



National Institute of  
Neurological Disorders  
and Stroke



**LEGISLATIVE UPDATE:**  
*Overview of Legislation from the 115<sup>th</sup> Congress*  
September 2017

**NINDS OFFICE OF SCIENCE POLICY & PLANNING**

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## Appropriations Update

|       | FY 2017 Omnibus  | FY 2018 President's Budget   | FY 2018 House Appropriations Committee   |
|-------|--|--|--|
| NIH   | \$34.1 billion, including \$352 million from 21 <sup>st</sup> Century Cures NIH Innovation Account (incl. \$10 million for BRAIN Initiative) | \$26.9 billion, including \$496 million from 21 <sup>st</sup> Century Cures NIH Innovation Account (incl. \$86 million for BRAIN initiative) | \$35.2 billion, including \$496 million from 21 <sup>st</sup> Century Cures NIH Innovation Account (incl. \$86 million for BRAIN Initiative) |
| NINDS | \$1.783 billion  | \$1.356 billion  | \$1.810 billion  |

### FY 2017

**FY 2017 Omnibus.** On May 1, 2017, the House and Senate released the FY 2017 Omnibus spending bill that included the 11 unfinished FY 2017 Appropriations bills, and funds the government through the end of FY 2017. The bill provides a total of \$34.1 billion for NIH (\$2 billion increase or 6.2% over FY 2016), which includes \$352 million from 21<sup>st</sup> Century Cures Innovation Fund, and \$1.783 billion for NINDS. It also increases Alzheimer's disease research by \$400 million, and increases funding for BRAIN initiative by \$110 million (including \$10 million from 21<sup>st</sup> Century Cures Innovation Fund). The House and Senate passed the Omnibus bill on May 3, 2017, and on May 4, 2017, respectively. The bill was signed by the President on May 5, 2017 ([P.L. 115-31](#))

### FY 2018

**FY 2018 President's Budget.** On May 23, 2017, the President released the full FY2018 budget request "A New Foundation for American Greatness." The budget requests \$26.9 for NIH, a \$7.2 billion decrease from the FY 2017 enacted level. The requested amount includes \$496 million (\$86 million for BRAIN initiative) for implementing the 21<sup>st</sup> Century Cures Act in FY2018.

The request restructures global health research at NIH by eliminating the Fogarty International Center, consolidates the Agency for Healthcare Research and Quality (AHRQ) into NIH as a new National Institute for Research on Safety and Quality (NIRSQ), and proposes changes to the reimbursement of indirect costs for NIH grants, which will be capped at 10% of total research.

**House Appropriations.** On July 19, 2017, the House Appropriations Committee [approved](#) the FY 2018 Labor, Health and Human Services, Education funding bill, [H.R. 3358](#). The bill would provide a total of \$35.2 billion for NIH, an increase of \$1.1 billion above the FY 2017 enacted

level and \$8.3 billion above the President's budget request. The bill includes increased funds for several research initiatives, including Alzheimer's disease research (\$400 million increase for NIA), the BRAIN Initiative (\$86 million total; \$43 million for NINDS and NIMH, respectively).

The bill also includes provisions requiring NIH to continue reimbursing grantee research institutions for facilities and administrative costs (indirect costs), and prohibiting use of funds for research on fetal tissue obtained from an induced abortion.

### **Appropriations Outlook**

As of August 30, 2017, there has been no further action on the FY 2018 House Labor, Health and Human Services, Education Appropriations bill, H.R. 3358, and there is no Senate version of the bill. After returning from the August recess, Congress will need to pass all 12 FY 2018 Appropriations bills or agree to a Continuing Resolution to fund the government before the fiscal year ends on September 30.

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

### Alzheimer's Disease

**Background:** In order to afford a convenient way for members of the public to contribute to funding for medical research relating to Alzheimer's disease, the bill directs the United States Postal Service to issue and sell an Alzheimer's Disease Research Semipostal Stamp. Proceeds from the sale of the stamp must be transferred to the National Institutes of Health. Similar bills were introduced in the House and Senate during the 113<sup>th</sup> and 114<sup>th</sup> Congress, but failed to pass out of committee.

