

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1844

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health with respect to research and related activities concerning osteoporosis and related bone disorders.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 22, 1993

Ms. SNOWE introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health with respect to research and related activities concerning osteoporosis and related bone disorders.

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.**

4 This Act may be cited as the “Osteoporosis and Re-  
5 lated Bone Disorders Research, Education, and Health  
6 Services Act of 1993”.

7 **SEC. 2. FINDINGS.**

8 The Congress finds that—

1           (1) osteoporosis, or porous bone, is a condition  
2 characterized by an excessive loss of bone tissue and  
3 an increased susceptibility to fractures of the hip,  
4 spine, and wrist;

5           (2) an estimated 25,000,000 Americans have  
6 osteoporosis, with many cases undiagnosed because  
7 the condition develops without symptoms until a  
8 strain, bump, or fall causes a fracture;

9           (3) between 3 and 4 million Americans have  
10 Paget's disease, Osteogenesis Imperfecta, and other  
11 related metabolic bone disorders;

12           (4) osteoporosis is responsible for 1,300,000  
13 bone fractures annually, including more than  
14 250,000 hip fractures, 500,000 vertebral fractures,  
15 200,000 fractures of the wrist, and the remaining  
16 fractures at other limb sites;

17           (5) osteoporosis affects one-third to one-half of  
18 all postmenopausal women and nearly half of all  
19 people over age 75;

20           (6) direct medical costs of osteoporosis reached  
21 an estimated \$10,000,000,000 in 1988 for the Unit-  
22 ed States, not including the costs of family care and  
23 lost work for caregivers;

24           (7) direct medical costs of osteoporosis are ex-  
25 pected to increase precipitously because the propor-

1       tion of the population comprised of older persons is  
2       expanding and each generation of older persons  
3       tends to have a higher incidence of osteoporosis than  
4       preceding generations;

5               (8) technology now exists, and new technology  
6       is developing, that will permit early diagnosis and  
7       prevention of osteoporosis as well as management of  
8       the condition once it has developed;

9               (9) funding for research on osteoporosis and re-  
10      lated bone disorders is severely constrained at key  
11      research institutes, including the National Institute  
12      of Arthritis and Musculoskeletal and Skin Diseases,  
13      the National Institute on Aging, and the National  
14      Institute of Diabetes and Digestive and Kidney Dis-  
15      eases;

16              (10) further research is needed to improve med-  
17      ical knowledge concerning—

18                   (A) cellular mechanisms related to the  
19                   processes of bone resorption and bone forma-  
20                   tion, and the effect of different agents on bone  
21                   remodeling;

22                   (B) risk factors for osteoporosis, including  
23                   newly discovered risk factors, risk factors relat-  
24                   ed to groups not ordinarily studied, such as  
25                   men and minorities, and the relationship of

1 aging processes to the development of  
2 osteoporosis;

3 (C) bone mass measurement technology,  
4 including techniques for making faster and  
5 more precise measurements and for interpreting  
6 measurements;

7 (D) calcium, including bioavailability, in-  
8 take requirements, and the role of calcium in  
9 building heavier and denser skeletons;

10 (E) prevention and treatment, including  
11 the efficacy of current therapies, alternative  
12 drug therapies for prevention and treatment,  
13 and the role of exercise; and

14 (F) rehabilitation; and

15 (11) further educational efforts are needed to  
16 increase public and professional knowledge of the  
17 causes of, methods for avoiding, and treatment of  
18 osteoporosis.

19 **SEC. 3. OSTEOPOROSIS RESEARCH.**

20 Subpart 4 of part C of title IV of the Public Health  
21 Service Act (42 U.S.C. 285d et seq.) is amended—

22 (1) by inserting after the subpart designation  
23 and heading the following:

24 “DIVISION A—ARTHRITIS”;

25 and

1 (2) by adding at the end the following:

2 “DIVISION B—OSTEOPOROSIS

3 **“SEC. 442A. DEFINITIONS.**

4 “As used in this division:

5 “(1) **ADVISORY PANEL.**—The term ‘Advisory  
6 Panel’ means the Advisory Panel on Osteoporosis  
7 and Related Disorders, established in section 442D.

