112TH CONGRESS 1ST SESSION

S. 966

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 SENATE OF THE UNITED STATES

May 12, 2011

Mrs. GILLIBRAND introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2011".
- 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-

- bility, support, and protection for the body and acts
 as a storehouse for essential minerals.
- 3 (2) Osteoporosis is a condition in which the 4 bones become weak and can break from a minor fall 5 or, in serious cases, from simple actions such as 6 sneezing. An estimated 34,000,000 Americans have 7 low bone mass or osteopenia, which puts them at 8 risk for osteoporosis and bone fractures. In addition, 9 10,000,000 Americans have osteoporosis.
 - (3) Eight million of those with osteoporosis are women, and an estimated 2,000,000 American men have osteoporosis. The United States Surgeon General says that by 2020 one in two Americans over age 50 is expected to have or to be at risk of developing osteoporosis of the hip; even more will be at risk of developing osteoporosis at any site in the skeleton.
 - (4) According to estimated figures, osteoporosis was responsible for more than 2,000,000 fractures in 2005, including hip, spine, wrist, and other fractures. The number of fractures due to osteoporosis is expected to rise to more than 3,000,000 by 2025. Approximately 1 in 2 women and up to 1 in 4 men over age 50 will break a bone because of osteoporosis.

- (5) An average of 24 percent of hip fracture patients age 50 and older die in the year following their fracture.
 - (6) Osteoporosis costs our health care system an estimated \$19,000,000,000 each year. By 2025, experts predict that osteoporosis will account for \$25,300,000,000 in costs.
 - (7) Individuals with certain diseases are at higher risk of developing osteoporosis. For example, diabetes patients are at increased risk for developing an osteoporosis-related fracture. Cancer patients are also at increased risk because many cancer therapies, such as chemotherapy and corticosteroids, have direct negative effects on bone. Also, certain cancers, including prostate and breast cancer, may be treated with hormonal therapy, which can cause bone loss.
 - (8) Osteogenesis imperfecta is characterized by fragile bones and frequent fractures. It is estimated to afflict an estimated 40,000 people.
 - (9) Paget's disease of the bone, a geriatric disorder that results in enlarged and deformed bones in one or more parts of the body, afflicts an estimated 700,000 Americans over the age of 60.
 - (10) Lifestyle factors can affect bone health.

 For example, the chemicals in cigarette smoke are

- 1 harmful to bone cells and smoking may make it
- 2 harder to absorb calcium. Heavy drinking can re-
- duce bone formation and may also affect the body's
- 4 calcium supply.
- 5 (11) The 2004 Surgeon General's Report,
- 6 "Bone Health and Osteoporosis: A Report of the
- 7 Surgeon General", said that Americans must be en-
- 8 couraged to: get enough calcium and vitamin D; en-
- 9 gage in regular weight-bearing and muscle-strength-
- ening exercise; avoid smoking and excessive alcohol;
- and talk to their healthcare providers about bone
- health.
- 13 (12) The Nation's annual direct and indirect
- 14 costs for bone and joint health are
- 15 \$849,000,000,000—7.7 percent of the United States
- 16 gross domestic product.
- 17 (13) Greater efforts and commitments are need-
- 18 ed from Congress, the States, providers, and pa-
- 19 tients to lessen the burden of osteoporosis and re-
- 20 lated bone diseases on Americans.
- 21 SEC. 3. NATIONAL BONE HEALTH PROGRAM.
- 22 Part B of title III of the Public Health Service Act
- 23 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
- 24 tion 314 the following:

1 "SEC. 315. NATIONAL BONE HEALTH PROGRAM.

- 2 "(a) Establishment of Program.—The Secretary
- 3 may develop and implement a National Bone Health Pro-
- 4 gram (in this section referred to as the 'Program') con-
- 5 sistent with this section.
- 6 "(b) Control, Prevention, and Surveil-
- 7 LANCE.—
- 8 "(1) IN GENERAL.—Under the Program, the
- 9 Secretary, acting through the Director of the Cen-
- ters for Disease Control and Prevention, may, di-
- 11 rectly or through competitive grants to eligible enti-
- ties, conduct, support, and promote the coordination
- of research, investigations, demonstrations, training,
- and studies relating to the control, prevention, and
- 15 surveillance of osteoporosis and related bone dis-
- eases.
- 17 "(2) Training and technical assistance.—
- With respect to the planning, development, and op-
- eration of any activity carried out under paragraph
- 20 (1), the Secretary may provide training, technical
- assistance, supplies, equipment, or services, and may
- assign any officer or employee of the Department of
- Health and Human Services to a State or local
- health agency, or to any public or nonprofit entity
- designated by a State health agency, in lieu of pro-
- viding grant funds under this subsection.

