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## Appropriations Update

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<td>NIH</td>
<td>$37.1 billion, including $496 million from 21st Century Cures NIH Innovation Account (incl. $86 million for the BRAIN Initiative) and $500 million for targeted research related to pain and opioids</td>
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<td>$39.1 billion, including $711 million from 21st Century Cures NIH Innovation Account (incl. $115 million for the BRAIN Initiative), and $500 million for research related to pain and opioids</td>
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<td>NINDS</td>
<td>$2.188 billion, including $43 million for the BRAIN Initiative and $250 million for research related to pain and opioids</td>
<td>$1.839 billion, including $57.5 million for the BRAIN Initiative</td>
<td>$2.228 billion, including $57.5 million for the BRAIN Initiative and $250 million for research related to pain and opioids</td>
<td>$2.275 billion, including $57.5 million for the BRAIN Initiative and $250 million for research related to pain and opioids</td>
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### 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 proposes 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 House Appropriations.** On July 11, 2018, The House Appropriations Committee approved H.R. 6470, the Departments of Labor, Health and Human Services, and Education appropriations bill on a vote of 30-22. The bill proposes $38.3 billion in FY 2019 funding for NIH ($1.25 billion above FY 2018 Omnibus), which includes $429 million for the BRAIN Initiative.

The bill also includes a total of $2.25 billion for Alzheimer’s disease and related dementias (AD/ADRD) research, $400 million for the Cancer Moonshot initiative, $437 million for the All of Us research, and expands support for research related to opioids and pain management as well as for the Down syndrome research initiative established in fiscal year 2018. It also proposes to provide $5 million to CDC to set up a neurological diseases surveillance program, which was authorized by the 21st Century Cures Act.

**FY 2019 Senate Appropriations.** The Senate introduced S. 3158, the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019 on June 28, 2018. The Senate then rolled the L-HHS appropriations provisions into the House-passed Defense appropriations bill, H.R. 6157, as a consolidated appropriations measure that includes FY2019 appropriations for Defense and Labor-HHS-Education, and passed H.R. 6157, the Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, on a vote of 85-7 on August 23, 2018. The bill maintains the levels proposed by the Senate LHHS Appropriations subcommittee, and the Senate appropriations committee of $39.1 billion in FY 2019 funding for NIH ($2 billion above FY 2018 Omnibus.) This includes $500 million for research on opioid addiction and non-opioid treatments for pain, $250 million of which is directed to NINDS.

The bill also includes $2.34 billion for AD/ADRD research, $429 million for the BRAIN Initiative, and $376 million for the All of Us Research initiative. $5 million is included for CDC to establish a neurological diseases surveillance program.
Legislation of Interest to NINDS Introduced in the 115th 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 113th and 114th Congress, but failed to pass out of committee.

H.R. 2973 / S. 2208 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. On December 7, 2017, Senator Edward Markey (D-MA) introduced S. 2208 which was referred to the Committee on Homeland Security and Governmental Affairs. No further action has occurred.
**Autism**

**Background:** The Vaccine Safety Study Act has been introduced by Rep. Bill Posey (R-FL) during the 113th and 114th Congresses as H.R. 1757 and H.R. 1636, respectively but failed to pass out of Committee. The bill, if enacted, would direct the Secretary of Health and Human Services to issue a request for proposals to conduct a vaccine safety study.

**H.R. 3615 Vaccine Safety Study Act**

**Provisions of the Legislation/Impact on NIH:** The bill directs the Secretary of Health and Human Services, acting through the Director of the NIH, to conduct or support a comprehensive study comparing total health outcomes, including risk of autism, in vaccinated versus unvaccinated populations in the United States, and to determine whether exposure to vaccines or vaccine components is associated with autism spectrum disorders, chronic conditions, or other neurological conditions.

**Status:** On August 4, 2017, Representative Bill Posey (R-FL) introduced H.R. 3615 which was referred to the House Energy and Commerce Subcommittee on Health. No further action has occurred.
Global Brain Health

Background: The Global Brain Health Act of 2015 was introduced into the House in the 114th Congress, but failed to pass out of Committee. The bill, if enacted, would support United States Government programs related to autism, hydrocephalus and Alzheimer’s and other forms of dementia and contained provisions similar to those in the Global Brain Health Act of 2017.

