



National Institute of
Neurological Disorders
and Stroke



LEGISLATIVE UPDATE:
Overview of Legislation from the 114th Congress
May 2016

NINDS OFFICE OF SCIENCE POLICY & PLANNING

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Appropriations Update

	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 House Appropriations Committee	FY 2016 Senate Appropriations Committee	Consolidated Appropriations Act, 2016	FY 2017 President's Budget
NIH	\$30.3 billion	\$31.3 billion	\$31.4 billion	\$32.3 billion	\$32.3 billion	\$33.1 billion
NINDS	\$1.60 billion	\$1.66 billion	\$1.66 billion	\$1.695 billion	\$1.695 billion	\$1.695 billion

FY 2016

In the absence of any enacted appropriations bills at the start of FY 2016 (October 1, 2015), Congress passed a series of three Continuing Resolutions to fund the government ([P.L. 114-53](#), [P.L. 114-96](#), [P.L. 114-100](#)) as an Omnibus appropriations bill was being negotiated. In late October and early November, Congress also passed, and the President signed into law ([P.L. 114-74](#)) the Bipartisan Budget Agreement, a two-year budget package that included a suspension of the debt ceiling and top-line spending levels.

On December 18, 2015, the House passed the Consolidated Appropriations Act, 2016 (Omnibus) by a vote of [316-113](#), which the Senate passed by a vote of [65-33](#) and the President signed into law ([P.L. 114-113](#)). Under this bill, NIH receives a \$2 billion boost (~6.5%) over FY2015 enacted levels, totaling \$32 billion in FY2016, including \$1.70 billion for NINDS. The bill directs \$150 million, an increase of \$85 million, to the BRAIN Initiative, pooled from various ICs. It also provides a \$350 million increase to NIA for Alzheimer's disease research, \$200 million for the Precision Medicine Initiative (\$130 million in the Common Fund and \$70 million to NCI), and \$100 million increase to combat antimicrobial resistance. The bill includes a number of provisions affecting NIH, including provisions to: 1) enter into an agreement with the National Academy of Sciences for a study of policies affecting the next generation of researchers in the U.S.; 2) increase stipends for NRSA grantees at least consistent with the Federal employee pay raise; 3) strengthen privacy protections for human research participants; and 4) continue to support high-risk, high-reward research.

FY 2017

The FY2017 President's budget was released on February 9, 2016. The President requested \$33.136 billion for NIH for FY2017, \$825 million (2.5%) above the FY2016 level. The request includes \$1.825 billion from mandatory funds and a \$1.067 billion reduction in discretionary funds relative to FY2016. Based on comments from Committee Members during the House and Senate L-HHS Appropriations hearings, both Democrats and Republications expressed concern with using mandatory funding streams to fund NIH, citing feasibility and lack of appropriate oversight. Meanwhile, several Committee Members supported identifying potential ways to maintain or increase overall NIH funding through discretionary spending.

Of the total requested funds for NIH in FY2017, \$680 million would support the Cancer Moonshot Initiative, \$300 million (\$100 million increase) would support the Precision Medicine Initiative and \$195 million (\$45 million increase) would support the BRAIN Initiative. The budget request states that NIH would spend \$910 million on Alzheimer's research in FY2017 (the same amount as in FY2016), spread across NIA, NINDS, and other ICs. The budget request also states that NIH should continue to emphasize High-Risk, High Reward research.

Pending Legislation Directly Relevant to NINDS

21st Century Cures Initiative (House) / Continuing America's Leadership in Medical Innovation for Patients (Senate)

Background: In April 2014, House Energy and Commerce Committee Chairman Fred Upton (R-MI) and Congresswoman Diana DeGette (D-CO) began the bipartisan *21st Century Cures Initiative* (<http://energycommerce.house.gov/cures>) to help accelerate the discovery, development, and delivery of promising new treatments. They hosted 12 hearings and roundtable discussions in Washington, DC from May through September, 2014, and House Members held additional roundtable discussions in their local districts. They solicited ideas from expert witnesses, government agencies, and the public on how to modernize regulatory procedures to keep pace with scientific and technological advances, how to foster new therapeutic development, and how to ensure that these new treatments reach the people who need them. On January 27, 2015, they released the first discussion draft, which was a 393-page document intended to start the conversation about potential provisions of the bill. The bill underwent substantial revisions before it passed the House on July 10, 2015.

