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111TH CONGRESS
1ST SESSION

H. R. 1483

To direct the Secretary of Health and Human Services to implement a National Neurotechnology Initiative, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 12, 2009

Mr. KENNEDY (for himself, Ms. ROS-LEHTINEN, Mr. FILNER, and Mr. WU) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To direct the Secretary of Health and Human Services to implement a National Neurotechnology Initiative, 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 ''National Neurotechnology Initiative Act''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) While the field of neuroscience is highly advanced, our understanding of how the brain works

still has many gaps and our ability to repair damage remains limited.

(2) Nearly 100,000,000 Americans suffer from a brain or nervous system disease, injury, or disorder, and the national economic burden of such brain-related illnesses has reached over $1,000,000,000,000 per year and is growing alarmingly due to an aging population.

(3) Critical unmet medical needs exist in almost every area of the brain and nervous system, including Alzheimer's disease, addiction, anxiety, chronic pain, depression, epilepsy, hearing loss, multiple sclerosis, obesity, Parkinson's disease, schizophrenia, sleep, spinal cord injury, stroke, traumatic brain injury, and more.

(4) While the science of the brain is moving forward more rapidly than any other science today, we must ensure these discoveries quickly become tools to improve the human condition.

(5) Neurotechnology holds the potential to transform nearly every aspect of our lives from medicine to defense to education to computing, as well as our conception of the human mind.

(6) A global race is underway to determine the country that will lead the neurotechnology economy,

which will have long-lasting implications on employment, infrastructure development, and regional competitiveness.

(7) Federal leadership is needed to accelerate and coordinate the development of neurotechnology and bring the benefits to those in need across the Nation.

(8) Therefore, it is in the national interest for the Federal Government to increase investment and interagency coordination of Federal neurotechnology research, development, and commercialization programs.

SEC. 3. DEFINITIONS.

In this Act:

(1) INITIATIVE.—The term ''Initiative'' means the National Neurotechnology Initiative implemented under section 4.

(2) NEUROTECHNOLOGY.—The term ''neurotechnology'' means the science and technology that allows an individual to analyze, understand, treat, and heal the brain and nervous system.

(3) QUALIFIED STAFF.—The term ''qualified staff'' means a Food and Drug Administration employee who has academic training or significant experience in neurotechnology or related fields, or who

has satisfactorily completed a Food and Drug Administration neuroscience training course.

(4) RELATED FIELDS.—The term ''related fields'' means neuroscience, neuromedicine, cognitive science, behavioral psychology, neuropharmacology, neuropsychiatry, neuroimaging, neuroregeneration, neurorehabilitation, neuromodulation, neurostimulation, biomedical engineering, bioengineering, molecular biology, computer science, robotics, and such other fields as the Director of the National Neurotechnology Coordinating Office determines to be related to neurotechnology.

(5) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(6) TRANSLATIONAL.—The term ''translational'' means relating to research that is focused on converting laboratory findings into patient treatments.

SEC. 4. NATIONAL NEUROTECHNOLOGY INITIATIVE.

(a) IN GENERAL.—The Secretary shall implement a National Neurotechnology Initiative under which, acting through appropriate agencies, councils, and the National Neurotechnology Coordination Office established pursuant to section 5, the Secretary shall—

(1) establish goals, priorities, and metrics for evaluation for Federal neurotechnology research, development, commercialization, and other activities;

(2) increase the investment in Federal research, development, and translational programs in neurotechnology, and related fields as appropriate, to achieve the goals described in paragraph (1); and

(3) increase interagency coordination of Federal neurotechnology research, development, and other activities undertaken pursuant to the Initiative.

(b) AREAS OF CONCENTRATION.—The Initiative shall—

(1) coordinate, support, and extend the neurotechnology-related activities of the National Institutes of Health and the work of the Blueprint for Neuroscience Research developed under section 6(a);

(2) coordinate and promote neuroscience small business innovation research programs;

(3) facilitate testing and evaluation of advances in neuromedicine, including drugs, diagnostics, and devices; and

(4) coordinate and promote the study of the social, ethical, and legal aspects of neurotechnology.

SEC. 5. COORDINATION.

