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113TH CONGRESS
2D 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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Regenerative Medicine Promotion Act of 2014''.

SEC. 2. FINDINGS.

Congress finds the following:

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

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

(2) Regenerative medicine products have already successfully treated numerous health conditions and have the potential to provide cures, treatments and diagnostics for a range of diseases and disabilities including diabetes, spinal cord injury, heart disease, stroke, various forms of cancer, and other age-related conditions that represent a huge quality of life, social, and economic burden on society.

(3) A United States national strategy on regenerative medicine is critical to ensure that this technology fulfills its potential to cure and treat diseases and disabilities, reduce overall health care spending, and promote economic growth.

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

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

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

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

SEC. 3. REPORT ON ONGOING FEDERAL PROGRAMS AND ACTIVITIES REGARDING REGENERATIVE MEDICINE.

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

SEC. 4. ESTABLISHMENT OF REGENERATIVE MEDICINE COORDINATING COUNCIL.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish, in the Office of the Secretary, a Regenerative Medicine Coordinating Council (in this section referred to as the ''Council'').

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

(1) The Secretary of Commerce.

(2) The Secretary of Defense.

(3) The Secretary of Health and Human Services.

(4) The Secretary of the Treasury.

(5) The Secretary of Veterans Affairs.

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

(7) The Administrator of the Centers for Medicare & Medicaid Services.

(8) The Commissioner of Food and Drugs.

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

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

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

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

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

searchers from academic institutions, patient advocates, persons with expertise in drug discovery, persons with expertise in drug development, persons with expertise in basic research, persons with expertise in translational research, persons with expertise in medical device development, persons with expertise in biomaterials, and persons with expertise in clinical research.

(e) FUNCTIONS.—The Council shall—

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

(2) develop national goals for regenerative medicine research and product development;

(3) prepare a plan specifying priorities for research into regenerative medicine;

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

(5) identify areas where such funding is inadequate or duplicative;

(6) make recommendations regarding Federal regulatory, reimbursement, and other policies that will support development and marketing of regenerative medicine products;

(7) develop consensus standards regarding scientific issues critical to regulatory approval of regenerative medicine products; and

(8) determine the need for establishing centers of excellence or consortia to further advance regenerative medicine.

(f) TRANSPARENCY; REPORTING REQUIREMENTS.—

(1) TRANSPARENCY.—The Council shall adopt procedures to ensure the receipt of public input, such as holding public stakeholder meetings or creating advisory boards.

(2) ANNUAL REPORTS.—The Council shall submit an annual report on its activities to Congress, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs. Each such report shall—

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

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

(C) identify regenerative medicine products currently on the market and those in development;

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

(E) assess the impact of regenerative medicine on the Nation's economy, including with respect to—

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

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

(iii) increases in tax revenues.

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