The Senate Health, Education, Labor and Pensions (HELP) Committee is conducting a parallel effort through a bipartisan working group led by Senator Lamar Alexander (R-TN) and Senator Patty Murray (D-WA). On January 29, 2015, they kicked off the Senate effort by releasing a white paper titled [Innovation for Healthier Americans: Identifying Opportunities for Meaningful Reform to Our Nation's Medical Product Discovery and Development](#), and since then the Committee has held [four hearings](#) on the discovery and development process for drugs and medical devices.

While the Senate HELP Committee originally planned to release their own draft of a bill (rather than take up the House version) by the end of 2015, they later decided to consider several stand-alone bills. In three markup sessions (February 9, March 9, and April 6, 2016), the Committee reported 19 bills aimed at enhancing NIH and FDA. During the latter two markups, Senator Elizabeth Warren (D-MA) introduced and withdrew an amendment ([S. 2624](#)) which would provide mandatory funding to NIH and FDA (*see page 27 for details*). Democrats have stated that they would like to see mandatory funding for NIH included in a final Senate bill. Chairman Alexander has suggested he is open to considering mandatory funding for NIH for targeted, time-limited initiatives (e.g., BRAIN, Precision Medicine, and Cancer Moonshot Initiatives). As of this writing, plans for a final Senate package were not clear.

H.R. 6 *21st Century Cures Act*

Provisions of the Legislation/Impact on NIH: The House-passed 21st Century Cures bill includes four titles.

Title 1: Discovery is largely focused on NIH. Provisions in this title would:

- Authorize \$1.5 billion increases in NIH base funding levels for each of the next 3 years and create the NIH Innovation Fund, which would be funded by an additional \$1.75 billion for each of the next five years, supplementing, not supplanting regular NIH

appropriations. The Innovation Fund would be distributed to ICs for high risk, high reward research, early stage investigators, and both person- and project-based grants.

- Increase NIH accountability by mandating NIH-wide strategic planning, creating 5 year renewable terms for IC Directors, requiring IC directors to review and certify each R-series grant, and calling for the IOM to conduct a study on duplication.
- Require the NIH Director to implement measures to reduce the administrative burden on grantees, taking into account recommendations, evaluations and plans researched by the Scientific Management Review Board, the National Academy of Sciences, the 2007 and 2012 Faculty Burden Survey, and the Research Business Models Working Group.
- Support young scientists by updating the loan repayment program and requiring a report on NIH's efforts to attract, retain, and develop emerging scientists, including underrepresented individuals in the sciences, such as women and minorities.
- Establish a Capstone Grant Program to facilitate lab closures at the end of a scientist's career.
- Establish a prize competition program within NIH to incentivize health innovation by offering competitors the chance to win a prize for creating breakthrough research and technology.
- Exempt NIH from government-wide restrictions on data collection under the Paperwork Reduction Act.
- Establish the National Neurological Diseases Surveillance System at the Centers for Disease Control (CDC) to collect incidence, prevalence and other data on neurological diseases.
- Improve data sharing and data registries, including authorizing the NIH Director to mandate sharing of certain types of data; standardizing data in www.clinicaltrials.gov, implementing a system to make all clinical trial data from qualified clinical trials available for conducting further research; requiring NIH to fund grants to collect and interpret data on the natural history of diseases, particularly for rare diseases; and requiring the HHS Secretary to revise several provisions in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to clarify certain permissible uses of protected health information.
- Focus on pediatric research, including requiring the establishment of the National Pediatric Research Network, voicing support for the establishment of a global pediatric clinical trials network, and requiring NIH to develop guidelines on addressing the consideration of age as an inclusion variable in research involving human subjects.
- Give NCATS more flexibility and the authority to conduct a broader range of research.
- Encourage vaccine, antibiotic, and Lyme disease research as well as high risk, high reward research.
- Establish the Council for 21st Century Cures, which would be a non-profit corporation, public-private partnership tasked with accelerating the "discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients".
- Express the "Sense of Congress" that participation in or sponsorship of scientific conferences and meetings is essential to the mission of NIH and that NIMHD should include within its strategic plan ways to increase representation of underrepresented communities in clinical trials.

