

103D CONGRESS  
1ST SESSION

# S. 1

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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## IN THE SENATE OF THE UNITED STATES

JANUARY 21 (legislative day, JANUARY 5), 1993

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

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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  
5 “National Institutes of Health Revitalization Act of  
6 1993”.

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

Sec. 1. Short title; table of contents.

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

Subtitle A—Research Freedom

PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL  
RESEARCH

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

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

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

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

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

PART II—OFFICE OF RESEARCH ON WOMEN'S HEALTH

Sec. 141. Establishment.

PART III—OFFICE OF RESEARCH ON MINORITY HEALTH

Sec. 151. Establishment.

Subtitle C—Scientific Integrity

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

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

- Sec. 201. Health promotion research dissemination.
- Sec. 202. Programs for increased support regarding certain States and researchers.
- Sec. 203. Children's vaccine initiative.
- Sec. 204. Plan for use of animals in research.
- Sec. 205. Increased participation of women and members of underrepresented minorities in fields of biomedical and behavioral research.

- Sec. 206. Requirements regarding surveys of sexual behavior.
- Sec. 207. Discretionary fund of Director of National Institutes of Health.
- Sec. 208. Miscellaneous provisions.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL  
RESEARCH INSTITUTES

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

TITLE IV—NATIONAL CANCER INSTITUTE

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

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

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

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

- Sec. 601. Provisions regarding nutritional disorders.

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

- Sec. 701. Juvenile arthritis.

TITLE VIII—NATIONAL INSTITUTE ON AGING

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

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS  
DISEASES

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

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN  
DEVELOPMENT

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

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

Subtitle B—Program Regarding Obstetrics and Gynecology

Sec. 1011. Establishment of program.

Subtitle C—Child Health Research Centers

Sec. 1021. Establishment of centers.

Subtitle D—Study Regarding Adolescent Health

Sec. 1031. Prospective longitudinal study.

TITLE XI—NATIONAL EYE INSTITUTE

Sec. 1101. Clinical research on diabetes eye care.

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL  
DISORDERS AND STROKE

Sec. 1201. Research on multiple sclerosis.

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH  
SCIENCES

Sec. 1301. Applied Toxicological Research and Testing Program.

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

Sec. 1401. Additional authorities.

Sec. 1402. Authorization of appropriations.

Subtitle B—Financial Assistance

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

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

Sec. 1421. Establishment of Center.

Sec. 1422. Conforming provisions.

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF  
HEALTH

Subtitle A—Division of Research Resources

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

Sec. 1502. Biomedical and behavioral research facilities.

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

Subtitle B—National Center for Nursing Research

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

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

Subtitle C—National Center for Human Genome Research

Sec. 1521. Purpose of Center.

#### TITLE XVI—AWARDS AND TRAINING

##### Subtitle A—National Research Service Awards

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

Sec. 1602. Service payback requirements.

##### Subtitle B—Acquired Immune Deficiency Syndrome

Sec. 1611. Loan repayment program.

##### Subtitle C—Loan Repayment for Research Generally

Sec. 1621. Establishment of program.

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

Sec. 1631. Establishment of programs.

Sec. 1632. Funding.

##### Subtitle E—Funding for Awards and Training Generally

Sec. 1641. Authorization of appropriations.

#### TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

Sec. 1701. Establishment of Foundation.

#### TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

Sec. 1801. Revision and extension of various programs.

#### TITLE XIX—STUDIES

Sec. 1901. Acquired immune deficiency syndrome.

Sec. 1902. Malnutrition in the elderly.

Sec. 1903. Research activities on chronic fatigue syndrome.

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

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

Sec. 1906. Procurement.

Sec. 1907. Report concerning leading causes of death.

Sec. 1908. Relationship between the consumption of legal and illegal drugs.

#### TITLE XX—MISCELLANEOUS PROVISIONS

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

Sec. 2002. Technical corrections.

Sec. 2003. Biennial report on carcinogens.

Sec. 2004. Master plan for physical infrastructure for research.

Sec. 2005. Transfer of provisions of title xxvii.

Sec. 2006. Certain authorization of appropriations.

Sec. 2007. Prohibition against SHARP adult sex survey and the American teenage sex survey.

Sec. 2008. Support for bioengineering research.

TITLE XXI—EFFECTIVE DATES

Sec. 2101. Effective dates.

1 **TITLE I—GENERAL PROVISIONS**

2 **REGARDING TITLE IV OF PUB-**

3 **LIC HEALTH SERVICE ACT**

4 **Subtitle A—Research Freedom**

5 **PART I—REVIEW OF PROPOSALS FOR**

6 **BIOMEDICAL AND BEHAVIORAL RESEARCH**

7 **SEC. 101. ESTABLISHMENT OF CERTAIN PROVISIONS RE-**

8 **GARDING RESEARCH CONDUCTED OR SUP-**

9 **PORTED BY NATIONAL INSTITUTES OF**

10 **HEALTH.**

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

14 “CERTAIN PROVISIONS REGARDING REVIEW AND

15 APPROVAL OF PROPOSALS FOR RESEARCH

16 “SEC. 492A. (a) REVIEW AS PRECONDITION TO RE-  
17 SEARCH.—

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 ap-

1           prove or fund any application that is subject to  
2           review under section 491(a) by an Institutional  
3           Review Board unless the application has under-  
4           gone review in accordance with such section and  
5           has been recommended for approval by a major-  
6           ity of the members of the Board conducting  
7           such review.

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

16          “(2) PEER REVIEW.—In the case of any appli-  
17          cation submitted to the Secretary for financial as-  
18          sistance to conduct research, the Secretary may not  
19          approve or fund any application that is subject to  
20          technical and scientific peer review under section  
21          492(a) unless the application has undergone peer re-  
22          view in accordance with such section and has been  
23          recommended for approval by a majority of the  
24          members of the entity conducting such review.

25          “(b) ETHICAL REVIEW OF RESEARCH.—

1           “(1) PROCEDURES REGARDING WITHHOLDING  
2           OF FUNDS.—If research has been recommended for  
3           approval for purposes of subsection (a), the Sec-  
4           retary may not withhold funding for the research on  
5           ethical grounds unless—

6                   “(A) the Secretary convenes an advisory  
7                   board in accordance with paragraph (4) to  
8                   study the ethical implications of the research;  
9                   and

10                   “(B) the majority of the advisory board  
11                   recommends that, on ethical grounds, the Sec-  
12                   retary withhold funds for the research.

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

19           “(3) PRELIMINARY MATTERS REGARDING USE  
20           OF PROCEDURES.—

21                   “(A) If the Secretary makes a determina-  
22                   tion that an advisory board should be convened  
23                   for purposes of paragraph (1), the Secretary  
24                   shall, through a statement published in the



1 Federal Register, announce the intention of the  
2 Secretary to convene such a board.

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

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

17 “(4) ETHICS ADVISORY BOARDS.—

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

22 “(B)(i) An ethics board shall advise, con-  
23 sult with, and make recommendations to the  
24 Secretary regarding the ethics of the project of

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

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

17 “(C) An ethics board shall be composed of  
18 no fewer than 14, and no more than 20, indi-  
19 viduals who are not officers or employees of the  
20 United States. The Secretary shall make ap-  
21 pointments to the board from among individ-  
22 uals with special qualifications and competence  
23 to provide advice and recommendations regard-  
24 ing ethical matters in biomedical and behavioral  
25 research. 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 theo-  
8           logian; 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  
14          an ethics board shall be for the life of the  
15          board. If such a member does not serve the full  
16          term of such service, the individual appointed to  
17          fill the resulting vacancy shall be appointed for  
18          the remainder of the term of the predecessor of  
19          the individual.

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) With respect to information relevant  
9           to the duties described in subparagraph (B)(i),  
10          an ethics board shall have access to all such in-  
11          formation possessed by the Department of  
12          Health and Human Services, or available to the  
13          Secretary 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  
17          time engaged in traveling for purposes of such  
18          duties. Such compensation may not be provided  
19          in an amount in excess of the maximum rate of  
20          basic pay payable for GS-18 of the General  
21          Schedule.

22          “(J) The Secretary, acting through the Di-  
23          rector of the National Institutes of Health,  
24          shall provide to each ethics board such staff

1 and other assistance as may be necessary to  
2 carry out the duties of the board.

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

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

10 **SEC. 111. ESTABLISHMENT OF AUTHORITIES.**

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

14 “RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

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

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

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

24 “(b) INFORMED CONSENT OF DONOR.—

25 “(1) IN GENERAL.—In research carried out  
26 under subsection (a), human fetal tissue may be

1 used only if the woman providing the tissue makes  
2 a statement, made in writing and signed by the  
3 woman, declaring that—

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

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

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

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

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

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

24 “(ii) no alteration of the timing,  
25 method, or procedures used to terminate

1 the pregnancy was made solely for the pur-  
2 poses 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  
6 the woman with regard to—

7 “(i) such physician’s interest, if any,  
8 in the research to be conducted with the  
9 tissue; 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 tis-  
13 sue and that are in addition to risks of  
14 such type that are associated with the  
15 woman’s 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  
2           pursuant to a spontaneous or induced abortion  
3           or subsequent to a stillbirth; and

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

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

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

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

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

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

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



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

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

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

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

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

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

1           “(2) RESEARCH CONDUCTED BY SECRETARY.—

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

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

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

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

16           “PROHIBITIONS REGARDING HUMAN FETAL TISSUE

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

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

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

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

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

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

13 “(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### 13               **PART III—MISCELLANEOUS REPEALS**

#### 14       **SEC. 121. REPEALS.**

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

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

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

22       and

23               (2) by striking section 499; and

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

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

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

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

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

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

14 “INCLUSION OF WOMEN AND MINORITIES IN CLINICAL  
15 RESEARCH

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 **SEC. 141. ESTABLISHMENT.**

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

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

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

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

15 “PART F—RESEARCH ON WOMEN’S HEALTH

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

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

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

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

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

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

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

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

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

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

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

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

23           “(c) COORDINATING COMMITTEE.—

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

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

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

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

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

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

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

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

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

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

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

11 “(d) ADVISORY COMMITTEE.—

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

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



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

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

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

12 “(4) The Advisory Committee shall—

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

17 “(i) research on women’s health;

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

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

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

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

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

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

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

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

20                  “(i) compliance with section 492B;

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

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

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

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

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

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

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

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

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

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

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

9           “(a) DATA SYSTEM.—

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

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

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

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

15 **“SEC. 486B. BIENNIAL REPORT.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 **SEC. 151. ESTABLISHMENT.**

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

10 “OFFICE OF RESEARCH ON MINORITY HEALTH

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

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

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

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

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





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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(f) PROTECTION OF WHISTLEBLOWERS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1                   “CHILDREN’S VACCINE INITIATIVE

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

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

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

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

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

11           “PLAN FOR USE OF ANIMALS IN RESEARCH

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

20 “REQUIREMENTS REGARDING SURVEYS OF SEXUAL  
21 BEHAVIOR

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

9 “(c) INFORMATION CLEARINGHOUSE.—

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

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



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

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

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

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

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

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

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

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

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

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

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

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

23       “(g) COORDINATING COMMITTEE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “BREAST AND GYNECOLOGICAL CANCERS

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

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

9       “(c) PROGRAMS FOR BREAST CANCER.—

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23                           “PROSTATE CANCER

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

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

3 “(b) COORDINATION WITH OTHER INSTITUTES.—

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

10 “(c) PROGRAMS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15           “AUTHORIZATION OF APPROPRIATIONS

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

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

23           “(1) BREAST CANCER.—

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

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

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

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

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



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

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

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

23       (c) CONFORMING AMENDMENTS.—

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

1 (A) by striking subsection (a);

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

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

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

9 “CERTAIN USES OF FUNDS”.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1           “NATIONAL CENTER ON SLEEP DISORDERS

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

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

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

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

17           “AUTHORIZATION OF APPROPRIATIONS

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

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

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

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

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

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

12 “NUTRITIONAL DISORDERS PROGRAM

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 (2) in subsection (b)—

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

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

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

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

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



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

7 (d) ADVISORY BOARD.—

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

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

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

20 (B) in paragraph (1)(B)—

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

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

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

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

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

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

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

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

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

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

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

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

4 (2) redesignated as section 445G; and

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

6 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

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

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

13 “ALZHEIMER’S DISEASE REGISTRY

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

16 (2) by striking subsection (c).

