human Services.

24 (d) *REPORT.*—The Secretary shall ensure that, not
25 later than October 1, 1994, the study required in subsection
26 (a) is completed and a report describing the findings made

1 *as a result of the study is submitted to the Committee on*
 2 *Energy and Commerce of the House of Representatives, and*
 3 *to the Committee on Labor and Human Resources of the*
 4 *Senate.*

5 ***Subtitle C—National Center for***
 6 ***Human Genome Research***

7 ***SEC. 1521. PURPOSE OF CENTER.***

8 *Title IV of the Public Health Service Act, as amended*
 9 *by section 141(a)(1) of this Act and by paragraphs (1)(B)*
 10 *and (3)(B) of section 1511(b) of this Act, is amended—*

11 *(1) in section 401(b)(2), by adding at the end the*
 12 *following new subparagraph:*

13 *“(D) The National Center for Human Genome*
 14 *Research.”; and*

15 *(2) in part E, by adding at the end the following*
 16 *new subpart:*

17 *“Subpart 3—National Center for Human Genome*
 18 *Research*

19 *“PURPOSE OF THE CENTER*

20 *“SEC. 485B. (a) The general purpose of the National*
 21 *Center for Human Genome Research (hereafter in this sub-*
 22 *part referred to as the ‘Center’) is to characterize the struc-*
 23 *ture and function of the human genome, including the map-*
 24 *ping and sequencing of individual genes. Such purpose in-*
 25 *cludes—*

1 “(1) *planning and coordinating the research goal*
2 *of the genome project;*

3 “(2) *reviewing and funding research proposals;*

4 “(3) *developing training programs;*

5 “(4) *coordinating international genome research;*

6 “(5) *communicating advances in genome science*
7 *to the public; and*

8 “(6) *reviewing and funding proposals to address*
9 *the ethical and legal issues associated with the genome*
10 *project.*

11 “(b) *The Director of the Center may conduct and sup-*
12 *port research training—*

13 “(1) *for which fellowship support is not provided*
14 *under section 487; and*

15 “(2) *that is not residency training of physicians*
16 *or other health professionals.*

17 “(c)(1) *Except as provided in paragraph (2), of the*
18 *amounts appropriated to carry out subsection (a) for a fis-*
19 *cal year, the Director of the Center shall make available*
20 *not less than 5 percent for carrying out paragraph (6) of*
21 *such subsection.*

22 “(2) *With respect to providing funds under subsection*
23 *(a)(6) for proposals to address the ethical issues associated*
24 *with the genome project, paragraph (1) shall not apply for*
25 *a fiscal year if the Director of the Center certifies to the*

1 *Committee on Energy and Commerce of the House of Rep-*
 2 *resentatives, and to the Committee on Labor and Human*
 3 *Resources of the Senate, that the Director has determined*
 4 *that an insufficient number of such proposals meet the ap-*
 5 *plicable requirements of sections 491 and 492.”.*

6 **TITLE XVI—AWARDS AND**
 7 **TRAINING**
 8 **Subtitle A—National Research**
 9 **Service Awards**

10 **SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDI-**
 11 **VIDUALS FROM DISADVANTAGED BACK-**
 12 **GROUNDS.**

13 *Section 487(a) of the Public Health Service Act (42*
 14 *U.S.C. 288(a)(4)) is amended by adding at the end the fol-*
 15 *lowing paragraph:*

16 “(4) *The Secretary shall carry out paragraph (1) in*
 17 *a manner that will result in the recruitment of women, and*
 18 *individuals from disadvantaged backgrounds, into fields of*
 19 *biomedical or behavioral research and in the provision of*
 20 *research training to women and such individuals.”.*

21 **Subtitle B—Acquired Immune**
 22 **Deficiency Syndrome**

23 **SEC. 1611. LOAN REPAYMENT PROGRAM.**

24 *Section 487A of the Public Health Service Act (42*
 25 *U.S.C. 288–1) is amended to read as follows:*

1 “*LOAN REPAYMENT PROGRAM FOR RESEARCH WITH*
2 *RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME*

3 “*SEC. 487A. (a) IN GENERAL.—*

4 “(1) *AUTHORITY FOR PROGRAM.—Subject to*
5 *paragraph (2), the Secretary shall carry out a pro-*
6 *gram of entering into agreements with appropriately*
7 *qualified health professionals under which such health*
8 *professionals agree to conduct, as employees of the Na-*
9 *tional Institutes of Health, research with respect to*
10 *acquired immune deficiency syndrome in consider-*
11 *ation of the Federal Government agreeing to repay,*
12 *for each year of such service, not more than \$20,000*
13 *of the principal and interest of the educational loans*
14 *of such health professionals.*

15 “(2) *LIMITATION.—The Secretary may not enter*
16 *into an agreement with a health professional pursu-*
17 *ant to paragraph (1) unless such professional—*

18 “(A) *has a substantial amount of edu-*
19 *cational loans relative to income; and*

20 “(B) *agrees to serve as an employee of the*
21 *National Institutes of Health for purposes of*
22 *paragraph (1) for a period of not less than 3*
23 *years.*

24 “(b) *APPLICABILITY OF CERTAIN PROVISIONS.—With*
25 *respect to the National Health Service Corps Loan Repay-*

1 *ment Program established in subpart III of part D of title*
 2 *III, the provisions of such subpart shall, except as inconsis-*
 3 *ent with subsection (a) of this section, apply to the program*
 4 *established in such subsection (a) in the same manner and*
 5 *to the same extent as such provisions apply to the National*
 6 *Health Service Corps Loan Repayment Program established*
 7 *in such subpart.*

8 “(c) *AUTHORIZATION OF APPROPRIATIONS.—For the*
 9 *purpose of carrying out this section, there are authorized*
 10 *to be appropriated such sums as may be necessary for each*
 11 *of the fiscal years 1994 through 1996.”.*

12 ***Subtitle C—Loan Repayment for***
 13 ***Research Generally***

14 ***SEC. 1621. ESTABLISHMENT OF PROGRAM.***

15 *Part G of title IV of the Public Health Service Act,*
 16 *as redesignated by section 141(a)(2) of this Act and as*
 17 *amended by section 1002 of this Act, is amended by insert-*
 18 *ing after section 487B the following new section:*

19 “*LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY*

20 “*SEC. 487C. (a) IN GENERAL.—*

21 “(1) *AUTHORITY FOR PROGRAM.—Subject to*
 22 *paragraph (2), the Secretary shall carry out a pro-*
 23 *gram of entering into agreements with appropriately*
 24 *qualified health professionals under which such health*
 25 *professionals agree to conduct research, as employees*
 26 *of the National Institutes of Health, in consideration*

1 of the Federal Government agreeing to repay, for each
2 year of such service, not more than \$20,000 of the
3 principal and interest of the educational loans of such
4 health professionals.

