



National Institute of
Neurological Disorders
and Stroke



LEGISLATIVE UPDATE:

Overview of Legislation from the 113th Congress and Outlook for the 114th Congress
January 2015

NINDS OFFICE OF SCIENCE POLICY & PLANNING

For more information on NINDS' legislative activities and links to legislative resources, please visit the NINDS Office of Science Policy and Planning website: <http://www.ninds.nih.gov/ospp>

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Appropriations update

FY 2015

The President's FY 2015 budget was released on March 4, 2014. The budget would have allocated \$30.4 billion to NIH, which is \$211 million (0.7%) above the FY 2014 level. NINDS would have received \$1.61 billion under the FY 2015 President's budget, which is an increase of approximately \$23 million (1.4%) from the FY 2014 funding level. The proposed increase largely reflected funding for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.

In early spring 2014, Dr. Collins, accompanied by several institute directors including then NINDS Director Dr. Story Landis, testified at two hearings related to the FY 15 budget – one before the House Appropriations Subcommittee on Labor, HHS, Education and Related Agencies and one before the Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies (L-HHS). See the “Recent Hearings” section of this report for more information.

To avoid a government shutdown at the beginning of the fiscal year (October 1, 2014), President Obama signed a Continuing Resolution (P.L. 113-164) on September 19, 2014, to fund all federal agencies through December 11, 2014. Additional short-term Continuing Resolutions were signed until Congress passed the “Consolidated and Further Continuing Appropriations Act, 2015” (P.L. 113-235). President Obama signed the FY2015 omnibus budget on December 16, 2014. The bill provides \$1,605,205,000 for NINDS, which is an increase of \$17 million or 1.1% from the FY 2014 funding level.

As part of the omnibus, Congress added \$25 million to the NIH FY 2015 budget specifically for the BRAIN Initiative. The agreement also includes an increase of \$25 million for that National Institute on Aging (NIA), with the expectation that a significant portion of this increase will be directed to research on Alzheimer's disease, based on scientific opportunity and the outcome of the peer review process. In addition, the explanatory statement that accompanied the omnibus budget included language related to several policy issues relevant to NIH including: decreasing the average age at which investigators first obtain R01 funding; developing ways to address issues related to reproducibility of research; and requirements related to sex of experimental models and analysis of data by sex in grant applications and progress reports.

FY 2016

The President's FY 2016 budget is expected to be released on February 2, 2015.

Legislative highlights from the 113th Congress of interest to NINDS

Public Laws

P.L. 113-55: The Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Reauthorization Act

The legislation contains three titles:

- Title I: PREEMIE Act Reauthorization: This act has no NIH provisions, but includes provisions for other HHS agencies, such as CDC.
- Title II: National Pediatric Research Network: This title includes an amended version of H.R. 225, the National Pediatric Research Network Act of 2013, which passed the House but saw no further action in the Senate. Provisions of H.R. 225 included authorizing the NIH Director, acting through the Director of NICHD and in collaboration with other institutes, to establish a National Pediatric Research Network, consisting of up to 20 pediatric research consortia that conduct basic, clinical, behavioral, and translational research and train researchers in pediatric research techniques. H.R. 225 would have also required the NIH Director to establish a data coordinating center to distribute scientific findings, to provide assistance in the design of collaborative research projects and the management, analysis and storage of data, to organize and conduct multisite monitoring activities, and to provide assistance to the CDC in the establishment of patient registries. As amended by this title, the NIH Director may provide for the establishment of a National Pediatric Research Network, which may include both new awards to consortia or existing NICHD pediatric research consortia, centers, and networks. Other key changes include striking the data coordinating center and eliminating references to specific diseases (the amended title mentions pediatric rare diseases and those related to birth defects, while H.R. 225 included specific references to SMA, Duchenne muscular dystrophy, Down syndrome, and Fragile X).
- Title III: Chimp Act Amendments: This title amends the Chimpanzee Health Improvement, Maintenance, and Protection Act (CHIMP Act), which established a system of sanctuaries for chimpanzees that have been designated as being no longer needed in research. The title authorizes appropriations to the NIH to provide funds for the care, maintenance, and transportation of all chimpanzees otherwise under the ownership or control of the NIH in the amounts of: \$12.4 m in FY2014; \$11.65 m in FY2015; \$10.9 m in FY2016; \$10.15 m in FY2017; and \$9.4 m in FY2018. This title also charges the Secretary of HHS with making determinations on whether certain facilities meet requirements to be a part of the federal sanctuary system. In addition, the title requires the GAO to conduct an independent evaluation of the cost of care of NIH owned chimpanzees and requires the NIH to submit a biennial report to relevant House and Senate committees regarding the care, maintenance and transportation of the chimpanzees owned or controlled by NIH and the cost related to such activities.