8 “(2) **COUNCIL.**—The term ‘Council’ means the  
9 Interagency Council on Osteoporosis and Related  
10 Disorders, established in section 442C.

11 “(3) **DEPARTMENT.**—The term ‘Department’  
12 means the Department of Health and Human Serv-  
13 ices.

14 “(4) **RELATED DISORDERS.**—The term ‘related  
15 bone disorders’ includes—

16 “(A) Paget’s disease, a bone disease char-  
17 acterized by enlargement and loss of density  
18 with bowing and deformity of the bones;

19 “(B) Osteogenesis Imperfecta, a familial  
20 disease marked by extreme brittleness of the  
21 long bones;

22 “(C) hyperparathyroidism, a condition  
23 characterized by the presence of excess para-  
24 thormone in the body resulting in disturbance

1 of calcium metabolism with loss of calcium from  
2 bone and renal damage;

3 “(D) hypoparathyroidism, a condition  
4 characterized by the absence of parathormone  
5 resulting in disturbances of calcium metabolism;

6 “(E) renal bone disease, a disease charac-  
7 terized by metabolic disturbances from dialysis,  
8 renal transplants, or other renal disturbances;

9 “(F) primary or postmenopausal  
10 osteoporosis and secondary osteoporosis, such  
11 as that induced by corticosteroids; and

12 “(G) other general disorders of bone and  
13 mineral metabolism including abnormalities of  
14 vitamin D.

15 “(5) RESOURCE CENTER.—The term ‘Resource  
16 Center’ means the Resource Center on Osteoporosis  
17 and Related Disorders, established in section 442E.

18 **“SEC. 442B. EXPANSION OF RESEARCH ON OSTEOPOROSIS**

19 **AND RELATED BONE DISORDERS.**

20 “(a) RESEARCH.—The Director of the National Insti-  
21 tute of Arthritis and Musculoskeletal and Skin Diseases,  
22 the Director of the National Institute on Aging, and the  
23 Director of the National Institute of Diabetes and Diges-  
24 tive and Kidney Diseases shall expand and intensify re-  
25 search on osteoporosis and related bone disorders. The re-

1 search shall be in addition to research that is authorized  
2 under any other provision of law.

3       “(b) RESEARCH CENTERS.—The Director of the Na-  
4 tional Institute of Arthritis and Musculoskeletal and Skin  
5 Diseases shall increase the number of Specialized Centers  
6 of Research devoted to research on osteoporosis and relat-  
7 ed bone disorders. The Director of the National Institute  
8 on Aging shall increase the number of program project  
9 grants devoted to creating centers of excellence in  
10 osteoporosis and related bone disorders. The Director of  
11 the National Institute of Diabetes and Digestive and Kid-  
12 ney Diseases shall increase the number of program  
13 projects grants in osteoporosis.

14       “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
15 are authorized to be appropriated to carry out this section  
16 \$36,000,000 for the National Institute of Arthritis and  
17 Musculoskeletal and Skin Diseases, \$24,000,000 for the  
18 National Institute on Aging, and \$2,000,000 for the Na-  
19 tional Institute of Diabetes and Digestive and Kidney Dis-  
20 eases for each of the fiscal years 1994 through 1996, and  
21 such sums as may be necessary for subsequent fiscal  
22 years. These funds are in addition to amounts authorized  
23 to be appropriated for biomedical research relating to  
24 osteoporosis and related bone disorders under any other  
25 provision of law.

