

103D CONGRESS
1ST SESSION

S. 1

AN ACT

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

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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”.

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

Sec. 1. Short title; table of contents.

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

Subtitle A—Research Freedom

PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL
RESEARCH

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

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

Sec. 111. Establishment of authorities.

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

Sec. 113. Report by General Accounting Office on adequacy of requirements.

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

Sec. 131. Requirement of inclusion in research.

Sec. 132. Peer review.

Sec. 133. Applicability to current projects.

PART II—OFFICE OF RESEARCH ON WOMEN’S HEALTH

Sec. 141. Establishment.

PART III—OFFICE OF RESEARCH ON MINORITY HEALTH

Sec. 151. Establishment.

Subtitle C—Scientific Integrity

Sec. 161. Establishment of Office of Scientific Integrity.

Sec. 162. Commission on Scientific Integrity.

Sec. 163. Protection of whistleblowers.

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TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

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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.
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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 bone 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 Research.
- 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.

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Sec. 1031. Prospective longitudinal study.

TITLE XI—NATIONAL EYE INSTITUTE

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TITLE XX—MISCELLANEOUS PROVISIONS

- Sec. 2001. Designation of Senior Biomedical Research Service in honor of Silvio O. Conte, and limitation on number of members.
- Sec. 2002. Technical corrections.
- Sec. 2003. Technical corrections with respect to the Agency for Health Care Policy and Research.
- Sec. 2004. Technical corrections with respect to the Health Professions Education Extension Amendments of 1992.
- Sec. 2005. Biennial report on carcinogens.
- Sec. 2006. Master plan for physical infrastructure for research.
- Sec. 2007. Transfer of provisions of title XXVII.
- Sec. 2008. Certain authorization of appropriations.
- Sec. 2009. Prohibition against SHARP adult sex survey and the American teenage sex survey.
- Sec. 2010. Support for bioengineering research.
- Sec. 2011. Admission to the United States of aliens infected with the AIDS virus.
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- 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:

1 “CERTAIN PROVISIONS REGARDING REVIEW AND
2 APPROVAL OF PROPOSALS FOR RESEARCH

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

5 “(1) PROTECTION OF HUMAN RESEARCH SUB-
6 JECTS.—

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

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

1 “(2) PEER REVIEW.—In the case of any appli-
2 cation submitted to the Secretary for financial as-
3 sistance to conduct research, the Secretary may not
4 approve or fund any application that is subject to
5 technical and scientific peer review under section
6 492(a) unless the application has undergone peer re-
7 view in accordance with such section and has been
8 recommended for approval by a majority of the
9 members of the entity conducting such review.

10 “(b) ETHICAL REVIEW OF RESEARCH.—

11 “(1) PROCEDURES REGARDING WITHHOLDING
12 OF FUNDS.—If research has been recommended for
13 approval for purposes of subsection (a), the Sec-
14 retary may not withhold funding for the research on
15 ethical grounds unless—

16 “(A) the Secretary convenes an advisory
17 board in accordance with paragraph (4) to
18 study the ethical implications of the research;
19 and

20 “(B)(i) the majority of the advisory board
21 recommends that, on ethical grounds, the Sec-
22 retary withhold funds for the research; or

23 “(ii) the majority of such board rec-
24 ommends that the Secretary not withhold funds
25 for the research on ethical grounds, but the

1 Secretary finds, on the basis of the report sub-
2 mitted under paragraph (4)(B)(ii), that there is
3 a reasonable basis for overruling the board's
4 recommendations.

5 “(2) APPLICABILITY.—The limitation estab-
6 lished in paragraph (1) regarding the authority to
7 withhold funds on ethical grounds shall apply with-
8 out regard to whether the withholding such funds is
9 characterized as a disapproval, a moratorium, a pro-
10 hibition, or other description.

11 “(3) PRELIMINARY MATTERS REGARDING USE
12 OF PROCEDURES.—

13 “(A) If the Secretary makes a determina-
14 tion that an advisory board should be convened
15 for purposes of paragraph (1), the Secretary
16 shall, through a statement published in the
17 Federal Register, announce the intention of the
18 Secretary to convene such a board.

19 “(B) A statement issued under subpara-
20 graph (A) shall include a request that inter-
21 ested individuals submit to the Secretary rec-
22 ommendations specifying the particular individ-
23 uals who should be appointed to the advisory
24 board involved. The President shall consider

1 such recommendations in making appointments
2 to the board.

3 “(C) The President may not make appoint-
4 ments to an advisory board under paragraph
5 (1) until the expiration of the 30-day period be-
6 ginning on the date on which the statement re-
7 quired in subparagraph (A) is made with re-
8 spect to the board.

9 “(4) ETHICS ADVISORY BOARDS.—

10 “(A) Any advisory board convened for pur-
11 poses of paragraph (1) shall be known as an
12 ethics advisory board (hereafter in this para-
13 graph referred to as an ‘ethics board’).

14 “(B)(i) An ethics board shall advise, con-
15 sult with, and make recommendations to the
16 Secretary regarding the ethics of the project of
17 biomedical or behavioral research with respect
18 to which the board has been convened.

19 “(ii) Not later than 180 days after the
20 date on which the statement required in para-
21 graph (3)(A) is made with respect to an ethics
22 board, the board shall submit to the Secretary,
23 and to the Committee on Energy and Com-
24 merce of the House of Representatives and the
25 Committee on Labor and Human Resources of

1 the Senate, a report describing the findings of
2 the board regarding the project of research in-
3 volved and making a recommendation under
4 clause (i) of whether the Secretary should or
5 should not withhold funds for the project. The
6 report shall include the information considered
7 in making the findings.

8 “(C) An ethics board shall be composed of
9 no fewer than 14, and no more than 20, indi-
10 viduals who are not officers or employees of the
11 United States. The President shall make ap-
12 pointments to the board from among individ-
13 uals with special qualifications and competence
14 to provide advice and recommendations regard-
15 ing ethical matters in biomedical and behavioral
16 research. Of the members of the board—

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

19 “(ii) no fewer than 1 shall be an
20 ethicist;

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

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

1 “(v) no fewer than one-third, and no
2 more than one-half, shall be scientists with
3 substantial accomplishments in biomedical
4 or behavioral research.

5 “(D) The term of service as a member of
6 an ethics board shall be for the life of the
7 board. If such a member does not serve the full
8 term of such service, the individual appointed to
9 fill the resulting vacancy shall be appointed for
10 the remainder of the term of the predecessor of
11 the individual.

12 “(E) A member of an ethics board shall be
13 subject to removal from the board by the Presi-
14 dent for neglect of duty or malfeasance or for
15 other good cause shown.

16 “(F) The President shall designate an in-
17 dividual from among the members of an ethics
18 board to serve as the chair of the board.

19 “(G) In carrying out subparagraph (B)(i)
20 with respect to a project of research, an ethics
21 board shall conduct inquiries and hold public
22 hearings.

23 “(H) With respect to information relevant
24 to the duties described in subparagraph (B)(i),
25 an ethics board shall have access to all such in-

1 formation possessed by the Department of
2 Health and Human Services, or available to the
3 Secretary from other agencies.

4 “(I) Members of an ethics board shall re-
5 ceive compensation for each day engaged in car-
6 rying out the duties of the board, including
7 time engaged in traveling for purposes of such
8 duties. Such compensation may not be provided
9 in an amount in excess of the maximum rate of
10 basic pay payable for GS-18 of the General
11 Schedule.

12 “(J) The Secretary, acting through the Di-
13 rector of the National Institutes of Health,
14 shall provide to each ethics board such reason-
15 able staff and assistance as may be necessary to
16 carry out the duties of the board.

17 “(K) An ethics board shall terminate 30
18 days after the date on which the report required
19 in subparagraph (B)(ii) is submitted to the Sec-
20 retary and the congressional committees speci-
21 fied in such subparagraph.”.

1 **PART II—RESEARCH ON TRANSPLANTATION OF**
2 **FETAL TISSUE**

3 **SEC. 111. ESTABLISHMENT OF AUTHORITIES.**

4 Part G of title IV of the Public Health Service Act
5 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
6 tion 498 the following new section:

7 “RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

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

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

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

17 “(b) INFORMED CONSENT OF DONOR.—

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

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

25 “(B) the donation is made without any re-
26 striction regarding the identity of individuals

1 who may be the recipients of transplantations
2 of the tissue; and

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

5 “(2) ADDITIONAL STATEMENT.—In research
6 carried out under subsection (a), human fetal tissue
7 may be used only if the attending physician with re-
8 spect to obtaining the tissue from the woman in-
9 volved makes a statement, made in writing and
10 signed by the physician, declaring that—

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

13 “(i) the consent of the woman for the
14 abortion was obtained prior to requesting
15 or obtaining consent for the tissue to be
16 used in such research; and

17 “(ii) no alteration of the timing,
18 method, or procedures used to terminate
19 the pregnancy was made solely for the pur-
20 poses of obtaining the tissue;

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

23 “(C) full disclosure has been provided to
24 the woman with regard to—

1 “(i) such physician’s interest, if any,
2 in the research to be conducted with the
3 tissue; and

4 “(ii) any known medical risks to the
5 woman or risks to her privacy that might
6 be associated with the donation of the tis-
7 sue and that are in addition to risks of
8 such type that are associated with the
9 woman’s medical care.

10 “(c) INFORMED CONSENT OF RESEARCHER AND
11 DONEE.—In research carried out under subsection (a),
12 human fetal tissue may be used only if the individual with
13 the principal responsibility for conducting the research in-
14 volved makes a statement, made in writing and signed by
15 the individual, declaring that the individual—

16 “(1) is aware that—

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

18 “(B) the tissue may have been obtained
19 pursuant to a spontaneous or induced abortion
20 or subsequent to a stillbirth; and

21 “(C) the tissue was donated for research
22 purposes;

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

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

5 “(4) has had no part in any decisions as to the
6 timing, method, or procedures used to terminate the
7 pregnancy made solely for the purposes of the re-
8 search.

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

10 “(1) IN GENERAL.—In research carried out
11 under subsection (a), human fetal tissue may be
12 used only if the head of the agency or other entity
13 conducting the research involved certifies to the Sec-
14 retary that the statements required under sub-
15 sections (b)(1), (b)(2), and (c) will be available for
16 audit by the Secretary.

17 “(2) CONFIDENTIALITY OF AUDIT.—Any audit
18 conducted by the Secretary pursuant to paragraph
19 (1) shall be conducted in a confidential manner to
20 protect the privacy rights of the individuals and enti-
21 ties involved in such research, including such indi-
22 viduals and entities involved in the donation, trans-
23 fer, receipt, or transplantation of human fetal tissue.
24 With respect to any material or information obtained
25 pursuant to such audit, the Secretary shall—

1 “(A) use such material or information only
2 for the purposes of verifying compliance with
3 the requirements of this section;

4 “(B) not disclose or publish such material
5 or information, except where required by Fed-
6 eral law, in which case such material or infor-
7 mation shall be coded in a manner such that
8 the identities of such individuals and entities
9 are protected; and

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

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

14 “(1) RESEARCH CONDUCTED BY RECIPIENTS
15 OF ASSISTANCE.—The Secretary may not provide
16 support for research under subsection (a) unless the
17 applicant agrees to conduct the research in accord-
18 ance with applicable State and local law.

19 “(2) RESEARCH CONDUCTED BY SECRETARY.—
20 The Secretary may conduct research under sub-
21 section (a) only in accordance with applicable State
22 and local law.

23 “(f) DEFINITION.—For purposes of this section, the
24 term ‘human fetal tissue’ means tissue or cells obtained

1 from a dead human embryo or fetus after a spontaneous
 2 or induced abortion, or after a stillbirth.”.

3 **SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITA-**
 4 **TION OR ACCEPTANCE OF TISSUE AS DI-**
 5 **RECTED DONATION FOR USE IN TRANSPLAN-**
 6 **TATION.**

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

10 “PROHIBITIONS REGARDING HUMAN FETAL TISSUE

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

15 “(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS
 16 DIRECTED DONATION FOR USE IN TRANSPLANTATION.—
 17 It shall be unlawful for any person to solicit or knowingly
 18 acquire, receive, or accept a donation of human fetal tissue
 19 for the purpose of transplantation of such tissue into an-
 20 other person if the donation affects interstate commerce,
 21 the tissue will be or is obtained pursuant to an induced
 22 abortion, and—

23 “(1) the donation will be or is made pursuant
 24 to a promise to the donating individual that the do-
 25 nated tissue will be transplanted into a recipient
 26 specified by such individual;

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

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

7 “(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

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

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

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

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

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

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

6 **SEC. 113. REPORT BY GENERAL ACCOUNTING OFFICE ON**
7 **ADEQUACY OF REQUIREMENTS.**

8 (a) IN GENERAL.—With respect to research on the
9 transplantation of human fetal tissue for therapeutic pur-
10 poses, the Comptroller General of the United States shall
11 conduct an audit for the purpose of determining—

12 (1) whether and to what extent such research
13 conducted or supported by the Secretary of Health
14 and Human Services has been conducted in accord-
15 ance with section 498A of the Public Health Service
16 Act (as added by section 111 of this Act); and

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

20 (b) REPORT.—Not later than May 19, 1995, the
21 Comptroller General of the United States shall complete
22 the audit required in subsection (a) and submit to the
23 Committee on Energy and Commerce of the House of
24 Representatives, and to the Committee on Labor and

1 Human Resources of the Senate, a report describing the
2 findings made pursuant to the audit.

3 **PART III—MISCELLANEOUS REPEALS**

4 **SEC. 121. REPEALS.**

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

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

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

12 and

13 (2) by striking section 499; and

14 (3) by redesignating section 499A as section
15 499.

16 (c) NULLIFICATION OF CERTAIN REGULATION.—The
17 provisions of section 204(d) of part 46 of title 45 of the
18 Code of Federal Regulations (45 CFR 46.204(d)) shall
19 not have any legal effect.

1 **Subtitle B—Clinical Research Eq-**
2 **uity Regarding Women and Mi-**
3 **norities**

4 **PART I—WOMEN AND MINORITIES AS SUBJECTS**
5 **IN CLINICAL RESEARCH**

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

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

10 “INCLUSION OF WOMEN AND MINORITIES IN CLINICAL
11 RESEARCH

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

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

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

19 “(b) The requirement established in subsection (a)
20 regarding women and members of minority groups shall
21 not apply to a project of clinical research if the inclusion,
22 as subjects in the project, of women and members of mi-
23 nority groups, respectively—

24 “(1) is inappropriate with respect to the health
25 of the subjects;

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

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

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

14 “(d)(1) The Director of NIH, in consultation with the
15 Director of the Office of Research on Women’s Health and
16 the Director of the Office of Research on Minority Health,
17 shall establish guidelines regarding—

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

22 “(B) the manner in which such projects are re-
23 quired to be designed and carried out for purposes
24 of subsection (c), including a specification of the cir-
25 cumstances in which the requirement of such sub-

1 section does not apply on the basis of impracticabil-
2 ity; and

3 “(C) the conduct of outreach programs for the
4 recruitment of women and members of minority
5 groups as subjects in such research.

6 “(2) The guidelines established under paragraph
7 (1)—

8 “(A) may not provide that the cost of including
9 women and minorities in clinical research is a per-
10 missible consideration regarding the circumstances
11 described in subparagraph (A) of such paragraph;
12 and

13 “(B) may provide that such circumstances in-
14 clude circumstances in which there are scientific rea-
15 sons for believing that the variables proposed to be
16 studied do not affect women or minorities differently
17 than other subjects in the research.

18 “(3) The guidelines required in paragraph (1) shall
19 be established and published in the Federal Register not
20 later than 180 days after the date of the enactment of
21 the National Institutes of Health Revitalization Act of
22 1993.

23 “(4) For fiscal year 1994 and subsequent fiscal years,
24 the Director of NIH may not provide funding for any
25 project of clinical research to be conducted or supported

1 by any agency of the National Institutes of Health unless
2 the project specifies the manner in which the research will
3 comply with subsection (a).

4 “(e) The advisory council of each national research
5 institute shall annually submit to the Director of NIH and
6 the Director of the institute involved a report describing
7 the manner in which the agency has complied with sub-
8 section (a).”.

9 **SEC. 132. PEER REVIEW.**

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

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

20 “(2) Paragraph (1) shall not apply to any proposed
21 project for clinical research that, pursuant to subsection
22 (b) of section 492B, is not subject to the requirement of
23 subsection (a) of such section regarding the inclusion of
24 women and members of minority groups as subjects in
25 clinical research.”.

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

2 Section 492B of the Public Health Service Act, as
3 added by section 131 of this Act, shall not apply with re-
4 spect to projects of clinical research for which initial fund-
5 ing was provided prior to the date of the enactment of
6 this Act. With respect to the inclusion of women and mi-
7 norities as subjects in clinical research conducted or sup-
8 ported by the National Institutes of Health, any policies
9 of the Secretary of Health and Human Services regarding
10 such inclusion that are in effect on the day before the date
11 of the enactment of this Act shall continue to apply to
12 the projects referred to in the preceding sentence.

13 **PART II—OFFICE OF RESEARCH ON WOMEN'S**
14 **HEALTH**

15 **SEC. 141. ESTABLISHMENT.**

16 (a) IN GENERAL.—Title IV of the Public Health
17 Service Act, as amended by section 2 of Public Law 101-
18 613, is amended—

19 (1) by redesignating section 486 as section
20 485A;

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

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

1 “PART F—RESEARCH ON WOMEN’S HEALTH

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

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

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

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

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

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

18 “(4) promote coordination and collaboration
19 among entities conducting research identified under
20 any of paragraphs (1) through (3);

21 “(5) encourage the conduct of such research by
22 entities receiving funds from the national research
23 institutes;

24 “(6) recommend an agenda for conducting and
25 supporting such research;

1 “(7) promote the sufficient allocation of the re-
2 sources of the national research institutes for con-
3 ducting and supporting such research;

4 “(8) assist in the administration of section
5 492B with respect to the inclusion of women as sub-
6 jects in clinical research; and

7 “(9) prepare the report required in section
8 486B.

9 “(c) COORDINATING COMMITTEE.—

10 “(1) In carrying out subsection (b), the Direc-
11 tor of the Office shall establish a committee to be
12 known as the Coordinating Committee on Research
13 on Women’s Health (hereafter in this subsection re-
14 ferred to as the ‘Coordinating Committee’).

15 “(2) The Coordinating Committee shall be com-
16 posed of the Directors of the national research insti-
17 tutes (or the designees of the Directors) and other
18 appropriate entities.

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

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

24 “(A) identifying the need for such re-
25 search, and making an estimate each fiscal year

1 of the funds needed to adequately support the
2 research;

3 “(B) identifying needs regarding the co-
4 ordination of research activities, including in-
5 tramural and extramural multidisciplinary ac-
6 tivities;

7 “(C) supporting the development of meth-
8 odologies to determine the circumstances in
9 which obtaining data specific to women (includ-
10 ing data relating to the age of women and the
11 membership of women in ethnic or racial
12 groups) is an appropriate function of clinical
13 trials of treatments and therapies;

14 “(D) supporting the development and ex-
15 pansion of clinical trials of treatments and
16 therapies for which obtaining such data has
17 been determined to be an appropriate function;
18 and

19 “(E) encouraging the national research in-
20 stitutes to conduct and support such research,
21 including such clinical trials.

22 “(d) ADVISORY COMMITTEE.—

23 “(1) In carrying out subsection (b), the Direc-
24 tor of the Office shall establish an advisory commit-
25 tee to be known as the Advisory Committee on Re-

1 search on Women’s Health (hereafter in this sub-
2 section referred to as the ‘Advisory Committee’).

3 “(2)(A) The Advisory Committee shall be com-
4 posed of no fewer than 12, and not more than 18
5 individuals, who are not officers or employees of the
6 Federal Government. The Director of the Office
7 shall make appointments to the Advisory Committee
8 from among physicians, practitioners, scientists, and
9 other health professionals, whose clinical practice,
10 research specialization, or professional expertise in-
11 cludes a significant focus on research on women’s
12 health. A majority of the members of the Advisory
13 Committee shall be women.