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

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

21 “AGING PROCESSES REGARDING WOMEN

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

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

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

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

11 “AUTHORIZATION OF APPROPRIATIONS

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

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

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

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

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

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

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

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

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

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

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

15 “RESEARCH CENTERS REGARDING CHRONIC FATIGUE  
16 SYNDROME

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

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

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

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

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

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

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

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

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

14 “RESEARCH CENTERS WITH RESPECT TO  
15 CONTRACEPTION AND INFERTILITY

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 “PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

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

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

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

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

24 “CHILD HEALTH RESEARCH CENTERS

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



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

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

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

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

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

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

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

15       “CLINICAL RESEARCH ON EYE CARE AND DIABETES

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

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

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

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

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

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

12 “RESEARCH ON MULTIPLE SCLEROSIS

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

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

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

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

1 “APPLIED TOXICOLOGICAL RESEARCH AND TESTING  
2 PROGRAM

3 “SEC. 463A. (a) There is established within the Insti-  
4 tute a program for conducting applied research and test-  
5 ing regarding toxicology, which program shall be known  
6 as the Applied Toxicological Research and Testing Pro-  
7 gram.

8 “(b) In carrying out the program established under  
9 subsection (a), the Director of the Institute shall, with re-  
10 spect to toxicology, carry out activities—

11 “(1) to expand knowledge of the health effects  
12 of environmental agents;

13 “(2) to broaden the spectrum of toxicology in-  
14 formation that is obtained on selected chemicals;

15 “(3) to develop and validate assays and proto-  
16 cols, including alternative methods that can reduce  
17 or eliminate the use of animals in acute or chronic  
18 safety testing;

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



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

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

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

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

12       **Subtitle A—General Provisions**

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

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

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

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

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

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

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

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

10          (c) TECHNICAL AND CONFORMING AMENDMENTS.—

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

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

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

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

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

3 “AUTHORIZATION OF APPROPRIATIONS

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

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

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

## 16 **Subtitle B—Financial Assistance**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 “NATIONAL INFORMATION CENTER

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 (2) in part E—

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

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

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

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

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

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

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

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

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



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

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

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

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

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

19              “(2) DUTIES.—

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

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

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

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

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

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

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

9           “(3) MEMBERSHIP.—

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

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

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

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

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

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

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

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

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

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

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

24 “(5) CERTAIN AUTHORITIES.—

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

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

10          “(6) TERMS.—

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

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

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

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

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

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

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

15                  “(c) REQUIREMENTS FOR GRANTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17          “(2) CONSIDERATION OF CERTAIN FACTORS.—

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

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



1                   “(i) interdisciplinary research;

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

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

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

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

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

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

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

7           “(D) The applicant—

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

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

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

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

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

5 “(e) AMOUNT OF GRANT; PAYMENTS.—

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

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

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

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

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

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

10           “(A) the amount of any other Federal  
11       grant that the applicant has obtained, or is as-  
12       sured of obtaining, with respect to construction  
13       that is to be financed in part by a grant author-  
14       ized under this section; and

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

18           “(4) WAIVER OF LIMITATIONS.—The limita-  
19       tions imposed by paragraph (1) may be waived at  
20       the discretion of the Director for applicants meeting  
21       the conditions described in paragraphs (1) and (2)  
22       of subsection (c).

23           “(f) RECAPTURE OF PAYMENTS.—If, not later than  
24       20 years after the completion of construction for which  
25       a grant has been awarded under subsection (a)—

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

4           “(2) the facility shall cease to be used for the  
5           research purposes for which it was constructed (un-  
6           less the Director determines, in accordance with reg-  
7           ulations, that there is good cause for releasing the  
8           applicant or other owner from obligation to do so);  
9           the United States shall be entitled to recover from the ap-  
10          plicant or other owner of the facility the amount bearing  
11          the same ratio to the current value (as determined by an  
12          agreement between the parties or by action brought in the  
13          United States District Court for the district in which such  
14          facility is situated) of the facility as the amount of the  
15          Federal participation bore to the cost of the construction  
16          of such facility.

17          “(g) NONINTERFERENCE WITH ADMINISTRATION OF  
18          ENTITIES.—Except as otherwise specifically provided in  
19          this section, nothing contained in this part shall be con-  
20          strued as authorizing any department, agency, officer, or  
21          employee of the United States to exercise any direction,  
22          supervision, or control over, or impose any requirement  
23          or condition with respect to the administration of any en-  
24          tity funded under this part.



1 year is subject to the availability of qualified applicants  
2 for such awards.

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

## 12 **Subtitle B—National Center for** 13 **Nursing Research**

### 14 **SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR** 15 **NURSING RESEARCH AS NATIONAL INSTI-** 16 **TUTE OF NURSING RESEARCH.**

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

20 (1) in section 483—

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

23 (B) by striking “The general purpose” and  
24 all that follows through “is” and inserting the  
25 following: “The general purpose of the National

1 Institute of Nursing Research (hereafter in this  
2 subpart referred to as the ‘Institute’) is”;

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

5 (3) in section 485—

6 (A) in subsection (a), in each of para-  
7 graphs (1) through (3), by striking “Center”  
8 each place such term appears and inserting  
9 “Institute”;

10 (B) in subsection (b)—

11 (i) in paragraph (2)(A), by striking  
12 “Center” and inserting “Institute”; and

13 (ii) in paragraph (3)(A), in the first  
14 sentence, by striking “Center” and insert-  
15 ing “Institute”; and

16 (C) in subsections (d) through (g), by  
17 striking “Center” each place such term appears  
18 and inserting “Institute”; and

19 (4) in section 485A (as redesignated by section  
20 141(a)(1) of this Act), by striking “Center” each  
21 place such term appears and inserting “Institute”.

22 (b) CONFORMING AMENDMENTS.—

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



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

3 “(Q) The National Institute of Nursing  
4 Research.”; and

5 (B) in paragraph (2), by striking subpara-  
6 graph (D).

7 (2) TRANSFER OF STATUTORY PROVISIONS.—  
8 Sections 483 through 485A of the Public Health  
9 Service Act, as amended by subsection (a) of this  
10 section—

11 (A) are transferred to part C of title IV of  
12 such Act;

13 (B) are redesignated as sections 464V  
14 through 464Y of such part; and

15 (C) are inserted, in the appropriate se-  
16 quence, at the end of such part.

17 (3) HEADING FOR NEW SUBPART.—Title IV of  
18 the Public Health Service Act, as amended by the  
19 preceding provisions of this section, is amended—

20 (A) in part C, by inserting before section  
21 464V the following new heading:

22 “Subpart 17—National Institute of Nursing Research”;  
23 and

24 (B) by striking the heading for subpart 3  
25 of part E.

1           (4) CROSS-REFERENCES.—Title IV of the Pub-  
2       lic Health Service Act, as amended by the preceding  
3       provisions of this section, is amended in subpart 17  
4       of part C—

5           (A) in section 464W, by striking “section  
6       483” and inserting “section 464V”;

7           (B) in section 464X(g), by striking “sec-  
8       tion 486” and inserting “section 464Y”; and

9           (C) in section 464Y, in the last sentence,  
10       by striking “section 485(g)” and inserting “sec-  
11       tion 464X(g)”.

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

13       (a) IN GENERAL.—The Secretary of Health and  
14       Human Services, acting through the Director of the Na-  
15       tional Institute of Nursing Research, shall enter into a  
16       contract with a public or nonprofit private entity to con-  
17       duct a study for the purpose of determining whether and  
18       to what extent there is a need for an increase in the num-  
19       ber of nurses in hospitals and nursing homes in order to  
20       promote the quality of patient care and reduce the inci-  
21       dence among nurses of work-related injuries and stress.

22       (b) NATIONAL ACADEMY OF SCIENCES.—The Sec-  
23       retary shall request the National Academy of Sciences to  
24       enter into the contract under subsection (a) to conduct  
25       the study described in such subsection. If such Institute

1 declines to conduct the study, the Secretary shall carry  
2 out such subsection through another public or nonprofit  
3 private entity.

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

5 (1) The term “nurse” means a registered nurse,  
6 a licensed practical nurse, a licensed vocational  
7 nurse, and a nurse assistant.

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

10 (d) REPORT.—The Secretary shall ensure that, not  
11 later than October 1, 1994, the study required in sub-  
12 section (a) is completed and a report describing the find-  
13 ings made as a result of the study is submitted to the  
14 Committee on Energy and Commerce of the House of  
15 Representatives, and to the Committee on Labor and  
16 Human Resources of the Senate.

## 17 **Subtitle C—National Center for** 18 **Human Genome Research**

### 19 **SEC. 1521. PURPOSE OF CENTER.**

20 Title IV of the Public Health Service Act, as amended  
21 by sections 141(a)(1) and 1611(b)(1)(B) of this Act, is  
22 amended—

23 (1) in section 401(b)(2), by adding at the end  
24 the following new subparagraph:

1 “(D) The National Center for Human Genome  
2 Research.”; and

3 (2) in part E, by adding at the end the follow-  
4 ing new subpart:

5 “Subpart 4—National Center for Human Genome  
6 Research

7 “PURPOSE OF THE CENTER

8 “SEC. 485B. (a) The general purpose of the National  
9 Center for Human Genome Research (hereafter in this  
10 subpart referred to as the ‘Center’) is to characterize the  
11 structure and function of the human genome, including  
12 the mapping and sequencing of individual genes. Such  
13 purpose includes—

14 “(1) planning and coordinating the research  
15 goal of the genome project;

16 “(2) reviewing and funding research proposals;

17 “(3) developing training programs;

18 “(4) coordinating international genome re-  
19 search;

20 “(5) communicating advances in genome science  
21 to the public; and

22 “(6) reviewing and funding proposals to address  
23 the ethical issues associated with the genome  
24 project.

1       “(b)(1) Except as provided in paragraph (2), of the  
2 amounts appropriated to carry out subsection (a) for a  
3 fiscal year, the Director of the Center shall make available  
4 not less than 5 percent for carrying out paragraph (6)  
5 of such subsection.

6       “(2) With respect to providing funds under sub-  
7 section (a)(6) for proposals to address the ethical issues  
8 associated with the genome project, paragraph (1) shall  
9 not apply for a fiscal year if the Director of the Center  
10 certifies to the Committee on Energy and Commerce of  
11 the House of Representatives, and to the Committee on  
12 Labor and Human Resources of the Senate, that the Di-  
13 rector has determined that an insufficient number of such  
14 proposals meet the applicable requirements of sections 491  
15 and 492.”.

16                   **TITLE XVI—AWARDS AND**  
17                                   **TRAINING**

18                   **Subtitle A—National Research**  
19                                   **Service Awards**

20   **SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDI-**  
21                                   **VIDUALS FROM DISADVANTAGED BACK-**  
22                                   **GROUND.**

23       Section 487(a) of the Public Health Service Act (42  
24 U.S.C. 288(a)(4)) is amended by adding at the end the  
25 following paragraph:

1       “(4) The Secretary shall carry out paragraph (1) in  
2 a manner that will result in the recruitment of women,  
3 and members from underrepresented minority groups, into  
4 fields of biomedical or behavioral research and in the pro-  
5 vision of research training to women and such individ-  
6 uals.”.

