



National Institute of  
Neurological Disorders  
and Stroke



**LEGISLATIVE UPDATE:**

*Summary of Legislation from the 114<sup>th</sup> Congress  
Relevant Bills and Committee Leadership in the 115<sup>th</sup> Congress  
February 2017*

**NINDS OFFICE OF SCIENCE POLICY & PLANNING**

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## Appropriations Update

	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 House Appropriations Committee	FY 2017 Senate Appropriations Committee	FY 2017 Continuing Resolution #2
NIH	\$32.3 billion	\$33.1 billion	\$33.3 billion	\$34.1 billion	\$32.2 billion + \$352 million for 21 <sup>st</sup> Century Cures NIH Innovation Account (incl. \$10 million for BRAIN initiative)
NINDS	\$1.695 billion	\$1.695 billion	\$1.751 billion	\$1.803 billion	\$1.693 billion

### FY 2017

President's budget. The FY 2017 President's budget was released on February 9, 2016. The President requested \$33.1 billion for NIH for FY 2017, \$825 million (2.5%) above the FY 2016 level. The request includes \$1.825 billion from mandatory funds and a \$1.067 billion reduction in discretionary funds relative to FY 2016.

House and Senate action. On June 9, 2016, the Senate Appropriations Committee [approved](#) its FY 2017 Appropriations bill ([S. 3040](#)). The bill would provide a total \$34.1 billion for NIH (\$2 billion increase over FY 2016) and \$1.80 billion for NINDS. On July 14, 2016, the House Appropriations Committee [approved](#) its FY 2017 Appropriations bill ([H.R. 5926](#)). The bill would provide a total \$33.3 billion for NIH (\$1.25 billion increase over FY 2016) and \$1.75 billion for NINDS. Neither the Senate nor House appropriations bill was brought to the floor.

Continuing Resolution 1. On September 28, 2016, the [House](#) and [Senate](#) passed a Continuing Resolution (CR), titled the "Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act" ([H.R. 5325](#)). In addition to providing funding for all Federal agencies through December 9, 2016 at FY 2016 levels, the bill included \$1.1 billion for Zika and an across-the-board cut of 0.5 percent. The CR was signed by the President on September 29, 2016 ([P.L. 114-223](#)).

Continuing Resolution 2. On December 8-9, 2016, the [House](#) and [Senate](#) passed a CR, titled the "Further Continuing and Security Assistance Appropriations Act, 2017" ([H.R. 2028](#)). In addition to providing funding for all Federal agencies through April 28, 2017 at FY 2016 levels, the bill appropriated the first year of funding for the NIH Innovation Projects. The NIH Innovation Account was established by the 21<sup>st</sup> Century Cures Act ([P.L. 114-255](#), see page 4), which authorized \$4.8 billion for NIH over 10 years, including \$1.511 billion for the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, \$1.455 billion for the Precision Medicine Initiative (PMI), \$1.8 billion for the Beau Biden Cancer Moonshot, and \$30 million for regenerative medicine using adult stem cells. The CR was signed by the President on December 10, 2016 ([P.L. 114-254](#)).

## Legislative Highlights from the 114th Congress

### Public Laws

#### *P.L. 114-198: Comprehensive Addiction and Recovery Act*

This law (formerly [S. 524](#)) will establish programs in the Department of Health and Human Services (HHS), Department of Justice (DOJ), and Department of Veterans Affairs to improve the treatment and recovery of individuals with substance abuse disorders and strengthen prevention and education efforts.

Specifically relevant to NIH, the law has a provision related to enhancing pain research at NIH. It states that the NIH Director may intensify and coordinate fundamental, translational, and clinical research of the NIH with respect to:

1. The understanding of pain;
2. The discovery and development of therapies for chronic pain; and
3. The development of alternatives to opioids for effective pain treatments.

The law states that the prioritization and direction of the federally-funded portfolio of pain research studies shall consider recommendations made by the Interagency Pain Research Coordinating Committee, as well as the Pain Management Best Practices Inter-Agency Task Force, the National Pain Strategy, the Federal Pain Research Strategy, and the NIH-Wide Strategic Plan for FY 2016-2020.

#### *P.L. 114-255: 21<sup>st</sup> Century Cures Act*

This law (formerly [H.R. 34](#)) includes provisions affecting NIH and FDA, which are intended to help accelerate the discovery, development, and delivery of promising new treatments, as well as mental health provisions affecting SAMHSA.

**Background:** Efforts leading to the 21<sup>st</sup> Century Cures Act began in April 2014, when House Energy and Commerce Committee Chairman Fred Upton (R-MI) and Congresswoman Diana DeGette (D-CO) began the bipartisan *21st Century Cures Initiative* (<http://energycommerce.house.gov/cures>). After 12 hearings and roundtable discussions and substantial revisions of the first discussion draft, [H.R. 6](#) passed the House on July 10, 2015.

The Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) led the Senate effort. The Committee released a [white paper](#), held [four hearings](#) and three markup session, and reported 19 bills aimed at enhancing NIH and FDA, before progress stalled due to disagreements over source and amount of funding for the legislation.

In the fall of 2016, a compromise between House and Senate Cures provisions was inserted into [H.R. 34](#), originally the Tsunami Warning, Education, and Research Act. The bill was approved by the House (by a vote of [392-26](#)) and the Senate (by a vote of [94-5](#)), then was signed by the President on December 13, 2016. The law authorizes the NIH Innovation Fund (see below), for which FY 2017 funds were appropriated by the Further Continuing and Security Assistance Appropriations Act, 2017 ([P.L. 114-254](#)).

### **Provisions of the Legislation/Impact on NIH:**

- **NIH Innovation Account.** The law establishes the Beau Biden Cancer Moonshot and NIH Innovation Account in the Treasury. It authorizes \$4.8 billion over 10 years to be transferred into this account. Funds may be used to carry out the BRAIN Initiative®, PMI, cancer research, and “regenerative medicine.”
  - Funding comes from the Affordable Care Act’s prevention fund, Medicare and Medicaid changes, and a drawdown of the Strategic Petroleum Reserve.
  - ***Funds would need to be appropriated each year*** in order to be transferred to NIH, not to exceed these amounts: \$1.511 billion over 10 years for the BRAIN Initiative®, \$1.455 billion over 10 years for the PMI, \$1.8 billion over 7 years for cancer research, and \$30 million over 4 years for “regenerative medicine.”
- **PMI authorization.** Authorizes the HHS Secretary to carry out the Precision Medicine Initiative.
- **Opioid abuse crisis.** Provides \$1 billion over 2 years (subject to annual appropriations) for grants to the states to supplement opioid abuse prevention and treatment activities. (No specific NIH provisions)
- **National Neurological Conditions Surveillance System.** Requires the HHS Secretary, through CDC, to improve the collection of information on the incidence and prevalence of neurological diseases and conditions, which may be through the establishment of a registry. Relevant information may include natural history of the disease; prevention of the disease; detection, management, and treatment approaches for the disease; and the development of outcomes measures.
- **Next Generation of Researchers Initiative.** Creates this initiative in the NIH Office of the Director to coordinate policies and programs to improve opportunities for new researchers. Requires NIH to report to Congress on any actions taken in response to recommendations from the National Academy of Sciences as part of the study on policies affecting the next generation of researchers.
- **Loan repayment program.** Increases the maximum yearly loan repayment amount from \$35,000 to \$50,000.
- **EUREKA prizes.** Authorizes the NIH Director to support innovation prize competitions to advance biomedical science and improve health outcomes for diseases that are serious and represent a significant burden in the United States.
- **High-risk, high-reward research.** Encourages such research and authorizes NIH ICs to use transactions other than a contract, grant, or cooperative agreement for the Precision Medicine Initiative, and for up to 50% of the funds available in the NIH Common Fund.
- **NIH coordination.** Requires NIH to update the Rehabilitation Research Plan at least every 5 years; assemble data on study populations of clinical research, specifying

inclusion of women, members of minority groups, and relevant age categories; improve research related to minority populations and update guidelines for the inclusion of women in clinical research; hold a workshop to get input on appropriate age groups in research and update policies; and establishes a task force to address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women.

- NIH administration. Requires NIH to develop a six-year strategic plan, within 2 years of enactment and every six years thereafter; sets IC Directors to 5-year terms with no limits on the number of reappointments; and requires IC Directors to review and make the final decision on all “R” awards.
- Conduct of biomedical research. Several provisions related to reducing administrative burden for researchers, ensuring privacy protection for human research, and harmonizing privacy regulations. Allows NIH to require awardees to share the data that is generated from NIH-funded research. Requires the HHS Secretary, acting through the NIH Director, to convene a working group to develop recommendations for a formal policy to enhance the rigor and reproducibility of NIH-funded scientific research.
- ClinicalTrials.gov. Several provisions related to reporting on trial registration compliance, receiving recommendations to improve the site, and consideration by NIH Director of compliance before awarding future grants.
- Pediatric research. Requires NIH to continue to support the National Pediatric Research Network and Global Pediatric Clinical Study Network.

**Non-NIH provisions:**

- Establishes a FDA Innovation Account, similar to the NIH Innovation Account, authorized for \$500 million over 9 years.
- Several provisions aimed to streamline FDA approval processes for drugs and medical devices and incorporate patient experience data, enhance interoperability among electronic health records, address antimicrobial resistance, and reform of mental health services.