Title II: Development is focused on the Food and Drug Administration (FDA) and includes provisions on clinical trial design, the review process for drugs and devices, manufacturing processes and oversight, hiring and pay for FDA employees, and outreach to the patient and scientific communities. Of interest to NIH, provisions in this title would require the HHS Secretary to harmonize differences between the HHS and FDA Human Subject Regulations and require the NIH Director to finalize the “Draft NIH Policy on Use of Single Institutional Review Board for Multi-Site Research” within 1 year of bill enactment.

Title III: Delivery is centered on the Centers for Medicare and Medicaid Services (CMS) and includes provisions on interoperability of electronic health records, telehealth, coverage determination and pricing transparency for certain products and services, payments for continuing medical education materials and events, and prevention of prescription drug abuse.

Title IV: Medicaid, Medicare, and Other Reforms includes offsets for the cost of carrying out the bill as well as some miscellaneous items. Provisions in this title would limit federal Medicaid reimbursement to states for durable medical equipment to Medicare payment rates, limit federal payment for X-ray imaging services that use film, delay certain Medicare prescription drug plan prepayments, and direct the Secretary of Energy to sell oil from the Strategic Petroleum Reserve to offset the cost of the 21st Century Cures Act. This title also includes a provision directing the HHS Secretary to reach out to historically Black colleges and universities, Hispanic-serving institutions, Native American colleges, and rural colleges to ensure that health professionals from underrepresented populations are aware of research opportunities.

Status: The Committee released drafts of the bill on January 27, April 29, and May 13, 2015. The bill was marked up by House Energy and Commerce Health Subcommittee on May 14, 2015. On May 21, 2015, a fourth version of the bill passed the full Energy and Commerce Committee. On July 10, 2015, the House passed H.R. 6, the 21st Century Cures Act, as amended, by a vote of 344-77. The above summary is of the amended version of the bill.

Related Bills:

A number of the provisions of the 21st Century Cures Act were also introduced as stand-alone bills:

- [H.R. 2419](#) – To reauthorize funding for the National Institutes of Health.
- [H.R. 2420](#) – To reduce administrative burdens on researchers.
- [H.R. 2421](#) – To increase accountability at the National Institutes of Health.
- [H.R. 2436](#) – To amend the PHS Act with respect to appropriate age groupings to be included in research studies involving human subjects.
- [H.R. 2439](#) – To amend the PHS Act with respect to the Silvio O. Conte Senior Biomedical Research Service.
- [H.R. 2440](#) – To improve loan repayment programs of the National Institutes of Health.
- [H.R. 2447](#) – To provide for an NIH research strategic plan.
- [H.R. 2448](#) – To authorize a program of high-risk, high-reward research.
- [H.R. 2456](#) – To ensure the sharing of data generated from research with the public.
- [H.R. 2548](#) – To amend the PHS Act with respect to a national pediatric research network.

- [S. 1421](#) – To authorize a 6-month extension of certain exclusivity periods for new drugs indicated for a rare disease or condition.

A number of related bills were approved by the Senate Committee on Health, Education, Labor, and Pensions (HELP) at three recent markups:

- [H.R. 1537](#) / [S. 1878](#) – To reauthorize the priority review voucher program for rare pediatric diseases.
- [H.R. 3466](#) / [S. 2014](#) – To amend the PHS Act to establish the Next Generation of Researchers Initiative.
- [S. 800](#) – To require the National Center for Medical Rehabilitation Research (NCMRR), which is part of NICHD, to develop a comprehensive research plan and update it periodically (not less than every 5 years). *[See page 29 for details]*
- [S. 849](#) – To improve the collection of epidemiological and surveillance data on neurological diseases. *[See page 16 for details]*
- [S. 1622](#) - To allow non-local IRB review for device trials.
- [S. 2030](#) – To facilitate the development, review, and approval of drugs addressing an unmet need by allowing consideration of data and information previously submitted in other precision drug applications.
- [S. 2700](#) – To help NIH and FDA hire qualified staff by increasing the number of people eligible for the Senior Biomedical Research Service and raising their salary cap; to exempt NIH research from Paperwork Reduction Act requirements.
- [S. 2713](#) – To provide broad authorization for the HHS Secretary to establish and carry out the Precision Medicine Initiative, authorize the NIH Director to require data sharing, and provide Other Transactions Authority to ICs and OD offices.
- [S. 2742](#) – Several provisions affecting reporting, administrative burden of grantees, reimbursement for research substances and living organisms, amendments to clinicaltrials.gov, terms for IC Directors, and reduced restrictions on NCATS clinical trials.
- [S. 2745](#) – Would require NIH to regularly develop a six-year strategic plan.