7 **SEC. 1602. SERVICE PAYBACK REQUIREMENTS.**

8       Paragraph (2) of section 487(c) of the Public Health  
9 Service Act (42 U.S.C. 288(c)(2)) is amended to read as  
10 follows:

11       “(2)(A) For the initial year for which an individual  
12 receives a National Research Service Award for the con-  
13 duct of postdoctoral training or research, such individual  
14 shall engage in one year of health research or teaching  
15 or any combination thereof which is in accordance with  
16 the usual patterns of academic employment, or complete  
17 a second year of training or research under such Award.

18       “(B) Service obligations for National Research Serv-  
19 ice Awards that are less than 12 months may be satis-  
20 fied—

21               “(i) by the conduct of health research or teach-  
22 ing or any combination thereof which is in accord-  
23 ance with the usual patterns of academic employ-  
24 ment for a period of time equal to the amount of  
25 time under the Award; or

1           “(ii) by reimbursing the Federal Government  
2           for the amounts provided to such individual under  
3           the Award.

4           **Subtitle B—Acquired Immune**  
5           **Deficiency Syndrome**

6           **SEC. 1611. LOAN REPAYMENT PROGRAM.**

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

9           “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH  
10          RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

11          “SEC. 487A. (a) IN GENERAL.—

12                 “(1) AUTHORITY FOR PROGRAM.—Subject to  
13                 paragraph (2), the Secretary shall carry out a pro-  
14                 gram of entering into agreements with appropriately  
15                 qualified health professionals under which such  
16                 health professionals agree to conduct, as employees  
17                 of the National Institutes of Health, research with  
18                 respect to acquired immune deficiency syndrome in  
19                 consideration of the Federal Government agreeing to  
20                 repay, for each year of such service, not more than  
21                 \$20,000 of the principal and interest of the edu-  
22                 cational loans of such health professionals.

23                 “(2) LIMITATION.—The Secretary may not  
24                 enter into an agreement with a health professional  
25                 pursuant to paragraph (1) unless such profes-  
26                 sional—

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

3           “(B)(i) was not employed at the National  
4           Institutes of Health during the 1-year period  
5           preceding the date of the enactment of the  
6           Health Professions Reauthorization Act of  
7           1988; or

8           “(ii) agrees to serve as an employee of  
9           such Institutes for purposes of paragraph (1)  
10          for a period of not less than 3 years.”.

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

20          “(c) FUNDING; REIMBURSABLE TRANSFERS.—

21                 “(1) AUTHORIZATION OF APPROPRIATIONS.—  
22                 For the purpose of carrying out this section, there  
23                 are authorized to be appropriated such sums as may  
24                 be necessary for each of the fiscal years 1994  
25                 through 1996.



1           “(2) TRANSFERS FOR RELATED PROGRAM.—  
2           The Commissioner of Food and Drugs may carry  
3           out for the Food and Drug Administration a pro-  
4           gram similar to the program established in sub-  
5           section (a), which program shall be carried out with  
6           respect to the review of applications concerning ac-  
7           quired immune deficiency syndrome that are submit-  
8           ted to such Commissioner. From the amounts appro-  
9           priated under paragraph (1) for a fiscal year, the  
10          Secretary may transfer amounts to the Commis-  
11          sioner for the purpose of carrying out such program.  
12          The Commissioner shall provide a reimbursement to  
13          the Secretary for the amount so transferred, and the  
14          reimbursement shall be available only for the pro-  
15          gram established in subsection (a). Any transfer and  
16          reimbursement made for purposes of this paragraph  
17          for a fiscal year shall be completed by April 1 of  
18          such year.”.

19           **Subtitle C—Loan Repayment for**  
20           **Research Generally**

21           **SEC. 1621. ESTABLISHMENT OF PROGRAM.**

22           Part G of title IV of the Public Health Service Act,  
23           as redesignated by section 141(a)(2) of this Act and as  
24           amended by section 1002 of this Act, is amended by in-  
25           serting after section 487B the following new section:



1           “(ii) agrees to serve as an employee of  
2           such Institutes for purposes of paragraph (1)  
3           for a period of not less than 3 years.”.

4           “(b) APPLICABILITY OF CERTAIN PROVISIONS.—  
5 With respect to the National Health Service Corps Loan  
6 Repayment Program established in subpart III of part D  
7 of title III, the provisions of such subpart shall, except  
8 as inconsistent with subsection (a) of this section, apply  
9 to the program established in such subsection (a) in the  
10 same manner and to the same extent as such provisions  
11 apply to the National Health Service Corps Loan Repay-  
12 ment Program established in such subpart.

13           “(c) AUTHORIZATION OF APPROPRIATIONS.—For the  
14 purpose of carrying out this section other than with re-  
15 spect to acquired immune deficiency syndrome, there are  
16 authorized to be appropriated such sums as may be nec-  
17 essary for each of the fiscal years 1994 through 1996.”.

18 **Subtitle D—Scholarship and Loan**  
19 **Repayment Programs Regard-**  
20 **ing Professional Skills Needed**  
21 **by Certain Agencies**

22 **SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL**  
23 **INSTITUTES OF HEALTH.**

24           Part G of title IV of the Public Health Service Act,  
25 as redesignated by section 141(a)(2) of this Act and as

1 amended by section 1621 of this Act, is amended by in-  
2 serting after section 487C the following new sections:

3 “UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING  
4 PROFESSIONS NEEDED BY NATIONAL RESEARCH IN-  
5 STITUTES

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

7 “(1) IN GENERAL.—Subject to section  
8 487(a)(1)(C), the Secretary, acting through the Di-  
9 rector of NIH, may carry out a program of entering  
10 into contracts with individuals described in para-  
11 graph (2) under which—

12 “(A) the Director of NIH agrees to provide  
13 to the individuals scholarships for pursuing, as  
14 undergraduates at accredited institutions of  
15 higher education, academic programs appro-  
16 priate for careers in professions needed by the  
17 National Institutes of Health; and

18 “(B) the individuals agree to serve as em-  
19 ployees of the National Institutes of Health, for  
20 the period described in subsection (c), in posi-  
21 tions that are needed by the National Institutes  
22 of Health and for which the individuals are  
23 qualified.

24 “(2) INDIVIDUALS FROM DISADVANTAGED  
25 BACKGROUNDS.—The individuals referred to in  
26 paragraph (1) are individuals who—

1           “(A) are enrolled or accepted for enroll-  
2           ment as full-time undergraduates at accredited  
3           institutions of higher education; and

4           “(B) are from minority groups that are  
5           underrepresented in the fields of biomedical or  
6           behavioral research.

7           “(b) FACILITATION OF INTEREST OF STUDENTS IN  
8 CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In  
9 providing employment to individuals pursuant to contracts  
10 under subsection (a)(1), the Director of NIH shall carry  
11 out activities to facilitate the interest of the individuals  
12 in pursuing careers as employees of the National Insti-  
13 tutes of Health.

14           “(c) PERIOD OF OBLIGATED SERVICE.—

15           “(1) DURATION OF SERVICE.—For purposes of  
16 subparagraph (B) of subsection (a)(1), the period of  
17 service for which an individual is obligated to serve  
18 as an employee of the National Institutes of Health  
19 is 12 months for each academic year for which the  
20 scholarship under such subsection is provided.

21           “(2) SCHEDULE FOR SERVICE.—

22           “(A) Subject to subparagraph (B), the Di-  
23 rector of NIH may not provide a scholarship  
24 under subsection (a) unless the individual ap-  
25 plying for the scholarship agrees that—

1           “(i) the individual will serve as an em-  
2           ployee of the National Institutes of Health  
3           full-time for not less than 10 consecutive  
4           weeks of each year during which the indi-  
5           vidual is attending the educational institu-  
6           tion involved and receiving such a scholar-  
7           ship;

8           “(ii) the period of service as such an  
9           employee that the individual is obligated to  
10          provide under clause (i) is in addition to  
11          the period of service as such an employee  
12          that the individual is obligated to provide  
13          under subsection (a)(1)(B); and

14          “(iii) not later than 60 days after ob-  
15          taining the educational degree involved, the  
16          individual will begin serving full-time as  
17          such an employee in satisfaction of the pe-  
18          riod of service that the individual is obli-  
19          gated to provide under subsection  
20          (a)(1)(B).

21          “(B) The Director of NIH may defer the  
22          obligation of an individual to provide a period  
23          of service under subsection (a)(1)(B), if the Di-  
24          rector determines that such a deferral is appro-  
25          priate.

1           “(3) APPLICABILITY OF CERTAIN PROVISIONS  
2           RELATING TO APPOINTMENT AND COMPENSATION.—  
3           For any period in which an individual provides serv-  
4           ice as an employee of the National Institutes of  
5           Health in satisfaction of the obligation of the indi-  
6           vidual under subsection (a)(1)(B) or paragraph  
7           (2)(A)(i), the individual may be appointed as such  
8           an employee without regard to the provisions of title  
9           5, United States Code, relating to appointment and  
10          compensation.

11          “(d) PROVISIONS REGARDING SCHOLARSHIP.—

12           “(1) APPROVAL OF ACADEMIC PROGRAM.—The  
13           Director of NIH may not provide a scholarship  
14           under subsection (a) for an academic year unless—

15                   “(A) the individual applying for the schol-  
16                   arship has submitted to the Director a proposed  
17                   academic program for the year and the Director  
18                   has approved the program; and

19                   “(B) the individual agrees that the pro-  
20                   gram will not be altered without the approval of  
21                   the Director.

22           “(2) ACADEMIC STANDING.—The Director of  
23           NIH may not provide a scholarship under subsection  
24           (a) for an academic year unless the individual apply-  
25           ing for the scholarship agrees to maintain an accept-

1 able level of academic standing, as determined by  
2 the educational institution involved in accordance  
3 with regulations issued by the Secretary.

4 “(3) LIMITATION ON AMOUNT.—The Director  
5 of NIH may not provide a scholarship under sub-  
6 section (a) for an academic year in an amount ex-  
7 ceeding \$20,000.

8 “(4) AUTHORIZED USES.—A scholarship pro-  
9 vided under subsection (a) may be expended only for  
10 tuition expenses, other reasonable educational ex-  
11 penses, and reasonable living expenses incurred in  
12 attending the school involved.

13 “(5) CONTRACT REGARDING DIRECT PAYMENTS  
14 TO INSTITUTION.—In the case of an institution of  
15 higher education with respect to which a scholarship  
16 under subsection (a) is provided, the Director of  
17 NIH may enter into a contract with the institution  
18 under which the amounts provided in the scholarship  
19 for tuition and other educational expenses are paid  
20 directly to the institution. Payments to the institu-  
21 tion under the contract may be made without regard  
22 to section 3324 of title 31, United States Code.

23 “(e) PENALTIES FOR BREACH OF SCHOLARSHIP  
24 CONTRACT.—The provisions of section 338E shall apply  
25 to the program established in subsection (a) to the same



1 extent and in the same manner as such provisions apply  
2 to the National Health Service Corps Loan Repayment  
3 Program established in section 338B.

4 “(f) REQUIREMENT OF APPLICATION.—The Director  
5 of NIH may not provide a scholarship under subsection  
6 (a) unless an application for the scholarship is submitted  
7 to the Director and the application is in such form, is  
8 made in such manner, and contains such agreements, as-  
9 surances, and information as the Director determines to  
10 be necessary to carry out this section.

