

111TH CONGRESS
1ST SESSION

S. 914

To establish an independent Cures Acceleration Network agency, to sponsor promising translational research to bridge the gap between laboratory discoveries and life-saving therapies, to reauthorize the National Institutes of Health, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 28, 2009

Mr. SPECTER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish an independent Cures Acceleration Network agency, to sponsor promising translational research to bridge the gap between laboratory discoveries and life-saving therapies, to reauthorize the National Institutes of Health, 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 “Cures Acceleration
5 Network and National Institutes of Health Reauthoriza-
6 tion Act of 2009”.

1 **SEC. 2. CURES ACCELERATION NETWORK.**

2 (a) DEFINITIONS.—In this section—

3 (1) the term “medical product” means a drug,
4 device, biological product, or product that is a com-
5 bination of drugs, devices, and biological products;

6 (2) the terms “drug” and “device” have the
7 meanings given such terms in section 201 of the
8 Federal Food, Drug, and Cosmetic Act; and

9 (3) the term “biological product” has the mean-
10 ing given such term in section 351 of the Public
11 Health Service Act.

12 (b) ESTABLISHMENT OF THE CURES ACCELERATION
13 NETWORK.—There is established an independent agency
14 to be known as the Cures Acceleration Network (referred
15 to in this section as “CAN”), which shall—

16 (1) be under the direction of a CAN Review
17 Board (referred to in this section as the “Board”),
18 described in subsection (d); and

19 (2) award grants and contracts to eligible enti-
20 ties, as described in subsection (e), to accelerate the
21 development of cures and treatments of diseases, in-
22 cluding through the development of medical products
23 and behavioral therapies.

24 (c) FUNCTIONS.—The functions of the CAN are to—

1 (1) identify and promote revolutionary advances
2 in basic research, translating scientific discoveries
3 from bench to bedside;

4 (2) award grants and contracts to eligible enti-
5 ties;

6 (3) provide the resources through grants and
7 contracts necessary for independent investigators,
8 research organizations, biotechnology companies,
9 academic research institutions, and other entities to
10 develop medical products for the treatment and cure
11 of diseases and disorders;

12 (4) reduce the barriers between laboratory dis-
13 coveries and clinical trials for new therapies;

14 (5) facilitate priority review in the Food and
15 Drug Administration for the medical products fund-
16 ed by the CAN; and

17 (6) accept donations, bequests, and gifts to the
18 CAN.

19 (d) CAN BOARD.—

20 (1) ESTABLISHMENT.—There is established a
21 Cures Acceleration Network Review Board (referred
22 to in this section as the “Board”), which shall direct
23 the activities of the Cures Acceleration Network.

24 (2) MEMBERSHIP.—

25 (A) IN GENERAL.—

1 (i) APPOINTMENT.—The Board shall
 2 be comprised of 24 members who are ap-
 3 pointed by the President and who serve at
 4 the pleasure of the President.

5 (ii) CHAIRPERSON AND VICE CHAIR-
 6 PERSON.—The President, by and with the
 7 advice and consent of the Senate, shall
 8 designate, from among the 24 members
 9 appointed under clause (i), one Chair-
 10 person of the Board (referred to in this
 11 section as the “Chairperson”) and one Vice
 12 Chairperson.

13 (B) TERMS.—

14 (i) IN GENERAL.—Each member shall
 15 be appointed to serve a 4-year term, except
 16 that any member appointed to fill a va-
 17 cancy occurring prior to the expiration of
 18 the term for which the member’s prede-
 19 cessor was appointed shall be appointed for
 20 the remainder of such term.

21 (ii) CONSECUTIVE APPOINTMENTS;
 22 MAXIMUM TERMS.—A member may be ap-
 23 pointed to serve not more than 3 terms on
 24 the Board, and may not serve more than
 25 2 such terms consecutively.

1 (C) QUALIFICATIONS.—

2 (i) IN GENERAL.—The President shall
3 appoint individuals to the Board based
4 solely upon the individual's established
5 record of distinguished service in one of
6 the areas of expertise described in clause
7 (ii). Each individual appointed to the
8 Board shall be of distinguished achieve-
9 ment and have a broad range of discipli-
10 nary interests.

