



National Institute of
Neurological Disorders
and Stroke



LEGISLATIVE UPDATE:
Legislative Highlights from the 115th Congress
Relevant Bills and Committee Leadership in the 116th Congress
February 2019

NINDS OFFICE OF SCIENCE POLICY & PLANNING

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Appropriations Update

	FY 2018 Omnibus	FY 2019 President's Budget	FY 2019 Appropriations
NIH	\$37.1 billion, including \$496 million from 21 st Century Cures NIH Innovation Account (incl. \$86 million for the BRAIN Initiative) and \$500 million for targeted research related to pain and opioids	\$34.8 billion, including \$711 million from 21 st Century Cures NIH Innovation Account (incl. \$115 million for the BRAIN Initiative) and additional \$750 million to fight opioid crisis and address serious mental illness	\$39.1 billion, including \$711 million from 21 st Century Cures NIH Innovation Account (incl. \$115 million for the BRAIN Initiative), and \$500 million for research related to pain and opioids
NINDS	\$2.188 billion, including \$43 million for the BRAIN Initiative and \$250 million for research related to pain and opioids	\$1.839 billion, including \$57.5 million for the BRAIN Initiative	\$2.274 billion, including \$57.5 million for the BRAIN Initiative and \$250 million for research related to pain and opioids

FY 2018

FY 2018 Omnibus. The FY 2018 Consolidated Appropriations Act ([P.L. 115-141](#)) that funds the government through the end of FY 2018 was signed by the President on March 23, 2018, after House and Senate passed it on March 22, 2018, and on March 23, 2018, respectively. The Omnibus spending bill provides \$37.1 billion for NIH (\$3 billion increase, or 8.8%, above FY 2017), which includes \$496 million from 21st Century Cures NIH Innovation Account, and \$2.188 billion for NINDS.

The bill includes targeted funds for several initiatives and research areas, including \$140 million for the BRAIN Initiative, \$414 million for Alzheimer's disease and related dementias research, \$50 million for antibiotic resistance research and \$40 million for development of a universal flu vaccine. In addition, the bill provides \$500 million that would be available for two years for targeted research related to opioid addiction, development of opioid alternatives, pain management, and addiction treatment.

FY 2019

FY 2019 President's Budget. President's Budget for FY 2019 was released on February 12, 2018. [The Budget](#) proposes \$34.8 billion in FY 2019 funding for NIH (\$699 million above FY 2018 Continuing Resolution (CR)) and provides an additional \$750 million as part of the HHS-wide \$10 billion investment to fight the opioid crisis and address serious mental illness. The proposal also includes a dedicated fund of \$100 million to supplement the Next Generation Researchers Initiative efforts, \$50 million for prize competitions, and \$30 million to support the final stages of Big Data to Knowledge initiative.

In addition, the Budget proposed to consolidate targeted HHS research programs within NIH to establish three new NIH Institutes: National Institute for Research on Safety and Quality

(NIRSQ), National Institute for Occupational Safety and Health (NIOSH), and National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR).

FY 2019 Appropriations. On September 28, 2018, [H.R. 6157](#) Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 became public law (P.L. No:115-245). This two-bill “minibus” included funding for the Defense and Labor-HHS-Education agencies, including NIH, for the entire fiscal year of 2019, as well as a continuing resolution to fund the rest of the federal government through December 7, 2018.

Under this Appropriations Act, NIH received an increase of \$2 billion, increasing the NIH funding to a total of \$39.1 billion. This is the fourth year in a row that NIH has received a substantial boost in funding after years of flat budgets. The Law also includes \$5 million to CDC to establish a neurological diseases surveillance program.

The \$39.1 billion for NIH includes an increase of \$425 million for Alzheimer’s disease and related dementias (AD/ADRD) (bringing the total to \$2.34 billion), \$115 million for the BRAIN Initiative (a total of \$429 million), and \$500 million for research related to opioid addiction, development of opioid alternatives, pain management, and addiction treatment (\$250 million each to NINDS and the National Institute on Drug Abuse).

2018-19 Partial Federal Government Shutdown and the President’s Budget for FY 2020.

Agencies that were not funded under P.L. 115-245 were affected by the partial government shutdown from December 22, 2018 to January 25, 2019 and are currently being funded through a Continuing Resolution (CR) through February 15, 2019. Due to the partial government shutdown, the President’s budget proposal for FY 2020 will not be released by the first Monday in February, and the timeline for its release has not been made public.