## **Other Legislation**

A number of other bills specific to various diseases or other topics of interest to NINDS were introduced in the 114<sup>th</sup> Congress, but failed to pass both the House and Senate. Some of these are briefly summarized below.

### ***Legislation Directly Relevant to NINDS***

- **Alzheimer's Disease (AD)**. On August 1, 2016, NIH released an updated bypass budget proposal for FY 2018: [Stopping Alzheimer's Disease and Related Dementias: Advancing Our Nation's Research Agenda](#). Introduced bills would provide for issuance of a semipostal stamp for AD research ([H.R. 3092](#)) or authorize the NIH Director to work with other federal agencies to establish prize challenges informed by the research milestones contained in the National Plan to Address Alzheimer's Disease ([S. 2067/H.R. 5073](#)).
- **Autism**. The bill ([H.R. 1636](#)) would direct the HHS Secretary, acting through the NIH Director, to conduct or support a study comparing total health outcomes of vaccinated to unvaccinated people. Outcomes would include incidence and risk of autism, chronic and other neurological conditions.
- **Cerebral Cavernous Malformations (CCM)**. The bills ([S. 1391 / H.R. 2480](#)) would direct NINDS, NCATS, and NHLBI to strengthen and coordinate basic, translational, and clinical research on CCM.
- **Concussion**. One bill ([H.R. 1271](#)) would direct the CDC to establish a national surveillance system that would provide for systemic research, treatment, prevention, awareness, and dissemination of information with respect to sports-related and other concussions. Another bill ([H.R. 2932](#)) would require HHS to establish a grants program to award competitive grants to eligible national nonprofit organizations to improve the health and positive youth development impacts of youth sports participation. It would also authorize the CDC and NIH to undertake, support, enhance, and expand research and prevention efforts to advance youth sports safety.
- **Hereditary Hemorrhagic Telangiectasia (HHT)**. The bill ([H.R. 1849](#)) would require the CDC Director to conduct population screening, develop guidelines for diagnosis and intervention, develop a standardized survey and screening tool on family history, establish a resource center for disseminating information, support public awareness programs, and designate HHT Treatment Centers of Excellence. It would also require the HHS Secretary, in consultation with the NIH and CDC Directors, to facilitate coordinating activities related to HHT.
- **Huntington's Disease**. The bill ([H.R. 842](#)) 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

NINDS, NIH, and other relevant organizations and to waive the 24-month waiting period for Medicare eligibility for individuals disabled by Huntington's disease.

- **Neurological Diseases Surveillance.** Introduced bills were introduced that would authorize the HHS Secretary to improve the collection of epidemiological and surveillance data on neurological diseases ([H.R. 292](#) / [S. 849](#)) or hydrocephalus in particular ([H.R. 2313](#)). Similar provisions were included in the 21<sup>st</sup> Century Cures Act, which became law ([P.L. 114-255](#), see page 4).
- **Tourette Syndrome.** The bills ([H.R. 619](#) / [S. 276](#)) would direct the HHS Secretary, acting through the NIH Director, to expand, intensify and coordinate activities of the NIH related to Tourette syndrome.

### *Legislation of Broad Interest to NIH*

- **American COMPETES Reauthorization.** The bill ([H.R. 1806](#)) would reauthorize funding for the NSF, OSTP, NIST, and the DOE's science programs for FY 2016 and 2017. A number of provisions would directly affect NIH or NIH grantees or may broadly affect federal science agencies.
- **Clinical Data Registries.** One bill ([H.R. 617](#)) would amend the PHS Act to clarify that the clinical trial registry data bank requirements apply regardless of the trial outcomes. Another bill ([H.R. 965](#)) would require the issuance of guidance on the application of the Federal policy for the protection of human subjects with respect to clinical data registries.
- **Comparative Effectiveness Research.** Among other provisions related to repeal of the Affordable Care Act (ACA), the bill ([S. 1718](#)) would prohibit data obtained from the conduct of Comparative Effectiveness Research (CER) to deny or delay coverage of an item or service under a Federal health care program. Of interest to NIH, the HHS Secretary would be required to ensure that CER conducted or supported by the Federal Government accounts for factors contributing to differences in the treatment response and treatment preferences of patients, including patient-reported outcomes, genomics and personalized medicine, the unique needs of health disparity populations, and indirect patient benefit.
- **Federal Advisory Committees.** The bill ([H.R. 2347](#)) would require that all appointments to advisory committees be made without regard to political affiliation or political activity; extend all of the FACA requirements (except charters) to working groups; allow the public to make recommendations for committee members; require that advisory committee members be designated as a "special government employee" or "a representative"; and expand transparency requirements.
- **Fetal Tissue Research.** Introduced bills would require that only human fetal tissue obtained from stillbirth could be used for transplantation research ([H.R. 3171](#) and [H.R. 3215](#)), prohibit the exchange of "valuable consideration" (e.g. payment) for fetal tissue



([H.R. 3429](#)), prohibit the use of tissue from a spontaneous or induced abortion in research conducted or supported by the NIH ([HR 3729](#)), or prohibit the provision of Federal funds to an entity that receives compensation for facilitating the donation of fetal tissue derived from an abortion ([S. 1917](#)).

