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

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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.

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 ''Cures Acceleration Network and National Institutes of Health Reauthorization Act of 2009''.

SEC. 2. CURES ACCELERATION NETWORK.

(a) DEFINITIONS.—In this section—

(1) the term ''medical product'' means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products;

(2) the terms ''drug'' and ''device'' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act; and

(3) the term ''biological product'' has the meaning given such term in section 351 of the Public Health Service Act.

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

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

(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of cures and treatments of diseases, including through the development of medical products and behavioral therapies.

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

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

(2) award grants and contracts to eligible entities;

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

(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies;

(5) facilitate priority review in the Food and Drug Administration for the medical products funded by the CAN; and

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

(d) CAN BOARD.—

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

(2) MEMBERSHIP.—

(A) IN GENERAL.—

(i) APPOINTMENT.—The Board shall be comprised of 24 members who are appointed by the President and who serve at the pleasure of the President.

(ii) CHAIRPERSON AND VICE CHAIRPERSON.—The President, by and with the advice and consent of the Senate, shall designate, from among the 24 members appointed under clause (i), one Chairperson of the Board (referred to in this section as the ''Chairperson'') and one Vice Chairperson.

(B) TERMS.—

(i) IN GENERAL.—Each member shall be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term.

(ii) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board, and may not serve more than 2 such terms consecutively.

(C) QUALIFICATIONS.—

(i) IN GENERAL.—The President shall appoint individuals to the Board based solely upon the individual's established record of distinguished service in one of the areas of expertise described in clause (ii). Each individual appointed to the Board shall be of distinguished achievement and have a broad range of disciplinary interests.

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

(I) For each of the fields of—

(aa) basic research;

(bb) medicine;

(cc) biopharmaceuticals;

(dd) discovery and delivery of medical products;

(ee) bioinformatics and gene therapy;

(ff) medical instrumentation; and

(gg) regulatory review and approval of medical products,

the President shall select at least 1 individual who is eminent in such fields.

(II) At least 4 individuals shall be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing.

(III) At least 8 individuals shall represent disease advocacy organizations.

(3) EX-OFFICIO MEMBERS.—

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

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

(ii) a representative of the Office of the Assistant Secretary of Defense for Health Affairs, recommended by the Secretary of Defense;

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

Veterans Health Administration, recommended by the Secretary of Veterans Affairs;

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

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

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

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

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

(B) review applications for grants and contracts under subsection (e) and make recommendations to the Chairperson.

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

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

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

(C) define the duties, and supervise and direct the activities, of any employees appointed under subparagraph (B);

(D) use experts and consultants, including a panel of experts who may be employed as authorized by section 3109 of title 5, United States Code;

(E) accept and utilize the services of voluntary and uncompensated personnel and reimburse such personnel for travel expenses, as described in paragraph (7)(B);

(F) make advance, progress, or other payments without regard to section 3324 of title 31, United States Code;

(G) rent office space in the District of Columbia for use by the CAN;

(H) enter into agreements with other Federal agencies to carry out oversight of the grant

program under subsection (e), which agreements may include provisions for financial reimbursement for the oversight provided by such agencies; and

(I) make other necessary expenditures.

(6) MEETINGS.—

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

(B) QUORUM; REQUIREMENTS; LIMITATIONS.—

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

(ii) CHAIRPERSON OR VICE CHAIRPERSON.—Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

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

(iv) DIVERSE REPRESENTATION.—At each meeting of the Board, there shall be not less than one scientist, one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization.

(7) COMPENSATION AND TRAVEL EXPENSES.—

(A) COMPENSATION.—Members shall receive compensation at a rate to be fixed by the Chairperson but not to exceed a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the performance of the duties of the Board. All members of the Board who are officers or employees of the Untied States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

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

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

(e) GRANT PROGRAM.—

(1) GRANTS AND CONTRACTS.—The Chairperson shall, through the Board of the CAN, award grants and contracts to eligible entities to assist such entities in carrying out projects described in paragraph (3).

(2) AWARD PROCESS.—The Chairperson of the Board may award a grant or contract under this subsection to an eligible entity only upon the approval of a majority of a quorum of the Board.

