



LEGISLATIVE UPDATE:

Overview of legislation of interest to NINDS from the 112th Congress and outlook for the 113th Congress
January 2013

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

Table of Contents

Appropriations Update

FY 2013

The President's FY 2013 budget was released on February 13, 2012. The budget would allocate \$30.6 billion to NIH, which is the same funding level as FY 2012. NINDS would receive \$1.625 billion under the FY 2013 President's budget, which is a decrease of 0.1% from the FY 2012 funding level.

On June 14, 2012, the Senate Committee on Appropriations marked up and reported out S. 3295, the FY2013 Senate Labor-HHS-Education Appropriations bill. The bill would provide \$30.7 billion for NIH and \$1.630 billion for NINDS, which is similar to the FY 2012 funding level. The full Senate has not yet voted on this bill or any other appropriations bill. Although the House Labor-HHS-Education Appropriations Subcommittee approved a spending bill July 19, 2012, it has not been taken up by the full House Appropriations Committee. Under the House draft spending bill, NIH would receive \$30.6 billion, and the NINDS budget would be \$1.624 billion. The bill also contained language that would reduce the salary cap for grantees and prohibit economic and patient-centered outcomes research. Additionally, 90% of the aggregate amount of funds appropriated to the NIH would need to be allocated to extramural activities, 10 percent for intramural activities, and at least 55 percent toward basic science activities.

In the absence of any Senate action on FY 2013 Appropriations bills, President Obama signed a Continuing Resolution (PL 112-175) on September 28, 2012, to keep the government running through March 27, 2013.

As a result of the Budget Control Act of 2011 (P.L. 112-25), which became law on August 2, 2011, and the inability of a bipartisan "supercommittee" to agree on recommendations for achieving deficit reduction levels specified in the Act, automatic cuts to both defense and non-defense discretionary spending (a process known as "sequestration") were scheduled to begin in January 2013. Just prior to these cuts taking effect, Congress passed, and President Obama signed, the American Taxpayer Relief Act, which - in addition to other provisions- postpones the sequestration until March 1, 2013.

In December of 2012, the Treasury Department began suspending or delaying certain payments to extend the government's borrowing authority and delay reaching the debt limit. Unless Congress takes action, the federal government is expected to reach its \$16.4 trillion debt limit in mid-February or early March of 2013.

FY 2014

Given the uncertainties surrounding the FY 2013 budget and possible spending cuts, the release of the President's FY 2014 budget will most likely be delayed and there has been no release date officially announced yet.

Legislative highlights from the 112th Congress of interest to NINDS

Public Laws

P.L. 112-32: The Combating Autism Reauthorization Act of 2011

The Combating Autism Act of 2006 (P.L. 109-416) established an Interagency Autism Coordinating Committee (IACC) that includes representatives from HHS agencies, the Department of Education, and public members. The IACC was mandated to develop and annually update a strategic plan for the conduct of, and support for, autism spectrum disorder research. The provision of the Combating Autism Act of 2006 that establishes the IACC was scheduled to sunset on September 30, 2011. On September 30, 2011, President Obama signed P.L. 112-32, the Combating Autism Reauthorization Act of 2011. The bill reauthorizes autism programs for another three years through FY 2014. These programs include surveillance and research activities, education programs, and the Interagency Autism Coordinating Committee.

P.L. 112-81: National Defense Authorization Act for Fiscal Year 2012 [includes SBIR/STTR reauthorization]

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grant programs at the NIH and similar programs at other Federal agencies provide a funding source for U.S. small businesses. On December 31, 2011, President Obama signed into law the National Defense Authorization Act for Fiscal Year 2012, which includes provisions reauthorizing the SBIR/STTR programs. The SBIR/STTR provisions reauthorize the programs for 6 years and increase SBIR/STTR awards to \$150,000 for Phase I and \$1 million for Phase II awards. Provisions of particular significance to NIH increase the SBIR set aside to 3.2 percent over six years and increase the STTR set aside to 0.45 percent over six years; allow small business concerns majority-owned and controlled by venture capital firms to be eligible for up to 25 percent of the SBIR funds; allow agencies to apply for waivers to exceed the hard cap on awards under the guidelines for Phase I and Phase II awards; and grant NIH a one-year exception to the rule shortening the time span for final decisions to not more than 90 days after the date a solicitation closes.