1 **“SEC. 442C. INTERAGENCY COUNCIL ON OSTEOPOROSIS**  
2 **AND RELATED BONE DISORDERS.**

3 “(a) ESTABLISHMENT.—There is established in the  
4 Department an Interagency Council on Osteoporosis and  
5 Related Disorders. The Council shall be composed of—

6 “(1) the Assistant Secretary for Health;

7 “(2) the Surgeon General of the United States;

8 “(3) the Assistant Secretary for Planning and  
9 Evaluation of the Department;

10 “(4) the Director of the National Institute of  
11 Arthritis and Musculoskeletal and Skin Diseases;

12 “(5) the Director of the National Institute on  
13 Aging;

14 “(6) the Director of the National Institute of  
15 Diabetes, Digestive, and Kidney Diseases;

16 “(7) the Director of the National Institute of  
17 Mental Health;

18 “(8) the Director of the National Institute of  
19 Child Health and Human Development;

20 “(9) the Administrator of the Health Care Fi-  
21 nancing Administration;

22 “(10) the Administrator for Health Care Policy  
23 and Research;

24 “(11) the Director of the Bureau of Child and  
25 Maternal Health;

26 “(12) the Commissioner of Food and Drugs;

1           “(13) the Director of the National Institute of  
2           Dental Research;

3           “(14) the Commissioner on Aging;

4           “(15) the Director of the Office of Disease Pre-  
5           vention and Health Promotion; and

6           “(16) such additional members as the Secretary  
7           considers appropriate.

8           “(b) FUNCTIONS.—The Council shall—

9           “(1) coordinate research conducted by or  
10          through the Department on osteoporosis and related  
11          bone disorders;

12          “(2) establish a mechanism for sharing infor-  
13          mation on osteoporosis and related bone disorders  
14          among all officers and employees of the Department  
15          involved in carrying out programs serving older per-  
16          sons, midlife women, and young persons, in order to  
17          provide for full communication and exchange of in-  
18          formation;

19          “(3) review and coordinate the most promising  
20          areas of research concerning osteoporosis and relat-  
21          ed bone disorders;

22          “(4) assist the National Institute of Arthritis  
23          and Musculoskeletal and Skin Diseases, the National  
24          Institute on Aging, the National Institute of Diabe-  
25          tes, Digestive and Kidney Disease, the National In-

1       stitute on Dental Research, and other institutes in  
2       developing and coordinating plans for research on  
3       osteoporosis and related bone disorders;

4             “(5) assist the Office of Disease Prevention and  
5       Health Promotion and the Administration on Aging  
6       and other offices in developing and coordinating  
7       plans for education and health promotion on  
8       osteoporosis and related bone disorders; and

9             “(6) establish mechanisms to use the results of  
10      research concerning osteoporosis and related bone  
11      disorders in the development of policies, programs,  
12      and other measures to improve the quality of life for  
13      older Americans.

14          “(c) CHAIRPERSON.—The Secretary shall select a  
15      Chairperson or co-Chairpersons for the Council from  
16      among its members.

17          “(d) QUORUM.—A majority of the members of the  
18      Council shall constitute a quorum, but a lesser number  
19      may hold hearings.

20          “(e) MEETINGS.—The Council shall meet periodically  
21      at the call of the Chairperson, but not less often than twice  
22      each year.

23          “(f) EXECUTIVE SECRETARY.—The Secretary shall  
24      appoint an Executive Secretary for the Council.

1       “(g) ADMINISTRATIVE STAFF AND SUPPORT.—The  
2 Secretary shall provide the Council with such additional  
3 administrative staff and support as may be necessary to  
4 enable the Council to carry out its functions.

5       “(h) REPORTS.—

6           “(1) INITIAL REPORT.—

7                   “(A) PREPARATION.—Not later than 9  
8 months after the date of enactment of this divi-  
9 sion, the Executive Secretary of the Council  
10 shall prepare a report detailing the research  
11 plans referred to in paragraphs (4) and (5) of  
12 subsection (b). The report shall describe the ac-  
13 tivities to be carried out under the research  
14 plans during each of the fiscal years 1994  
15 through 1996.

16                   “(B) OTHER FEDERAL PROGRAMS.—To  
17 the maximum extent feasible, the report shall  
18 ensure that activities carried out under the re-  
19 search plans are coordinated with, and use the  
20 resources of, other Federal programs concern-  
21 ing osteoporosis and related bone disorders, in-  
22 cluding—

23                           “(i) centers supported by the National  
24                           Institute of Arthritis and Musculoskeletal  
25                           and Skin Diseases, the National Institute

1 on Aging, and the National Institute of Di-  
2 abetes, Digestive and Kidney Disease;

3 “(ii) other centers supported by Fed-  
4 eral funds involved in research on  
5 osteoporosis and related bone disorders;  
6 and

7 “(iii) other programs concerning  
8 osteoporosis and related bone disorders  
9 that are planned or conducted by Federal  
10 agencies such as the Administration on  
11 Aging and the Office of Disease Prevention  
12 and Health Promotion, Federal agencies  
13 outside the Department, State or local  
14 agencies, community organizations, or pri-  
15 vate foundations.