11 (ii) EXPERTISE.—The President shall
12 select individuals based upon the following
13 requirements:

14 (I) For each of the fields of—

15 (aa) basic research;

16 (bb) medicine;

17 (cc) biopharmaceuticals;

18 (dd) discovery and delivery
19 of medical products;

20 (ee) bioinformatics and gene
21 therapy;

22 (ff) medical instrumentation;

23 and

24 (gg) regulatory review and
25 approval of medical products,

1 the President shall select at least 1 in-
2 dividual who is eminent in such fields.

3 (II) At least 4 individuals shall
4 be recognized leaders in professional
5 venture capital or private equity orga-
6 nizations and have demonstrated ex-
7 perience in private equity investing.

8 (III) At least 8 individuals shall
9 represent disease advocacy organiza-
10 tions.

11 (3) EX-OFFICIO MEMBERS.—

12 (A) APPOINTMENT.—In addition to the 24
13 Board members described in paragraph (2), the
14 President shall appoint as ex-officio members of
15 the Board—

16 (i) a representative of the National
17 Institutes of Health, recommended by the
18 Secretary of the Department of Health and
19 Human Services;

20 (ii) a representative of the Office of
21 the Assistant Secretary of Defense for
22 Health Affairs, recommended by the Sec-
23 retary of Defense;

24 (iii) a representative of the Office of
25 the Under Secretary for Health for the

1 Veterans Health Administration, rec-
 2 ommended by the Secretary of Veterans
 3 Affairs;

4 (iv) a representative of the National
 5 Science Foundation, recommended by the
 6 Chair of the National Science Board; and

7 (v) a representative of the Food and
 8 Drug Administration, recommended by the
 9 Commissioner of Food and Drugs.

10 (B) TERMS.—Each ex-officio member shall
 11 serve a 3-year term on the Board, except that
 12 the Chairperson may adjust the terms of the
 13 initial ex-officio members in order to provide for
 14 a staggered term of appointment for all such
 15 members.

16 (4) RESPONSIBILITIES OF THE BOARD.—The
 17 Board shall—

18 (A) advise the Chairperson with respect to
 19 policies, programs, and procedures for carrying
 20 out the Chairperson’s duties; and

21 (B) review applications for grants and con-
 22 tracts under subsection (e) and make rec-
 23 ommendations to the Chairperson.

24 (5) AUTHORITY OF THE CHAIRPERSON.—The
 25 Chairperson may—

1 (A) prescribe regulations regarding the
2 manner in which the Chairperson's duties shall
3 be carried out, as the Chairperson determines
4 necessary;

5 (B) appoint employees, subject to civil
6 service laws, as necessary to carry out the
7 Chairperson's functions;

8 (C) define the duties, and supervise and di-
9 rect the activities, of any employees appointed
10 under subparagraph (B);

11 (D) use experts and consultants, including
12 a panel of experts who may be employed as au-
13 thorized by section 3109 of title 5, United
14 States Code;

15 (E) accept and utilize the services of vol-
16 untary and uncompensated personnel and reim-
17 burse such personnel for travel expenses, as de-
18 scribed in paragraph (7)(B);

19 (F) make advance, progress, or other pay-
20 ments without regard to section 3324 of title
21 31, United States Code;

22 (G) rent office space in the District of Co-
23 lumbia for use by the CAN;

24 (H) enter into agreements with other Fed-
25 eral agencies to carry out oversight of the grant

1 program under subsection (e), which agree-
 2 ments may include provisions for financial reim-
 3 bursement for the oversight provided by such
 4 agencies; and

5 (I) make other necessary expenditures.

6 (6) MEETINGS.—

7 (A) IN GENERAL.—The Board shall meet 4
 8 times per calendar year, at the call of the
 9 Chairperson.

10 (B) QUORUM; REQUIREMENTS; LIMITA-
 11 TIONS.—

12 (i) QUORUM.—A quorum shall consist
 13 of a total of 13 members of the Board, ex-
 14 cluding ex-officio members, with diverse
 15 representation as described in clause (iv).