H.R. 4621 Global Brain Health Act of 2017

Provisions of the Legislation/Impact on NIH: The bill directs the U.S. Agency for International Development (USAID) to establish and administer a health and education grant program (Global Autism Assistance Program), and amends the Foreign Assistance Act of 1981 to authorize the President to provide assistance to support a network of trained medical practitioners to treat hydrocephalus in children in developing countries. It also directs the Secretary of Health and Human Services to negotiate with the World Health Organization to develop a plan for addressing Alzheimer’s disease and other forms of dementia (the Global Alzheimer’s Disease and Dementia Action Plan) in order to facilitate public-private partnerships to identify new treatment approaches for AD and other forms of dementia, and to establish the Global Alzheimer’s Disease and Dementia Fund to support the Plan’s implementation.

Status: On December 12, 2017, Representative Christopher Smith (R-NJ) introduced H.R. 4621 which was referred to the House Committee on Foreign Affairs, Energy and Commerce. 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 112th 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 113th and 114th 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.
**Opioid / Pain research**

**H.R. 4501 / S. 2004: Combating the Opioid Epidemic Act**

**Provisions of the Legislation/Impact on NIH:** The purpose of this bill is to increase funding for the State response to the opioid misuse crisis and to provide funding for research on addiction and pain related to the substance misuse crisis. The bill, if enacted, would authorize to appropriate $50,400,000 per year for 4 years (fiscal years 2018 through 2022) to the National Institutes of Health to award grants for the purpose of conducting research on addiction and pain related to substance misuse.

**Status:** S. 2004, was introduced by Sen. Bob Casey (D-PA) on October 25, 2017 and was referred to the Senate Committee on Health, Education, Labor, and Pensions. The House version of the bill, H.R. 4501, was introduced by Rep. David Loebsack (D-IA) on November 30, 2017 and was referred to the House Committee on Energy and Commerce. No further action has occurred.

**H.R. 4733 / S. 2260 Opioids and STOP Pain Initiative Act**

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would establish and fund an Opioids and STOP Pain Initiative to expand, intensify, and coordinate fundamental, translational, and clinical research of the National Institutes of Health with respect to opioid abuse, the understanding of pain, and the discovery and development of safer and more effective treatments and preventive interventions for pain. The bill authorizes and appropriates $5,000,000,000 to the NIH Innovation Account to be used to administer the Opioids and STOP Pain Initiative and establishes a “Pain Therapy Screening Program” that would be modeled after the NINDS Epilepsy Therapy Screening Program to support the development of new pre-clinical models for pain disorders, and the application of these models in drug, device or other therapy screening.

**Status:** On December 21, 2017, Rep. Peter Welch (D-VT) introduced H.R. 4733, which was referred to the Committee on Energy and Commerce. On the same day, Senator Brian Schatz (D-HI) introduced S. 2260, which was referred to the Committee on Finance. No further action has occurred.

**S. 2680 Opioid Crisis Response Act**

**Background:** The Opioid Crisis Response Act is a result of 7 bipartisan hearings on the opioid crisis with FDA, NIH, CDC, and SAMSHA. The bill contains 40 proposals that would improve the ability of NIH, FDA, CDC, SAMHSA, HRSA, as well as the Departments of Education and Labor to address the opioid crisis.

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, includes provisions from the ACE Research Act (**S.2406 / H.R.5002; see page 21**) and would increase flexibility for NIH to support high impact, cutting-edge projects that address the opioids crisis more quickly and
efficiently, including finding new non-addictive pain treatments, by giving the NIH Director “Other Transactions Authority (OTA)” for research leading to prevention, diagnosis, and treatment of diseases and disorders, or research urgently required to respond to a public health threat. OTA describes the streamlined procedures that federal agencies may use to procure innovative research or prototypes, without the constraints of a typical contract, grant, or cooperative agreement. The bill includes NIH as a member of the Interagency Task Force on Trauma-Informed Care and proposes to revise the activities and reporting requirements for the Interagency Pain Research Coordinating Committee (IPRCC).

**Status:** On April 16, 2018, Sen. Alexander Lamar (R-TN) introduced S. 2680, which was referred to the Committee on Health, Education, Labor, and Pensions. On April 24, 2018, the bill was marked up and favorably reported out of Committee by a vote of 23-0. On May 7, 2018, the bill was placed on the Senate Legislative Calendar.