14 “(B) Members of the Advisory Committee shall
15 receive compensation for each day engaged in carry-
16 ing out the duties of the Committee, including time
17 engaged in traveling for purposes of such duties.
18 Such compensation may not be provided in an
19 amount in excess of the maximum rate of basic pay
20 payable for GS-18 of the General Schedule.

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

23 “(4) The Advisory Committee shall—

24 “(A) advise the Director of the Office on
25 appropriate research activities to be undertaken

1 by the national research institutes with respect
2 to—

3 “(i) research on women’s health;

4 “(ii) research on gender differences in
5 clinical drug trials, including responses to
6 pharmacological drugs;

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

9 “(iv) research on obstetrical and gyne-
10 cological health conditions, diseases, and
11 treatments; and

12 “(v) research on women’s health con-
13 ditions which require a multidisciplinary
14 approach;

15 “(B) report to the Director of the Office
16 on such research;

17 “(C) provide recommendations to such Di-
18 rector regarding activities of the Office (includ-
19 ing recommendations on the development of the
20 methodologies described in subsection (c)(4)(C)
21 and recommendations on priorities in carrying
22 out research described in subparagraph (A));
23 and

1 “(D) assist in monitoring compliance with
2 section 492B regarding the inclusion of women
3 in clinical research.

4 “(5)(A) The Advisory Committee shall prepare
5 a biennial report describing the activities of the
6 Committee, including findings made by the Commit-
7 tee regarding—

8 “(i) compliance with section 492B;

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

12 “(iii) the level of funding needed for such
13 research.

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

17 “(e) REPRESENTATION OF WOMEN AMONG RE-
18 SEARCHERS.—The Secretary, acting through the Assist-
19 ant Secretary for Personnel and in collaboration with the
20 Director of the Office, shall determine the extent to which
21 women are represented among senior physicians and sci-
22 entists of the national research institutes and among phy-
23 sicians and scientists conducting research with funds pro-
24 vided by such institutes, and as appropriate, carry out ac-
25 tivities to increase the extent of such representation.

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

2 “(1) The term ‘women’s health conditions’, with
3 respect to women of all age, ethnic, and racial
4 groups, means all diseases, disorders, and conditions
5 (including with respect to mental health)—

6 “(A) unique to, more serious, or more
7 prevalent in women;

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

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

16 “(2) The term ‘research on women’s health’
17 means research on women’s health conditions, in-
18 cluding research on preventing such conditions.

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

21 “(a) DATA SYSTEM.—

22 “(1) The Director of NIH, in consultation with
23 the Director of the Office, shall establish a data sys-
24 tem for the collection, storage, analysis, retrieval,
25 and dissemination of information regarding research

1 on women’s health that is conducted or supported by
2 the national research institutes. Information from
3 the data system shall be available through informa-
4 tion systems available to health care professionals
5 and providers, researchers, and members of the
6 public.

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

21 “(b) CLEARINGHOUSE.—The Director of NIH, in
22 consultation with the Director of the Office and with the
23 National Library of Medicine, shall establish, maintain,
24 and operate a program to provide information on research

1 and prevention activities of the national research institutes
2 that relate to research on women's health.

3 **“SEC. 486B. BIENNIAL REPORT.**

4 “(a) IN GENERAL.—With respect to research on
5 women's health, the Director of the Office shall, not later
6 than February 1, 1994, and biennially thereafter, prepare
7 a report—

8 “(1) describing and evaluating the progress
9 made during the preceding 2 fiscal years in research
10 and treatment conducted or supported by the Na-
11 tional Institutes of Health;

12 “(2) describing and analyzing the professional
13 status of women physicians and scientists of such
14 Institutes, including the identification of problems
15 and barriers regarding advancements;

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

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

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

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

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

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

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

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

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

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

19 **HEALTH**

20 **SEC. 151. ESTABLISHMENT.**

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

24 “OFFICE OF RESEARCH ON MINORITY HEALTH

25 “SEC. 403A. (a) ESTABLISHMENT.—There is estab-
26 lished within the Office of the Director of NIH an office

1 to be known as the Office of Research on Minority Health
2 (in this section referred to as the ‘Office’). The Office shall
3 be headed by a director, who shall be appointed by the
4 Director of NIH.

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

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

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

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

15 “(4) encourage the conduct of such research by
16 entities receiving funds from the national research
17 institutes;

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

20 “(6) promote the sufficient allocation of the re-
21 sources of the national research institutes for con-
22 ducting and supporting such research; and

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

1 shall by regulation require that each entity that applies
2 for a grant, contract, or cooperative agreement under this
3 Act for any project or program that involves the conduct
4 of biomedical or behavioral research submit in or with its
5 application for such grant, contract, or cooperative agree-
6 ment assurances satisfactory to the Secretary that such
7 entity—

8 “(1) has established (in accordance with regula-
9 tions which the Secretary shall prescribe) an admin-
10 istrative process to review reports of scientific mis-
11 conduct in connection with biomedical and behav-
12 ioral research conducted at or sponsored by such en-
13 tity; and

14 “(2) will report to the Director any investiga-
15 tion of alleged scientific misconduct in connection
16 with projects for which funds have been made avail-
17 able under this Act that appears substantial.

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

21 “(1) response to information provided to the
22 Director respecting scientific misconduct in connec-
23 tion with projects for which funds have been made
24 available under this Act;

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

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

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

7 “(d) MONITORING BY DIRECTOR.—The Secretary
8 shall by regulation establish procedures for the Director
9 to monitor administrative processes and investigations
10 that have been established or carried out under this sec-
11 tion.

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

16 (b) ESTABLISHMENT OF DEFINITION OF SCIENTIFIC
17 MISCONDUCT.—Not later than 90 days after the date on
18 which the report required under section 152(d) is submit-
19 ted to the Secretary of Health and Human Services, such
20 Secretary shall by regulation establish a definition for the
21 term “scientific misconduct” for purposes of section 493
22 of the Public Health Service Act, as amended by sub-
23 section (a) of this section.

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

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

6 (b) DUTIES.—The Commission shall develop rec-
7 ommendations for the Secretary of Health and Human
8 Services on the administration of section 493 of the Public
9 Health Service Act (as amended and added by section 161
10 of this Act).

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

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

18 (2) three shall be individuals with experience in
19 investigating allegations of misconduct with respect
20 to scientific research;

21 (3) three shall be representatives of institutions
22 of higher education at which biomedical or behav-
23 ioral research is conducted; and

24 (4) three shall be individuals who are not de-
25 scribed in paragraphs (1), (2), or (3), at least one

1 of whom shall be an attorney and at least one of
2 whom shall be an ethicist.

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

10 (e) REPORT.—Not later than 120 days after the date
11 of enactment of this section, the Commission shall prepare
12 and submit to the Secretary of Health and Human Serv-
13 ices, the Committee on Energy and Commerce of the
14 House of Representatives, and the Committee on Labor
15 and Human Resources of the Senate, a report containing
16 the recommendations developed under subsection (b).

17 **SEC. 163. PROTECTION OF WHISTLEBLOWERS.**

18 Section 493 of the Public Health Service Act, as
19 amended by section 161 of this Act, is amended by adding
20 at the end the following new subsection:

21 “(f) PROTECTION OF WHISTLEBLOWERS.—

22 “(1) IN GENERAL.—In the case of any entity
23 required to establish administrative processes under
24 subsection (b), the Secretary shall by regulation es-
25 tablish standards for preventing, and for responding

1 to the occurrence of retaliation by such entity, its of-
2 ficials or agents, against an employee in the terms
3 and conditions of employment in response to the em-
4 ployee having in good faith—

5 “(A) made an allegation that the entity, its
6 officials or agents, has engaged in or failed to
7 adequately respond to an allegation of scientific
8 misconduct; or

9 “(B) cooperated with an investigation of
10 such an allegation.

11 “(2) MONITORING BY SECRETARY.—The Sec-
12 retary shall establish by regulation procedures for
13 the Director to monitor the implementation of the
14 standards established by an entity under paragraph
15 (1) for the purpose of determining whether the pro-
16 cedures have been established, and are being uti-
17 lized, in accordance with the standards established
18 under such paragraph.

19 “(3) NONCOMPLIANCE.—The Secretary shall by
20 regulation establish remedies for noncompliance by
21 an entity, its officials or agents, which has engaged
22 in retaliation in violation of the standards estab-
23 lished under paragraph (1). Such remedies may in-
24 clude termination of funding provided by the Sec-
25 retary for such project or recovery of funding being

1 provided by the Secretary for such project, or other
2 actions as appropriate.

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

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

15 “(A) will maintain the procedures de-
16 scribed in the regulations; and

17 “(B) will otherwise be subject to the regu-
18 lations.”.

19 **SEC. 164. REQUIREMENT OF REGULATIONS REGARDING**
20 **PROTECTION AGAINST FINANCIAL CON-**
21 **FLICTS OF INTEREST IN CERTAIN PROJECTS**
22 **OF RESEARCH.**

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

1 “PROTECTION AGAINST FINANCIAL CONFLICTS OF
2 INTEREST IN CERTAIN PROJECTS OF RESEARCH

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

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

21 “(2) RELEVANT PROJECTS.—A project of re-
22 search referred to in paragraph (1) is a project of
23 clinical research whose purpose is to evaluate the
24 safety or effectiveness of a drug, medical device, or

1 treatment and for which such entity is receiving as-
2 sistance from the Secretary.

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

9 “(A) to have in effect at the time the en-
10 tity applies for the assistance and throughout
11 the period during which the assistance is re-
12 ceived, a process for identifying such financial
13 interests as defined in paragraph (1) that exist
14 regarding the project; and

15 “(B) to report to the Director such finan-
16 cial interest as defined in paragraph (1) identi-
17 fied by the entity and how any such financial
18 interest identified by the entity will be managed
19 or eliminated such that the project in question
20 will be protected from bias that may stem from
21 such financial interest.

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

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

5 “(A) shall require that, as a condition of
6 receiving assistance, the entity disclose the ex-
7 istence of a financial interest as defined in
8 paragraph (1) in each public presentation of the
9 results of such project; and

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

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

13 “(A) The term ‘financial interest’ includes
14 the receipt of consulting fees or honoraria and
15 the ownership of stock or equity.

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

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

1 **SEC. 165. EFFECTIVE DATES.**

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

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

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

18 **SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINA-**
19 **TION.**

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

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

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

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

14 “(A) a summary of the Associate Direc-
15 tor’s review of existing dissemination policies
16 and techniques together with a detailed state-
17 ment concerning any modification or restructur-
18 ing, or recommendations for modification or re-
19 structuring, of such policies and techniques;
20 and

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

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

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

6 “(g)(1)(A) In the case of entities described in sub-
7 paragraph (B), the Director of NIH, acting through the
8 Director of the National Center for Research Resources,
9 shall establish a program to enhance the competitiveness
10 of such entities in obtaining funds from the national re-
11 search institutes for conducting biomedical and behavioral
12 research.

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

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

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

1 ration of applications for obtaining funds from the
2 national research institutes;

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

5 “(iii) assist the entities in implementing such
6 plan.

7 “(2) The Director of NIH shall establish a program
8 of supporting projects of biomedical or behavioral research
9 whose principal researchers are individuals who have not
10 previously served as the principal researchers of such
11 projects supported by the Director.”.

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

13 Part A of title IV of the Public Health Service Act
14 (42 U.S.C. 281 et seq.) is amended by adding at the end
15 the following new section:

16 “CHILDREN’S VACCINE INITIATIVE

17 “SEC. 404. (a) DEVELOPMENT OF NEW VAC-
18 CINES.—The Secretary, in consultation with the Director
19 of the National Vaccine Program under title XXI and act-
20 ing through the Directors of the National Institute for Al-
21 lergy and Infectious Diseases, the National Institute for
22 Child Health and Human Development, the National In-
23 stitute for Aging, and other public and private programs,
24 shall carry out activities, which shall be consistent with
25 the global Children’s Vaccine Initiative, to develop afford-
26 able new and improved vaccines to be used in the United

1 States and in the developing world that will increase the
2 efficacy and efficiency of the prevention of infectious dis-
3 eases. In carrying out such activities, the Secretary shall,
4 to the extent practicable, develop and make available vac-
5 cines that require fewer contacts to deliver, that can be
6 given early in life, that provide long lasting protection,
7 that obviate refrigeration, needles and syringes, and that
8 protect against a larger number of diseases.

9 “(b) REPORT.—In the report required in section
10 2104, the Secretary, acting through the Director of the
11 National Vaccine Program under title XXI, shall include
12 information with respect to activities and the progress
13 made in implementing the provisions of this section and
14 achieving its goals.

15 “(c) AUTHORIZATION OF APPROPRIATIONS.—In ad-
16 dition to any other amounts authorized to be appropriated
17 for activities of the type described in this section, there
18 are authorized to be appropriated to carry out this section
19 \$20,000,000 for fiscal year 1994, and such sums as may
20 be necessary for each of the fiscal years 1995 and 1996.”.

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

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

1 “PLAN FOR USE OF ANIMALS IN RESEARCH

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

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

7 “(A) methods of biomedical research and
8 experimentation that do not require the use of
9 animals;

10 “(B) methods of such research and experi-
11 mentation that reduce the number of animals
12 used in such research; and

13 “(C) methods of such research and experi-
14 mentation that produce less pain and distress in
15 such animals;

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

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

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

24 “(b) Not later than October 1, 1993, the Director
25 of NIH shall submit to the Committee on Energy and

1 Commerce of the House of Representatives, and to the
2 Committee on Labor and Human Resources of the Senate,
3 the plan required in subsection (a) and shall begin imple-
4 mentation of the plan.

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

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

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

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

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

1 and members of underrepresented minority groups in the
2 fields of biomedical and behavioral research.”.

3 **SEC. 206. REQUIREMENTS REGARDING SURVEYS OF SEX-**
4 **UAL BEHAVIOR.**

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

8 “REQUIREMENTS REGARDING SURVEYS OF SEXUAL
9 BEHAVIOR

10 “SEC. 404B. With respect to any survey of human
11 sexual behavior proposed to be conducted or supported
12 through the National Institutes of Health, the survey may
13 not be carried out unless—

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

17 “(2) the Secretary, in accordance with section
18 492A, makes a determination that the information
19 expected to be obtained through the survey will as-
20 sist—

21 “(A) in reducing the incidence of sexually
22 transmitted diseases, the incidence of infection
23 with the human immunodeficiency virus, or the
24 incidence of any other infectious disease; or

25 “(B) in improving reproductive health or
26 other conditions of health.”.

1 **SEC. 207. DISCRETIONARY FUND OF DIRECTOR OF NA-**
2 **TIONAL INSTITUTES OF HEALTH.**

3 Section 402 of the Public Health Service Act, as
4 amended by section 205 of this Act, is amended by adding
5 at the end the following new subsection:

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

12 “(A) providing for research on matters that
13 have not received significant funding relative to
14 other matters, responding to new issues and sci-
15 entific emergencies, and acting on research opportu-
16 nities of high priority;

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

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

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

1 expenditures made under this section during the preceding
2 fiscal year. The report may contain such comments of the
3 Secretary regarding this section as the Secretary deter-
4 mines to be appropriate.

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

9 **SEC. 208. MISCELLANEOUS PROVISIONS.**

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

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

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

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

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

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

8 (c) DAY CARE REGARDING CHILDREN OF EMPLOY-
9 EES.—Section 402 of the Public Health Service Act, as
10 amended by section 207 of this Act, is amended by adding
11 at the end the following new subsection:

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

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

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

1 **TITLE III—GENERAL PROVI-**
2 **SIONS RESPECTING NA-**
3 **TIONAL RESEARCH INSTI-**
4 **TUTES**

5 **SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS**
6 **OF NATIONAL RESEARCH INSTITUTES.**

7 (a) ESTABLISHMENT OF GENERAL AUTHORITY RE-
8 GARDING DIRECT FUNDING.—

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

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

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

16 (C) by adding at the end the following new
17 subparagraph:

18 “(C) shall receive from the President and the
19 Office of Management and Budget directly all funds
20 appropriated by the Congress for obligation and ex-
21 penditure by the Institute.”.

22 (2) CONFORMING AMENDMENT.—Section
23 413(b)(9) of the Public Health Service Act (42
24 U.S.C. 285a-2(b)(9)) is amended—

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

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

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

7 (1) by amending paragraph (3) to read as fol-
8 lows:

9 “(3) may, in consultation with the advisory
10 council for the Institute and with the approval of the
11 Director of NIH—

12 “(A) establish technical and scientific peer
13 review groups in addition to those appointed
14 under section 402(b)(6); and

15 “(B) appoint the members of peer review
16 groups established under subparagraph (A);
17 and”; and

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

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

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

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

8 "RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND
9 RELATED BONE DISORDERS

10 "SEC. 410. (a) ESTABLISHMENT.—The Directors of
11 the National Institute of Arthritis and Musculoskeletal
12 and Skin Diseases, the National Institute on Aging, the
13 National Institute of Diabetes, Digestive and Kidney Dis-
14 eases, and the National Institute of Dental Research, shall
15 expand and intensify the programs of such Institutes with
16 respect to research and related activities concerning
17 osteoporosis, Paget's disease, and related bone disorders.

18 "(b) COORDINATION.—The Directors referred to in
19 subsection (a) shall jointly coordinate the programs re-
20 ferred to in such subsection and consult with the Arthritis
21 and Musculoskeletal Diseases Interagency Coordinating
22 Committee and the Interagency Task Force on Aging Re-
23 search.

24 "(c) INFORMATION CLEARINGHOUSE.—

25 "(1) IN GENERAL.—In order to assist in carry-
26 ing out the purpose described in subsection (a), the

1 Director of NIH shall provide for the establishment
2 of an information clearinghouse on osteoporosis and
3 related bone disorders to facilitate and enhance
4 knowledge and understanding on the part of health
5 professionals, patients, and the public through the
6 effective dissemination of information.

7 “(2) ESTABLISHMENT THROUGH GRANT OR
8 CONTRACT.—For the purpose of carrying out para-
9 graph (1), the Director of NIH shall enter into a
10 grant, cooperative agreement, or contract with a
11 nonprofit private entity involved in activities regard-
12 ing the prevention and control of osteoporosis and
13 related bone disorders.

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

19 **SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM**
20 **FOR TRAUMA RESEARCH.**

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

1 Commerce of the House of Representatives, and to
2 the Committee on Labor and Human Resources of
3 the Senate, together with an estimate of the funds
4 needed for each of the fiscal years 1994 through
5 1996 to implement the plan.

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

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

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

14 “(3) shall, as appropriate, provide for collabora-
15 tion among such agencies in carrying out such ac-
16 tivities.

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

19 “(1) studies with respect to all phases of trau-
20 ma care, including prehospital, resuscitation, sur-
21 gical intervention, critical care, infection control,
22 wound healing, nutritional care and support, and
23 medical rehabilitation care;

24 “(2) basic and clinical research regarding the
25 response of the body to trauma and the acute treat-

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

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

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

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

14 “(g) COORDINATING COMMITTEE.—

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

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

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

1 “(B) effective collaboration among the
2 agencies in carrying out the activities.

3 “(3) COMPOSITION.—The Coordinating Com-
4 mittee shall be composed of the Directors of each of
5 the agencies that, under subsection (c), have respon-
6 sibilities under the Program, and any other individ-
7 uals who are practitioners in the trauma field as
8 designated by the Director of the National Institutes
9 of Health.

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

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

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

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

20 “(b) CONFORMING AMENDMENT.—Section 402 of the
21 Public Health Service Act, as amended by section 208(c)
22 of this Act, is amended by adding at the end the following
23 new subsection:

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

4 **TITLE IV—NATIONAL CANCER**
5 **INSTITUTE**

6 **SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVI-**
7 **TIES REGARDING BREAST CANCER.**

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

11 “BREAST AND GYNECOLOGICAL CANCERS

12 “SEC. 417. (a) EXPANSION AND COORDINATION OF
13 ACTIVITIES.—The Director of the Institute, in consulta-
14 tion with the National Cancer Advisory Board, shall ex-
15 pand, intensify, and coordinate the activities of the Insti-
16 tute with respect to research on breast cancer, ovarian
17 cancer, and other cancers of the reproductive system of
18 women.