16 (ii) CHAIRPERSON OR VICE CHAIR-
 17 PERSON.—Each meeting of the Board shall
 18 be attended by either the Chairperson or
 19 the Vice Chairperson.

20 (iii) LIMITATION.—No member or ex-
 21 officio member of the Board may attend
 22 more than 2 meetings of the Board each
 23 calendar year with the exceptions of the
 24 Chairperson and Vice Chairperson, who
 25 may attend all such meetings.

1 (iv) DIVERSE REPRESENTATION.—At
 2 each meeting of the Board, there shall be
 3 not less than one scientist, one representa-
 4 tive of a disease advocacy organization,
 5 and one representative of a professional
 6 venture capital or private equity organiza-
 7 tion.

8 (7) COMPENSATION AND TRAVEL EXPENSES.—

9 (A) COMPENSATION.—Members shall re-
 10 ceive compensation at a rate to be fixed by the
 11 Chairperson but not to exceed a rate equal to
 12 the daily equivalent of the annual rate of basic
 13 pay prescribed for level IV of the Executive
 14 Schedule under section 5315 of title 5, United
 15 States Code, for each day (including travel
 16 time) during which the member is engaged in
 17 the performance of the duties of the Board. All
 18 members of the Board who are officers or em-
 19 ployees of the United States shall serve without
 20 compensation in addition to that received for
 21 their services as officers or employees of the
 22 United States.

23 (B) TRAVEL EXPENSES.—Members of the
 24 Board shall be allowed travel expenses, includ-
 25 ing per diem in lieu of subsistence, at rates au-

1 thorized for persons employed intermittently by
2 the Federal Government under section 5703(b)
3 of title 5, United States Code, while away from
4 their homes or regular places of business in the
5 performance of services for the Board.

6 (e) GRANT PROGRAM.—

7 (1) GRANTS AND CONTRACTS.—The Chair-
8 person shall, through the Board of the CAN, award
9 grants and contracts to eligible entities to assist
10 such entities in carrying out projects described in
11 paragraph (3).

12 (2) AWARD PROCESS.—The Chairperson of the
13 Board may award a grant or contract under this
14 subsection to an eligible entity only upon the ap-
15 proval of a majority of a quorum of the Board.

16 (3) USE OF FUNDS.—Funds awarded under
17 this subsection shall be used—

18 (A) to accelerate the development of cures
19 and treatments, including through the develop-
20 ment of medical products, behavioral therapies,
21 and biomarkers that demonstrate the safety or
22 effectiveness of medical products; or

23 (B) to help the award recipient establish
24 protocols that comply with Food and Drug Ad-
25 ministration standards and otherwise permit

1 the recipient to meet regulatory requirements at
2 all stages of development, manufacturing, re-
3 view, approval, and safety surveillance of a
4 medical product.

5 (4) ELIGIBLE ENTITIES.—To receive a grant or
6 contract under this subsection, an entity shall—

7 (A) be—

8 (i) an individual;

9 (ii) a group of individuals; or

10 (iii) a public or private entity, which
11 may include a private or public research
12 institution, an institution of higher edu-
13 cation, a medical center, a biotechnology
14 company, a pharmaceutical company, a
15 disease advocacy organization, a patient
16 advocacy organization, or an academic re-
17 search institution;

18 (B) submit an application containing—

19 (i) a detailed description of the project
20 for which the entity seeks such grant or
21 contract;

22 (ii) a timetable for such project;

23 (iii) an assurance that the entity will
24 submit—

1 (I) interim reports describing the
2 entity's—

3 (aa) progress in carrying out
4 the project; and

5 (bb) compliance with all pro-
6 visions of this section and condi-
7 tions of receipt of such grant or
8 contract; and

9 (II) a final report at the conclu-
10 sion of the grant period, describing
11 the outcomes of the project; and

12 (iv) a description of the protocols the
13 entity will follow to comply with Food and
14 Drug Administration standards and regu-
15 latory requirements at all stages of devel-
16 opment, manufacturing, review, approval,
17 and safety surveillance of a medical prod-
18 uct; and

19 (C) provide such additional information as
20 the Chairperson may require.