P.L. 113-157: Autism Collaboration, Accountability, Research, Education, and Support Act of 2014 or the Autism CARES Act of 2014

This law reauthorizes research, surveillance, and education activities related to autism spectrum disorders conducted by various HHS agencies including CDC, HRSA, and NIH. Specifically, the bill would expand the Interagency Autism Coordinating Committee (IACC) to include services and not just research responsibilities. The law also requires the Secretary of HHS to designate an existing official within HHS to oversee a National Autism Spectrum Disorder Initiative. This initiative would implement a strategic plan for the conduct of autism spectrum disorder (ASD) research and ensure that ASD research activities in DHHS and other Federal agencies are not unnecessarily duplicative. Versions of the Autism CARES Act were introduced in the House and Senate: HR 4631 by Representative Chris Smith (R-NJ) and S. 2449 by Senator Robert Menendez (D-NJ). After passing the House in June 2014, and the Senate in late July 2014, the bill was signed into law by the President on August 8, 2014.

P.L. 113-166: Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education (MD-CARE) Amendments of 2014

This law is the second reauthorization of the MD-CARE Act. The original MD-CARE Act, signed into law in 2001 (P.L. 107-84), amended Title IV of the Public Health Service Act to require the Director of NIH, in coordination with the Directors of NINDS, NIAMS, NICHD, and other national research institutes, to expand and intensify programs with respect to research and related activities in muscular dystrophy. The MD-CARE Act also established the Muscular Dystrophy Coordinating Committee (MDCC) and required NIH to fund and coordinate Muscular Dystrophy Centers of Excellence. In 2008, Congress reauthorized the law (P.L. 110-361) which formalized in statute the naming of the muscular dystrophy centers of excellence as the Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers, and required the MDCC to give special consideration to enhance the clinical research infrastructure to test emerging therapies for the various forms of muscular dystrophy.

The most recent authorization adds cardiac and pulmonary functions to the research areas covered by the Wellstone Centers, adds members to the MDCC, and specifies twice-yearly meetings of the Committee. The law also includes provisions related to evaluation and approval of emerging therapies, considerations for pediatric and adult patients with muscular dystrophy and expanding epidemiological data collection and dissemination. After passing the House in July 2014 and the Senate in September 2014, the bill was signed into law (P.L. 113-166) by the President on September 26, 2014.

P.L. 113-235: The Alzheimer's Accountability Act of 2014 (included in the Consolidated and Further Continuing Appropriations Act, 2015)

The Alzheimer's Accountability Act was introduced in both the House and Senate (H.R. 4351; S. 2192) in the 113th Congress. Language from the bills was included in the Consolidated and

Further Continuing Appropriations Act, 2015 and requires the NIH Director to prepare an annual budget estimate for the NIH initiatives related to the National Alzheimer's Plan (specified by the National Alzheimer's Project Act; P.L. 111-375). The budget is to be submitted directly to the President for review and transmittal to Congress, annually through 2025.

P.L. 113-196: Traumatic Brain Injury Reauthorization Act of 2014

The TBI Act, which first became law in 1996, amended the Public Health Service Act to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury. The law authorized funding for prevention, surveillance, research and State grant programs to improve service delivery and access for individuals with TBI. It was reauthorized in 2000 as an amendment to the Children's Health Act of 2000, and was reauthorized a second time as the TBI Act of 2008 (P.L. 110-206). The 2014 reauthorization was signed by the President on November 26, 2014.

