



LEGISLATIVE UPDATE:

Overview of Public Laws, Appropriations, and Pending Legislation from the 113th Congress
January 2014

NINDS OFFICE OF SCIENCE POLICY & PLANNING

Special thanks to the NIH Office of Legislative Policy & Analysis and the NIH Office of Budget for providing information for some of these reports

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Appropriations Update

FY 2014

The President's FY 2014 budget was released on April 10, 2013. The budget would allocate \$31.3 billion to NIH, which is \$471 million above the FY 2012 level. NINDS would receive \$1.64 billion under the FY 2014 President's budget, which is an increase of approximately 1.2% from the FY 2012 funding level. The sequester was not taken into account for purposes of this budget.

Priorities for NIH outlined in the President's budget include: unlocking the mysteries of the nervous system through the Human Connectome Project and the Brain Research through Application of Innovative Neurotechnologies (BRAIN) Initiative; developing policies, tools and training to facilitate the use of Big Data through the Big Data to Knowledge Program; and ways to recruit and train a diverse scientific workforce.

On July 11, 2013, the Senate Committee on Appropriations reported out S. 1284, the FY 2014 Senate Labor-HHS-Education Appropriations bill. The bill would provide \$31 billion for NIH and \$1.63 billion for NINDS. The full Senate did not take up this bill, nor was there any action in the House.

In the absence of FY 2014 appropriations, there was a lapse in government funding resulting in a partial government shutdown at the start of the 2014 fiscal year on October 1, 2013. On October 17, 2013, the President signed into law the Continuing Appropriation Act, 2014, as P.L. 113-46, a bill that ended the 16 day Government shutdown. The law provided funding for all federal agencies through January 15, 2014, at the final FY2013 level which includes cuts due to the sequester.

Following the shutdown, Congress worked to pass a joint budget resolution, which was signed into law on December 26, 2013. The budget agreement modified sequester caps on discretionary spending over the next two years, setting top-line spending for FY 2014 at \$1.012 trillion and for FY 2015 at \$1.104 trillion. It is the first conferenced and passed top-line spending agreement since the mid-1980s.

With little time to pass individual appropriations bills, the Consolidated Appropriations Act, 2014 (H.R. 3547), an omnibus appropriations bill that includes all 12 appropriations measures, was introduced in the House on January 13, 2014. The omnibus bill includes \$29.9 billion for NIH, approximately \$1 billion above the FY 2013 level, and allocates \$1.588 billion to NINDS, which is a 3.6% increase over the final FY2013 level but approximately 2.3% below the FY2012 level. Following, a short (3 day) CR to keep the government funded while Congress acted on the omnibus, the House and Senate both passed the omnibus bill, and it was signed by the President.

Public Laws

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

Title I: PREEMIE Act Reauthorization

Title II: National Pediatric Research Network

Title III: CHIMP Act Amendments

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.

Pending Legislation

Alzheimer's Disease

Background: The National Alzheimer's Project Act was signed into law (P.L. 111-375) on January 4, 2011, and was the only Alzheimer's disease (AD) research bill to be passed by the 111th Congress. This legislation requires the HHS Secretary to develop an annually updated plan for overcoming AD and to evaluate annually all federally funded efforts in AD research, care and services. As part of this plan, NIA convened the AD Research Summit: Path to Treatment and Prevention in May 2012 and NINDS convened the AD-Related Dementias: Research Challenges and Opportunities Workshop in May 2013 to develop recommendations for research priorities for AD and AD-Related Dementias. On April 24, 2013, the Senate Special Committee on Aging held a hearing on the National Plan to Address Alzheimer's disease. The hearing focused primarily on AD research including research priorities and planning, and the development of therapies to delay disease progression.

Bills that would establish additional funds for AD research have been introduced in previous Congresses. These include the Making Investments Now for Dementia (MIND) Act of 2011, which would authorize the Secretary of the Treasury to issue bonds to aid in the funding of AD research, and the Alzheimer's Breakthrough Act of 2009, which would authorize up to \$2 billion for AD research at NIH. Neither of these bills passed out of committee.

The most recent budgets released by the White House have included additional funds for AD research. The FY 2013 President's Budget included \$80 million in funding for AD research in FY 2013, utilizing funds in the Affordable Care Act's Prevention and Public Health Trust Fund; however, this transfer was not approved by Congress and was not included in the continuing resolutions that funded NIH in FY 2013. The FY 2014 President's budget and the FY2014 omnibus appropriations bill increased the National Institute on Aging (NIA) budget by \$80 million dollars with the expectation that a significant proportion of the funds would be directed to AD research; however, the language stipulated that the exact amount should be determined by scientific opportunity. Other legislation relevant to AD introduced in the 113th Congress includes:

H.R. 1508/S. 1091 *Alzheimer's Disease Research Semipostal Stamp*

Provisions of the Legislation/Impact on NIH: The bill would provide for an issuance of a semipostal stamp for AD research. This stamp shall be made available to the public for a period of 6 years, beginning no later than 12 months after the date of the enactment of this Act. All amounts becoming available from the sale of the Alzheimer's Disease Research Semipostal Stamp shall be transferred to the NIH, to contribute to funding for medical research relating to AD, through payments made at least twice a year.