5 “(2) *LIMITATION.*—The Secretary may not enter
6 into an agreement with a health professional pursu-
7 ant to paragraph (1) unless such professional—

8 “(A) has a substantial amount of edu-
9 cational loans relative to income; and

10 “(B) agrees to serve as an employee of the
11 National Institutes of Health for purposes of
12 paragraph (1) for a period of not less than 3
13 years.

14 “(b) *APPLICABILITY OF CERTAIN PROVISIONS.*—With
15 respect to the National Health Service Corps Loan Repay-
16 ment Program established in subpart III of part D of title
17 III, the provisions of such subpart shall, except as inconsis-
18 tent with subsection (a) of this section, apply to the program
19 established in such subsection (a) in the same manner and
20 to the same extent as such provisions apply to the National
21 Health Service Corps Loan Repayment Program established
22 in such subpart.

23 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—For the
24 purpose of carrying out this section other than with respect
25 to acquired immune deficiency syndrome, there are author-

1 ized to be appropriated such sums as may be necessary for
2 each of the fiscal years 1994 through 1996.”.

3 **Subtitle D—Scholarship and Loan**
4 **Repayment Programs Regarding**
5 **Professional Skills Needed by**
6 **Certain Agencies**

7 **SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL**
8 **INSTITUTES OF HEALTH.**

9 Part G of title IV of the Public Health Service Act,
10 as redesignated by section 141(a)(2) of this Act and as
11 amended by section 1621 of this Act, is amended by insert-
12 ing after section 487C the following new sections:

13 “UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING
14 PROFESSIONS NEEDED BY NATIONAL RESEARCH IN-
15 STITUTES

16 “SEC. 487D. (a) ESTABLISHMENT OF PROGRAM.—

17 “(1) IN GENERAL.—Subject to section
18 487(a)(1)(C), the Secretary, acting through the Direc-
19 tor of NIH, may carry out a program of entering into
20 contracts with individuals described in paragraph (2)
21 under which—

22 “(A) the Director of NIH agrees to provide
23 to the individuals scholarships for pursuing, as
24 undergraduates at accredited institutions of
25 higher education, academic programs appro-

1 *priate for careers in professions needed by the*
2 *National Institutes of Health; and*

3 “(B) *the individuals agree to serve as em-*
4 *ployees of the National Institutes of Health, for*
5 *the period described in subsection (c), in posi-*
6 *tions that are needed by the National Institutes*
7 *of Health and for which the individuals are*
8 *qualified.*

9 “(2) *INDIVIDUALS FROM DISADVANTAGED BACK-*
10 *GROUND.*—*The individuals referred to in paragraph*
11 *(1) are individuals who—*

12 “(A) *are enrolled or accepted for enrollment*
13 *as full-time undergraduates at accredited institu-*
14 *tions of higher education; and*

15 “(B) *are from disadvantaged backgrounds.*

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, subject to paragraph (2)(A), 12 months for each*
4 *academic year for which the scholarship under such*
5 *subsection is provided.*

6 “(2) *SCHEDULE FOR SERVICE.*—

7 “(A) *Subject to subparagraph (B), the Di-*
8 *rector of NIH may not provide a scholarship*
9 *under subsection (a) unless the individual apply-*
10 *ing for the scholarship agrees that—*

11 “(i) *the individual will serve as an em-*
12 *ployee of the National Institutes of Health*
13 *full-time for not less than 10 consecutive*
14 *weeks of each year during which the indi-*
15 *vidual is attending the educational institu-*
16 *tion involved and receiving such a scholar-*
17 *ship;*

18 “(ii) *the period of service as such an*
19 *employee that the individual is obligated to*
20 *provide under clause (i) is in addition to*
21 *the period of service as such an employee*
22 *that the individual is obligated to provide*
23 *under subsection (a)(1)(B); and*

24 “(iii) *not later than 60 days after ob-*
25 *taining the educational degree involved, the*

1 *individual will begin serving full-time as*
2 *such an employee in satisfaction of the pe-*
3 *riod of service that the individual is obli-*
4 *gated to provide under subsection (a)(1)(B).*

5 *“(B) The Director of NIH may defer the ob-*
6 *ligation of an individual to provide a period of*
7 *service under subsection (a)(1)(B), if the Direc-*
8 *tor determines that such a deferral is appro-*
9 *priate.*

10 *“(3) APPLICABILITY OF CERTAIN PROVISIONS RE-*
11 *LATING TO APPOINTMENT AND COMPENSATION.—For*
12 *any period in which an individual provides service as*
13 *an employee of the National Institutes of Health in*
14 *satisfaction of the obligation of the individual under*
15 *subsection (a)(1)(B) or paragraph (2)(A)(i), the indi-*
16 *vidual may be appointed as such an employee with-*
17 *out regard to the provisions of title 5, United States*
18 *Code, relating to appointment and compensation.*

19 *“(d) PROVISIONS REGARDING SCHOLARSHIP.—*

20 *“(1) APPROVAL OF ACADEMIC PROGRAM.—The*
21 *Director of NIH may not provide a scholarship under*
22 *subsection (a) for an academic year unless—*

23 *“(A) the individual applying for the schol-*
24 *arship has submitted to the Director a proposed*

1 *academic program for the year and the Director*
2 *has approved the program; and*

3 “(B) *the individual agrees that the program*
4 *will not be altered without the approval of the*
5 *Director.*

6 “(2) *ACADEMIC STANDING.—The Director of*
7 *NIH may not provide a scholarship under subsection*
8 *(a) for an academic year unless the individual apply-*
9 *ing for the scholarship agrees to maintain an accept-*
10 *able level of academic standing, as determined by the*
11 *educational institution involved in accordance with*
12 *regulations issued by the Secretary.*

13 “(3) *LIMITATION ON AMOUNT.—The Director of*
14 *NIH may not provide a scholarship under subsection*
15 *(a) for an academic year in an amount exceeding*
16 *\$20,000.*

17 “(4) *AUTHORIZED USES.—A scholarship pro-*
18 *vided under subsection (a) may be expended only for*
19 *tuition expenses, other reasonable educational ex-*
20 *periences, and reasonable living expenses incurred in at-*
21 *tending the school involved.*

22 “(5) *CONTRACT REGARDING DIRECT PAYMENTS*
23 *TO INSTITUTION.—In the case of an institution of*
24 *higher education with respect to which a scholarship*
25 *under subsection (a) is provided, the Director of NIH*