This law reauthorizes certain TBI prevention and surveillance or registry programs, as well as grants to states and Indian consortia for TBI services. The law requires the Secretary of HHS to develop a plan for improved coordination of Federal activities with respect to traumatic brain injury, including identifying areas for improved coordination between relevant Federal agencies and programs. The law also directs the Director of the CDC, in consultation with the Director of NIH, to review the scientific evidence related to brain injury management in children and identify opportunities for research, to be submitted to Congress within two years.

Other Legislation

A number of other bills specific to various diseases or other topics of interest to NINDS were introduced in the 113th Congress, but failed to pass both the House and Senate. Some of these are briefly summarized below.

H.R. 1619: *Making Investments Now for Dementia (MIND) Act of 2013* - *[no action beyond introduction and referral to appropriate committees]*

This bill would allow the Secretary of the Treasury, in consultation with the Secretary of HHS and the NIH Director, to issue bonds to aid in the funding of Alzheimer's disease research. The bill would require that the proceeds from the sale of such bonds go to the NIH for the sole purpose of providing additional funds for Alzheimer's disease research. This bill was introduced in the 112th and 111th Congresses as well.

H.R. 4798: *United States-Israel Alzheimer's Disease Cooperation Act* - *[no action beyond introduction and referral to appropriate committees]*

This bill directs the Secretary of HHS to establish a program of grants to support research on the development and commercialization of tools, treatments, and cures for Alzheimer's disease and other dementias. Projects must be joint ventures between U.S. and Israeli non-governmental entities or the U.S. and Israeli governments.

H.R. 2521 / S. 1223: *Cavernous Angioma Research Resource Act of 2013* - *[no action beyond introduction and referral to appropriate committees]*

Cavernous angioma is a collection of small blood vessels in the central nervous system that is enlarged and irregular in structure. These bills would authorize the NIH Director, acting through the NINDS Director, to expand, intensify, and coordinate basic, translational, and clinical research on cavernous angioma. The bills would also authorize creation of a clinical trial network for multi-site drug trials for cavernous angioma with a coordinating center to develop patient education, outreach and awareness programs, and training programs for clinicians and researchers. The bills authorize a "consortium", which may be one component of the coordinating center mentioned above.

The bills would also authorize the CDC to award grants for a surveillance program and epidemiological studies for cavernous angioma, and they would direct the Commissioner of the FDA to consider investigational new drug applications for cavernous angioma and orphan product development for rare subpopulations of cavernous angioma requiring unique pharmacological intervention.

H.R. 4592: *Hereditary Hemorrhagic Telangiectasia Diagnosis and Treatment Act of 2014*
S. 908: *Hereditary Hemorrhagic Telangiectasia Diagnosis and Treatment Act of 2013* - *[no action beyond introduction and referral to appropriate committees]*

The bills would require the CDC director to conduct population screening, develop guideline for diagnosis and intervention, and designate HHT Treatment Centers of Excellence. These bills would direct the Secretary, in consultation with the NIH and CDC directors, to establish and implement an HHT initiative to assist in coordinating activities to improve early detection, screening, and treatment of people who suffer from HHT, via a Coordinating Committee. The Committee would develop a plan to advance research and understanding of HHT by supporting research on HHT across NIH institutes and centers, including NHLBI, NINDS, NIDDK, NICHD, NCI, and ORDR.

H.R. 1015 / S. 723: *Huntington's Disease Parity Act of 2013* - *[no action beyond introduction and referral to appropriate committees]*

These bills would require the Social Security Commissioner to revise the medical and evaluation criteria for determining disability in a person diagnosed with adult onset and juvenile Huntington's disease in consultation with the NINDS, the NIH, and other relevant organizations and to waive the 24-month waiting period for Medicare eligibility for individuals disabled by Huntington's disease. Identical bills have been introduced in the 110th, 111th, and 112th Congresses, but the bills failed to pass out of Committee.