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**H.R. 4938  Respond to the Needs in the Opioid War (NOW) Act**

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would establish an Opioid Epidemic Response Fund within the Treasury to carry out HHS programs and activities specified in the legislation to address the opioid epidemic. For each of the FYs 2018-2022, $5 billion would be transferred from the general fund of the Treasury to the Response Fund. The funds cannot be transferred until appropriated, are in addition to funds otherwise available, and available until expended. The bill would provide NIH with $500 million for each of the FYs 2018-2022 to: 1) accelerate research, including non-opioid medications and intervention such as non-addictive medications to manage pain and treat substance use disorders; 2) conduct and support research on which treatments are optimal for which patients; and 3) conduct and support research to create longer-lasting or faster acting antidotes for overdoses, particularly for fentanyl and carfentanil overdoses.

**Status:** On February 6, 2018, Representative Ann Kuster (D-NH), introduced H.R. 4938, the Respond to the Needs in the Opioid War (NOW) Act. It was jointly referred to the House Committees on Energy and Commerce, Judiciary, Ways and Means, Education and the Workforce, and Budget. No further action has occurred.

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**H.R. 5261  Treatment, Education, and Community Help (TEACH) to Combat Addiction Act of 2018**

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would authorize $2 million for each of the FYs 2019-2023 for the Centers of Excellence in Pain Education under the Pain Consortium that would coordinate the development, evaluation, and distribution of pain management curriculum for health professional schools.

**Status:** On March 13, 2018, Rep. Bill Johnson (R-OH) introduced H.R. 5261, which was referred to the House Energy and Commerce Subcommittee on Health. On April 25, 2018, the bill was forwarded to the Full Committee. On May 9, 2018, the bill was reported to the House.
On June 12, 2018, the bill was passed by the House. On June 13, 2018, the bill was received in the Senate and referred to the Committee on Health, Education, Labor, and Pensions.

**H.R. 5531  Opioid Emergency Response Act**

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would establish the Opioids and STOP Pain Initiative, authorizing and appropriating $500,000,000 over 5 fiscal years to the NIH Innovation Account. The Director of NIH would use these funds to supplement, not supplant, existing funding for pain and opioid research programs, including: the Pain Therapy Screening Program modeled after the Epilepsy Therapy Screening Program; research on medication-assisted therapy and opioid overdose reversal treatments; research priority areas identified in the Comprehensive Addiction and Recovery Act of 2016; and the Federal Pain Research Strategy.

**Status:** On April 17, 2018, Rep. Vern Buchanan (R-FL) introduced H.R. 5531, which was jointly referred to the House Committees on Energy and Commerce, Ways and Means, the Budget, Veterans’ Affairs, Oversight and Government Reform, and the Judiciary.

**H.R. 5927 Neonatal Abstinence Syndrome Best Practice Act**

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would require the NIH Director to expand, intensify, and coordinate research and other agency activities regarding the prevention, identification, and treatment of prenatal opioid exposure and neonatal abstinence syndrome. Based on the research, the NIH Director would be required to establish, update, and disseminate best practices regarding screening and treatment for pregnant women and their babies.

**Status:** On May 23, 2018, Representative Darren Soto (D-FL), introduced H.R. 5927 which was referred to the House Energy and Commerce Committee. No further action has occurred.

**H.R. 6 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act**

**Background:** This bill consolidates over 50 separate bills introduced in the 115th Congress by Members of Congress to address the opioid epidemic.

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

- Section 7042, ACE Research Act, would provide the NIH Director Other Transactions Authority (OTA) for “high impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders, or research urgently required to respond to a public health threat” (H.R. 5002/S. 2406, and section 201 of S. 2680).
- Title IX, Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act, would add a new Schedule A to the Controlled Substances Act to place synthetic
anallogues of already-controlled substances under the Controlled Substances Act framework. The bill requires a registration and notice process for Schedule A research that does not require the Attorney General to review the protocol, the primary reason for the length of time it takes to obtain a registration. In addition, the bill allows applicants to continue their research while their applications are pending, contingent upon compliance with Schedule A requirements and that such research cannot be a “coincident activity” (H.R. 2851).

- Section 6032, the Opioid Addiction Action Plan Act, would 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 (H.R. 5590/S. 2769).

- Section 7022, the Indexing Narcotics, Fentanyl, and Opioids (INFO) Act, would 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 and NCCIH (Section 2 of H.R. 4284).

- Section 7023, the Indexing Narcotics, Fentanyl, and Opioids (INFO) Act, would 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 Institutes the HHS Secretary determines appropriate (Section 3 of H.R. 4284).

