



National Institute of
Neurological Disorders
and Stroke



LEGISLATIVE UPDATE:
Overview of Legislation from the 115th Congress
May 2018

NINDS OFFICE OF SCIENCE POLICY & PLANNING

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***New items in this update are highlighted in yellow.**

Appropriations Update

| | FY 2017 Omnibus | FY 2018 President's Budget | FY 2018 Omnibus | FY 2019 President's Budget |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NIH | \$34.1 billion, including \$352 million from 21 st Century Cures NIH Innovation Account (incl. \$10 million for BRAIN Initiative) | \$26.9 billion, including \$496 million from 21 st Century Cures NIH Innovation Account (incl. \$86 million for BRAIN initiative) | \$37.1 billion, including \$496 million from 21 st Century Cures NIH Innovation Account (incl. \$86 million for 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; additional \$750 million to fight opioid crisis and address serious mental illness |
| NINDS | \$1.783 billion | \$1.356 billion | \$2.188 billion, including \$43 million for the BRAIN Initiative (from 21 st Century Cures) | \$1.839 billion, including \$57.5 million for the BRAIN Initiative (from 21 st Century Cures). |

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 \$2.145 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).

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, SAMSHA, 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 19) 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 also proposes to update the activities and reporting requirements for the Interagency Pain Research Coordinating Committee (IPRCC) to improve scientific understanding of pain and to advance understanding of risk factors that could lead to substance use disorders.

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.

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 carfentanyl 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.

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.

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.

H.R. 427 / S. 1147: *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. 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 on March 21, 2017 by Rep. Yvette D. Clarke (D-NY) and no further action has occurred. S. 1999 was introduced by Senator Richard Blumenthal (D-CT) on October 24, 2017 and 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](#) *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 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 (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.

[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 and 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.

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 disproportionally 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. S. 2406 became part of S. 2680 ([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.

Recent Hearings of Interest

FY 2019 Appropriations Hearings

Senate Labor, Health and Human Services, Education and Related Agencies Subcommittee Hearing to Review the FY 2019 for the NIH

Planned for May 17, 2018

Senate Labor, Health and Human Services, Education and Related Agencies Subcommittee: FY 2019 Budget Hearing – Department of Health and Human Services

May 11, 2018

HHS Secretary Alex Azar appeared before the Senate Labor, Health, and Human Services, Education and Related Agencies Subcommittee on May 11, 2018 to discuss the Department of Health and Human Services' FY 2019 budget request. Secretary Azar talked about his priorities for the Department, such as fighting the opioid crisis and tackling drug prices. Members were supportive of the commitment to NIH research and funding to combat the opioid crisis that was reflected in the budget request.

House Labor, Health and Human Services, Education and Related Agencies Subcommittee: FY 2019 Budget Hearing – National Institutes of Health

April 11, 2018

The House Labor, Health and Human Services, Education and Related Agencies Subcommittee held a hearing to discuss the NIH budget for FY 2019 on April 11, 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. Norman Sharpless (Director, NCI), and Dr. Nora Volkow (Director, NIDA). Members showed bipartisan support for NIH and expressed interest in a variety of topics such as how NIH is addressing the opioid epidemic, including the recently launched HEAL Initiative, marijuana research, and a trans-NIH research initiative on Down syndrome. Members also expressed concerns about conflicts of interest associated with the NIAAA moderate alcohol consumption study, and recruitment and retention of the next generation of scientists in the biomedical research workforce.

House Labor, Health and Human Services, Education and Related Agencies Subcommittee: FY 2019 Budget Hearing – Department of Health and Human Services

March 15, 2018

HHS Secretary Alex Azar appeared before the House Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee on March 15, 2018, to discuss the President's FY 2019 proposed budget for the Department of Health and Human Services. Several members supported increases to NIH above those in the FY 2019 President's Budget. Ranking member Rosa DeLauro (D-CT) expressed her support for the HHS-wide \$10 billion investment in fighting the opioid epidemic.