11 “(g) AVAILABILITY OF AUTHORIZATION OF APPRO-  
12 PRIATIONS.—Amounts appropriated for a fiscal year for  
13 scholarships under this section shall remain available until  
14 the expiration of the second fiscal year beginning after the  
15 fiscal year for which the amounts were appropriated.

16 “LOAN REPAYMENT PROGRAM REGARDING CLINICAL  
17 RESEARCHERS FROM DISADVANTAGED BACKGROUNDS

18 “SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—

19 “(1) IN GENERAL.—Subject to section  
20 487(a)(1)(C), the Secretary, acting through the Di-  
21 rector of NIH may, subject to paragraph (2), carry  
22 out a program of entering into contracts with appro-  
23 priately qualified health professionals who are from  
24 disadvantaged backgrounds under which such health  
25 professionals agree to conduct clinical research as  
26 employees of the National Institutes of Health in

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

5 “(2) LIMITATION.—The Director of NIH may  
6 not enter into a contract with a health professional  
7 pursuant to paragraph (1) unless such professional  
8 has a substantial amount of education loans relative  
9 to income.

10 “(3) APPLICABILITY OF CERTAIN PROVISIONS  
11 REGARDING OBLIGATED SERVICE.—Except to the ex-  
12 tent inconsistent with this section, the provisions of  
13 sections 338C and 338E shall apply to the program  
14 established in paragraph (1) to the same extent and  
15 in the same manner as such provisions apply to the  
16 National Health Service Corps Loan Repayment  
17 Program established in section 338B.

18 “(b) AVAILABILITY OF AUTHORIZATION OF APPRO-  
19 PRIATIONS.—Amounts appropriated for a fiscal year for  
20 contracts under subsection (a) shall remain available until  
21 the expiration of the second fiscal year beginning after the  
22 fiscal year for which the amounts were appropriated.”.

23 **SEC. 1632. FUNDING.**

24 Section 487(a)(1) of the Public Health Service Act  
25 (42 U.S.C. 288(a)(1)) is amended—

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

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

5 (3) by adding at the end the following new sub-  
6 paragraph:

7 “(C) provide contracts for scholarships and loan  
8 repayments in accordance with sections 487D and  
9 487E, subject to providing not more than an aggre-  
10 gate 50 such contracts during the fiscal years 1994  
11 through 1996.”.

## 12 **Subtitle D—Funding**

### 13 **SEC. 1641. AUTHORIZATION OF APPROPRIATIONS.**

14 Section 487(d) of the Public Health Service Act (42  
15 U.S.C. 288(d)) is amended—

16 (1) in the first sentence, by amending the sen-  
17 tence to read as follows: “For the purpose of carry-  
18 ing out this section, there are authorized to be ap-  
19 propriated \$400,000,000 for fiscal year 1994, and  
20 such sums as may be necessary for each of the fiscal  
21 years 1995 and 1996.”; and

22 (2) in paragraph (3)—

23 (A) by striking “one-half of one percent”  
24 each place such term appears and inserting “1  
25 percent”; and

1 (B) by striking “780, 784, or 786” and in-  
2 serting “747, 748, or 749”.

3 **TITLE XVII—NATIONAL FOUNDA-**  
4 **TION FOR BIOMEDICAL RE-**  
5 **SEARCH**

6 **SEC. 1701. ESTABLISHMENT OF FOUNDATION.**

7 Section 499 of the Public Health Service Act, as re-  
8 designated by section 121(b), is amended to read as fol-  
9 lows:

10 **“SEC. 499A. ESTABLISHMENT AND DUTIES OF FOUNDATION.**

11 “(a) IN GENERAL.—The Secretary shall establish a  
12 nonprofit corporation to be known as the National Foun-  
13 dation for Biomedical Research (hereafter in this section  
14 referred to as the ‘Foundation’). The Foundation shall  
15 not, except for the purposes of the Ethics in Government  
16 Act and the Technology Transfer Act, be an agency or  
17 instrumentality of the United States Government.

18 “(b) PURPOSE OF FOUNDATION.—The purpose of  
19 the Foundation shall be to conduct and support research  
20 with respect to any particular disease or groups of diseases  
21 or any other aspect of human health.

22 “(c) ENDOWMENT FUND.—

23 “(1) IN GENERAL.—In carrying out subsection  
24 (b), the Foundation shall establish a fund whose pri-  
25 mary purpose shall be to provide endowments for po-

1       sitions at the National Institutes of Health to con-  
2       duct biomedical research, and dedicated to the pur-  
3       pose described in such subsection. Such positions  
4       may be held by scientists without regard to whether  
5       the scientists are employees of the Federal Govern-  
6       ment. Subject to subsection (g)(1)(B), the fund shall  
7       consist of such donations as may be provided by  
8       non-Federal entities and such non-Federal assets of  
9       the Foundation (including earnings of the Founda-  
10      tion and the fund) as the Foundation may elect to  
11      transfer to the fund.

12           “(2) AUTHORIZED EXPENDITURES OF FUND.—  
13      The provision of endowments under paragraph (1)  
14      shall be the primary function of the fund established  
15      under such paragraph. Such endowments may be ex-  
16      pended only for the compensation of individuals  
17      holding the positions, for staff, equipment, quarters,  
18      travel, and other expenditures that are appropriate  
19      in supporting the positions, and for recruiting indi-  
20      viduals to hold the positions endowed by the fund.

21           “(d) CERTAIN ACTIVITIES OF FOUNDATION.—In car-  
22      rying out subsection (b), and subject to subsection (c), the  
23      Foundation may provide for the following with respect to  
24      the purpose described in such subsection:

1           “(1) Endowed chairs for distinguished senior  
2 investigators.

3           “(2) Positions for support of visiting scientists  
4 in mid-career who participate in the National Insti-  
5 tutes of Health Scholars program.

6           “(3) Studies, projects, and research conducted  
7 by scientists under paragraphs (1) and (2).

8           “(4) Forums for the exchange of information  
9 between scientists. Participants in such forums may  
10 include institutions of higher education and appro-  
11 priate private and public organizations.

12           “(5) Meetings, conferences, courses, and train-  
13 ing workshops.

14           “(6) Programs to improve the collection and  
15 analysis of data.

16           “(7) Programs for writing, editing, printing,  
17 and publishing of books and other materials.

18           “(8) Other activities to carry out the purpose  
19 described in subsection (b).

20           “(e) POWERS.—In carrying out subsection (b), the  
21 Foundation shall—

22           “(1) operate under the direction of its Board;

23           “(2) adopt, alter, and use a corporate seal,  
24 which shall be judicially noticed;

1           “(3) provide for 1 or more officers, employees,  
2           and agents, as may be necessary, define their duties,  
3           and require surety bonds or make other provisions  
4           against losses occasioned by acts of such persons;

5           “(4) hire, promote, compensate, and discharge  
6           officers and employees of the Foundation;

7           “(5) prescribe by its Board its bylaws, as de-  
8           scribed in subsection (g)(1)(A);

9           “(6) with the consent of any executive depart-  
10          ment or independent agency, use the information,  
11          services, staff, and facilities of such in carrying out  
12          this section;

13          “(7) sue and be sued in its corporate name, and  
14          complain and defend in courts of competent jurisdic-  
15          tion;

16          “(8) modify or consent to the modification of  
17          any contract or agreement to which it is a party or  
18          in which it has an interest under this subtitle;

19          “(9) establish a mechanism for the selection of  
20          candidates, subject to the approval of the Director of  
21          the National Institutes of Health for the endowed  
22          scientific positions within the organizational struc-  
23          ture of the intramural research programs of the Na-  
24          tional Institutes of Health and candidates for par-

1 participation in the National Institutes of Health Schol-  
2 ars program;

3 “(10) enter into contracts with public and pri-  
4 vate organizations for the writing, editing, printing,  
5 and publishing of books and other material;

6 “(11) take such action as may be necessary to  
7 obtain patents and licenses for devices and proce-  
8 dures developed by the Foundation and its employ-  
9 ees;

10 “(12) accept, hold, administer, invest, and  
11 spend any gift, devise, or bequest of real or personal  
12 property made to the Foundation;

13 “(13) enter into such other contracts, leases,  
14 cooperative agreements, and other transactions as  
15 the Executive Director considers appropriate to con-  
16 duct the activities of the Foundation;

17 “(14) appoint other groups of advisors as may  
18 be determined necessary from time to time to carry  
19 out the functions of the Foundation; and

20 “(15) exercise other powers as set forth in this  
21 section, and such other incidental powers as are nec-  
22 essary to carry out its powers, duties, and functions  
23 in accordance with this subtitle.

24 “(f) GENERAL STRUCTURE OF FOUNDATION; NON-  
25 PROFIT STATUS.—



1           “(1) BOARD OF DIRECTORS.—The Foundation  
2 shall have a board of directors (in this part referred  
3 to as the ‘Board’), which shall be established and  
4 conducted in accordance with subsection (g). The  
5 Board shall establish the general policies of the  
6 Foundation for carrying out subsection (b), includ-  
7 ing the establishment of the bylaws of the Founda-  
8 tion.

9           “(2) EXECUTIVE DIRECTOR.—The Foundation  
10 shall have an executive director (in this part referred  
11 to as the ‘Director’), who shall be appointed by the  
12 Board, who shall serve at the pleasure of the Board,  
13 and for whom the Board shall establish the rate of  
14 compensation. Subject to compliance with the poli-  
15 cies and bylaws established by the Board pursuant  
16 to paragraph (1), the Director shall be responsible  
17 for the daily operations of the Foundation in carry-  
18 ing out subsection (b).

19           “(3) NONPROFIT STATUS.—In carrying out  
20 subsection (b), the Board shall establish such poli-  
21 cies and bylaws under paragraph (1), and the Direc-  
22 tor shall carry out such activities under paragraph  
23 (2), as may be necessary to ensure that the Founda-  
24 tion maintains status as an organization that—

1           “(A) is described in subsection (c)(3) of  
2 section 501 of the Internal Revenue Code of  
3 1986; and

4           “(B) is, under subsection (a) of such sec-  
5 tion, exempt from taxation.

6           “(4) LIAISON.—The Director of the National  
7 Institutes of Health shall serve as the liaison rep-  
8 resentative of the National Institutes of Health to  
9 the Board and the Foundation.

10          “(g) BOARD OF DIRECTORS.—

11           “(1) CERTAIN BYLAWS.—

12           “(A) In establishing bylaws under sub-  
13 section (f)(1), the Board shall ensure that the  
14 bylaws of the Foundation include bylaws for the  
15 following:

16           “(i) Policies for the selection of the  
17 officers, employees, agents, and contractors  
18 of the Foundation.

19           “(ii) Policies for the acquisition, hold-  
20 ing, and transfer of property.

21           “(iii) Policies, including ethical stand-  
22 ards, for the acceptance and disposition of  
23 donations to the Foundation and for the  
24 disposition of the assets of the Foundation.

1           “(iv) Policies for the conduct of the  
2           general operations of the Foundation.

3           “(v) Policies for writing, editing,  
4           printing, and publishing of books and other  
5           materials, and the acquisition of patents  
6           and licenses for devices and procedures de-  
7           veloped by the Foundation.

8           “(B) In establishing bylaws under sub-  
9           section (f)(1), the Board shall ensure that the  
10          bylaws of the Foundation (and activities carried  
11          out under the bylaws) do not—

12           “(i) reflect unfavorably upon the abil-  
13          ity of the Foundation, or the National In-  
14          stitutes of Health, to carry out its respon-  
15          sibilities or official duties in a fair and ob-  
16          jective manner; or

17           “(ii) compromise, or appear to com-  
18          promise, the integrity of any governmental  
19          program or any officer or employee in-  
20          volved in such program.