H.R. 3351: *Return to Work Awareness Act of 2013*

S. 1026: *Return to Work Act of 2013* - *[no action beyond introduction and referral to appropriate committees]*

After suffering a stroke in 2012 and crediting much of his recovery to intensive rehabilitation, Senator Mark Kirk (R-IL) has shown a strong interest in rehabilitation research and return to work. The purpose of these bills is to assist survivors of stroke in returning to work, by authorizing the Secretary of Labor, acting through the Job Accommodation Network, to promote awareness and assistance among employers to enable survivors of stroke and TBI to return to work. There are no provisions directly related to NIH.

H.R. 4221 / S. 2851: *Collaborative Academic Research Efforts for Tourette Syndrome Act of 2014* - *[no action beyond introduction and referral to appropriate committees]*

These bills would direct the Secretary of HHS, acting through the Director of NIH, to expand, intensify and coordinate activities of the NIH related to Tourette syndrome. Specifically, the bills would require the Secretary to develop a system to collect epidemiologic data on Tourette syndrome, fund 4 to 6 Centers of Excellence for Tourette Syndrome, and conduct research on symptomology and treatment options for Tourette patients. These bills were also introduced in the 112th Congress.

H.R. 4472: *The US-Israeli Global Neuroscience Partnership Act of 2014* - *[no action beyond introduction and referral to appropriate committees]*

The bill would provide for the establishment of a grant program to support United States-Israeli cooperation for neuroscience-related research, and for other purposes. H.R. 4472 would require

the Secretary, acting through the Director of NIH, to award grants to eligible entities for neuroscience-related research and establish in NIH an International Neuroscience Related Research Advisory Board. The bill also includes sunset provisions that provide for the termination of the program and the Advisory Board upon the expiration of the 7-year period that begins on the date of the enactment of the Act.

Bills introduced in the 114th Congress relevant to NINDS

Neurological Diseases Surveillance System

Background: Legislation to create patient registries for neurological disease has been introduced in previous Congresses. Most recently, the “National Neurological Diseases Surveillance System Act of 2011” was introduced in the House and Senate (H.R. 2595 / S. 425) during the 112th Congress. The bills were referred to the relevant committees, but no further action occurred.

H.R. 292: Advancing Research for Neurological Diseases Act of 2015

This bill – identical to the version introduced in the 112th Congress - authorizes the Secretary of HHS, acting through the CDC, to enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, such as multiple sclerosis and Parkinson's disease. This information would be incorporated into a National Neurological Diseases Surveillance System, which would be designed to facilitate further research on neurological disease.

Status: The bill was introduced on January 13, 2015, by Rep. Michael Burgess (R-TX) and was referred to the House Energy and Commerce Committee.

21st Century Cures Initiative

The bipartisan initiative, “21st Century Cures” was initiated by the House Energy and Commerce Committee Chairman Fred Upton (R-MI) and Congresswoman Diana DeGette (D-CO) during the 113th Congress. They hosted 12 hearings and roundtable discussions in Washington, DC from May through September, 2014, to discuss how to collaboratively accelerate the discovery, development, and delivery of new treatments and cures. In addition, House Members held 15 roundtable discussions in their local districts. The discussions brought together researchers, medical professionals, leaders in the biotech and pharmaceutical industries, and patient advocacy groups to discuss the state of research and development. The Initiative solicited ideas from the expert witnesses and the public on how to modernize regulatory procedures to keep pace with scientific and technological advances and foster new therapeutic development.

Dr. Collins participated in two Congressional hearings on May 6, 2014, and September 10, 2014, which were the opening and final hearings for the Initiative, respectively. He also traveled to Lancaster, PA on August 29, 2014, and Kalamazoo, MI on October 7, 2014, to speak at two of the local district roundtables. Dr. Collins highlighted the issues of unstable NIH funding, the challenges faced by young scientists, the administrative burden of grant writing and reporting, and the need to maintain patient privacy in clinical trials. Additional themes of the discussions included reducing the cost and length of clinical trials, accelerating the FDA approval process for drugs and devices, improving data sharing from trials and medical records, and creating economic incentives for drug development for serious, rare, or antibiotic-resistant diseases.