16 “(C) DISTRIBUTION.—The Executive Sec-  
17 retary of the Council shall—

18 “(i) transmit the report to Congress;  
19 and

20 “(ii) make the report available to the  
21 public and to the Advisory Panel.

22 “(2) SUBSEQUENT REPORTS.—Not later than  
23 12 months after the date on which the report re-  
24 quired by paragraph (1) is transmitted to Congress,

1 and annually thereafter, the Executive Secretary of  
2 the Council shall—

3 “(A) prepare a report that—

4 “(i) describes research and edu-  
5 cational initiatives sponsored by the Fed-  
6 eral Government on osteoporosis and relat-  
7 ed bone disorders; and

8 “(ii) makes recommendations for new  
9 research and educational initiatives on  
10 osteoporosis and related bone disorders;  
11 and

12 “(B) transmit the report to Congress and  
13 make the report available to the public.

14 **“SEC. 442D. ADVISORY PANEL ON OSTEOPOROSIS AND RE-**  
15 **LATED DISORDERS.**

16 “(a) ESTABLISHMENT.—There is established in the  
17 Department an Advisory Panel on Osteoporosis and Relat-  
18 ed Disorders. The Advisory Panel shall be composed of  
19 the following 15 voting members and additional nonvoting,  
20 ex officio members:

21 “(1) VOTING MEMBERS.—The Director of the  
22 Office of Technology Assessment shall appoint to the  
23 Advisory Panel—

24 “(A) 5 members who are biomedical re-  
25 search scientists with demonstrated achieve-

1           ment in biomedical research on osteoporosis and  
2           related bone disorders, including at least 1 re-  
3           searcher at a specialized center for research in  
4           osteoporosis;

5           “(B) 2 members with demonstrated  
6           achievements in research on community-based  
7           and family services covering osteoporosis and  
8           related bone disorders;

9           “(C) 1 member who is knowledgeable in  
10          health promotion and disease prevention pro-  
11          grams concerning osteoporosis and related bone  
12          disorders;

13          “(D) 2 members who are associated with  
14          specialized bone programs affiliated with aca-  
15          demic health centers;

16          “(E) 2 members who are experts in private  
17          health care insurance and long-term care fi-  
18          nancing; and

19          “(F) 3 members who are representatives of  
20          national voluntary organizations that are con-  
21          cerned with the problems of individuals with  
22          osteoporosis and related bone disorders and  
23          their families.

1           “(2) NONVOTING, EX OFFICIO MEMBERS.—The  
2     Advisory Panel shall include as nonvoting, ex officio  
3     members—

4           “(A) the Chairperson of the Council;

5           “(B) the Director of National Institute of  
6     Arthritis and Musculoskeletal and Skin Dis-  
7     eases;

8           “(C) the Director of the National Institute  
9     on Aging;

10          “(D) the Director of the National Institute  
11     of Diabetes and Digestive and Kidney Diseases;  
12     and

13          “(E) such other members as the Secretary  
14     may appoint.

15          “(3) APPOINTMENT.—The Director of the Of-  
16     fice of Technology Assessment shall appoint mem-  
17     bers to the Advisory Panel within 90 days after the  
18     date of enactment of this division. The Director shall  
19     not appoint to the Advisory Panel individuals who  
20     are officers or employees of the Federal Government.