21 (5) STUDY SECTIONS OF THE CENTER FOR SCI-
22 ENTIFIC REVIEW.—

23 (A) IN GENERAL.—The Chairperson may
24 enter into an interagency agreement with the
25 Center for Scientific Review within the National

Institutes of Health to use the study sections of such Center to review applications submitted under paragraphs (4)(B) and additional information submitted under (4)(C) and to make recommendations to the Board. The Chairperson shall promulgate regulations and procedures to—

(i) ensure that each study section reviewing applications is composed of diverse members, as described in subparagraph (B);

(ii) require such study sections to create written records summarizing—

(I) all meetings and discussions of the study section; and

(II) the recommendations made by such study section to the Board; and

(iii) make the records described in clause (ii) available to the public in a manner that protects the privacy of applicants and panel members and any proprietary information from applicants.

(B) MEMBERSHIP.—The Chairperson shall ensure that the study sections of the Center for

Scientific Review that review applications submitted under this subsection are selected solely on the basis of established records of distinguished service and include—

(i) for each of the fields of—

(I) basic research;

(II) medicine;

(III) biopharmaceuticals;

(IV) discovery and delivery of medical products;

(V) bioinformatics and gene therapy; and

(VI) medical instrumentation, at least 2 individuals with expertise in such fields;

(ii) at least 3 representatives of professional venture capital or private equity organizations with demonstrated experience in private equity investing; and

(iii) at least 3 representatives of disease advocacy organizations.

(C) FINANCIAL COMPENSATION.—Any agreement under subparagraph (A) shall include an arrangement whereby the Chairperson

reimburses the Center for Scientific Review for the services provided under such subparagraph.

(6) AWARDS.—

(A) THE CURES ACCELERATION PARTNERSHIP AWARDS.—

(i) INITIAL AWARD AMOUNT.—Each award under this subparagraph shall be not more than \$15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment, except that the Chairperson of the Board may increase the award amount for an eligible entity if the Board so determines by a majority vote.

(ii) FUNDING IN SUBSEQUENT FISCAL YEARS.—An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Board the information required under subparagraphs (B) and (C) of paragraph (4). The Chairperson may fund a project of such eligible entity in an amount not to exceed \$15,000,000 for a fiscal year subsequent to the initial award under

1 clause (i) if the Board so determines by
 2 majority vote.

3 (iii) MATCHING FUNDS.—As a condi-
 4 tion for receiving a grant or contract under
 5 this subparagraph, an eligible entity shall
 6 contribute to the project non-Federal funds
 7 in the amount of \$1 for every \$3 awarded
 8 under clauses (i) and (ii), except that the
 9 Chairperson may waive or modify such
 10 matching requirement by a majority vote
 11 of the Board.

12 (B) THE CURES ACCELERATION GRANT
 13 AWARDS.—

14 (i) INITIAL AWARD AMOUNT.—Each
 15 award under this subparagraph shall be
 16 not more than \$15,000,000 per project for
 17 the first fiscal year for which the project is
 18 funded, which shall be payable in one pay-
 19 ment, except that the Chairperson of the
 20 Board may increase the award amount for
 21 an eligible entity if the Board so deter-
 22 mines by a majority vote.

23 (ii) FUNDING IN SUBSEQUENT FISCAL
 24 YEARS.—An eligible entity receiving an
 25 award under clause (i) may apply for addi-

1 tional funding for such project by submit-
 2 ting to the Board the information required
 3 under subparagraphs (B) and (C) of para-
 4 graph (4). The Chairperson may fund a
 5 project of such eligible entity in an amount
 6 not to exceed \$15,000,000 for a fiscal year
 7 subsequent to the initial award under
 8 clause (i) if the Board so determines by
 9 majority vote.

10 (7) SUSPENSION OF AWARDS FOR DEFAULTS,
 11 NONCOMPLIANCE WITH PROVISIONS AND PLANS,
 12 AND DIVERSION OF FUNDS; REPAYMENT OF
 13 FUNDS.—The Chairperson may suspend the award
 14 to any entity upon noncompliance by such entity
 15 with provisions and plans under this section or di-
 16 version of funds.