Legislative Highlights from the 115th Congress

Public Laws

P.L. 115-271: SUPPORT for Patients and Communities Act

This law (formerly [H.R. 6 the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act](#)) will help in overall efforts to combat the opioid crisis by advancing treatment and recovery initiatives, improving prevention, protecting our communities, and bolstering our efforts to fight deadly illicit synthetic drugs like fentanyl.

The law has several provisions that requires the HHS Secretary to coordinate efforts at agencies such as CDC, NIH, FDA, SAMHSA, and CMS. Specifically relevant to NIH, the law has provisions that:

1. **Task the HHS Secretary, in collaboration with the Pain Management Best Practices Inter-Agency Task Force, with developing an action plan to provide recommendations on changes to the Medicare and Medicaid programs** to enhance the treatment and prevention of opioid addiction and the coverage and reimbursement of MAT for opioid addiction. CMS must convene a stakeholder meeting to solicit public comment on the action plan. Meeting participants must include FDA, NIH, biopharmaceutical industry members, and medical researchers, among others.
2. **Require the HHS Secretary to establish a public information dashboard** that, among other things, provides recommendations for health care providers on alternatives to controlled substances for pain management, including approaches studied by the NIH Pain Consortium, NCCIH, and other ICs at NIH as appropriate
3. **Require the HHS Secretary to establish an Interagency Substance Use Disorder Coordinating Committee to coordinate all efforts within HHS.** Membership includes the NIH Director and the Directors of NIH Institutes the HHS Secretary determines appropriate.
4. Require the HHS Secretary, in coordination with CDC, NIH, and SAMHSA, to develop and **submit a report to Congress on opioids prescribing practices regarding pregnant women**
5. Require the HHS Secretary to **carry out a demonstration program to award grants to eligible hospitals and emergency departments to develop, implement, enhance, or study alternatives to opioids for pain management in such settings.** The Secretary must implement a process for recipients of grants to share evidence-based and best practices and promote consultation with persons having robust knowledge, including emergency departments and physicians that have successfully implemented programs that use alternatives to opioids to pain management such as approaches studied through NCCIH or other NIH ICs, as appropriate
6. **Establish an Interagency Task Force on Trauma-Informed Care** to identify, evaluate, and make recommendations (1) regarding best practices for children and their families who have or at risk of experiencing trauma and (2) ways in which Federal agencies can

better coordinate to improve the response to those affected by substance use disorders and other forms of trauma. NIH is one of a number of Federal agencies on the Task Force.

7. **Provide Other Transactions Authority (OTA) to the NIH Director for “high-impact cutting edge research** that fosters scientific creativity and increases fundamental biological understanding leading to prevention, diagnosis, and treatment of diseases and disorders, or research urgently required to respond to a public health threat.”
8. **Amend the duties of the Interagency Pain Research Coordinating Committee** by specifying what must be included in the research summary and in the identification of the research gaps. The provision also includes a new reporting requirement that the HHS Secretary ensure recommendations and actions taken by the NIH Director regarding topics discussed at IPRCC meetings are included in appropriate reports to Congress.
9. **Make various amendments to the Office of National Drug Control Policy.** Among them is a provision titled Harm Reduction Programs which requires the Director of ONDCP, when developing the national drug control policy, including policies relating to syringe exchange programs, to be based on scientific evidence. The development of any such policy relating to harm reduction programs must be done in consultation with NIH and the National Academy of Sciences.

P.L. 115-334: Agriculture Improvement Act of 2018

This law (formerly [H.R. 2 Agriculture Improvement of 2018; also known as the “farm bill”](#)) reauthorizes through FY2023 and modifies Department of Agriculture (USDA) programs that address commodity support, nutrition assistance, farm credit, rural development, research and extension activities, among others.

Of interest to NIH is a provision that excludes hemp extracts [e.g. cannabidiol (CBD) and tetrahydrocannabinol (THC) with a concentration of <0.3%] from the Controlled Substances Act. This means that it could potentially be easier for researchers to obtain authorization to test hemp extracts and conduct research on CBD derived from hemp.

Legislation of Interest to NINDS Introduced in the 116th Congress

Marijuana Research

[H.R. 127](#): *Compassionate Access, Research Expansion, and Respect States (CAREERS) Act of 2019*

Background: The CAREERS Act has previously been introduced during the 114th, and 115th Congresses by Representative Steve Cohen (D-TN) and Senator Cory Booker (D-NJ); however, they never passed out of Committee. This bill is identical to [H.R. 2920](#) in the 115th Congress.