- Section 7092, the Alternatives to Opioids in the Emergency Department (ALTO) Act, would require the HHS Secretary to carry out a 3-year demonstration program to award grants to eligible hospitals and emergency departments to develop, implement, enhance, or study alternative pain management protocols and treatments that limit the use of opioids in emergency departments. The Secretary must implement a process for recipients of grants to consult with each other and with persons having robust knowledge, including emergency departments and physicians that have successfully deployed alternative pain management protocols, such as non-drug approaches studied through NCCIH, including acupuncture that limit the use of opioids (H.R. 5197).

- Section 7212, the Securing Opioids and Unused Narcotics with Deliberate Disposal (SOUND) and Packaging Act, would authorize the HHS Secretary, after consultation with relevant stakeholders, to issue an order requiring manufacturers to improve packaging or ways of disposing drugs to help mitigate the risk of abuse or misuse. Representatives from NIH and NIDA are listed among the stakeholders with whom the Secretary may consult (H.R. 5687).

**Status:** On June 13, 2018, Rep. Greg Walden (R-OR) introduced H.R. 6. It was jointly referred to the House Committees on Energy and Commerce, Ways and Means, and the Judiciary. On June 22, 2018, the House passed the bill by a vote of 396-14. On June 25, 2018, the bill was received in the Senate. No further action has occurred.
**Tourette Syndrome**

**Background:** The Collaborative Academic Research Efforts for Tourette Syndrome Act was introduced during the 112th, 113th, and 114th 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.


**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. S. 1147 was introduced on May 17, 2017 to the Senate HELP Committee by Senator Robert Menendez (D-NJ).
Traumatic Brain Injury

Concussion

Background: The Concussion Awareness and Education Act of 2014 and 2015 were introduced into the House and Senate in the 113th and 114th 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.

Traumatic Brain Injury

H.R. 5528 Speed Warrior Outcomes, Research, Detection and Diagnosis (SWORDD) Act of 2018

Provisions of the Legislation/Impact on NIH: This bill would direct the Secretary of Defense to submit a plan to Congress for improvements to traumatic brain injury and post-traumatic stress research. The plan should describe actions for the Director of the Defense Health Agency to maximize the coordination and use of scientific research efforts carried out by the DoD, NIH, VA, major universities, and private firms, and describe new processes to accelerate scientific research and delivery of breakthrough therapies for TBI and post-traumatic stress.

Status: H.R.5528 was introduced by Rep. Don Bacon (R-NE) on April 17, 2018 and was referred to the House Committee on Armed Services. 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 114th 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 / S. 1999:** *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 by Rep. Yvette D. Clarke (D-NY) on March 21, 2017 and was referred to the House Energy and Commerce Subcommittee on Health. No further action has occurred.  S. 1999 was introduced by Senator Richard Blumenthal (D-CT) on October 24, 2017 and was referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred.
Legislation of Broad Interest to NIH Introduced in the 115th 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 114th 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/S. 2956** Patients First Act of 2017 / Patients First Act of 2018

**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. S. 2956, the Patients First Act of 2018, was introduced by Senator Roger Wicker (R-MS) on May 24, 2018. It was referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred for both Senate and House versions of the bill.
Marijuana Research

**H.R. 714 Legitimate Use of Medicinal Marihuana 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 114th 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 (CARERS) 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.

**S. 1803 Marijuana Effective Drug Studies (MEDS) Act of 2017**

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would establish a new registration process for marijuana research that is separate from the process for research involving other schedule I drugs. The goal of the bill is to streamline the process for researchers who want to conduct marijuana studies.
Status: On September 13, 2017, Senator Orrin Hatch (R-UT) introduced S. 1803, which was referred to the Senate Committee on the Judiciary. The bill is identical to S. 3077 from the 114th Congress. No further action has occurred.

**S.3174 Marijuana Freedom and Opportunity Act**

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would authorize $500 million to be appropriated to the Secretary of HHS over five years for critical public health research to better understand the effects of THC on the brain and the efficacy of medicinal marijuana for specific ailments. The bill instructs the Secretary of Health and Human Services in consultation with the Director of the NIH and the Commissioner of the FDA to conduct research on the health impacts of marijuana including the effects of THC on the human brain, efficacy of medical marijuana as a treatment for specific ailments, and additional exploration of medical benefits and uses.

Status: On June 28, 2018, Senator Chuck Schumer (D-NY) introduced S. 3174 which was referred to the Senate Committee on the Judiciary. No further action has occurred.