19 “(b) COORDINATION WITH OTHER INSTITUTES.—
20 The Director of the Institute shall coordinate the activities
21 of the Director under subsection (a) with similar activities
22 conducted by other national research institutes and agen-
23 cies of the National Institutes of Health to the extent that
24 such Institutes and agencies have responsibilities that are
25 related to breast cancer and other cancers of the reproduc-
26 tive system of women.

1 “(c) PROGRAMS FOR BREAST CANCER.—

2 “(1) IN GENERAL.—In carrying out subsection
3 (a), the Director of the Institute shall conduct or
4 support research to expand the understanding of the
5 cause of, and to find a cure for, breast cancer. Ac-
6 tivities under such subsection shall provide for an
7 expansion and intensification of the conduct and
8 support of—

9 “(A) basic research concerning the etiology
10 and causes of breast cancer;

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

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

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

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

1 treatment research and related activities on
2 breast cancer.

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

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

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

24 “(B) Not later than May 1, 1993, the Di-
25 rector of the Institute shall submit a copy of

1 the plan to the President’s Cancer Panel, the
2 Secretary and the Director of NIH.

3 “(C) The Director of the Institute shall
4 submit any revisions of the plan to the Presi-
5 dent’s Cancer Panel, the Secretary, and the Di-
6 rector of NIH.

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

14 “(d) OTHER CANCERS.—In carrying out subsection
15 (a), the Director of the Institute shall conduct or support
16 research on ovarian cancer and other cancers of the repro-
17 ductive system of women. Activities under such subsection
18 shall provide for the conduct and support of—

19 “(1) basic research concerning the etiology and
20 causes of ovarian cancer and other cancers of the re-
21 productive system of women;

22 “(2) clinical research and related activities into
23 the causes, prevention, detection and treatment of
24 ovarian cancer and other cancers of the reproductive
25 system of women;

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

4 “(4) information and education programs with
5 respect to ovarian cancer and other cancers of the
6 reproductive system of women in accordance with
7 section 413; and

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

11 “(e) REPORT.—The Director of the Institute shall
12 prepare, for inclusion in the biennial report submitted
13 under section 407, a report that describes the activities
14 of the National Cancer Institute under the research pro-
15 grams referred to in subsection (a), that shall include—

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

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

20 “(3) a description and evaluation of the
21 progress made, during the period for which such re-
22 port is prepared, in the research programs on breast
23 cancer and cancers of the reproductive system of
24 women;

1 “(4) a summary and analysis of expenditures
2 made, during the period for which such report is
3 made, for activities with respect to breast cancer and
4 cancers of the reproductive system of women con-
5 ducted and supported by the National Institutes of
6 Health; and

7 “(5) such comments and recommendations as
8 the Director considers appropriate.”.

9 **SEC. 402. EXPANSION AND INTENSIFICATION OF ACTIVI-**
10 **TIES REGARDING PROSTATE CANCER.**

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

14 “PROSTATE CANCER

15 “SEC. 417A. (a) EXPANSION AND COORDINATION
16 OF ACTIVITIES.—The Director of the Institute, in con-
17 sultation with the National Cancer Advisory Board, shall
18 expand, intensify, and coordinate the activities of the In-
19 stitute with respect to research on prostate cancer.

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

1 “(c) PROGRAMS.—

2 “(1) IN GENERAL.—In carrying out subsection
3 (a), the Director of the Institute shall conduct or
4 support research to expand the understanding of the
5 cause of, and to find a cure for, prostate cancer. Ac-
6 tivities under such subsection shall provide for an
7 expansion and intensification of the conduct and
8 support of—

9 “(A) basic research concerning the etiology
10 and causes of prostate cancer;

11 “(B) clinical research and related activities
12 concerning the causes, prevention, detection and
13 treatment of prostate cancer;

14 “(C) prevention and control and early de-
15 tection programs with respect to prostate can-
16 cer in accordance with section 412, particularly
17 as it relates to intensifying research on the role
18 of prostate specific antigen for the screening
19 and early detection of prostate cancer;

20 “(D) an Inter-Institute Task Force, under
21 the direction of the Director of the Institute, to
22 provide coordination between relevant National
23 Institutes of Health components of research ef-
24 forts on prostate cancer;

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

3 “(F) information and education programs
4 with respect to prostate cancer in accordance
5 with section 413; and

6 “(G) research and demonstration centers
7 with respect to prostate cancer in accordance
8 with section 414, including the development and
9 operation of centers for prostate cancer re-
10 search to bring together basic and clinical, bio-
11 medical and behavioral scientists to conduct
12 basic, clinical, epidemiological, psychosocial,
13 prevention and treatment research and related
14 activities on prostate cancer.

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

21 “(2) IMPLEMENTATION OF PLAN FOR PRO-
22 GRAMS.—

23 “(A) The Director of the Institute shall en-
24 sure that the research programs described in
25 paragraph (1) are implemented in accordance

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

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

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

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

1 **SEC. 403. AUTHORIZATION OF APPROPRIATIONS.**

2 (a) IN GENERAL.—Subpart 1 of part C of title IV
3 of the Public Health Service Act, as amended by section
4 402 of this Act, is amended by adding at the end the fol-
5 lowing new section:

6 “AUTHORIZATION OF APPROPRIATIONS

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

12 “(b) BREAST CANCER AND GYNECOLOGICAL CAN-
13 CERS.—

14 “(1) BREAST CANCER.—

15 “(A) For the purpose of carrying out sub-
16 paragraph (A) of section 417(c)(1), there are
17 authorized to be appropriated \$225,000,000 for
18 fiscal year 1994, and such sums as may be nec-
19 essary for each of the fiscal years 1995 and
20 1996. Such authorizations of appropriations are
21 in addition to the authorizations of appropria-
22 tions established in subsection (a) with respect
23 to such purpose.

24 “(B) For the purpose of carrying out sub-
25 paragraphs (B) through (E) of section
26 417(c)(1), there are authorized to be appro-

1 appropriated \$100,000,000 for fiscal year 1994, and
2 such sums as may be necessary for each of the
3 fiscal years 1995 and 1996. Such authoriza-
4 tions of appropriations are in addition to the
5 authorizations of appropriations established in
6 subsection (a) with respect to such purpose.

7 “(2) OTHER CANCERS.—For the purpose of
8 carrying out subsection (d) of section 417, there are
9 authorized to be appropriated \$75,000,000 for fiscal
10 year 1994, and such sums as are necessary for each
11 of the fiscal years 1995 and 1996. Such authoriza-
12 tions of appropriations are in addition to the author-
13 izations of appropriations established in subsection
14 (a) with respect to such purpose.

15 “(c) PROSTATE CANCER.—For the purpose of carry-
16 ing out section 417A, there are authorized to be appro-
17 priated \$72,000,000 for fiscal year 1994, and such sums
18 as may be necessary for each of the fiscal years 1995 and
19 1996. Such authorizations of appropriations are in addi-
20 tion to the authorizations of appropriations established in
21 subsection (a) with respect to such purpose.

22 “(d) ALLOCATION REGARDING CANCER CONTROL.—
23 Of the amounts appropriated for the National Cancer In-
24 stitute for a fiscal year, the Director of the Institute is
25 authorized to make available not less than 10 percent for

1 carrying out the cancer control activities authorized in sec-
 2 tion 412 and for which budget estimates are made under
 3 section 413(b)(9) for the fiscal year.”.

4 (b) CONFORMING AMENDMENTS.—

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

7 (A) by striking subsection (a);

8 (B) by redesignating subsection (b) as sub-
 9 section (a);

10 (C) by redesignating paragraph (5) of sub-
 11 section (a) (as so redesignated) as subsection
 12 (b); and

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

15 “CERTAIN USES OF FUNDS”.

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

20 **TITLE V—NATIONAL HEART,**
 21 **LUNG, AND BLOOD INSTITUTE**

22 **SEC. 501. EDUCATION AND TRAINING.**

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

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

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

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

5 “(5) shall, in consultation with the advisory
6 council for the Institute, conduct appropriate intra-
7 mural training and education programs, including
8 continuing education and laboratory and clinical re-
9 search training programs.”.

10 **SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CAR-**
11 **DIOVASCULAR DISEASES.**

12 Section 422(a)(1) of the Public Health Service Act
13 (42 U.S.C. 285b-4(a)(1)) is amended—

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

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

18 (3) by adding at the end thereof the following
19 new subparagraph:

20 “(D) three centers for basic and clinical re-
21 search into, training in, and demonstration of, ad-
22 vanced diagnostic, prevention, and treatment (in-
23 cluding genetic studies, intrauterine environment
24 studies, postnatal studies, heart arrhythmias, and

1 of Health, and similar activities of other public enti-
2 ties and nonprofit entities.

3 “(c)(1) The Director of the National Institutes of
4 Health shall establish a committee to be known as the
5 Sleep Disorders Coordinating Committee (hereafter in this
6 section referred to as the ‘Coordinating Committee’).

7 “(2) The Coordinating Committee shall be composed
8 of the directors of the National Institutes of Health, the
9 National Institute on Aging, the National Institute of
10 Child Health and Human Development, the National
11 Heart, Lung and Blood Institute, the National Institute
12 of Neurological Disorders and Stroke, the National Insti-
13 tute of Mental Health, and of such other national research
14 institutes as the Director of the National Institutes of
15 Health determines to be appropriate, and shall include
16 representation from other Federal departments and agen-
17 cies whose programs involve sleep disorders.

18 “(3) The Director of the National Health, Lung, and
19 Blood Institute shall serve as the chairperson of the Co-
20 ordinating Committee.

21 “(4) The Coordinating Committee shall make rec-
22 ommendations to the Director of the National Institutes
23 of Health and the Director of the Center with respect to
24 the content of the plan required in subsection (e), with
25 respect to the activities of the Center that are carried out

1 in conjunction with other agencies of the National Insti-
2 tutes of Health, and with respect to the activities of the
3 Center that are carried out in conjunction with other agen-
4 cies of the Federal Government.

5 “(d)(1) The Director of the National Institutes of
6 Health shall establish a board to be known as the Sleep
7 Disorders Research Advisory Board (hereafter in this sec-
8 tion referred to as the ‘Advisory Board’).

9 “(2) The Advisory Board shall advise, assist, consult
10 with, and make recommendations to the Director of the
11 National Institutes of Health, through the Director of the
12 Institute, and the Director of the Center concerning mat-
13 ters relating to the scientific activities carried out by and
14 through the Center and the policies respecting such activi-
15 ties, including recommendations with respect to the plan
16 required in subsection (c).

17 “(3)(A) The Director of the National Institutes of
18 Health shall appoint to the Advisory Board 12 appro-
19 priately qualified representatives of the public who are not
20 officers or employees of the Federal Government. Of such
21 members, eight shall be representatives of health and sci-
22 entific disciplines with respect to sleep disorders and four
23 shall be individuals representing the interests of individ-
24 uals with or undergoing treatment for sleep disorders.

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

3 “(i) The Director of the National Institutes of
4 Health.

5 “(ii) The Director of the Center.

6 “(iii) The Director of the National Heart, Lung
7 and Blood Institute.

8 “(iv) The Director of the National Institute of
9 Mental Health.

10 “(v) The Director of the National Institute on
11 Aging.

12 “(vi) The Director of the National Institute of
13 Child Health and Human Development.

14 “(vii) The Director of the National Institute of
15 Neurological Disorders and Stroke.

16 “(viii) The Assistant Secretary for Health.

17 “(ix) The Assistant Secretary of Defense
18 (Health Affairs).

19 “(x) The Chief Medical Director of the Veter-
20 ans’ Administration.

21 “(4) The members of the Advisory Board shall, from
22 among the members of the Advisory Board, designate an
23 individual to serve as the chairperson of the Advisory
24 Board.

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

6 “(e)(1) After consultation with the Director of the
7 Center, the advisory board established under subsection
8 (d), and the coordinating committee established under
9 subsection (c), the Director of the National Institutes of
10 Health shall develop a comprehensive plan for the conduct
11 and support of sleep disorders research.

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

17 “(3) The Director of the National Institutes of
18 Health (after consultation with the Director of the Center,
19 the advisory board established under subsection (d), and
20 the coordinating committee established under subsection
21 (c)) shall revise the plan developed under paragraph (1)
22 as appropriate.

23 “(f) The Director of the Center, in cooperation with
24 the Centers for Disease Control, is authorized to coordi-
25 nate activities with the Department of Transportation, the

1 Department of Defense, the Department of Education, the
2 Department of Labor, and the Department of Commerce
3 to collect data, conduct studies, and disseminate public in-
4 formation concerning the impact of sleep disorders and
5 sleep deprivation.”.

6 **SEC. 504. AUTHORIZATION OF APPROPRIATIONS.**

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

10 “AUTHORIZATION OF APPROPRIATIONS

11 “SEC. 425. (a) For the purpose of carrying out this
12 subpart, there are authorized to be appropriated
13 \$1,500,000,000 for fiscal year 1994, and such sums as
14 may be necessary for each of the fiscal years 1995 and
15 1996.

16 “(b) Of the amounts appropriated under paragraph
17 (1) for a fiscal year, the Director of the Institute is au-
18 thorized to make available not less than 10 percent for
19 carrying out community-based prevention and control ac-
20 tivities that include clinical investigations, clinical trials,
21 epidemiologic studies, and prevention demonstration and
22 education projects.”.

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

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

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

9 “NUTRITIONAL DISORDERS PROGRAM

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

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

22 “(c) In carrying out the program established under
23 subsection (a), the Director of the Institute shall carry out
24 activities to facilitate and enhance knowledge and under-
25 standing of nutritional disorders, including obesity, on the

1 part of health professionals, patients, and the public
2 through the effective dissemination of information.”.

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

6 (1) by redesignating subsection (d) as sub-
7 section (e); and

8 (2) by inserting after subsection (c) the follow-
9 ing new subsection:

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

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

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

22 “(A) utilize the facilities of a single institution,
23 or be formed from a consortium of cooperating insti-
24 tutions, meeting such research and training quali-
25 fications as may be prescribed by the Director;

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

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

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

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

18 **SEC. 701. JUVENILE ARTHRITIS.**

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

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

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

9 (2) in subsection (b)—

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

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

14 (C) by adding at the end thereof the fol-
15 lowing new paragraph:

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

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

24 “(f) Not later than October 1, 1994, the Director
25 shall establish a multipurpose arthritis and musculo-

1 skeletal disease center for the purpose of expanding the
2 level of research into the cause, diagnosis, early detection,
3 prevention, control, and treatment of, and rehabilitation
4 of children with arthritis and musculoskeletal diseases.”.

5 (d) ADVISORY BOARD.—

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

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

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

18 (B) in paragraph (1)(B)—

19 (i) by striking “six” and inserting
20 “eight”; and

21 (ii) by striking “including” and all
22 that follows and inserting the following:
23 “including one member who is a person
24 who has such a disease, one person who is
25 the parent of an adult with such a disease,

1 and two members who are parents of chil-
2 dren with arthritis.”.

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

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

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

10 (3) by adding at the end the following para-
11 graph:

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

17 **TITLE VIII—NATIONAL**
18 **INSTITUTE ON AGING**

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

20 (a) IN GENERAL.—Section 12 of Public Law 99-158
21 (99 Stat. 885) is—

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

25 (2) redesignated as section 445G; and

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

2 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

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

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

9 “ALZHEIMER’S DISEASE REGISTRY

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

12 (2) by striking subsection (c).

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

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

17 “AGING PROCESSES REGARDING WOMEN

18 “SEC. 445H. The Director of the Institute, in addi-
19 tion to other special functions specified in section 444 and
20 in cooperation with the Directors of the other national re-
21 search institutes and agencies of the National Institutes
22 of Health, shall conduct research into the aging processes
23 of women, with particular emphasis given to the effects
24 of menopause and the physiological and behavioral
25 changes occurring during the transition from pre- to post-
26 menopause, and into the diagnosis, disorders, and com-

1 plications related to aging and loss of ovarian hormones
2 in women.”.

3 **SEC. 803. AUTHORIZATION OF APPROPRIATIONS.**

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

7 “AUTHORIZATION OF APPROPRIATIONS

8 “SEC. 445I. For the purpose of carrying out this sub-
9 part, there are authorized to be appropriated
10 \$500,000,000 for fiscal year 1994, and such sums as may
11 be necessary for each of the fiscal years 1995 and 1996.”.

12 **SEC. 804. CONFORMING AMENDMENT.**

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

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

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

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

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

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

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

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

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

12 “RESEARCH CENTERS REGARDING CHRONIC FATIGUE
13 SYNDROME

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

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

1 (b) EXTRAMURAL STUDY SECTION.—Not later than
2 6 months after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services shall establish an
4 extramural study section for chronic fatigue syndrome re-
5 search.

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

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

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

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

23 Subpart 7 of part C of title IV of the Public Health
24 Service Act, as amended by section 3 of Public Law 101–

1 613, is amended by adding at the end the following new
2 section:

3 “RESEARCH CENTERS WITH RESPECT TO
4 CONTRACEPTION AND INFERTILITY

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

13 “(b) In carrying out subsection (a), the Director of
14 the Institute shall, subject to the extent of amounts made
15 available in appropriations Acts, provide for the establish-
16 ment of three centers with respect to contraception and
17 for two centers with respect to infertility.

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

20 “(A) conduct clinical and other applied re-
21 search, including—

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

1 “(ii) for centers with respect to infertility,
2 clinical trials of new or improved drugs and de-
3 vices for the diagnosis and treatment of infertil-
4 ity in males and females;

5 “(B) develop protocols for training physicians,
6 scientists, nurses, and other health and allied health
7 professionals;

8 “(C) conduct training programs for such indi-
9 viduals;

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

12 “(E) disseminate information to such profes-
13 sionals and the public.

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

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

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

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

3 “(f) Support of a center under subsection (a) may
4 be for a period not exceeding 5 years. Such period may
5 be extended for one or more additional periods not exceed-
6 ing 5 years if the operations of such center have been re-
7 viewed by an appropriate technical and scientific peer re-
8 view group established by the Director and if such group
9 has recommended to the Director that such period should
10 be extended.

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

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

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

21 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
22 RESPECT TO CONTRACEPTION AND INFERTILITY

23 “SEC. 487B. (a) The Secretary, in consultation with
24 the Director of the National Institute of Child Health and
25 Human Development, shall establish a program of enter-
26 ing into agreements with qualified health professionals (in-

1 cluding graduate students) under which such health pro-
 2 fessionals agree to conduct research with respect to con-
 3 traception, or with respect to infertility, in consideration
 4 of the Federal Government agreeing to repay, for each
 5 year of such service, not more than \$20,000 of the prin-
 6 cipal and interest of the educational loans of such health
 7 professionals.

8 “(b) The provisions of sections 338B, 338C, and
 9 338E shall apply to the program established in subsection
 10 (a) to the same extent and in the same manner as such
 11 provisions apply to the National Health Service Corps
 12 Loan Repayment Program established in subpart III of
 13 part D of title III.

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

18 **Subtitle B—Program Regarding** 19 **Obstetrics and Gynecology**

20 **SEC. 1011. ESTABLISHMENT OF PROGRAM.**

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

24 “PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

25 “SEC. 452B. The Director of the Institute shall es-
 26 tablish and maintain within the Institute an intramural

1 laboratory and clinical research program in obstetrics and
2 gynecology.”.

3 **Subtitle C—Child Health Research** 4 **Centers**

5 **SEC. 1021. ESTABLISHMENT OF CENTERS.**

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

9 “CHILD HEALTH RESEARCH CENTERS

10 “SEC. 452C. The Director of the Institute shall de-
11 velop and support centers for conducting research with re-
12 spect to child health. Such centers shall give priority to
13 the expeditious transfer of advances from basic science to
14 clinical applications and improving the care of infants and
15 children.”.

16 **Subtitle D—Study Regarding** 17 **Adolescent Health**

18 **SEC. 1031. PROSPECTIVE LONGITUDINAL STUDY.**

19 Subpart 7 of part C of title IV of the Public Health
20 Service Act, as amended by section 1021 of this Act, is
21 amended by adding at the end the following new section:

22 “PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT
23 HEALTH

24 “SEC. 452D. (a) IN GENERAL.—Not later than No-
25 vember 1, 1993, the Director of the Institute shall initiate
26 a 3-year study for the purpose of providing information

1 on the general health and well-being of adolescents in the
2 United States, including, with respect to such adolescents,
3 information on—

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

6 “(2) the influence on health of factors particu-
7 lar to the communities in which the adolescents
8 reside.