- **Funding for NIH.** Introduced bills ([H.R. 531 / S. 318](#); [H.R. 2104 / S. 289](#); [H.R. 744 / S. 320](#); [H.R. 1360](#); [H.R. 2653](#)) would authorize funding increases up to a certain amount to NIH. Two bills ([S. 2624](#) and [H.R. 777](#)) would appropriate funds to NIH.
- **Reducing Administrative Burden.** The bill ([H.R. 1119](#)) would require the OSTP Director to establish a working group responsible for reviewing Federal regulations affecting research and research universities and to make recommendations to minimize regulatory burden on research institutions.
- **Rehabilitation Research.** The identical bills ([S. 800/H.R. 1469/H.R. 1631](#)) would direct the National Center for Medical Rehabilitation Research (NCMRR) Director to develop a comprehensive research plan in consultation with the coordinating committee and update it not less than every five years.
- **Science Prizes.** One bill ([H.R. 1162](#)) would clarify that agencies may partner with both nonprofit and for-profit entities in the private sector to support competitions. Another bill ([S. 2113](#)) would authorize federal agencies to use crowdsourcing and citizen science approaches to conduct activities designed to advance the agency's mission.
- **Sex Differences Research.** The bill ([H.R. 2101](#)) would direct the FDA to ensure that the design and size of clinical trials for products granted expedited approval under any program within Sec. 506 of the Federal Food, Drug, and Cosmetic Act are sufficient to determine the safety and effectiveness of such products for both men and women.
- **Small Business Innovation.** 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. These programs require that any federal agency that provides more than \$100 million in research funding set aside a certain percentage of the agency budget for SBIR/STTR. Two bills were introduced ([H.R. 4783](#) and [S. 2812](#)), which would reauthorize the SBIR/STTR programs. On December 8, the Senate agreed to the conference report on [S. 2943](#), the National Defense Authorization Act. Of interest to NIH, it includes a clean extension of the SBIR/STTR programs through FY 2022.

## Legislation of Interest to NINDS Introduced in the 115<sup>th</sup> Congress

### Tourette Syndrome

**Background:** The Collaborative Academic Research Efforts for Tourette Syndrome Act was introduced during the 112<sup>th</sup>, 113<sup>th</sup>, and 114<sup>th</sup> Congresses by Representative Rep. Albio Sires (D-NJ) and Senator Robert Menendez (D-NJ); however, neither bill passed out of Committee.

**H.R. 427:** *Collaborative Academic Research Efforts for Tourette Syndrome Act of 2017*

**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 bill would require the Secretary to develop a system to collect epidemiologic data on Tourette syndrome, fund 4 to 6 Collaborative Research Centers for Tourette Syndrome, and conduct research on symptomology and treatment options for Tourette patients.

**Status:** H.R.427 was introduced by Rep. Albio Sires (D-NJ) on January 10, 2017 and referred to the House Committee on Energy and Commerce. No further action has occurred.

## **Committee Leadership of Interest to NIH in the 115<sup>th</sup> Congress**

(as of January 25, 2017)

### **Authorizers**

#### **House Committee on Energy and Commerce**

- Chairman Greg Walden (R-OR)
- Ranking Member Frank Pallone, Jr (D-NJ)

#### **Subcommittee on Health**

- Chairman Michael Burgess (R-TX)
- Ranking Member Gene Green (D-TX)

#### **Senate Committee on Health, Education, Labor & Pensions (HELP)**

- Chairman Lamar Alexander (R-TN)
- Ranking Member Patty Murray (D-WA)

### **Appropriators**

#### **House Appropriations Committee**

- Chairman Rodney Frelinghuysen (R-NJ)
- Ranking Member Nita Lowey (D-NY)

#### **Subcommittee on Labor, Health and Human Services, Education (L-HHS)**

- Chairman Tom Cole (R-OK)
- Ranking Member Rosa DeLauro (D-CT)

#### **Senate Appropriations Committee**

- Chairman Thad Cochran (R-MS)
- Ranking Member Patrick Leahy (D-VT)

#### **Subcommittee on Labor, Health and Human Services, Education (L-HHS)**

- Chairman Roy Blunt (R-MO)
- Ranking Member Patty Murray (D-WA)