

111TH CONGRESS
1ST SESSION

H. R. 3856

To amend the Public Health Service Act to provide for osteoporosis and related bone disease education, research, and surveillance, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 20, 2009

Ms. BERKLEY (for herself, Mr. BURGESS, Mrs. DAVIS of California, Mr. HIGGINS, Ms. LEE of California, Ms. KILPATRICK of Michigan, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. CORRINE BROWN of Florida, Mr. KLEIN of Florida, Ms. LORETTA SANCHEZ of California, Ms. TITUS, Ms. TSONGAS, Ms. DEGETTE, Mr. LEWIS of Georgia, Ms. WOOLSEY, Ms. MOORE of Wisconsin, Ms. SCHAKOWSKY, Mr. DONNELLY of Indiana, Ms. SCHWARTZ, Mr. DOGGETT, Ms. MATSUI, Ms. HIRONO, Mrs. NAPOLITANO, Mr. FARR, Mr. PASCRELL, Mr. CAPUANO, Mr. GENE GREEN of Texas, Ms. WATSON, Mr. KENNEDY, Mr. HARE, Mr. CLEAVER, Mrs. HALVORSON, Ms. PINGREE of Maine, Ms. JACKSON-LEE of Texas, Mr. SIRES, Mr. ORTIZ, Mr. DAVIS of Illinois, Mr. NADLER of New York, Mr. MATHESON, Ms. BALDWIN, Mr. KAGEN, Ms. WASSERMAN SCHULTZ, Ms. HARMAN, Ms. ESHOO, Mr. McDERMOTT, Mr. THOMPSON of California, Mr. COHEN, Ms. SHEA-PORTER, Mr. ENGEL, Mr. WEXLER, Ms. CASTOR of Florida, Mrs. CHRISTENSEN, Ms. RICHARDSON, Mr. CROWLEY, Mr. WEINER, Mr. YARMUTH, Ms. MARKEY of Colorado, Mrs. MALONEY, Ms. FUDGE, Mr. PAYNE, Mrs. LOWEY, Ms. ZOE LOFGREN of California, and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to provide for osteoporosis and related bone disease education, research, and surveillance, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Bone Health Pro-
5 motion and Research Act of 2009”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) Bone health is critical to the overall health
9 and quality of life of Americans. Bone provides mo-
10 bility, support, and protection for the body and acts
11 as a storehouse for essential minerals.

12 (2) Osteoporosis is a condition in which the
13 bones become weak and can break from a minor fall
14 or, in serious cases, from simple actions such as
15 sneezing. An estimated 34,000,000 Americans have
16 low bone mass or osteopenia, which puts them at
17 risk for osteoporosis and bone fractures. In addition,
18 10,000,000 Americans have osteoporosis.

19 (3) Eight million of those with osteoporosis are
20 women, and an estimated 2,000,000 American men
21 have osteoporosis. The United States Surgeon Gen-
22 eral says that by 2020 one in two Americans over
23 age 50 is expected to have or to be at risk of devel-
24 oping osteoporosis of the hip; even more will be at

1 risk of developing osteoporosis at any site in the
2 skeleton.

3 (4) According to estimated figures, osteoporosis
4 was responsible for more than 2,000,000 fractures
5 in 2005, including hip, spine, wrist, and other frac-
6 tures. The number of fractures due to osteoporosis
7 is expected to rise to more than 3,000,000 by 2025.
8 Approximately 1 in 2 women and up to 1 in 4 men
9 over age 50 will break a bone because of
10 osteoporosis.

11 (5) An average of 24 percent of hip fracture pa-
12 tients age 50 and older die in the year following
13 their fracture.

14 (6) Osteoporosis costs our health care system
15 an estimated \$19,000,000,000 each year. By 2025,
16 experts predict that osteoporosis will account for
17 \$25,300,000,000 in costs.

18 (7) Individuals with certain diseases are at
19 higher risk of developing osteoporosis. For example,
20 diabetes patients are at increased risk for developing
21 an osteoporosis-related fracture. Cancer patients are
22 also at increased risk because many cancer thera-
23 pies, such as chemotherapy and corticosteroids, have
24 direct negative effects on bone. Also, certain cancers,

1 including prostate and breast cancer, may be treated
2 with hormonal therapy, which can cause bone loss.