21          “(2) COMPOSITION.—

22           “(A) The Foundation shall have a Board  
23          of Directors (hereafter referred to in this sec-  
24          tion as the ‘Board’), which shall initially be  
25          composed of ex officio and appointed members

1 in accordance with this subsection until such  
2 time as all the appointed members, including  
3 the Chairperson, are fully appointed by the  
4 Board under paragraph (4).

5 “(B) The ex officio members of the Coun-  
6 cil shall be—

7 “(i) the Chairperson and ranking mi-  
8 nority member of the Subcommittee on  
9 Health and the Environment (Committee  
10 on Energy and Commerce) or their des-  
11 ignees, in the case of the House of Rep-  
12 resentatives;

13 “(ii) the Chairperson and ranking mi-  
14 nority member of the Committee on Labor  
15 and Human Resources or their designees,  
16 in the case of the Senate; and

17 “(iii) the Director of the National In-  
18 stitutes of Health.

19 “(C) The ex officio members of the Board  
20 under subparagraph (B) shall appoint to the  
21 Council 9 individuals. Of such appointed mem-  
22 bers—

23 “(i) 2 shall be representatives of the  
24 general biomedical field;

1                   “(ii) 2 shall be representatives of the  
2                   general biobehavioral field; and

3                   “(iii) 3 shall be representatives of the  
4                   general public.

5                   “(3) CHAIRPERSON.—The ex officio members of  
6                   the Board under paragraph (2)(B) shall designate  
7                   an appointed member of the Board to serve as the  
8                   first Chairperson of the Board. Subsequently, the  
9                   Chairperson of the Board shall be chosen by the  
10                  Board according to its bylaws.

11                  “(4) APPOINTMENTS, VACANCIES, AND  
12                  TERMS.—The following shall apply to the Board:

13                   “(A) Any vacancy in the membership of  
14                   the Board shall be filled by appointment by the  
15                   Board, after consideration of suggestions made  
16                   by the Chairperson and the Director regarding  
17                   the appointments. Any such vacancy shall be  
18                   filled not later than the expiration of the 180-  
19                   day period beginning on the date on which the  
20                   vacancy occurs.

21                   “(B) The term of office of each member of  
22                   the Board appointed under subparagraph (A)  
23                   shall be 5 years, except that the terms of office  
24                   for the initial appointed members of the Board  
25                   shall expire as determined by the Chairperson

1 of the Board, in consultation with the Director  
2 of the National Institutes of Health.

3 “(C) A vacancy in the membership of the  
4 Board shall not affect the power of the Board  
5 to carry out the duties of the Board. If a mem-  
6 ber of the Board does not serve the full term  
7 applicable under subparagraph (B), the individ-  
8 ual appointed to fill the resulting vacancy shall  
9 be appointed for the remainder of the term of  
10 the predecessor of the individual.

11 “(5) COMPENSATION.—Members of the Board  
12 may not receive compensation for service on the  
13 Board. Such members may be reimbursed for travel,  
14 subsistence, and other necessary expenses incurred  
15 in carrying out the duties of the Board, as set forth  
16 in the bylaws issued by the Board.

17 “(h) INCORPORATION.—The initial members of the  
18 Board shall serve as incorporators and shall take whatever  
19 actions necessary to incorporate the Foundation.

20 “(i) GENERAL PROVISIONS.—

21 “(1) ADMINISTRATIVE CONTROL.—No officer,  
22 employee, or member of the Board of the Founda-  
23 tion may exercise any administrative or managerial  
24 control over any Federal employee.

1           “(2) APPLICABILITY OF CERTAIN STANDARDS  
2           TO NON-FEDERAL EMPLOYEES.—In the case of any  
3           individual who is not an employee of the Federal  
4           Government and who serves with financial support  
5           from the Foundation, the Foundation shall negotiate  
6           a memorandum of understanding with the individual  
7           and the Director of the National Institutes of Health  
8           specifying that the individual—

9                   “(A) shall be subject to the ethical and  
10                  procedural standards regulating Federal em-  
11                  ployment, scientific investigation, and research  
12                  findings (including publications and patents)  
13                  that are required of individuals employed by the  
14                  National Institutes of Health, including stand-  
15                  ards under this Act, the Ethics in Government  
16                  Act, and the Technology Transfer Act; and

17                   “(B) shall be subject to such ethical and  
18                  procedural standards under chapter 11 of title  
19                  18, United States Code (relating to conflicts of  
20                  interest), as the Director of the National Insti-  
21                  tutes of Health determines is appropriate, ex-  
22                  cept such memorandum may not provide that  
23                  the individual shall be subject to the standards  
24                  of section 209 of such chapter.

1           “(3) FINANCIAL CONFLICTS OF INTEREST.—  
2           Any individual who is an officer, employee, or mem-  
3           ber of the Board of the Foundation may not directly  
4           or indirectly participate in the consideration or de-  
5           termination by the Foundation of any question af-  
6           fecting—

7                   “(A) any direct or indirect financial inter-  
8                   est of the individual; or

9                   “(B) any direct or indirect financial inter-  
10                  est of any business organization or other entity  
11                  of which the individual is an officer or employee  
12                  or in which the individual has a direct or indi-  
13                  rect financial interest.

14           “(4) AUDITS; AVAILABILITY OF RECORDS.—The  
15           Foundation shall—

16                   “(A) provide for biennial audits of the fi-  
17                   nancial condition of the Foundation; and

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

23           “(5) REPORTS.—

24                   “(A) Not later than February 1 of each  
25                  fiscal year, the Foundation shall publish a re-



1 port describing the activities of the Foundation  
2 during the preceding fiscal year. Each such re-  
3 port shall include for the fiscal year involved a  
4 comprehensive statement of the operations, ac-  
5 tivities, financial condition, and accomplish-  
6 ments of the Foundation.

7 “(B) With respect to the financial condi-  
8 tion of the Foundation, each report under sub-  
9 paragraph (A) shall include the source, and a  
10 description of, all gifts to the Foundation of  
11 real or personal property, and the source and  
12 amount of all gifts to the Foundation of money.  
13 Each such report shall include a specification of  
14 any restrictions on the purposes for which gifts  
15 to the Foundation may be used.

16 “(C) The Foundation shall make copies of  
17 each report submitted under subparagraph (A)  
18 available for public inspection, and shall upon  
19 request provide a copy of the report to any indi-  
20 vidual for a charge not exceeding the cost of  
21 providing the copy.

22 “(j) FEDERAL FUNDING.—

23 “(1) AUTHORITY FOR ANNUAL GRANTS.—

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

1 shall for each of the fiscal years 1994 through  
2 1996, make a grant to the Foundation.

3 “(B) A grant under subparagraph (A) may  
4 be expended only for the purpose of the admin-  
5 istrative expenses of the Foundation.

6 “(C) A grant under subparagraph (A) may  
7 not be expended to provide amounts for the  
8 fund established under subsection (c).

9 “(2) FUNDING FOR GRANTS.—

10 “(A) For the purpose of grants under  
11 paragraph (1), there is authorized to be appro-  
12 priated \$500,000 for each of the fiscal years  
13 1994 through 1996.

14 “(B) For the purpose of grants under  
15 paragraph (1), the Secretary may for each fis-  
16 cal year make available not more than  
17 \$500,000 from the amounts appropriated for  
18 the fiscal year for the programs of the National  
19 Institutes of Health. Such amounts may be  
20 made available without regard to whether  
21 amounts have been appropriated under sub-  
22 paragraph (A).”.

1 **TITLE XVIII—RESEARCH WITH**  
2 **RESPECT TO ACQUIRED IM-**  
3 **MUNE DEFICIENCY SYN-**  
4 **DROME**

5 **SEC. 1801. REVISION AND EXTENSION OF VARIOUS PRO-**  
6 **GRAMS.**

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

9 (1) in section 2304(c)(1)—

10 (A) in the matter preceding subparagraph  
11 (A), by inserting after “Director of such Insti-  
12 tute” the following: “(and may provide advice  
13 to the Directors of other agencies of the Na-  
14 tional Institutes of Health, as appropriate)”;  
15 and

16 (B) in subparagraph (A), by inserting be-  
17 fore the semicolon the following: “, including  
18 recommendations on the projects of research  
19 with respect to diagnosing immune deficiency  
20 and with respect to predicting, diagnosing, pre-  
21 venting, and treating opportunistic cancers and  
22 infectious diseases”;

23 (2) in section 2311(a)(1), by inserting before  
24 the semicolon the following: “, including evaluations  
25 of methods of diagnosing immune deficiency and

1 evaluations of methods of predicting, diagnosing,  
2 preventing, and treating opportunistic cancers and  
3 infectious diseases”;

4 (3) in section 2315—

5 (A) in subsection (a)(2), by striking “inter-  
6 national research” and all that follows and in-  
7 serting “international research and training  
8 concerning the natural history and pathogenesis  
9 of the human immunodeficiency virus and the  
10 development and evaluation of vaccines and  
11 treatments for acquired immune deficiency syn-  
12 drome and opportunistic infections.”; and

13 (B) in subsection (f), by striking “and  
14 1991” and inserting “through 1996”;

15 (4) in section 2318—

16 (A) in subsection (a)(1)—

17 (i) by inserting after “The Secretary”  
18 the following: “, acting through the Direc-  
19 tor of the National Institutes of Health  
20 and after consultation with the Adminis-  
21 trator for Health Care Policy and Re-  
22 search,”; and

23 (ii) by striking “syndrome” and in-  
24 serting “syndrome, including treatment

1 and prevention of HIV infection and relat-  
2 ed conditions among women”; and

3 (B) in subsection (e), by striking “1991.”  
4 and inserting the following: “1991, and such  
5 sums as may be necessary for each of the fiscal  
6 years 1994 through 1996.”;

7 (5) in section 2320(b)(1)(A), by striking “syn-  
8 drome” and inserting “syndrome and the natural  
9 history of such infection”;

10 (6) in the part heading for part D, by striking  
11 “DIRECTOR OF THE NATIONAL INSTITUTES OF  
12 HEALTH” and inserting “OFFICE OF AIDS RE-  
13 SEARCH”;

14 (7) in section 2351—

15 (A) by redesignating subsections (a), (b)  
16 and (c) as subsections (b), (d) and (e), respec-  
17 tively;

18 (B) by striking subsection (a) and insert-  
19 ing the following new subsection:

20 “(a) IN GENERAL.—In carrying out research with re-  
21 spect to acquired immune deficiency syndrome, the Sec-  
22 retary, acting through the Director of the National Insti-  
23 tutes of Health—

1           “(1) shall establish an office to be known as the  
2 Office of AIDS Research, which Office shall be  
3 headed by a Director who shall be—

4           “(A) appointed by the Secretary;

5           “(B) determined by the Secretary to be an  
6 individual who is an outstanding scientist and a  
7 highly skilled administrator; and

8           “(C) the primary Federal official respon-  
9 sible for the conduct of AIDS-related research  
10 at the National Institutes of Health; and

11          “(2) shall provide administrative support and  
12 support services to the Director of such Office.”;

13          (C) in subsection (b) (as so redesign-  
14 nated)—

15               (i) by striking the subsection designa-  
16 tion and all that follows through paragraph  
17 (1) and inserting in lieu thereof the follow-  
18 ing:

19          “(b) ACTIVITIES OF THE OFFICE OF AIDS RE-  
20 SEARCH.—

21               “(1) IN GENERAL.—The Secretary, acting  
22 through the director of the Office of AIDS Research,  
23 shall ensure that AIDS research activities are co-  
24 ordinated across and throughout the institutes, cen-

1       ters, and divisions of the National Institutes of  
2       Health.

