

110TH CONGRESS
2D SESSION

H. R. 5989

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

IN THE HOUSE OF REPRESENTATIVES

MAY 7, 2008

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

A BILL

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

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

8 (1) While the field of neuroscience is highly ad-
9 vanced, our understanding of how the brain works

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

3 (2) Nearly 100,000,000 Americans suffer from
4 a brain or nervous system disease, injury, or dis-
5 order, and the national economic burden of such
6 brain-related illnesses has reached over
7 \$1,000,000,000,000 per year and is growing alarm-
8 ingly due to an aging population.

9 (3) Critical unmet medical needs exist in almost
10 every area of the brain and nervous system, includ-
11 ing Alzheimer's disease, addiction, anxiety, chronic
12 pain, depression, epilepsy, hearing loss, multiple
13 sclerosis, obesity, Parkinson's disease, schizophrenia,
14 sleep, spinal cord injury, stroke, traumatic brain in-
15 jury, and more.

16 (4) While the science of the brain is moving for-
17 ward more rapidly than any other science today, we
18 must ensure these discoveries quickly become tools
19 to improve the human condition.

20 (5) Neurotechnology holds the potential to
21 transform nearly every aspect of our lives from med-
22 icine to defense to education to computing, as well
23 as our conception of the human mind.

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

1 which will have long-lasting implications on employ-
2 ment, infrastructure development, and regional com-
3 petitiveness.

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

8 (8) Therefore, it is in the national interest for
9 the Federal Government to increase investment and
10 interagency coordination of Federal neurotechnology
11 research, development, and commercialization pro-
12 grams.

13 **SEC. 3. DEFINITIONS.**

14 In this Act:

15 (1) INITIATIVE.—The term “Initiative” means
16 the National Neurotechnology Initiative implemented
17 under section 4.

18 (2) NEUROTECHNOLOGY.—The term “neuro-
19 technology” means the science and technology that
20 allows an individual to analyze, understand, treat,
21 and heal the brain and nervous system.

22 (3) QUALIFIED STAFF.—The term “qualified
23 staff” means a Food and Drug Administration em-
24 ployee who has academic training or significant ex-
25 perience in neurotechnology or related fields, or who

1 has satisfactorily completed a Food and Drug Ad-
2 ministration neuroscience training course.

3 (4) RELATED FIELDS.—The term “related
4 fields” means neuroscience, neuromedicine, cognitive
5 science, behavioral psychology, neuropharmacology,
6 neuropsychiatry, neuroimaging, neuroregeneration,
7 neurorehabilitation, neuromodulation, neurostimula-
8 tion, biomedical engineering, bioengineering, molec-
9 ular biology, computer science, robotics, and such
10 other fields as the Director of the National Neuro-
11 technology Coordinating Office determines to be re-
12 lated to neurotechnology.

13 (5) SECRETARY.—The term “Secretary” means
14 the Secretary of Health and Human Services.

15 (6) TRANSLATIONAL.—The term “translation-
16 al” means relating to research that is focused on
17 converting laboratory findings into patient treat-
18 ments.

19 **SEC. 4. NATIONAL NEUROTECHNOLOGY INITIATIVE.**

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

1 (1) establish goals, priorities, and metrics for
2 evaluation for Federal neurotechnology research, de-
3 velopment, commercialization, and other activities;

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

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

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

13 (1) coordinate, support, and extend the
14 neurotechnology-related activities of the National In-
15 stitutes of Health and the work of the Blueprint for
16 Neuroscience Research developed under section 6(a);

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

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

22 (4) coordinate and promote the study of the so-
23 cial, ethical, and legal aspects of neurotechnology.

1 **SEC. 5. COORDINATION.**

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

6 (1) coordinate Federal neurotechnology activi-
7 ties among the Department of Health and Human
8 Services, the National Institutes of Health, the Food
9 and Drug Administration, the Department of De-
10 fense, the Department of Veterans Affairs, and
11 other Federal agencies;

12 (2) serve as the point of contact on Federal
13 neurotechnology activities for academia, industry,
14 professional societies, State neurotechnology pro-
15 grams, interested citizen groups, and others to facili-
16 tate the exchange of technical and programmatic in-
17 formation;

18 (3) conduct public outreach, including dissemi-
19 nation of findings and recommendations of the Na-
20 tional Neurotechnology Advisory Council established
21 under subsection (c), as appropriate;

22 (4) promote access to, and the early application
23 of, the technologies, innovations, and expertise de-
24 rived from activities conducted under the Initiative
25 by agencies and systems across the Federal Govern-

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

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

5 (b) REPORT.—The Director of the National
6 Neurotechnology Coordination Office shall annually sub-
7 mit to the Secretary a report on the status of the Initia-
8 tive. Such reports shall contain the results of an evaluation
9 of the effectiveness of the Initiative in the year for which
10 the report is being prepared and the goals and bench-
11 marks for the following year. The Secretary shall transmit
12 a copy of each report under this subsection to the Com-
13 mittee on Energy and Commerce of the House of Rep-
14 resentatives and the Committee on Health, Education,
15 Labor, and Pensions of the Senate.