**H.R. 2973** *To Provide for the Issuance of an Alzheimer's Disease Research Semipostal Stamp*

**Provisions of the Legislation/Impact on NIH:** All amounts becoming available from the sale of the Alzheimer's Disease Research Semipostal Stamp shall be transferred to the National Institutes of Health, for the purpose of funding medical research relating to Alzheimer's disease through payments which shall be made at least twice a year.

**Status:** On June 23, 2017, Representative Maxine Waters (D-CA) introduced H.R. 2973. H.R. 2973 was referred to the House Energy and Commerce Subcommittee on Health. No further action has occurred.

## **Concussion**

**Background:** The Concussion Awareness and Education Act of 2014 and 2015 were introduced into the House and Senate in the 113<sup>th</sup> and 114<sup>th</sup> Congress, but failed to pass out of committee. The bill would have directed the Director of the National Institutes of Health (NIH) and the Secretary of Defense (DOD) to act in coordination to conduct or support research on concussion in youth, required the NIH to maintain a national brain tissue and biological sample repository for research on concussions, and required establishment of a Concussion Research Commission that studies the activities conducted pursuant to the Act and formulate systemic recommendations.

### **H.R. 2360** *Concussion Awareness and Education Act of 2017*

**Provisions of the Legislation/Impact on NIH:** The bill directs the NIH to conduct or support research designed to inform the creation of guidelines for the management of short- and long-term sequelae of concussion in youth; research on the effects of concussions and repetitive head impacts on quality of life and the activities of daily living; research to identify predictors, and modifiers of outcomes, of concussions in youth; and research on age- and sex-related biomechanical determinants of injury risk for concussion in youth.

**Status:** On May 4, 2017, Representative Joy Beatty (D-OH) introduced H.R. 2360. H.R. 2360 was referred to the House Committee on Energy and Commerce and to the Subcommittee on Health on May 05, 2017. No further action has occurred.

## **Cerebral Cavernous Malformations**

**Background:** The Cavernous Angioma CARE Center Act of 2012 was introduced in both the House and Senate in the 112<sup>th</sup> 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), to train medical students and residents, and to maintain programs dedicated to patient advocacy, outreach and education. Similar bills were introduced in the House and Senate in the 113<sup>th</sup> and 114<sup>th</sup> Congress; the bills were never taken up by Committee.

**[H.R. 1255](#)** *Cerebral Cavernous Malformations Clinical Awareness, Research, and Education (CCM-CARE) Act of 2017*

**Provisions of the Legislation/Impact on NIH:** The bill would direct NINDS, NCATS, and NHLBI to strengthen and coordinate basic, translational, and clinical research on CCM. The bill would direct NIH to establish a network of CCM Clinical Research Centers, including 2 coordinating centers and 6 to 10 participating centers. The coordinating centers would facilitate clinical trials, translational research, and enhance medical care for CCM patients. NIH would also be required to convene a CCM Research Consortium, which would include representatives from the coordinating centers and from at least one patient advocacy group, and may also include NIH or FDA representatives in an advisory role. The Consortium's role would be to develop training programs for clinicians and scientists and develop patient education and outreach programs and materials. The bill would direct the CDC to create a National CCM Epidemiology Program and a National Surveillance Program, and would direct the FDA to support Investigational New Drug Applications and Orphan Drug status for CCM drugs for rare subpopulations of CCM, including subpopulations with the common Hispanic mutation or CCM3 gene mutations.

**Status:** On February 28, 2017, Representative Ben Ray Lujan (D-NM) introduced H.R. 1255. H.R. 1255 was referred to the House Committee on Energy and Commerce. No further action has occurred.

## **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 with similar provisions to the bill described below 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.



## **Unruptured Brain Aneurysm**

**Background:** Ellie's Law was first introduced by Rep. Yvette Clarke (D-NY) and Rep. Renee Ellmers (R-NC) in the 114<sup>th</sup> 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.

**H.R. 1648:** *Ellie's Law, or A Bill to Provide for Further Comprehensive Research At National Institute of Neurological Disorders and Stroke on Unruptured Intracranial Aneurysms*

**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 2018 through 2022, to remain available through September 30, 2026.

