

111TH CONGRESS
2^D SESSION

H. R. 6173

To provide for a Federal initiative to support regenerative medicine through increased 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

SEPTEMBER 22, 2010

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

A BILL

To provide for a Federal initiative to support regenerative medicine through increased 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 2010”.

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 **SEC. 2. FINDINGS.**

12 Congress finds the following:

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

16 (2) Regenerative medicine has the potential to
17 provide cures, treatments and diagnostics for a
18 range of diseases and disabilities including diabetes,
19 spinal cord injury, heart disease, stroke, and various
forms of cancer.

(3) 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.

1 (4) The Department of Health and Human
2 Services and the Multi-Agency Tissue Engineering
3 Science Interagency Working Group have endorsed a
4 national initiative to support research and product
5 development in regenerative medicine.

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

14 **SEC. 3. REPORT ON ONGOING FEDERAL PROGRAMS AND**
15 **ACTIVITIES REGARDING REGENERATIVE**
16 **MEDICINE.**

17 Not later than 90 days after the date of the enact-
18 ment of this Act, the Secretary of Health and Human
19 Services shall provide for the completion, and submission
20 to the Congress, of a report identifying all ongoing Federal
21 programs and activities regarding regenerative medicine.

22 **SEC. 4. ESTABLISHMENT OF REGENERATIVE MEDICINE CO-**
23 **ORDINATING COUNCIL.**

24 (a) ESTABLISHMENT.—The Secretary of Health and
25 Human Services shall establish, in the Office of the Sec-

1 retary, a Regenerative Medicine Coordinating Council (in
2 this section referred to as the “Council”).

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

5 (1) The Secretary of Commerce.

6 (2) The Secretary of Defense.

7 (3) The Secretary of Health and Human Serv-
8 ices.

9 (4) The Secretary of the Treasury.

10 (5) The Secretary of Veterans Affairs.

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

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

15 (8) The Commissioner of Food and Drugs.

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

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

20 (11) Such other members as may be appointed
21 by the Secretary.

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

24 (d) MEMBERS APPOINTED BY SECRETARY.—The
25 members of the Council appointed by the Secretary under

1 subsection (b)(11) shall include insurers, persons from
2 academic institutions, patient advocates, persons with ex-
3 pertise in drug discovery, persons with expertise in drug
4 development, persons with expertise in basic research, per-
5 sons with expertise in translational research, persons with
6 expertise in medical device development, persons with ex-
7 pertise in biomaterials, and person with expertise in clin-
8 ical research.

9 (e) FUNCTIONS.—The Council shall—

10 (1) consult with and provide information to the
11 Secretary of Health and Human Services for pur-
12 poses of preparing the report required by section 3;

13 (2) prepare, and keep up-to-date, a national
14 strategy for the promotion of research into regenera-
15 tive medicine and the development of drugs, biologi-
16 cal products, medical devices, and biomaterials for
17 use in regenerative medicine;

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

20 (4) not later than 120 days after the date of
21 the enactment of this Act, establish priorities for the
22 award of grants under sections 5 and 6 (relating to
23 grants for basic or preclinical research into regen-
24 erative medicine and for development of drugs, bio-

1 logical products, medical devices, and biomaterials
2 for use in regenerative medicine, respectively);

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

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

7 (7) make recommendations regarding Federal
8 regulatory, reimbursement, and other policies that
9 will support development and marketing of regenera-
10 tive medicine products;

11 (8) develop consensus standards regarding sci-
12 entific issues critical to regulatory approval of regen-
13 erative medicine products; and

14 (9) determine the need for establishing centers
15 of excellence or consortia to further advance regen-
16 erative medicine.

17 (f) TRANSPARENCY; REPORTING REQUIREMENTS.—

18 (1) TRANSPARENCY.—The Council shall adopt
19 procedures to ensure the receipt of public input,
20 such as holding public stakeholder meetings or cre-
21 ating advisory boards.

22 (2) ANNUAL REPORTS.—The Council shall sub-
23 mit an annual report on its activities to the Con-
24 gress, the Director of the National Institutes of

1 Health, and the Commissioner of Food and Drugs.

2 Each such report shall—

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

6 (B) identify regenerative medicine products
7 currently on the market and those in develop-
8 ment;

9 (C) identify regenerative medicine research
10 and technological advances and discoveries that
11 occurred in the previous year; and

12 (D) assess the impact of regenerative med-
13 icine on the Nation's economy, including with
14 respect to—

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

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

20 (iii) increases in tax revenues.

