



National Institute of
Neurological Disorders
and Stroke



LEGISLATIVE UPDATE:
Overview of Legislation from the 116th Congress
September 2020

NINDS OFFICE OF SCIENCE POLICY & PLANNING

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Appropriations Update

	FY 2019 Appropriations	FY 2020 Appropriations	FY 2021 President's Budget	FY 2021 House Appropriations
NIH	\$39.1 billion, including \$711 million from 21 st Century Cures NIH Innovation Account (incl. \$115 million for the BRAIN Initiative), and \$500 million for research related to pain and opioids	\$41.7 billion, including \$492 million from the 21 st Century Cures NIH Innovation Account (incl. \$140 million for the BRAIN Initiative) and \$500 million for research related to pain and opioids	\$38.7 billion, including \$404 million from the 21 st Century Cures NIH Innovation Account (incl. \$100 million for the BRAIN Initiative) and \$533 million for the HEAL Initiative	\$47 billion, including \$404 million from the 21 st Century Cures NIH Innovation Account (incl. \$100 million for the BRAIN Initiative), \$537 million for the HEAL initiative and research related to opioids, and \$5 billion in COVID-19 emergency funding to offset costs of lost research productivity
NINDS	\$2.274 billion, including \$57.5 million for the BRAIN Initiative and \$250 million for research related to pain and opioids	\$2.445 billion, including \$70 million for the BRAIN Initiative and \$250 million for research related to pain and opioids	\$2.245 billion, including \$50 million for the BRAIN Initiative and \$250 million for research related to pain and opioids	\$2.622 billion, including \$50 million for the BRAIN Initiative, \$268 million for research related to pain and opioids, and \$157 million in COVID-19 emergency funding from NIH OD to offset costs from lost productivity

FY 2020

FY 2020 Appropriations. On December 16, 2019, the House and Senate Appropriations Committees released the FY2020 Further Consolidated Appropriations Act that includes spending bills for Labor, Health and Human Services and Related Agencies which include NIH ([H.R. 1865](#)). The President signed the bill (now Public Law No: 116-94) on December 20, 2019, ending the second Continuing Resolution since the beginning of FY 2020. The agreement provides \$41.7 billion for NIH, including \$492 million from the 21st Century Cures Act, and \$2.44 billion for NINDS. NIH receives an increase of \$2.6 billion (6.7% percent) above FY 2019 enacted level, which provides no less than 3.3% funding increase above FY 2019 enacted level for every Institute and Center at NIH. Also included in the agreement are a total of \$2.8 billion for AD/ABRD research, \$500 million for the BRAIN Initiative, \$500 million for opioid/pain research, \$50 million for the Childhood Cancer Data Initiative, and \$12.5 million for

firearm research, including by tracking gun-related deaths and injuries, as well as identifying correlations like the relationship between victim and shooter.

FY 2020 COVID-19 Supplemental Appropriations

Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. On March 4, 2020, the House passed [H.R. 6074](#), the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. On March 5, 2020, the Senate passed H.R. 6074 by a vote of 96-1, and the President signed this bill into law on March 6, 2020. The law provides \$8.3 billion in emergency supplemental appropriations for federal agencies to address the COVID-19 pandemic in the U.S. In this bill, \$836 million was distributed to NIAID to prevent, prepare, and respond to coronavirus with at least \$10 million to be transferred to NIEHS for worker-based training to prevent and reduce exposure of hospital employees, emergency first responders, and other frontline workers who are at risk of exposure to coronavirus through their work duties.

Coronavirus Aid, Relief, and Economic Security (CARES) Act. On March 25, 2020, the Senate passed [H.R. 748](#), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, by a vote of 96-0. The House passed the bill on March 27, 2020, and the President signed it into law on the same day. The law provides \$2 trillion in funding to address the health and economic effects of COVID-19 in the U.S., including additional funds to NIH. These funds are distributed to prevent, prepare for, and respond to coronavirus, domestically and internationally as follows: \$103 million for NHLBI, \$706 million for NIAID, \$60 million for NIBIB, \$10 million for NLM, \$36 million for NCATS, and \$30 million for the Office of the Director.