"(3) Osteoporosis and related bone dis-EASE PREVENTION RESEARCH AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Sec-retary may provide additional grant support under this subsection to encourage the expansion of re-search related to the prevention and management of osteoporosis and related bone diseases at the Centers for Disease Control and Prevention.

"(4) ELIGIBLE ENTITY.—For purposes of this subsection, the term 'eligible entity' means a national public or private nonprofit entity that demonstrates to the satisfaction of the Secretary, in the application described in subsection (e), the ability of the entity to carry out the activities described in paragraph (1).

"(c) EDUCATION AND OUTREACH.—

- "(1) IN GENERAL.—Under the Program, the Secretary may coordinate and carry out national education and outreach activities, directly or through the provision of grants to eligible entities, to support, develop, and implement education initiatives and outreach strategies appropriate for osteoporosis and related bone diseases.
- 24 "(2) Initiatives and strategies implemented under paragraph (1)

- may include public awareness campaigns, public service announcements, and community partnership workshops, as well as programs targeted at businesses and employers, managed care organizations, and health care providers.
 - "(3) Priority.—In carrying out paragraph (1), the Secretary—
 - "(A) may emphasize prevention, early diagnosis, and appropriate management of osteoporosis and related bone disease, and opportunities for effective patient self-management; and
 - "(B) may give priority to reaching highrisk or underserved populations.
 - "(4) Collaboration.—In carrying out this subsection, the Secretary shall consult and collaborate with the Advisory Committee established in subsection (g).
 - "(5) ELIGIBLE ENTITY.—For purposes of this subsection, the term 'eligible entity' means a national public or private nonprofit entity that demonstrates to the satisfaction of the Secretary, in the application described in subsection (e), the ability of the entity to carry out the activities described in paragraph (1).

"(d) Comprehensive State Grants.—

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- "(1) IN GENERAL.—Under the Program, the Secretary may award grants to eligible entities to provide support for comprehensive osteoporosis and related bone disease control and prevention programs and to enable such entities to provide public health surveillance, prevention, and control activities related to osteoporosis and related bone diseases.
 - "(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection, an entity shall be a State or Indian tribe.
 - "(3) APPLICATION.—To be eligible to receive a grant under this subsection, an entity shall submit to the Secretary an application at such time, in such manner, and containing such agreements, assurances, and information as the Secretary may require, including a comprehensive osteoporosis and related bone disease control and prevention plan that—
 - "(A) is developed with the advice of stakeholders from the public, private, and nonprofit sectors that have expertise relating to osteoporosis and related bone disease control, prevention, and treatment that increase the

1	quality	of	life	and	decrease	the	level	of	dis-
2	ability;								

- "(B) is intended to reduce the morbidity of osteoporosis and related bone diseases, with priority on preventing and controlling osteoporosis and related bone diseases in at-risk populations and reducing disparities in osteoporosis and related bone disease prevention, diagnosis, management, and quality of care in underserved populations;
- "(C) describes the osteoporosis and related bone disease services and activities to be undertaken or supported by the entity; and
- "(D) demonstrates the relationship the entity has with the community and local entities and how the entity plans to involve such community and local entities in carrying out the activities described in paragraph (1).
- "(4) USE OF FUNDS.—An eligible entity may use amounts received under a grant awarded under this subsection to conduct, in a manner consistent with the comprehensive osteoporosis and related bone disease control and prevention plan submitted by the entity in the application under paragraph (3)—