21          “(b) FUNCTIONS.—The Advisory Panel shall advise  
22     the Secretary and Council with respect to the identifica-  
23     tion of—

24           “(1) research priorities for projects on  
25     osteoporosis, related bone disorders, and the care of

1 individuals with osteoporosis or related bone dis-  
2 orders;

3 “(2) emerging issues in and promising areas of  
4 biomedical, clinical, and behavioral research on  
5 osteoporosis and related bone disorders;

6 “(3) emerging issues in research on health serv-  
7 ices for individuals, and the families of individuals,  
8 with osteoporosis or related bone disorders;

9 “(4) emerging issues in home-based and com-  
10 munity-based services and systems of services for in-  
11 dividuals, and the families of individuals, with  
12 osteoporosis or related bone disorders;

13 “(5) emerging issues in financing health care  
14 services and social services for individuals, and the  
15 families of individuals, with osteoporosis and related  
16 bone disorders;

17 “(6) emerging issues in health promotion pro-  
18 grams concerning osteoporosis; and

19 “(7) emerging issues in professional and public  
20 education concerning osteoporosis.

21 “(c) CHAIRPERSON.—The Secretary shall appoint a  
22 Chairperson of the Advisory Panel from among the mem-  
23 bers appointed.

24 “(d) TERM OF OFFICE.—The term of a member of  
25 the Advisory Panel shall be for the life of the Advisory

1 Panel. A vacancy on the Advisory Panel shall be filled in  
2 the same manner as the original appointment was made.  
3 A vacancy on the Advisory Panel shall not affect its  
4 powers.

5 “(e) QUORUM.—A majority of the members of the  
6 Advisory Panel appointed shall constitute a quorum, but  
7 a lesser number may hold hearings. The Advisory Panel  
8 may establish such subcommittees as the Advisory Panel  
9 considers appropriate.

10 “(f) MEETINGS.—The Advisory Panel shall meet at  
11 the call of the Chairperson, but not less often than twice  
12 per year.

13 “(g) EXECUTIVE SECRETARY.—The Executive Sec-  
14 retary of the Council shall serve as Executive Secretary  
15 of the Advisory Panel.

16 “(h) STAFF AND SUPPORT.—The Secretary shall pro-  
17 vide the Advisory Panel with such additional administra-  
18 tive staff and support as may be necessary to enable the  
19 Advisory Panel to carry out its functions.

20 “(i) COMPENSATION AND TRAVEL EXPENSES.—

21 “(1) COMPENSATION.—Subject to paragraph  
22 (2), no member of the Advisory Panel shall receive  
23 compensation for service on the Advisory Panel.

24 “(2) TRAVEL EXPENSES.—Each member of the  
25 Advisory Panel shall receive reimbursement for trav-

1 el, subsistence, and other necessary expenses in-  
2 curred in the performance of duties of the Advisory  
3 Panel.

4 “(j) REPORT.—The Advisory Panel shall—

5 “(1) prepare an annual report, which shall con-  
6 tain recommendations for administrative and legisla-  
7 tive actions to—

8 “(A) improve services, education, and in-  
9 formation for individuals, and families of indi-  
10 viduals, with osteoporosis and related bone dis-  
11 orders;

12 “(B) improve professional education; and

13 “(C) provide for promising biomedical re-  
14 search related to osteoporosis and related bone  
15 disorders; and

16 “(2) transmit the annual report to the Con-  
17 gress, the Secretary, and the Council and make it  
18 available to the public.

19 “(k) AUTHORIZATION OF APPROPRIATIONS.—There  
20 are authorized to be appropriated to carry out this section  
21 \$200,000 for each of fiscal years 1994 through 1996.

22 **“SEC. 442E. RESOURCE CENTER ON OSTEOPOROSIS AND**  
23 **RELATED DISORDERS.**

24 “(a) ESTABLISHMENT.—The Director of the Na-  
25 tional Institute of Arthritis and Musculoskeletal and Skin

1 Diseases shall make grants or enter into contracts with  
2 eligible organizations to establish a Resource Center on  
3 Osteoporosis and Related Disorders.

4 “(b) PURPOSE.—The purpose of the Resource Center  
5 shall be to facilitate and enhance knowledge and under-  
6 standing of osteoporosis and related bone disorders by dis-  
7 seminating information about research results, services  
8 and educational materials, to health professionals, pa-  
9 tients, and the public.