16 (c) ADVISORY COUNCIL.—

17 (1) IN GENERAL.—The Secretary shall estab-
18 lish, or designate an existing entity as, a National
19 Neurotechnology Advisory Council.

20 (2) QUALIFICATIONS.—

21 (A) IN GENERAL.—The Advisory Council
22 shall consist primarily of members from aca-
23 demic institutions, not-for-profit organizations,
24 and industry.

1 (B) REQUIREMENTS.—Members of the Ad-
2 visory Council shall be qualified to provide ad-
3 vice and information on neurotechnology re-
4 search, development, demonstrations, education,
5 technology transfer, commercial application, de-
6 livery, access, or ethical, legal, and social issues
7 related to neurotechnology.

8 (C) RECOMMENDATIONS.—In appointing
9 members to, or designating an entity as, an Ad-
10 visory Council, the Secretary may seek and give
11 consideration to recommendations from the
12 Congress, industry, the scientific and medical
13 communities (including the National Academy
14 of Sciences, scientific and medical professional
15 societies, not-for-profit organizations, and aca-
16 demia), the defense community, State and local
17 governments, regional neurotechnology pro-
18 grams, and other appropriate organizations.

19 (3) DUTIES.—The Advisory Council shall pro-
20 vide advice to the Director of the National
21 Neurotechnology Coordination Office on matters re-
22 lating to the Initiative, including assessing—

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

1 (B) progress made in implementing the
2 Initiative;

3 (C) the need to revise the Initiative;

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

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

11 (F) the management, coordination, imple-
12 mentation, and activities of the Initiative; and

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

15 (d) AUTHORIZATION OF APPROPRIATIONS.—

16 (1) OFFICE.—There is authorized to be appro-
17 priated to carry out subsections (a) and (b)
18 \$4,000,000 for each of fiscal years 2009, 2010,
19 2011, and 2012.

20 (2) ADVISORY COUNCIL.—There is authorized
21 to be appropriated to carry out subsection (c)
22 \$1,000,000 for each of fiscal years 2009, 2010,
23 2011, and 2012.

1 **SEC. 6. PROGRAMS RELATED TO THE NATIONAL INSTI-**
2 **TUTES OF HEALTH.**

3 (a) **BLUEPRINT FOR NEUROSCIENCE RESEARCH.**—

4 The Director of the National Institutes of Health shall
5 develop a program or designate an existing program, to
6 be known as the Blueprint for Neuroscience Research, for
7 collaboration among the institutes, centers, and offices of
8 the National Institutes of Health that support neuro-
9 science research within the National Institutes of Health.
10 Such program shall—

11 (1) identify pervasive challenges in neuroscience
12 and any technological barriers to solving such chal-
13 lenges; and

14 (2) support the development of new tools, train-
15 ing opportunities, and other resources to assist
16 neuroscientists in both basic and clinical research.

17 (b) **SMALL BUSINESS INNOVATION RESEARCH.**—In
18 carrying out their duties under the Small Business Inno-
19 vation Research Program, the directors of each of the in-
20 stitutes of the National Institutes of Health shall—

21 (1) where appropriate, give high priority to
22 small business concerns that participate in or con-
23 duct neurotechnology research and development
24 projects; and

25 (2) annually report to the Director of the Na-
26 tional Neurotechnology Coordination Office con-

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

3 (c) SMALL BUSINESS TECHNOLOGY TRANSFER.—In
4 carrying out their duties under the Small Business Tech-
5 nology Transfer Program, the directors of each of the in-
6 stitutes of the National Institutes of Health shall—

7 (1) where appropriate, give high priority to
8 small business concerns that participate in or con-
9 duct neurotechnology research and development
10 projects; and

11 (2) annually report to the Director of the Na-
12 tional Neurotechnology Coordination Office con-
13 cerning the percentage of Small Business Tech-
14 nology Transfer funding being used for such
15 projects.