(a) IN GENERAL.—The Secretary shall establish a National Neurotechnology Coordination Office, to be headed by a director to be appointed by the Secretary, that shall—

(1) coordinate Federal neurotechnology activities among the Department of Health and Human Services, the National Institutes of Health, the Food and Drug Administration, the Department of Defense, the Department of Veterans Affairs, and other Federal agencies;

(2) serve as the point of contact on Federal neurotechnology activities for academia, industry, professional societies, State neurotechnology programs, interested citizen groups, and others to facilitate the exchange of technical and programmatic information;

(3) conduct public outreach, including dissemination of findings and recommendations of the National Neurotechnology Advisory Council established under subsection (c), as appropriate;

(4) promote access to, and the early application of, the technologies, innovations, and expertise derived from activities conducted under the Initiative by agencies and systems across the Federal Govern-

ment, and by United States industry, including start-up companies; and

(5) provide technical and administrative support to the National Neurotechnology Advisory Council.

(b) REPORT.—The Director of the National Neurotechnology Coordination Office shall annually submit to the Secretary a report on the status of the Initiative. Such reports shall contain the results of an evaluation of the effectiveness of the Initiative in the year for which the report is being prepared and the goals and benchmarks for the following year. The Secretary shall transmit a copy of each report under this subsection to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(c) ADVISORY COUNCIL.—

(1) IN GENERAL.—The Secretary shall establish, or designate an existing entity as, a National Neurotechnology Advisory Council.

(2) QUALIFICATIONS.—

(A) IN GENERAL.—The Advisory Council shall consist primarily of members from academic institutions, not-for-profit organizations, and industry.

(B) REQUIREMENTS.—Members of the Advisory Council shall be qualified to provide advice and information on neurotechnology research, development, demonstrations, education, technology transfer, commercial application, delivery, access, or ethical, legal, and social issues related to neurotechnology.

(C) RECOMMENDATIONS.—In appointing members to, or designating an entity as, an Advisory Council, the Secretary may seek and give consideration to recommendations from the Congress, industry, the scientific and medical communities (including the National Academy of Sciences, scientific and medical professional societies, not-for-profit organizations, and academia), the defense community, State and local governments, regional neurotechnology programs, and other appropriate organizations.

(3) DUTIES.—The Advisory Council shall provide advice to the Director of the National Neurotechnology Coordination Office on matters relating to the Initiative, including assessing—

(A) trends and developments in neurotechnology and related fields;

(B) progress made in implementing the Initiative;

(C) the need to revise the Initiative;

(D) the balance among the components of the Initiative, including funding levels for the program component areas;

(E) whether the program component areas, priorities, and technical goals developed by the Council are helping to maintain United States leadership in neurotechnology and related fields;

(F) the management, coordination, implementation, and activities of the Initiative; and

(G) whether ethical, legal, and social issues are adequately addressed by the Initiative.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) OFFICE.—There is authorized to be appropriated to carry out subsections (a) and (b) $4,000,000 for each of fiscal years 2010, 2011, 2012, and 2013.

(2) ADVISORY COUNCIL.—There is authorized to be appropriated to carry out subsection (c) $1,000,000 for each of fiscal years 2010, 2011, 2012, and 2013.

SEC. 6. PROGRAMS RELATED TO THE NATIONAL INSTITUTES OF HEALTH.

(a) BLUEPRINT FOR NEUROSCIENCE RESEARCH.—The Director of the National Institutes of Health shall develop a program or designate an existing program, to be known as the Blueprint for Neuroscience Research, for collaboration among the institutes, centers, and offices of the National Institutes of Health that support neuroscience research within the National Institutes of Health. Such program shall—

(1) identify pervasive challenges in neuroscience and any technological barriers to solving such challenges; and

(2) support the development of new tools, training opportunities, and other resources to assist neuroscientists in both basic and clinical research.

(b) SMALL BUSINESS INNOVATION RESEARCH.—In carrying out their duties under the Small Business Innovation Research Program, the directors of each of the institutes of the National Institutes of Health shall—

(1) where appropriate, give high priority to small business concerns that participate in or conduct neurotechnology research and development projects; and

(2) annually report to the Director of the National Neurotechnology Coordination Office con-

cerning the percentage of Small Business Innovation Research funding being used for such projects.

(c) SMALL BUSINESS TECHNOLOGY TRANSFER.—In carrying out their duties under the Small Business Technology Transfer Program, the directors of each of the institutes of the National Institutes of Health shall—

(1) where appropriate, give high priority to small business concerns that participate in or conduct neurotechnology research and development projects; and

(2) annually report to the Director of the National Neurotechnology Coordination Office concerning the percentage of Small Business Technology Transfer funding being used for such projects.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) BLUEPRINT FOR NEUROSCIENCE RESEARCH.—There are authorized to be appropriated to carry out subsection (a)—

(A) $80,000,000 for fiscal year 2010;

(B) $88,000,000 for fiscal year 2011;

(C) $96,800,000 for fiscal year 2012; and

(D) $106,480,000 for fiscal year 2013.