Other Legislation

A number of other bills specific to various diseases or other topics of interest to NINDS were introduced in the 112th Congress, but failed to pass both the House and Senate. These include:

H.R. 1897: Alzheimer's Breakthrough Act of 2011- [no action beyond introduction and referral to appropriate committees]

Unlike the National Alzheimer's Project Act, which involves HHS and other federal agencies, this legislation is focused exclusively on NIH funded research on AD. This bill would direct NIH to establish an annually updated strategic plan for AD research. Additionally, NIH would report to Congress budget estimates of the amounts required to carry out the strategic plan, and funds in the existing NIH budget available to be used for AD activities. The bill also encourages the establishment of public-private partnerships.

H.R. 610: *Making Investments Now for Dementia (MIND) Act of 2011* – [no action beyond introduction and referral to appropriate committees]

This bill would authorize the Secretary of the Treasury to issue bonds to aid in the funding of Alzheimer’s disease research. The bill would require the Secretary of the Treasury in consultation with the Secretary of Health and Human Services and the NIH Director to submit an annual report describing the implementation of the program, including a description of the use of funds and status of the program.

H.R. 2006/S.1128: *National Autism Spectrum Disorders Initiative Act of 2011* – [no action beyond introduction and referral to appropriate committees]

The bill would establish a National Autism Spectrum Disorders Initiative within HHS for research on prevention, treatment, services, and cures for people with Autism Spectrum Disorders (ASD). The Secretary (or designee) would oversee ASD research conducted at NIH, approve the strategic plan for ASD, allocate funds within NIH for ASD research, plan and evaluate NIH research on ASD, communicate information concerning ASD to relevant government agencies, and consult with the IACC, advisory councils, and the heads of the agencies of the NIH. These provisions would sunset 7 years after the date of enactment.

H.R. 2695/ S. 1840: *Trisomy 21 Research Centers of Excellence Act of 2011* – [no action beyond introduction and referral to appropriate committees]

This legislation would require the NIH Director acting through the NICHD, to expand and intensify research activities of the NIH related to Down syndrome, including a research plan to be updated every five years. The bill would also require NIH to establish at least six centers of excellence that would conduct basic, translational and clinical research, building upon the recommendations set forth in the NIH Research Plan on Down Syndrome. The bill would also authorize the NIH Director to establish a Down Syndrome Consortium to facilitate the exchange of information, and require the Secretary of HHS to prepare and submit an annual report to Congress.

H.R. 2696 / S. 1841: *Trisomy 21 Research Resource Act of 2011*- [no action beyond introduction and referral to appropriate committees]

Research provisions would direct NICHD to expand and intensify research and related activities concerning Down syndrome, in coordination with an NIH working group comprising representatives of the relevant institutes, centers, and offices. A Down syndrome research plan would be updated every five years. In support of basic, translational and clinical research, the NIH Director would be authorized to establish several research resources, including a contact registry, a research database, and a biobank for Down syndrome. The bill would also authorize a Down syndrome consortium to facilitate the exchange of information and to make the research effort on Down syndrome more efficient and effective. CDC activities would also be authorized, and an annual report to Congress would be required.

H.R.- 1513/S. 810: *Great Ape Protection and Cost Savings Act of 2011*- [H.R. 1513: no action beyond introduction and referral; S.810: Reported out of Senate Committee on Environment and Public Works]

Within 3 years of enactment, the bill would end all invasive research on great apes (chimpanzees, gorillas, bonobos, orangutans, and gibbons). All great apes currently housed in laboratories would be moved to sanctuaries. During the Committee mark-up, the bill was amended to provide a contingency exemption for research if an emerging or reemerging disease or condition should arise in the future. The amendment would also create a Task Force to review funding proposals once the Secretary determines that there is such a research need that might require the chimp model for research.