**H.R. 5520 VA Medical Cannabis Research Act**

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would authorize the VA Secretary to conduct and support research relating to the efficacy and safety of certain forms of cannabis on the health outcomes of veterans diagnosed with chronic pain, post-traumatic stress disorder, and other conditions the Secretary determines appropriate. The amended bill requires the VA Secretary to ensure that research is conducted in accordance with applicable regulations relating to the oversight of research, including regulations prescribed by the Office of Research and Development of the VA, HHS, the FDA, and DEA.

Status: Representative Timothy J. Walz (D-MN) introduced H.R. 5520 on April 16, 2018. The bill was reported, as amended, by the House Committee on Veterans Affairs on May 18, 2018. No further action has occurred.
Medical Research Funding

**S. 640 American Cures Act**

**Background:** The identical bill has been introduced in the 113th and 114th Congresses by Senator Richard Durbin (D-IL). A House version of the same bill has been introduced in the 114th Congress by Representative Anna Eshoo (D-CA). These bills never passed out of Committee.

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would make cap adjustments to permit larger increases for NIH, CDC, the defense health program in DoD, and the VA.

**Status:** On March 15, 2017, Senator Richard Durbin (D-IL) introduced S. 640, which was referred to the Senate Committee on Budget. No further action has occurred.

**H.R. 4487 / S. 2172 Medical Innovation Act of 2017**

**Background:** The identical bill has been introduced to the Senate and House in the 114th Congress as S. 320 and H.R. 744 but did not pass out of Committee.

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would authorize the collection of supplemental payments to increase congressional investments in medical research, and for other purposes. The bill amends the Public Health Service Act to require certain drug manufacturers to make payments to fund research supported by the FDA and the NIH. The NIH's priority use for payments must include supporting: (1) research that fosters radical innovation, (2) research that advances fundamental knowledge, (3) research related to diseases that disproportionately account for federal health care spending, and (4) early career scientists.

**Status:** H.R. 4487 was introduced by Rep. Peter Welch (D-VT) and referred to the House Committee on Energy and Commerce on November 29, 2017. S. 2172 was introduced Sen. Elizabeth Warren (D-MA) on the same day, and was referred to the Senate Committee on Health, Education, Labor and Pensions. No further action has occurred.

**S. 2212 National Biomedical Research Act**

**Background:** The National Biomedical Research Act has been introduced in the 114th Congress on March 3, 2016 by Senator Elizabeth Warren (D-MA) but failed to pass out of Committee.

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would establish a “Biomedical Innovation Fund” to provide funding for NIH and FDA. Authorized uses of the funds of interest to NIH include (1) basic research on the underlying basis for disease to better address disease prevention, diagnosis, and treatment; (2) research that fosters disruptive innovation; (3) research related to diseases that disproportionately account for Federal health care
spending; (4) early career scientists; (5) research efforts that increase the potential for breakthrough discoveries across a diverse set of investigators, research groups, and institutions.

Status: S. 2212 was introduced by Sen. Elizabeth Warren (D-MA) on December 7, 2017, and was referred to the Senate Committee on Health, Education, Labor and Pensions. No further action has occurred.

S.2406 / H.R.5002  Advance Cutting Edge (ACE) Research Act

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would 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. OTA describes the streamlined procedures that federal agencies may use to procure innovative research or prototypes, without the constraints of a typical contract, grant, or cooperative agreement.

Status: On February 8, 2018, Senator Lamar Alexander (R-TN) introduced S. 2406, the ACE Research Act, and on February 13, 2018, Representative Debbie Dingell (D-MI) introduced the companion bill in the House. S. 2406 was referred to the Senate Committee on Health, Education, Labor, and Pensions and H.R 5002 was referred to the House Committee on Energy and Commerce Subcommittee on Health. On April 25, 2018, H.R. 5002 was forwarded to the Full Committee. On June 12, 2018, H.R. 5002 was passed by the House. On June 13, 2018, H.R. 5002 was received by the Senate and referred to the Committee on Health, Education, Labor, and Pensions. S. 2406 became part of S. 2680 the Opioids Crisis Response Act of 2018 (see page 9).

H.R. 5115 Rare Disease Advancement, Research, and Education (RARE) Act of 2018

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would expand and improve the programs and activities of the Department of Health and Human Services for awareness, education, research, surveillance, diagnosis, and treatment concerning rare diseases and conditions. The bill authorizes $10 million to be appropriated every year from FY 2019 through FY 2023 to support rare disease research. It also directs the HHS Secretary to enhance rare disease research by establishing an integrated surveillance system, also known as the National Rare Disease or Condition Surveillance System.