1 *may enter into a contract with the institution under*
2 *which the amounts provided in the scholarship for*
3 *tuition and other educational expenses are paid di-*
4 *rectly to the institution.*

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 *priated \$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. DATE CERTAIN FOR APPOINTMENT OF BOARD***
 15 ***MEMBERS.***

16 *Section 499 of the Public Health Service Act, as reded-*
 17 *ignated by section 121(b)(3) of this Act, is amended in sub-*
 18 *section (c)(1)(C) by inserting after and below clause (iii)*
 19 *the following:*

20 *“Not later than April 1, 1993, the Secretary*
 21 *shall convene a meeting of the ex officio members*
 22 *of the Board for the purpose of making the ap-*
 23 *pointments required in this subparagraph.”.*

1 **SEC. 1702. MISCELLANEOUS PROVISIONS.**

2 *Section 499 of the Public Health Service Act, as redesi-*
3 *gnated by section 121(b)(3) of this Act, is amended—*

4 *(1) in subsection (a)—*

5 *(A) in the first sentence, by inserting after*
6 *“Secretary” the following: “, acting through the*
7 *Director of NIH,”; and*

8 *(B) in the second sentence, by striking “the*
9 *purposes of” and all that follows through*
10 *“Transfer Act,” and inserting the following: “the*
11 *purposes of the Ethics in Government Act of*
12 *1978 and the Stevenson-Wydler Technology In-*
13 *novation Act of 1980,”;*

14 *(2) in subsection (b)(2), by striking “Ethics”*
15 *and all that follows and inserting the following: “Eth-*
16 *ics in Government Act of 1978, and the Stevenson-*
17 *Wydler Technology Innovation Act of 1980.”;*

18 *(3) in subsection (c)—*

19 *(A) in paragraph (1)—*

20 *(i) in subparagraph (A), in the second*
21 *sentence, by inserting “, except the ex officio*
22 *members,” after “Foundation”;*

23 *(ii) in subparagraph (B), in the mat-*
24 *ter preceding clause (i), by striking “Coun-*
25 *cil” and inserting “Board”;* and

1 (iii) in subparagraph (C), in the first
2 sentence, by striking “Council” and insert-
3 ing “Board”; and

4 (B) in paragraph (3)(A), by striking “para-
5 graph (2)(C)” and inserting “paragraph
6 (1)(C)”;

7 (4) in subsection (g)(8), by striking “subtitle”
8 and inserting “part”; and

9 (5) in subsection (i)(1), by striking “1995” and
10 inserting “1996”.

11 **TITLE XVIII—RESEARCH WITH**
12 **RESPECT TO ACQUIRED IM-**
13 **MUNE DEFICIENCY SYN-**
14 **DROME**

15 **Subtitle A—Office of AIDS Research**

16 **SEC. 1801. ESTABLISHMENT OF OFFICE.**

17 (a) *IN GENERAL.*—Part D of title XXIII of the Public
18 *Health Service Act (42 U.S.C. 300cc–41 et seq.) is amend-*
19 *ed—*

20 (1) *by striking the part designation and the*
21 *heading for the part;*

22 (2) *by redesignating section 2351 as section*
23 *2354; and*

24 (3) *by inserting before section 2354 (as so redesi-*
25 *gnated) the following:*

1 “PART D—OFFICE OF AIDS RESEARCH

2 “Subpart I—Interagency Coordination of Activities

3 “**SEC. 2351. ESTABLISHMENT OF OFFICE.**

4 “(a) *IN GENERAL.*—There is established within the
5 National Institutes of Health an office to be known as the
6 Office of AIDS Research. The Office shall be headed by a
7 director, who shall be appointed by the Secretary.

8 “(b) *DUTIES.*—

9 “(1) *INTERAGENCY COORDINATION OF AIDS AC-*
10 *TIVITIES.*—With respect to acquired immune defi-
11 ciency syndrome, the Director of the Office shall plan,
12 coordinate, and evaluate research and other activities
13 conducted or supported by the agencies of the Na-
14 tional Institutes of Health.

15 “(2) *CONSULTATIONS.*—The Director of the Of-
16 fice shall carry out this subpart (including developing
17 and revising the plan required in section 2353) in
18 consultation with the heads of the agencies of the Na-
19 tional Institutes of Health, with the advisory councils
20 of the agencies, and with the advisory council estab-
21 lished under section 2352.

22 “**SEC. 2352. ADVISORY COUNCIL.**

23 “(a) *IN GENERAL.*—The Secretary shall establish an
24 advisory council for the purpose of providing advice to the

1 *Director of the Office on carrying out this part. (Such coun-*
2 *cil is referred to in this section as the 'Advisory Council'.)*

3 “(b) *COMPOSITION, COMPENSATION, TERMS, CHAIR,*
4 *ETC.—Subsections (b) through (g) of section 406 apply to*
5 *the Advisory Council to the same extent and in the same*
6 *manner as such subsections apply to advisory councils for*
7 *the national research institutes, except that, in addition to*
8 *the ex officio members specified in section 406(b)(2), there*
9 *shall serve as ex officio members of the Advisory Council*
10 *the chairs of the advisory councils for each of the National*
11 *Cancer Institute, the National Institute on Allergy and In-*
12 *fectious Diseases, the National Institute on Drug Abuse, and*
13 *the National Institute on Mental Health.*

14 **“SEC. 2353. COMPREHENSIVE PLAN FOR EXPENDITURE OF**
15 **APPROPRIATIONS.**

16 “(a) *IN GENERAL.—Subject to the provisions of this*
17 *section and other applicable law, the Director of the Office,*
18 *in carrying out section 2351, shall—*

19 “(1) *establish a comprehensive plan for the con-*
20 *duct and support of all AIDS activities of the agen-*
21 *cies of the National Institutes of Health (which plan*
22 *shall be first established under this paragraph not*
23 *later than 12 months after the date of the enactment*
24 *of the National Institutes of Health Revitalization Act*
25 *of 1993);*

1 “(2) ensure that the Plan establishes priorities
2 among the AIDS activities that such agencies are au-
3 thorized to carry out;

4 “(3) ensure that the Plan establishes objectives
5 regarding such activities, describes the means for
6 achieving the objectives, and designates the date by
7 which the objectives are expected to be achieved;

8 “(4) ensure that all amounts appropriated for
9 such activities are expended in accordance with the
10 Plan;

11 “(5) review the Plan not less than annually, and
12 revise the Plan as appropriate; and

13 “(6) ensure that the Plan serves as a broad,
14 binding statement of policies regarding AIDS activi-
15 ties of the agencies, but does not remove the respon-
16 sibility of the heads of the agencies for the approval
17 of specific programs or projects, or for other details of
18 the daily administration of such activities, in accord-
19 ance with the Plan.

