

113TH CONGRESS
2^D SESSION

S. 2126

To launch a national strategy to support regenerative medicine through the establishment of a Regenerative Medicine Coordinating Council, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 13, 2014

Mrs. BOXER (for herself and Mr. KIRK) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To launch a national strategy to support regenerative medicine through the establishment of a Regenerative Medicine Coordinating Council, 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 “Regenerative Medicine
5 Promotion Act of 2014”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Regenerative medicine has the potential to
9 treat many chronic diseases, promote economic

1 growth, and reduce health care spending in the
2 United States.

3 (2) Regenerative medicine products have al-
4 ready successfully treated numerous health condi-
5 tions and have the potential to provide cures, treat-
6 ments and diagnostics for a range of diseases and
7 disabilities including diabetes, spinal cord injury,
8 heart disease, stroke, various forms of cancer, and
9 other age-related conditions that represent a huge
10 quality of life, social, and economic burden on soci-
11 ety.

12 (3) A United States national strategy on regen-
13 erative medicine is critical to ensure that this tech-
14 nology fulfills its potential to cure and treat diseases
15 and disabilities, reduce overall health care spending,
16 and promote economic growth.

17 (4) The Department of Defense has stated that
18 regenerative medicine has the potential to treat
19 many battlefield injuries such as burns, that it has
20 the potential to heal wounds without scarring, and
21 that it has the potential to be used for craniofacial
22 reconstruction, limb reconstruction, regeneration,
23 and transplantation.

24 (5) The Department of Health and Human
25 Services and the Multi-Agency Tissue Engineering

1 Science Interagency Working Group have endorsed a
2 national initiative to support research and product
3 development in regenerative medicine.

4 (6) The Department of Health and Human
5 Services has said the potential benefits of regenera-
6 tive medicine in improved health care and economic
7 savings are enormous. States that have invested in
8 regenerative medicine have experienced economic
9 growth and see future growth potential, including an
10 increase in biotech employment, payroll increases,
11 and proportional impacts on tax receipts.

12 **SEC. 3. REPORT ON ONGOING FEDERAL PROGRAMS AND**
13 **ACTIVITIES REGARDING REGENERATIVE**
14 **MEDICINE.**

15 Not later than 90 days after the date of the enact-
16 ment of this Act, the Comptroller General of the United
17 States shall provide for the completion, and submission
18 to Congress, of a report identifying all ongoing Federal
19 programs and activities regarding regenerative medicine.

20 **SEC. 4. ESTABLISHMENT OF REGENERATIVE MEDICINE CO-**
21 **ORDINATING COUNCIL.**

22 (a) ESTABLISHMENT.—The Secretary of Health and
23 Human Services shall establish, in the Office of the Sec-
24 retary, a Regenerative Medicine Coordinating Council (in
25 this section referred to as the “Council”).

1 (b) COMPOSITION.—The Council shall be composed
2 of the following:

3 (1) The Secretary of Commerce.

4 (2) The Secretary of Defense.

5 (3) The Secretary of Health and Human Serv-
6 ices.

7 (4) The Secretary of the Treasury.

8 (5) The Secretary of Veterans Affairs.

9 (6) The Administrator of the Agency for
10 Healthcare Research and Quality.

11 (7) The Administrator of the Centers for Medi-
12 care & Medicaid Services.

13 (8) The Commissioner of Food and Drugs.

14 (9) The Director of the National Institutes of
15 Health.

16 (10) The Director of the National Institutes of
17 Standards and Technology.

18 (11) Such other members as may be appointed
19 by the Secretary of Health and Human Services.

20 (c) CHAIR.—The Secretary of Health and Human
21 Services shall be the Chair of the Council.

22 (d) MEMBERS APPOINTED BY SECRETARY.—The
23 members of the Council appointed by the Secretary of
24 Health and Human Services under subsection (b)(11)
25 shall include health insurers, regenerative medicine re-

1 searchers from academic institutions, patient advocates,
2 persons with expertise in drug discovery, persons with ex-
3 pertise in drug development, persons with expertise in
4 basic research, persons with expertise in translational re-
5 search, persons with expertise in medical device develop-
6 ment, persons with expertise in biomaterials, and persons
7 with expertise in clinical research.

8 (e) FUNCTIONS.—The Council shall—

9 (1) prepare, and keep up-to-date, a national
10 strategy to support research into regenerative medi-
11 cine and enable the development of drugs, biological
12 products, medical devices, and biomaterials for use
13 in regenerative medicine;

14 (2) develop national goals for regenerative med-
15 icine research and product development;

16 (3) prepare a plan specifying priorities for re-
17 search into regenerative medicine;

18 (4) identify sources of funding for research into
19 regenerative medicine;

20 (5) identify areas where such funding is inad-
21 equate or duplicative;

22 (6) make recommendations regarding Federal
23 regulatory, reimbursement, and other policies that
24 will support development and marketing of regenera-
25 tive medicine products;

1 (7) develop consensus standards regarding sci-
2 entific issues critical to regulatory approval of regen-
3 erative medicine products; and

4 (8) determine the need for establishing centers
5 of excellence or consortia to further advance regen-
6 erative medicine.

7 (f) TRANSPARENCY; REPORTING REQUIREMENTS.—

8 (1) TRANSPARENCY.—The Council shall adopt
9 procedures to ensure the receipt of public input,
10 such as holding public stakeholder meetings or cre-
11 ating advisory boards.

12 (2) ANNUAL REPORTS.—The Council shall sub-
13 mit an annual report on its activities to Congress,
14 the Director of the National Institutes of Health,
15 and the Commissioner of Food and Drugs. Each
16 such report shall—

17 (A) provide details on progress in meeting
18 goals identified by the Council for regenerative
19 medicine;

20 (B) provide recommendations regarding
21 funding, regulatory, or other policies to achieve
22 regenerative medicine goals identified by the
23 Council;

1 (C) identify regenerative medicine products
2 currently on the market and those in develop-
3 ment;

4 (D) identify regenerative medicine research
5 and technological advances and discoveries that
6 occurred in the previous year; and

7 (E) assess the impact of regenerative medi-
8 cine on the Nation's economy, including with
9 respect to—

10 (i) the number of people employed in
11 companies or research institutions working
12 in regenerative medicine;

13 (ii) the number of companies pursuing
14 regenerative medicine products; and

15 (iii) increases in tax revenues.

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