Status: On April 11, 2013, Representative Edward Markey (D-MA) introduced H.R. 1508 which was referred to the House Oversight and Government Reform and House Energy and Commerce Committees. On June 4, 2013, Senator Barbara Mikulski (D-MD) introduced S. 1091 which was

referred to the Senate Committee on Homeland Security and Governmental Affairs. No further action has occurred on either of these bills.

H.R. 1619 *Making Investments Now for Dementia (MIND) Act of 2013*

Provisions of the Legislation/Impact on NIH: H.R. 1619 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.

Status: On April 18, 2013, Representative Michael Burgess (R-TX) introduced H.R. 1619 which was referred to the House Ways and Means and House Energy and Commerce Committees. No further action has occurred.

Cavernous Angioma

Background: Cavernous angioma is a collection of small blood vessels in the central nervous system that is enlarged and irregular in structure. Although some people with cavernous angioma will never have any related medical problems, others will have serious symptoms, including seizures, headaches, paralysis, hearing or vision changes, or cerebral hemorrhage.

The Cavernous Angioma CARE Center Act of 2012 was introduced into both the House and Senate in the 112th Congress, but failed to pass out of committee. The bill would have directed the Secretary to establish a Cavernous Angioma Clinical Care, Awareness, Research, and Education (CARE) Center at a university in the southwest United States to conduct basic, translational and clinical research on cavernous angioma (also called cerebral cavernous malformations). The center would have been involved in training medical students and residents, and would have maintained programs dedicated to patient advocacy, outreach and education.

H.R.2521 / S.1223 *Cavernous Angioma Research Resource Act of 2013*

Provisions of the Legislation/Impact on NIH: This bill would authorize the NIH Director, acting through the NINDS Director, to expand, intensify, and coordinate basic, translational, and clinical research on cavernous angioma. The bill 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 bill also authorizes a cavernous angioma “consortium”, including participation from NIH entities, and other agencies, organizations, and patients with an interest in cavernous angioma. The consortium may be one component of the coordinating center mentioned above.

The bill would also authorize the CDC to award grants for a surveillance program and epidemiological studies for cavernous angioma, and it 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.

Status: On June 26, 2013, Representative Ben Ray Lujan (D-NM) introduced H.R. 2521 which was referred to the House Energy and Commerce Subcommittee on Health, and Senator Tom Udall (D-NM) introduced S. 1223 which was referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred.

Hereditary Hemorrhagic Telangiectasia

Background: The Hereditary Hemorrhagic Telangiectasia Diagnosis and Treatment Act of 2011 was introduced in both the House and Senate in the 112th Congress, but the bills failed to pass out of Committee. The bill was reintroduced in the 113th Congress with identical provisions.

S. 908 *Hereditary Hemorrhagic Telangiectasia Diagnosis and Treatment Act of 2013*

Provisions of the Legislation/Impact on NIH: This bill would create an initiative to assist in coordinating activities to improve early detection screening, and treatment of Hereditary Hemorrhagic Telangiectasia (HHT), specifically focusing on research and physician and public awareness. HHS and NIH would be required to establish a 12-member HHT Coordinating Committee, which would have four members from NIH, four researchers, and four members from HHT Treatment Centers of Excellence. The Committee would 1) develop and coordinate implementation of a plan for HHT research at NHLBI, NINDS, NIDDK, NICHD, and ORDR, and 2) evaluate and make recommendations regarding the prioritization and award of NIH research grants for HHT. This bill has a number of provisions to be carried out by the Center for Disease Control, including surveillance, information dissemination and screening activities, as well as providing funding for HHT Treatment Centers of Excellence to improve patient access to information, treatment, and care. Additionally the bill would require the Centers for Medicare and Medicaid Services (CMS) to award grants for analysis of CMS data on HHT.

Status: On May 8, 2013, Senator Tim Johnson (D-SD) introduced S. 908 which was referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred.

Huntington's Disease

Background: The Huntington Disease Parity Act was introduced during the 110th, 111th, and 112th Congresses, but the bills failed to pass out of Committee. The bill was reintroduced in the 113th Congress with identical provisions.

H.R. 1015/S. 723 *Huntington's Disease Parity Act of 2013*

Provisions of the Legislation/Impact on NIH: The bill 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.