17 (8) AUDITS.—The Chairperson may enter into
 18 agreements with other entities to conduct periodic
 19 audits of the projects funded by grants or contracts
 20 awarded under this subsection.

21 (9) CLOSEOUT PROCEDURES.—At the end of a
 22 grant or contract period, a recipient shall follow the
 23 closeout procedures under section 74.71 of title 45,
 24 Code of Federal Regulations (or any successor regu-
 25 lation).

1 (f) STAFF.—The CAN may employ such officers and
 2 employees (including experts and consultants), appointed
 3 by the Chairperson, as may be necessary to enable the
 4 CAN to carry out its functions under this section, and may
 5 employ and fix the compensation of such officers and em-
 6 ployees.

7 (g) GIFTS, BEQUESTS, AND DEVISES.—

8 (1) IN GENERAL.—The CAN may accept dona-
 9 tions, bequests, and devises, with or without condi-
 10 tions, and transfers for tax purposes, for the pur-
 11 pose of aiding or facilitating the work of the CAN
 12 subject to the following:

13 (A) In any case in which money or other
 14 property is donated, bequeathed, or devised to
 15 the CAN without designation for the benefit of
 16 which such property is intended, and without
 17 condition or restriction other than that such
 18 property be used for the purposes of the CAN,
 19 such property shall be deemed to have been do-
 20 nated, bequeathed, or devised to the CAN and
 21 the Chairperson shall have authority to receive
 22 such property.

23 (B) In any case in which any money or
 24 other property is donated, bequeathed, or de-
 25 vised to the CAN with a condition or restric-

tion, such property shall be deemed to have been donated, bequeathed, or devised to the CAN whose function it is to carry out the purpose or purposes described, or referred to, by the terms of such condition or restriction, and the Chairperson shall have authority to receive such property.

(C) For the purposes of subparagraph (B), if one or more of the purposes of such a condition or restriction is covered by the functions of the CAN, or if some of the purposes of such a condition or restriction are covered by the CAN, the Board shall determine an equitable manner for distribution by the CAN of the property so donated, bequeathed, or devised.

(D) For the purpose of Federal income tax, gift tax, and estate tax laws, any money or other property donated, bequeathed, or devised to the Chairperson pursuant to authority derived under this subsection shall be deemed to have been donated, bequeathed, or devised to, or for the use of, the United States.

(h) CONFLICTS OF INTEREST.—

(1) IN GENERAL.—The Chairperson shall develop and enforce conflict of interest policies for the

1 CAN and shall respond in a timely manner when
2 such policies have been violated by a recipient of
3 funds provided under a grant or contract awarded
4 under this section.

5 (2) INFORMATION.—

6 (A) IN GENERAL.—In the case in which
7 the principal investigator for a recipient de-
8 scribed under subparagraph (B) has a conflict
9 of interest, the Chairperson shall require the re-
10 cipient to provide to the Chairperson the fol-
11 lowing information:

12 (i) The degree of the primary inves-
13 tigator's financial interest, estimated to the
14 nearest \$1,000.

15 (ii) A detailed report explaining how
16 the recipient will manage the primary in-
17 vestigator's conflict of interest.

18 (B) RECIPIENT.—A recipient described in
19 this subparagraph is a recipient—

20 (i) of a grant or contract awarded
21 under subsection (e); and

22 (ii) that receives more than \$250,000
23 under such grant or contract.

1 (i) AUTHORIZATION OF APPROPRIATIONS.—For pur-
 2 poses of carrying out this section, there are authorized to
 3 be appropriated—

4 (1) for fiscal year 2010, \$1,000,000,000 for
 5 awards described under subsection (e)(6)(A), includ-
 6 ing associated administrative costs;

7 (2) for fiscal year 2010, \$1,000,000,000 for
 8 awards described under subsection (e)(6)(B), includ-
 9 ing associated administrative costs; and

10 (3) such sums as may be necessary for subse-
 11 quent fiscal years.

12 **SEC. 3. ORGANIZATION OF NATIONAL INSTITUTES OF**
 13 **HEALTH.**

14 (a) REDESIGNATION OF CENTER ON MINORITY
 15 HEALTH AND HEALTH DISPARITIES.—Title IV of the
 16 Public Health Service Act (42 U.S.C. 281 et seq.) is
 17 amended—

18 (1) by redesignating subpart 6 of part E as
 19 subpart 20;

20 (2) by transferring subpart 20, as so redesign-
 21 nated, to part C of such title IV;

22 (3) by inserting subpart 20, as so redesignated,
 23 after subpart 19 of such part C; and

24 (4) in subpart 20, as so redesignated—

1 (A) by redesignating sections 485E
 2 through 485H as sections 464z-3 through
 3 464z-6, respectively;

4 (B) by striking “National Center on Mi-
 5 nority Health and Health Disparities” each
 6 place such term appears and inserting “Na-
 7 tional Institute on Minority Health and Health
 8 Disparities”; and

9 (C) by striking “Center” each place such
 10 term appears and inserting “Institute”.

11 (b) PURPOSE OF INSTITUTE.—Subsection (h) of sec-
 12 tion 464z-3 of the Public Health Service Act, as so redes-
 13 ignated, is amended—

14 (1) in paragraph (1), by striking “research en-
 15 dowments at centers of excellence under section
 16 736.” and inserting the following: “research endow-
 17 ments—

18 “(1) at centers of excellence under section 736;
 19 and

20 “(2) at centers of excellence under section
 21 464z-4.”; and

22 (2) in paragraph (2)(A), by striking “average”
 23 and inserting “median”.

24 (c) TECHNICAL AMENDMENT.—Section 401(b)(24)
 25 of the Public Health Service Act (42 U.S.C. 281(b)(24))

1 is amended by striking “Center” and inserting “Insti-
2 tute”.

3 (d) CONFORMING AMENDMENT.—Subsection (d)(1)
4 of section 903 of the Public Health Service Act (42 U.S.C.
5 299a–1(d)(1)) is amended by striking “section 485E” and
6 inserting “section 464z–3”.

7 **SEC. 4. CONFLICTS OF INTEREST.**

8 Section 402 of the Public Health Service Act (42
9 U.S.C. 282) is amended by adding at the end the fol-
10 lowing:

11 “(m) ENFORCEMENT OF CONFLICT OF INTEREST
12 POLICIES.—

13 “(1) IN GENERAL.—The Director shall develop
14 and enforce the conflict of interest policies for the
15 National Institutes of Health and shall respond in a
16 timely manner when such policies have been violated
17 by a recipient of funds provided under a grant or
18 contract awarded under this title.

19 “(2) INFORMATION.—

20 “(A) IN GENERAL.—In the case in which
21 the principal investigator for a recipient de-
22 scribed under subparagraph (B) has a conflict
23 of interest, the Director shall require the recipi-
24 ent to provide to the Director the following in-
25 formation:

1 “(i) The degree of the primary inves-
 2 tigator’s financial interest, estimated to the
 3 nearest \$1,000.

4 “(ii) A detailed report explaining how
 5 the recipient will manage the primary in-
 6 vestigator’s conflict of interest.

7 “(B) RECIPIENT.—A recipient described in
 8 this subparagraph is a recipient—

9 “(i) of a grant or contract awarded
 10 under this title; and

11 “(ii) that receives more than
 12 \$250,000 under such grant or contract.”.

13 **SEC. 5. AUTHORIZATION OF APPROPRIATIONS.**

14 (a) AUTHORIZATION OF APPROPRIATIONS.—Section
 15 402A of the Public Health Service Act (42 U.S.C. 282a)
 16 is amended by striking paragraphs (1) through (3) of sub-
 17 section (a) and inserting the following:

18 “(1) \$40,000,000,000 for fiscal year 2010; and

19 “(2) such sums as may be necessary for each
 20 of fiscal years 2011 and 2012.”.

21 (b) OFFICE OF THE DIRECTOR.—Subparagraph (b)
 22 of section 402A of the Public Health Service Act (42
 23 U.S.C. 282a(b)) is amended by striking “2007 through
 24 2009” and inserting “2010 through 2012”.

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