(2) SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS TECHNOLOGY TRANSFER.—

(A) IN GENERAL.—There are authorized to be appropriated to carry out subsections (b) and (c)—

(i) $75,000,000 for fiscal year 2010;

(ii) $82,500,000 for fiscal year 2011;

(iii) $90,750,000 for fiscal year 2012; and

(iv) $99,825,000 for fiscal year 2013.

(B) LIMITATION.—None of the funding authorized by this paragraph may be counted toward the expenditure amounts required by subsections (f) and (n) of section 9 of the Small Business Act (15 U.S.C. 638).

SEC. 7. PROGRAMS RELATED TO THE FOOD AND DRUG ADMINISTRATION.

(a) FDA REVIEW.—The Commissioner of Food and Drugs shall direct the Director of the Center for Drug Evaluation and Research, the Director of the Center for Biologics Evaluation and Research, and the Director of the Center for Devices and Radiological Health to improve the timeliness of the review process for neurology and psychiatry by—

(1) increasing, through recruitment and training, the number of qualified staff within such Centers; and

(2) improving the processes for creating guidelines with respect to neurology and psychiatry and communicating those guidelines to industry.

(b) NEUROTECHNOLOGY STANDARDS WORKGROUPS.—The Commissioner of Food and Drugs shall sponsor workgroups including academic and industry representatives to develop standards for preclinical testing and clinical trial endpoints for emerging brain and nervous system indications for which clear and achievable standards do not otherwise exist on the date of the enactment of this Act.

(c) AUTHORIZATION OF APPROPRIATIONS.—

(1) FDA REVIEW.—There are authorized to be appropriated to carry out subsection (a)—

(A) $26,000,000 for fiscal year 2010;

(B) $28,600,000 for fiscal year 2011;

(C) $31,460,000 for fiscal year 2012; and

(D) $34,606,000 for fiscal year 2013.

(2) NEUROTECHNOLOGY STANDARDS WORKGROUPS.—There is authorized to be appropriated to carry out subsection (b) $4,000,000 for each of fiscal years 2010, 2011, 2012, and 2013.

SEC. 8. PROGRAMS RELATED TO ETHICAL, LEGAL, AND SOCIAL ISSUES.

(a) AMERICAN NEUROTECHNOLOGY STUDY CENTER.—The Director of the National Neurotechnology Coordination Office shall—

(1) provide for the establishment, on a merit-reviewed and competitive basis, of an American Neurotechnology Study Center that shall—

(A) establish a research program to identify ethical, legal, and social issues related to neurotechnology and related fields, and ensure that the results of such research are widely disseminated; and

(B) conduct, coordinate, collect, and disseminate studies on such issues; and

(2) provide for public input and outreach to be integrated into the Initiative by the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events, as appropriate.

(b) STUDY ON THE RESPONSIBLE DEVELOPMENT OF NEUROTECHNOLOGY.—The American Neurotechnology Study Center established under subsection (a) shall conduct a study to assess the need for standards, guidelines, or strategies for ensuring the responsible development of neurotechnology, including—

(1) the safety of use of brain interface devices;

(2) human subject guidelines for research and development of neurotechnology;

(3) the use of neurotechnology in the enhancement of human intelligence;

(4) the development of defensive technologies relating to neurotechnology;

(5) the use of neurotechnology in developing artificial intelligence;

(6) the potential to ease the health care burden through use of neurotechnology; and

(7) the development of appropriate ethical standards and guidelines for research and development in neurotechnology.

(c) STUDY ON THE ECONOMIC IMPACT OF NEUROTECHNOLOGY.—The Director of the National Neurotechnology Coordination Office shall, on a merit-reviewed and competitive basis, provide for the conduct of an annual study to assess the need for analyses, programs, reports, or strategies for ensuring the development of neurotechnology, including analyzing—

(1) the economic burden of brain and nervous system disorders and illness;

(2) the economic growth potential of neurotechnology;

(3) national and regional neurotechnology assets; and

(4) global neurotechnology assets.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to carry out subsection (a) and (b) $8,000,000 for each of fiscal years 2010, 2011, 2012, and 2013.

(2) STUDY ON THE RESPONSIBLE DEVELOPMENT OF NEUROTECHNOLOGY.—There is authorized to be appropriated to carry out subsection (c) $2,000,000 for each of fiscal years 2010, 2011, 2012, and 2013.

(3) LIMITATION.—No more than $250,000 per fiscal year shall be used to carry out subsection (a)(2).

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