

**Union Calendar No. 12**

103D CONGRESS  
1ST SESSION

**H. R. 4**

**[Report No. 103-28]**

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**A BILL**

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

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MARCH 9, 1993

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 5, 1993

Mr. WAXMAN (for himself, Mr. UPTON, Mrs. SCHROEDER, Ms. SNOWE, Mrs. COLLINS of Illinois, Ms. DANNER, Ms. ENGLISH, Mrs. JOHNSON of Connecticut, Mrs. KENNELLY, Ms. LAMBERT, Mr. LEHMAN, Mrs. LOWEY of New York, Mrs. LLOYD, Mr. MARKEY, Mrs. MINK, Mrs. MORELLA, Ms. MOLINARI, Ms. NORTON, Mr. RICHARDSON, Ms. PELOSI, Mr. SANDERS, Ms. SCHENK, Mr. SHARP, Ms. SLAUGHTER, Mr. STUDDS, Mr. SYNAR, Mr. TOWNS, Mrs. UNSOELD, Ms. WATERS, Ms. WOOLSEY, and Mr. WYDEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

MARCH 9, 1993

Additional sponsors: Miss COLLINS of Michigan, Mr. SWIFT, Ms. KAPTUR, Mr. BOUCHER, Ms. FURSE, Ms. SHEPHERD, Mrs. BYRNE, Mr. SHAYS, Mr. DIXON, and Mr. EDWARDS of California

MARCH 9, 1993

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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

[For text of introduced bill, see copy of bill as introduced on January 5, 1993]

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# A BILL

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

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

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

4 (a) *SHORT TITLE.*—*This Act may be cited as the “Na-*  
 5 *tional Institutes of Health Revitalization Act of 1993”.*

6 (b) *TABLE OF CONTENTS.*—*The table of contents for*  
 7 *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. Miscellaneous provisions.

## TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Sec. 301. Appointment and authority of Directors of national research institutes.

Sec. 302. Program of research on osteoporosis, Paget's disease, and related disorders.

Sec. 303. Establishment of interagency program for trauma research.

## TITLE IV—NATIONAL CANCER INSTITUTE

Sec. 401. Expansion and intensification of activities regarding breast cancer.

Sec. 402. Expansion and intensification of activities regarding prostate cancer.

Sec. 403. Authorization of appropriations.

## TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Sec. 501. Education and training.

Sec. 502. Centers for the study of pediatric cardiovascular diseases.

Sec. 503. National Center on Sleep Disorders.

Sec. 504. Authorization of appropriations.

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

Sec. 601. Provisions regarding nutritional disorders.

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

*Sec. 701. Juvenile arthritis.*

*TITLE VIII—NATIONAL INSTITUTE ON AGING*

*Sec. 801. Alzheimer's disease registry.*

*Sec. 802. Aging processes regarding women.*

*Sec. 803. Authorization of appropriations.*

*Sec. 804. Conforming amendment.*

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

*Sec. 901. Tropical diseases.*

*Sec. 902. Chronic fatigue syndrome.*

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

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

*Sec. 1001. Grants and contracts for research centers.*

*Sec. 1002. Loan repayment program for research with respect to contraception  
and infertility.*

*Subtitle B—Program Regarding Obstetrics and Gynecology*

*Sec. 1011. Establishment of program.*

*Subtitle C—Child Health Research Centers*

*Sec. 1021. Establishment of centers.*

*Subtitle D—Study Regarding Adolescent Health*

*Sec. 1031. Prospective longitudinal study.*

*TITLE XI—NATIONAL EYE INSTITUTE*

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

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

*Sec. 1201. Research on multiple sclerosis.*

*TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH  
SCIENCES*

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

*Sec. 1302. Study of environmental and other risks contributing to incidence of  
breast and prostate cancer.*

## 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.*

*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.*

*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 the tissue to be used*  
22                              *in such research; and*

23                              “(ii) *no alteration of the timing, meth-*  
24                              *od, or procedures used to terminate the*

1           *pregnancy was made solely for the purposes*  
2           *of obtaining the tissue;*

3           “(B) *the tissue has been donated by the*  
4           *woman in accordance with paragraph (1); and*

5           “(C) *full disclosure has been provided to the*  
6           *woman with regard to—*

7                   “(i) *such physician’s interest, if any,*  
8                   *in the research to be conducted with the tis-*  
9                   *sue; and*

10                   “(ii) *any known medical risks to the*  
11                   *woman or risks to her privacy that might*  
12                   *be associated with the donation of the tissue*  
13                   *and that are in addition to risks of such*  
14                   *type that are associated with the woman’s*  
15                   *medical care.*

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

22                   “(1) *is aware that—*

23                   “(A) *the tissue is human fetal tissue;*

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

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

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

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

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

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

17                 “(1) IN GENERAL.—In research carried out  
18                 under subsection (a), human fetal tissue may be used  
19                 only if the head of the agency or other entity conduct-  
20                 ing the research involved certifies to the Secretary  
21                 that the statements required under subsections (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 *ected; 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) *DEFINITION.*—*For purposes of this section, the*  
 6           *term ‘human fetal tissue’ means tissue or cells obtained*  
 7           *from a dead human embryo or fetus after a spontaneous*  
 8           *or induced abortion, or after a stillbirth.’.*

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

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

16           “*PROHIBITIONS REGARDING HUMAN FETAL TISSUE*

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

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

1 *tissue will be or is obtained pursuant to an induced abor-*  
2 *tion, and—*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21           (1) *whether and to what extent such research*  
22 *conducted or supported by the Secretary of Health*  
23 *and Human Services has been conducted in accord-*  
24 *ance with section 498A of the Public Health Service*  
25 *Act (as added by section 111 of this Act); and*

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

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

11                           ***PART III—MISCELLANEOUS REPEALS***

12           ***SEC. 121. REPEALS.***

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

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

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

19                           (2) *by striking section 499; and*

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

21           (c) *NULLIFICATION OF CERTAIN PROVISIONS.*—*The*  
22           *provisions of Executive Order 12806 (57 Fed. Reg. 21589*  
23           *(May 21, 1992)) shall not have any legal effect. The provi-*  
24           *sions of section 204(d) of part 46 of title 45 of the Code*

1 of Federal Regulations (45 CFR 46.204(d)) shall not have  
2 any legal effect.