Paycheck Protection Program and Health Care Enhancement Act. On April 21, 2020 the Senate passed [H.R. 266](#), the Paycheck Protection Program and Health Care Enhancement Act by a voice vote, and on April 23, the House passed it by a vote of 388-5. The President signed H.R. 266 into law on April 24, 2020. The law provides \$383.4 billion in funding to recapitalize programs and address the health and economic effects of COVID-19. The law includes an additional \$1.8 billion for NIH to develop, improve and implement testing and associated technologies. Of the funds provided for NIH: \$306 million is allocated to NCI for serological testing, \$500 million is allocated to NIBIB to accelerate research and point of care. \$1 billion is allocated to the Office of the Director develop, validate, improve, and implement testing and associated technologies; to accelerate research, development, and implementation of point of care and other rapid testing; and for partnerships with governmental and non-governmental entities to research, develop, and implement the activities referred to above. The OD funds may be transferred to the accounts of the Institutes and Centers of the NIH for coronavirus-related purposes.

Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act. On May 12, 2020, [H.R. 6800](#), the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) was introduced in the House. On May 15, 2020, the House passed H.R. 6800 by a vote of 208-199. No further action has occurred as of May 19, 2020. The bill, if enacted, would provide \$4.745 billion to NIH for expanding COVID-19-related research on the NIH campus and at academic institutions across the country and to support the shutdown and startup costs of biomedical research laboratories nationwide. If enacted, it would provide NIAID with \$500

million and NIMH with \$200 million to prevent, prepare for, and respond to coronavirus. The Office of the Director (OD) would receive \$3 billion to offset the costs related to reductions in lab productivity resulting from the coronavirus pandemic and up to \$1.02 billion would be to support additional scientific research or the programs and platforms that support research. The OD funds may be transferred to the accounts of Institutes and Centers of the NIH. The bill also includes 1) a provision to make the remaining unobligated balances of the FY2020 funds in the NIH Accounts available for one additional fiscal year, through FY 2021, and 2) a provision that would make funds that were available for obligation through FY 2015 and were obligated for multi-year research grants to be available through FY 2021, if the NIH Director determines that the project suffered an interruption of activities attributable to SARS-CoV-2.

Coronavirus Response Additional Supplemental Appropriations Act, 2020. On July 27, 2020, the Senate introduced [S. 4320](#), the Coronavirus Response Additional Supplemental Appropriations Act, 2020 as part of the 4th COVID-19 stimulus package, Health, Economic Assistance, Liability Protection and Schools (HEALS) Act. No further action has occurred since the bill's introduction. The bill, if enacted, would provide \$15.5 billion in supplemental appropriations to NIH with five-year availability. These funds would be distributed for research to prevent, prepare for, and respond to coronavirus, domestically and internationally, as follows: \$290 million for NHLBI, \$200 million for NIDDK, \$172.6 million for NICHD, \$200 million for NIMH, \$64.3 million for NIMHD, \$1.22 million for NCATS, and \$480.5 million for NIAID, to include \$55 million for Regional Biocontainment Laboratories. This bill would also provide \$12.9 billion for the Office of the Director, which would include \$10.1 billion for offsetting the costs related to reductions in lab productivity, \$1.3 billion for additional scientific research, \$1.24 billion to accelerate the research and development of therapeutic interventions and vaccines in partnership, and \$240 million for supplements to existing research training awards for extensions and other costs. These OD funds may be transferred to the accounts of Institutes and Centers of the NIH.

FY2021

FY 2021 President's Budget. The [President's Budget](#) for FY2021 was released on February 10, 2020. The Budget proposes \$38.7 billion in FY 2021 funding for NIH (\$3.0 billion below FY 2020 enacted funding; 7.2% decrease), including \$404 million in resources available through the 21st Century Cures Act and a total of \$1.4 billion to support research on pain and opioids across NIH. The proposal also includes \$355 million to the new National Institute for Research on Safety and Quality (NIRSQ) to continue research currently administered by the Agency for Healthcare Research and Quality (AHRQ), \$30 million to create a consortium with industry, academic, and federal stakeholders to scale up and increase the efficiency of vector production to speed up new gene therapy clinical trials and patient treatments, \$300 million to continue the long-term effort to strengthen stewardship of NIH buildings and facilities, and \$50 million to support research on pediatric cancer.

FY 2021 House Appropriations. On July 13, 2020, the House Appropriations Committee voted to approve the [FY 2021 Labor, Health and Human Services, and Education appropriations bill](#). The bill provides \$47 billion for NIH, which includes \$42 billion for annual appropriations and

\$5 billion in COVID-19 emergency appropriations for the NIH OD to offset costs from lost research productivity (no less than \$2.5 billion must be transferred to NIH ICs in proportion to their share of appropriations in FY 2020). This bill also includes \$404 million from the 21st Century Cures NIH Innovation Account as well as targeted funds for several research areas, including \$2.9 billion for Alzheimer's disease, \$500 million for the All of Us precision medicine research initiative, \$500 million for the BRAIN Initiative, and \$537 million for the HEAL initiative and opioid-related research. Also included in the bill are \$25 million for research to help prevent firearm-related injuries and mortality, \$80 million for Research Centers in Minority Institutions, and \$50 million for the Childhood Cancer Data Initiative.

For NINDS, the bill provides \$2.622 billion, and \$50 million from the NIH Innovation Account will be transferred to NINDS and NIMH respectively for the BRAIN Initiative. The Committee also provides \$268 million for the HEAL Initiative for NINDS and NIDA, respectively. The bill provides NINDS with \$157 million in COVID-19 emergency funding transferred from NIH OD to offset the costs from lost research productivity.

On July 31, 2020, the House approved its first package of FY 2021 spending measures by a vote of 217-197. This 6-bill minibus ([H.R. 7617](#)) combines 6 of the 12 annual appropriations bills needed for the new fiscal year: Labor-HHS-Education that includes the NIH budget, Defense, Commerce-Justice Science, Energy and Water Development, Financial Services and General Government, and Transportation-Housing and Urban Development bills. In the approved minibus package, there are no major changes to the previously introduced Labor-HHS-Education bill that would affect NIH.

FY 2021 Senate Appropriations. The Senate Appropriations Committees have not yet introduced any of their FY2021 bills.

Legislation of Interest to NINDS Introduced in the 116th Congress

ALS

[H.R. 5480](#): *ALS Placebo No More Act*

Background: The bill was introduced to expand the role of the Federal Government in developing incentives to expand access to investigational therapies for life-threatening conditions with fewer than two treatments.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would require the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) to collaborate on any current amyotrophic lateral sclerosis (ALS) trial to ensure that all patients in treatment and placebo arms are provided access to the drug. The bill also requires FDA to move expeditiously to implement its guidance on ALS clinical trials to assure that all trials going forward shall require treatment arms for all patients.

Status: On December 18, 2019, Representative Jeff Fortenberry (R-NE) introduced the ALS Placebo No More Act to the House Committee on Energy and Commerce. The bill was referred to the Subcommittee on Health on December 19, 2019. No further action has occurred.

[H.R. 7071](#): *Accelerating Access to Critical Therapies for ALS Act*

Background: This bill was introduced with the goal of accelerating access to clinical therapies for the treatment of amyotrophic lateral sclerosis and other rapidly progressive neurodegenerative diseases by establishing a grant program, as well as a new FDA center, the Center of Excellence for Neurodegenerative Diseases. The center shall have duties and authorities similar to those of the FDA's Oncology Center of Excellence, which helps expedite the development of medical products and assists providers in requesting access to investigational drugs. This bill would authorize \$75 million per year for FY2021-2022 and \$150 million per year for FY 2023-2024. to carry out the activities in this Act.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would direct the Secretary of HHS to establish a grant program in collaboration with NIH to facilitate access to investigational therapies for amyotrophic lateral sclerosis and other rapidly progressive neurodegenerative diseases.

Status: On June 1, 2020, Representative Jeff Fortenberry (R-NE) introduced the Accelerating Access to Critical Therapies for ALS Act to the House Committee on Energy and Commerce. No further action has occurred.

Autism

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

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

Status: H.R. 1058 was introduced by Representative Christopher Smith (R-NJ) and referred to the House Committee on Energy and Commerce on February 7, 2019. S. 427 was introduced by Senator Robert Menendez (D-NJ) and referred to the Senate Committee on Health, Education, Labor, and Pensions on February 7, 2019. On July 24, 2019 the House passed H.R. 1058, under suspension of the rules, by voice vote. No further action has occurred.

Lyme Disease and Other Tick-Borne Diseases

H.R. 220: *National Lyme Disease and Tick-borne Diseases Control and Accountability Act of 2019*

Background: Bills similar to H.R. 220 have been introduced during the 113th, 114th, and 115th Congresses by Representative Christopher Smith (R-NJ), but no further action was taken.

Provisions of the Legislation/Impact on NIH: This bill, if enacted, would direct the Secretary of HHS to expand and intensify epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne diseases and encourage the solicitation of proposals for collaborative, multidisciplinary research that would involve national research institutes and national centers of the NIH in intramural and extramural research on tick-borne disease, such as the NINDS conducting or sponsoring research on neurologic Lyme disease. The bill also directs the Secretary in cooperation with the Director of the Office, and acting through the Directors of CDC and NIH to conduct and support research to develop new and improved diagnostic tests for tick-borne diseases, as well as sponsor a state-of-the-science conference on Lyme disease and other tick-borne disease including identification of research gaps and top research priorities no later than 24 months after the date of enactment.

Status: On January 3, 2019, H.R. 220 was introduced by Rep. Chris Smith (R-NJ) and was referred to the House Committee on Energy and Commerce. No further action has occurred.

Marijuana Research

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

Background: The CARERS Act has previously been introduced during the 114th, and 115th Congresses by Representative Steve Cohen (D-TN) and Senator Cory Booker (D-NJ); however, no further action was taken. This bill is identical to [H.R. 2920](#) in the 115th Congress.

Provisions of the Legislation/Impact on NIH: Among other provisions, the bill, if enacted, would exclude cannabidiol from the definition of marijuana, terminate the “Guidance on Procedures for the Provision of Marijuana for Medical Research,” and require the DEA to issue

at least 3 licenses to manufacture and distribute marijuana and marijuana-derivatives for research approved by the FDA.

Status: H.R.127 was introduced by Representative Steve Cohen (D-TN) on January 3, 2019, and was jointly referred to the House Committees on Energy and Commerce, the Judiciary, and Veterans' Affairs. No further action has occurred.

[H.R. 4322 /S. 2400](#): *Expanding Cannabis Research and Information Act*

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would give the Director of NIH authority to designate institutions of higher education as Centers of Excellence to do interdisciplinary research related to cannabis.

Status: H.R. 4322 was introduced by Representative Donna Shalala (D-FL) on September 12, 2019 and was referred to the Committee on Energy and Commerce. On October 2, 2019, the bill was referred to the Subcommittee on Crime, Terrorism, and Homeland Security. S. 2400 was introduced by Senator Richard Durbin (D-IL) on July 31, 2019, and was referred to the Committee on Health, Education, Labor, and Pensions. No further action has occurred.

ME/CFS

[H.R. 7057](#): *Understanding COVID-19 Subsets and ME/CFS Act*

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would direct the NIH Director to coordinate with the NINDS Director to conduct and support research and related activities concerning the diagnosis, treatment, and risk factors of post-viral chronic neuroimmune diseases, specifically ME/CFS, COVID-19 patients exhibiting ME/CFS symptoms, and survivors of COVID-19 with ME/CFS, implement a system to collect data on ME/CFS, award grants and contracts to public or non-profit private entities to expand collaborative research centers for ME/CFS, develop a research agenda in coordination with the NINDS Director, Trans-NIH ME/CFS Working Group, interagency partners, stakeholders, and disease experts, prioritize and expand ME/CFS research programs, and submit a report to Congress no later than 24 months after the date of enactment of the Act on the progress made in gathering data and expanding research on the onset and clinical care of COVID-19 survivors with ME/CFS. The bill would authorize funds (\$15 million/year from FY 2021 to FY 2024; a total of \$60 million) to carry out the activities included in the Act. The bill also directs the Secretary of HHS to engage in public awareness and education activities to increase understanding and recognition of ME/CFS.

Status: On May 28, 2020, Representative Jamie Raskin (D-MD) introduced H.R. 7057, the Understanding COVID-19 Subsets and ME/CFS Act, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

SBIR and STTR awards

[H.R. 206](#): *Encouraging Small Business Innovation Act*

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would expand the funding opportunities for SBIR and STTR awards to include small business investment companies.

Status: On January 3, 2019, Representative Harley Rouda (D-CA) introduced H.R. 206, the Encouraging Small Business Innovation Act, which was referred to the House Committee on Small Business and Science, Space, and Technology. On January 14, 2019, the bill passed the House. On January 15, 2019, the bill was received in the Senate and referred to the Senate Committee on Small Business and Entrepreneurship. No further action has occurred.

Scientific Integrity

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

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

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

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

Tourette Syndrome

[*H.R. 1131*](#): *Collaborative Academic Research Efforts for Tourette Syndrome Act of 2019*

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

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

Status: H.R. 1131 was introduced by Representative Albio Sires (D-NJ) and referred to the House Committee on Energy and Commerce on February 8, 2019. No further action has occurred.

Unruptured Intracranial Aneurysms

***H.R. 594:** To provide for further comprehensive research at the National Institute of Neurological Disorders and Stroke on unruptured intracranial aneurysms*

Background: Previously introduced as Ellie’s Law, this bill was first introduced by Rep. Yvette Clarke (D-NY) and Rep. Renee Ellmers (R-NC) in the 114th Congress but no further action was taken. It was introduced again in the 115th Congress. No further action was taken. The bill is named in remembrance of Ellie Helton, a 14-year-old from North Carolina, who unexpectedly passed away from a ruptured aneurysm.

Provisions of the Legislation/Impact on NIH: This bill would support further comprehensive research on unruptured intracranial aneurysms to study a broader patient population diversified by age, sex, and race by authorizing \$5,000,000 to be appropriated to the NINDS for each of fiscal years 2020 through 2024, to remain available through September 30, 2027.

Status: H.R.594 was introduced by Rep. Yvette Clark (D-NY) on January 16, 2019, and was referred to the House Committee on Energy and Commerce. No further action has occurred.

Legislation of Interest to NIH Introduced in the 116th Congress

Federal Advisory Committee Act (FACA)

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

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

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

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

Fetal Tissue Policy

Background: On June 5, 2019, the Department of Health and Human Services (HHS) [announced](#) that the Administration will not renew an existing contract with the University of California at San Francisco to develop mice with humanized immune systems using human fetal tissue and will discontinue research in the NIH intramural research program that requires new acquisition of fetal tissue from elective abortions.

Impact on NIH: Universities and other institutions that have already received funds from NIH to carry out research using human fetal tissue may continue their work. However, for any new or competitively renewing applications for grants and cooperative agreements submitted for due dates on or after September 25, 2019 and R&D contract proposals submitted to solicitations issued after September 25, 2019 that involve the proposed use of human fetal tissue obtained from elective abortions, an ethics advisory board will be convened to review the research proposal and recommend whether, in light of the ethical considerations, NIH should fund the research project—pursuant to a law passed by Congress. HHS will also undertake changes to its regulations and NIH grants policy to adopt or strengthen safeguards and program integrity requirements applicable to extramural research involving human fetal tissue. [The Human Fetal Tissue Research Ethics Advisory Board](#) met on July 31, 2020 to discuss 14 research proposals, which included both grants and contracts. The Board voted to recommend that HHS Secretary Alex Azar withhold funds for 13 of the research proposals and not withhold funds for one research proposal. Secretary Azar will make a final decision about whether to fund each proposal.

Status: NIH released two notices (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html>; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-137.html>) on July 26,

2019, and August 23, 2019, to inform the extramural research community of the new HHS requirements and a recently published [Frequently Asked Questions \(FAQs\)](#) to provide guidance about changes regarding NIH-supported research involving the use of human fetal tissue.

Foreign Influence on Research

[S. 2133](#) / [H.R.3038](#): *Secure American Research Act of 2019 / Securing American Science and Technology Act of 2019*

Background: This bill was introduced for the first time in the 116th Congress in order to establish an interagency working group for coordination and development of Federal research protection, and for other purposes.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would establish an interagency working group to coordinate activities to protect federally funded research and development from foreign interference, cyberattacks, theft, or espionage and to develop common definitions and best practices for Federal science agencies and grantees. Membership of this interagency working group would include a representative from NIH.

