



National Institute of
Neurological Disorders
and Stroke



LEGISLATIVE UPDATE:
Overview of Legislation from the 116th Congress
May 2019

NINDS OFFICE OF SCIENCE POLICY & PLANNING

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Appropriations Update

	FY 2018 Omnibus	FY 2019 Appropriations	FY 2020 President's Budget	FY 2020 House 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	\$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	\$34.4 billion, including \$492 million from the 21 st Century Cures NIH Innovation Account (incl. \$140 million for the BRAIN Initiative) and \$1.3 billion for research related to pain and opioids (incl. \$500 million for the HEAL Initiative)	\$41.1 billion, including \$492 million from the 21 st Century Cures NIH Innovation Account (incl. \$140 million for the BRAIN Initiative)
NINDS	\$2.188 billion, including \$43 million for the BRAIN Initiative and \$250 million for research related to pain and opioids	\$2.274 billion, including \$57.5 million for the BRAIN Initiative and \$250 million for research related to pain and opioids	\$2.026 billion, including \$70 million for the BRAIN Initiative and \$250 million for research related to pain and opioids	\$2.386 billion, including \$70 million for the BRAIN Initiative

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 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).

FY 2020

FY 2020 President's Budget. The [President's Budget](#) for FY2020 was released on March 11, 2019. The Budget proposes \$34.4 billion in FY 2020 funding for NIH (\$4.9 billion below FY 2019 enacted funding; 12.5% decrease), including \$492 million in resources available through the 21st Century Cures Act and a total of \$1.3 billion to support research on pain and opioids across NIH. The proposal also includes \$256 million to the new National Institute for Research on Safety and Quality (NIRSQ) to continue research currently administered by the Agency for Healthcare Research and Quality (AHRQ), \$100 million to support the Next Generation Researchers Initiative by prioritizing meritorious applications from early stage and at-risk investigators, and \$50 million to support research on pediatric cancer.

FY 2020 House Appropriations. On May 8, 2019, the House Appropriations Committee voted to approve the [FY 2020 Labor, Health and Human Services, and Education appropriations bill](#). The bill provides \$41.1 billion for NIH (5.1% above FY 2019 enacted level; and a \$2 billion increase for the 4th consecutive year), which includes \$492 million from the 21st Century Cures NIH Innovation Account. The bill includes targeted funds for several research areas, including \$2.4 billion for Alzheimer's disease, \$500 million for the All of Us precision medicine research initiative, and \$411 million for the BRAIN Initiative. Also included in the bill are \$25 million for research to help prevent firearm-related injuries and mortality and \$75 million for Research Centers in Minority Institutions. The bill also provides \$50 million for the Childhood Cancer Data Initiative as included in the President's budget proposal.

For NINDS, the bill provides \$2.316 billion, and \$70 million from the NIH Innovation Account will be transferred to NINDS and NIMH respectively for the BRAIN Initiative. The Committee also provides no less than the FY 2019 enacted level of \$250 million for the HEAL Initiative for NINDS and NIDA, respectively. In addition, the NIH Director will have the authority to transfer funds set aside for pain and opioids research between Institutes and Centers.

Legislation of Interest to NINDS Introduced in the 116th Congress

Autism

[H.R. 1058](#) / [S. 427](#): *Autism CARES Act of 2019*

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would reauthorize existing federal autism programs for another 5 years through 2024 and require a report on the health and well-being of individuals with autism across their lifespan.

Status: H.R. 1058 was introduced by Representative Christopher Smith (R-NJ) and referred to the House Committee on Energy and Commerce on February 7, 2019. S. 427 was introduced by Senator Robert Menendez (D-NJ) and referred to the Senate Committee on Health, Education, Labor, and Pensions on February 7, 2019. 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 no further action was taken.

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.

Marijuana Research

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

Background: The CARERS Act has previously been introduced during the 114th, and 115th Congresses by Representative Steve Cohen (D-TN) and Senator Cory Booker (D-NJ); however, no further action was taken. 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. On January 15, 2019, the bill was received in the Senate and referred to the Senate Committee on Small Business and Entrepreneurship. No further action has occurred.

Scientific Integrity

[H.R. 1709](#) / [S. 775](#): *Scientific Integrity Act*

Background: Bills with the same title and substantially similar language were initially introduced in the 115th Congress (2017-2018) by Representative Paul Tonko (D-NY) as [H.R. 1358](#) and by Senator Bill Nelson (D-FL) as [S. 338](#). No further action was taken.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would add detailed guidance on ethical conduct at government agencies that fund or conduct science. The guidance includes limiting agencies’ oversight and censorship of their employees’ publications and public statements, protecting employees from retaliation or censorship on the basis of politics, and protecting scientific findings from suppression or alteration.

Status: H.R. 1709 was introduced by Representative Paul Tonko (D-NY) and referred to the House Committee on Science, Space, and Technology on March 13, 2019. S. 775 was introduced by Senator Brian Schatz (D-HI) and referred to the Senate Committee on Commerce, Science, and Transportation on March 13, 2019. No further action has occurred.

Tourette Syndrome

H.R. 1131: *Collaborative Academic Research Efforts for Tourette Syndrome Act of 2019*

Background: The Collaborative Academic Research Efforts for Tourette Syndrome Act was initially introduced in the 112th Congress (2011-2012) by Representative Albio Sires (D-NJ) as [H.R. 3760](#) and by Senator Robert Menendez (D-NJ) as [S. 2321](#). The bill has been introduced in every Congress since then, but no further action was taken.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would require NIH to expand, intensify, and coordinate research on Tourette syndrome. Specifically, it would require the Secretary of HHS – acting through the Director of NIH – to develop a patient data collection system and four to six Collaborative Research Centers focused on Tourette Syndrome, and to set aside an unspecified amount of NIH funding each year for Tourette Syndrome research.