3 **Subtitle B—Clinical Research Eq-**  
4 **uity Regarding Women and Mi-**  
5 **norities**

6 **PART I—WOMEN AND MINORITIES AS SUBJECTS**  
7 **IN CLINICAL RESEARCH**

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

9 Part G of title IV of the Public Health Service Act,  
10 as amended by section 101 of this Act, is amended by insert-  
11 ing after section 492A the following new section:

12 “INCLUSION OF WOMEN AND MINORITIES IN CLINICAL  
13 RESEARCH

14 “SEC. 492B. (a) REQUIREMENT OF INCLUSION.—

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

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

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

22 “(2) OUTREACH REGARDING PARTICIPATION AS  
23 SUBJECTS.—The Director of NIH, in consultation  
24 with the Director of the Office of Research on Wom-  
25 en’s Health and the Director of the Office of Research  
26 on Minority Health, shall conduct or support out-

1        *reach programs for the recruitment of women and*  
2        *members of minority groups as subjects in projects of*  
3        *clinical research.*

4        “(b) *INAPPLICABILITY OF REQUIREMENT.*—The re-  
5        *quirement established in subsection (a) regarding women*  
6        *and members of minority groups shall not apply to a*  
7        *project of clinical research if the inclusion, as subjects in*  
8        *the project, of women and members of minority groups, re-*  
9        *spectively—*

10            “(1) *is inappropriate with respect to the health*  
11            *of the subjects;*

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

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

16        “(c) *DESIGN OF CLINICAL TRIALS.*—*In the case of any*  
17        *clinical trial in which women or members of minority*  
18        *groups will under subsection (a) be included as subjects, the*  
19        *Director of NIH shall ensure that the trial is designed and*  
20        *carried out in a manner sufficient to provide for a valid*  
21        *analysis of whether the variables being studied in the trial*  
22        *affect women or members of minority groups, as the case*  
23        *may be, differently than other subjects in the trial.*

24        “(d) *GUIDELINES.*—

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

8                   “(A) the circumstances under which the in-  
9                   clusion of women and minorities as subjects in  
10                  projects of clinical research is inappropriate for  
11                  purposes of subsection (b);

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

15                  “(C) the operation of outreach programs  
16                  under subsection (a).

17           “(2) *CERTAIN PROVISIONS.*—With respect to the  
18           circumstances under which the inclusion of women or  
19           members of minority groups (as the case may be) as  
20           subjects in a project of clinical research is inappro-  
21           priate for purposes of subsection (b), the following ap-  
22           plies to guidelines under paragraph (1):

23                   “(A)(i) In the case of a clinical trial, the  
24                   guidelines shall provide that the costs of such in-  
25                   clusion in the trial is not a permissible consider-

1            *ation in determining whether such inclusion is*  
2            *inappropriate.*

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

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

19           *“(i) the effects that the variables to be*  
20           *studied in the trial have on women or mem-*  
21           *bers of minority groups, respectively; and*

22           *“(ii) the effects that the variables have*  
23           *on the individuals who would serve as sub-*  
24           *jects in the trial in the event that such in-*  
25           *clusion were not required.*

1       “(e) *DATE CERTAIN FOR GUIDELINES; APPLICABIL-*  
2 *ITY.—*

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

8               “(2) *APPLICABILITY.—For fiscal year 1995 and*  
9 *subsequent fiscal years, the Director of NIH may not*  
10 *approve any proposal of clinical research to be con-*  
11 *ducted or supported by any agency of the National*  
12 *Institutes of Health unless the proposal specifies the*  
13 *manner in which the research will comply with this*  
14 *section.*

15       “(f) *REPORTS BY ADVISORY COUNCILS.—The advisory*  
16 *council of each national research institute shall annually*  
17 *submit to the Director of NIH and the Director of the insti-*  
18 *tute involved a report describing the manner in which the*  
19 *agency has complied with this section.*

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

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

23               “(2) *The term ‘minority group’ includes sub-*  
24 *populations of minority groups. The Director of NIH*  
25 *shall, through the guidelines established under sub-*

1        *section (d), define the terms ‘minority group’ and*  
2        *‘subpopulation’ for purposes of the preceding sen-*  
3        *tence.’.*

4        **SEC. 132. PEER REVIEW.**

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

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

14            *“(2) Paragraph (1) shall not apply to any proposal*  
15        *for clinical research that, pursuant to subsection (b) of sec-*  
16        *tion 492B, is not subject to the requirement of subsection*  
17        *(a) of such section regarding the inclusion of women and*  
18        *members of minority groups as subjects in clinical re-*  
19        *search.’.*

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

21        *Section 492B of the Public Health Service Act, as*  
22        *added by section 131 of this Act, shall not apply with re-*  
23        *spect to projects of clinical research for which initial fund-*  
24        *ing was provided prior to the date of the enactment of this*  
25        *Act. With respect to the inclusion of women and minorities*

1 *as subjects in clinical research conducted or supported by*  
2 *the National Institutes of Health, any policies of the Sec-*  
3 *retary of Health and Human Services regarding such inclu-*  
4 *sion that are in effect on the day before the date of the enact-*  
5 *ment of this Act shall continue to apply to the projects re-*  
6 *ferred to in the preceding sentence.*

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

8 **HEALTH**

9 **SEC. 141. ESTABLISHMENT.**

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

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

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

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

18 *“PART F—RESEARCH ON WOMEN’S HEALTH*

19 **“SEC. 486. OFFICE OF RESEARCH ON WOMEN’S HEALTH.**

20 *“(a) ESTABLISHMENT.—There is established within*  
21 *the Office of the Director of NIH an office to be known as*  
22 *the Office of Research on Women’s Health (in this part re-*  
23 *ferred to as the ‘Office’). The Office shall be headed by a*  
24 *director, who shall be appointed by the Director of NIH.*

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

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

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

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

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

13          “(5) encourage the conduct of such research by  
14 entities receiving funds from the national research in-  
15 stitutes;

16          “(6) recommend an agenda for conducting and  
17 supporting such research;

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

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

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

25          “(c) COORDINATING COMMITTEE.—

1           “(1) In carrying out subsection (b), the Director  
2 of the Office shall establish a committee to be known  
3 as the Coordinating Committee on Research on Women’s Health (hereafter in this subsection referred to as  
4 the ‘Coordinating Committee’).  
5

6           “(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the designees of the Directors).  
7  
8

9           “(3) The Director of the Office shall serve as the chair of the Coordinating Committee.  
10

11           “(4) With respect to research on women’s health, the Coordinating Committee shall assist the Director of the Office in—  
12  
13

14                   “(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;  
15  
16

17                   “(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;  
18  
19  
20

21                   “(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial  
22  
23  
24  
25

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

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

7           “(E) *encouraging the national research in-*  
8           *stitutes to conduct and support such research, in-*  
9           *cluding such clinical trials.*

10          “(d) *ADVISORY COMMITTEE.—*

11           “(1) *In carrying out subsection (b), the Director*  
12           *of the Office shall establish an advisory committee to*  
13           *be known as the Advisory Committee on Research on*  
14           *Women’s Health (hereafter in this subsection referred*  
15           *to as the ‘Advisory Committee’).*

16           “(2) *The Advisory Committee shall be composed*  
17           *of no fewer than 12, and not more than 18 individ-*  
18           *uals, who are not officers or employees of the Federal*  
19           *Government. The Director of the Office shall make ap-*  
20           *pointments to the Advisory Committee from among*  
21           *physicians, practitioners, scientists, and other health*  
22           *professionals, whose clinical practice, research spe-*  
23           *cialization, or professional expertise includes a sig-*  
24           *nificant focus on research on women’s health. A ma-*

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

3                *“(3) The Director of the Office shall serve as the*  
4        *chair of the Advisory Committee.*

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

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

9                                *“(i) research on women’s health;*

10                              *“(ii) research on gender differences in*  
11        *clinical drug trials, including responses to*  
12        *pharmacological drugs;*

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

15                              *“(iv) research on obstetrical and gyne-*  
16        *cological health conditions, diseases, and*  
17        *treatments; and*

18                              *“(v) research on women’s health condi-*  
19        *tions which require a multidisciplinary ap-*  
20        *proach;*

21                              *“(B) report to the Director of the Office on*  
22        *such research;*

23                              *“(C) provide recommendations to such Di-*  
24        *rector regarding activities of the Office (includ-*  
25        *ing recommendations on the development of the*

1           methodologies described in subsection (c)(4)(C)  
2           and recommendations on priorities in carrying  
3           out research described in subparagraph (A)); and

4           “(D) assist in monitoring compliance with  
5           section 492B regarding the inclusion of women  
6           in clinical research.