Status: H.R. 5115 was introduced by Rep. Andre Carson (D-IN) on February 27, 2018 and was referred to the House Energy and Commerce Subcommittee on Health. No further action has occurred.

H.R. 5455  Accelerating Biomedical Research Act
**Background:** The Accelerating Biomedical Research Act has been introduced in the 113th and 114th Congresses by Rep. Rosa DeLauro (D-CT) and by Sen. Tom Harkin (D-IA) and Sen. Barbara Mikulski but failed to pass out of Committee.

**Provisions of the Legislation/Impact on NIH:** The bill, if enacted, would prioritize funding for NIH to discover treatments and cures, to maintain global leadership in medical innovation, and to restore the purchasing power which the NIH had after the historic doubling campaign that ended in fiscal year 2003.

**Status:** H.R. 5455 was introduced by Rep. Rosa DeLauro (D-CT) and was referred to the House Committee on the Budget on April 10, 2018. No further action has occurred.
Palliative Care Research

**H.R. 1676  Palliative Care and Hospice Education and Training Act**

**Provisions of the Legislation/Impact on NIH:** This bill, if enacted, requires NIH to develop and implement a Trans-NIH strategy to expand and intensify national research programs in palliative care in order to address the quality of care and quality of life for patients with serious or life-threatening illnesses. Specifically mentioned illnesses include: cancer; heart, kidney, liver, lung, and infectious diseases; as well as neurodegenerative diseases such as dementia, Parkinson’s disease, or amyotrophic lateral sclerosis. The bill also requires NIH to include information about research on palliative care in the NIH Triennial Report.

**Status:** Representative Eliot L. Engel (D-NY) introduced H.R. 1676 on March 22, 2017. On June 27, 2018, the Energy and Commerce Committee Health Subcommittee voted to advance the bill as amended. It was received in the Senate and was referred to the Committee on Health, Education, Labor, and Pensions on July 24, 2018. No further action has occurred.
Recent Hearings of Interest

The Senate Health, Education, Labor, and Pension (HELP) Committee Hearing

Prioritizing Cures: Science and Stewardship at the NIH
August 23, 2018

The Senate HELP Committee held a hearing on August 23, 2018. NIH Director Dr. Francis Collins testified before the Committee and was accompanied by Dr. Diana Bianchi (Director, NICHD), Dr. Anthony Fauci (Director, NIAID), Dr. Richard Hodes (Director, NIA), and Dr. Norman Sharpless (Director, NCI). Members asked how increased funding for NIH is being spent in supporting the next generation of scientists, precision medicine, opioid and pain research, pediatric research, and gene therapies for neurological diseases, among others. Chairman Alexander was interested in what NIH is doing to protect the integrity of US biomedical research from undue foreign influence.

The House Energy and Commerce Subcommittee on Health Hearing

21st Century Cures Implementation: Updates from NIH and FDA
July 25, 2018

Drs. Francis Collins (NIH Director), Stephanie Devaney (All of Us Deputy Director), Norman Sharpless (NCI Director), and Scott Gottlieb (FDA Commissioner) appeared before the House Energy and Commerce Subcommittee on Health to provide updates on the progress NIH and FDA have made since the last update in November 2017. Members asked questions about research initiatives, such as All of Us and Cancer Moonshot, supported by the NIH Innovation fund that was authorized by 21st Century Cures. Other topics of interest included reducing administrative burden for researchers, and advances in opioid and pain research and neurological disease research.

FY 2019 Appropriations Hearings

Senate Labor, Health and Human Services, Education and Related Agencies Subcommittee Hearing to Review the FY 2019 Budget Request for the NIH
May 17, 2018

The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies held a hearing on May 17, 2018 to review the fiscal year 2019 funding request and budget justification for the NIH. Dr. Francis Collins (NIH Director) testified before the Committee, and was accompanied by Drs. Walter Koroshetz (NINDS Director), Norman Sharpless (NCI Director), Anthony Fauci (NIAID Director), Richard Hodes (NIA Director), and Nora Volkow (NIDA Director). Among the topics discussed were research on Alzheimer’s disease and related dementias, the effects of social media on adolescent brain development, and non-addictive pain treatments. Members were also interested in the public-private partnership on opioid and pain research and the role of private partners in the Helping to End Addiction Long-term (HEAL) Initiative.