3 (8) Osteogenesis imperfecta is characterized by
4 fragile bones and frequent fractures. It is estimated
5 to afflict an estimated 40,000 people.

6 (9) Paget's disease of the bone, a geriatric dis-
7 order that results in enlarged and deformed bones in
8 one or more parts of the body, afflicts an estimated
9 700,000 Americans over the age of 60.

10 (10) Lifestyle factors can affect bone health.
11 For example, the chemicals in cigarette smoke are
12 harmful to bone cells and smoking may make it
13 harder to absorb calcium. Heavy drinking can re-
14 duce bone formation and may also affect the body's
15 calcium supply.

16 (11) The 2004 Surgeon General's Report,
17 "Bone Health and Osteoporosis: A Report of the
18 Surgeon General," said that Americans must be en-
19 couraged to: get enough calcium and vitamin D; en-
20 gage in regular weight-bearing and muscle-strength-
21 ening exercise; avoid smoking and excessive alcohol;
22 and talk to their healthcare providers about bone
23 health.

24 (12) Greater efforts and commitments are need-
25 ed from Congress, the States, providers, and pa-

1 tients to lessen the burden of osteoporosis and re-
2 lated bone diseases on Americans.

3 **SEC. 3. NATIONAL BONE HEALTH PROGRAM.**

4 Part B of title III of the Public Health Service Act
5 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
6 tion 314 the following:

7 **“SEC. 315. NATIONAL BONE HEALTH PROGRAM.**

8 “(a) ESTABLISHMENT OF PROGRAM.—The Secretary
9 may develop and implement a National Bone Health Pro-
10 gram (in this section referred to as the ‘Program’) con-
11 sistent with this section.

12 “(b) CONTROL, PREVENTION, AND SURVEIL-
13 LANCE.—

14 “(1) IN GENERAL.—Under the Program, the
15 Secretary, acting through the Director of the Cen-
16 ters for Disease Control and Prevention, may, di-
17 rectly or through competitive grants to eligible enti-
18 ties, conduct, support, and promote the coordination
19 of research, investigations, demonstrations, training,
20 and studies relating to the control, prevention, and
21 surveillance of osteoporosis and related bone dis-
22 eases.

23 “(2) TRAINING AND TECHNICAL ASSISTANCE.—
24 With respect to the planning, development, and op-
25 eration of any activity carried out under paragraph

1 (1), the Secretary may provide training, technical
2 assistance, supplies, equipment, or services, and may
3 assign any officer or employee of the Department of
4 Health and Human Services to a State or local
5 health agency, or to any public or nonprofit entity
6 designated by a State health agency, in lieu of pro-
7 viding grant funds under this subsection.

8 “(3) OSTEOPOROSIS AND RELATED BONE DIS-
9 EASE PREVENTION RESEARCH AT THE CENTERS FOR
10 DISEASE CONTROL AND PREVENTION.—The Sec-
11 retary may provide additional grant support under
12 this subsection to encourage the expansion of re-
13 search related to the prevention and management of
14 osteoporosis and related bone diseases at the Centers
15 for Disease Control and Prevention.

16 “(4) ELIGIBLE ENTITY.—For purposes of this
17 subsection, the term ‘eligible entity’ means a na-
18 tional public or private nonprofit entity that dem-
19 onstrates to the satisfaction of the Secretary, in the
20 application described in subsection (e), the ability of
21 the entity to carry out the activities described in
22 paragraph (1).

23 “(c) EDUCATION AND OUTREACH.—

24 “(1) IN GENERAL.—Under the Program, the
25 Secretary may coordinate and carry out national

1 education and outreach activities, directly or through
2 the provision of grants to eligible entities, to sup-
3 port, develop, and implement education initiatives
4 and outreach strategies appropriate for osteoporosis
5 and related bone diseases.

6 “(2) INITIATIVES AND STRATEGIES.—Initiatives
7 and strategies implemented under paragraph (1)
8 may include public awareness campaigns, public
9 service announcements, and community partnership
10 workshops, as well as programs targeted at busi-
11 nesses and employers, managed care organizations,
12 and health care providers.