9 “(b) DESIGN OF STUDY.—

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

18 “(2) POPULATION-SPECIFIC ANALYSES.—The
19 study required in subsection (a) shall be conducted
20 with respect to the population of adolescents who are
21 female, the population of adolescents who are male,
22 various socioeconomic populations of adolescents,
23 and various racial and ethnic populations of adoles-
24 cents. The study shall be designed and conducted in
25 a manner sufficient to provide for a valid analysis of

1 whether there are significant differences among such
 2 populations in health status and whether and to
 3 what extent any such differences are due to factors
 4 particular to the populations involved.

5 “(c) COORDINATION WITH WOMEN’S HEALTH INI-
 6 TIATIVE.—With respect to the national study of women
 7 being conducted by the Secretary and known as the Wom-
 8 en’s Health Initiative, the Secretary shall ensure that such
 9 study is coordinated with the component of the study re-
 10 quired in subsection (a) that concerns adolescent females,
 11 including coordination in the design of the 2 studies.”.

12 **TITLE XI—NATIONAL EYE** 13 **INSTITUTE**

14 **SEC. 1101. CLINICAL AND HEALTH SERVICES RESEARCH ON** 15 **EYE CARE AND DIABETES.**

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

19 “CLINICAL RESEARCH ON EYE CARE AND DIABETES

20 “SEC. 456. (a) PROGRAM OF GRANTS.—The Director
 21 of the Institute, in consultation with the advisory council
 22 for the Institute, may award research grants to one or
 23 more Diabetes Eye Research Institutions for the support
 24 of programs in clinical or health services aimed at—

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

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

6 “(3) assisting in translation of the latest re-
7 search advances into clinical practice; and

8 “(4) expanding the knowledge of the eye and
9 diabetes through further research.

10 “(b) USE OF FUNDS.—Amounts received under a
11 grant awarded under this section shall be used for the fol-
12 lowing:

13 “(1) Establishing the biochemical, cellular, and
14 genetic mechanisms associated with diabetic eye dis-
15 ease and the earlier detection of pending eye abnor-
16 malities. The focus of work under this paragraph
17 shall require that ophthalmologists have training in
18 the most up-to-date molecular and cell biological
19 methods.

20 “(2) Establishing new frontiers in technology,
21 such as video-based diagnostic and research re-
22 sources, to—

23 “(A) provide improved patient care;

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

1 “(C) provide for the assessment of risks
2 for the development and progression of diabetic
3 eye disease and a more immediate evaluation of
4 various therapies aimed at preventing diabetic
5 eye disease.

6 Such technologies shall be designed to permit eval-
7 uations to be performed both in humans and in ani-
8 mal models.

9 “(3) The translation of the results of vision re-
10 search into the improved care of patients with dia-
11 betic eye disease. Such translation shall require the
12 application of institutional resources that encompass
13 patient care, clinical research and basic laboratory
14 research.

15 “(4) The conduct of research concerning the
16 outcomes of eye care treatments and eye health edu-
17 cation programs as they relate to patients with dia-
18 betic eye disease, including the evaluation of regional
19 approaches to such research.

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

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

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

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

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

12 “RESEARCH ON MULTIPLE SCLEROSIS

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

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

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

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

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

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

6 (b) TECHNICAL AMENDMENT.—Section 463 of the
7 Public Health Service Act (42 U.S.C. 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—

17 “(i) the Board has under paragraph
18 (2) recommended the application for ap-
19 proval; or

20 “(ii) the Director makes a written de-
21 termination (setting forth in detail the Di-
22 rector’s reasons for rejecting the rec-
23 ommendations of the Board) to approve a
24 grant despite the adverse recommendation
25 of the Board.

1 “(2) DUTIES.—

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

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

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

22 “(D) In carrying out subparagraph (A),
23 the Board shall prepare an annual report for
24 the Director of the Center and the Advisory
25 Council describing the activities of the Board in

1 the fiscal year for which the report is made.
2 Each such report shall be available to the pub-
3 lic, and shall—

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

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

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

14 “(3) MEMBERSHIP.—

15 “(A) Subject to subparagraph (B), the
16 Board shall be composed of not more than 9
17 members appointed by the Secretary, acting
18 through the Director of the National Institutes
19 of Health, and ex officio members as the Direc-
20 tor of the Center may determine.

21 “(B) Not more than 2 individuals who are
22 officers or employees of the Federal Govern-
23 ment may serve as members of the Board.

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

1 ship on the Board, the Secretary shall ensure that
2 the members are individuals who, by the virtue of
3 their training or experience, are eminently qualified
4 to perform peer review functions. In selecting such
5 individuals for such membership, the Secretary shall
6 ensure that the members of the Board collectively—

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

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

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

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

23 “(5) CERTAIN AUTHORITIES.—

24 “(A) In carrying out paragraph (2), the
25 Board may establish subcommittees, convene

1 workshops and conferences, and collect data as
2 the Board considers appropriate.

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

8 “(6) TERMS.—

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

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

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

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

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

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

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

13 “(c) REQUIREMENTS FOR GRANTS.—

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

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

22 “(B) The applicant provides assurances
23 satisfactory to the Director that—

24 “(i) for not less than 20 years after
25 completion of the construction, the facility

1 will be used for the purposes of research
2 for which it is to be constructed;

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

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

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

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

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

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

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

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

9 “(v) the age and condition of existing
10 research facilities and equipment.

11 “(D) The applicant has demonstrated a
12 commitment to enhancing and expanding the
13 research productivity of the applicant.

14 “(2) CONSIDERATION OF CERTAIN FACTORS.—
15 In making grants under subsection (a), the Director
16 of the Center may, in addition to the requirements
17 established in paragraph (1), consider the following
18 factors:

19 “(A) To what extent the applicant has the
20 capacity to broaden the scope of research and
21 research training programs of the applicant by
22 promoting—

23 “(i) interdisciplinary research;

24 “(ii) research on emerging tech-
25 nologies, including those involving novel

1 analytical techniques or computational
2 methods; or

3 “(iii) other novel research mechanisms
4 or programs.

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

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

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

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

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

3 “(D) The applicant—

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

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

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

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

1 “(e) AMOUNT OF GRANT; PAYMENTS.—

2 “(1) AMOUNT.—The amount of any grant
3 awarded under subsection (a) shall be determined by
4 the Director of the Center, except that such amount
5 shall not exceed—

6 “(A) 50 percent of the necessary cost of
7 the construction of a proposed facility as deter-
8 mined by the Director; or

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

14 “(2) RESERVATION OF AMOUNTS.—On approval
15 of any application for a grant under subsection (a),
16 the Director of the Center shall reserve, from any
17 appropriation available therefore, the amount of
18 such grant, and shall pay such amount, in advance
19 or by way of reimbursement, and in such install-
20 ments consistent with the construction progress, as
21 the Director may determine appropriate. The res-
22 ervation of the Director of any amount by the Direc-
23 tor under this paragraph may be amended by the
24 Director, either on the approval of an amendment of

1 the application or on the revision of the estimated
2 cost of construction of the facility.

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

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

12 “(B) the amount of any non-Federal funds
13 required to be expended as a condition of such
14 other Federal grant.

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

20 “(f) RECAPTURE OF PAYMENTS.—If, not later than
21 20 years after the completion of construction for which
22 a grant has been awarded under subsection (a)—

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

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

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

22 “(h) GUIDELINES.—Not later than 6 months after
23 the date of the enactment of this section, the Director of
24 the Center, after consultation with the Advisory Council,

1 shall issue guidelines with respect to grants under sub-
2 section (a).

3 “(i) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section and section 481B,
5 there are authorized to be appropriated \$150,000,000 for
6 fiscal year 1994, and such sums as may be necessary for
7 each of the fiscal years 1995 and 1996.”.

8 **SEC. 1503. CONSTRUCTION PROGRAM FOR NATIONAL PRI-**
9 **MATE RESEARCH CENTER.**

10 Subpart 1 of part E of title IV of the Public Health
11 Service Act, as amended by section 1502 of this Act, is
12 amended by adding at the end the following new section:

13 “CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH
14 ON PRIMATES

15 “SEC. 481B. (a) The Director of the National Insti-
16 tutes of Health, acting through the Director of the Na-
17 tional Center for Research Resources, may award grants
18 and contracts to public or nonprofit private entities to con-
19 struct, renovate, or otherwise improve such regional cen-
20 ters.

21 “(b) The Director of NIH may not make a grant or
22 enter into a contract under subsection (a) unless the appli-
23 cant for such assistance agrees, with respect to the costs
24 to be incurred by the applicant in carrying out the purpose
25 described in such subsection, to make available (directly
26 or through donations from public or private entities) non-

1 Federal contributions in cash toward such costs in an
2 amount equal to not less than \$1 for each \$4 of Federal
3 funds provided in such assistance.

4 “(c) The Secretary may reserve not more than
5 \$7,000,000 of the amounts appropriated under section
6 481A(i) for each fiscal year to carry out this section.”.

7 **Subtitle B—National Center for** 8 **Nursing Research**

9 **SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR** 10 **NURSING RESEARCH AS NATIONAL INSTI-** 11 **TUTE OF NURSING RESEARCH.**

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

15 (1) in section 483—

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

18 (B) by striking “The general purpose” and
19 all that follows through “is” and inserting the
20 following: “The general purpose of the National
21 Institute of Nursing Research (hereafter in this
22 subpart referred to as the ‘Institute’) is”;

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

25 (3) in section 485—

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

5 (B) in subsection (b)—

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

8 (ii) in paragraph (3)(A), in the first
9 sentence, by striking “Center” and insert-
10 ing “Institute”; and

11 (C) in subsections (d) through (g), by
12 striking “Center” each place such term appears
13 and inserting “Institute”; and

14 (4) in section 485A (as redesignated by section
15 141(a)(1) of this Act), by striking “Center” each
16 place such term appears and inserting “Institute”.

17 (b) CONFORMING AMENDMENTS.—

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

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

23 “(Q) The National Institute of Nursing
24 Research.”; and

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

3 (2) TRANSFER OF STATUTORY PROVISIONS.—
4 Sections 483 through 485A of the Public Health
5 Service Act, as amended by subsection (a) of this
6 section—

7 (A) are transferred to part C of title IV of
8 such Act;

9 (B) are redesignated as sections 464V
10 through 464Y of such part; and

11 (C) are inserted, in the appropriate se-
12 quence, at the end of such part.

13 (3) HEADING FOR NEW SUBPART.—Title IV of
14 the Public Health Service Act, as amended by the
15 preceding provisions of this section, is amended—

16 (A) in part C, by inserting before section
17 464V the following new heading:

18 “Subpart 17—National Institute of Nursing Research”;

19 and

20 (B) by striking the heading for subpart 3
21 of part E.

22 (4) CROSS-REFERENCES.—Title IV of the Pub-
23 lic Health Service Act, as amended by the preceding
24 provisions of this section, is amended in subpart 17
25 of part C—

1 (A) in section 464W, by striking “section
2 483” and inserting “section 464V”;

3 (B) in section 464X(g), by striking “sec-
4 tion 486” and inserting “section 464Y”; and

5 (C) in section 464Y, in the last sentence,
6 by striking “section 485(g)” and inserting “sec-
7 tion 464X(g)”.

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

9 (a) IN GENERAL.—The Secretary of Health and
10 Human Services, acting through the Director of the Na-
11 tional Institute of Nursing Research and in collaboration
12 with the Division of Nursing of the Health Resources and
13 Services Administration, shall enter into a contract with
14 a public or nonprofit private entity to conduct a study for
15 the purpose of determining whether and to what extent
16 there is a need for an increase in the number of nurses
17 in hospitals and nursing homes in order to promote the
18 quality of patient care and reduce the incidence among
19 nurses of work-related injuries and stress.

20 (b) NATIONAL ACADEMY OF SCIENCES.—The Sec-
21 retary shall request the National Academy of Sciences to
22 enter into the contract under subsection (a) to conduct
23 the study described in such subsection. If such Institute
24 declines to conduct the study, the Secretary shall carry

1 out such subsection through another public or nonprofit
2 private entity.

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

4 (1) The term “nurse” means a registered nurse,
5 a licensed practical nurse, a licensed vocational
6 nurse, and a nurse assistant.

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

9 (d) REPORTS.—The Secretary shall ensure that, not
10 later than 18 months after the date of enactment of this
11 Act, an interim report describing the preliminary findings
12 of the study conducted under this section will be issued,
13 and not later than 3 years after such date of enactment,
14 a final report shall be issued. Such reports shall be submit-
15 ted to the Committee on Energy and Commerce of the
16 House of Representatives, and to the Committee on Labor
17 and Human Resources of the Senate.

18 **Subtitle C—National Center for**
19 **Human Genome Research**

20 **SEC. 1521. PURPOSE OF CENTER.**

21 Title IV of the Public Health Service Act, as amended
22 by sections 141(a)(1) and 1611(b)(1)(B) of this Act, is
23 amended—

24 (1) in section 401(b)(2), by adding at the end
25 the following new subparagraph:

1 “(b)(1) Except as provided in paragraph (2), of the
2 amounts appropriated to carry out subsection (a) for a
3 fiscal year, the Director of the Center is authorized to
4 make available not less than 5 percent for carrying out
5 paragraph (6) of such subsection.

6 “(2) With respect to providing funds under sub-
7 section (a)(6) for proposals to address the ethical and legal
8 issues, including the issuing of patents, associated with the
9 genome project, paragraph (1) shall not apply for a fiscal
10 year if the Director of the Center certifies to the Commit-
11 tee on Energy and Commerce of the House of Representa-
12 tives, and to the Committee on Labor and Human Re-
13 sources of the Senate, that the Director has determined
14 that an insufficient number of such proposals meet the
15 applicable requirements of sections 491 and 492.

16 “(3) In carrying out the provisions of paragraph (1),
17 the Director of the Center shall consider proposals from
18 qualified public and nonprofit academic or research facili-
19 ties.”.

1 **TITLE XVI—AWARDS AND**
2 **TRAINING**
3 **Subtitle A—National Research**
4 **Service Awards**

5 **SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDI-**
6 **VIDUALS FROM DISADVANTAGED BACK-**
7 **GROUND.**

8 Section 487(a) of the Public Health Service Act (42
9 U.S.C. 288(a)(4)) is amended by adding at the end the
10 following paragraph:

11 “(4) The Secretary shall carry out paragraph (1) in
12 a manner that will result in the recruitment of women,
13 and members from underrepresented minority groups, into
14 fields of biomedical or behavioral research and in the pro-
15 vision of research training to women and such individ-
16 uals.”.

17 **SEC. 1602. SERVICE PAYBACK REQUIREMENTS.**

18 Paragraph (2) of section 487(c) of the Public Health
19 Service Act (42 U.S.C. 288(c)(2)) is amended to read as
20 follows:

21 “(2)(A) For the initial year for which an individual
22 receives a National Research Service Award for the con-
23 duct of postdoctoral training or research, such individual
24 shall engage in one year of health research or teaching
25 or any combination thereof which is in accordance with

1 the usual patterns of academic employment, or complete
 2 a second year of training or research under such Award.

3 “(B) Service obligations for National Research Serv-
 4 ice Awards that are less than 12 months may be satis-
 5 fied—

6 “(i) by the conduct of health research or teach-
 7 ing or any combination thereof which is in accord-
 8 ance with the usual patterns of academic employ-
 9 ment for a period of time equal to the amount of
 10 time under the Award; or

11 “(ii) by reimbursing the Federal Government
 12 for the amounts provided to such individual under
 13 the Award.”.

14 **Subtitle B—Acquired Immune** 15 **Deficiency Syndrome**

16 **SEC. 1611. LOAN REPAYMENT PROGRAM.**

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

19 “LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
 20 RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

21 “SEC. 487A. (a) IN GENERAL.—

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

1 of the National Institutes of Health, research with
2 respect to acquired immune deficiency syndrome in
3 consideration of the Federal Government agreeing to
4 repay, for each year of such service, not more than
5 \$20,000 of the principal and interest of the edu-
6 cational loans of such health professionals.

7 “(2) LIMITATION.—The Secretary may not
8 enter into an agreement with a health professional
9 pursuant to paragraph (1) unless such profes-
10 sional—

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

13 “(B)(i) was not employed at the National
14 Institutes of Health during the 1-year period
15 preceding the date of the enactment of the
16 Health Professions Reauthorization Act of
17 1988; or

18 “(ii) agrees to serve as an employee of
19 such Institutes for purposes of paragraph (1)
20 for a period of not less than 3 years.”.

21 “(b) APPLICABILITY OF CERTAIN PROVISIONS.—
22 With respect to the National Health Service Corps Loan
23 Repayment Program established in subpart III of part D
24 of title III, the provisions of such subpart shall, except
25 as inconsistent with subsection (a) of this section, apply

1 to the program established in such subsection (a) in the
2 same manner and to the same extent as such provisions
3 apply to the National Health Service Corps Loan Repay-
4 ment Program established in such subpart.

5 “(c) FUNDING; REIMBURSABLE TRANSFERS.—

6 “(1) AUTHORIZATION OF APPROPRIATIONS.—

7 For the purpose of carrying out this section, there
8 are authorized to be appropriated such sums as may
9 be necessary for each of the fiscal years 1994
10 through 1996.

11 “(2) TRANSFERS FOR RELATED PROGRAM.—

12 The Commissioner of Food and Drugs may carry
13 out for the Food and Drug Administration a pro-
14 gram similar to the program established in sub-
15 section (a), which program shall be carried out with
16 respect to the review of applications concerning ac-
17 quired immune deficiency syndrome that are submit-
18 ted to such Commissioner. From the amounts appro-
19 priated under paragraph (1) for a fiscal year, the
20 Secretary may transfer amounts to the Commis-
21 sioner for the purpose of carrying out such program.
22 The Commissioner shall provide a reimbursement to
23 the Secretary for the amount so transferred, and the
24 reimbursement shall be available only for the pro-
25 gram established in subsection (a). Any transfer and

1 reimbursement made for purposes of this paragraph
2 for a fiscal year shall be completed by April 1 of
3 such year.”.

4 **Subtitle C—Loan Repayment for** 5 **Research Generally**

6 **SEC. 1621. ESTABLISHMENT OF PROGRAM.**

7 Part G of title IV of the Public Health Service Act,
8 as redesignated by section 141(a)(2) of this Act and as
9 amended by section 1002 of this Act, is amended by in-
10 serting after section 487B the following new section:

11 “LOAN REPAYMENT PROGRAM FOR RESEARCH
12 GENERALLY

13 “SEC. 487C. (a) IN GENERAL.—

14 “(1) AUTHORITY FOR PROGRAM.—Subject to
15 paragraph (2), the Secretary shall carry out a pro-
16 gram of entering into agreements with appropriately
17 qualified health professionals under which such
18 health professionals agree to conduct research, as
19 employees of the National Institutes of Health, in
20 consideration of the Federal Government agreeing to
21 repay, for each year of such service, not more than
22 \$20,000 of the principal and interest of the edu-
23 cational loans of such health professionals.

24 “(2) LIMITATION.—The Secretary may not
25 enter into an agreement with a health professional

1 pursuant to paragraph (1) unless such profes-
2 sional—

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

5 “(B)(i) was not employed at the National
6 Institutes of Health during the 1-year period
7 preceding the date of the enactment of the
8 Health Professions Reauthorization Act of
9 1988; or

10 “(ii) agrees to serve as an employee of
11 such Institutes for purposes of paragraph (1)
12 for a period of not less than 3 years.”.

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

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

1 authorized to be appropriated such sums as may be nec-
 2 essary for each of the fiscal years 1994 through 1996.”.

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

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

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

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

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

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

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

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

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

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

12 “(A) are enrolled or accepted for enroll-
13 ment as full-time undergraduates at accredited
14 institutions of higher education; and

15 “(B) are from minority groups that are
16 underrepresented in the fields of biomedical or
17 behavioral research.