Status: On March 6, 2013, Representative Bill Pascrell (D-NJ) introduced H.R. 1015 which was referred to the House Committee on Ways and Means. On April 15, 2013, Senator Kristen Gillibrand (D-NY) introduced S. 723 which was referred to the Senate Committee on Finance. No further action has occurred.

Muscular Dystrophy

Background: On December 18, 2001, the President signed into law the Muscular Dystrophy Community Assistance, Research and Education (MD-CARE) Amendments of 2001 (P.L. 107-84). The NIH-related provisions in the MD-CARE Act 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 bill (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.

H.R. 594/S. 315: *Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education (MD-CARE) Amendments of 2013*

Provisions of the Legislation/Impact on NIH: These bills would reauthorize and extend the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments (MD-CARE) of 2008. The bills add cardiac and pulmonary function to the research areas covered by the Wellstone Centers, add members to the Muscular Dystrophy Coordinating Committee, and specify twice-yearly meetings of the Committee. The bills also include 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.

Status: On February 2, 2013, Representative Michael Burgess (R-TX) introduced H.R. 594 which was referred to the House Committee on Energy and Commerce. On February 13, 2013, Senator Amy Klobuchar (D-MN) introduced S. 315 which was referred to the Committee on Health, Education, Labor, and Pensions. No further action has occurred on either bill.

Rehabilitation/Stroke Rehabilitation

Background: 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.

S. 1027: *To Improve, Coordinate, and Enhance Rehabilitation Research at the NIH*

Provisions of the Legislation/Impact on NIH: S 1027 amends the Public Health Service Act to authorize the Secretary of Health and Human Services (HHS) to: (1) establish a working group made up of representatives from various Institutes and Centers within the NIH to update NIH rehabilitation research priorities, and (2) enter into interagency agreements to coordinate rehabilitation research conducted by agencies outside of HHS. The bill also requires the Secretary to report to Congress on the feasibility of implementing the changes proposed in the Blue Ribbon Panel Recommendations on Rehabilitation Research.

Status: S.1027 was introduced on May 22, 2013, by Sens. Mark Kirk (R-IL) and Tim Johnson (D-SD), and referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred.

S.1026: *Return to Work Act of 2013*

Provisions of the Legislation/Impact on NIH: The purpose of this bill 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 to return to work. There are no provisions directly related to NIH.

Status: S.1026 was introduced on May 22, 2013, by Sens. Mark Kirk (R-IL) and referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred.

Traumatic Brain Injury

Background: The first version of the Traumatic Brain Injury (TBI) Act became law in 1996. The TBI Act of 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 (Public Law 110-206). In May 2012, Representative Bill Pascrell (D-NJ) introduced the TBI Act of 2012 in the House; it did not pass out of committee. The bill introduced in the 113th Congress is similar to the one introduced in the 112th Congress.

H.R. 1098: *Traumatic Brain Injury Reauthorization Act of 2013*

Provisions of the Legislation/Impact on NIH: This bill would reauthorize the TBI Act through 2018. It also calls for the Secretary of HHS to coordinate with other Federal agencies as appropriate and to establish and implement a national plan for TBI activities described in the Act.

Status: On March 12, 2013, Representative Bill Pascrell (D-NJ) introduced H.R. 1098, which was referred to the House Committee on Energy and Commerce. On December 10, 2013, the House Energy and Commerce Committee, Subcommittee on Health, agreed to the bill with an amendment in the nature of a substitute. The following day, the full Committee favorably reported the bill by voice vote. Recognizing NIH's existing authority to conduct TBI research, the amended bill has no specific provisions for NIH and leaves the current interagency TBI research program of the Public Health Service act untouched. The bill includes a provision requiring the Secretary of HHS, acting through NIH and CDC, to submit a report that identifies which of the recommendations from a June 2013 report (detailing ways CDC, NIH, the Department of Veterans Affairs, and the Department of Defense can further collaborate on TBI) have been adopted and how the additional recommendations will be addressed.

Tourette Syndrome

Background: Tourette Syndrome (TS) is a neurological disorder characterized by repetitive, stereotyped involuntary movements and vocalizations called tics. TS can be a chronic condition with symptoms lasting a lifetime; however, in many individuals, the condition may improve in their late teens and early 20s. Similar legislation was introduced during the 112th Congress by Representative Rep. Albio Sires (D-NJ) and Senator Robert Menendez (D-NJ); however, neither bill passed out of committee.

H.R. 146/S.637 *Collaborative Academic Research Efforts for Tourette Syndrome Act of 2013.*

Provisions of the Legislation/Impact on NIH: This bill 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.

Status: H.R. 146 was introduced by Representative Rep. Albio Sires (D-NJ) on January 4, 2013 and referred to the House Committee on Energy and Commerce. S. 637 was introduced by Senator Robert Menendez (D-NJ) on March 19, 2013 and referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred.