



### **LEGISLATIVE UPDATE:**

Overview of Legislation from the 115<sup>th</sup> Congress February 2018

NINDS OFFICE OF SCIENCE POLICY & PLANNING

# Contents

Appropriations Update	3
Legislation of Interest to NINDS Introduced in the 115th Congress	5
Alzheimer's Disease	5
Autism	6
Global Brain Health	7
Concussion	8
Cerebral Cavernous Malformations	9
Opioid / Pain research	
Tourette Syndrome	11
Unruptured Brain Aneurysm	
Legislation of Broad Interest to NIH Introduced in the 115th Congress	13
Fetal Tissue and Stem Cell Research	
Marijuana Research	
Medical Research Funding	
Recent Hearings of Interest	19
Hearings on Opioid Crisis	
Hearings on 21st Century Cures Act Implementation	19

# **Appropriations Update**

	FY 2017	FY 2018	FY 2018 House	FY 2018 Senate
	Omnibus	President's	Appropriations	Appropriations
		Budget	Committee	Committee
NIH	\$34.1 billion, including \$352 million from	\$26.9 billion, including \$496 million from	\$35.2 billion, including \$496 million from 21st	\$36.1 billion, including \$496 million from 21st
	21st Century Cures NIH Innovation Account (incl. \$10 million for BRAIN Initiative)	21st Century Cures NIH Innovation Account (incl. \$86 million for BRAIN initiative)	Century Cures NIH Innovation Account (incl. \$86 million for BRAIN Initiative)	Century Cures NIH Innovation Account (incl. \$86 million for BRAIN Initiative)
NINDS	\$1.783 billion	\$1.356 billion	\$1.810 billion	\$1.905 billion

#### 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.

<u>House Appropriations.</u> On July 19, 2017, the House Appropriations Committee <u>approved</u> the FY 2018 Labor, Health and Human Services, Education funding bill, <u>H.R. 3358</u>. 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.

In July 2017, the House introduced <u>H.R. 3354</u>, which packages together the eight regular appropriations bills for FY 2018, including the Labor, Health and Human Services, Education

funding bill. <u>H.R. 3354</u> passed the House on September 14, 2017. There has been no action on an omnibus appropriations bill in the Senate.

<u>Senate Appropriations.</u> On September 7, 2017, the Senate Appropriations Committee approved the FY 2018 Labor, HHS, Education bill, <u>S. 1771</u>. The bill contains funding for NIH in the amount of \$36.1 billion, a \$2 billion increase over FY 2017, including a \$414 million increase for Alzheimer's disease research and a \$140 million increase for the BRAIN Initiative that includes \$86 million; \$43 million for NINDS and NIMH, respectively from the NIH Innovation Account.

The bill rejects the President's proposal to dramatically cut facilities and administrative costs (indirect costs), and includes language to ensure NIH adheres to its current policies for calculating these costs.

Continuing Resolutions (CR). A Continuing Resolution (P.L. 115-56, Continuing Appropriations Act, 2018 and Supplemental Appropriations for Disaster Relief Requirements Act, 2017) was passed by Congress and signed by the President on September 8, 2017, to extend government funding through December 8, 2017 and give Congress more time to work on a full FY 2018 appropriations package. This CR was added to a legislative package that includes \$15.25 Billion in emergency funding for hurricane recovery as well as a suspension of the debt limit through December 8, 2017.

Since December 8, 2017, three additional CRs have been in effect. On December 7-8, 2017, House and Senate passed and the President signed <u>H.J.Res. 123/P.L. 115-90</u>, a two-week CR to keep the government funded at the FY 2017 funding level through December 22, 2017. On December 21, 2017, Congress passed and the President signed the third CR (<u>H.R. 1370/P.L. 115-96</u>) for FY 2018 to prevent a government shutdown and extend government funding through January 19, 2018. Following a 3 day government shutdown, Congress passed and the President signed a fourth CR to fund the government through February 8, 2018 (<u>H.R.195</u>).

#### **Supplemental Appropriations for FY 2018**

On December 21, 2017, the House passed <u>H.R. 4667</u> "Making further supplemental appropriations for the fiscal year ending September 30, 2018, for disaster assistance for Hurricanes Harvey, Irma, and Maria, and calendar year 2017 wildfires, and for other purposes," by a vote of <u>251-169</u>. This \$81 billion disaster relief measure includes \$15 million for NIH. If enacted, \$15 million would be transferred to the NIH Office of the Director for the purpose of supporting the repair or rebuilding of non-Federal biomedical or behavioral research facilities damaged as a result of the hurricanes. The Senate has not yet taken up the bill.

# 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 / 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 113<sup>th</sup> and 114<sup>th</sup> Congresses as <u>H.R. 1757</u> and <u>H.R. 1636</u>, 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 114<sup>th</sup> 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.

### 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.

### **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

### **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 / 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).

### **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 / 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 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 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 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 (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 and was referred to the Senate Committee on the Judiciary. The bill is identical to S. 3077 from the 114<sup>th</sup> Congress. No further action has occurred.

### **Medical Research Funding**

S. 640 American Cures Act

**Background:** The identical bill has been introduced in the 113<sup>th</sup> and 114<sup>th</sup> Congresses by Senator Richard Durbin (D-IL). A House version of the same bill has been introduced in the 114<sup>th</sup> 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 114<sup>th</sup> 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 114<sup>th</sup> 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.

# **Recent Hearings of Interest**

### **Hearings on Opioid Crisis**

Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies Hearing "Addressing the Opioid Crisis in America: Prevention, Treatment, and Recovery"

December 5, 2017

The Senate L-HHS Appropriations Subcommittee held a hearing to identify areas of priority that FY 2018 funding should focus on when addressing the opioid crisis. Witnesses included Dr. Francis S. Collins (Director, NIH), the Honorable Patrick J. Kennedy (Former Congressman (D-RI), President's Commission on Combatting Drug Addiction and the Opioid Crisis), Dr. Elinore McCance-Katz (Assistant Secretary for Mental Health and Substance Use, SAMHSA), and Dr. Debra Houry (Director, National Center For Injury Prevention And Control, CDC). In his statement, Dr. Collins highlighted the research progress made by NIH, including Narcan, the nasal spray form of naloxone that resulted from NIH's partnership with industry. He also talked about a public-private partnership among NIH, FDA, and more than thirty pharmaceutical companies that aims to develop more potent, non-addictive pain treatments as well as more effective ways to reverse overdose. Subcommittee members were interested in what Congress could do to help NIH accelerate research efforts in pain/opioid research that would help solve the opioid crisis.

House Energy and Commerce Committee Hearing "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives"
October 25, 2017

In 2016, the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act became public law. A number of provisions included in these Acts provide funding to help states and territories combat addiction and establish strategies and new programs to address the opioid crisis. On October 25, 2017, the House Energy and Commerce Committee held a hearing to get a status update on how these provisions are being implemented. Dr. Nora Volkow (Director, the National Institute on Drug Abuse (NIDA)) testified, and discussed the current state of research on more effective drugs for addiction treatment and non-opioid alternatives of pain treatment.

#### **Hearings on 21st Century Cures Act Implementation**

Senate Health, Education, Labor & Pensions (HELP) Committee Hearing
"Implementation of the 21st Century Cures Act: Progress and the Path Forward for Medical Innovation"

December 7, 2017

Dr. Francis Collins (NIH) and Dr. Scott Gottlieb (FDA) testified before the Senate HELP Committee to update the Committee on progress that NIH and FDA have made since the 21st

Century Cures Act became Law. Members expressed significant bipartisan support for biomedical research supported by NIH, and were interested in a wide variety of topics such as the BRAIN Initiative, regenerative medicine, opioid/pain research, how NIH prioritizes funding, and supporting the future generation of young scientists.

House Energy and Commerce Committee Hearing "Implementing the 21st Century Cures Act: An Update from FDA and NIH"

November 30, 2017

The House Energy and Commerce Committee also held a hearing to examine how the 21<sup>st</sup> Century Cures Act has been implemented by the NIH and FDA. Dr. Francis Collins (NIH) and Dr. Scott Gottlieb (FDA) appeared as witnesses. Dr. Collins thanked the Committee for the additional funding provided through the 21<sup>st</sup> Century Cures Act that has accelerated research progress for the NIH Innovation Projects, which include the BRAIN Initiative, Cancer Moonshot, Regenerative medicine, and All of Us. Members asked about advances in Alzheimer's disease, cancer therapies, new antibiotics, and pain treatments, and were interested in what NIH could do in terms of regulating drug prices and supporting the next generation of biomedical researchers.