20 “(b) CERTAIN COMPONENTS OF PLAN.—With respect
21 to AIDS activities of the agencies of the National Institutes
22 of Health, the Director of the Office shall ensure that the
23 Plan—

24 “(1) provides for basic research;

25 “(2) provides for applied research;

1 “(3) provides for research that is conducted by
2 the agencies;

3 “(4) provides for research that is supported by
4 the agencies;

5 “(5) provides for proposals developed pursuant to
6 solicitations by the agencies and for proposals devel-
7 oped independently of such solicitations; and

8 “(6) provides for behavioral research and social
9 sciences research.

10 “(c) BUDGET ESTIMATES.—

11 “(1) FULL-FUNDING BUDGET.—

12 “(A) With respect to a fiscal year, the Di-
13 rector of the Office shall prepare and submit di-
14 rectly to the President, for review and transmit-
15 tal to the Congress, a budget estimate for carry-
16 ing out the Plan for the fiscal year, after reason-
17 able opportunity for comment (but without
18 change) by the Secretary, the Director of the Na-
19 tional Institutes of Health, and the advisory
20 council established under section 2352. The budg-
21 et estimate shall include an estimate of the num-
22 ber and type of personnel needs for the Office.

23 “(B) The budget estimate submitted under
24 subparagraph (A) shall estimate the amounts
25 necessary for the agencies of the National Insti-

1 *tutes of Health to carry out all AIDS activities*
2 *determined by the Director of the Office to be ap-*
3 *propriate, without regard to the probability that*
4 *such amounts will be appropriated.*

5 *“(2) ALTERNATIVE BUDGETS.—*

6 *“(A) With respect to a fiscal year, the Di-*
7 *rector of the Office shall prepare and submit to*
8 *the Secretary and the Director of the National*
9 *Institutes of Health the budget estimates de-*
10 *scribed in subparagraph (B) for carrying out the*
11 *Plan for the fiscal year. The Secretary and such*
12 *Director shall consider each of such estimates in*
13 *making recommendations to the President re-*
14 *garding a budget for the Plan for such year.*

15 *“(B) With respect to the fiscal year in-*
16 *volved, the budget estimates referred to in sub-*
17 *paragraph (A) for the Plan are as follows:*

18 *“(i) The budget estimate submitted*
19 *under paragraph (1).*

20 *“(ii) A budget estimate developed on*
21 *the assumption that the amounts appro-*
22 *priated will be sufficient only for—*

23 *“(I) continuing the conduct by the*
24 *agencies of the National Institutes of*
25 *Health of existing AIDS activities (if*

1 *approved for continuation), and con-*
2 *tinuing the support of such activities*
3 *by the agencies in the case of projects*
4 *or programs for which the agencies*
5 *have made a commitment of continued*
6 *support; and*

7 “(II) *carrying out, of activities*
8 *that are in addition to activities speci-*
9 *fied in subclause (I), only such activi-*
10 *ties for which the Director determines*
11 *there is the most substantial need.*

12 “(iii) *Such other budget estimates as*
13 *the Director of the Office determines to be*
14 *appropriate.*

15 “(d) *FUNDING.—*

16 “(1) *AUTHORIZATION OF APPROPRIATIONS.—For*
17 *the purpose of carrying out AIDS activities under the*
18 *Plan, there are authorized to be appropriated such*
19 *sums as may be necessary for each of the fiscal years*
20 *1994 through 1996.*

21 “(2) *DIRECT RECEIPT BY DIRECTOR OF NA-*
22 *TIONAL INSTITUTES OF HEALTH.—For the first fiscal*
23 *year beginning after the date on which the Plan first*
24 *established under section 2353(a)(1) has been in effect*
25 *for 12 months, and for each subsequent fiscal year, the*

1 *Director of the National Institutes of Health shall re-*
2 *ceive directly from the President and the Director of*
3 *the Office of Management and Budget all funds avail-*
4 *able for AIDS activities of the National Institutes of*
5 *Health.*

6 “(3) *DISBURSEMENT TO AGENCIES.*—

7 “(A) *With respect to the disbursement by*
8 *the Director of the National Institutes of Health*
9 *of amounts for carrying out AIDS activities*
10 *specified in subsection (c)(2)(B)(ii)(I) for the fis-*
11 *cal year involved, the Director shall, to the extent*
12 *practicable, disburse all of such amounts to the*
13 *agencies of such Institutes not later than 30 days*
14 *after the date on which the Director receives*
15 *amounts under paragraph (2).*

16 “(B) *With respect to the disbursement by*
17 *the Director of the National Institutes of Health*
18 *of amounts for carrying out AIDS activities of*
19 *the National Institutes of Health in addition to*
20 *the activities specified in subparagraph (A) for*
21 *the fiscal year, the Director shall, to the extent*
22 *practicable, disburse all of such amounts to the*
23 *agencies of the National Institutes of Health not*
24 *later than 90 days after the date on which the*

1 Director receives amounts under paragraph
2 (2).”.

3 (b) *CONFORMING AMENDMENTS.*—Section 2354 of the
4 *Public Health Service Act*, as redesignated by subsection
5 (a)(2) of this section, is amended—

6 (1) in the heading for the section, by striking
7 “**ESTABLISHMENT OF**” and inserting “**ADDI-**
8 **TIONAL**”;

9 (2) in subsection (a)—

10 (A) in the matter preceding paragraph (1),
11 by striking “In carrying out” and all that fol-
12 lows and inserting the following: “In carrying
13 out AIDS research, the Director of the Of-
14 fice—”;

15 (B) by striking paragraphs (1) and (2) and
16 redesignating paragraphs (3) through (8) as
17 paragraphs (1) through (6);

18 (C) in paragraph (3) (as so redesignated),
19 by striking “may” and all that follows in the
20 matter preceding subparagraph (A) and insert-
21 ing the following: “may support—”;

22 (D) in paragraph (5) (as so redesignated)—

23 (i) in subparagraph (A)—

1 “(I) by striking “may” and all
2 that follows through “acquire,” and in-
3 serting “may acquire,”; and

4 “(II) by striking “Director” and
5 all that follows through “determines”
6 and inserting “Director of the Office
7 determines”;

8 (ii) in subparagraph (B), by striking
9 “may” and all that follows through “make
10 grants” and inserting “may make grants”;
11 and

12 (iii) in subparagraph (C), by striking
13 “may” and all that follows through “ac-
14 quire,” and inserting “may acquire,”; and
15 (E) in each of paragraphs (2), (3)(A), and
16 (4) (as so redesignated), by striking “research re-
17 lating to acquired immune deficiency syndrome”
18 and inserting “AIDS research”;

19 (3) in subsection (b), in the matter preceding
20 paragraph (1), by striking “The Director” and all
21 that follows through “shall” and inserting “The Di-
22 rector of the Office shall”; and

23 (4) in subsection (c), by striking “the Director”
24 and all that follows through “shall” and inserting
25 “the Director of the Office shall”.