13 “(3) PRIORITY.—In carrying out paragraph (1),
14 the Secretary—

15 “(A) may emphasize prevention, early di-
16 agnosis, and appropriate management of
17 osteoporosis and related bone disease, and op-
18 portunities for effective patient self-manage-
19 ment; and

20 “(B) may give priority to reaching high-
21 risk or underserved populations.

22 “(4) COLLABORATION.—In carrying out this
23 subsection, the Secretary shall consult and collabo-
24 rate with the Advisory Committee established in sub-
25 section (g).

1 “(5) ELIGIBLE ENTITY.—For purposes of this
2 subsection, the term ‘eligible entity’ means a na-
3 tional public or private nonprofit entity that dem-
4 onstrates to the satisfaction of the Secretary, in the
5 application described in subsection (e), the ability of
6 the entity to carry out the activities described in
7 paragraph (1).

8 “(d) COMPREHENSIVE STATE GRANTS.—

9 “(1) IN GENERAL.—Under the Program, the
10 Secretary may award grants to eligible entities to
11 provide support for comprehensive osteoporosis and
12 related bone disease control and prevention pro-
13 grams and to enable such entities to provide public
14 health surveillance, prevention, and control activities
15 related to osteoporosis and related bone diseases.

16 “(2) ELIGIBILITY.—To be eligible to receive a
17 grant under this subsection, an entity shall be a
18 State or Indian tribe.

19 “(3) APPLICATION.—To be eligible to receive a
20 grant under this subsection, an entity shall submit
21 to the Secretary an application at such time, in such
22 manner, and containing such agreements, assur-
23 ances, and information as the Secretary may re-
24 quire, including a comprehensive osteoporosis and

1 related bone disease control and prevention plan
2 that—

3 “(A) is developed with the advice of stake-
4 holders from the public, private, and nonprofit
5 sectors that have expertise relating to
6 osteoporosis and related bone disease control,
7 prevention, and treatment that increase the
8 quality of life and decrease the level of dis-
9 ability;

10 “(B) is intended to reduce the morbidity of
11 osteoporosis and related bone diseases, with pri-
12 ority on preventing and controlling osteoporosis
13 and related bone diseases in at-risk populations
14 and reducing disparities in osteoporosis and re-
15 lated bone disease prevention, diagnosis, man-
16 agement, and quality of care in underserved
17 populations;

18 “(C) describes the osteoporosis and related
19 bone disease services and activities to be under-
20 taken or supported by the entity; and

21 “(D) demonstrates the relationship the en-
22 tity has with the community and local entities
23 and how the entity plans to involve such com-
24 munity and local entities in carrying out the ac-
25 tivities described in paragraph (1).

1 “(4) USE OF FUNDS.—An eligible entity may
2 use amounts received under a grant awarded under
3 this subsection to conduct, in a manner consistent
4 with the comprehensive osteoporosis and related
5 bone disease control and prevention plan submitted
6 by the entity in the application under paragraph
7 (3)—

8 “(A) public health surveillance and epide-
9 miological activities relating to the prevalence of
10 osteoporosis and related bone disease and as-
11 sessment of disparities in osteoporosis and re-
12 lated bone disease prevention, diagnosis, man-
13 agement, and care;

14 “(B) public information and education pro-
15 grams; and

16 “(C) education, training, and clinical skills
17 improvement activities for health professionals,
18 including allied health personnel.

19 “(e) GENERAL APPLICATION.—To be eligible to re-
20 ceive a grant under this section, except under subsection
21 (d), an entity shall submit to the Secretary an application
22 at such time, in such manner, and containing such agree-
23 ments, assurances, and information as the Secretary may
24 require, including a description of how funds received
25 under a grant awarded under this section will supplement

1 or fulfill unmet needs identified in a comprehensive
2 osteoporosis and related bone disease control and preven-
3 tion plan of the entity.

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

5 “(1) INDIAN TRIBE.—The term ‘Indian tribe’
6 has the meaning given such term in section 4(e) of
7 the Indian Self-Determination and Education Assist-
8 ance Act.

9 “(2) STATE.—The term ‘State’ means any
10 State of the United States, the District of Columbia,
11 the Commonwealth of Puerto Rico, the Virgin Is-
12 lands, American Samoa, Guam, and the Northern
13 Mariana Islands.