**Status,** H.R. 1648 was introduced on March 21, 2017 by Rep. Yvette D. Clarke (D-NY) and no further action has occurred.

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

### Fetal Tissue and Stem Cell Research

[H.R. 1203](#) *Safe Responsible Ethical Scientific Endeavors Assuring Research for Compassionate Healthcare (Safe RESEARCH) Act*

**Background:** Safe RESEARCH Act was introduced in the 114<sup>th</sup> Congress on October 8, 2015 by Rep. James Sensenbrenner (R-WI) but did not pass out of Committee.

**Provisions of the Legislation/Impact on NIH:** This bill would prohibit the use of tissue from a spontaneous or induced abortion in research conducted or supported by the NIH. Research with human fetal tissue conducted or supported by the NIH must meet requirements, including informed consent requirements for the donor and researcher, currently applied only to research on the transplantation of human fetal tissue for therapeutic purposes.

**Status:** H.R. 1203 was introduced by Rep. Jim Sensenbrenner (R-WI) on February 17, 2017 and referred to the House Energy and Commerce Committee. No further action has occurred.

[H.R. 2918](#) *Patients First Act of 2017*

**Background:** Patients First Act has been introduced in several previous Congresses with similar provisions to the bill but did not pass out of Committee.

**Provisions of the Legislation/Impact on NIH:** This bill requires the Department of Health and Human Services (HHS) to conduct and support basic and applied research to develop techniques for the isolation, derivation, production, testing, and human clinical use of stem cells that may result in improved understanding of, or treatments for, diseases and other adverse health conditions, provided that the techniques will not involve: (1) the creation of a human embryo for research purposes; (2) the destruction or discarding of, or risk of injury to, a living human embryo; or (3) the use of any stem cell the derivation or provision of which would be inconsistent with this bill.

**Status:** H.R. 2918 was introduced by Rep. Jim Banks (R-IN) on June 15, 2017 and referred to the House Energy and Commerce Subcommittee on Health on June 16, 2017. No further action has occurred.

## **Marijuana Research**

### **H.R. 714** *Legitimate Use of Medicinal Marijuana Act (LUMMA)*

**Provisions of the Legislation/Impact on NIH:** The bill if enacted would reschedule marijuana from a schedule I to a schedule II substance under the Controlled Substances Act. The bill would also authorize physicians to prescribe marijuana for medical use in states that allow it. The bill's goal of rescheduling is focused on relieving administrative burden on scientists conducting research on marijuana.

**Status:** On January 27, 2017, Representative Morgan Griffith (R-VA), introduced H.R. 714, which was referred to House Energy and Commerce Committee. No further action has occurred.

### **H.R. 715** *Compassionate Access Act*

**Provisions of the Legislation/Impact on NIH:** The bill if enacted would provide for the rescheduling of marijuana, the medical use of marijuana in accordance with state law, and the exclusion of cannabidiol from the definition of marijuana. The bill's goal of rescheduling is focused on relieving administrative burden on scientists conducting research on marijuana.

**Status:** On January 27, 2017, Representative Morgan Griffith (R-VA) introduced H.R. 715, which was referred to House Energy and Commerce, House Judiciary Committees. No further action has occurred.

### **H.R. 1227** *Ending Federal Marijuana Prohibition Act*

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would remove marijuana from the schedule of controlled substances under the Controlled Substances Act. Excluding marijuana from the Controlled Substances Act could ease barriers related to conducting marijuana research. H.R. 1227 is identical to S. 2237, introduced by Senator Bernie Sanders (I-VT) in the 114<sup>th</sup> Congress.

**Status:** On February 27, 2017, Representative Tom Garrett (R-VA) introduced H.R. 1227, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

### **S. 1276** *Cannabidiol Research Expansion Act*

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, directs the Secretary of Health and Human Services to expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on cannabidiol and other nonpsychoactive components of marijuana to better determine their potential therapeutic effects on serious medical conditions, including intractable epilepsy.

**Status:** On May 25, 2017, Senator Dianne Feinstein (D-CA) introduced S. 1276, which was referred to the Committee on the Judiciary. No further action has occurred.