1 **SEC. 1802. ESTABLISHMENT OF EMERGENCY DISCRE-**
 2 **TIONARY FUND.**

3 *Part D of title XXIII of the Public Health Service Act,*
 4 *as amended by section 1801 of this Act, is amended by add-*
 5 *ing at the end the following subpart:*

6 *“Subpart II—Emergency Discretionary Fund*

7 **“SEC. 2356. EMERGENCY DISCRETIONARY FUND.**

8 *“(a) IN GENERAL.—*

9 *“(1) ESTABLISHMENT.—There is established a*
 10 *fund consisting of such amounts as may be appro-*
 11 *priated under subsection (g). Subject to the provisions*
 12 *of this section, the Director of the Office, after con-*
 13 *sultation with the advisory council established under*
 14 *section 2352, may expend amounts in the Fund for*
 15 *the purpose of conducting and supporting such*
 16 *projects of AIDS research and other AIDS activities*
 17 *as may be authorized in this Act for the National In-*
 18 *stitutes Health.*

19 *“(2) PRECONDITIONS TO USE OF FUND.—*
 20 *Amounts in the Fund may be expended for an AIDS*
 21 *project only if—*

22 *“(A) the Director of the Office has made a*
 23 *determination that there is a significant need for*
 24 *the project; and*

25 *“(B) as of June 30 of the fiscal year preced-*
 26 *ing the fiscal year in which the determination is*

1 *made, such need was not provided for in any ap-*
2 *propriations Act passed by the House of Rep-*
3 *resentatives to make appropriations for the De-*
4 *partments of Labor, Health and Human Services*
5 *(including the National Institutes of Health),*
6 *Education, and related agencies for the fiscal*
7 *year in which the determination is made.*

8 “(3) *TWO-YEAR USE OF FUND FOR PROJECT IN-*
9 *INVOLVED.—In the case of an AIDS project, obligations*
10 *of amounts in the Fund may not be made for the*
11 *project after the expiration of the 2-year period begin-*
12 *ning on the date on which the initial obligation of*
13 *such amounts is made for the project.*

14 “(b) *PEER REVIEW.—With respect to an AIDS project*
15 *carried out with amounts in the Fund, this section may*
16 *not be construed as waiving applicable requirements for*
17 *peer review.*

18 “(c) *LIMITATIONS ON USE OF FUND.—*

19 “(1) *CONSTRUCTION OF FACILITIES.—Amounts*
20 *in the Fund may not be used for the construction,*
21 *renovation, or relocation of facilities, or for the acqui-*
22 *sition of land.*

23 “(2) *CONGRESSIONAL DISAPPROVAL OF*
24 *PROJECTS.—*

1 “(A) Amounts in the Fund may not be ex-
2 pended for the fiscal year involved for an AIDS
3 project, or category of such projects, for which—

4 “(i)(I) amounts were made available
5 in an appropriations Act for the preceding
6 fiscal year; and

7 “(II) amounts are not made available
8 in any appropriations Act for the fiscal
9 year involved; or

10 “(ii) amounts are by law prohibited
11 from being expended.

12 “(B) A determination under subparagraph
13 (A)(i) of whether amounts have been made avail-
14 able in appropriations Acts for a fiscal year
15 shall be made without regard to whether such
16 Acts make available amounts for the Fund.

17 “(3) INVESTMENT OF FUND AMOUNTS.—Amounts
18 in the Fund may not be invested.

19 “(d) APPLICABILITY OF LIMITATION REGARDING NUM-
20 BER OF EMPLOYEES.—The purposes for which amounts in
21 the Fund may be expended include the employment of indi-
22 viduals necessary to carry out AIDS projects approved
23 under subsection (a). Any individual employed under the
24 preceding sentence may not be included in any determina-
25 tion of the number of full-time equivalent employees for the

1 *Department of Health and Human Services for the purpose*
2 *of any limitation on the number of such employees estab-*
3 *lished by law prior to, on, or after the date of the enactment*
4 *of the National Institutes of Health Revitalization Act of*
5 *1993.*

6 “(e) *REPORT TO CONGRESS.*—*Not later than February*
7 *1 of each fiscal year, the Director of the Office shall submit*
8 *to the Committee on Energy and Commerce of the House*
9 *of Representatives, and to the Committee on Labor and*
10 *Human Resources of the Senate, a report on the AIDS*
11 *projects carried out during the preceding fiscal year with*
12 *amounts in the Fund. The report shall provide a descrip-*
13 *tion of each such project and an explanation of the reasons*
14 *underlying the use of the Fund for the project.*

15 “(f) *DEFINITIONS.*—*For purposes of this section:*

16 “(1) *The term ‘AIDS project’ means a project de-*
17 *scribed in subsection (a).*

18 “(2) *The term ‘Fund’ means the fund established*
19 *in subsection (a).*

20 “(g) *FUNDING.*—

21 “(1) *AUTHORIZATION OF APPROPRIATIONS.*—*For*
22 *the purpose of providing amounts for the Fund, there*
23 *is authorized to be appropriated \$100,000,000 for*
24 *each of the fiscal years 1994 through 1996.*

1 “(2) *AVAILABILITY.*—Amounts appropriated for
2 *the Fund are available until expended.*”.

3 **SEC. 1803. GENERAL PROVISIONS.**

4 *Part D of title XXIII of the Public Health Service Act,*
5 *as amended by section 1802 of this Act, is amended by add-*
6 *ing at the end the following subpart:*

7 *“Subpart III—General Provisions*

8 **“SEC. 2359. GENERAL PROVISIONS REGARDING THE OF-**
9 **OFFICE.**

10 “(a) *ADMINISTRATIVE SUPPORT FOR OFFICE.*—The
11 *Secretary, acting through the Director of the National Insti-*
12 *tutes of Health, shall provide administrative support and*
13 *support services to the Director of the Office.*

14 “(b) *DEFINITIONS.*—For purposes of this part:

15 “(1) *The term ‘AIDS activities’ means AIDS re-*
16 *search and other activities that relate to acquired im-*
17 *une deficiency syndrome.*

18 “(2) *The term ‘AIDS research’ means research*
19 *with respect to acquired immune deficiency syndrome.*

20 “(3) *The term ‘Office’ means the Office of AIDS*
21 *Research.*

22 “(4) *The term ‘Plan’ means the plan required in*
23 *section 2353(a)(1).*”.