Outlook: The House Energy and Commerce Committee is expected to produce legislative proposals in early 2015 relevant to the topics discussed as part of this Initiative. Rep. Upton plans to bring the proposals to the House floor by the middle of 2015.

More information on this initiative can be found at: <http://energycommerce.house.gov/cures>.

Relevant hearings during the 113th Congress

Alzheimer's Biomedical Research Outlook; Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies

On February 26, 2014, the Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies held a hearing on Alzheimer's Disease. The first panel consisted of Dr. Francis Collins, Director, NIH, who was accompanied by Dr. Story Landis, Director, National Institute of Neurological Disorders and Stroke (NINDS) and Dr. Richard Hodes, Director, National Institute on Aging (NIA). The second panel consisted of Seth Rogen, Actor, Dennis Moore, former Congressman (D-KS), and Dr. Michael Hurd, Director, Rand Center for the Study of Aging. Dr. Collins spoke about the burden of Alzheimer's disease and about NIH research directed at this disease. He highlighted recent scientific advances such as imaging technology, which allows for earlier diagnosis of Alzheimer's, and early interventions for treating the disease. He referenced the recently launched Accelerating Medicines Partnership (AMP) and the role it will play in accelerating the identification and testing of drug targets for Alzheimer's disease as well as several other diseases. He mentioned how the BRAIN initiative will create tools that will be of value to researchers working on Alzheimer's and other neurological disorders. Questions from Members in attendance included the relationship between Alzheimer's and Down syndrome, ways to fast track Alzheimer's disease research, research on the aging process in general, ways to lower the risk of dementia or Alzheimer's disease, and the hope for a cure for Alzheimer's disease.

Future of Biomedical Research; House Appropriations Subcommittee on Labor, HHS, Education and Related Agencies

On March 26, 2014, the House Appropriations Subcommittee on L-HHS held a hearing on the Future of Biomedical Research. Dr. Francis Collins, Director, NIH, testified. He was accompanied by Dr. Harold Varmus, Director, NCI, Dr. Anthony Fauci, Director, NIAID; Dr. Gary Gibbons, Director, NHLBI, and Dr. Story Landis, Director, NINDS. In his testimony, Dr. Collins highlighted how NIH-funded advances in recent years have led the way for uncovering thousands of new risk factors and therapeutic targets. He also talked about the promise of the BRAIN initiative. Members present at the hearing asked about many topics relevant to NIH including priority setting and strategic planning at NIH, concerns about HHS taps on the NIH budget, the inclusion of women and minorities in clinical trials, scientific integrity, young investigators, and global competitiveness.

Hearing on President Obama's Proposed Fiscal 2015 Budget Request for the NIH; Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies

On April 2, 2014, Dr. Collins testified at this Senate Appropriations subcommittee hearing on the FY15 budget. He was accompanied by Dr. Harold Varmus, Director, NCI; Dr. Anthony Fauci, Director, NIAID; Dr. Gary Gibbons, Director, NHLBI; Dr. Story Landis, Director, NINDS; and Dr. Christopher Austin, Director, NCATS. Dr. Collins spoke about the negative impact of sequestration for NIH, and the fact that NIH has lost more than 20% of its purchasing power over

the last ten years. He expressed optimism that we have turned the corner after a difficult decade. He talked about new opportunities including the Accelerating Medicines Partnership (AMP), and BRAIN. Members present at the hearing asked about topics including stroke rehabilitation, women's health, developing budget for Alzheimer's disease research, and several other topics similar to those discussed at the House hearing on March 26th.