7           “(5)(A) The Advisory Committee shall prepare a  
8           biennial report describing the activities of the Com-  
9           mittee, including findings made by the Committee re-  
10          garding—

11           “(i) compliance with section 492B;

12           “(ii) the extent of expenditures made for re-  
13          search on women’s health by the agencies of the  
14          National Institutes of Health; and

15           “(iii) the level of funding needed for such  
16          research.

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

20           “(e) REPRESENTATION OF WOMEN AMONG RESEARCH-  
21          ERS.—The Secretary, acting through the Assistant Sec-  
22          retary for Personnel and in collaboration with the Director  
23          of the Office, shall determine the extent to which women  
24          are represented among senior physicians and scientists of  
25          the national research institutes and among physicians and

1 *scientists conducting research with funds provided by such*  
2 *institutes, and as appropriate, carry out activities to in-*  
3 *crease the extent of such representation.*

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

5 *“(1) The term ‘women’s health conditions’, with*  
6 *respect to women of all age, ethnic, and racial groups,*  
7 *means all diseases, disorders, and conditions (includ-*  
8 *ing with respect to mental health)—*

9 *“(A) unique to, more serious, or more prev-*  
10 *alent in women;*

11 *“(B) for which the factors of medical risk or*  
12 *types of medical intervention are different for*  
13 *women, or for which it is unknown whether such*  
14 *factors or types are different for women; or*

15 *“(C) with respect to which there has been*  
16 *insufficient clinical research involving women as*  
17 *subjects or insufficient clinical data on women.*

18 *“(2) The term ‘research on women’s health’*  
19 *means research on women’s health conditions, includ-*  
20 *ing research on preventing such conditions.*

21 **“SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE**

22 **ON RESEARCH ON WOMEN’S HEALTH.**

23 *“(a) DATA SYSTEM.—*

24 *“(1) The Director of NIH, in consultation with*  
25 *the Director of the Office and the Director of the Na-*

1        *tional Library of Medicine, shall establish a data sys-*  
2        *tem for the collection, storage, analysis, retrieval, and*  
3        *dissemination of information regarding research on*  
4        *women’s health that is conducted or supported by the*  
5        *national research institutes. Information from the*  
6        *data system shall be available through information*  
7        *systems available to health care professionals and*  
8        *providers, researchers, and members of the public.*

9            *“(2) The data system established under para-*  
10        *graph (1) shall include a registry of clinical trials of*  
11        *experimental treatments that have been developed for*  
12        *research on women’s health. Such registry shall in-*  
13        *clude information on subject eligibility criteria, sex,*  
14        *age, ethnicity or race, and the location of the trial site*  
15        *or sites. Principal investigators of such clinical trials*  
16        *shall provide this information to the registry within*  
17        *30 days after it is available. Once a trial has been*  
18        *completed, the principal investigator shall provide the*  
19        *registry with information pertaining to the results,*  
20        *including potential toxicities or adverse effects associ-*  
21        *ated with the experimental treatment or treatments*  
22        *evaluated.*

23            *“(b) CLEARINGHOUSE.—The Director of NIH, in con-*  
24        *sultation with the Director of the Office and with the Na-*  
25        *tional Library of Medicine, shall establish, maintain, and*

1 *operate a program to provide information on research and*  
2 *prevention activities of the national research institutes that*  
3 *relate to research on women's health.*

4 ***“SEC. 486B. BIENNIAL REPORT.***

5 *“(a) IN GENERAL.—With respect to research on wom-*  
6 *en's health, the Director of the Office shall, not later than*  
7 *February 1, 1994, and biennially thereafter, prepare a re-*  
8 *port—*

9 *“(1) describing and evaluating the progress made*  
10 *during the preceding 2 fiscal years in research and*  
11 *treatment conducted or supported by the National In-*  
12 *stitutes of Health;*

13 *“(2) describing and analyzing the professional*  
14 *status of women physicians and scientists of such In-*  
15 *stitutes, including the identification of problems and*  
16 *barriers regarding advancements;*

17 *“(3) summarizing and analyzing expenditures*  
18 *made by the agencies of such Institutes (and by such*  
19 *Office) during the preceding 2 fiscal years; and*

20 *“(4) making such recommendations for legisla-*  
21 *tive and administrative initiatives as the Director of*  
22 *the Office determines to be appropriate.*

23 *“(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR*  
24 *OF NIH.—The Director of the Office shall submit each re-*  
25 *port prepared under subsection (a) to the Director of NIH*

1 *for inclusion in the report submitted to the President and*  
2 *the Congress under section 403.”*

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

6 *(1) in paragraph (10), by striking “and” after*  
7 *the semicolon at the end;*

8 *(2) in paragraph (11), by striking the period at*  
9 *the end and inserting “; and”; and*

10 *(3) by inserting after paragraph (11) the follow-*  
11 *ing new paragraph:*

12 *“(12) after consultation with the Director of the*  
13 *Office of Research on Women’s Health, shall ensure*  
14 *that resources of the National Institutes of Health are*  
15 *sufficiently allocated for projects of research on wom-*  
16 *en’s health that are identified under section 486(b).”*

17 ***PART III—OFFICE OF RESEARCH ON MINORITY***  
18 ***HEALTH***

19 ***SEC. 151. ESTABLISHMENT.***

20 *Part A of title IV of the Public Health Service Act*  
21 *(42 U.S.C. 281 et seq.) is amended by adding at the end*  
22 *the following section:*

23 *“OFFICE OF RESEARCH ON MINORITY HEALTH*

24 *“SEC. 404. (a) ESTABLISHMENT.—There is established*  
25 *within the Office of the Director of NIH an office to be*  
26 *known as the Office of Research on Minority Health (in*

1 *this section referred to as the ‘Office’). The Office shall be*  
2 *headed by a director, who shall be appointed by the Director*  
3 *of NIH.*

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

5 *“(1) identify projects of research on minority*  
6 *health that should be conducted or supported by the*  
7 *national research institutes;*

8 *“(2) identify multidisciplinary research relating*  
9 *to research on minority health that should be so con-*  
10 *ducted or supported;*

11 *“(3) promote coordination and collaboration*  
12 *among entities conducting research identified under*  
13 *paragraph (1) or (2);*

14 *“(4) encourage the conduct of such research by*  
15 *entities receiving funds from the national research in-*  
16 *stitutes;*

17 *“(5) recommend an agenda for conducting and*  
18 *supporting such research;*

19 *“(6) promote the sufficient allocation of the re-*  
20 *sources of the national research institutes for conduct-*  
21 *ing and supporting such research; and*

22 *“(7) assist in the administration of section 492B*  
23 *with respect to the inclusion of members of minority*  
24 *groups as subjects in clinical research.”.*