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

(A) to accelerate the development of cures and treatments, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or

(B) to help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit

the recipient to meet regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

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

(A) be—

(i) an individual;

(ii) a group of individuals; or

(iii) a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease advocacy organization, a patient advocacy organization, or an academic research institution;

(B) submit an application containing—

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

(ii) a timetable for such project;

(iii) an assurance that the entity will submit—

(I) interim reports describing the entity's—

(aa) progress in carrying out the project; and

(bb) compliance with all provisions of this section and conditions of receipt of such grant or contract; and

(II) a final report at the conclusion of the grant period, describing the outcomes of the project; and

(iv) a description of the protocols the entity will follow to comply with Food and Drug Administration standards and regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product; and

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

(5) STUDY SECTIONS OF THE CENTER FOR SCIENTIFIC REVIEW.—

(A) IN GENERAL.—The Chairperson may enter into an interagency agreement with the 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

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

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

(B) THE CURES ACCELERATION GRANT 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 addi-

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

(7) SUSPENSION OF AWARDS FOR DEFAULTS, NONCOMPLIANCE WITH PROVISIONS AND PLANS, AND DIVERSION OF FUNDS; REPAYMENT OF FUNDS.—The Chairperson may suspend the award to any entity upon noncompliance by such entity with provisions and plans under this section or diversion of funds.

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

(9) CLOSEOUT PROCEDURES.—At the end of a grant or contract period, a recipient shall follow the closeout procedures under section 74.71 of title 45, Code of Federal Regulations (or any successor regulation).

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

(g) GIFTS, BEQUESTS, AND DEVISES.—

(1) IN GENERAL.—The CAN may accept donations, bequests, and devises, with or without conditions, and transfers for tax purposes, for the purpose of aiding or facilitating the work of the CAN subject to the following:

(A) In any case in which money or other property is donated, bequeathed, or devised to the CAN without designation for the benefit of which such property is intended, and without condition or restriction other than that such property be used for the purposes of the CAN, such property shall be deemed to have been donated, bequeathed, or devised to the CAN and the Chairperson shall have authority to receive such property.

(B) In any case in which any money or other property is donated, bequeathed, or devised 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

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

(2) INFORMATION.—

(A) IN GENERAL.—In the case in which the principal investigator for a recipient described under subparagraph (B) has a conflict of interest, the Chairperson shall require the recipient to provide to the Chairperson the following information:

(i) The degree of the primary investigator's financial interest, estimated to the nearest $1,000.

(ii) A detailed report explaining how the recipient will manage the primary investigator's conflict of interest.

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

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

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

(i) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated—

(1) for fiscal year 2010, $1,000,000,000 for awards described under subsection (e)(6)(A), including associated administrative costs;

(2) for fiscal year 2010, $1,000,000,000 for awards described under subsection (e)(6)(B), including associated administrative costs; and

(3) such sums as may be necessary for subsequent fiscal years.

SEC. 3. ORGANIZATION OF NATIONAL INSTITUTES OF HEALTH.

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

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

(2) by transferring subpart 20, as so redesignated, to part C of such title IV;

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

(4) in subpart 20, as so redesignated—

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

(B) by striking ''National Center on Minority Health and Health Disparities'' each place such term appears and inserting ''National Institute on Minority Health and Health Disparities''; and

(C) by striking ''Center'' each place such term appears and inserting ''Institute''.

(b) PURPOSE OF INSTITUTE.—Subsection (h) of section 464z–3 of the Public Health Service Act, as so redesignated, is amended—

(1) in paragraph (1), by striking ''research endowments at centers of excellence under section 736.'' and inserting the following: ''research endowments—

''(1) at centers of excellence under section 736; and

''(2) at centers of excellence under section 464z–4.''; and

(2) in paragraph (2)(A), by striking ''average'' and inserting ''median''.

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

is amended by striking ''Center'' and inserting ''Institute''.

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

SEC. 4. CONFLICTS OF INTEREST.

Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by adding at the end the following:

''(m) ENFORCEMENT OF CONFLICT OF INTEREST POLICIES.—

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

''(2) INFORMATION.—

''(A) IN GENERAL.—In the case in which the principal investigator for a recipient described under subparagraph (B) has a conflict of interest, the Director shall require the recipient to provide to the Director the following information:

''(i) The degree of the primary investigator's financial interest, estimated to the nearest $1,000.

''(ii) A detailed report explaining how the recipient will manage the primary investigator's conflict of interest.

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

''(i) of a grant or contract awarded under this title; and

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

SEC. 5. AUTHORIZATION OF APPROPRIATIONS.

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

''(1) $40,000,000,000 for fiscal year 2010; and

''(2) such sums as may be necessary for each of fiscal years 2011 and 2012.''.

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

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