Subtitle B—Certain Programs**SEC. 1811. REVISION AND EXTENSION OF CERTAIN PROGRAMS.**

Title XXIII of the Public Health Service Act (42 U.S.C. 300cc et seq.) is amended—

(1) in section 2304(c)(1)—

(A) in the matter preceding subparagraph (A), by inserting after “Director of such Institute” the following: “(and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate)”; and

(B) in subparagraph (A), by inserting before the semicolon the following: “, including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases”;

(2) in section 2311(a)(1), by inserting before the semicolon the following: “, including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases”;

(3) in section 2315—

1 (A) in subsection (a)(2), by striking “inter-
2 national research” and all that follows and in-
3 serting “international research and training
4 concerning the natural history and pathogenesis
5 of the human immunodeficiency virus and the
6 development and evaluation of vaccines and
7 treatments for acquired immune deficiency syn-
8 drome and opportunistic infections.”; and

9 (B) in subsection (f), by striking “there are
10 authorized” and all that follows and inserting
11 “there are authorized to be appropriated such
12 sums as may be necessary for each fiscal year.”;

13 (4) in section 2318—

14 (A) in subsection (a)(1)—

15 (i) by inserting after “The Secretary”
16 the following: “, acting through the Director
17 of the National Institutes of Health and
18 after consultation with the Administrator
19 for Health Care Policy and Research,”; and

20 (ii) by striking “syndrome” and insert-
21 ing “syndrome, including treatment and
22 prevention of HIV infection and related
23 conditions among women”; and

24 (B) in subsection (e), by striking “1991.”
25 and inserting the following: “1991, and such

1 *sums as may be necessary for each of the fiscal*
2 *years 1994 through 1996.”;*

3 (5) *in section 2320(b)(1)(A), by striking “syn-*
4 *drome” and inserting “syndrome and the natural his-*
5 *tory of such infection”;*

6 (6) *in section 2320(e)(1), by striking “there are*
7 *authorized” and all that follows and inserting “there*
8 *are authorized to be appropriated such sums as may*
9 *be necessary for each fiscal year.”;*

10 (7) *in section 2341(d), by striking “there are au-*
11 *thorized” and all that follows and inserting “there are*
12 *authorized to be appropriated such sums as may be*
13 *necessary for each fiscal year.”; and*

14 (8) *in section 2361, by striking “For purposes”*
15 *and all that follows and inserting the following:*

16 *“For purposes of this title:*

17 *“(1) The term ‘infection’, with respect to the etio-*
18 *logic agent for acquired immune deficiency syndrome,*
19 *includes opportunistic cancers and infectious diseases*
20 *and any other conditions arising from infection with*
21 *such etiologic agent.*

22 *“(2) The term ‘treatment’, with respect to the*
23 *etiologic agent for acquired immune deficiency syn-*
24 *drome, includes primary and secondary prophyl-*
25 *axis.”.*

TITLE XIX—STUDIES**SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.**

(a) *THIRD-PARTY PAYMENTS REGARDING CERTAIN CLINICAL TRIALS.*—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of—

(1) *determining the policies of third-party payors regarding the payment of the costs of appropriate health services that are provided incident to the participation of individuals as subjects in clinical trials conducted in the development of drugs with respect to acquired immune deficiency syndrome; and*

(2) *developing recommendations regarding such policies.*

(b) *ADVISORY COMMITTEES.*—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of determining—

(1) *whether the activities of the various advisory committees established in the National Institutes of Health regarding acquired immune deficiency syndrome are being coordinated sufficiently; and*

(2) *whether the functions of any of such advisory committees should be modified in order to achieve greater efficiency.*

1 (c) *VACCINES FOR HUMAN IMMUNODEFICIENCY*
2 *VIRUS.*—

3 (1) *IN GENERAL.*—*The Secretary of Health and*
4 *Human Services, acting through the National Insti-*
5 *tutes of Health, shall develop a plan for the appro-*
6 *prate inclusion of HIV-infected women, including*
7 *pregnant women, HIV-infected infants, and HIV-in-*
8 *fected children in studies conducted by or through the*
9 *National Institutes of Health concerning the safety*
10 *and efficacy of HIV vaccines for the treatment and*
11 *prevention of HIV infection. Such plan shall ensure*
12 *the full participation of other Federal agencies cur-*
13 *rently conducting HIV vaccine studies and require*
14 *that such studies conform fully to the requirements of*
15 *part 46 of title 45, Code of Federal Regulations.*

16 (2) *REPORT.*—*Not later than 180 days after the*
17 *date of the enactment of this Act, the Secretary of*
18 *Health and Human Services shall prepare and sub-*
19 *mit to the Committee on Energy and Commerce of the*
20 *House of Representatives, and the Committee on*
21 *Labor and Human Resources of the Senate, a report*
22 *concerning the plan developed under paragraph (1).*

23 (3) *IMPLEMENTATION.*—*Not later than 12*
24 *months after the date of the enactment of this Act, the*
25 *Secretary of Health and Human Services shall imple-*

1 *ment the plan developed under paragraph (1), includ-*
2 *ing measures for the full participation of other*
3 *Federal agencies currently conducting HIV vaccine*
4 *studies.*

5 (4) *For the purpose of carrying out this sub-*
6 *section, there are authorized to be appropriated such*
7 *sums as may be necessary for each of the fiscal years*
8 *1994 through 1996.*

9 **SEC. 1902. MALNUTRITION IN THE ELDERLY.**

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 National Institute*
14 *on Aging, coordinating with the Agency for Health*
15 *Care Policy and Research and, to the degree possible,*
16 *in consultation with the head of the National Nutri-*
17 *tion Monitoring System established under section*
18 *1428 of the Food and Agriculture Act of 1977 (7*
19 *U.S.C. 3178), shall conduct a 3-year nutrition screen-*
20 *ing and intervention activities study of the elderly.*

21 (2) *EFFICACY AND COST-EFFECTIVENESS OF NU-*
22 *TRITION SCREENING AND INTERVENTION ACTIVI-*
23 *TIES.—In conducting the study, the Secretary shall*
24 *determine the efficacy and cost-effectiveness of nutri-*
25 *tion screening and intervention activities conducted*