18 “(b) FACILITATION OF INTEREST OF STUDENTS IN
19 CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In
20 providing employment to individuals pursuant to contracts
21 under subsection (a)(1), the Director of NIH shall carry
22 out activities to facilitate the interest of the individuals
23 in pursuing careers as employees of the National Insti-
24 tutes of Health.

25 “(c) PERIOD OF OBLIGATED SERVICE.—

1 “(1) DURATION OF SERVICE.—For purposes of
2 subparagraph (B) of subsection (a)(1), the period of
3 service for which an individual is obligated to serve
4 as an employee of the National Institutes of Health
5 is 12 months for each academic year for which the
6 scholarship under such subsection is provided.

7 “(2) SCHEDULE FOR SERVICE.—

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

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

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

1 “(iii) not later than 60 days after ob-
2 taining the educational degree involved, the
3 individual will begin serving full-time as
4 such an employee in satisfaction of the pe-
5 riod of service that the individual is obli-
6 gated to provide under subsection
7 (a)(1)(B).

8 “(B) The Director of NIH may defer the
9 obligation of an individual to provide a period
10 of service under subsection (a)(1)(B), if the Di-
11 rector determines that such a deferral is appro-
12 priate.

13 “(3) APPLICABILITY OF CERTAIN PROVISIONS
14 RELATING TO APPOINTMENT AND COMPENSATION.—
15 For any period in which an individual provides serv-
16 ice as an employee of the National Institutes of
17 Health in satisfaction of the obligation of the indi-
18 vidual under subsection (a)(1)(B) or paragraph
19 (2)(A)(i), the individual may be appointed as such
20 an employee without regard to the provisions of title
21 5, United States Code, relating to appointment and
22 compensation.

23 “(d) PROVISIONS REGARDING SCHOLARSHIP.—

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

4 “(A) the individual applying for the schol-
5 arship has submitted to the Director a proposed
6 academic program for the year and the Director
7 has approved the program; and

8 “(B) the individual agrees that the pro-
9 gram will not be altered without the approval of
10 the Director.

11 “(2) ACADEMIC STANDING.—The Director of
12 NIH may not provide a scholarship under subsection
13 (a) for an academic year unless the individual apply-
14 ing for the scholarship agrees to maintain an accept-
15 able level of academic standing, as determined by
16 the educational institution involved in accordance
17 with regulations issued by the Secretary.

18 “(3) LIMITATION ON AMOUNT.—The Director
19 of NIH may not provide a scholarship under sub-
20 section (a) for an academic year in an amount ex-
21 ceeding \$20,000.

22 “(4) AUTHORIZED USES.—A scholarship pro-
23 vided under subsection (a) may be expended only for
24 tuition expenses, other reasonable educational ex-

1 penses, and reasonable living expenses incurred in
2 attending the school involved.

3 “(5) CONTRACT REGARDING DIRECT PAYMENTS
4 TO INSTITUTION.—In the case of an institution of
5 higher education with respect to which a scholarship
6 under subsection (a) is provided, the Director of
7 NIH may enter into a contract with the institution
8 under which the amounts provided in the scholarship
9 for tuition and other educational expenses are paid
10 directly to the institution. Payments to the institu-
11 tion under the contract may be made without regard
12 to section 3324 of title 31, United States Code.

13 “(e) PENALTIES FOR BREACH OF SCHOLARSHIP
14 CONTRACT.—The provisions of section 338E shall apply
15 to the program established in subsection (a) to the same
16 extent and in the same manner as such provisions apply
17 to the National Health Service Corps Loan Repayment
18 Program established in section 338B.

19 “(f) REQUIREMENT OF APPLICATION.—The Director
20 of NIH may not provide a scholarship under subsection
21 (a) unless an application for the scholarship is submitted
22 to the Director and the application is in such form, is
23 made in such manner, and contains such agreements, as-
24 surances, and information as the Director determines to
25 be necessary to carry out this section.

1 “(g) AVAILABILITY OF AUTHORIZATION OF APPRO-
2 PRIATIONS.—Amounts appropriated for a fiscal year for
3 scholarships under this section shall remain available until
4 the expiration of the second fiscal year beginning after the
5 fiscal year for which the amounts were appropriated.

6 “LOAN REPAYMENT PROGRAM REGARDING CLINICAL
7 RESEARCHERS FROM DISADVANTAGED BACKGROUNDS

8 “SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—

9 “(1) IN GENERAL.—Subject to section
10 487(a)(1)(C), the Secretary, acting through the Di-
11 rector of NIH may, subject to paragraph (2), carry
12 out a program of entering into contracts with appro-
13 priately qualified health professionals who are from
14 disadvantaged backgrounds under which such health
15 professionals agree to conduct clinical research as
16 employees of the National Institutes of Health in
17 consideration of the Federal Government agreeing to
18 pay, for each year of such service, not more than
19 \$20,000 of the principal and interest of the edu-
20 cational loans of the health professionals.

21 “(2) LIMITATION.—The Director of NIH may
22 not enter into a contract with a health professional
23 pursuant to paragraph (1) unless such professional
24 has a substantial amount of education loans relative
25 to income.

1 “(3) APPLICABILITY OF CERTAIN PROVISIONS
2 REGARDING OBLIGATED SERVICE.—Except to the ex-
3 tent inconsistent with this section, the provisions of
4 sections 338C and 338E shall apply to the program
5 established in paragraph (1) to the same extent and
6 in the same manner as such provisions apply to the
7 National Health Service Corps Loan Repayment
8 Program established in section 338B.

9 “(b) AVAILABILITY OF AUTHORIZATION OF APPRO-
10 PRIATIONS.—Amounts appropriated for a fiscal year for
11 contracts under subsection (a) shall remain available until
12 the expiration of the second fiscal year beginning after the
13 fiscal year for which the amounts were appropriated.”.

14 **SEC. 1632. FUNDING.**

15 Section 487(a)(1) of the Public Health Service Act
16 (42 U.S.C. 288(a)(1)) is amended—

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

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

21 (3) by adding at the end the following new sub-
22 paragraph:

23 “(C) provide contracts for scholarships and loan
24 repayments in accordance with sections 487D and
25 487E, subject to providing not more than an aggre-

1 gate 50 such contracts during the fiscal years 1994
2 through 1996.”.

3 **Subtitle E—Funding**

4 **SEC. 1641. AUTHORIZATION OF APPROPRIATIONS.**

5 Section 487(d) of the Public Health Service Act (42
6 U.S.C. 288(d)) is amended—

7 (1) in the first sentence, by amending the sen-
8 tence to read as follows: “For the purpose of carry-
9 ing out this section, there are authorized to be ap-
10 propriated \$400,000,000 for fiscal year 1994, and
11 such sums as may be necessary for each of the fiscal
12 years 1995 and 1996.”; and

13 (2) in paragraph (3)—

14 (A) by striking “one-half of one percent”
15 each place such term appears and inserting “1
16 percent”; and

17 (B) by striking “780, 784, or 786” and in-
18 serting “747, 748, or 749”.

19 **TITLE XVII—NATIONAL FOUNDA-**
20 **TION FOR BIOMEDICAL RE-**
21 **SEARCH**

22 **SEC. 1701. NATIONAL FOUNDATION FOR BIOMEDICAL RE-**
23 **SEARCH.**

24 Section 499 of the Public Health Service Act, as re-
25 designated by section 121(b), is amended—

1 (1) in subsection (a), by striking “, except for”
2 and all that follows through “Transfer Act”;

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

6 (3) by striking subsection (b) and inserting in
7 lieu thereof the following new subsections:

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

13 “(c) CERTAIN ACTIVITIES OF FOUNDATION.—

14 “(1) IN GENERAL.—In carrying out subsection
15 (b), the Foundation may solicit and accept gifts,
16 grants, and other donations, establish accounts, and
17 invest and expend funds in support of the following
18 activities with respect to the purpose described in
19 such subsection:

20 “(A) A program to provide and administer
21 endowed positions that are associated with the
22 research program of the National Institutes of
23 Health. Such endowments may be expended for
24 the compensation of individuals holding the po-
25 sitions, for staff, equipment, quarters, travel,

1 and other expenditures that are appropriate in
2 supporting the endowed positions.

3 “(B) A program to provide and administer
4 fellowships and grants to research personnel in
5 order to work and study in association with the
6 National Institutes of Health. Such fellowships
7 and grants may include stipends, travel, health
8 insurance benefits and other appropriate ex-
9 penses. The recipients of fellowships shall be se-
10 lected by the donors and the Foundation upon
11 the recommendation of the National Institutes
12 of Health employees in the laboratory where the
13 fellow would serve, and shall be subject to the
14 agreement of the Director of the National Insti-
15 tutes of Health and the Executive Director of
16 the Foundation.

17 “(C) Supplementary programs to provide
18 for—

19 “(i) scientists of other countries to
20 serve in research capacities in the United
21 States in association with the National In-
22 stitutes of Health or elsewhere, or opportu-
23 nities for employees of the National Insti-
24 tutes of Health or other public health offi-

1 cials in the United States to serve in such
2 capacities in other countries, or both;

3 “(ii) the conduct and support of stud-
4 ies, projects, and research, which may in-
5 clude stipends, travel and other support for
6 personnel in collaboration with national
7 and international non-profit and for-profit
8 organizations;

9 “(iii) the conduct and support of fo-
10 rums, meetings, conferences, courses, and
11 training workshops that may include un-
12 dergraduate, graduate, post-graduate, and
13 post-doctoral accredited courses and the
14 maintenance of accreditation of such
15 courses by the Foundation at the State
16 and national level for college or continuing
17 education credits or for degrees;

18 “(iv) programs to support and encour-
19 age teachers and students of science at all
20 levels of education and programs for the
21 general public which promote the under-
22 standing of science;

23 “(v) programs for writing, editing,
24 printing, publishing, and vending of books
25 and other materials; and

1 “(vi) the conduct of other activities to
2 carry out and support the purpose de-
3 scribed in subsection (b).

4 “(2) FEES.—The Foundation may assess fees
5 for the provision of professional, administrative and
6 management services by the Foundation in amounts
7 determined reasonable and appropriate by the Exec-
8 utive Director.

9 “(3) AUTHORITY OF FOUNDATION.—The Foun-
10 dation shall be the sole entity responsible for carry-
11 ing out the activities described in this subsection.”;

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

13 (A) in paragraph (1)—

14 (i) by striking “members of the Foun-
15 dation” in subparagraph (A) and inserting
16 “appointed members of the Board”;

17 (ii) by striking “Council” in subpara-
18 graph (B) and inserting “Board”;

19 (iii) by striking “Council” in subpara-
20 graph (C) and inserting “Board”; and

21 (iv) by adding at the end thereof the
22 following new subparagraphs:

23 “(D)(i) Not later than 30 days after the
24 date of enactment of the National Institutes of
25 Health Revitalization Act of 1993, the Director

1 of the National Institutes of Health shall con-
2 vene a meeting of the ex officio members of the
3 Board to—

4 “(I) incorporate the Foundation and
5 establish the general policies of the Foun-
6 dation for carrying out the purposes of
7 subsection (b), including the establishment
8 of the bylaws of the Foundation; and

9 “(II) appoint the members of the
10 Board in accordance with subparagraph
11 (C).

12 “(ii) Upon the appointment of the mem-
13 bers of the Board under clause (i)(II), the
14 terms of service of the ex officio members of the
15 Board as members of the Board shall termi-
16 nate.

17 “(E) The agreement of not less than three-
18 fifths of the members of the ex officio members
19 of the Board shall be required for the appoint-
20 ment of each member to the initial Board.

21 “(F) No employee of the National Insti-
22 tutes of Health shall be appointed as a member
23 of the Board.

24 “(G) The Board may, through amend-
25 ments to the bylaws of the Foundation, provide

1 that the number of members of the Board shall
2 be greater than the number specified in sub-
3 paragraph (C).”;

4 (B) in paragraph (2)—

5 (i) by inserting “(A)” before “The
6 ex”;

7 (ii) by striking “an appointed member
8 of the Board to serve as the Chair” and in-
9 serting “an individual to serve as the ini-
10 tial Chairperson”; and

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

13 “(B) Upon the termination of the term of serv-
14 ice of the initial Chairperson of the Board, the ap-
15 pointed members of the Board shall elect a member
16 of the Board to serve as the Chairperson of the
17 Board.”;

18 (C) in paragraph (3)(A), by striking
19 “(2)(C)” and inserting “(1)(C)”; and

20 (D) by adding at the end thereof the fol-
21 lowing new paragraphs:

22 “(5) MEETINGS AND QUORUM.—A majority of
23 the members of the Board shall constitute a quorum
24 for purposes of conducting the business of the
25 Board.

1 “(6) CERTAIN BYLAWS.—

2 “(A) In establishing bylaws under this sub-
3 section, the Board shall ensure that the follow-
4 ing are provided for:

5 “(i) Policies for the selection of the
6 officers, employees, agents, and contractors
7 of the Foundation.

8 “(ii) Policies, including ethical stand-
9 ards, for the acceptance, solicitation, and
10 disposition of donations and grants to the
11 Foundation and for the disposition of the
12 assets of the Foundation. Policies with re-
13 spect to ethical standards shall ensure that
14 officers, employees and agents of the
15 Foundation (including members of the
16 Board) avoid encumbrances that would re-
17 sult in a conflict of interest, including a fi-
18 nancial conflict of interest or a divided al-
19 legiance. Such policies shall include re-
20 quirements for the provision of information
21 concerning any ownership or controlling in-
22 terest in entities related to the activities of
23 the Foundation by such officers, employees
24 and agents and their spouses and relatives.

1 “(iii) Policies for the conduct of the
2 general operations of the Foundation.

3 “(iv) Policies for writing, editing,
4 printing, publishing, and vending of books
5 and other materials.

6 “(B) In establishing bylaws under this sub-
7 section, the Board shall ensure that such by-
8 laws (and activities carried out under the by-
9 laws) do not—

10 “(i) reflect unfavorably upon the abil-
11 ity of the Foundation or the National In-
12 stitutes of Health to carry out its respon-
13 sibilities or official duties in a fair and ob-
14 jective manner; or

15 “(ii) compromise, or appear to com-
16 promise, the integrity of any governmental
17 agency or program, or any officer or em-
18 ployee involved in such program.”;

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

20 (A) by inserting “, and define the duties of
21 the officers and employees” before the semi-
22 colon in paragraph (4);

23 (B) by striking paragraph (5);

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

4 (D) by striking paragraph (8) (as so redesi-
5 gnated), and inserting the following new para-
6 graph:

7 “(8) establish a process for the selection of can-
8 didates for positions under subsection (c);”

9 (E) by inserting “solicit” after the para-
10 graph designation in paragraph (11) (as so re-
11 designated);

12 (F) by striking “Executive” in paragraph
13 (12) (as so redesignated);

14 (G) by striking “and” at the end of para-
15 graph (13) (as so redesignate); and

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

18 “(14) enter into such other contracts, leases,
19 cooperative agreements, and other transactions as
20 the Director considers appropriate to conduct the ac-
21 tivities of the Foundation; and”;

22 (6) by inserting after subsection (j) (as so re-
23 designated), the following new subsections:

24 “(k) GENERAL PROVISIONS.—

1 “(1) FOUNDATION INTEGRITY.—The members
2 of the Board shall be accountable for the integrity
3 of the operations of the Foundation and shall ensure
4 such integrity through the development and enforce-
5 ment of criteria and procedures relating to stand-
6 ards of conduct (including those developed under
7 subsection (d)(2)(B)(i)(II)), financial disclosure
8 statements, conflict of interest rules, recusal and
9 waiver rules, audits and other matter determined ap-
10 propriate by the Board.

11 “(2) FINANCIAL CONFLICTS OF INTEREST.—
12 Any individual who is an officer, employee, or mem-
13 ber of the Board of the Foundation may not (in ac-
14 cordance with policies and requirements developed
15 under subsection (d)(2)(B)(i)(II)) personally or sub-
16 stantially participate in the consideration or deter-
17 mination by the Foundation of any matter that
18 would directly or predictably affect any financial in-
19 terest of the individual or a relative (as such term
20 is defined in section 109(16) of the Ethics in Gov-
21 ernment Act of 1978) of the individual, of any busi-
22 ness organization or other entity, or of which the in-
23 dividual is an officer or employee, or is negotiating
24 for employment, or in which the individual has any
25 other financial interest.

1 “(3) AUDITS; AVAILABILITY OF RECORDS.—The
2 Foundation shall—

3 “(A) provide for annual audits of the fi-
4 nancial condition of the Foundation; and

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

10 “(4) REPORTS.—

11 “(A) Not later than 5 months following the
12 end of each fiscal year, the Foundation shall
13 publish a report describing the activities of the
14 Foundation during the preceding fiscal year.
15 Each such report shall include for the fiscal
16 year involved a comprehensive statement of the
17 operations, activities, financial condition, and
18 accomplishments of the Foundation.

19 “(B) With respect to the financial condi-
20 tion of the Foundation, each report under sub-
21 paragraph (A) shall include the source, and a
22 description of, all gifts or grants to the Founda-
23 tion of real or personal property, and the source
24 and amount of all gifts or grants to the Foun-
25 dation of money. Each such report shall include

1 a specification of any restrictions on the pur-
2 poses for which gifts or grants to the Founda-
3 tion may be used.

4 “(C) The Foundation shall make copies of
5 each report submitted under subparagraph (A)
6 available for public inspection, and shall upon
7 request provide a copy of the report to any indi-
8 vidual for a charge not exceeding the cost of
9 providing the copy.

10 “(D) The Board shall annually hold a pub-
11 lic meeting to summarize the activities of the
12 Foundation and distribute written reports con-
13 cerning such activities and the scientific results
14 derived from such activities.

15 “(5) SERVICE OF FEDERAL EMPLOYEES.—Fed-
16 eral employees may serve on committees advisory to
17 the Foundation and otherwise cooperate with and
18 assist the Foundation in carrying out its function, so
19 long as the employees do not direct or control Foun-
20 dation activities.

21 “(6) RELATIONSHIP WITH EXISTING ENTI-
22 TIES.—The Foundation may, pursuant to appro-
23 priate agreements, merge with, acquire, or use the
24 resources of existing nonprofit private corporations
25 with missions similar to the purposes of the Founda-

1 tion, such as the Foundation for Advanced Edu-
2 cation in the Sciences.

3 “(7) INTELLECTUAL PROPERTY RIGHTS.—The
4 Board shall adopt written standards with respect to
5 the ownership of any intellectual property rights de-
6 rived from the collaborative efforts of the Founda-
7 tion prior to the commencement of such efforts.

8 “(8) NATIONAL INSTITUTES OF HEALTH
9 AMENDMENTS OF 1990.—The activities conducted in
10 support of the National Institutes of Health Amend-
11 ments of 1990 (Public Law 101-613) and the
12 amendments made by such Act, shall not be nullified
13 by the enactment of this section.

14 “(9) LIMITATION OF ACTIVITIES.—The Foun-
15 dation shall exist solely as an entity to work in col-
16 laboration with the research programs of the Na-
17 tional Institutes of Health. The Foundation may not
18 undertake activities (such as the operation of inde-
19 pendent laboratories or competing for Federal re-
20 search funds) that are independent of those of the
21 National Institutes of Health research programs.

22 “(l) DUTIES OF THE DIRECTOR.—

23 “(1) APPLICABILITY OF CERTAIN STANDARDS
24 TO NON-FEDERAL EMPLOYEES.—In the case of any
25 individual who is not an employee of the Federal

1 Government and who serves in association with the
2 National Institutes of Health, with respect to finan-
3 cial assistance received from the Foundation, the
4 Foundation may not provide the assistance of, or
5 otherwise permit the work at the National Institutes
6 of Health to begin until a memorandum of under-
7 standing between the individual and the Director of
8 the National Institutes of Health, or the designee of
9 such Director, has been executed specifying that the
10 individual shall be subject to such ethical and proce-
11 dural standards of conduct relating to duties per-
12 formed at the National Institutes of Health, as the
13 Director of the National Institutes of Health deter-
14 mines is appropriate.