Driving Innovation through Federal Investments; Senate Appropriations Committee

On April 29, 2014, Barbara Mikulski, Chairwoman of the Senate Appropriations Committee, held this hearing to discuss the issue of discovery and innovation and the need for Federal investment in research and development. The witnesses testifying at the hearing were: Dr. John Holdren, Director, White House Office of Science and Technology Policy (OSTP); Dr. Ernest Moniz, Secretary, Department of Energy (DOE); Dr. Francis Collins, Director, NIH; Dr. France A. Cordova, Director, National Science Foundation (NSF); and Dr. Arati Parabhakar, Director, Defense Advanced Research Projects Agency (DARPA). Like other members present, Senator Mikulski expressed concern that we are running an innovation deficit. Not only does this innovation deficit affect our current research and development but it also hampers our pipeline of the next generation of researchers and scientists. In his testimony, Dr. Collins highlighted the immense economic impact and return on investment of NIH research, including the Human Genome Project. He stressed the success of collaborations with other agencies, and promising scientific opportunities such as the BRAIN initiative. He noted the importance of a bipartisan plan to secure a steady funding trajectory for biomedical research. Members of the Committee asked about priority setting at NIH, overlap and duplication in research across the government, and global investment in research and investments made by other countries.

Frontiers of Human Brain Research; House Science, Space, and Technology Subcommittee on Research and Technology

On July 31, 2013, at the request of Chairman Larry Bucshon (R-IN), Dr. Story Landis, Director, NINDS, testified before the House Science, Space, and Technology, Subcommittee on Research and Technology at a hearing entitled, "Frontiers of Human Brain Research." Dr. Marcus Raichle, Professor, Washington University in St. Louis, Mr. Michael McLoughlin, Deputy Executive, Johns Hopkins University Applied Physics Laboratory, and Dr. Gene Robinson, Professor, University of Illinois, also testified. Written statements from each of the witnesses can be found at: <http://science.house.gov/hearing/subcommittee-research-and-technology-hearing-frontiers-human-brain-research>. In her testimony, Dr. Landis talked about the importance of neuroscience research for developing new treatments and preventing disease, and she highlighted basic science advances that are changing our understanding of how the brain functions and enabling the development of new treatments. She also described the BRAIN Initiative, focusing on interagency and interdisciplinary collaborations, and the potential for this Initiative to transform our understanding of how the brain functions, which may lead to the development of new therapies for neurological diseases. Committee members asked questions about the BRAIN Initiative, foreign investments in neuroscience, the importance of interdisciplinary neuroscience research, computing and data challenges for neuroscience, imaging, prosthetics and neural interfaces for prosthetics, nanotechnology, training new scientists, Alzheimer's disease, Huntington's disease, and multiple sclerosis.

Hearing on President Obama’s Proposed Fiscal 2014 Budget Request for the NIH; Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies

On May 15, 2013, the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies held a hearing on the FY 2014 budget for NIH at which NIH Director Dr. Francis Collins testified. He was accompanied by Drs. Harold Varmus, Director, NCI; Anthony Fauci, Director, NIAID; Gary Gibbons, Director, NHLBI; Story Landis, Director, NINDS; and Richard Hodes, Director, NIA. In his testimony, Dr. Collins expressed his concern over NIH’s loss of purchasing power for research over the last 10 years and the consequences of declining budgets for NIH. He highlighted ways NIH has been accelerating scientific discovery despite the fiscal climate, and mentioned personalized therapies for cancer treatment, advances in iPS cells, and the new BRAIN Initiative. He also expressed his fear that sequestration has the potential to turn students and young scientists away from pursuing careers in research. Dr. Collins’ written statement:

<http://www.nih.gov/about/director/budgetrequest/fy2014testimony.htm>. Committee members present at the hearing expressed their overwhelming support for NIH and its successes in improving human health, and asked questions related to many of the themes in Dr. Collins’ testimony, as well as their own interests, including the BRAIN initiative, Alzheimer’s disease, autism, clinical trial participation, suicides, and ways to protect both established and new investigators given the challenging budget climate.

Oversight Hearing—Health and Human services Public Health and Research Organizations; House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies

On March 5, 2013, the House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies held an oversight hearing on the HHS agencies. As the President’s FY 2014 budget had not yet been released, the purpose of the hearing was to educate members about NIH’s activities and priorities. NIH Director Dr. Francis Collins testified with the directors of other HHS agencies about the core mission, budget and scope of operations of their agencies. Dr. Collins’ written statement can be found at:

<http://appropriations.house.gov/uploadedfiles/hhrg-113-ap07-wstate-collinsmdpdf-20130305.pdf>.