[S. 1374](#) / [H.R. 2920](#) *Compassionate Access, Research Expansion, and Respect States (CAREERS) Act of 2017*

**Provisions of the Legislation/Impact on NIH:** The bill, among other provisions, 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 three licenses to manufacture and distribute marijuana and marijuana-derivatives for research approved by the FDA.

**Status:** On June 15, 2017, Senator Cory Booker (D-NJ) introduced S. 1374, which was referred to the Committee on the Judiciary. On June 15, 2017, Representative Steve Cohen (D-TN) introduced H.R. 2920, which was referred to the House Committee on Energy and Commerce Subcommittee on Health. No further action has occurred for both Senate and House bills.

[H.R. 3391](#) *Medical Marijuana Research Act of 2017*

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would establish a separate registration process for marijuana research, requiring the Attorney General to approve applications within 60 days if certain conditions are met.

**Status:** On July 25, 2017, Representative Andy Harris (R-MD) introduced H.R. 3391, which was jointly referred to the House Committees on Energy and Commerce and the Judiciary. No further action has occurred.

[S. 1689](#) *Marijuana Justice Act of 2017*

**Provisions of the Legislation/Impact on NIH:** The bill, among other provisions, if enacted, would remove marijuana from the list of controlled substances, which could ease barriers related to conducting marijuana research.

**Status:** On August 1, 2017, Senator Cory Booker (D-NJ) introduced S. 1689. The bill was referred to the Senate Committee on the Judiciary. No further action has occurred.

## Recent Hearings of Interest

### Appropriations Hearings

#### [House L-HHS Appropriations Subcommittee Hearing on Department of Health and Humans Services FY 2018 Budget](#)

March 29, 2017

The House Appropriations Labor, Health and Human Services Subcommittee held a budget hearing with Secretary of Health and Human Services Tom Price. Members expressed concerns about the President's FY18 proposal to decrease NIH funding. Secretary Price emphasized the need for decreasing duplication and increasing efficiency within the Department of Health and Human Services. The hearing also included a discussion of the amount of indirect costs that NIH pays to academic institutions, and whether reducing these costs would direct more funds to actual research.

#### [House Oversight Hearing on Advances in Biomedical Research](#)

May 17, 2017

The House Appropriations Labor, Health and Human Services Subcommittee held an oversight hearing "Advances in Biomedical Research" on May 17, 2017. Drs. Francis Collins (NIH Director), Anthony Fauci (NIAID Director), Gary Gibbons (NHLBI Director), Joshua Gordon (NIMH Director), Doug Lowey (NCI Acting Director), and Nora Volkow (NIDA Director) appeared as witnesses. Dr. Collins emphasized the important role of NIH in leveraging basic science for medical advances and training young investigators. Members expressed concerns about the President's proposed NIH budget cut for FY18 and its impact for medical research and economic development. They also discussed how NIH is addressing rising public health issues, including emerging infectious diseases, opioid abuse, suicide and mental health, being a good steward of taxpayer dollars, and sustaining a stable funding environment for biomedical researchers.

#### [Senate Hearing on the FY2018 Budget Request for the National Institutes of Health](#)

June 22, 2017

The Senate Appropriations Labor, Health and Human Services Subcommittee held a hearing on the FY2018 Budget Request for NIH. Drs. Francis Collins (NIH Director), Anthony Fauci (NIAID Director), Gary Gibbons (NHLBI Director), Joshua Gordon (NIMH Director), Richard Hodes (NIA Director), Doug Lowey (NCI Director), and Nora Volkow (NIDA Director) appeared as witnesses. Among the Committee members, there was significant bipartisan support for NIH, and opposition to the NIH cuts proposed in the President's budget. In his statement, Dr. Collins talked about leveraging basic science, fostering new scientific talent, and pursuing treatments for rare diseases. He mentioned the BRAIN initiative and the new Next Generation Researchers Initiative. Members asked about how the proposed cap on indirect research costs would impede research, and ways NIH could play a role in reducing administrative burdens on investigators. Members also asked about the opioid epidemic, vascular dementias, pediatric

research, duplication across multiple agencies, and ways to give NIH credit – in the public eye – for its contributions to the development of drugs or other therapeutic products.