16 (d) AUTHORIZATION OF APPROPRIATIONS.—

17 (1) BLUEPRINT FOR NEUROSCIENCE RE-
18 SEARCH.—There are authorized to be appropriated
19 to carry out subsection (a)—

20 (A) \$80,000,000 for fiscal year 2009;

21 (B) \$88,000,000 for fiscal year 2010;

22 (C) \$96,800,000 for fiscal year 2011; and

23 (D) \$106,480,000 for fiscal year 2012.

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

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

4 (i) \$75,000,000 for fiscal year 2009;

5 (ii) \$82,500,000 for fiscal year 2010;

6 (iii) \$90,750,000 for fiscal year 2011;

7 and

8 (iv) \$99,825,000 for fiscal year 2012.

9 (B) LIMITATION.—None of the funding au-
10 thorized by this paragraph may be counted to-
11 ward the expenditure amounts required by sub-
12 sections (f) and (n) of section 9 of the Small
13 Business Act (15 U.S.C. 638).

14 **SEC. 7. PROGRAMS RELATED TO THE FOOD AND DRUG AD-**
15 **MINISTRATION.**

16 (a) FDA REVIEW.—The Commissioner of Food and
17 Drugs shall direct the Director of the Center for Drug
18 Evaluation and Research, the Director of the Center for
19 Biologics Evaluation and Research, and the Director of
20 the Center for Devices and Radiological Health to improve
21 the timeliness of the review process for neurology and psy-
22 chiatry by—

23 (1) increasing, through recruitment and train-
24 ing, the number of qualified staff within such Cen-
25 ters; and

1 (2) improving the processes for creating guide-
2 lines with respect to neurology and psychiatry and
3 communicating those guidelines to industry.

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

12 (c) AUTHORIZATION OF APPROPRIATIONS.—

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

15 (A) \$26,000,000 for fiscal year 2009;

16 (B) \$28,600,000 for fiscal year 2010;

17 (C) \$31,460,000 for fiscal year 2011; and

18 (D) \$34,606,000 for fiscal year 2012.

19 (2) NEUROTECHNOLOGY STANDARDS
20 WORKGROUPS.—There is authorized to be appro-
21 priated to carry out subsection (b) \$4,000,000 for
22 each of fiscal years 2009, 2010, 2011, and 2012.

1 **SEC. 8. PROGRAMS RELATED TO ETHICAL, LEGAL, AND SO-**
2 **CIAL ISSUES.**

3 (a) AMERICAN NEUROTECHNOLOGY STUDY CEN-
4 TER.—The Director of the National Neurotechnology Co-
5 ordination Office shall—

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

9 (A) establish a research program to iden-
10 tify ethical, legal, and social issues related to
11 neurotechnology and related fields, and ensure
12 that the results of such research are widely dis-
13 seminated; and

14 (B) conduct, coordinate, collect, and dis-
15 seminate studies on such issues; and

16 (2) provide for public input and outreach to be
17 integrated into the Initiative by the convening of
18 regular and ongoing public discussions, through
19 mechanisms such as citizens' panels, consensus con-
20 ferences, and educational events, as appropriate.

21 (b) STUDY ON THE RESPONSIBLE DEVELOPMENT OF
22 NEUROTECHNOLOGY.—The American Neurotechnology
23 Study Center established under subsection (a) shall con-
24 duct a study to assess the need for standards, guidelines,
25 or strategies for ensuring the responsible development of
26 neurotechnology, including—

- 1 (1) the safety of use of brain interface devices;
- 2 (2) human subject guidelines for research and
3 development of neurotechnology;
- 4 (3) the use of neurotechnology in the enhance-
5 ment of human intelligence;
- 6 (4) the development of defensive technologies
7 relating to neurotechnology;
- 8 (5) the use of neurotechnology in developing ar-
9 tificial intelligence;
- 10 (6) the potential to ease the health care burden
11 through use of neurotechnology; and
- 12 (7) the development of appropriate ethical
13 standards and guidelines for research and develop-
14 ment in neurotechnology.

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

- 22 (1) the economic burden of brain and nervous
23 system disorders and illness;
- 24 (2) the economic growth potential of
25 neurotechnology;

1 (3) national and regional neurotechnology as-
2 sets; and

3 (4) global neurotechnology assets.

4 (d) AUTHORIZATION OF APPROPRIATIONS.—

5 (1) IN GENERAL.—There is authorized to be
6 appropriated to carry out subsection (a) and (b)
7 \$8,000,000 for each of fiscal years 2009, 2010,
8 2011, and 2012.

9 (2) STUDY ON THE RESPONSIBLE DEVELOP-
10 MENT OF NEUROTECHNOLOGY.—There is authorized
11 to be appropriated to carry out subsection (c)
12 \$2,000,000 for each of fiscal years 2009, 2010,
13 2011, and 2012.

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

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