1 *in the elderly health and long-term care continuum,*
2 *and of a program that would institutionalize nutri-*
3 *tion screening and intervention activities. In evaluat-*
4 *ing such a program, the Secretary shall determine—*

5 *(A) if health or quality of life is measurably*
6 *improved for elderly individuals who receive rou-*
7 *tine nutritional screening and treatment;*

8 *(B) if federally subsidized home or institu-*
9 *tional care is reduced because of increased inde-*
10 *pendence of elderly individuals resulting from*
11 *improved nutritional status;*

12 *(C) if a multidisciplinary approach to nu-*
13 *tritional care is effective in addressing the nutri-*
14 *tional needs of elderly individuals; and*

15 *(D) if reimbursement for nutrition screen-*
16 *ing and intervention activities is a cost-effective*
17 *approach to improving the health status of elder-*
18 *ly individuals.*

19 *(3) POPULATIONS.—The populations of elderly*
20 *individuals in which the study will be conducted shall*
21 *include populations of elderly individuals who are—*

22 *(A) living independently, including—*

23 *(i) individuals who receive home and*
24 *community-based services or family sup-*
25 *port;*

1 (ii) individuals who do not receive ad-
2 ditional services and support;

3 (iii) individuals with low incomes; and

4 (iv) individuals who are minorities;

5 (B) hospitalized, including individuals ad-
6 mitted from home and from institutions; and

7 (C) institutionalized in residential facilities
8 such as nursing homes and adult homes.

9 (b) *MALNUTRITION STUDY.*—The Secretary, acting
10 through the National Institute on Aging, shall conduct a
11 3-year study to determine the extent of malnutrition in el-
12 derly individuals in hospitals and long-term care facilities
13 and in elderly individuals who are living independently.

14 (c) *REPORT.*—The Secretary shall submit a report to
15 the Committee on Labor and Human Resources of the Sen-
16 ate and the Committee on Energy and Commerce of the
17 House of Representatives containing the findings resulting
18 from the studies described in subsections (a) and (b), in-
19 cluding a determination regarding whether a program that
20 would institutionalize nutrition screening and intervention
21 activities should be adopted, and the rationale for the deter-
22 mination.

23 (d) *ADVISORY PANEL.*—

24 (1) *ESTABLISHMENT.*—The Secretary, acting
25 through the Director of the National Institute on

1 *Aging, shall establish an advisory panel that shall*
2 *oversee the design, implementation, and evaluation of*
3 *the studies described in subsections (a) and (b).*

4 (2) *COMPOSITION.*—*The advisory panel shall in-*
5 *clude representatives appointed for the life of the*
6 *panel by the Secretary from the Health Care Financ-*
7 *ing Administration, the Social Security Administra-*
8 *tion, the National Center for Health Statistics, the*
9 *Administration on Aging, the National Council on*
10 *the Aging, the American Dietetic Association, the*
11 *American Academy of Family Physicians, and such*
12 *other agencies or organizations as the Secretary deter-*
13 *mines to be appropriate.*

14 (3) *COMPENSATION AND EXPENSES.*—

15 (A) *COMPENSATION.*—*Each member of the*
16 *advisory panel who is not an employee of the*
17 *Federal Government shall receive compensation*
18 *at the daily equivalent of the rate specified for*
19 *level V of the Executive Schedule under section*
20 *5316 of title 5, United States Code, for each day*
21 *the member is engaged in the performance of du-*
22 *ties for the advisory panel, including attendance*
23 *at meetings and conferences of the panel, and*
24 *travel to conduct the duties of the panel.*

1 (B) *TRAVEL EXPENSES.*—Each member of
2 the advisory panel shall receive travel expenses,
3 including per diem in lieu of subsistence, at
4 rates authorized for employees of agencies under
5 subchapter I of chapter 57 of title 5, United
6 States Code, for each day the member is engaged
7 in the performance of duties away from the home
8 or regular place of business of the member.

9 (4) *DETAIL OF FEDERAL EMPLOYEES.*—On the
10 request of the advisory panel, the head of any Federal
11 agency shall detail, without reimbursement, any of
12 the personnel of the agency to the advisory panel to
13 assist the advisory panel in carrying out its duties.
14 Any detail shall not interrupt or otherwise affect the
15 civil service status or privileges of the Federal em-
16 ployee.

17 (5) *TECHNICAL ASSISTANCE.*—On the request of
18 the advisory panel, the head of a Federal agency shall
19 provide such technical assistance to the advisory
20 panel as the advisory panel determines to be nec-
21 essary to carry out its duties.

22 (6) *TERMINATION.*—Notwithstanding section 15
23 of the Federal Advisory Committee Act (5 U.S.C.
24 App.), the advisory panel shall terminate 3 years
25 after the date of enactment of this Act.

1 **SEC. 1903. RESEARCH ACTIVITIES ON CHRONIC FATIGUE**
2 **SYNDROME.**

3 *The Secretary of Health and Human Services shall,*
4 *not later than May 1, 1993, and annually thereafter for*
5 *the next 3 years, prepare and submit to the Committee on*
6 *Energy and Commerce of the House of Representatives and*
7 *the Committee on Labor and Human Resources of the Sen-*
8 *ate, a report that summarizes the research activities con-*
9 *ducted or supported by the National Institutes of Health*
10 *concerning chronic fatigue syndrome. Such report should*
11 *include information concerning grants made, cooperative*
12 *agreements or contracts entered into, intramural activities,*
13 *research priorities and needs, and a plan to address such*
14 *priorities and needs.*

15 **SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL**
16 **AGENTS IN DEVELOPMENT OF DEFENSES**
17 **AGAINST BIOLOGICAL WARFARE.**

18 *The Secretary of Health and Human Services, in con-*
19 *sultation with other appropriate executive agencies, shall*
20 *report to the House Energy and Commerce Committee and*
21 *the Senate Labor and Human Resources Committee on the*
22 *appropriateness and impact of the National Institutes of*
23 *Health assuming responsibility for the conduct of all Fed-*
24 *eral research, development, testing, and evaluation func-*
25 *tions relating to medical countermeasures against*
26 *biowarfare threat agents. In preparing the report, the Sec-*

1 *retary shall identify the extent to which such activities are*
2 *carried out by agencies other than the National Institutes*
3 *of Health, and assess the impact (positive and negative) of*
4 *the National Institutes of Health assuming responsibility*
5 *for such activities, including the impact under the Budget*
6 *Enforcement Act and the Omnibus Budget Reconciliation*
7 *Act of 1990 on existing National Institutes of Health re-*
8 *search programs as well as other programs within the cat-*
9 *egory of domestic discretionary spending. The Secretary*
10 *shall submit the report not later than 12 months after the*
11 *date of the enactment of this Act.*