3           “(2) GENERAL DUTIES.—The Director of the  
4       Office of AIDS Research shall, based upon a strate-  
5       gic plan as defined in paragraph (3), develop and  
6       implement a budget for AIDS-related research at  
7       the National Institutes of Health and coordinate all  
8       AIDS-related research activities conducted at the in-  
9       stitutes, centers, and divisions of the National Insti-  
10      tutes of Health, and conduct evaluations on all such  
11      programs.

12           “(3) STRATEGIC PLAN.—

13           “(A) DEVELOPMENT.—The Director of the  
14      Office of AIDS Research shall, with the advice  
15      of the directors of the institutes, centers, and  
16      divisions of the National Institutes of Health,  
17      and in consultation with the advisory council es-  
18      tablished in paragraph (5) and the coordinating  
19      groups established in subparagraph (B), de-  
20      velop and implement a comprehensive, long-  
21      range plan for the conduct and support of such  
22      research by the National Institutes of Health.  
23      Such plan shall be updated annually, and  
24      shall—

1           “(i) determine and prioritize among  
2           critical scientific AIDS-related questions;

3           “(ii) based upon such determinations,  
4           specify the range of objectives to be  
5           achieved, the date the objectives are ex-  
6           pected to be achieved, and provide an esti-  
7           mate of the resources needed to achieve  
8           the objectives by such date;

9           “(iii) evaluate the sufficiency of exist-  
10          ing AIDS research programs to meet such  
11          objectives, and establish standard evalua-  
12          tion criteria, timelines and objectives for  
13          future program evaluation activities; and

14          “(iv) make recommendations for  
15          changes and necessary resource allocation  
16          in and among such programs.

17          “(B) COORDINATING GROUPS.—The Direc-  
18          tor of the Office of AIDS Research shall estab-  
19          lish AIDS coordinating groups for each re-  
20          search discipline within the AIDS research pro-  
21          gram, composed of representatives of relevant  
22          agencies of the National Institutes of Health  
23          and qualified extramural scientists, to evaluate  
24          and assess the efforts of the AIDS Research  
25          Program at the National Institutes of Health,



1 to advise on the development of the strategic  
2 plan described in subparagraph (A), and to de-  
3 termine the extent to which such efforts are in  
4 accordance with such strategic plan.

5 “(4) COORDINATION.—The Director of the Of-  
6 fice of AIDS Research shall act as the primary Fed-  
7 eral official with responsibility for overseeing all  
8 AIDS-related research efforts undertaken by the Na-  
9 tional Institutes of Health, and

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

14 “(B) shall maintain communications with  
15 all relevant Public Health Service agencies and  
16 with various other departments of the Federal  
17 Government, to ensure the timely transmission  
18 of information concerning advances in AIDS-re-  
19 lated research and the clinical treatment of  
20 AIDS and its related conditions, to these var-  
21 ious agencies for dissemination to affected com-  
22 munities and health care providers.

23 “(5) ADVISORY COUNCIL.—

24 “(A) ESTABLISHMENT.—The Director of  
25 the Office of AIDS Research shall establish an

1 advisory council to be known as the Office of  
2 AIDS Research Advisory Council (hereafter re-  
3 ferred to as the “Council”), which shall serve to  
4 replace the AIDS Program Advisory Committee  
5 which is operating on the date of enactment of  
6 this subsection.

7 “(B) COMPOSITION.—The Council shall be  
8 composed of biomedical, behavioral, and social  
9 scientists, and representatives of diverse HIV  
10 affected communities, and shall be appointed by  
11 the Director.

12 “(C) AUTHORITY.—The Council shall, con-  
13 sistent with section 406—

14 “(i) advise the Director of the Office  
15 of AIDS Research and make recommenda-  
16 tions concerning the development of the  
17 AIDS-related research budget, and the de-  
18 velopment and implementation of the stra-  
19 tegic plan for AIDS-related research at the  
20 National Institutes of Health;

21 “(ii) provide the second level of peer  
22 review for awards made directly to the Of-  
23 fice of AIDS Research from the discre-  
24 tionary fund described in paragraph (7);  
25 and

1           “(iii) carry out such other activities  
2           determined appropriate by the Director of  
3           the Office of AIDS Research.

4           “(6) BUDGETARY AUTHORITY.—The Director  
5           of the Office of AIDS Research shall—

6           “(A) in consultation with the advisory  
7           council established under paragraph (5) and  
8           based upon budget requests and additional ad-  
9           vice from the directors of the institutes, centers,  
10          and divisions of the National Institutes of  
11          Health, prepare and submit, directly to the  
12          President for review and transmittal to Con-  
13          gress, an annual budget estimate for the AIDS-  
14          related research program conducted within the  
15          agencies of the National Institutes of Health,  
16          after reasonable opportunity for comment (but  
17          without change) by the Secretary and the Di-  
18          rector of the National Institutes of Health;

19          “(B) receive from the President and the  
20          Office of Management and Budget directly all  
21          AIDS-related research funds appropriated by  
22          Congress for obligation and expenditure by the  
23          agencies of the National Institutes of Health in  
24          accordance with the strategic plan developed  
25          under paragraph (3)(A); and

1           “(C) distribute AIDS research funding to  
2 the various institutes, centers, and divisions of  
3 the National Institutes of Health in accordance  
4 with the strategic plan.

5           “(7) DISCRETIONARY FUND.—

6           “(A) AVAILABILITY OF FUNDS.—The Sec-  
7 retary shall ensure that not to exceed 25 per-  
8 cent of the funds available in excess of the  
9 amount of baseline AIDS research spending  
10 during the previous fiscal year, but in no event  
11 less than \$50,000,000 each fiscal year, be made  
12 available to the Director of the Office of AIDS  
13 Research for the establishment of an AIDS re-  
14 search discretionary fund.

15           “(B) USE.—The Director of the Office of  
16 AIDS Research, in consultation with the advi-  
17 sory council established under paragraph (5),  
18 shall use amounts in the AIDS research discre-  
19 tionary fund to—

20                   “(i) fund emergency AIDS research  
21 programs;

22                   “(ii) fund programs for the conduct of  
23 research aimed at filling gaps that exist in  
24 existing research programs;

1           “(iii) conduct conferences, convene  
2           committees, hold meetings or carry out  
3           other activities determined appropriate by  
4           the Director.

5           “(C) REDUCTION IN ADMINISTRATIVE IM-  
6           PEDIMENTS.—Notwithstanding any other provi-  
7           sion of law, with respect to the number of full-  
8           time equivalent individuals employed, the Direc-  
9           tor of the Office of AIDS Research shall be per-  
10          mitted to authorize the employment of such  
11          full-time equivalent individuals to perform  
12          AIDS-related research through the agencies of  
13          the National Institutes of Health.

14          “(c) OTHER DUTIES.—The director of the office—  
15          ”; and

16                 (ii) by redesignating paragraphs (2)  
17                 through (8) (as such paragraphs existed  
18                 one day prior to the date of enactment of  
19                 this Act) as paragraphs (1) through (7),  
20                 respectively; and

21                 (C) in subsection (c) (as added by the  
22                 amendment made by subparagraph (B)) by  
23                 striking “for the appropriate national research  
24                 institute of the National Institutes of Health”

1 in paragraph (4) (as so designated by the  
2 amendments made by subparagraph (B));

3 (8) in section 2361, by striking “For purposes”  
4 and all that follows and inserting the following:

5 “For purposes of this title:

6 “(1) The term ‘infection’, with respect to the  
7 etiologic agent for acquired immune deficiency syn-  
8 drome, includes opportunistic cancers and infectious  
9 diseases and any other conditions arising from infec-  
10 tion with such etiologic agent.

11 “(2) The term ‘treatment’, with respect to the  
12 etiologic agent for acquired immune deficiency syn-  
13 drome, includes primary and secondary prophylaxis.”;

14 (9) in section 2315(f), by striking “there are  
15 authorized” and all that follows and inserting “there  
16 are authorized to be appropriated such sums as may  
17 be necessary for each fiscal year.”;

18 (10) in section 2320(e)(1), by striking “there  
19 are authorized” and all that follows and inserting  
20 “there are authorized to be appropriated such sums  
21 as may be necessary for each fiscal year.”; and

22 (11) in section 2341(d), by striking “there are  
23 authorized” and all that follows and inserting “there  
24

1 are authorized to be appropriated such sums as may  
2 be necessary for each fiscal year.”.

### 3 **TITLE XIX—STUDIES**

#### 4 **SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.**

5 (a) CERTAIN DRUG-RELEASE MECHANISMS.—

6 (1) The Secretary of Health and Human Serv-  
7 ices shall, subject to paragraph (2), enter into a con-  
8 tract with a public or nonprofit private entity to con-  
9 duct a study for the purpose of determining, with re-  
10 spect to acquired immune deficiency syndrome, the  
11 impact of parallel-track drug-release mechanisms on  
12 public and private clinical research, and on the ac-  
13 tivities of the Commissioner of Food and Drugs re-  
14 garding the approval of drugs.

15 (2) The Secretary of Health and Human Serv-  
16 ices shall request the Institute of Medicine of the  
17 National Academy of Sciences to enter into the con-  
18 tract under paragraph (1) to conduct the study de-  
19 scribed in such paragraph. If such Institute declines  
20 to conduct the study, the Secretary shall carry out  
21 paragraph (1) through another public or nonprofit  
22 private entity.

23 (b) THIRD-PARTY PAYMENTS REGARDING CERTAIN  
24 CLINICAL TRIALS.—The Secretary of Health and Human  
25 Services shall conduct a study for the purpose of—

1           (1) determining the policies of third-party  
2 payors regarding the payment of the costs of appro-  
3 priate health services that are provided incident to  
4 the participation of individuals as subjects in clinical  
5 trials conducted in the development of drugs with re-  
6 spect to acquired immune deficiency syndrome; and

7           (2) developing recommendations regarding such  
8 policies.

9           (c) ADVISORY COMMITTEES.—The Secretary of  
10 Health and Human Services, acting through the Director  
11 of the National Institutes of Health, shall conduct a study  
12 for the purpose of determining—

13           (1) whether the activities of the various advi-  
14 sory committees established in the National Insti-  
15 tutes of Health regarding acquired immune defi-  
16 ciency syndrome are being coordinated sufficiently;  
17 and

18           (2) whether the functions of any of such advi-  
19 sory committees should be modified in order to  
20 achieve greater efficiency.

21           (d) VACCINES FOR HUMAN IMMUNODEFICIENCY  
22 VIRUS.—

23           (1) IN GENERAL.—The Secretary of Health and  
24 Human Services, acting through the National Insti-  
25 tutes of Health, shall develop a plan for the appro-



1        appropriate inclusion of HIV-infected women, including  
2        pregnant women, HIV-infected infants, and HIV-in-  
3        fected children in studies conducted by or through  
4        the National Institutes of Health concerning the  
5        safety and efficacy of HIV vaccines for the treat-  
6        ment and prevention of HIV infection. Such plan  
7        shall ensure the full participation of other Federal  
8        agencies currently conducting HIV vaccine studies  
9        and require that such studies conform fully to the  
10       requirements of part 46 of title 45, Code of Federal  
11       Regulations.

12            (2) REPORT.—Not later than 180 days after  
13       the date of the enactment of this Act, the Secretary  
14       of Health and Human Services shall prepare and  
15       submit to the Committee on Energy and Commerce  
16       of the House of Representatives, and the Committee  
17       on Labor and Human Resources of the Senate, a re-  
18       port concerning the plan developed under paragraph  
19       (1).

