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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.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Regenerative Medicine Promotion Act of 2011”.

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

- 3 Sec. 1. Short title; table of contents.
- 4 Sec. 2. Findings.
- 5 Sec. 3. Report on ongoing Federal programs and activities regarding regenerative medicine.
- 6 Sec. 4. Establishment of regenerative medicine coordinating council.
- 7 Sec. 5. Grants for basic or preclinical research into regenerative medicine.
- 8 Sec. 6. Grants for development of drugs, biological products, medical devices, and biomaterials for use in regenerative medicine.
- 9 Sec. 7. Supporting innovation in regenerative medicine through cures acceleration network.
- 10 Sec. 8. Funding for food and drug administration research.

11 **3 SEC. 2. FINDINGS.**

12 Congress finds the following:

13 (1) Regenerative medicine has the potential to
14 treat many chronic diseases, promote economic
15 growth, and reduce health care spending in the
16 United States.

17 (2) Regenerative medicine products have already
18 successfully treated numerous health conditions,
19 and have the potential to provide cures, treatments,
20 and diagnostics for a range of diseases and
21 disabilities including diabetes, spinal cord injury,
22 heart disease, stroke, and various forms of cancer.

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

1 (4) The Department of Defense has stated that
2 regenerative medicine has the potential to treat
3 many battlefield injuries such as burns, that it has
4 the potential to heal wounds without scarring, and
5 that it has the potential to be used for traumatic
6 brain injury and other forms of trauma, craniofacial
7 reconstruction, limb reconstruction, regeneration,
8 and transplantation.

9 (5) The Department of Health and Human
10 Services and the Multi-Agency Tissue Engineering
11 Science Interagency Working Group have endorsed a
12 national initiative to support research and product
13 development in regenerative medicine.

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

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

4 Not later than 180 days after the date of the enact-
5 ment of this Act, the Comptroller General of the United
6 States shall provide for the completion, and submission
7 to the Congress, of a report identifying all ongoing Federal
8 programs and activities regarding regenerative medicine.

9 **SEC. 4. ESTABLISHMENT OF REGENERATIVE MEDICINE CO-**
10 **ORDINATING COUNCIL.**

11 (a) ESTABLISHMENT.—The Secretary of Health and
12 Human Services shall establish, within six months of the
13 enactment of this Act, in the Office of the Secretary, a
14 Regenerative Medicine Coordinating Council (in this sec-
15 tion referred to as the “Council”).

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

18 (1) The Secretary of Commerce.

19 (2) The Secretary of Defense.

20 (3) The Secretary of Health and Human Serv-
21 ices.

22 (4) The Secretary of the Treasury.

23 (5) The Secretary of Veterans Affairs.

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

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

3 (8) The Commissioner of Food and Drugs.

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

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

8 (11) The members appointed by the Secretary
9 under subsection (d).

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

12 (d) MEMBERS APPOINTED BY SECRETARY.—The
13 Secretary shall appoint at least 5 persons to serve as mem-
14 bers of the Council under subsection (b)(11). The mem-
15 bers of the Council appointed under the preceding sen-
16 tence shall include persons with expertise in third-party
17 payment, regenerative medicine researchers from aca-
18 demic institutions, patient advocates, persons with exper-
19 tise in drug discovery, persons with expertise in drug de-
20 velopment, persons with expertise in basic research, per-
21 sons with expertise in translational research, persons with
22 expertise in medical device development, persons with ex-
23 pertise in biomaterials, clinicians, and persons with exper-
24 tise in clinical research.

25 (e) FUNCTIONS.—The Council shall—

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

5 (2) prepare, and keep up-to-date, a national
6 strategy to support research into regenerative medi-
7 cine and the development of drugs, biological prod-
8 ucts, medical devices, and biomaterials for use in re-
9 generative medicine;

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

12 (4) not later than 1 year after the date of the
13 enactment of this Act, establish priorities for the
14 award of grants under sections 5 and 6 (relating to
15 grants for basic or preclinical research into regen-
16 erative medicine and for development of drugs, bio-
17 logical products, medical devices, and biomaterials
18 for use in regenerative medicine, respectively);

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

21 (6) identify areas where such funding is inad-
22 equate;

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

1 that will support development and marketing of re-
2 generative medicine products;

3 (8) facilitate development of consensus stand-
4 ards regarding scientific issues critical to regulatory
5 approval of regenerative medicine products; and

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

9 (f) **TRANSPARENCY; REPORTING REQUIREMENTS.**—

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

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

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

22 (B) make recommendations regarding
23 funding, regulatory, or other policies to achieve
24 regenerative medicine goals identified by the
25 Council;

1 (C) identify all regenerative medicine prod-
2 ucts currently on the market and those in devel-
3 opment;

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;

15 (iii) increases in tax revenues; and

16 (iv) the impact on national health
17 spending.

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

20 (a) GRANTS FOR BASIC OR PRECLINICAL RE-
21 SEARCH.—The Secretary may make grants to eligible enti-
22 ties for the purpose of funding basic or preclinical research
23 into regenerative medicine.