10 “(c) FUNCTIONS.—An organization receiving a grant  
11 or contract under this section shall—

12 “(1) compile, archive, and disseminate informa-  
13 tion concerning research, demonstration, evaluation,  
14 and training programs and projects concerning  
15 osteoporosis and related bone disorders;

16 “(2) annually publish a summary of the infor-  
17 mation compiled under paragraph (1) during the  
18 preceding 12-month period, and make the informa-  
19 tion available on request to appropriate individuals  
20 and entities, including educational institutions, re-  
21 search entities, and Federal and public agencies;

22 “(3) provide information and assistance in  
23 accessing community services to patients and the  
24 public;

1           “(4) coordinate regional training programs for  
2           the development of health professional resource net-  
3           works on osteoporosis and related bone disorders;  
4           and

5           “(5) maintain a resource library on osteoporosis  
6           and related bone disorders.

7           “(d) INFORMATION SYSTEM AND TELEPHONE  
8           LINE.—

9           “(1) INFORMATION SYSTEM.—An organization  
10          receiving a grant or contract under this section shall  
11          establish a central computerized information system  
12          to—

13                 “(A) compile and disseminate information  
14                 concerning initiatives by State and local govern-  
15                 ments and private entities to provide programs  
16                 and services for individuals with osteoporosis;  
17                 and

18                 “(B) translate scientific and technical in-  
19                 formation concerning the initiatives into infor-  
20                 mation readily understandable by the general  
21                 public, and make the information available on  
22                 request.

23           “(2) TELEPHONE LINE.—An organization re-  
24          ceiving a grant or contract under this section shall  
25          establish a national toll-free telephone line to make

1 available the information described in paragraph (1)  
2 and information concerning Federal programs, serv-  
3 ices, and benefits for individuals with osteoporosis  
4 and their families.

5 “(e) FEES.—In accordance with regulations issued by  
6 the Secretary, the organization receiving a grant or con-  
7 tract under this section shall charge appropriate fees for  
8 providing information through the Research Center as  
9 specified in subsections (c) or (d). The organization may  
10 make exceptions to the fees for individuals and organiza-  
11 tions who are not financially able to pay the fees. The or-  
12 ganization shall transfer the sums obtained from payment  
13 of the fees to the Secretary, who shall use the sums to  
14 carry out this section.

15 “(f) APPLICATION OR PROPOSAL.—In order to re-  
16 ceive a grant or enter into a contract under this section,  
17 an organization shall submit an application or proposal  
18 to the Director of the National Institute of Arthritis and  
19 Musculoskeletal and Skin Diseases. The application or  
20 proposal shall contain—

21 “(1) information demonstrating that the organi-  
22 zation has a network of contacts that will enable the  
23 organization to receive information necessary to op-  
24 erate the central computerized information system  
25 described in subsection (d)(1); and

1           “(2) such other information as the Director  
2           may prescribe.

3           “(g) ELIGIBLE ORGANIZATIONS.—Organizations eli-  
4           gible to receive grants under this section shall include pub-  
5           lic and private nonprofit organizations that are knowledge-  
6           able about osteoporosis and related bone disorders. The  
7           Secretary shall establish additional eligibility criteria for  
8           organizations to receive grants or enter into contracts  
9           under this section.

10          “(h) RESEARCH SUMMARIES.—The Director of the  
11          National Institute of Arthritis and Musculoskeletal and  
12          Skin Diseases, the National Institute on Aging, the Na-  
13          tional Institute of Diabetes, Digestive, and Kidney Dis-  
14          eases, the National Institute on Dental Research, and  
15          other agencies specified by the Secretary shall provide to  
16          the Resource Center summaries of the findings of research  
17          conducted on osteoporosis, related bone disorders, or rel-  
18          evant treatments for osteoporosis or related bone dis-  
19          orders.

20          “(i) AUTHORIZATION OF APPROPRIATIONS.—There  
21          are authorized to be appropriated to carry out this section  
22          \$500,000 for fiscal year 1994, and such sums as may be  
23          necessary for fiscal years 1995 and 1996.”.

○

HR 1844 IH—2