20            (3) IMPLEMENTATION.—Not later than 12  
21       months after the date of the enactment of this Act,  
22       the Secretary of Health and Human Services shall  
23       implement the plan developed under paragraph (1),  
24       including measures for the full participation of other

1 Federal agencies currently conducting HIV vaccine  
2 studies.

3 (4) For the purpose of carrying out this sub-  
4 section, there are authorized to be appropriated such  
5 sums as may be necessary for each of the fiscal  
6 years 1994 through 1996.

7 **SEC. 1902. MALNUTRITION IN THE ELDERLY.**

8 (a) STUDY.—

9 (1) IN GENERAL.—The Secretary of Health and  
10 Human Services (referred to in this section as the  
11 “Secretary”), acting through the National Institute  
12 on Aging, coordinating with the Agency for Health  
13 Care Policy and Research and, to the degree pos-  
14 sible, in consultation with the head of the National  
15 Nutrition Monitoring System established under sec-  
16 tion 1428 of the Food and Agriculture Act of 1977  
17 (7 U.S.C. 3178), shall conduct a 3-year nutrition  
18 screening and intervention activities study of the el-  
19 derly.

20 (2) EFFICACY AND COST-EFFECTIVENESS OF  
21 NUTRITION SCREENING AND INTERVENTION ACTIVI-  
22 TIES.—In conducting the study, the Secretary shall  
23 determine the efficacy and cost-effectiveness of nu-  
24 trition screening and intervention activities con-  
25 ducted in the elderly health and long-term care con-

1       tinuum, and of a program that would institutionalize  
2       nutrition screening and intervention activities. In  
3       evaluating such a program, the Secretary shall de-  
4       termine—

5               (A) if health or quality of life is measur-  
6               ably improved for elderly individuals who re-  
7               ceive routine nutritional screening and treat-  
8               ment;

9               (B) if federally subsidized home or institu-  
10              tional care is reduced because of increased inde-  
11              pendence of elderly individuals resulting from  
12              improved nutritional status;

13             (C) if a multidisciplinary approach to nu-  
14             tritional care is effective in addressing the nu-  
15             tritional needs of elderly individuals; and

16             (D) if reimbursement for nutrition screen-  
17             ing and intervention activities is a cost-effective  
18             approach to improving the health status of el-  
19             derly individuals.

20       (3) POPULATIONS.—The populations of elderly  
21       individuals in which the study will be conducted  
22       shall include populations of elderly individuals who  
23       are—

24             (A) living independently, including—

1 (i) individuals who receive home and  
2 community-based services or family sup-  
3 port;

4 (ii) individuals who do not receive ad-  
5 ditional services and support;

6 (iii) individuals with low incomes; and

7 (iv) individuals who are minorities;

8 (B) hospitalized, including individuals ad-  
9 mitted from home and from institutions; and

10 (C) institutionalized in residential facilities  
11 such as nursing homes and adult homes.

12 (b) MALNUTRITION STUDY.—The Secretary, acting  
13 through the National Institute on Aging, shall conduct a  
14 3-year study to determine the extent of malnutrition in  
15 elderly individuals in hospitals and long-term care facili-  
16 ties and in elderly individuals who are living independ-  
17 ently.

18 (c) REPORT.—The Secretary shall submit a report to  
19 the Committee on Labor and Human Resources of the  
20 Senate and the Committee on Energy and Commerce of  
21 the House of Representatives containing the findings re-  
22 sulting from the studies described in subsections (a) and  
23 (b), including a determination regarding whether a pro-  
24 gram that would institutionalize nutrition screening and

1 intervention activities should be adopted, and the rationale  
2 for the determination.

3 (d) ADVISORY PANEL.—

4 (1) ESTABLISHMENT.—The Secretary, acting  
5 through the Director of the National Institute on  
6 Aging, shall establish an advisory panel that shall  
7 oversee the design, implementation, and evaluation  
8 of the studies described in subsections (a) and (b).

9 (2) COMPOSITION.—The advisory panel shall in-  
10 clude representatives appointed for the life of the  
11 panel by the Secretary from the Health Care Fi-  
12 nancing Administration, the Social Security Admin-  
13 istration, the National Center for Health Statistics,  
14 the Administration on Aging, the National Council  
15 on the Aging, the American Dietetic Association, the  
16 American Academy of Family Physicians, and such  
17 other agencies or organizations as the Secretary de-  
18 termines to be appropriate.

19 (3) COMPENSATION AND EXPENSES.—

20 (A) COMPENSATION.—Each member of the  
21 advisory panel who is not an employee of the  
22 Federal Government shall receive compensation  
23 for each day engaged in carrying out the duties  
24 of the panel, including time engaged in travel-  
25 ing for purposes of such duties. Such com-

1           pensation may not be provided in an amount in  
2           excess of the maximum rate of basic pay pay-  
3           able for GS-18 of the General Schedule.

4           (B) TRAVEL EXPENSES.—Each member of  
5           the advisory panel shall receive travel expenses,  
6           including per diem in lieu of subsistence, at  
7           rates authorized for employees of agencies  
8           under subchapter I of chapter 57 of title 5,  
9           United States Code, for each day the member  
10          is engaged in the performance of duties away  
11          from the home or regular place of business of  
12          the member.

13          (4) DETAIL OF FEDERAL EMPLOYEES.—On the  
14          request of the advisory panel, the head of any Fed-  
15          eral agency shall detail, without reimbursement, any  
16          of the personnel of the agency to the advisory panel  
17          to assist the advisory panel in carrying out its du-  
18          ties. Any detail shall not interrupt or otherwise af-  
19          fect the civil service status or privileges of the Fed-  
20          eral employee.

21          (5) TECHNICAL ASSISTANCE.—On the request  
22          of the advisory panel, the head of a Federal agency  
23          shall provide such technical assistance to the advi-  
24          sory panel as the advisory panel determines to be  
25          necessary to carry out its duties.



1 on the appropriateness and impact of the National Insti-  
2 tutes of Health assuming responsibility for the conduct of  
3 all Federal research, development, testing, and evaluation  
4 functions relating to medical countermeasures against  
5 biowarfare threat agents. In preparing the report, the Sec-  
6 retary shall identify the extent to which such activities are  
7 carried out by agencies other than the National Institutes  
8 of Health, and assess the impact (positive and negative)  
9 of the National Institutes of Health assuming responsibil-  
10 ity for such activities, including the impact under the  
11 Budget Enforcement Act and the Omnibus Budget Rec-  
12 onciliation Act of 1990 on existing National Institutes of  
13 Health research programs as well as other programs with-  
14 in the category of domestic discretionary spending. The  
15 Secretary shall submit the report not later than 12 months  
16 after the date of the enactment of this Act.

17 **SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETEN-**  
18 **TION AND TURNOVER.**

19 (a) STUDY OF PERSONNEL SYSTEM.—Not later than  
20 1 year after the date of the enactment of this Act, the  
21 Secretary of Health and Human Services, acting through  
22 the Director of the National Institutes of Health, shall  
23 conduct a study to review the retention, recruitment, va-  
24 cancy and turnover rates of support staff, including fire-  
25 fighters, law enforcement, procurement officers, techni-



1 cians, nurses and clerical employees, to ensure that the  
2 National Institutes of Health is adequately supporting the  
3 conduct of efficient, effective and high quality research for  
4 the American public. The Director of NIH shall work in  
5 conjunction with appropriate employee organizations and  
6 representatives in developing such a study.

7 (b) SUBMISSION TO CONGRESS.—Not later than 1  
8 year after the date of the enactment of this Act, the Sec-  
9 retary of Health and Human Services shall prepare and  
10 submit to the Committee on Energy and Commerce of the  
11 House of Representatives, and to the Committee on Labor  
12 and Human Resources of the Senate, a report containing  
13 the study conducted under subsection (a) together with  
14 the recommendations of the Secretary concerning the en-  
15 actment of legislation to implement the results of such  
16 study.

17 **SEC. 1906. PROCUREMENT.**

18 (a) IN GENERAL.—The Director of the National In-  
19 stitutes of Health and the Administrator of the General  
20 Services Administration shall jointly conduct a study to  
21 develop a streamlined procurement system for the Na-  
22 tional Institutes of Health that complies with the require-  
23 ments of Federal law.

24 (b) REPORT.—Not later than March 1, 1994, the of-  
25 ficials specified in subsection (a) shall complete the study

1 required in such subsection and shall submit to the Com-  
2 mittee on Energy and Commerce of the House of Rep-  
3 resentatives, and the Committee on Labor and Human Re-  
4 sources of the Senate, a report describing the findings  
5 made as a result of the study.

6 **SEC. 1907. REPORT CONCERNING LEADING CAUSES OF**  
7 **DEATH.**

8 (a) REPORT.—The Secretary of Health and Human  
9 Services shall, not later than February 1, 1993, prepare  
10 a report that lists—

11 (1) the 20 illnesses that, in terms of mortality,  
12 number of years of expected life lost, and of number  
13 of preventable years of life lost, are the leading  
14 causes of death in the United States and the number  
15 of deaths from each such cause, the age-specific and  
16 age-adjusted death rates for each such cause, the  
17 death rate per 100,000 population for each such  
18 cause, the percentage of change in cause specific  
19 death rates for each age group, and the percentage  
20 of total deaths for each such cause;

21 (2) the amount expended by the Department of  
22 Health and Human Services for research, preven-  
23 tion, and education with respect to each of the 20  
24 illnesses described in paragraph (1) for the most re-

1 cent year for which the actual expenditures are  
2 known;

3 (3) an estimate by the Secretary of the amount  
4 to be expended on research, prevention, and edu-  
5 cation with respect to each of the 20 illnesses de-  
6 scribed in paragraph (1) for the year for which the  
7 report is prepared; and

8 (4) with respect to the years specified in para-  
9 graphs (2) and (3), the percentage of the total of  
10 the annual expenditures for research, prevention,  
11 and education on the 20 illnesses described in para-  
12 graph (1) that are attributable to each illness.

13 (b) SUBMISSION TO CONGRESS.—The Secretary of  
14 Health and Human Services shall submit the report re-  
15 quired under subsection (a), together with relevant budget  
16 information, to the Committee on Energy and Commerce  
17 and the Committee on Appropriations of the House of  
18 Representatives and the Committee on Labor and Human  
19 Resources and the Committee on Appropriations of the  
20 Senate.

21 **SEC. 1908. RELATIONSHIP BETWEEN THE CONSUMPTION**  
22 **OF LEGAL AND ILLEGAL DRUGS.**

23 (a) IN GENERAL.—The Secretary of Health and  
24 Human Services, acting through the Commissioner of  
25 Food and Drugs, shall review and consider all existing rel-

1 evant data and research concerning whether there is a re-  
2 lationship between an individual's receptivity to use or  
3 consume legal drugs and the consumption or abuse by the  
4 individual of illegal drugs. On the basis of such review,  
5 the Secretary shall determine whether additional research  
6 is necessary. If the Secretary determines additional re-  
7 search is required, the Secretary shall conduct a study of  
8 those subjects where the Secretary's review indicates addi-  
9 tional research is needed, including, if necessary, a review  
10 of—

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

14           (2) the correlation of legal drug abuse with ille-  
15           gal drug abuse; and

16           (3) other matters that the Secretary determines  
17           appropriate.

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

1 of this Act, the Secretary shall prepare and submit, to the  
2 Committee on Energy and Commerce of the House of  
3 Representatives and Committee on Labor and Human Re-  
4 sources of the Senate, a report containing the results of  
5 the additional research conducted under subsection (b).