Status: On July 16, 2019, Senator Jon Cornyn (R-TX) introduced S. 2133, the Secure American Research Act of 2019. S. 2133 was referred to the Senate Committee on Homeland Security and Governmental Affairs. On May 30, 2019, Representative Mikie Sherrill (D-NJ) introduced H.R. 3038 which was referred to the Committee on Science, Space, and Technology. No further action has occurred.

Pain and Opioids Research

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

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

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

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

Patient-Centered Outcomes Research Institute Reauthorization

[S. 2897](#): *Patient-Centered Outcomes Research Institute (PCORI) Reauthorization Act*

Background: Patient-Centered Outcomes Research Institute (PCORI) is a non-profit corporation to fund comparative effectiveness research and is funded through the Patient-Centered Outcomes Research Trust Fund. During FY2013-FY2019 PCORI received about \$150 million from this fund annually but the funding expired at the end of FY2019. [H.R. 3030](#) is a related bill that was introduced on June 4, 2019 by Representative Diana DeGette (D-CO).

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would extend appropriations and transfers to the Patient-Centered Outcomes Research Trust Fund, thereby reauthorizing the PCORI. The bill requires the PCORI-funded research to take outcomes data into account, establishes a new expert advisory panel for high-impact research, and increases the membership of the PCORI Board to 27. NIH is represented on the PCORI Board of Governors, and the methodology committee. In addition, NIH collaborates with PCORI on research projects.

Status: S. 2897 was referred to the Senate Committee on Finance by Senator Mark Warner (D-VA) and no further action has occurred. This particular bill was not enacted. However, the FY2020 L-HHS Appropriations bill that was enacted on December 20, 2019, extends funding for PCORI from FY2020 through FY2029.

Sexual Harassment in Science

[H.R. 36](#): *Combatting Sexual Harassment in Science Act of 2019*

Background: The purpose is to provide for research to better understand the causes and consequences of sexual harassment affecting individuals in the scientific, technical, engineering, and mathematics workforce and to examine policies to reduce the prevalence and negative impact of such harassment, as well as for other purposes. This bill has not been introduced in previous Congresses.

Provisions of the Legislation/Impact on NIH: The bill, if enacted, would require that the Director of the Office of Science and Technology Policy (OSTP) to establish an interagency working group for the purpose of coordinating Federal science agency efforts to reduce the prevalence of sexual harassment and gender harassment involving grant personnel and develop policy guidelines in this space that apply to all Federal science agencies.

Status: On January 3, 2019, H.R. 36 was introduced by Representative Eddie Bernice Johnson (D-TX), and was reported (amended) by the Committee on Science, Space, and Technology on July 12, 2019. The bill passed the House on July 23, 2019 and was received in the Senate to be referred to the Committee on Health, Education, Labor, and Pensions on July 24, 2019. No further action has occurred.

Trans-NIH Initiatives

H.R. 3: *Elijah E. Cummings Lower Drug Costs Now Act*

Background: H.R. 3 is a package bill that includes a number of measures that reflect priorities of the House majority (Democrats) regarding drug costs. This bill has not been introduced in previous Congresses. Following approval by the House, the bill has been sent to the Senate for consideration, but is not expected to be approved by the Senate.

Provisions of the Legislation/Impact on NIH: Of interest to NIH the bill would 1) provide/extend funding for the NIH Innovation Projects authorized in the 21st Century Cures Act (All of Us, BRAIN Initiative, Cancer Moonshot, Regenerative Medicine) through 2030, 2) create a new NIH Innovation Project to support research on rare diseases and provide its funding for FY 2021-2030, 3) establish a Clinical Trial Accelerator pilot program at NIH to award multi-year contracts to eligible entities to support phase II clinical trials and phase III clinical trials, and 4) provide NIH with \$240 million for each of FY 2021-2025 to carry out activities related to opioid use disorders and pain management research. In addition, the bill would authorize NIH to award grants or contracts to SBIR/STTR awardees to develop, expand, and enhance the commercialization of biomedical products.

Status: On September 19, 2019, H.R. 3 was introduced by Representative Frank Pallone (D-NJ) and was referred to the House Energy and Commerce Committee. December 12, 2019, the House passed H.R.3 by a recorded vote of 230-192. No further action has occurred.