12 **SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETEN-**
13 **TION AND TURNOVER.**

14 (a) *STUDY OF PERSONNEL SYSTEM.*—Not later than
15 1 year after the date of the enactment of this Act, the Sec-
16 retary of Health and Human Services, acting through the
17 Director of the National Institutes of Health, shall conduct
18 a study to review the retention, recruitment, vacancy and
19 turnover rates of support staff, including firefighters, law
20 enforcement, procurement officers, technicians, nurses and
21 clerical employees, to ensure that the National Institutes of
22 Health is adequately supporting the conduct of efficient, ef-
23 fective and high quality research for the American public.
24 *The Director of NIH shall work in conjunction with appro-*

1 *priate employee organizations and representatives in devel-*
2 *oping such a study.*

3 *(b) SUBMISSION TO CONGRESS.—Not later than 1 year*
4 *after the date of the enactment of this Act, the Secretary*
5 *of Health and Human Services shall prepare and submit*
6 *to the Committee on Energy and Commerce of the House*
7 *of Representatives, and to the Committee on Labor and*
8 *Human Resources of the Senate, a report containing the*
9 *study conducted under subsection (a) together with the rec-*
10 *ommendations of the Secretary concerning the enactment*
11 *of legislation to implement the results of such study.*

12 **SEC. 1906. PROCUREMENT.**

13 *(a) IN GENERAL.—The Director of the National Insti-*
14 *tutes of Health and the Administrator of the General Serv-*
15 *ices Administration shall jointly conduct a study to develop*
16 *a streamlined procurement system for the National Insti-*
17 *tutes of Health that complies with the requirements of Fed-*
18 *eral law.*

19 *(b) REPORT.—Not later than March 1, 1994, the offi-*
20 *cial specified in subsection (a) shall complete the study re-*
21 *quired in such subsection and shall submit to the Committee*
22 *on Energy and Commerce of the House of Representatives,*
23 *and the Committee on Labor and Human Resources of the*
24 *Senate, a report describing the findings made as a result*
25 *of the study.*

1 **SEC. 1907. CHRONIC PAIN CONDITIONS.**

2 (a) *IN GENERAL.*—The Director of the National Insti-
3 tutes of Health (in this section referred to as the ‘Director’),
4 acting through the Director of the National Institute of Den-
5 tal Research and as appropriate through the heads of other
6 agenices of such Institutes, shall conduct a study for the
7 purpose of determining the incidence in the United States
8 of cases of chronic pain and the effect of such cases on the
9 costs of health care in the United States.

10 (b) *CERTAIN ELEMENTS OF STUDY.*—The cases of
11 chronic pain with respect to which the study required in
12 subsection (a) is conducted shall include reflex sympathetic
13 dystrophy syndrome, temporomandibular joint disorder,
14 post-herpetic neuropathy, painful diabetic neuropathy,
15 phantom pain, and post-stroke pain.

16 (c) *REPORT.*—Not later than 2 years after the date of
17 the enactment of this Act, the Director shall complete the
18 study required in subsection (a) and submit to the the Com-
19 mittee on Energy and Commerce of the House of Represent-
20 atives, and to the Committee on Labor and Human Re-
21 sources of the Senate, a report describing the findings made
22 as a result of the study.

23 **SEC. 1908. BACK INJURIES.**

24 (a) *IN GENERAL.*—The Director of the National Insti-
25 tutes of Health, acting through the appropriate national re-

1 *search institute, shall conduct a study of back injuries, with*
2 *consideration of the following:*

3 (1) *Accurate diagnosis, and the appropriate form*
4 *of treatment.*

5 (2) *Providing for return to employment as soon*
6 *as is practicable.*

7 (3) *Minimizing the probability of recurrence.*

8 (4) *A comparison of conventional treatments and*
9 *alternative treatments.*

10 (5) *Costs to the health care system.*

11 (6) *Costs to the economy generally.*

12 (b) *REPORT.—Not later than 1 year after the date of*
13 *the enactment of this Act, the Director of the National Insti-*
14 *tute of Health shall complete the study required in sub-*
15 *section (a) and submit to the Committee on Energy and*
16 *Commerce of the House of Representatives, and to the Com-*
17 *mittee on Labor and Human Resources of the Senate, a*
18 *report describing the findings made as a result of the study.*

1 **TITLE XX—MISCELLANEOUS**
2 **PROVISIONS**

3 **SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RE-**
4 **SEARCH SERVICE IN HONOR OF SILVIO O.**
5 **CONTE; LIMITATION ON NUMBER OF MEM-**
6 **BERS.**

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 **SEC. 2003. CERTAIN AUTHORIZATION OF APPROPRIATIONS.**

2 *Section 399L(a) of the Public Health Service Act (42*
3 *U.S.C. 280e-4(a)), as added by Public Law 102-515 (106*
4 *Stat. 3376), is amended—*

5 *(1) in the first sentence, by striking “the Sec-*
6 *retary” and all that follows and inserting the follow-*
7 *ing: “there are authorized to be appropriated*
8 *\$30,000,000 for fiscal year 1994, and such sums as*
9 *may be necessary for each of the fiscal years 1995*
10 *through 1996.”; and*

11 *(2) in the second sentence, by striking “Out of*
12 *any amounts used” and inserting “Of the amounts*
13 *appropriated under the preceding sentence”.*

14 **SEC. 2004. BUY-AMERICAN PROVISIONS.**

15 *No funds appropriated pursuant to this Act may be*
16 *used to fund a grant or contract unless the recipient agrees*
17 *that substantially all goods and services acquired with such*
18 *grant or contract assistance will be produced in the United*
19 *States.*

20 **TITLE XXI—EFFECTIVE DATES**

21 **SEC. 2101. EFFECTIVE DATES.**

22 *Subject to section 165, this Act and the amendments*
23 *made by this Act take effect upon the date of the enactment*
24 *of this Act.*

1 **SEC. 2005. PROHIBITION AGAINST FURTHER FUNDING FOR**
2 **PROJECT ARIES.**

3 *For fiscal year 1994 and each subsequent fiscal year,*
4 *the project administered by the University of Washington*
5 *at Seattle and known as Project Aries may not receive any*
6 *funding from any agency of the National Institutes of*
7 *Health, other than payments under awards made for fiscal*
8 *year 1993 or prior fiscal years.*

Attest:

Clerk.

S 1 EAH—2

S 1 EAH—3

S 1 EAH—4

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