1	"(A) public health surveillance and epide-
2	miological activities relating to the prevalence of
3	osteoporosis and related bone disease and as-
4	sessment of disparities in osteoporosis and re-
5	lated bone disease prevention, diagnosis, man-
6	agement, and care;
7	"(B) public information and education pro-
8	grams; and
9	"(C) education, training, and clinical skills
10	improvement activities for health professionals,
11	including allied health personnel.
12	"(e) General Application.—To be eligible to re-
13	ceive a grant under this section, except under subsection
14	(d), an entity shall submit to the Secretary an application
15	at such time, in such manner, and containing such agree-
16	ments, assurances, and information as the Secretary may
17	require, including a description of how funds received
18	under a grant awarded under this section will supplement
19	or fulfill unmet needs identified in a comprehensive
20	osteoporosis and related bone disease control and preven-
21	tion plan of the entity.
22	"(f) Definitions.—For purposes of this section:
23	"(1) Indian tribe.—The term 'Indian tribe'
24	has the meaning given such term in section 4(e) of

the Indian Self-Determination and Education Assistance Act.

"(2) STATE.—The term 'State' means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands.

"(g) Advisory Committee.—

"(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to be known as the Osteoporosis and Related Bone Disease Advisory Committee (referred to in this section as the 'Advisory Committee'). The Advisory Committee shall be composed of at least one member, to be appointed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention, representing each of the following:

"(A) National voluntary health organizations that focus on issues relating to osteoporosis or other bone diseases.

"(B) Professional societies that focus on issues relating to osteoporosis or other bone diseases.

"(C) The Centers for Disease Control and Prevention, to include, upon the recommendation of the Director of the Centers, representatives of the Coordinating Center for Health Promotion, the Coordinating Center for Health Information and Service, and the Coordinating Center for Environmental Health and Injury Prevention.

- "(D) State public health departments.
- "(E) The National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Cancer Institute, the National Institute of Biomedical Imaging and Bioengineering, the National Institute of Child Health and Human Development, 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 Dietary Supplements, the Office of

1	Rare Diseases, and the Office of Research on
2	Women's Health.
3	"(F) Patients with osteoporosis or related
4	bone diseases or their family members.
5	"(G) The Office on Women's Health in the
6	Department of Health and Human Services.
7	"(H) Clinicians with expertise on
8	osteoporosis or related bone diseases.
9	"(I) Other stakeholders from the public,
10	private, and nonprofit sectors with expertise re-
11	lating to osteoporosis or other bone disease con-
12	trol, prevention, and treatment.
13	"(2) Duties.—The Advisory Committee shall
14	advise the Secretary and the Assistant Secretary for
15	Health regarding the manner in which such officials
16	can—
17	"(A) ensure interagency coordination and
18	communication and minimize overlap regarding
19	efforts to address osteoporosis and related bone
20	diseases;
21	"(B) conduct and support national edu-
22	cation and outreach activities;
23	"(C) identify opportunities to coordinate
24	efforts with other Federal and State agencies

1	and private organizations addressing such dis-
2	eases;
3	"(D) ensure that public health policy deci-
4	sions and information disseminated to the pub-
5	lic and physicians are evidence-based and popu-
6	lation-focused;
7	"(E) advise relevant Federal agencies on
8	priorities related to osteoporosis and related
9	bone diseases;
10	"(F) conduct surveillance and data collec-
11	tion and disseminate epidemiological informa-
12	tion in accordance with section 32OB; and
13	"(G) expand and intensify research on
14	osteoporosis and related bone diseases in ac-
15	cordance with section 404I.
16	"(h) Authorization of Appropriations.—There
17	are authorized to be appropriated to carry out this section
18	\$22,000,000 for each of fiscal years 2011 through 2013.".
19	SEC. 4. HHS RESEARCH ACTIVITIES WITH RESPECT TO
20	OSTEOPOROSIS AND RELATED BONE DIS-
21	EASES.
22	Part A of title IV of the Public Health Service Act
23	(42 U.S.C. 281 et seq.) is amended by adding at the end
24	the following:

1 "SEC. 404I. BONE HEALTH INITIATIVE.