Status: H.R. 1131 was introduced by Representative Albio Sires (D-NJ) and referred to the House Committee on Energy and Commerce on February 8, 2019. 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 no further action was taken. It was introduced again in the 115th Congress. No further action was taken. 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.

Legislation of Interest to NIH Introduced in the 116th Congress

Federal Advisory Committee Act (FACA)

[H.R. 1608](#) / [S. 1220](#): *Federal Advisory Committee Act Amendments of 2019*

Background: The Federal Advisory Committee Act Amendments bill was initially introduced in the 110th Congress (2007-2008) by Representative William Lacy Clay, Jr. (D-MO), as [H.R. 5687](#). The bill has been introduced in every Congress since then and has passed the House on more than one occasion.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would require that NIH's 26,000+ first-level peer reviewers be converted to Special Government Employees (SGE), which requires the completion of 13 forms, totaling about 90 pages. It takes 6-12 months per person to clear these forms. NIH could not hold meetings until the clearance process is complete.

Status: Representative William Lacy Clay, Jr. (D-MO) introduced H.R. 1608 on March 7, 2019. On March 12, 2019, the bill passed the House. On April 11, 2019, Senator Rob Portman (R-OH) introduced the Senate version of the bill, S. 1220. No further action has occurred.

Pain and Opioids Research

[S. 418](#): *FDA Accountability for Public Safety Act*

Background: The FDA Accountability for Public Safety Act was initially introduced in the 114th Congress (2015-2016) by Senator Joe Manchin (D-WV) as [S. 954](#), but no further action was taken. The bill was introduced again in the 115th Congress. No further action was taken.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would make it easier for the FDA to deny new opioid drug applications. Specifically, it would add the requirement of a dissenting report directly from the Commissioner of Food and Drugs in order to override a denial decision by the FDA advisory council.

Status: S. 418 was introduced by Senator Joe Manchin (D-WV) and referred to the Senate Committee on Health, Education, Labor, and Pensions on February 7, 2019. No further action has occurred.

Recent Hearings of Interest

The Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education

Senate L-HHS, Education, and Related Agencies Appropriations Subcommittee Hearing on the NIH Budget for FY 2020

April 11, 2019

The Senate L-HHSE Subcommittee held a hearing on April 11, 2019 to discuss the NIH budget for fiscal year 2020. NIH Director Dr. Francis Collins testified before the Subcommittee and was accompanied by Dr. Anthony Fauci (Director, NIAID), Dr. Gary Gibbons (Director, NHLBI), Dr. Jon Lorsch (Director, NIGMS), Dr. Doug Lowy (Deputy Director, NCI), Dr. Griffin Rodgers (Director, NIDDK), and Dr. Nora Volkow (Director, NIDA). Senators asked about NIH-supported research in disease areas including amyotrophic lateral sclerosis and Alzheimer's disease. Senators also asked about NIH's efforts to enhance data sharing, to coordinate with other research-funding agencies and private organizations, to train the next generation of researchers, and to protect intellectual property. Chairman Blunt and Ranking Member Murray expressed their opposition to the proposed NIH budget cuts in the FY 2020 President's Budget.

The House Appropriations Subcommittee on Labor, Health and Human Services, and Education

House Labor-HHS Appropriations Subcommittee Hearing on the NIH Budget for FY 2020

April 2, 2019

On April 2, 2019, NIH Director Dr. Francis Collins testified before the House Appropriations Labor-HHSE Subcommittee and was accompanied by Dr. Diana Bianchi (Director, NICHD), Dr. Anthony Fauci (Director, NIAID), Dr. Gary Gibbons (Director, NHLBI), Dr. Doug Lowy (Deputy Director, NCI), and Dr. Nora Volkow (Director, NIDA). Members asked about NIH-supported research and plans in numerous disease areas, including opioid use disorder, Alzheimer's disease, Down syndrome, and autism. Members also asked what NIH has done to support pediatric research, drug development, rigor and reproducibility, and training the next generation of researchers. Chairwoman DeLauro and Ranking Member Cole expressed their opposition to the NIH budget cuts proposed in the FY 2020 President's Budget.

The Senate Special Committee on Aging

Alzheimer's: New Directions in Biomedical Research and Caregiving

April 2, 2019

The Senate Special Committee on Aging held a hearing on April 2, 2019 to discuss the latest research and care advances in Alzheimer's disease and Alzheimer's disease-related dementias

(AD/ADRD). Dr. Richard Hodes (Director, NIA) testified, along with several patient advocates and a medical professional. Dr. Hodes provided details about the growth of research funding for AD/ADRD and collaboration within NIH to study the link between AD and Down syndrome. Dr. Hodes also described recent progress in the AD/ADRD field, including the expansion of the health care and research workforce, drug development projects focused on novel pathological mechanisms, and advances in AD genomics.

The Senate Committee on Health, Education, Labor, and Pensions

Managing Pain During the Opioid Crisis

February 12, 2019

On February 12, the Senate HELP Committee held a hearing, “Managing Pain During the Opioid Crisis” to discuss the steps that Congress can take to support people in managing their pain. Pain researchers, a director of a non-profit organization for pain advocacy, and a medical director at a health insurance provider testified before the committee. Topics that members expressed interest in included research on pain, addiction, and cannabinoids, improving physician and patient education on opioid use, unintended consequences of the CDC guidelines, and reimbursement issues for non-pharmacological pain management strategies.