15 “(2) SUPPORT SERVICES.—The Director of the
16 National Institutes of Health may provide facilities,
17 utilities and support services to the Foundation if it
18 is determined by the Director to be advantageous to
19 the research programs of the National Institutes of
20 Health.”;

21 (7) in subsection (m) (as so redesignated)—

22 (A) by striking “\$200,000” each place that
23 such appears and inserting “\$500,000”; and

24 (B) by striking “1995” in paragraph (1)
25 and inserting “1996”; and

1 (8) by adding at the end thereof the following
2 new subsections:

3 “(n) LIMITATION.—The Secretary shall ensure that
4 no extramural funds made available by the National Insti-
5 tutes of Health are provided to the Foundation or for ac-
6 tivities provided for under subparagraphs (A) and (B) of
7 subsection (c)(1).

8 “(o) REPORT ON ADEQUACY OF COMPLIANCE.—

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

13 “(A) whether the Foundation is in compli-
14 ance with the guidelines established under this
15 section; and

16 “(B) whether the procedures utilized under
17 this section are adequate to prevent conflicts of
18 interest involving the Foundation, the employ-
19 ees of the Foundation or members of the Board
20 of the Foundation.

21 “(2) REPORT.—Not later than 18 months after
22 the date on which the Foundation is incorporated,
23 the Comptroller General of the United States shall
24 complete the audit required under paragraph (1)
25 and prepare and submit to the Committee on En-

1 ergy and Commerce of the House of Representatives
2 and the Committee on Labor and Human Resources
3 of the Senate, a report describing the findings made
4 with respect to such audit.”.

5 **TITLE XVIII—RESEARCH WITH**
6 **RESPECT TO ACQUIRED IM-**
7 **MUNE DEFICIENCY SYN-**
8 **DROME**

9 **SEC. 1801. REVISION AND EXTENSION OF VARIOUS PRO-**
10 **GRAMS.**

11 (a) AMENDMENTS.—Title XXIII of the Public Health
12 Service Act (42 U.S.C. 300cc et seq.) is amended—

13 (1) in section 2304(c)(1)—

14 (A) in the matter preceding subparagraph
15 (A), by inserting after “Director of such Insti-
16 tute” the following: “(and may provide advice
17 to the Directors of other agencies of the Na-
18 tional Institutes of Health, as appropriate)”;
19 and

20 (B) in subparagraph (A), by inserting be-
21 fore the semicolon the following: “, including
22 recommendations on the projects of research
23 with respect to diagnosing immune deficiency
24 and with respect to predicting, diagnosing, pre-

1 venting, and treating cancers, opportunistic in-
2 fections, and infectious diseases”;

3 (2) in section 2311(a)(1), by inserting before
4 the semicolon the following: “, including evaluations
5 of methods of diagnosing immune deficiency and
6 evaluations of methods of predicting, diagnosing,
7 preventing, and treating cancers, opportunistic infec-
8 tions, and infectious diseases”;

9 (3) in section 2315(a)(2), by striking “inter-
10 national research” and all that follows and inserting
11 “international research and training concerning the
12 natural history and pathogenesis of the human
13 immunodeficiency virus and the development and
14 evaluation of vaccines and treatments for acquired
15 immune deficiency syndrome and opportunistic infec-
16 tions.”;

17 (4) in section 2318—

18 (A) in subsection (a)(1)—

19 (i) by inserting after “The Secretary”
20 the following: “, acting through the Direc-
21 tor of the National Institutes of Health
22 and after consultation with the Adminis-
23 trator for Health Care Policy and Re-
24 search,”; and

1 (ii) by striking “syndrome” and in-
2 sserting “syndrome, including treatment
3 and prevention of HIV infection and relat-
4 ed conditions among women”; and

5 (B) in subsection (e), by striking “1991.”
6 and inserting the following: “1991, and such
7 sums as may be necessary for each of the fiscal
8 years 1994 through 1996.”;

9 (5) in section 2320(b)(1)(A), by striking “syn-
10 drome” and inserting “syndrome and the natural
11 history of such infection”;

12 (6) in the part heading for part D, by striking
13 “DIRECTOR OF THE NATIONAL INSTITUTES OF
14 HEALTH” and inserting “OFFICE OF AIDS RE-
15 SEARCH”;

16 (7) in section 2351—

17 (A) by redesignating subsections (a), (b)
18 and (c) as subsections (c), (d) and (e), respec-
19 tively;

20 (B) by inserting after the section heading
21 the following new subsections:

22 “(a) IN GENERAL.—In carrying out research with re-
23 spect to acquired immune deficiency syndrome, the Sec-
24 retary, acting through the Director of the National Insti-
25 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—

4 “(A) be appointed by the Secretary;

5 “(B) be determined by the Secretary to be
6 an individual who is an outstanding scientist
7 and a highly skilled administrator;

8 “(C) report directly to the Director of the
9 National Institutes of Health; and

10 “(D) be the primary Federal official re-
11 sponsible for the conduct of AIDS-related re-
12 search at the National Institutes of Health; and

13 “(2) shall provide administrative support and
14 support services to the Director of such Office and
15 shall ensure that such support takes maximum ad-
16 vantage of existing administrative structures at the
17 institutes, centers and divisions of the National In-
18 stitutes of Health to the fullest extent practicable.

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 oversee the implementation of a scientifically justi-
7 fied budget for AIDS-related research at the Na-
8 tional Institutes of Health and coordinate all AIDS-
9 related research activities conducted at the insti-
10 tutes, centers, and divisions of the National Insti-
11 tutes of Health, and conduct evaluations on all such
12 programs.

13 “(3) STRATEGIC PLAN.—

14 “(A) DEVELOPMENT.—The Director of the
15 Office of AIDS Research shall, based on the ad-
16 vice of the directors of the institutes, centers,
17 and divisions of the National Institutes of
18 Health, and in consultation with the advisory
19 council established in paragraph (5) and the co-
20 ordinating groups established in subparagraph
21 (B), develop and oversee the implementation of
22 a comprehensive, long-range plan for the con-
23 duct and support of such research by the insti-
24 tutes, centers and divisions of the National In-

1 stitutes of Health. Such plan shall be updated
2 annually, and shall—

3 “(i) determine the appropriate overall
4 balance between basic and applied research
5 and between intramural and extramural re-
6 search;

7 “(ii) determine and prioritize among
8 critical scientific AIDS-related questions;

9 “(iii) based upon such determinations,
10 specify the broad short and long range ob-
11 jectives to be achieved, and provide an esti-
12 mate of the resources needed to achieve
13 such objectives;

14 “(iv) evaluate the sufficiency of exist-
15 ing AIDS research programs to meet such
16 objectives, and establish evaluation criteria,
17 timelines and objectives for future program
18 evaluation activities; and

19 “(v) make recommendations for
20 changes and necessary resource allocation
21 in and among such programs.

22 “(B) COORDINATING GROUPS.—The Direc-
23 tor of the Office of AIDS Research shall estab-
24 lish AIDS coordinating groups for each re-
25 search discipline within the AIDS research pro-

1 gram, composed of representatives of relevant
2 agencies of the National Institutes of Health
3 and qualified extramural scientists, to evaluate
4 and assess the efforts of the AIDS Research
5 Program at the National Institutes of Health,
6 to advise on the development of the strategic
7 plan described in subparagraph (A), and to de-
8 termine the extent to which such efforts are in
9 accordance with such strategic plan.

10 “(4) COORDINATION.—The Director of the Of-
11 fice of AIDS Research shall act as the primary Fed-
12 eral official with responsibility for overseeing all
13 AIDS-related research efforts undertaken by the Na-
14 tional Institutes of Health, and

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

19 “(B) shall maintain communications with
20 all relevant Public Health Service agencies and
21 with various other departments of the Federal
22 Government, to ensure the timely transmission
23 of information concerning advances in AIDS-re-
24 lated research and the clinical treatment of
25 AIDS and its related conditions, between these

1 various agencies for dissemination to affected
2 communities and health care providers.

3 “(5) ADVISORY COUNCIL.—

4 “(A) ESTABLISHMENT.—The Secretary
5 shall, consistent with section 406, establish an
6 advisory council to be known as the Office of
7 AIDS Research Advisory Council (hereafter re-
8 ferred to as the ‘Council’), which shall serve to
9 replace the AIDS Program Advisory Committee
10 which is operating on the date of enactment of
11 this subsection.

12 “(B) COMPOSITION.—The Council shall be
13 composed of biomedical, behavioral, and social
14 scientists, and representatives of diverse HIV
15 affected communities, and shall be appointed by
16 the Secretary.

17 “(C) AUTHORITY.—The Council shall—

18 “(i) advise the Director of the Office
19 of AIDS Research and make recommenda-
20 tions concerning the development of the
21 AIDS-related research budget, and the de-
22 velopment and implementation of the stra-
23 tegic plan for AIDS-related research at the
24 National Institutes of Health;

1 “(ii) provide the second level of peer
2 review for awards made directly from the
3 Office of AIDS Research from the discre-
4 tionary fund described in paragraph (7);
5 and

6 “(iii) carry out such other activities
7 determined appropriate by the Director of
8 the Office of AIDS Research.

9 “(6) BUDGETARY AUTHORITY.—The Director
10 of the Office of AIDS Research shall—

11 “(A) in accordance with the strategic plan
12 established under paragraph (3), in consultation
13 with the Council, and based on budget requests
14 and additional advice from the directors of the
15 institutes, centers and divisions of the National
16 Institutes of Health, prepare and submit di-
17 rectly to the President for review and transmit-
18 tal to Congress, an annual, scientifically justi-
19 fied budget estimate for AIDS-related research
20 conducted within the agencies of the National
21 Institutes of Health, after reasonable oppor-
22 tunity for comment (but without change) by the
23 Secretary and the Director of the National In-
24 stitutes of Health, which shall include the
25 amount of funds required (as requested by the

1 directors of such institutes, centers and divi-
2 sions) for—

3 “(i) the continued funding of the com-
4 mitment base (ongoing program initiatives)
5 at the sole discretion of the directors of
6 such institutes, centers and divisions; and

7 “(ii) the funding of new and compet-
8 ing program initiatives through such insti-
9 tutes, centers and divisions, at the discre-
10 tion of the Director of the Office of AIDS
11 Research;

12 “(B) receive from the President and the
13 Office of Management and Budget directly all
14 AIDS-related research funds appropriated by
15 Congress for transfer to, and obligation and ex-
16 penditure by, the institutes, centers and divi-
17 sions of the National Institutes of Health in ac-
18 cordance with the budget delineated under
19 clauses (i) and (ii) of subparagraph (A); and

20 “(C) distribute AIDS research funding to
21 the various institutes, centers, and divisions of
22 the National Institutes of Health in accordance
23 with the budget delineated under clauses (i)
24 and (ii) of subparagraph (A).

1 The provisions of this paragraph shall become effective in the fiscal year following the submission of the consolidated AIDS budget.

4 “(7) DISCRETIONARY FUND.—

5 “(A) AVAILABILITY OF FUNDS.—The Secretary shall ensure that not to exceed 25 percent of the funds available in excess of the amount of baseline AIDS research spending during the previous fiscal year, be made available to the Director of the Office of AIDS Research for the establishment of an AIDS research discretionary fund.

13 “(B) USE.—The Director of the Office of AIDS Research, in consultation with the advisory council established under paragraph (5), shall use amounts in the AIDS research discretionary fund, either through the institutes, centers and divisions of the National Institutes of Health or grants made directly by the Office of AIDS Research, to—

21 “(i) fund emergency AIDS research programs;

23 “(ii) fund programs for the conduct of research aimed at filling gaps that exist in 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 relating to the number of individuals
8 who may be employed as full-time equivalent in-
9 dividuals, with respect to the number of full-
10 time equivalent individuals so employed, the Di-
11 rector of the Office of AIDS Research shall be
12 permitted to authorize the employment of such
13 full-time equivalent individuals to perform
14 AIDS-related research through the institutes,
15 centers and divisions of the National Institutes
16 of Health as described in clauses (i) and (ii) of
17 subparagraph (B) and subject to appropria-
18 tions.”;

19 (C) in subsection (c) (as so redesign-
20 ated)—

21 (i) by striking the subsection designa-
22 tion and all that follows through paragraph
23 (1) and inserting the following:

24 “(c) OTHER DUTIES.—The director of the office—
25 ”;

1 (ii) by redesignating paragraphs (2)
2 through (8) as paragraphs (1) through (7),
3 respectively;

4 (iii) by striking “for the appropriate
5 national research institute of the National
6 Institutes of Health” in paragraph (4) (as
7 so redesignated); and

8 (iv) by inserting “cannot reasonably
9 be accomplished within the United States
10 and” after “if such research” in paragraph
11 (4)(A) (as so redesignated); and

12 (D) by adding at the end thereof the fol-
13 lowing new subsection:

14 “(f) EVALUATION AND REPORT.—

15 “(1) EVALUATION.—Not later than 5 years
16 after the date of enactment of this Act, the Sec-
17 retary shall conduct an evaluation to—

18 “(A) determine the effect of this section on
19 the planning and coordination of the AIDS re-
20 search programs at the institutes, centers and
21 divisions of the National Institutes of Health;

22 “(B) evaluate the extent to which this sec-
23 tion has eliminated the duplication of adminis-
24 trative resources among such institutes, centers
25 and divisions; and

1 “(C) provide recommendations concerning
2 future alterations with respect to this section.

3 “(2) REPORT.—Not later than 1 year after the
4 date on which the evaluation is commenced under
5 paragraph (1), the Secretary shall prepare and sub-
6 mit to the Committee on Labor and Human Re-
7 sources of the Senate and the Committee on Energy
8 and Commerce of the House of Representatives, a
9 report concerning the results of such evaluation.”;

10 (8) in section 2361, by striking “For purposes”
11 and all that follows and inserting the following:

12 “For purposes of this title:

13 “(1) The term ‘infection’, with respect to the
14 etiologic agent for acquired immune deficiency syn-
15 drome, includes cancers, opportunistic infections,
16 and infectious diseases and any other conditions
17 arising from infection with such etiologic agent.

18 “(2) The term ‘treatment’, with respect to the
19 etiologic agent for acquired immune deficiency syn-
20 drome, includes primary and secondary prophylaxis.”;

22 (9) in section 2315(f), by striking “there are
23 authorized” and all that follows and inserting “there
24 are authorized to be appropriated such sums as may
25 be necessary for each fiscal year.”;

1 (10) in section 2320(e)(1), by striking “there
2 are authorized” and all that follows and inserting
3 “there are authorized to be appropriated such sums
4 as may be necessary for each fiscal year.”; and

5 (11) in section 2341(d), by striking “there are
6 authorized” and all that follows and inserting “there
7 are authorized to be appropriated such sums as may
8 be necessary for each fiscal year.”.

9 **TITLE XIX—STUDIES**

10 **SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.**

11 (a) CERTAIN DRUG-RELEASE MECHANISMS.—

12 (1) The Secretary of Health and Human Serv-
13 ices shall, subject to paragraph (2), enter into a con-
14 tract with a public or nonprofit private entity to con-
15 duct a study for the purpose of determining, with re-
16 spect to acquired immune deficiency syndrome, the
17 impact of parallel-track drug-release mechanisms on
18 public and private clinical research, and on the ac-
19 tivities of the Commissioner of Food and Drugs re-
20 garding the approval of drugs.

21 (2) The Secretary of Health and Human Serv-
22 ices shall request the Institute of Medicine of the
23 National Academy of Sciences to enter into the con-
24 tract under paragraph (1) to conduct the study de-
25 scribed in such paragraph. If such Institute declines

1 to conduct the study, the Secretary shall carry out
2 paragraph (1) through another public or nonprofit
3 private entity.

4 (b) THIRD-PARTY PAYMENTS REGARDING CERTAIN
5 CLINICAL TRIALS.—The Secretary of Health and Human
6 Services shall conduct a study for the purpose of—

7 (1) determining the policies of third-party
8 payors regarding the payment of the costs of appro-
9 priate health services that are provided incident to
10 the participation of individuals as subjects in clinical
11 trials conducted in the development of drugs with re-
12 spect to acquired immune deficiency syndrome; and

13 (2) developing recommendations regarding such
14 policies.

15 (c) ADVISORY COMMITTEES.—The Secretary of
16 Health and Human Services, acting through the Director
17 of the National Institutes of Health, shall conduct a study
18 for the purpose of determining—

19 (1) whether the activities of the various advi-
20 sory committees established in the National Insti-
21 tutes of Health regarding acquired immune defi-
22 ciency syndrome are being coordinated sufficiently;
23 and

1 (2) whether the functions of any of such advi-
2 sory committees should be modified in order to
3 achieve greater efficiency.

4 (d) VACCINES FOR HUMAN IMMUNODEFICIENCY
5 VIRUS.—

6 (1) IN GENERAL.—The Secretary of Health and
7 Human Services, acting through the National Insti-
8 tutes of Health, shall develop a plan for the appro-
9 priate inclusion of HIV-infected women, including
10 pregnant women, HIV-infected infants, and HIV-in-
11 fected children in studies conducted by or through
12 the National Institutes of Health concerning the
13 safety and efficacy of HIV vaccines for the treat-
14 ment and prevention of HIV infection. Such plan
15 shall ensure the full participation of other Federal
16 agencies currently conducting HIV vaccine studies
17 and require that such studies conform fully to the
18 requirements of part 46 of title 45, Code of Federal
19 Regulations.

20 (2) REPORT.—Not later than 180 days after
21 the date of the enactment of this Act, the Secretary
22 of Health and Human Services shall prepare and
23 submit to the Committee on Energy and Commerce
24 of the House of Representatives, and the Committee
25 on Labor and Human Resources of the Senate, a re-

1 port concerning the plan developed under paragraph
2 (1).

3 (3) IMPLEMENTATION.—Not later than 12
4 months after the date of the enactment of this Act,
5 the Secretary of Health and Human Services shall
6 implement the plan developed under paragraph (1),
7 including measures for the full participation of other
8 Federal agencies currently conducting HIV vaccine
9 studies.

10 (4) For the purpose of carrying out this sub-
11 section, there are authorized to be appropriated such
12 sums as may be necessary for each of the fiscal
13 years 1994 through 1996.

14 **SEC. 1902. MALNUTRITION IN THE ELDERLY.**

15 (a) STUDY.—

16 (1) IN GENERAL.—The Secretary of Health and
17 Human Services (referred to in this section as the
18 “Secretary”), acting through the National Institute
19 on Aging, coordinating with the Agency for Health
20 Care Policy and Research and, to the degree pos-
21 sible, in consultation with the head of the National
22 Nutrition Monitoring System established under sec-
23 tion 1428 of the Food and Agriculture Act of 1977
24 (7 U.S.C. 3178), shall conduct a 3-year nutrition

1 screening and intervention activities study of the el-
2 derly.

3 (2) EFFICACY AND COST-EFFECTIVENESS OF
4 NUTRITION SCREENING AND INTERVENTION ACTIVI-
5 TIES.—In conducting the study, the Secretary shall
6 determine the efficacy and cost-effectiveness of nu-
7 trition screening and intervention activities con-
8 ducted in the elderly health and long-term care con-
9 tinuum, and of a program that would institutionalize
10 nutrition screening and intervention activities. In
11 evaluating such a program, the Secretary shall de-
12 termine—

13 (A) if health or quality of life is measur-
14 ably improved for elderly individuals who re-
15 ceive routine nutritional screening and treat-
16 ment;

17 (B) if federally subsidized home or institu-
18 tional care is reduced because of increased inde-
19 pendence of elderly individuals resulting from
20 improved nutritional status;

21 (C) if a multidisciplinary approach to nu-
22 tritional care is effective in addressing the nu-
23 tritional needs of elderly individuals; and

24 (D) if reimbursement for nutrition screen-
25 ing and intervention activities is a cost-effective

1 approach to improving the health status of el-
2 derly individuals.

3 (3) POPULATIONS.—The populations of elderly
4 individuals in which the study will be conducted
5 shall include populations of elderly individuals who
6 are—

7 (A) living independently, including—

8 (i) individuals who receive home and
9 community-based services or family sup-
10 port;

11 (ii) individuals who do not receive ad-
12 ditional services and support;

13 (iii) individuals with low incomes; and

14 (iv) individuals who are minorities;

15 (B) hospitalized, including individuals ad-
16 mitted from home and from institutions; and

17 (C) institutionalized in residential facilities
18 such as nursing homes and adult homes.