Alzheimer's Disease

Background: The Consolidated Appropriations Act, 2016, included \$350 million additional funds to NIA specifically for Alzheimer's disease (AD) research in FY 2016. The bill encourages NIA to “continue addressing the research goals set forth in the National Plan to Address Alzheimer's Disease, as well as the recommendations from the Alzheimer's Disease Research Summit in 2015.”

FY 2014 and FY 2015 appropriations also included additional funds for AD research. Congress increased the appropriation to NIA by \$100 million dollars in FY2014 and by \$25 million in FY 2015 with the expectation that a significant proportion of the funds would be directed to AD research; however, the language stipulated that the exact amount should be determined by scientific opportunity.

The Alzheimer's Accountability Act of 2014 was signed into law on December 16, 2014 as part of the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235). This legislation requires the NIH Director to prepare an annual professional judgment or “bypass” budget estimate of the resources NIH needs to carry out the research goals set forth in the [National Plan to Address Alzheimer's Disease](#). Although the HHS Secretary and Advisory Council on Alzheimer's Research, Care, and Services are allowed to comment on the budget, they are not allowed to make changes before it is submitted to the President and transmitted to Congress. On July 27, 2015, NIH released the [Bypass Budget Proposal for Fiscal Year 2017—Reaching for a Cure: Alzheimer's Disease and Related Dementias Research at NIH](#), which estimates the *additional* funding needed to reach the ultimate research goal of the National Plan—to effectively treat and prevent Alzheimer's and related dementias by 2025.

Bills that would establish additional funds for AD research have been introduced in previous Congresses. These include the Making Investments Now for Dementia (MIND) Act of 2011, which would authorize the Secretary of the Treasury to issue bonds to aid in the funding of AD research, and the Alzheimer's Breakthrough Act of 2009, which would authorize up to \$2 billion for AD research at NIH. The Alzheimer's Disease Research Semipostal Stamp Act was previously introduced in both the House and Senate in the 113th Congress. None of these bills passed out of committee. In addition to these bills, one provision of the [American Health Care Reform Act of 2015](#) would establish a \$1 billion prize for the first applicant to discover a cure or vaccine for AD.

H.R. 3092 *Alzheimer's Disease Research Semipostal Stamp*

Provisions of the Legislation/Impact on NIH: The bill would provide for an issuance of a semipostal stamp for AD research. This stamp shall be made available to the public for a period of 6 years, beginning no later than 12 months after the date of the enactment of this Act. All amounts becoming available from the sale of the Alzheimer's Disease Research Semipostal Stamp shall be transferred to the NIH, to contribute to funding for medical research relating to AD, through payments made at least twice a year.

Status: On July 16, 2015, Representative Maxine Waters (D-CA) introduced H.R. 3092, which was referred to the House Committee on Oversight and Government Reform and House Committee on Energy and Commerce. No further action has occurred.

S. 2067/H.R. 5073 *Ensuring Useful Research Expenditures is Key for Alzheimer's (EUREKA) Act*

Provisions of the Legislation/Impact on NIH: The bill would authorize the NIH Director to work with other federal agencies to establish prize challenges informed by the research milestones contained in the National Plan to Address Alzheimer's Disease. These competitions would encourage more public-private collaboration and spur innovation by rewarding researchers who meet certain milestones with cash prizes. An advisory council that would include experts in organizing and managing such challenges as well as patient advocates and industry representatives would be formed to determine the competitions, while a separate judging panel would evaluate submissions and make recommendations for awards to the NIH Director.