6       **TITLE XX—MISCELLANEOUS**  
7                                   **PROVISIONS**

8 **SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RE-**  
9                                   **SEARCH SERVICE IN HONOR OF SILVIO O.**  
10                                   **CONTE, AND LIMITATION ON NUMBER OF**  
11                                   **MEMBERS.**

12       (a) IN GENERAL.—Section 228(a) of the Public  
13 Health Service Act (42 U.S.C. 237(a)), as added by sec-  
14 tion 304 of Public Law 101–509, is amended to read as  
15 follows:

16       “(a)(1) There shall be in the Public Health Service  
17 a Silvio O. Conte Senior Biomedical Research Service, not  
18 to exceed 750 members.

19       “(2) The authority established in paragraph (1) re-  
20 garding the number of members in the Silvio O. Conte  
21 Senior Biomedical Research Service is in addition to any  
22 authority established regarding the number of members  
23 in the commissioned Regular Corps, in the Reserve Corps,  
24 and in the Senior Executive Service. Such paragraph may  
25 not be construed to require that the number of members

1 in the commissioned Regular Corps, in the Reserve Corps,  
2 or in the Senior Executive Service be reduced to offset  
3 the number of members serving in the Silvio O. Conte Sen-  
4 ior Biomedical Research Service (hereafter in this section  
5 referred to as the ‘Service’).”.

6 (b) CONFORMING AMENDMENT.—Section 228 of the  
7 Public Health Service Act (42 U.S.C. 237), as added by  
8 section 304 of Public Law 101–509, is amended in the  
9 heading for the section by amending the heading to read  
10 as follows:

11 “SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH  
12 SERVICE”.

13 **SEC. 2002. TECHNICAL CORRECTIONS.**

14 (a) TITLE III.—Subsection (c) of section 316 of the  
15 Public Health Service Act (42 U.S.C. 247a(c)) is repealed.

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

18 (1) in section 406—

19 (A) in subsection (b)(2)(A), by striking  
20 “Veterans’ Administration” each place such  
21 term appears and inserting “Department of  
22 Veterans Affairs”; and

23 (B) in subsection (h)(2)(A)(v), by striking  
24 “Veterans’ Administration” and inserting “De-  
25 partment of Veterans Affairs”;

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

2  
3  
4  
5 (3) in section 421(b)(1), by inserting a comma after “may”;

6  
7 (4) in section 428(b), in the matter preceding paragraph (1), by striking “the the” and inserting “the”;

8  
9  
10 (5) in section 430(b)(2)(A)(i), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

11  
12  
13 (6) in section 439(b), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

14  
15  
16 (7) in section 442(b)(2)(A), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

17  
18  
19 (8) in section 464D(b)(2)(A), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

20  
21  
22 (9) in section 464E—

23 (A) in subsection (d), in the first sentence,  
24 by inserting “Coordinating” before “Committee”;  
25 and

1 (B) in subsection (e), by inserting “Coordi-  
2 nating” before “Committee” the first place  
3 such term appears;

4 (10) in section 464P(b)(6) (as added by section  
5 123 of Public Law 102-321 (106 Stat. 362)), by  
6 striking “Administration” and inserting “Institute”;

7 (11) in section 466(a)(1)(B), by striking “Vet-  
8 erans’ Administration” and inserting “Department  
9 of Veterans Affairs”;

10 (12) in section 480(b)(2)(A), by striking “Vet-  
11 erans’ Administration” and inserting “Department  
12 of Veterans Affairs”;

13 (13) in section 485(b)(2)(A), by striking “Vet-  
14 erans’ Administration” and inserting “Department  
15 of Veterans Affairs”;

16 (14) in section 487(d)(3), by striking “section  
17 304(a)(3)” and inserting “section 304(a)”; and

18 (15) in section 496(a), by striking “Such ap-  
19 propriations,” and inserting the following: “Appro-  
20 priations to carry out the purposes of this title,”.

21 (c) TITLE XXIII.—Part A of title XXIII of the Pub-  
22 lic Health Service Act (42 U.S.C. 300cc et seq.) is amend-  
23 ed—

24 (1) in section 2304—



1 (A) in the heading for the section, by strik-  
2 ing “**CLINICAL RESEARCH REVIEW COM-**  
3 **MITTEE**” and inserting “**RESEARCH ADVI-**  
4 **SORY COMMITTEE**”; and

5 (B) in subsection (a), by striking “AIDS  
6 Clinical Research Review Committee” and in-  
7 serting “AIDS Research Advisory Committee”;

8 (2) in section 2312(a)(2)(A), by striking “AIDS  
9 Clinical Research Review Committee” and inserting  
10 “AIDS Research Advisory Committee”;

11 (3) in section 2314(a)(1), in the matter preced-  
12 ing subparagraph (A), by striking “Clinical Research  
13 Review Committee” and inserting “AIDS Research  
14 Advisory Committee”;

15 (4) in section 2317(d)(1), by striking “Clinical  
16 Research Review Committee” and inserting “AIDS  
17 Research Advisory Committee established under sec-  
18 tion 2304”; and

19 (5) in section 2318(b)(3), by striking “Clinical  
20 Research Review Committee” and inserting “AIDS  
21 Research Advisory Committee”.

22 (d) SECRETARY.—Section 2(c) of the Public Health  
23 Service Act (42 U.S.C. 201(c)) is amended by striking  
24 “Health, Education, and Welfare” and inserting “Health  
25 and Human Services”.

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

3 (1) by striking “Health, Education, and Wel-  
4 fare” and inserting “Health and Human Services”;  
5 and

6 (2) by striking “Surgeon General” and insert-  
7 ing “Assistant Secretary for Health”.

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

10 (1) by striking “Health, Education, and Wel-  
11 fare” and inserting “Health and Human Services”;

12 (2) by striking “Surgeon General” the second  
13 and subsequent times that such term appears and  
14 inserting “Secretary”; and

15 (3) by inserting “, and the Agency for Health  
16 Care Policy and Research” before the first period.

17 (g) VOLUNTEER SERVICES.—Section 223 of the Pub-  
18 lic Health Service Act (42 U.S.C. 217b) is amended by  
19 striking “Health, Education, and Welfare” and inserting  
20 “Health and Human Services”.

21 **SEC. 2003. BIENNIAL REPORT ON CARCINOGENS.**

22 Section 301(b)(4) of the Public Health Service Act  
23 (42 U.S.C. 241(b)(4)) is amended by striking “an annual”  
24 and inserting in lieu thereof “a biennial”.

1 **SEC. 2004. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE**  
2 **FOR RESEARCH.**

3 Not later than 90 days after the date of the enact-  
4 ment of this Act, the Secretary of Health and Human  
5 Services, acting through the Director of the National In-  
6 stitutes of Health, shall present to the Congress a master  
7 plan to provide for the replacement or refurbishment of  
8 less than adequate buildings, utility equipment and dis-  
9 tribution systems (including the resources that provide  
10 electrical and other utilities, chilled water, air handling,  
11 and other services that the Secretary, acting through the  
12 Director, deems necessary), roads, walkways, parking  
13 areas, and grounds that underpin the laboratory and clini-  
14 cal facilities of the National Institutes of Health. Such  
15 plan may make recommendations for the undertaking of  
16 new projects that are consistent with the objectives of this  
17 section, such as encircling the National Institutes of  
18 Health Federal enclave with an adequate chilled water  
19 conduit.

20 **SEC. 2005. TRANSFER OF PROVISIONS OF TITLE XXVII.**

21 (a) IN GENERAL.—The Public Health Service Act  
22 (42 U.S.C. 201 et seq.), as amended by section 101 of  
23 Public Law 101–381 and section 304 of Public Law 101–  
24 509, is amended—

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

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

3           (3) by inserting such sections, in the appro-  
4           priate sequence, after section 228;

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

7           “PART A—ADMINISTRATION”; and

8           (5) by inserting before section 231 (as redesign-  
9           ated by paragraph (2) of this subsection) the fol-  
10          lowing new heading:

11          “Part B—Miscellaneous Provisions”.

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

14           (1) in the heading for title II, by inserting  
15           “AND MISCELLANEOUS PROVISIONS” after  
16           “ADMINISTRATION”;

17           (2) in section 406(a)(2), by striking “2701”  
18           and inserting “231”;

19           (3) in section 465(f), by striking “2701” and  
20           inserting “231”;

21           (4) in section 480(a)(2), by striking “2701”  
22           and inserting “231”;

23           (5) in section 485(a)(2), by striking “2701”  
24           and inserting “231”;

1           (6) in section 497, by striking “2701” and in-  
2           serting “231”;

3           (7) in section 505(a)(2), by striking “2701”  
4           and inserting “231”;

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

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

9   **SEC. 2006. CERTAIN AUTHORIZATION OF APPROPRIATIONS.**

10          Section 399L(a) of the Public Health Service Act (42  
11   U.S.C. 280e-4(a)), as added by Public Law 102-515 (106  
12   Stat. 3376), is amended—

13           (1) in the first sentence, by striking “the Sec-  
14           retary” and all that follows and inserting the follow-  
15           ing: “there are authorized to be appropriated  
16           \$30,000,000 for fiscal year 1994, and such sums as  
17           may be necessary for each of the fiscal years 1995  
18           through 1997.”; and

19           (2) in the second sentence, by striking “Out of  
20           any amounts used” and inserting “Of the amounts  
21           appropriated under the preceding sentence”.

1 **SEC. 2007. PROHIBITION AGAINST SHARP ADULT SEX SUR-**  
2 **VEY AND THE AMERICAN TEENAGE SEX SUR-**  
3 **VEY.**

4 The Secretary of Health and Human Services may  
5 not during fiscal year 1993 or any subsequent fiscal year  
6 conduct or support the SHARP survey of adult sexual be-  
7 havior or the American Teenage Study of adolescent sex-  
8 ual behavior. This section becomes effective April 15,  
9 1993.

10 **SEC. 2008. SUPPORT FOR BIOENGINEERING RESEARCH.**

11 (a) STUDY.—The Secretary of Health and Human  
12 Services, acting through the Director of the National In-  
13 stitutes of Health, shall conduct a study for the purpose  
14 of—

15 (1) determining the sources and amounts of  
16 public and private funding devoted to basic research  
17 in bioengineering and biomaterials sciences;

18 (2) evaluating whether that commitment is suf-  
19 ficient to maintain the innovative edge that the  
20 United States has in these technologies; and

21 (3) evaluating the need to modify the structure  
22 of the National Institutes of Health or any other  
23 Federal agency to achieve a greater commitment to  
24 innovation in bioengineering, and evaluating the  
25 need for better coordination and collaboration among

1 Federal agencies and between the public and private  
2 sectors.

3 In conducting such study, the Director shall work in con-  
4 junction with appropriate organizations and representa-  
5 tives including academics, industry leaders, bioengineering  
6 societies, and public agencies (such as the National  
7 Science Foundation, Veterans Administration, Depart-  
8 ment of Defense, National Aeronautics and Space Admin-  
9 istration, and the White House Office of Science and  
10 Technology Policy).

11 (b) REPORT.—Not later than 1 year after the date  
12 of enactment of this Act, the Secretary of Health and  
13 Human Services shall prepare and submit to the Commit-  
14 tee on Labor and Human Resources of the Senate, and  
15 the Committee on Energy and Commerce of the House  
16 of Representatives, a report containing the findings of the  
17 study conducted under subsection (a) together with rec-  
18 ommendations concerning the enactment of legislation to  
19 implement the results of such study.

## 20 **TITLE XXI—EFFECTIVE DATES**

### 21 **SEC. 2101. EFFECTIVE DATES.**

22 Subject to section 155, this Act and the amendments  
23 made by this Act take effect upon the date of the enact-  
24 ment of this Act.



S 1 IS—2

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