19 (b) MALNUTRITION STUDY.—The Secretary, acting
20 through the National Institute on Aging, shall conduct a
21 3-year study to determine the extent of malnutrition in
22 elderly individuals in hospitals and long-term care facili-
23 ties and in elderly individuals who are living independ-
24 ently.

1 (c) REPORT.—The Secretary shall submit a report to
2 the Committee on Labor and Human Resources of the
3 Senate and the Committee on Energy and Commerce of
4 the House of Representatives containing the findings re-
5 sulting from the studies described in subsections (a) and
6 (b), including a determination regarding whether a pro-
7 gram that would institutionalize nutrition screening and
8 intervention activities should be adopted, and the rationale
9 for the determination.

10 (d) ADVISORY PANEL.—

11 (1) ESTABLISHMENT.—The Secretary, acting
12 through the Director of the National Institute on
13 Aging, shall establish an advisory panel that shall
14 oversee the design, implementation, and evaluation
15 of the studies described in subsections (a) and (b).

16 (2) COMPOSITION.—The advisory panel shall in-
17 clude representatives appointed for the life of the
18 panel by the Secretary from the Health Care Fi-
19 nancing Administration, the Social Security Admin-
20 istration, the National Center for Health Statistics,
21 the Administration on Aging, the National Council
22 on the Aging, the American Dietetic Association, the
23 American Academy of Family Physicians, and such
24 other agencies or organizations as the Secretary de-
25 termines to be appropriate.

1 (3) COMPENSATION AND EXPENSES.—

2 (A) COMPENSATION.—Each member of the
3 advisory panel who is not an employee of the
4 Federal Government shall receive compensation
5 for each day engaged in carrying out the duties
6 of the panel, including time engaged in travel-
7 ing for purposes of such duties. Such com-
8 pensation may not be provided in an amount in
9 excess of the maximum rate of basic pay pay-
10 able for GS-18 of the General Schedule.

11 (B) TRAVEL EXPENSES.—Each member of
12 the advisory panel shall receive travel expenses,
13 including per diem in lieu of subsistence, at
14 rates authorized for employees of agencies
15 under subchapter I of chapter 57 of title 5,
16 United States Code, for each day the member
17 is engaged in the performance of duties away
18 from the home or regular place of business of
19 the member.

20 (4) DETAIL OF FEDERAL EMPLOYEES.—On the
21 request of the advisory panel, the head of any Fed-
22 eral agency shall detail, without reimbursement, any
23 of the personnel of the agency to the advisory panel
24 to assist the advisory panel in carrying out its du-
25 ties. Any detail shall not interrupt or otherwise af-

1 **SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL**
2 **AGENTS IN DEVELOPMENT OF DEFENSES**
3 **AGAINST BIOLOGICAL WARFARE.**

4 The Secretary of Health and Human Services, in con-
5 sultation with other appropriate executive agencies, shall
6 report to the House Energy and Commerce Committee
7 and the Senate Labor and Human Resources Committee
8 on the appropriateness and impact of the National Insti-
9 tutes of Health assuming responsibility for the conduct of
10 all Federal research, development, testing, and evaluation
11 functions relating to medical countermeasures against
12 biowarfare threat agents. In preparing the report, the Sec-
13 retary shall identify the extent to which such activities are
14 carried out by agencies other than the National Institutes
15 of Health, and assess the impact (positive and negative)
16 of the National Institutes of Health assuming responsibil-
17 ity for such activities, including the impact under the
18 Budget Enforcement Act and the Omnibus Budget Rec-
19 onciliation Act of 1990 on existing National Institutes of
20 Health research programs as well as other programs with-
21 in the category of domestic discretionary spending. The
22 Secretary shall submit the report not later than 12 months
23 after the date of the enactment of this Act.

1 **SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETEN-**
2 **TION AND TURNOVER.**

3 (a) STUDY OF PERSONNEL SYSTEM.—Not later than
4 1 year after the date of the enactment of this Act, the
5 Secretary of Health and Human Services, acting through
6 the Director of the National Institutes of Health, shall
7 conduct a study to review the retention, recruitment, va-
8 cancy and turnover rates of support staff, including fire-
9 fighters, law enforcement, procurement officers, techni-
10 cians, nurses and clerical employees, to ensure that the
11 National Institutes of Health is adequately supporting the
12 conduct of efficient, effective and high quality research for
13 the American public. The Director of NIH shall work in
14 conjunction with appropriate employee organizations and
15 representatives in developing such a study.

16 (b) SUBMISSION TO CONGRESS.—Not later than 1
17 year after the date of the enactment of this Act, the Sec-
18 retary of Health and Human Services shall prepare and
19 submit to the Committee on Energy and Commerce of the
20 House of Representatives, and to the Committee on Labor
21 and Human Resources of the Senate, a report containing
22 the study conducted under subsection (a) together with
23 the recommendations of the Secretary concerning the en-
24 actment of legislation to implement the results of such
25 study.

1 **SEC. 1906. PROCUREMENT.**

2 (a) IN GENERAL.—The Director of the National In-
3 stitutes of Health and the Administrator of the General
4 Services Administration shall jointly conduct a study to
5 develop a streamlined procurement system for the Na-
6 tional Institutes of Health that complies with the require-
7 ments of Federal law.

8 (b) REPORT.—Not later than March 1, 1994, the of-
9 ficials specified in subsection (a) shall complete the study
10 required in such subsection and shall submit to the Com-
11 mittee on Energy and Commerce of the House of Rep-
12 resentatives, and the Committee on Labor and Human Re-
13 sources of the Senate, a report describing the findings
14 made as a result of the study.

15 **SEC. 1907. REPORT CONCERNING LEADING CAUSES OF**
16 **DEATH.**

17 (a) REPORT.—The Secretary of Health and Human
18 Services shall, not later than October 1, 1993, prepare a
19 report that lists—

20 (1) the 20 illnesses that, in terms of mortality,
21 number of years of expected life lost, and of number
22 of preventable years of life lost, are the leading
23 causes of death in the United States and the number
24 of deaths from each such cause, the age-specific and
25 age-adjusted death rates for each such cause, the
26 death rate per 100,000 population for each such

1 cause, the percentage of change in cause specific
2 death rates for each age group, and the percentage
3 of total deaths for each such cause;

4 (2) the amount expended by the Department of
5 Health and Human Services for research, preven-
6 tion, and education with respect to each of the 20
7 illnesses described in paragraph (1) for the most re-
8 cent year for which the actual expenditures are
9 known;

10 (3) an estimate by the Secretary of the amount
11 to be expended on research, prevention, and edu-
12 cation with respect to each of the 20 illnesses de-
13 scribed in paragraph (1) for the year for which the
14 report is prepared; and

15 (4) with respect to the years specified in para-
16 graphs (2) and (3), the percentage of the total of
17 the annual expenditures for research, prevention,
18 and education on the 20 illnesses described in para-
19 graph (1) that are attributable to each illness.

20 (b) SUBMISSION TO CONGRESS.—The Secretary of
21 Health and Human Services shall submit the report re-
22 quired under subsection (a), together with relevant budget
23 information, to the Committee on Energy and Commerce
24 and the Committee on Appropriations of the House of
25 Representatives and the Committee on Labor and Human

1 Resources and the Committee on Appropriations of the
2 Senate.

3 **SEC. 1908. RELATIONSHIP BETWEEN THE CONSUMPTION**
4 **OF LEGAL AND ILLEGAL DRUGS.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services, acting through the Commissioner of
7 Food and Drugs, shall review and consider all existing rel-
8 evant data and research concerning whether there is a re-
9 lationship between an individual's receptivity to use or
10 consume legal drugs and the consumption or abuse by the
11 individual of illegal drugs. On the basis of such review,
12 the Secretary shall determine whether additional research
13 is necessary. If the Secretary determines additional re-
14 search is required, the Secretary shall conduct a study of
15 those subjects where the Secretary's review indicates addi-
16 tional research is needed, including, if necessary, a review
17 of—

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

21 (2) the correlation of legal drug abuse with ille-
22 gal drug abuse; and

23 (3) other matters that the Secretary determines
24 appropriate.

1 (b) REPORT.—Not later than 12 months after the
2 date of enactment of this Act, the Secretary shall prepare
3 and submit, to the Committee on Energy and Commerce
4 of the House of Representatives and Committee on Labor
5 and Human Resources of the Senate, a report containing
6 the results of the review conducted under subsection (b).
7 If the Secretary determines additional research is re-
8 quired, no later than 2 years after the date of enactment
9 of this Act, the Secretary shall prepare and submit, to the
10 Committee on Energy and Commerce of the House of
11 Representatives and Committee on Labor and Human Re-
12 sources of the Senate, a report containing the results of
13 the additional research conducted under subsection (b).

14 **SEC. 1909. COST OF CARE IN LAST 6 MONTHS OF LIFE.**

15 (a) STUDY.—

16 (1) IN GENERAL.—The Secretary of Health and
17 Human Services (referred to in this section as the
18 “Secretary”), acting through the Agency for Health
19 Care Policy and Research and, to the degree pos-
20 sible, in consultation with the Health Care Financ-
21 ing Administration, shall conduct a study, using the
22 most recent National Medical Expenditure Survey
23 database, to estimate the average amount of health
24 care expenditures incurred during the last 6 months
25 of life and during the last 3 months of life by—

1 (A) the population of individuals who are
2 65 years of age and older; and

3 (B) the total population, broken down
4 based on noninstitutionalized and institutional-
5 ized populations.

6 (2) ELEMENTS OF STUDY.—The study con-
7 ducted under paragraph (1) shall—

8 (A) be designed in a manner that will
9 produce estimates of health care costs expended
10 for health care provided to individuals during
11 the last 3 and 6 months of life;

12 (B) be designed to produce estimates of
13 such costs for the populations identified in sub-
14 paragraphs (A) and (B) of paragraph (1);

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

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

20 (i) as a percentage of the total na-
21 tional health care expenditures; and

22 (ii) for those age 65 years and over,
23 as a percentage of the total Medicare ex-
24 penditures for those age 65 years and over.

1 (b) REPORT.—Not later than 6 months after the date
2 of enactment of this section, the Secretary shall prepare
3 and submit to the Committee on Labor and Human Re-
4 sources of the Senate and the Committee on Energy and
5 Commerce of the House of Representatives, a report con-
6 taining the findings resulting from the study described in
7 subsection (a).

8 (c) 1996 NATIONAL MEDICAL EXPENDITURE SUR-
9 VEY.—

10 (1) IN GENERAL.—The Secretary, acting
11 through the Agency for Health Care Policy and Re-
12 search, shall ensure that the 1996 National Medical
13 Expenditure Survey is designed in a manner that
14 will produce an estimate of the amount expended for
15 health care provided to individuals during the last 3
16 and 6 months of life.

17 (2) POPULATIONS.—In designing the Survey
18 under paragraph (1), the Secretary shall ensure that
19 such Survey produces the data required under such
20 paragraph for the population of individuals who are
21 65 years of age or older, broken down based on
22 noninstitutionalized and institutionalized popu-
23 lations.

24 (d) EXPENDITURE STUDY.—

1 (1) IN GENERAL.—Not later than 6 months
2 after that date of enactment of this section, the Sec-
3 retary, acting through the Agency for Health Care
4 Policy and Research, shall design a study to produce
5 estimates of expenditures for health care provided to
6 children who are less than 1 year of age during the
7 last 3 and 6 months of life, and prepare and submit
8 to the Committee on Labor and Human Resources
9 of the Senate and the Committee on Energy and
10 Commerce of the House of Representatives, a report
11 concerning such design. The Secretary shall ensure
12 that such study is carried out not later than 2 years
13 after the date on which such study is designed.

14 (2) REPORT.—Not later than 30 months after
15 the date of enactment of this section, the Secretary
16 shall prepare and submit to the Committee on Labor
17 and Human Resources of the Senate and the Com-
18 mittee on Energy and Commerce of the House of
19 Representatives, a report concerning the study de-
20 scribed in paragraph (1).

21 (3) AUTHORIZATION OF APPROPRIATIONS.—
22 There are authorized to be appropriated such sums
23 as may be necessary to carry out this subsection.

1 **SEC. 1910. REDUCING ADMINISTRATIVE HEALTH CARE**
2 **COSTS.**

3 The Secretary of Health and Human Services, acting
4 through the Agency for Health Care Policy and Research
5 and, to the extent possible, in consultation with the Health
6 Care Financing Administration, may fund research to de-
7 velop a text-based standardized billing process, through
8 the utilization of text-based information retrieval and nat-
9 ural language processing techniques applied to automatic
10 coding and analysis of textual patient discharge sum-
11 maries and other text-based electronic medical records,
12 within a parallel general purpose (shared memory) high
13 performance computing environment. The Secretary shall
14 determine whether such a standardized approach to medi-
15 cal billing, through the utilization of the text-based hos-
16 pital discharge summary as well as electronic patient
17 records can reduce the administrative billing costs of
18 health care delivery.

19 **SEC. 1911. STUDY CONCERNING RADIOISOTOPES.**

20 (a) STUDY.—The Secretary of Health and Human
21 Services, in collaboration with the Secretary of Energy,
22 shall, subject to the availability of funds, conduct a study
23 concerning the use and availability of radioisotopes in the
24 United States for medical (both diagnostic and thera-
25 peutic) uses in relationship to other uses.

1 (b) SUBJECT OF STUDY.—In carrying out the study
2 under subsection (a), the Secretary shall—

3 (1) analyze the domestic isotope availability and
4 production in the United States as it relates to med-
5 ical (both diagnostic and therapeutic) needs;

6 (2) make recommendations concerning—

7 (A) isotope availability and production to
8 meet domestic demand; and

9 (B) the need for additional production ca-
10 pacity.

11 (c) 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 Energy and Natural Resources of the Senate and
15 the Committee on Energy and Commerce of the House
16 of Representatives, a report concerning the results of the
17 study conducted under this section together with the rec-
18 ommendations developed in such study.

19 **SEC. 1912. MEDICAL TECHNOLOGIES PRODUCTIVITY**
20 **STUDY.**

21 (a) FINDINGS.—Congress finds that—

22 (1)(A) the Congressional Budget Office, the
23 General Accounting Office, and the Office of Tech-
24 nology Assessment have cited health care technology
25 as a primary source of medical inflation; and

1 (B) data from the Office of Technology Assess-
2 ment suggest that no more than one quarter of the
3 12 to 13 percent annual increase in health care ex-
4 penditures, or an estimated 3 percent increase in
5 such expenditures, is attributable to health care
6 technology;

7 (2)(A) the 3 percent increase represents the
8 maximum increase in such expenditures, because the
9 Office of Technology Assessment arrives at the esti-
10 mate by exclusion; and

11 (B) the increase attributable to health care
12 technology may nevertheless amount to a direct in-
13 crease of as much as \$27,000,000,000 in health care
14 costs in 1993 and an even greater indirect increase
15 in such health care costs;

16 (3) one reason for the high increase in health
17 care costs attributable to health care technology is
18 that few incentives exist in the national research in-
19 stitutes of the National Institutes of Health to en-
20 courage the development of technology that improves
21 the productivity of health care delivery; and

22 (4) since the National Institutes of Health is a
23 major engine determining the direction of medical
24 technology as well as basic biomedical research, it is
25 appropriate, in the process of directing the medical

1 research and development resources of the National
2 Institutes of Health, to provide incentives that en-
3 courage the development of technology to improve
4 the productivity of health care delivery.

5 (b) STUDY.—The Secretary of Health and Human
6 Services shall conduct a study concerning—

7 (1) methods by which to encourage the develop-
8 ment of medical technologies that improve the pro-
9 ductivity, and thereby reduce the cost, of health care
10 delivery through changes in the scientific peer review
11 process; and

12 (2) methods by which to reduce the costs of the
13 production of new medical technologies and increase
14 the availability of such technologies through changes
15 in the scientific peer review process.

16 (c) REPORT.—Not later than 1 year after the date
17 of enactment of this Act, the Secretary of Health and
18 Human Services shall prepare and submit to the Commit-
19 tee on Labor and Human Resources of the Senate and
20 the Committee on Energy and Commerce of the House
21 of Representatives, a report concerning the study con-
22 ducted under subsection (b). Such report shall contain the
23 findings of the Secretary with respect to the study and
24 the recommendations of the Secretary for the implementa-
25 tion of measures to encourage enhanced productivity of

1 medical technologies and increase the availability of such
2 technologies through changes in the scientific peer review
3 process. Such report shall also contain the steps that the
4 Secretary proposes to implement the recommendations.

5 **SEC. 1913. SENTINEL DISEASE CONCEPT STUDY.**

6 (a) IN GENERAL.—The Director of the National In-
7 stitutes of Health, in cooperation with the Agency for
8 Toxic Substances and Disease Registry and the Centers
9 for Disease Control and Prevention, may design and im-
10 plement a pilot sentinel disease surveillance and follow-
11 up system.

12 (b) PURPOSE.—The purpose of the study conducted
13 under subsection (a) shall be to determine the applicability
14 of and the difficulties associated with the implementation
15 of the sentinel disease concept for identifying the relation-
16 ship between the occupation of household members and
17 the incidence of subsequent conditions or diseases in other
18 members of the household.

19 (c) REPORT.—Not later than 4 years after the date
20 of enactment of this Act, the Director of the National In-
21 stitutes of Health shall prepare and submit to the appro-
22 priate committees of Congress, a report concerning the re-
23 sults of the study conducted under subsection (a).

1 **SEC. 1914. CONGRESSIONAL APPROPRIATION OF FEDER-**
2 **ALLY SUPPORTED DISEASE RESEARCH.**

3 (a) FINDINGS.—Congress finds that—

4 (1) it is in the public interest to support nec-
5 essary and valuable biomedical research on diseases
6 and conditions that harm or kill individuals and that
7 threaten public health;

8 (2) it is in the public interest to allocate scarce
9 Federal taxpayer money for research that is based
10 on scientific merit and cost-effectiveness; and

11 (3) it is in the public interest for Members of
12 Congress to have a criteria or methodologies to in-
13 form and assist them in the decision making process
14 when allocating Federal taxpayer money for specific
15 biomedical research.

16 (b) STUDY.—

17 (1) CONTRACT.—The Secretary of Health and
18 Human Services shall, subject to the availability of
19 appropriations and subject to paragraph (2), enter
20 into a contract with a public or nonprofit private en-
21 tity to develop criteria or methodologies which Mem-
22 bers of Congress may use to assist and inform them
23 during consideration of allocations for biomedical re-
24 search.

25 (2) INSTITUTE OF MEDICINE.—The Secretary
26 of Health and Human Services shall request the In-

1 stitute of Medicine of the National Academy of
2 Sciences to enter into the contract under paragraph
3 (1) to conduct the study described in such para-
4 graph. If such Institute declines to conduct the
5 study, the Secretary shall carry out paragraph (1)
6 through another public or nonprofit private entity.

7 (3) ITEMS.—Items that may be considered in
8 the development of the criteria of methodologies may
9 include, but are not limited to, the following—

10 (A) the populations affected by, or poten-
11 tially affected by diseases and conditions that
12 are targets for research;

13 (B) the incidence and prevalence rates of
14 disease and conditions;

15 (C) mortality rates of the diseases and
16 conditions;

17 (D) rates of morbidity, impairment disabil-
18 ity, and health status and functional outcomes
19 of the diseases and conditions;

20 (E) the economic burden of the diseases
21 and conditions including past and projected ex-
22 penditures on diagnosis and treatment;

23 (F) other economic and social burdens;
24 and

1 (G) potential for medical research on spe-
2 cific diseases to assist basic research efforts.

3 (c) SUBMISSION TO CONGRESS.—Not later than 1
4 year after the date on which the contract under subsection
5 (b)(1) is signed, the Institutes of Medicine of the National
6 Academy of Sciences shall prepare and submit to the Sec-
7 retary of Health and Human Services, and the appropriate
8 committees of Congress, a report that includes the rec-
9 ommendations developed under subsection (b). Not later
10 than 90 days after the receipt of such report, the Sec-
11 retary of Health and Human Services shall submit com-
12 ments on the recommendations to the appropriate commit-
13 tees of Congress.