2	"(a) Expansion and Intensification of Activi-
3	TIES.—
4	"(1) IN GENERAL.—The Director of NIH shall
5	expand and intensify programs of the National Insti-
6	tutes of Health with respect to research and related
7	activities concerning osteoporosis and related bone
8	diseases, including osteogenesis imperfecta, Paget's
9	disease of bone, and rare bone diseases.
10	"(2) Coordination; consultation.—The Di-
11	rector of NIH shall carry out paragraph (1)—
12	"(A) in coordination with the directors of
13	the National Institute of Arthritis and Musculo-
14	skeletal and Skin Diseases, the National Cancer
15	Institute, the National Institute of Biomedical
16	Imaging and Bioengineering, the National In-
17	stitute of Child Health and Human Develop-
18	ment, the National Institute of Dental and
19	Craniofacial Research, the National Institute of
20	Diabetes and Digestive and Kidney Diseases,
21	the National Institute on Aging, the Office of
22	Rare Diseases, the Office of Research on Wom-
23	en's Health, and any other national research in-
24	stitutes or offices, as appropriate; and
25	"(B) in consultation with additional Fed-
26	eral officials, the advisory committee established

1	under section 315(g), and any national vol-
2	untary health organizations, professional soci-
3	eties, and private entities, as appropriate.
4	"(b) Planning Grants and Contracts for Inno-
5	VATIVE RESEARCH IN OSTEOPOROSIS AND RELATED
6	Bone Diseases.—
7	"(1) In general.—In carrying out subsection
8	(a)(1), the Director of NIH shall award planning
9	grants or contracts for the establishment of new re-
10	search programs, or enhancement of existing re-
11	search programs, that focus on osteoporosis and re-
12	lated bone diseases, including osteogenesis
13	imperfecta, Paget's disease of bone, and rare bone
14	diseases.
15	"(2) Research.—
16	"(A) Types of Research.—In carrying
17	out this subsection, the Secretary shall encour-
18	age basic, clinical, and translational research
19	that focuses on osteoporosis and related bone
20	diseases, including osteogenesis imperfecta,
21	Paget's disease of bone, and rare bone diseases.
22	"(B) Priority.—In awarding planning
23	grants or contracts under paragraph (1), the
24	Director of NIH may give priority to collabo-

rative partnerships, which may include aca-

1	demic health centers, private sector entities,
2	and nonprofit organizations.
3	"(C) NEW AND EARLY STAGE INVESTIGA-
4	TORS.—The Director of NIH shall make an ef-
5	fort to fund research by new and early stage in-
6	vestigators under paragraph (1).
7	"(c) Authorization of Appropriations.—For the
8	purpose of carrying out this section, there is authorized
9	to be appropriated \$250,000,000 for each of fiscal years
10	2011 through 2013. Such authorization shall be in addi-
11	tion to any authorization of appropriations under any
12	other provision of law to carry out research activities on
13	osteoporosis or related bone diseases.".
14	SEC. 5. SURVEILLANCE ACTIVITIES RELATED TO BONE DIS-
15	EASES AT THE CENTERS FOR DISEASE CON-
16	TROL AND PREVENTION.
17	Part B of title III of the Public Health Service Act
18	(42 U.S.C. 243 et seq.) is amended by inserting after sec-
19	tion 320A the following:
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	"SEC. 320B. SURVEILLANCE REGARDING OSTEOPOROSIS
21	"SEC. 320B. SURVEILLANCE REGARDING OSTEOPOROSIS AND RELATED BONE DISEASES.
21 22	
22	AND RELATED BONE DISEASES.
22 23	AND RELATED BONE DISEASES. "(a) In General.—The Secretary, acting through

- 1 collection, analysis, and reporting of data on osteoporosis
- 2 and related bone diseases, including osteogenesis
- 3 imperfecta and Paget's disease of bone.
- 4 "(b) Technical Assistance.—In awarding grants
- 5 and entering into agreements under subsection (a), the
- 6 Secretary may provide direct technical assistance in lieu
- 7 of cash.
- 8 "(c) Coordination With Advisory Committee
- 9 AND NIH.—The Secretary shall ensure that epidemiolog-
- 10 ical and other types of information obtained under sub-
- 11 section (a) is made available to the National Institutes of
- 12 Health. The advisory committee established under section
- 13 315(g) shall advise the Secretary in the coordination of
- 14 epidemiological efforts and in the expansion and inten-
- 15 sification of programs for conducting surveillance and
- 16 data collection activities under this section.
- 17 "(d) Authorization of Appropriations.—For the
- 18 purpose of carrying out this section, there is authorized
- 19 to be appropriated \$25,000,000 for each of fiscal years
- 20 2011 through 2015.".

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