21 **SEC. 5. GRANTS FOR BASIC OR PRECLINICAL RESEARCH**

22 **INTO REGENERATIVE MEDICINE.**

23 (a) GRANTS FOR BASIC OR PRECLINICAL RE-
24 SEARCH.—The Secretary may make grants to eligible enti-

1 ties for the purpose of funding basic or preclinical research
2 into regenerative medicine.

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

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

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

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

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

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

19 (e) DEFINITIONS.—In this section:

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

22 (2) The term “institution of higher education”
23 has the meaning given that term in section 101 of
24 the Higher Education Act of 1965 (20 U.S.C.
25 1001).

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

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

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

14 (d) DEFINITIONS.—In this section:

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

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

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

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

1 (B) a for-profit entity.

2 (4) The term “institution of higher education”
3 has the meaning given that term in section 101 of
4 the Higher Education Act of 1965 (20 U.S.C.
5 1001).

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

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

17 (7) The term “qualified nonprofit entity”
18 means an entity that—

19 (A) is described in section 501(c)(3) of the
20 Internal Revenue Code of 1986 (26 U.S.C.
21 501(c)(3)); and

22 (B) is exempt from tax under section
23 501(a) of the Internal Revenue Code of 1986
24 (26 U.S.C. 501(a)).

1 (8) The term “Secretary” means the Secretary
2 of Health and Human Services, acting through the
3 Director of the National Institutes of Health.

4 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry
5 out this section, there is authorized to be appropriated
6 \$100,000,000 for the period of fiscal years 2011 through
7 2016.

8 **SEC. 7. SUPPORTING INNOVATION IN REGENERATIVE MED-**
9 **ICINE THROUGH CURES ACCELERATION NET-**
10 **WORK.**

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

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

15 “(7) COLLABORATION.—With respect to activi-
16 ties of the Board relating to medical products and
17 behavioral therapies for use in regenerative medi-
18 cine, the Board shall collaborate with the Regenera-
19 tive Medicine Coordinating Council.”;

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

22 “(D) THE CURES ACCELERATION AWARDS
23 WITH RESPECT TO PRODUCTS AND THERAPIES
24 FOR USE IN REGENERATIVE MEDICINE.—The
25 Director of NIH may, without regard to sub-

1 paragraphs (A), (B), and (C), provide assist-
2 ance under paragraph (1) with respect to med-
3 ical products and behavioral therapies for use in
4 regenerative medicine, including assistance—

5 “(i) to perform clinical trials under a
6 protocol approved by the Commissioner of
7 Food and Drugs or studies which use good
8 manufacturing practice or good laboratory
9 practice procedures and the data from
10 which are intended for inclusion in an in-
11 vestigational new drug application or an
12 investigational device exemption applica-
13 tion; or

14 “(ii) to perform basic research or pre-
15 clinical studies in regenerative medicine the
16 data from which are not intended for inclu-
17 sion in an investigational new drug appli-
18 cation or an investigational device exemp-
19 tion application.”; and

20 (3) in subsection (g)—

21 (A) in paragraph (2), by striking “para-
22 graph (1)” and inserting “paragraph (1) or
23 (2)”;

24 (B) by redesignating paragraph (2) as
25 paragraph (3); and

1 (C) by inserting after paragraph (1) the
2 following:

3 “(2) REGENERATIVE MEDICINE.—For providing
4 assistance under subsection (e)(1) with respect to
5 medical products and behavioral therapies for use in
6 regenerative medicine, in addition to amounts au-
7 thorized to be appropriated by paragraph (1), there
8 are authorized to be appropriated \$100,000,000 for
9 each of fiscal years 2011 through 2015.”.

10 **SEC. 8. FUNDING FOR FOOD AND DRUG ADMINISTRATION**

11 **RESEARCH.**

12 (a) GRANTS.—The Secretary may—

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

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

19 (b) DEFINITIONS.—In this section:

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

1 quality, effectiveness, and manufacturing throughout
2 the product life cycle.

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

6 (c) AUTHORIZATION OF APPROPRIATIONS.—To carry
7 out this section, there are authorized to be appropriated
8 \$25,000,000 for fiscal year 2011 and \$125,000,000 for
9 the period of fiscal years 2012 through 2016.

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