H.R. 2595/S. 425: *National Neurological Diseases Surveillance System Act of 2011* – [no action beyond introduction and referral to appropriate committees]

This bill would authorize 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 an integrated surveillance system, the “National Neurological Diseases Surveillance System.” As part of this effort, the bill directs the Secretary to provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the US, and to collect other relevant information to the extent practicable, including: demographics associated with neurological disease; risk factors, including genetic and environmental risk factors; and diagnosis and disease progression markers. The bill directs the CDC to coordinate with other agencies, including NIH.

H.R. 2600: *National Pediatric Acquired Brain Injury Plan Act of 2011* – [no action beyond introduction and referral to appropriate committees]

This bill would authorize the Secretary of HHS to make payments to each State Lead Center of Excellence (as defined and designated under the National Pediatric Acquired brain Injury Plan) for the implementation of the plan. The Secretary would also submit an annual report containing an evaluation of federally funded pediatric acquired brain injury research and clinical care. This bill would sunset in 2018.

H.R. 6163/S. 3461: *National Pediatric Research Network Act of 2012* – [H.R. 6163: passed the House; S.3461: no action beyond introduction and referral]

This bill would authorize 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. The Director would be required to ensure that an appropriate number of awards “focus primarily on pediatric rare diseases or conditions (including any such diseases or conditions that are genetic disorders (such as spinal muscular atrophy and Duchenne muscular dystrophy) or are related to birth defects (such as Down syndrome and fragile X))” and that these consortia conduct/coordinate multisite clinical trials and disseminate any findings from the trials. Additionally the bill would 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.

H.R. 4238: *Traumatic Brain Injury Act of 2012* – [no action beyond introduction and referral to appropriate committees]

This bill would reauthorize the TBI Act through 2017. In addition to research activities that are currently authorized (including conducting research on acute care, rehabilitation, diagnosing, and treating TBI), the TBI Act of 2012 would also authorize NIH to conduct studies specific to the needs of children and youth with TBI.

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 in consultation with Federal, State, and local agencies and professional and patient stakeholders.

H.R. 3760/S. 2321 *Collaborative Academic Research Efforts for Tourette Syndrome Act of 2011* - [no action beyond introduction and referral to appropriate committees]

These bills 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.

Other Legislative Activities

Federal Neuroscience Initiative through the Office of Science and Technology Policy (OSTP)

The conference report of the Consolidated and Further Continuing Appropriations Act of 2012 (P.L. 112-55; providing funds for Agriculture; Commerce, Justice, Science (includes the National Science Foundation); and Transportation-HUD) included language, introduced by Rep. Chaka Fattah (D-PA), to establish an interagency working group to coordinate Federal investments in neuroscience research. Similar language was part of the report accompanying the FY 2013 Commerce, Justice, Science, and Related Agencies Appropriations Bill which was reported from the full House Appropriations Committee on April 26, 2012.

In addition, on April 16, 2012, Rep. Fattah introduced *H. Res. 613: Supporting the Office of Science and Technology Policy interagency working group to coordinate Federal investments in neuroscience research*. The resolution 1) applauds the establishment of the Office of Science and Technology Policy interagency working group to coordinate Federal investments in neuroscience research; 2) commends President Obama for the expeditious appointment of Dr. Philip Rubin to lead the group; 3) encourages the efficient and effective use of Federal research dollars; and 4) acknowledges the need for increased investment in the neurosciences. The resolution was referred to the House Energy and Commerce Committee, Subcommittee on Health.

Dr. Philip Rubin of Yale University has been appointed as the coordinator of this initiative. Dr. Robert Finkelstein, NINDS Director of Extramural Research, co-chairs the Interagency Working Group on Neuroscience (IWGN) which includes representatives from approximately 20 federal agencies that share an interest in neuroscience research.