## **Subtitle C—Research Integrity**

### **SEC. 161. ESTABLISHMENT OF OFFICE OF RESEARCH INTEGRITY.**

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

*“OFFICE OF RESEARCH INTEGRITY*

*“SEC. 493. (a) ESTABLISHMENT.*—

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

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

*“(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS CONDITION OF FUNDING FOR RESEARCH.*—The Secretary shall by regulation require that each entity that applies for a grant, contract, or cooperative agreement under this Act

1 *for any project or program that involves the conduct of bio-*  
2 *medical or behavioral research submit in or with its appli-*  
3 *cation for such grant, contract, or cooperative agreement*  
4 *assurances satisfactory to the Secretary that such entity—*

5           “(1) *has established (in accordance with regula-*  
6 *tions which the Secretary shall prescribe) an adminis-*  
7 *trative process to review reports of research mis-*  
8 *conduct in connection with biomedical and behavioral*  
9 *research conducted at or sponsored by such entity;*  
10 *and*

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

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

18           “(1) *response to information provided to the Di-*  
19 *rector respecting research misconduct in connection*  
20 *with projects for which funds have been made avail-*  
21 *able under this Act;*

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

24           “(3) *conduct of investigations, when appropriate;*  
25 *and*

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

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

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

11          (b) *ESTABLISHMENT OF DEFINITION OF RESEARCH*  
12          *MISCONDUCT.*—Not later than 90 days after the date on  
13          which the report required under section 162(d) is submitted  
14          to the Secretary of Health and Human Services, such Sec-  
15          retary shall by regulation establish a definition for the term  
16          “research misconduct” for purposes of section 493 of the  
17          Public Health Service Act, as amended by subsection (a)  
18          of this section.

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

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

1       (b) *DUTIES.*—*The Commission shall develop rec-*  
2 *ommendations for the Secretary of Health and Human*  
3 *Services on the administration of section 493 of the Public*  
4 *Health Service Act (as amended and added by section 161*  
5 *of this Act).*

6       (c) *COMPOSITION.*—*The Commission shall be composed*  
7 *of 12 members to be appointed by the Secretary of Health*  
8 *and Human Services. Not more than 3 members of the Com-*  
9 *mission may be officers or employees of the United States.*  
10 *Of the members of the Commission—*

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

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

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

19           (4) *three shall be individuals who are not de-*  
20 *scribed in paragraphs (1), (2), or (3), at least one of*  
21 *whom shall be an attorney and at least one of whom*  
22 *shall be an ethicist.*

23       (d) *COMPENSATION.*—*Members of the Commission*  
24 *may not receive compensation for service on the Commis-*  
25 *sion. Members may be reimbursed for travel, subsistence,*

1 *and other necessary expenses incurred in carrying out the*  
2 *duties of the Commission.*

3       (e) *REPORT.*—*Not later than 120 days after the date*  
4 *on which the Commission is established under subsection*  
5 *(a), the Commission shall prepare and submit to the Sec-*  
6 *retary of Health and Human Services, the Committee on*  
7 *Energy and Commerce of the House of Representatives, and*  
8 *the Committee on Labor and Human Resources of the Sen-*  
9 *ate, a report containing the recommendations developed*  
10 *under subsection (b).*

11 ***SEC. 163. PROTECTION OF WHISTLEBLOWERS.***

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

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

16               “(1) *IN GENERAL.*—*In the case of any entity re-*  
17 *quired to establish administrative processes under*  
18 *subsection (b), the Secretary shall by regulation estab-*  
19 *lish standards for preventing, and for responding to*  
20 *the occurrence of retaliation by such entity, its offi-*  
21 *cial or agents, against an employee in the terms and*  
22 *conditions of employment in response to the employee*  
23 *having in good faith—*

24                       “(A) *made an allegation that the entity, its*  
25 *officials or agents, has engaged in or failed to*

1           *adequately respond to an allegation of research*  
2           *misconduct; or*

3           *“(B) cooperated with an investigation of*  
4           *such an allegation.*

5           *“(2) MONITORING BY SECRETARY.—The Sec-*  
6           *retary shall establish by regulation procedures for the*  
7           *Director to monitor the implementation of the stand-*  
8           *ards established by an entity under paragraph (1) for*  
9           *the purpose of determining whether the procedures*  
10          *have been established, and are being utilized, in ac-*  
11          *cordance with the standards established under such*  
12          *paragraph.*

13          *“(3) NONCOMPLIANCE.—The Secretary shall by*  
14          *regulation establish remedies for noncompliance by an*  
15          *entity, its officials or agents, which has engaged in re-*  
16          *taliation in violation of the standards established*  
17          *under paragraph (1). Such remedies may include ter-*  
18          *mination of funding provided by the Secretary for*  
19          *such project or recovery of funding being provided by*  
20          *the Secretary for such project, or other actions as ap-*  
21          *propriate.*

22          *“(4) FINAL RULE FOR REGULATIONS.—The Sec-*  
23          *retary shall issue a final rule for the regulations re-*  
24          *quired in paragraph (1) not later than 180 days after*

1       *the date of the enactment of the National Institutes of*  
2       *Health Revitalization Act of 1993.*

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

10               “(A) *will maintain the procedures described*  
11       *in the regulations; and*

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

14       ***SEC. 164. REQUIREMENT OF REGULATIONS REGARDING***  
15               ***PROTECTION AGAINST FINANCIAL CON-***  
16               ***FLICTS OF INTEREST IN CERTAIN PROJECTS***  
17               ***OF RESEARCH.***

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

21       “*PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST*  
22               *IN CERTAIN PROJECTS OF RESEARCH*

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

24               “(1) *IN GENERAL.*—*The Secretary shall define by*  
25       *regulation, the specific circumstances that constitute*  
26       *the existence of a financial interest in a project on the*

1 *part of an entity or individual that will, or may be*  
2 *reasonably expected to, create a bias in favor of ob-*  
3 *taining results in such project that are consistent*  
4 *with such financial interest. Such definition shall*  
5 *apply uniformly to each entity or individual conduct-*  
6 *ing a research project under this Act. In the case of*  
7 *any entity or individual receiving assistance from the*  
8 *Secretary for a project of research described in para-*  
9 *graph (2), the Secretary shall by regulation establish*  
10 *standards for responding to, including managing, re-*  
11 *ducing, or eliminating, the existence of such a finan-*  
12 *cial interest. The entity may adopt individualized*  
13 *procedures for implementing the standards.*

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

20 *“(3) IDENTIFYING AND REPORTING TO THE DI-*  
21 *RECTOR.—The Secretary shall ensure that the stand-*  
22 *ards established under paragraph (1) specify that as*  
23 *a condition of receiving assistance from the Secretary*  
24 *for the project involved, an entity described in such*  
25 *subsection is required—*

1           “(A) to have in effect at the time the entity  
2           applies for the assistance and throughout the pe-  
3           riod during which the assistance is received, a  
4           process for identifying such financial interests as  
5           defined in paragraph (1) that exist regarding the  
6           project; and

7           “(B) to report to the Director such financial  
8           interest as defined in paragraph (1) identified  
9           by the entity and how any such financial inter-  
10          est identified by the entity will be managed or  
11          eliminated such that the project in question will  
12          be protected from bias that may stem from such  
13          financial interest.

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

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

22                 “(A) shall require that, as a condition of re-  
23                 ceiving assistance, the entity disclose the exist-  
24                 ence of a financial interest as defined in para-

1           *graph (1) in each public presentation of the re-*  
2           *sults of such project; and*

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

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

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

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

12          *“(b) FINAL RULE FOR REGULATIONS.—The Secretary*  
13          *shall issue a final rule for the regulations required in sub-*  
14          *section (a) not later than 180 days after the date of the*  
15          *enactment of the National Institutes of Health Revitaliza-*  
16          *tion Act of 1993.”.*

17          **SEC. 165. EFFECTIVE DATES.**

18          *(a) IN GENERAL.—The amendments made by this sub-*  
19          *title shall become effective on the date that occurs 180 days*  
20          *after the date on which the final rule required under section*  
21          *493(f)(4) of the Public Health Service Act, as amended by*  
22          *sections 161 and 163, is published in the Federal Register.*

23          *(b) AGREEMENTS AS A CONDITION OF FUNDING.—The*  
24          *requirements of subsection (f)(5) of section 493 of the Public*  
25          *Health Service Act, as amended by sections 161 and 163,*

1 *with respect to agreements as a condition of funding shall*  
2 *not be effective in the case of projects of research for which*  
3 *initial funding under the Public Health Service Act was*  
4 *provided prior to the effective date described in subsection*  
5 *(a).*

6 **TITLE II—NATIONAL INSTITUTES**  
7 **OF HEALTH IN GENERAL**

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

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

15 *“(1) annually review the efficacy of existing poli-*  
16 *cies and techniques used by the national research in-*  
17 *stitutes to disseminate the results of disease preven-*  
18 *tion and behavioral research programs;*

19 *“(2) recommend, coordinate, and oversee the*  
20 *modification or reconstruction of such policies and*  
21 *techniques to ensure maximum dissemination, using*  
22 *advanced technologies to the maximum extent prac-*  
23 *ticable, of research results to such entities; and*

24 *“(3) annually prepare and submit to the Direc-*  
25 *tor of NIH a report concerning the prevention and*

1       *dissemination activities undertaken by the Associate*  
2       *Director, including—*

3               “(A) a summary of the Associate Director’s  
4               review of existing dissemination policies and  
5               techniques together with a detailed statement  
6               concerning any modification or restructuring, or  
7               recommendations for modification or restructur-  
8               ing, of such policies and techniques; and

9               “(B) a detailed statement of the expendi-  
10              tures made for the prevention and dissemination  
11              activities reported on and the personnel used in  
12              connection with such activities.”.

13       **SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARD-**  
14                               **ING CERTAIN STATES AND RESEARCHERS.**

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

18               “(g)(1)(A) In the case of entities described in subpara-  
19              graph (B), the Director of NIH, acting through the Director  
20              of the National Center for Research Resources, shall estab-  
21              lish a program to enhance the competitiveness of such enti-  
22              ties in obtaining funds from the national research institutes  
23              for conducting biomedical and behavioral research.

24               “(B) The entities referred to in subparagraph (A) are  
25              entities that conduct biomedical and behavioral research

1 *and are located in a State in which the aggregate success*  
2 *rate for applications to the national research institutes for*  
3 *assistance for such research by the entities in the State has*  
4 *historically constituted a low success rate of obtaining such*  
5 *funds, relative to such aggregate rate for such entities in*  
6 *other States.*

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

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

15               “(ii) *assist the entities in developing a plan for*  
16 *biomedical or behavioral research proposals; and*

17               “(iii) *assist the entities in implementing such*  
18 *plan.*

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

1 **SEC. 203. ESTABLISHMENT OF OFFICE OF BEHAVIORAL RE-**  
2 **SEARCH.**

3 *Part A of title IV of the Public Health Service Act,*  
4 *as amended by section 151 of this Act, is amended by add-*  
5 *ing at the end the following new section:*

6 *“OFFICE OF BEHAVIORAL RESEARCH*

7 *“SEC. 404A. (a) There is established within the Office*  
8 *of the Director of NIH an office to be known as the Office*  
9 *of Behavioral Research (in this section referred to as the*  
10 *‘Office’). The Office shall be headed by a director, who shall*  
11 *be appointed by the Director of NIH.*

12 *“(b)(1) With respect to research on the relationship be-*  
13 *tween human behavior and the development, treatment, and*  
14 *prevention of medical conditions, the Director of the Office*  
15 *shall coordinate research conducted or supported by the*  
16 *agencies of the National Institutes of Health.*

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

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

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

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

1                   “CHILDREN’S VACCINE INITIATIVE

2           “SEC. 404B. (a) DEVELOPMENT OF NEW VACCINES.—

3   *The Secretary, in consultation with the Director of the Na-*  
4   *tional Vaccine Program under title XXI and acting through*  
5   *the Directors of the National Institute for Allergy and Infec-*  
6   *tious Diseases, the National Institute for Child Health and*  
7   *Human Development, the National Institute for Aging, and*  
8   *other public and private programs, shall carry out activi-*  
9   *ties, which shall be consistent with the global Children’s*  
10   *Vaccine Initiative, to develop affordable new and improved*  
11   *vaccines to be used in the United States and in the develop-*  
12   *ing world that will increase the efficacy and efficiency of*  
13   *the prevention of infectious diseases. In carrying out such*  
14   *activities, the Secretary shall, to the extent practicable, de-*  
15   *velop and make available vaccines that require fewer con-*  
16   *tacts to deliver, that can be given early in life, that provide*  
17   *long lasting protection, that obviate refrigeration, needles*  
18   *and syringes, and that protect against a larger number of*  
19   *diseases.*

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

1       “(c) *AUTHORIZATION OF APPROPRIATIONS.*—In addi-  
2       tion to any other amounts authorized to be appropriated  
3       for activities of the type described in this section, there are  
4       authorized to be appropriated to carry out this section  
5       \$50,000,000 for fiscal year 1994, and such sums as may  
6       be necessary for each of the fiscal years 1995 and 1996.”.

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

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

11               “*PLAN FOR USE OF ANIMALS IN RESEARCH*

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

15                       “(1) for the National Institutes of Health to con-  
16      duct or support research into—

17                               “(A) methods of biomedical research and ex-  
18                               perimentation that do not require the use of ani-  
19                               mals;

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

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

1           “(D) *methods of such research and experi-*  
2           *mentation that involve the use of marine life*  
3           *(other than marine mammals);*

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

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

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

11          “(b) *Not later than October 1, 1993, the Director of*  
12          *NIH shall submit to the Committee on Energy and Com-*  
13          *merce of the House of Representatives, and to the Committee*  
14          *on Labor and Human Resources of the Senate, the plan*  
15          *required in subsection (a) and shall begin implementation*  
16          *of the plan.*

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

23          “(d) *The Director of NIH shall take such actions as*  
24          *may be appropriate to convey to scientists and others who*  
25          *use animals in biomedical or behavioral research or experi-*

1 *mentation information respecting the methods found to be*  
2 *valid and reliable under subsection (a)(2).*

3       “(e)(1) *The Director of NIH shall establish within the*  
4 *National Institutes of Health a committee to be known as*  
5 *the Interagency Coordinating Committee on the Use of Ani-*  
6 *mals in Research (hereafter in this subsection referred to*  
7 *as the ‘Committee’).*

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

11       “(3) *The Committee shall be composed of—*

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

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

22       (b) *CONFORMING AMENDMENT.—Section 4 of the*  
23 *Health Research Extension Act of 1985 (Public Law 99–*  
24 *158; 99 Stat. 880) is repealed.*

1 **SEC. 206. INCREASED PARTICIPATION OF WOMEN AND DIS-**  
2 **ADVANTAGED INDIVIDUALS IN FIELDS OF**  
3 **BIOMEDICAL AND BEHAVIORAL RESEARCH.**

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

7 *“(h) The Secretary, acting through the Director of NIH*  
8 *and the Directors of the agencies of the National Institutes*  
9 *of Health, may conduct and support programs for research,*  
10 *research training, recruitment, and other activities to pro-*  
11 *vide for an increase in the number of women and individ-*  
12 *uals from disadvantaged backgrounds in the fields of bio-*  
13 *medical and behavioral research.”.*

14 **SEC. 207. REQUIREMENTS REGARDING SURVEYS OF SEXUAL**  
15 **BEHAVIOR.**

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

19 *“REQUIREMENTS REGARDING SURVEYS OF SEXUAL*  
20 *BEHAVIOR*

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

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

4           “(2) the Secretary, in accordance with section  
5 492A, makes a determination that the information ex-  
6 pected to be obtained through the survey will assist—

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

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

13 **SEC. 208. DISCRETIONARY FUND OF DIRECTOR OF NA-**  
14 **TIONAL INSTITUTES OF HEALTH.**

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

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

24                   “(A) providing for research on matters that have  
25 not received significant funding relative to other mat-

1        *ters, responding to new issues and scientific emer-*  
2        *gencies, and acting on research opportunities of high*  
3        *priority;*

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

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

9        *“(2) Not later than February 10 of each fiscal year,*  
10       *the Secretary shall submit to the Committee on Energy and*  
11       *Commerce of the House of Representatives, and to the Com-*  
12       *mittee on Labor and Human Resources of the Senate, a*  
13       *report describing the activities undertaken and expenditures*  
14       *made under this section during the preceding fiscal year.*  
15       *The report may contain such comments of the Secretary re-*  
16       *garding this section as the Secretary determines to be ap-*  
17       *propriate.*

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

22       **SEC. 209. MISCELLANEOUS PROVISIONS.**

23        *(a) TERM OF OFFICE FOR MEMBERS OF ADVISORY*  
24       *COUNCILS.—Section 406(c) of the Public Health Service*  
25       *Act (42 U.S.C. 284a(c)) is amended in the second sentence*

1 *by striking “until a successor has taken office” and insert-*  
2 *ing the following: “for 180 days after the date of such expi-*  
3 *ration”.*

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

6 *(1) in paragraph (3), by striking “and” at the*  
7 *end;*

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

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

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

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

23 *“(j)(1) The Director of NIH may establish a program*  
24 *to provide day care services for the employees of the Na-*  
25 *tional Institutes of Health similar to those services provided*

1 *by other Federal agencies (including the availability of day*  
 2 *care service on a 24-hour-a-day basis).*

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

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

9 **TITLE III—GENERAL PROVI-**  
 10 **SIONS RESPECTING NA-**  
 11 **TIONAL RESEARCH INSTI-**  
 12 **TUTES**

13 **SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS**  
 14 **OF NATIONAL RESEARCH INSTITUTES.**

15 (a) *ESTABLISHMENT OF GENERAL AUTHORITY RE-*  
 16 *GARDING DIRECT FUNDING.—*

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

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

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

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

1           “(C) shall receive from the President and the Of-  
2           fice of Management and Budget directly all funds ap-  
3           propriated by the Congress for obligation and expend-  
4           iture by the Institute.”.

5           (2)       CONFORMING        AMENDMENT.—Section  
6           413(b)(9) of the Public Health Service Act (42 U.S.C.  
7           285a–2(b)(9)) is amended—

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

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

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

14               (1) by amending paragraph (3) to read as fol-  
15          lows:

16               “(3) may, in consultation with the advisory  
17          council for the Institute and with the approval of the  
18          Director of NIH—

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

22                       “(B) appoint the members of peer review  
23          groups established under subparagraph (A);  
24          and”; and

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

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

6           **SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS,**  
7                           **PAGET’S DISEASE, AND RELATED BONE DIS-**  
8                           **ORDERS.**

9           Part B of title IV of the Public Health Service Act  
10          (42 U.S.C. 284 et seq.), as amended by section 121(b) of  
11          Public Law 102–321 (106 Stat. 358), is amended by adding  
12          at the end the following new section:

13          “RESEARCH ON OSTEOPOROSIS, PAGET’S DISEASE, AND  
14                           RELATED BONE DISORDERS

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

22          “(b) COORDINATION.—The Directors referred to in sub-  
23          section (a) shall jointly coordinate the programs referred  
24          to in such subsection and consult with the Arthritis and  
25          Musculoskeletal Diseases Interagency Coordinating Com-  
26          mittee and the Interagency Task Force on Aging Research.

1       “(c) *INFORMATION CLEARINGHOUSE.*—

2               “(1) *IN GENERAL.*—In order to assist in carry-  
3       ing out the purpose described in subsection (a), the  
4       Director of NIH shall provide for the establishment of  
5       an information clearinghouse on osteoporosis and re-  
6       lated bone disorders to facilitate and enhance knowl-  
7       edge and understanding on the part of health profes-  
8       sionals, patients, and the public through the effective  
9       dissemination of information.

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

17              “(d) *AUTHORIZATION OF APPROPRIATIONS.*—For the  
18       purpose of carrying out this section, there are authorized  
19       to be appropriated \$40,000,000 for fiscal year 1994, and  
20       such sums as may be necessary for each of the fiscal years  
21       1995 and 1996.”.

22       **SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM**  
23                               **FOR TRAUMA RESEARCH.**

24              “(a) *IN GENERAL.*—Title XII of the Public Health Serv-  
25       ice Act (42 U.S.C. 300d et seq.), as amended by title VI



1           “(2) *SUBMISSION TO CONGRESS.*—Not later than  
2           *June 1, 1993, the Director shall submit the plan re-*  
3           *quired in paragraph (1) to the Committee on Energy*  
4           *and Commerce of the House of Representatives, and*  
5           *to the Committee on Labor and Human Resources of*  
6           *the Senate, together with an estimate of the funds*  
7           *needed for each of the fiscal years 1994 through 1996*  
8           *to implement the plan.*

9           “(c) *PARTICIPATING AGENCIES; COORDINATION AND*  
10          *COLLABORATION.*—The Director—

11           “(1) *shall provide for the conduct of activities*  
12           *under the Program by the Directors of the agencies of*  
13           *the National Institutes of Health involved in research*  
14           *with respect to trauma;*

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

17           “(3) *shall, as appropriate, provide for collabora-*  
18           *tion among such agencies in carrying out such activi-*  
19           *ties.*

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

22           “(1) *studies with respect to all phases of trauma*  
23           *care, including prehospital, resuscitation, surgical*  
24           *intervention, critical care, infection control, wound*

1       *healing, nutritional care and support, and medical*  
2       *rehabilitation care;*

3               “(2) *basic and clinical research regarding the re-*  
4       *sponse of the body to trauma and the acute treatment*  
5       *and medical rehabilitation of individuals who are the*  
6       *victims of trauma; and*

7               “(3) *basic and clinical research regarding trau-*  
8       *ma care for pediatric and geriatric patients.*

9               “(e) *MECHANISMS OF SUPPORT.—In carrying out the*  
10       *Program, the Director, acting through the Directors of the*  
11       *agencies referred to in subsection (c)(1), may make grants*  
12       *to public and nonprofit entities, including designated trau-*  
13       *ma centers.*

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

18              “(g) *COORDINATING COMMITTEE.—*

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

23                      “(2) *DUTIES.—The Coordinating Committee*  
24       *shall make recommendations regarding—*

1           “(A) the activities of the Program to be car-  
2           ried out by each of the agencies represented on  
3           the Committee and the amount of funds needed  
4           by each of the agencies for such activities; and

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

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

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

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

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

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

23          (b) CONFORMING AMENDMENT.—Section 402 of the  
24          Public Health Service Act, as amended by section 209(c)

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

3       “(k) *The Director of NIH shall carry out the program*  
4 *established in part E of title XII (relating to interagency*  
5 *research on trauma).*”.

6       ***TITLE IV—NATIONAL CANCER***  
7                               ***INSTITUTE***

8       ***SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVI-***  
9                               ***TIES REGARDING BREAST CANCER.***

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

13                               “*BREAST AND GYNECOLOGICAL CANCERS*

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

20       “*(b) COORDINATION WITH OTHER INSTITUTES.—The*  
21 *Director of the Institute shall coordinate the activities of*  
22 *the Director under subsection (a) with similar activities*  
23 *conducted by other national research institutes and agencies*  
24 *of the National Institutes of Health to the extent that such*  
25 *Institutes and agencies have responsibilities that are related*

1 *to breast cancer and other cancers of the reproductive sys-*  
2 *tem of women.*

3 *“(c) PROGRAMS FOR BREAST CANCER.—*

4 *“(1) IN GENERAL.—In carrying out subsection*  
5 *(a), the Director of the Institute shall conduct or sup-*  
6 *port research to expand the understanding of the*  
7 *cause of, and to find a cure for, breast cancer. Activi-*  
8 *ties under such subsection shall provide for an expan-*  
9 *sion and intensification of the conduct and support*  
10 *of—*

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

13 *“(B) clinical research and related activities*  
14 *concerning the causes, prevention, detection and*  
15 *treatment of breast cancer;*

16 *“(C) control programs with respect to breast*  
17 *cancer in accordance with section 412, including*  
18 *community-based programs designed to assist*  
19 *women who are members of medically under-*  
20 *served populations, low-income populations, or*  
21 *minority groups;*

22 *“(D) information and education programs*  
23 *with respect to breast cancer in accordance with*  
24 *section 413; and*

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

10          *Not less than six centers shall be operated under sub-*  
11          *paragraph (E). Activities of such centers should in-*  
12          *clude supporting new and innovative research and*  
13          *training programs for new researchers. Such centers*  
14          *shall give priority to expediting the transfer of re-*  
15          *search advances to clinical applications.*

16                 “(2) IMPLEMENTATION OF PLAN FOR PRO-  
17                 GRAMS.—

18                 “(A) The Director of the Institute shall en-  
19                 sure that the research programs described in  
20                 paragraph (1) are implemented in accordance  
21                 with a plan for the programs. Such plan shall  
22                 include comments and recommendations that the  
23                 Director of the Institute considers appropriate,  
24                 with due consideration provided to the profes-  
25                 sional judgment needs of the Institute as ex-

1           *pressed in the annual budget estimate prepared*  
2           *in accordance with section 413(9). The Director*  
3           *of the Institute, in consultation with the Na-*  
4           *tional Cancer Advisory Board, shall periodically*  
5           *review and revise such plan.*

6           “(B) *Not later than May 1, 1993, the Direc-*  
7           *tor of the Institute shall submit a copy of the*  
8           *plan to the President’s Cancer Panel, the Sec-*  
9           *retary and the Director of NIH.*

10           “(C) *The Director of the Institute shall sub-*  
11           *mit any revisions of the plan to the President’s*  
12           *Cancer Panel, the Secretary, and the Director of*  
13           *NIH.*

14           “(D) *The Secretary shall provide a copy of*  
15           *the plan submitted under subparagraph (A), and*  
16           *any revisions submitted under subparagraph*  
17           *(C), to the Committee on Energy and Commerce*  
18           *of the House of Representatives and the Commit-*  
19           *tee on Labor and Human Resources of the Sen-*  
20           *ate.*

21           “(d) *OTHER CANCERS.—In carrying out subsection*  
22           *(a), the Director of the Institute shall conduct or support*  
23           *research on ovarian cancer and other cancers of the repro-*  
24           *ductive system of women. Activities under such subsection*  
25           *shall provide for the conduct and support of—*

1           “(1) *basic research concerning the etiology and*  
2           *causes of ovarian cancer and other cancers of the re-*  
3           *productive system of women;*

4           “(2) *clinical research and related activities into*  
5           *the causes, prevention, detection and treatment of*  
6           *ovarian cancer and other cancers of the reproductive*  
7           *system of women;*

8           “(3) *control programs with respect to ovarian*  
9           *cancer and other cancers of the reproductive system of*  
10          *women in accordance with section 412;*

11          “(4) *information and education programs with*  
12          *respect to ovarian cancer and other cancers of the re-*  
13          *productive system of women in accordance with sec-*  
14          *tion 413; and*

15          “(5) *research and demonstration centers with re-*  
16          *spect to ovarian cancer and cancers of the reproduc-*  
17          *tive system in accordance with section 414.*

18          “(e) *REPORT.—The Director of the Institute shall pre-*  
19          *pare, for inclusion in the biennial report submitted under*  
20          *section 407, a report that describes the activities of the Na-*  
21          *tional Cancer Institute under the research programs re-*  
22          *ferred to in subsection (a), that shall include—*

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



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

8       “(c) *PROGRAMS.*—

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

16                   “(A) *basic research concerning the etiology*  
17 *and causes of prostate cancer;*

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

21                   “(C) *prevention and control and early de-*  
22 *tection programs with respect to prostate cancer*  
23 *in accordance with section 412, particularly as*  
24 *it relates to intensifying research on the role of*

1           *prostate specific antigen for the screening and*  
2           *early detection of prostate cancer;*

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

8           “(E) *control programs with respect to pros-*  
9           *tate cancer in accordance with section 412;*

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

13          “(G) *research and demonstration centers*  
14          *with respect to prostate cancer in accordance*  
15          *with section 414, including the development and*  
16          *operation of centers for prostate cancer research*  
17          *to bring together basic and clinical, biomedical*  
18          *and behavioral scientists to conduct basic, clini-*  
19          *cal, epidemiological, psychosocial, prevention*  
20          *and control, treatment, research, and related ac-*  
21          *tivities on prostate cancer.*