Status: On September 22, 2015, Senator Roger Wicker (R-MS) introduced S. 2067, which was referred to the Senate Committee on Health, Education, Labor, and Pensions. On April 27, 2016, Representative Steve Cohen (D-TN) introduced H.R. 5073, which contains identical text to S. 2067 and was referred to the House Committee on Energy and Commerce.

Autism

Background: Since 2006, several bills that would require the HHS Secretary to conduct a study comparing the risk of autism in vaccinated and unvaccinated populations have been introduced in the House. In the 109th, 110th, and 111th Congresses, Representative Carolyn Maloney (D-NY) introduced the Comprehensive Comparative Study of Vaccinated and Unvaccinated Populations Act, and in the 113th Congress, Representative Bill Posey (R-FL) introduced that Vaccine Safety Study Act. The text of the current legislation, also introduced by Representative Posey, is similar to that of previous bills. None of these bills passed out of Committee.

[H.R. 1636](#) *Vaccine Safety Study Act*

Provisions of the Legislation/Impact on NIH: This bill would direct the HHS Secretary, acting through the NIH director, to conduct or support a study comparing total health outcomes of vaccinated to unvaccinated people. Outcomes would include incidence and risk of autism, chronic and other neurological conditions. Study investigators could not be Federal, State, or public health agency employees, be involved in immunization policy, have a history of a strong position on vaccine safety, or be Centers for Disease Control (CDC) or pharma employees. The request for proposals would be issued within 120 days of enactment, and the Secretary would be required to approve or disapprove proposals within 120 days of receipt.

Status: On March 25, 2015, Rep. Bill Posey (R-FL) introduced H.R. 1636. It was referred to the Committee on Energy and Commerce. No further action has occurred.

Cerebral Cavernous Malformations

Background: The Cavernous Angioma CARE Center Act of 2012 was introduced into 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. The Cavernous Angioma Research Resource Act of 2013, which was introduced into both the House and Senate in the 113th Congress, was similar to the CCM-CARE Act of 2015 (described below). These bills were never taken up by Committee.

[S. 1391](#) / [H.R. 2480](#) *Cerebral Cavernous Malformations Clinical Awareness, Research, and Education (CCM-CARE) Act of 2015*

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. Provisions of the bill would direct NIH to establish a network of CCM Clinical Research Centers, including 3 coordinating and 6 to 10 participating centers. The Coordinating Centers would facilitate clinical trials, translational research, and enhance medical care for CCM patients. NIH would convene a CCM Research Consortium, which would include representatives from the Coordinating Centers and a patient advocacy group, and may include NIH or FDA representatives as advisors, to develop training programs for clinicians and scientists and develop patient education and outreach programs. 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 May 20, 2015, Senator Tom Udall (D-NM) and Representative Ben Ray Lujan (D-NM) introduced S. 1391 and H.R. 2480, respectively. S. 1391 was referred to the Senate Committee on Health, Education, Labor, and Pensions, and H.R. 2480 was referred to the House Committee on Energy and Commerce. No further action has occurred.

Concussion

Background: The Concussion Awareness and Education Act was introduced in the House in the 113th Congress but failed to pass out of committee. In addition to establishing a CDC surveillance system for sports-related concussions and directing NIH to conduct research on youth concussions, the previous version of the bill would have required NIH to maintain a brain and tissue bank and contained provisions directed at the Department of Defense (DoD). Provisions related to the DoD and a brain and tissue bank at NIH are not included in the most recent version.

[H.R. 1271](#) *Concussion Awareness and Education Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill provides for systemic research, treatment, prevention, awareness, and dissemination of information with respect to sports-related and other concussions. The provisions would direct the CDC to establish a national surveillance system to collect data on the incidence of sports-related concussions in youth, including, to the extent feasible, demographics, pre-existing conditions, concussion history, use of protective equipment, qualifications of personnel diagnosing the concussions, and the causes, nature, and extent of the injury. The NIH would be required to conduct or support research on the effects of concussions on quality of life, to identify predictors or modifiers of outcomes, on age- and sex-related biomechanical determinants of risk for concussion, and to inform guidelines on concussion management. The HHS Secretary, through the CDC, would disseminate information to the public on concussions. The bill would establish a Concussion Research Commission, composed of 9 appointed members, to review the programs established by this bill and make recommendations for furthering the goals of the bill. The Commission would also be required to review and recommend corrections or updates to the National Academies report entitled “Sports-Related Concussions in Youth: Improving the Science, Changing the Culture.”

