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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

To launch a national strategy to support regenerative medicine through funding for research and commercial development of regenerative medicine products and development of a regulatory environment that enables rapid approval of safe and effective products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BILBRAY (for himself and Ms. DEGETTE) introduced the following bill; which was referred to the Committee on _____

A BILL

To launch a national strategy to support regenerative medicine through funding for research and commercial development of regenerative medicine products and development of a regulatory environment that enables rapid approval of safe and effective products, 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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Regenerative Medicine Promotion Act of 2011''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

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, and various forms of cancer.

(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 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 traumatic brain injury and other forms of trauma, 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 180 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 the 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, within six months of the enactment of this Act, 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) The members appointed by the Secretary under subsection (d).

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

(d) MEMBERS APPOINTED BY SECRETARY.—The Secretary shall appoint at least 5 persons to serve as members of the Council under subsection (b)(11). The members of the Council appointed under the preceding sentence shall include persons with expertise in third-party payment, regenerative medicine researchers 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, clinicians, and persons with expertise in clinical research.

(e) FUNCTIONS.—The Council shall—

(1) consult with, and provide information to, the Secretary of Health and Human Services for purposes of implementing any recommendations in the report required by section 3;

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

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

(4) not later than 1 year after the date of the enactment of this Act, establish priorities for the award of grants under sections 5 and 6 (relating to grants for basic or preclinical research into regenerative medicine and for development of drugs, biological products, medical devices, and biomaterials for use in regenerative medicine, respectively);

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

(6) identify areas where such funding is inadequate;

(7) make recommendations regarding Federal regulatory, reimbursement, tax, and other policies

that will support development and marketing of regenerative medicine products;

(8) facilitate development of consensus standards regarding scientific issues critical to regulatory approval of regenerative medicine products; and

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

(C) identify all 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;

(iii) increases in tax revenues; and

(iv) the impact on national health spending.

SEC. 5. GRANTS FOR BASIC OR PRECLINICAL RESEARCH INTO REGENERATIVE MEDICINE.

(a) GRANTS FOR BASIC OR PRECLINICAL RESEARCH.—The Secretary may make grants to eligible entities for the purpose of funding basic or preclinical research into regenerative medicine.

(b) CONDITIONS.—The Secretary may make a grant under this section for research only if—

(1) the research is carried out directly by the grant recipient;

(2) the research is partly funded by one or more private entities; and

(3) the amount of the grant does not exceed the total amount provided for the research by private entities (other than the grant recipient itself).

(c) TERMS AND CONDITIONS.—A grant under this section may be made on such terms and conditions as the Secretary determines appropriate.

(d) PRIORITY.—In awarding grants under this section, the Secretary shall take into consideration the priorities established by the Regenerative Medicine Coordinating Council under section 4(e).

(e) DEFINITIONS.—In this section:

(1) The term ''eligible entity'' means a nonprofit entity or an institution of higher education.

(2) The term ''institution of higher education'' has the meaning given that term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(3) The term ''nonprofit entity'' means an entity that—

(A) is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)); and

(B) is exempt from tax under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

(4) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health.

SEC. 6. GRANTS FOR DEVELOPMENT OF DRUGS, BIOLOGICAL PRODUCTS, MEDICAL DEVICES, AND BIOMATERIALS FOR USE IN REGENERATIVE MEDICINE.

(a) GRANTS FOR DRUG DEVELOPMENT.—The Secretary may make grants to eligible entities for the purpose of funding projects that have as their aim—

(1) the research and development of drugs, biological products, medical devices, and biomaterials for use in regenerative medicine; and

(2) the making of an investigational new drug application with respect to such drugs or biological products, or the making of an investigational device exemption application with respect to such devices, by not later than the end of the 4-year period beginning on the date on which such grant is made.

(b) TERMS AND CONDITIONS.—A grant under this section may be made on such terms and conditions as the Secretary determines appropriate.

(c) PRIORITY.—In awarding grants under this section, the Secretary shall take into consideration the priorities established by the Regenerative Medicine Coordinating Council under section 4(e).

(d) DEFINITIONS.—In this section:

(1) The term ''biological product'' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(2) The terms ''drug'' and ''medical device'' have the meanings given to the terms ''drug'' and ''device'', respectively, in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) The term ''eligible entity'' means a collaborative partnership including—

(A) a qualified nonprofit entity or an institution of higher education; and

(B) a for-profit entity.

(4) The term ''institution of higher education'' has the meaning given that term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(5) The term ''investigational new drug application'' means an investigational new drug application that is made to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 505(i)).

(6) The term ''investigational device exemption application'' means an application for an investigational device exemption that is made to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)).

(7) The term ''qualified nonprofit entity'' means an entity that—

(A) is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)); and

(B) is exempt from tax under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

(8) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health.

SEC. 7. SUPPORTING INNOVATION IN REGENERATIVE MEDICINE THROUGH CURES ACCELERATION NETWORK.

Section 402C of the Public Health Service Act (42 U.S.C. 282d) is amended—

(1) in subsection (d), by adding at the end the following:

''(7) COLLABORATION.—With respect to activities of the Board relating to medical products and behavioral therapies for use in regenerative medicine, the Board shall collaborate with the Regenerative Medicine Coordinating Council.''; and

(2) in subsection (e)(3), by adding at the end the following:

''(D) THE CURES ACCELERATION AWARDS WITH RESPECT TO PRODUCTS AND THERAPIES FOR USE IN REGENERATIVE MEDICINE.—The Director of NIH may, without regard to subparagraphs (A), (B), and (C), provide assistance under paragraph (1) with respect to medical products and behavioral therapies for use in regenerative medicine, including assistance—

''(i) to perform clinical trials under a protocol approved by the Commissioner of Food and Drugs or studies which use good manufacturing practice or good laboratory

practice procedures and the data from which are intended for inclusion in an investigational new drug application or an investigational device exemption application; or

''(ii) to perform basic research or preclinical studies in regenerative medicine the data from which are not intended for inclusion in an investigational new drug application or an investigational device exemption application.''.

SEC. 8. FUNDING FOR FOOD AND DRUG ADMINISTRATION RESEARCH.

(a) GRANTS.—The Secretary may—

(1) conduct, support, or collaborate in regulatory research for the purpose of assisting the Food and Drug Administration to perform its functions with respect to regenerative medicine; or

(2) make grants to fund regulatory research for such purpose.

(b) DEFINITIONS.—In this section:

(1) The term ''regulatory research'' means research regarding development, evaluation, and availability of new or improved tools, methods, standards, and applied science that support a better under-

standing and improved evaluation of product safety, quality, effectiveness, and manufacturing throughout the product life cycle.

(2) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.