22          *Not less than six centers shall be operated under sub-*  
23          *paragraph (G). Activities of such centers should in-*  
24          *clude supporting new and innovative research and*  
25          *training programs for new researchers. Such centers*

1     *shall give priority to expediting the transfer of re-*  
2     *search advances to clinical applications.*

3             “(2) *IMPLEMENTATION OF PLAN FOR PRO-*  
4     *GRAMS.—*

5             “(A) *The Director of the Institute shall en-*  
6     *sure that the research programs described in*  
7     *paragraph (1) are implemented in accordance*  
8     *with a plan for the programs. Such plan shall*  
9     *include comments and recommendations that the*  
10    *Director of the Institute considers appropriate,*  
11    *with due consideration provided to the profes-*  
12    *sional judgment needs of the Institute as ex-*  
13    *pressed in the annual budget estimate prepared*  
14    *in accordance with section 413(9). The Director*  
15    *of the Institute, in consultation with the Na-*  
16    *tional Cancer Advisory Board, shall periodically*  
17    *review and revise such plan.*

18            “(B) *Not later than May 1, 1993, the Direc-*  
19    *tor of the Institute shall submit a copy of the*  
20    *plan to the President’s Cancer Panel, the Sec-*  
21    *retary and the Director of NIH.*

22            “(C) *The Director of the Institute shall sub-*  
23    *mit any revisions of the plan to the President’s*  
24    *Cancer Panel, the Secretary, and the Director of*  
25    *NIH.*

1           “(D) *The Secretary shall provide a copy of*  
2           *the plan submitted under subparagraph (A), and*  
3           *any revisions submitted under subparagraph*  
4           *(C), to the Committee on Energy and Commerce*  
5           *of the House of Representatives and the Commit-*  
6           *tee on Labor and Human Resources of the Sen-*  
7           *ate.”.*

8   **SEC. 403. AUTHORIZATION OF APPROPRIATIONS.**

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

13                   “*AUTHORIZATION OF APPROPRIATIONS*

14           “*SEC. 417B. (a) ACTIVITIES GENERALLY.—For the*  
15          *purpose of carrying out this subpart, there are authorized*  
16          *to be appropriated \$3,200,000,000 for fiscal year 1994, and*  
17          *such sums as may be necessary for each of the fiscal years*  
18          *1995 and 1996.*

19           “(b) *BREAST CANCER AND GYNECOLOGICAL CAN-*  
20          *CERS.—*

21                   “(1) *BREAST CANCER.—*

22                           “(A) *For the purpose of carrying out sub-*  
23                           *paragraph (A) of section 417(c)(1), there are au-*  
24                           *thorized to be appropriated \$225,000,000 for fis-*  
25                           *cal year 1994, and such sums as may be nec-*  
26                           *essary for each of the fiscal years 1995 and 1996.*

1           *Such authorizations of appropriations are in ad-*  
2           *dition to the authorizations of appropriations es-*  
3           *tablished in subsection (a) with respect to such*  
4           *purpose.*

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

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

22           “(c) *PROSTATE CANCER.—For the purpose of carrying*  
23           *out section 417A, there are authorized to be appropriated*  
24           *\$72,000,000 for fiscal year 1994, and such sums as may*  
25           *be necessary for each of the fiscal years 1995 and 1996.*

1 *Such authorizations of appropriations are in addition to*  
2 *the authorizations of appropriations established in sub-*  
3 *section (a) with respect to such purpose.*

4 *“(d) ALLOCATION REGARDING CANCER CONTROL.—*

5 *“(1) IN GENERAL.—Of the amounts appro-*  
6 *priated for the National Cancer Institute for a fiscal*  
7 *year, the Director of the Institute shall make available*  
8 *not less than the applicable percentage specified in*  
9 *paragraph (2) for carrying out the cancer control ac-*  
10 *tivities authorized in section 412 and for which budg-*  
11 *et estimates are made under section 413(b)(9) for the*  
12 *fiscal year.*

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

15 *“(A) 7 percent, in the case of fiscal year*  
16 *1994;*

17 *“(B) 9 percent, in the case of fiscal year*  
18 *1995; and*

19 *“(C) 10 percent, in the case of fiscal year*  
20 *1996 and each subsequent fiscal year.”.*

21 *(b) CONFORMING AMENDMENTS.—*

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

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

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

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

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

8                     “CERTAIN USES OF FUNDS”.

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

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

15          ***SEC. 501. EDUCATION AND TRAINING.***

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

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

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

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

24                     “(5) shall, in consultation with the advisory  
25                     council for the Institute, conduct appropriate intra-  
26                     mural training and education programs, including

1 continuing education and laboratory and clinical re-  
2 search training programs.”.

3 **SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CARDIO-**  
4 **VASCULAR DISEASES.**

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

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

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

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

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

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

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

24 “NATIONAL CENTER ON SLEEP DISORDERS

25 “SEC. 424. (a) Not later than 1 year after the date  
26 of the enactment of the National Institutes of Health Revi-

1 *talization Act of 1993, the Director of the Institute shall*  
2 *establish the National Center on Sleep Disorders (in this*  
3 *section referred to as the 'Center'). The Center shall be head-*  
4 *ed by a director, who shall be appointed by the Director*  
5 *of the Institute.*

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

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

15 **SEC. 504. AUTHORIZATION OF APPROPRIATIONS.**

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

19               “AUTHORIZATION OF APPROPRIATIONS

20       “SEC. 425. *For the purpose of carrying out this sub-*  
21 *part, there are authorized to be appropriated*  
22 *\$1,500,000,000 for fiscal year 1994, and such sums as may*  
23 *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           *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       **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 igned 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, and the National Institute on Mental*  
13 *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                                   **FICE.**

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   mune 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).”.

1           **Subtitle B—Certain Programs**

2   **SEC. 1811. REVISION AND EXTENSION OF CERTAIN PRO-**  
3                           **GRAMS.**

4           *Title XXIII of the Public Health Service Act (42*  
5   *U.S.C. 300cc et seq.) is amended—*

6                   (1) *in section 2304(c)(1)—*

7                           (A) *in the matter preceding subparagraph*  
8                           (A), *by inserting after “Director of such Insti-*  
9                           *tute” the following: “(and may provide advice to*  
10                           *the Directors of other agencies of the National*  
11                           *Institutes of Health, as appropriate)”;* and

12                           (B) *in subparagraph (A), by inserting be-*  
13                           *fore the semicolon the following: “, including rec-*  
14                           *ommendations on the projects of research with*  
15                           *respect to diagnosing immune deficiency and*  
16                           *with respect to predicting, diagnosing, prevent-*  
17                           *ing, and treating opportunistic cancers and in-*  
18                           *fectious diseases”;*

19                           (2) *in section 2311(a)(1), by inserting before the*  
20                           *semicolon the following: “, including evaluations of*  
21                           *methods of diagnosing immune deficiency and evalua-*  
22                           *tions of methods of predicting, diagnosing, preventing,*  
23                           *and treating opportunistic cancers and infectious*  
24                           *diseases”;*

25                           (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.*

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 **TITLE XXI—EFFECTIVE DATES**15 **SEC. 2101. EFFECTIVE DATES.**

16 *Subject to section 165, this Act and the amendments*  
 17 *made by this Act take effect upon the date of the enactment*  
 18 *of this Act.*

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