Provisions of the Legislation/Impact on NIH: Among other provisions, the bill, if enacted, would exclude cannabidiol from the definition of marijuana, terminate the “Guidance on Procedures for the Provision of Marijuana for Medical Research,” and require the DEA to issue at least 3 licenses to manufacture and distribute marijuana and marijuana-derivatives for research approved by the FDA.

Status: H.R.127 was introduced by Representative Steve Cohen (D-TN) on January 3, 2019, and was jointly referred to the House Committees on Energy and Commerce, the Judiciary, and Veterans’ Affairs. No further action has occurred.

SBIR and STTR awards

[H.R. 206](#): *Encouraging Small Business Innovation Act*

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would expand the funding opportunities for SBIR and STTR awards to include small business investment companies.

Status: On January 3, 2019, Representative Harley Rouda (D-CA) introduced H.R. 206, the Encouraging Small Business Innovation Act, which was referred to the House Committee on Small Business and Science, Space, and Technology. On January 14, 2019, the bill passed the House. No further action has occurred.

Lyme Disease and Other Tick-Borne Diseases

[H.R. 220](#): *National Lyme Disease and Tick-borne Diseases Control and Accountability Act of 2019*

Background: Bills similar to H.R. 220 have been introduced during the 113th, 114th, and 115th Congresses by Representative Christopher Smith (R-NJ), but they did not pass out of Committee.

Provisions of the Legislation/Impact on NIH: This bill, if enacted, would direct the Secretary of HHS to expand and intensify epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne diseases and encourage the solicitation of proposals

for collaborative, multidisciplinary research that would involve national research institutes and national centers of the NIH in intramural and extramural research on tick-borne disease, such as the NINDS conducting or sponsoring research on neurologic Lyme disease. The bill also directs the Secretary in cooperation with the Director of the Office, and acting through the Directors of CDC and NIH to conduct and support research to develop new and improved diagnostic tests for tick-borne diseases, as well as sponsor a state-of-the-science conference on Lyme disease and other tick-borne disease including identification of research gaps and top research priorities no later than 24 months after the date of enactment.

Status: On January 3, 2019, H.R. 220 was introduced by Rep. Chris Smith (R-NJ) and was referred to the House Committee on Energy and Commerce. No further action has occurred.

Unruptured Intracranial Aneurysms

***H.R. 594:** To provide for further comprehensive research at the National Institute of Neurological Disorders and Stroke on unruptured intracranial aneurysms*

Background: Previously introduced as Ellie’s Law, this bill was first introduced by Rep. Yvette Clarke (D-NY) and Rep. Renee Ellmers (R-NC) in the 114th Congress but did not pass out of Committee. It was again introduced in the 115th Congress but did not pass out of Committee. The bill is named in remembrance of Ellie Helton, a 14-year-old from North Carolina, who unexpectedly passed away from a ruptured aneurysm.

Provisions of the Legislation/Impact on NIH: This bill would support further comprehensive research on unruptured intracranial aneurysms to study a broader patient population diversified by age, sex, and race by authorizing \$5,000,000 to be appropriated to the NINDS for each of fiscal years 2020 through 2024, to remain available through September 30, 2027.

Status: H.R.594 was introduced by Rep. Yvette Clark (D-NY) on January 16, 2019, and was referred to the House Committee on Energy and Commerce. No further action has occurred.

Committee Leadership of Interest to NIH in the 116th Congress (*new* = new to position) **Blue*** = Democrats; **Red**** = Republicans

Authorizers

House Committee on Energy and Commerce

- Chairman: **Frank Pallone Jr. (NJ)*** *new*
- Ranking member: **Greg Walden (OR)**** *new*

Subcommittee on Health

- Chairman: **Anna Eshoo (CA)*** *new*
- Ranking member: **Michael C. Burgess (TX)**** *new*

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

- Chairman: **Lamar Alexander (TN)****
- Ranking member: **Patty Murray (WA)***

Appropriators

House Appropriations Committee

- Chairwoman: **Nita M. Lowey (NY)*** *new*
- Ranking member: **Kay Granger (TX)**** *new*

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

- Chairwoman: **Rosa DeLauro (CN)*** *new*
- Ranking member: **Tom Cole (OK)**** *new*

Senate Appropriations Committee

- Chairman: **Richard Shelby (AL)****
- Ranking member: **Patrick Leahy (VT)***

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

- Chairman: **Roy Blunt (MO)****
- Ranking member: **Patty Murray (WA)***