14 (d) COSTS.—For the purpose of carrying out this sec-
15 tion, there are authorized to be appropriated such sums
16 as may be necessary for fiscal years 1994 and 1995.

17 **TITLE XX—MISCELLANEOUS**
18 **PROVISIONS**

19 **SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RE-**
20 **SEARCH SERVICE IN HONOR OF SILVIO O.**
21 **CONTE, AND LIMITATION ON NUMBER OF**
22 **MEMBERS.**

23 (a) IN GENERAL.—Section 228(a) of the Public
24 Health Service Act (42 U.S.C. 237(a)), as added by sec-

1 tion 304 of Public Law 101–509, is amended to read as
2 follows:

3 “(a)(1) There shall be in the Public Health Service
4 a Silvio O. Conte Senior Biomedical Research Service, not
5 to exceed 350 members.

6 “(2) The authority established in paragraph (1) re-
7 garding the number of members in the Silvio O. Conte
8 Senior Biomedical Research Service is in addition to any
9 authority established regarding the number of members
10 in the commissioned Regular Corps, in the Reserve Corps,
11 and in the Senior Executive Service. Such paragraph may
12 not be construed to require that the number of members
13 in the commissioned Regular Corps, in the Reserve Corps,
14 or in the Senior Executive Service be reduced to offset
15 the number of members serving in the Silvio O. Conte Sen-
16 ior Biomedical Research Service (hereafter in this section
17 referred to as the ‘Service’).”

18 (b) CONFORMING AMENDMENT.—Section 228 of the
19 Public Health Service Act (42 U.S.C. 237), as added by
20 section 304 of Public Law 101–509, is amended in the
21 heading for the section by amending the heading to read
22 as follows:

1 “SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH
2 SERVICE”.

3 **SEC. 2002. TECHNICAL CORRECTIONS.**

4 (a) TITLE III.—Subsection (c) of section 316 of the
5 Public Health Service Act (42 U.S.C. 247a(c)) is repealed.

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

8 (1) in section 406—

9 (A) in subsection (b)(2)(A), by striking
10 “Veterans’ Administration” each place such
11 term appears and inserting “Department of
12 Veterans Affairs”; and

13 (B) in subsection (h)(2)(A)(v), by striking
14 “Veterans’ Administration” and inserting “De-
15 partment of Veterans Affairs”;

16 (2) in section 408, in subsection (b) (as redesign-
17 nated by section 501(c)(1)(C) of this Act), by strik-
18 ing “Veterans’ Administration” and inserting “De-
19 partment of Veterans Affairs”;

20 (3) in section 421(b)(1), by inserting a comma
21 after “may”;

22 (4) in section 428(b), in the matter preceding
23 paragraph (1), by striking “the the” and inserting
24 “the”;

1 (5) in section 430(b)(2)(A)(i), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

2
3
4 (6) in section 439(b), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

5
6
7 (7) in section 442(b)(2)(A), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

8
9
10 (8) in section 464D(b)(2)(A), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

11
12
13 (9) in section 464E—

14 (A) in subsection (d), in the first sentence,
15 by inserting “Coordinating” before “Committee”;
16 and

17 (B) in subsection (e), by inserting “Coordinating” before “Committee” the first place
18 such term appears;

19
20 (10) in section 464P(b)(6) (as added by section
21 123 of Public Law 102-321 (106 Stat. 362)), by
22 striking “Administration” and inserting “Institute”;

23 (11) in section 466(a)(1)(B), by striking “Veterans’ Administration” and inserting “Department of Veterans Affairs”;

24
25

1 (12) in section 480(b)(2)(A), by striking “Vet-
2 erans’ Administration” and inserting “Department
3 of Veterans Affairs”;

4 (13) in section 485(b)(2)(A), by striking “Vet-
5 erans’ Administration” and inserting “Department
6 of Veterans Affairs”;

7 (14) in section 487(d)(3), by striking “section
8 304(a)(3)” and inserting “section 304(a)”; and

9 (15) in section 496(a), by striking “Such ap-
10 propriations,” and inserting the following: “Appro-
11 priations to carry out the purposes of this title,”.

12 (c) TITLE XV.—Title XV of the Public Health Serv-
13 ice Act is amended—

14 (1) in section 1501(b) (42 U.S.C. 300k(b)), by
15 striking “nonprofit”; and

16 (2) in section 1505(3) (42 U.S.C. 300n-1(3)),
17 by striking “nonprivate” and inserting “private”.

18 (d) TITLE XXIII.—Part A of title XXIII of the Pub-
19 lic Health Service Act (42 U.S.C. 300cc et seq.) is amend-
20 ed—

21 (1) in section 2304—

22 (A) in the heading for the section, by strik-
23 ing “**CLINICAL RESEARCH REVIEW COM-**
24 **MITTEE**” and inserting “**RESEARCH ADVI-**
25 **SORY COMMITTEE**”; and

1 (B) in subsection (a), by striking “AIDS
2 Clinical Research Review Committee” and in-
3 serting “AIDS Research Advisory Committee”;

4 (2) in section 2312(a)(2)(A), by striking “AIDS
5 Clinical Research Review Committee” and inserting
6 “AIDS Research Advisory Committee”;

7 (3) in section 2314(a)(1), in the matter preced-
8 ing subparagraph (A), by striking “Clinical Research
9 Review Committee” and inserting “AIDS Research
10 Advisory Committee”;

11 (4) in section 2317(d)(1), by striking “Clinical
12 Research Review Committee” and inserting “AIDS
13 Research Advisory Committee established under sec-
14 tion 2304”; and

15 (5) in section 2318(b)(3), by striking “Clinical
16 Research Review Committee” and inserting “AIDS
17 Research Advisory Committee”.

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

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

1 (1) by striking “Health, Education, and Wel-
2 fare” and inserting “Health and Human Services”;
3 and

4 (2) by striking “Surgeon General” and insert-
5 ing “Assistant Secretary for Health”.

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

8 (1) by striking “Surgeon General” the second
9 and subsequent times that such term appears and
10 inserting “Secretary”; and

11 (2) by inserting “, and the Agency for Health
12 Care Policy and Research” before the first period.

13 (h) VOLUNTEER SERVICES.—Section 223 of the Pub-
14 lic Health Service Act (42 U.S.C. 217b) is amended by
15 striking “Health, Education, and Welfare” and inserting
16 “Health and Human Services”.

17 **SEC. 2003. TECHNICAL CORRECTIONS WITH RESPECT TO**
18 **THE AGENCY FOR HEALTH CARE POLICY AND**
19 **RESEARCH.**

20 Title IX of the Public Health Service Act is amend-
21 ed—

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

23 (A) by striking “IN GENERAL” in para-
24 graph (1) and inserting “ADDITIONAL ASSESS-
25 MENTS”;

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

3 (C) by inserting after the subsection des-
4 ignation the following new paragraphs:

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

13 “(2) CONSIDERATIONS OF CERTAIN FACTORS.—
14 In making recommendations respecting health care
15 technologies, the Administrator shall consider the
16 safety, efficacy, and effectiveness, and, as appro-
17 priate, the appropriate uses of such technologies.
18 The Administrator shall also consider the cost effec-
19 tiveness of such technologies where cost information
20 is available and reliable.”; and

21 (D) by adding at the end thereof the fol-
22 lowing new paragraph:

23 “(5) CONSULTATIONS.—In carrying out this
24 subsection, the Administrator shall cooperate and
25 consult with the Director of the National Institutes

1 of Health, the Commissioner of Food and Drugs,
2 and the heads of any other interested Federal de-
3 partment or agency.”; and

4 (2) in section 914(a)(2)(C), by striking
5 “904(c)(2)” and inserting “904(d)(2)”.

6 **SEC. 2004. TECHNICAL CORRECTIONS WITH RESPECT TO**
7 **THE HEALTH PROFESSIONS EDUCATION EX-**
8 **TENSION AMENDMENTS OF 1992.**

9 (a) ASSISTANCE IN COLLECTION OF LOANS.—Sub-
10 part I of part A of title VII of the Public Health Service
11 Act is amended—

12 (1) in section 705(a)(2)—

13 (A) by inserting “and” after the semicolon
14 at the end of subparagraph (G);

15 (B) by striking subparagraph (H); and

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

18 (2) by adding at the end of section 707 the fol-
19 lowing new subsection:

20 “(j) SCHOOL COLLECTION ASSISTANCE.—An institu-
21 tion or postgraduate training program attended by a bor-
22 rower may assist in the collection of any loan of that bor-
23 rower made under this subpart which becomes delinquent.
24 The institution or postgraduate training program will not
25 be subject to section 809 of the Fair Debt Collection Prac-

1 tices Act for purposes of assisting in the collection of any
2 such loan.”.

3 (b) FINANCIAL NEED REQUIREMENT.—Subsection
4 (b) of section 722 is amended—

5 (1) by inserting “and” after the semicolon at
6 the end of paragraph (1);

7 (2) by striking paragraph (2); and

8 (3) by redesignating paragraph (3) as para-
9 graph (2).

10 (c) CENTERS OF EXCELLENCE.—Section
11 739(i)(2)(C) is amended by adding after the period the
12 following new sentence: “Health professional schools de-
13 scribed in paragraph (2) of subsection (c) are eligible for
14 funding under this subsection.”.

15 (d) TRAINEESHIPS FOR ADVANCED NURSE EDU-
16 CATION.—Subsection (a) of section 830 of the Public
17 Health Service Act is amended to read as follows:

18 “(a) IN GENERAL.—The Secretary may make grants
19 to public and nonprofit private entities to meet the cost
20 of—

21 “(1) traineeships for individuals in advanced-
22 degree programs in order to educate the individuals
23 to serve as nurse practitioners, nurse midwives,
24 nurse educators, or public health nurses, or in other

1 clinical nursing specialities determined by the Sec-
2 retary to require advanced education; and

3 “(2) traineeships for nurses in certificate nurse
4 midwifery programs which conform to guidelines es-
5 tablished by the Secretary under section 822(b), to
6 educate the nurses to serve as nurse midwives.”.

7 (e) CERTAIN GENERALLY APPLICABLE PROVI-
8 SIONS.—Subsection (d) of section 860 of the Public
9 Health Service Act is amended by striking “821, 822, 830,
10 and 831” and inserting in lieu thereof “821, 822, and
11 827”.

12 **SEC. 2005. BIENNIAL REPORT ON CARCINOGENS.**

13 Section 301(b)(4) of the Public Health Service Act
14 (42 U.S.C. 241(b)(4)) is amended by striking “an annual”
15 and inserting in lieu thereof “a biennial”.

16 **SEC. 2006. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE**
17 **FOR RESEARCH.**

18 Not later than June 1, 1994, the Secretary of Health
19 and Human Services, acting through the Director of the
20 National Institutes of Health, shall present to the Con-
21 gress a master plan to provide for the replacement or re-
22 furbishment of less than adequate buildings, utility equip-
23 ment and distribution systems (including the resources
24 that provide electrical and other utilities, chilled water, air
25 handling, and other services that the Secretary, acting

1 through the Director, deems necessary), roads, walkways,
2 parking areas, and grounds that underpin the laboratory
3 and clinical facilities of the National Institutes of Health.
4 Such plan may make recommendations for the undertak-
5 ing of new projects that are consistent with the objectives
6 of this section, such as encircling the National Institutes
7 of Health Federal enclave with an adequate chilled water
8 conduit.

9 **SEC. 2007. TRANSFER OF PROVISIONS OF TITLE XXVII.**

10 (a) IN GENERAL.—The Public Health Service Act
11 (42 U.S.C. 201 et seq.), as amended by section 101 of
12 Public Law 101–381 and section 304 of Public Law 101–
13 509, is amended—

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

16 (2) by redesignating such sections as sections
17 231 through 244, respectively;

18 (3) by inserting such sections, in the appro-
19 priate sequence, after section 228;

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

22 “PART A—ADMINISTRATION”; and

23 (5) by inserting before section 231 (as redesign-
24 nated by paragraph (2) of this subsection) the fol-
25 lowing new heading:

1 “PART B—MISCELLANEOUS PROVISIONS”.

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

4 (1) in the heading for title II, by inserting
5 “AND MISCELLANEOUS PROVISIONS” after
6 “ADMINISTRATION”;

7 (2) in section 406(a)(2), by striking “2701”
8 and inserting “231”;

9 (3) in section 465(f), by striking “2701” and
10 inserting “231”;

11 (4) in section 480(a)(2), by striking “2701”
12 and inserting “231”;

13 (5) in section 485(a)(2), by striking “2701”
14 and inserting “231”;

15 (6) in section 497, by striking “2701” and in-
16 serting “231”;

17 (7) in section 505(a)(2), by striking “2701”
18 and inserting “231”;

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

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

1 **SEC. 2008. CERTAIN AUTHORIZATION OF APPROPRIATIONS.**

2 Section 399L(a) of the Public Health Service Act (42
3 U.S.C. 280e-4(a)), as added by Public Law 102-515 (106
4 Stat. 3376), is amended—

5 (1) in the first sentence, by striking “the Sec-
6 retary” and all that follows and inserting the follow-
7 ing: “there are authorized to be appropriated
8 \$30,000,000 for fiscal year 1994, and such sums as
9 may be necessary for each of the fiscal years 1995
10 through 1997.”; and

11 (2) in the second sentence, by striking “Out of
12 any amounts used” and inserting “Of the amounts
13 appropriated under the preceding sentence”.

14 **SEC. 2009. PROHIBITION AGAINST SHARP ADULT SEX SUR-**
15 **VEY AND THE AMERICAN TEENAGE SEX SUR-**
16 **VEY.**

17 The Secretary of Health and Human Services may
18 not during fiscal year 1993 or any subsequent fiscal year
19 conduct or support the SHARP survey of adult sexual be-
20 havior or the American Teenage Study of adolescent sex-
21 ual behavior. This section becomes effective on the date
22 of enactment of this Act.

23 **SEC. 2010. SUPPORT FOR BIOENGINEERING RESEARCH.**

24 (a) STUDY.—The Secretary of Health and Human
25 Services, acting through the Director of the National In-

1 stitutes of Health, shall conduct a study for the purpose
2 of—

3 (1) determining the sources and amounts of
4 public and private funding devoted to basic research
5 in bioengineering, including biomaterials sciences,
6 cellular bioprocessing, tissue and rehabilitation engi-
7 neering;

8 (2) evaluating whether that commitment is suf-
9 ficient to maintain the innovative edge that the
10 United States has in these technologies;

11 (3) evaluating the role of the National Insti-
12 tutes of Health or any other Federal agency to
13 achieve a greater commitment to innovation in
14 bioengineering; and

15 (4) evaluating the need for better coordination
16 and collaboration among Federal agencies and be-
17 tween the public and private sectors.

18 In conducting such study, the Director shall work in con-
19 junction with appropriate organizations and representa-
20 tives including academics, industry leaders, bioengineering
21 societies, and public agencies.

22 (b) REPORT.—Not later than 1 year after the date
23 of enactment of this Act, the Secretary of Health and
24 Human Services shall prepare and submit to the Commit-
25 tee on Labor and Human Resources of the Senate, and

1 the Committee on Energy and Commerce of the House
2 of Representatives, a report containing the findings of the
3 study conducted under subsection (a) together with rec-
4 ommendations concerning the enactment of legislation to
5 implement the results of such study.

6 **SEC. 2011. ADMISSION TO THE UNITED STATES OF ALIENS**
7 **INFECTED WITH THE AIDS VIRUS.**

8 (a) **ADMISSION.**—Notwithstanding any other provi-
9 sion of law, regulations or directives concerning the exclu-
10 sion of aliens on health related grounds, infection with
11 HIV, the human immunodeficiency virus, shall constitute
12 a communicable disease of public health significance for
13 purposes of section 212(a)(1)(A)(i) of the Immigration
14 and Nationality Act (8 U.S.C. 1182(a)(1)(A)(i)).

15 (b) **REPORT REQUIRED.**—The President shall submit
16 a report by September 1, 1993, containing—

17 (1) an assessment of the anticipated costs of
18 the admission to the United States of persons with
19 HIV to public health care programs, including such
20 costs as will be borne by States and municipalities,
21 and private insurers and health care providers;

22 (2) an estimate of the number and origins of
23 persons infected with HIV likely to seek entry into
24 the United States before December 31, 2003;

1 (3) an assessment of the effectiveness of the
2 Immigration and Nationality Act in preventing per-
3 sons entering the United States likely to become a
4 public charge, as well as the ability to enforce this
5 Act with regard to persons infected with potentially
6 costly health conditions including, but not limited to
7 HIV;

8 (4) the cost implications of refugees entering or
9 likely to enter the United States, who carry the HIV
10 virus;

11 (5) a comparison of the anticipated public and
12 private health care costs associated with aliens in-
13 fected with HIV with the costs attributable to the
14 entry of aliens suffering from other health condi-
15 tions.

16 (c) HIV TESTING.—Except as otherwise provided in
17 subsection (d) the Attorney General, in consultation with
18 the Secretary of Health and Human Services, shall pro-
19 vide for the testing of aliens for infection with HIV in ac-
20 cordance with the policy in effect on January 1, 1993.

21 (d) WAIVER AUTHORITY.—Subsection (c) may be
22 waived by the Attorney General, in consultation with the
23 Secretary of Health and Human Services for non-immi-
24 grants who, except for the provisions of this Act, would

1 be admissible to the United States, and who seek admis-
2 sion for 30 days or less for the purpose of—

3 (1) attending educational or medical con-
4 ferences;

5 (2) receiving medical treatment;

6 (3) visiting close family members;

7 (4) conducting temporary business activities; or

8 (5) visiting for pleasure (tourism);

9 and in addition such non-immigrants may be admitted
10 without questions as to whether they are carriers of the
11 HIV virus, at the discretion of the Attorney General.

12 (e) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed to limit the authority of the Sec-
14 retary of HHS to prescribe regulations concerning com-
15 municable diseases of public health significance, other
16 than infection with the human immunodeficiency virus in
17 accordance with section 212(a)(1)(A)(i) of the Immigra-
18 tion and Nationality Act (8 U.S.C. 1182(a)(1)(A)(i)).

19 **SEC. 2012. SENSE OF THE CONGRESS REGARDING ACTION**
20 **ON A REQUEST FOR CERTAIN WAIVERS**
21 **UNDER THE MEDICAID PROGRAM.**

22 It is the sense of the Congress that—

23 (1) the Secretary of Health and Human Serv-
24 ices should be commended for her commitment to ei-
25 ther approve or deny the application for waivers to

1 conduct a demonstration project under section
2 1115(a) of the Social Security Act submitted by the
3 Oregon Department of Human Services on Novem-
4 ber 13, 1992, (hereafter referred to in this section
5 as the “application”) by March 19, 1993, and

6 (2) because the application for waivers has been
7 pending for one and a half years and the Oregon
8 State legislature faces a biennium budget currently
9 under consideration, a decision must be reached by
10 March 19, 1993, in order for the legislature to ap-
11 propriate the funds necessary to implement the Or-
12 egon plan.

13 **SEC. 2013. AUTHORIZATION OF APPROPRIATIONS.**

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

16 (1) in the first sentence of subsection (b), by
17 striking “1993 and 1994” and inserting “1993,
18 1994, and 1995”; and

19 (2) in subsection (d), by striking “in each of
20 the fiscal years 1993 and 1994” and inserting “for
21 each of the fiscal years 1993, 1994, and 1995”.

22 **SEC. 2014. VACCINE INJURY COMPENSATION PROGRAM.**

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

1 “(10) The Clerk of the United States Claims
2 Court is authorized to continue to receive, and for-
3 ward, petitions for compensation for a vaccine-relat-
4 ed injury or death associated with the administra-
5 tion of a vaccine on or after October 1, 1992.”.

6 **TITLE XXI—EFFECTIVE DATES**

7 **SEC. 2101. EFFECTIVE DATES.**

8 Subject to section 155, this Act and the amendments
9 made by this Act take effect upon the date of the enact-
10 ment of this Act.

 Passed the Senate February 18 (legislative day,
January 5), 1993.

Attest:

Secretary.

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