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

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

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

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

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

11 (d) PRIORITY.—In awarding grants under this sec-
12 tion, the Secretary shall take into consideration the prior-
13 ities established by the Regenerative Medicine Coordi-
14 nating Council under section 4(e).

15 (e) DEFINITIONS.—In this section:

16 (1) The term “eligible entity” means a non-
17 profit entity or an institution of higher education.

18 (2) The term “institution of higher education”
19 has the meaning given that term in section 101 of
20 the Higher Education Act of 1965 (20 U.S.C.
21 1001).

22 (3) The term “nonprofit entity” means an enti-
23 ty that—

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

4 (B) is exempt from tax under section
5 501(a) of the Internal Revenue Code of 1986
6 (26 U.S.C. 501(a)).

7 (4) The term “Secretary” means the Secretary
8 of Health and Human Services, acting through the
9 Director of the National Institutes of Health.

10 **SEC. 6. GRANTS FOR DEVELOPMENT OF DRUGS, BIOLOGI-**
11 **CAL PRODUCTS, MEDICAL DEVICES, AND BIO-**
12 **MATERIALS FOR USE IN REGENERATIVE**
13 **MEDICINE.**

14 (a) GRANTS FOR DRUG DEVELOPMENT.—The Sec-
15 retary may make grants to eligible entities for the purpose
16 of funding projects that have as their aim—

17 (1) the research and development of drugs, bio-
18 logical products, medical devices, and biomaterials
19 for use in regenerative medicine; and

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

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

4 (c) PRIORITY.—In awarding grants under this sec-
5 tion, the Secretary shall take into consideration the prior-
6 ities established by the Regenerative Medicine Coordi-
7 nating Council under section 4(e).

8 (d) DEFINITIONS.—In this section:

9 (1) The term “biological product” has the
10 meaning given the term in section 351(i) of the Pub-
11 lic Health Service Act (42 U.S.C. 262(i)).

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

16 (3) The term “eligible entity” means a collabo-
17 rative partnership including—

18 (A) a qualified nonprofit entity or an insti-
19 tution of higher education; and

20 (B) a for-profit entity.

21 (4) The term “institution of higher education”
22 has the meaning given that term in section 101 of
23 the Higher Education Act of 1965 (20 U.S.C.
24 1001).

1 (5) The term “investigational new drug applica-
2 tion” means an investigational new drug application
3 that is made to the Food and Drug Administration
4 under section 505(i) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 505(i)).

6 (6) The term “investigational device exemption
7 application” means an application for an investiga-
8 tional device exemption that is made to the Food
9 and Drug Administration under section 520(g) of
10 the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 360j(g)).

12 (7) The term “qualified nonprofit entity”
13 means an entity that—

14 (A) is described in section 501(c)(3) of the
15 Internal Revenue Code of 1986 (26 U.S.C.
16 501(c)(3)); and

17 (B) is exempt from tax under section
18 501(a) of the Internal Revenue Code of 1986
19 (26 U.S.C. 501(a)).

20 (8) The term “Secretary” means the Secretary
21 of Health and Human Services, acting through the
22 Director of the National Institutes of Health.

1 **SEC. 7. SUPPORTING INNOVATION IN REGENERATIVE MED-**
2 **ICINE THROUGH CURES ACCELERATION NET-**
3 **WORK.**

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

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

8 “(7) COLLABORATION.—With respect to activi-
9 ties of the Board relating to medical products and
10 behavioral therapies for use in regenerative medi-
11 cine, the Board shall collaborate with the Regenera-
12 tive Medicine Coordinating Council.”; and

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

15 “(D) THE CURES ACCELERATION AWARDS
16 WITH RESPECT TO PRODUCTS AND THERAPIES
17 FOR USE IN REGENERATIVE MEDICINE.—The
18 Director of NIH may, without regard to sub-
19 paragraphs (A), (B), and (C), provide assist-
20 ance under paragraph (1) with respect to med-
21 ical products and behavioral therapies for use in
22 regenerative medicine, including assistance—

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

1 practice procedures and the data from
2 which are intended for inclusion in an in-
3 vestigational new drug application or an
4 investigational device exemption applica-
5 tion; or

6 “(ii) to perform basic research or pre-
7 clinical studies in regenerative medicine the
8 data from which are not intended for inclu-
9 sion in an investigational new drug appli-
10 cation or an investigational device exemp-
11 tion application.”.

12 **SEC. 8. FUNDING FOR FOOD AND DRUG ADMINISTRATION**
13 **RESEARCH.**

14 (a) GRANTS.—The Secretary may—

15 (1) conduct, support, or collaborate in regu-
16 latory research for the purpose of assisting the Food
17 and Drug Administration to perform its functions
18 with respect to regenerative medicine; or

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

21 (b) DEFINITIONS.—In this section:

22 (1) The term “regulatory research” means re-
23 search regarding development, evaluation, and avail-
24 ability of new or improved tools, methods, standards,
25 and applied science that support a better under-

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

4 (2) The term “Secretary” means the Secretary
5 of Health and Human Services, acting through the
6 Commissioner of Food and Drugs.