14 “(g) ADVISORY COMMITTEE.—

15 “(1) ESTABLISHMENT.—Not later than 90 days
16 after the date of the enactment of this section, the
17 Secretary, acting through the Director of the Cen-
18 ters for Disease Control and Prevention, shall estab-
19 lish a committee to be known as the Osteoporosis
20 and Related Bone Disease Advisory Committee (re-
21 ferred to in this section as the ‘Advisory Com-
22 mittee’). The Advisory Committee shall be composed
23 of at least one member, to be appointed by the Sec-
24 retary, acting through the Director of the Centers

1 for Disease Control and Prevention, representing
2 each of the following:

3 “(A) National voluntary health organiza-
4 tions that focus on issues relating to
5 osteoporosis or other bone diseases.

6 “(B) Professional societies that focus on
7 issues relating to osteoporosis or other bone dis-
8 eases.

9 “(C) The Centers for Disease Control and
10 Prevention, to include, upon the recommenda-
11 tion of the Director of the Centers, representa-
12 tives of the Coordinating Center for Health
13 Promotion, the Coordinating Center for Health
14 Information and Service, and the Coordinating
15 Center for Environmental Health and Injury
16 Prevention.

17 “(D) State public health departments.

18 “(E) The National Institutes of Health, to
19 include, upon the recommendation of the Direc-
20 tor of the National Institutes of Health, rep-
21 resentatives of the National Institute of Arthri-
22 tis and Musculoskeletal and Skin Diseases, the
23 National Cancer Institute, the National Insti-
24 tute of Biomedical Imaging and Bioengineering,
25 the National Institute of Child Health and

1 Human Development, the National Institute of
2 Dental and Craniofacial Research, the National
3 Institute of Diabetes and Digestive and Kidney
4 Diseases, the National Institute on Aging, the
5 Office of Dietary Supplements, the Office of
6 Rare Diseases, and the Office of Research on
7 Women's Health.

8 “(F) Patients with osteoporosis or related
9 bone diseases or their family members.

10 “(G) The Office on Women's Health in the
11 Department of Health and Human Services.

12 “(H) Clinicians with expertise on
13 osteoporosis or related bone diseases.

14 “(I) Other stakeholders from the public,
15 private, and nonprofit sectors with expertise re-
16 lating to osteoporosis or other bone disease con-
17 trol, prevention, and treatment.

18 “(2) DUTIES.—The Advisory Committee shall
19 advise the Secretary and the Assistant Secretary for
20 Health regarding the manner in which such officials
21 can—

22 “(A) ensure interagency coordination and
23 communication and minimize overlap regarding
24 efforts to address osteoporosis and related bone
25 diseases;

1 “(B) conduct and support national edu-
2 cation and outreach activities;

3 “(C) identify opportunities to coordinate
4 efforts with other Federal and State agencies
5 and private organizations addressing such dis-
6 eases;

7 “(D) ensure that public health policy deci-
8 sions and information disseminated to the pub-
9 lic and physicians are evidence-based and popu-
10 lation-focused;

11 “(E) advise relevant Federal agencies on
12 priorities related to osteoporosis and related
13 bone diseases;

14 “(F) conduct surveillance and data collec-
15 tion and disseminate epidemiological informa-
16 tion in accordance with section 320B; and

17 “(G) expand and intensify research on
18 osteoporosis and related bone diseases in ac-
19 cordance with section 404I.

20 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
21 are authorized to be appropriated to carry out this sec-
22 tion—

23 “(1) for fiscal year 2010, \$22,000,000;

24 “(2) for fiscal year 2011, \$24,000,000;

25 “(3) for fiscal year 2012, \$26,000,000;

1 “(4) for fiscal year 2013, \$28,000,000; and
2 “(5) for fiscal year 2014, \$30,000,000.”.

3 **SEC. 4. HHS RESEARCH ACTIVITIES WITH RESPECT TO**
4 **OSTEOPOROSIS AND RELATED BONE DIS-**
5 **EASES.**

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

9 **“SEC. 404I. BONE HEALTH INITIATIVE.**

10 “(a) EXPANSION AND INTENSIFICATION OF ACTIVI-
11 TIES.—

12 “(1) IN GENERAL.—The Director of NIH shall
13 expand and intensify programs of the National Insti-
14 tutes of Health with respect to research and related
15 activities concerning osteoporosis and related bone
16 diseases, including osteogenesis imperfecta, Paget’s
17 disease of bone, and rare bone diseases.

18 “(2) COORDINATION; CONSULTATION.—The Di-
19 rector of NIH shall carry out paragraph (1)—

20 “(A) in coordination with the directors of
21 the National Institute of Arthritis and Musculo-
22 skeletal and Skin Diseases, the National Cancer
23 Institute, the National Institute of Biomedical
24 Imaging and Bioengineering, the National In-
25 stitute of Child Health and Human Develop-

ment, the National Institute of Dental and Craniofacial Research, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute on Aging, the Office of Rare Diseases, the Office of Research on Women's Health, and any other national research institutes or offices, as appropriate; and

“(B) in consultation with additional Federal officials, the advisory committee established under section 315(g), and any national voluntary health organizations, professional societies, and private entities, as appropriate.

“(b) PLANNING GRANTS AND CONTRACTS FOR INNOVATIVE RESEARCH IN OSTEOPOROSIS AND RELATED BONE DISEASES.—

“(1) IN GENERAL.—In carrying out subsection (a)(1), the Director of NIH shall award planning grants or contracts for the establishment of new research programs, or enhancement of existing research programs, that focus on osteoporosis and related bone diseases, including osteogenesis imperfecta, Paget's disease of bone, and rare bone diseases.

“(2) RESEARCH.—

1 “(A) TYPES OF RESEARCH.—In carrying
2 out this subsection, the Secretary shall encour-
3 age basic, clinical, and translational research
4 that focuses on osteoporosis and related bone
5 diseases, including osteogenesis imperfecta,
6 Paget’s disease of bone, and rare bone diseases.

7 “(B) PRIORITY.—In awarding planning
8 grants or contracts under paragraph (1), the
9 Director of NIH may give priority to collabo-
10 rative partnerships, which may include aca-
11 demic health centers, private sector entities,
12 and nonprofit organizations.

13 “(C) NEW AND EARLY STAGE INVESTIGA-
14 TORS.—The Director of NIH shall make an ef-
15 fort to fund research by new and early stage in-
16 vestigators under paragraph (1).

17 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
18 purpose of carrying out this section, there is authorized
19 to be appropriated \$300,000,000 for each of fiscal years
20 2010 through 2014. Such authorization shall be in addi-
21 tion to any authorization of appropriations under any
22 other provision of law to carry out research activities on
23 osteoporosis or related bone diseases.”.

1 **SEC. 5. SURVEILLANCE ACTIVITIES RELATED TO BONE DIS-**
 2 **EASES AT THE CENTERS FOR DISEASE CON-**
 3 **TROL AND PREVENTION.**

4 Part B of title III of the Public Health Service Act
 5 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
 6 tion 320A the following:

7 **“SEC. 320B. SURVEILLANCE REGARDING OSTEOPOROSIS**
 8 **AND RELATED BONE DISEASES.**

9 “(a) IN GENERAL.—The Secretary, acting through
 10 the Director of the Centers for Disease Control and Pre-
 11 vention, may award grants to and enter into cooperative
 12 agreements with public or nonprofit private entities for the
 13 collection, analysis, and reporting of data on osteoporosis
 14 and related bone diseases, including osteogenesis
 15 imperfecta and Paget’s disease of bone.

16 “(b) TECHNICAL ASSISTANCE.—In awarding grants
 17 and entering into agreements under subsection (a), the
 18 Secretary may provide direct technical assistance in lieu
 19 of cash.

20 “(c) COORDINATION WITH ADVISORY COMMITTEE
 21 AND NIH.—The Secretary shall ensure that epidemiolog-
 22 ical and other types of information obtained under sub-
 23 section (a) is made available to the National Institutes of
 24 Health. The advisory committee established under section
 25 315(g) shall advise the Secretary in the coordination of
 26 epidemiological efforts and in the expansion and inten-

1 sification of programs for conducting surveillance and
2 data collection activities under this section.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there is authorized
5 to be appropriated \$25,000,000 for each of fiscal years
6 2010 through 2014.”.

○