Status: On March 4, 2015, Rep. Joyce Beatty (D-OH) introduced H.R. 1271. It was referred to the Committee on Energy and Commerce and to the Subcommittee on Health. No further action has occurred.

[H.R. 2932](#) *PLAYS in Youth Sports Act*

Provisions of the Legislation/Impact on NIH: The bill requires HHS to establish: (1) an Organization Grants Program to award competitive grants to eligible national nonprofit organizations to improve the health and positive youth development impacts of youth sports participation, and (2) a grant selection board to select grant recipients. It also authorizes the CDC and NIH to undertake, support, enhance, and expand research and prevention efforts to advance youth sports safety.

Status: On June 25, 2015, Rep. Ron Kind (D-WI) introduced H.R. 2932. It was referred to the Committee on Education and the Workforce. No further action has occurred.

Hereditary Hemorrhagic Telangiectasia (HHT)

Background: The Hereditary Hemorrhagic Telangiectasia Diagnosis and Treatment Act of 2011 was introduced in both the House and Senate in the 112th and 113th Congresses, but the bills failed to pass out of Committee. The bill was reintroduced in the 114th Congress with nearly identical provisions.

H.R. 1849 *Hereditary Hemorrhagic Telangiectasia Diagnosis and Treatment Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill would require the CDC director to conduct population screening, develop guidelines for diagnosis and intervention, develop a standardized survey and screening tool on family history, establish a resource center for disseminating information, support public awareness programs, and designate HHT Treatment Centers of Excellence. This bill would direct the Secretary, in consultation with the NIH and CDC directors, to establish and implement an HHT initiative to assist in coordinating activities to improve early detection, screening, and treatment of people who suffer from HHT. It would also require the Secretary, in consultation with the NIH Director, to establish an HHT Coordinating Committee with four representatives of HHT Treatment Centers of Excellence; four experts in vascular, molecular, or basic science; and four NIH representatives. The Committee would develop and coordinate implementation of a plan to advance research and understanding of HHT by (A) conducting or supporting research on HHT across NIH ICs, including NHLBI, NINDS, NIDDK, NICHD, NCI, NCATS/ORDR and NIBIB; and (B) conducting evaluations and making recommendations to the Secretary, the Director of the NIH, and the Director of the NCI regarding the prioritization and award of NIH grants relating to HHT. Additionally, the bill would require the Centers for Medicare and Medicaid Services (CMS) to award grants for analysis of CMS data on HHT.

Status: On April 16, 2015, Rep. Edward Royce (R-CA) introduced H.R. 1849. It was referred to the Committee on Energy and Commerce, and to the Committee on Ways and Means. No further action has occurred.

Huntington's Disease

Background: The Huntington Disease Parity Act was introduced during the 110th, 111th, 112th, and 113th Congresses, but the bills failed to pass out of Committee. The bill was reintroduced in the 114th Congress with identical provisions.

[H.R. 842](#) *Huntington's Disease Parity Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill would require the Social Security Commissioner to revise the medical and evaluation criteria for determining disability in a person diagnosed with adult onset and juvenile Huntington's disease in consultation with NINDS, NIH, and other relevant organizations and to waive the 24-month waiting period for Medicare eligibility for individuals disabled by Huntington's disease.

Status: On February 10, 2015, Representative Adam Kinzinger (R-IL) introduced H.R. 842, which was referred to the House Committee on Ways and Means. No further action has occurred.

Neurological Diseases Surveillance

Background: In the 111th Congress, the House passed the “National Neurological Diseases Surveillance System Act of 2010” (H.R. 1362), which was initially introduced by Rep. Chris Van Hollen (D-MD) in 2009 as the “National MS and Parkinson’s Disease Registries Act” and subsequently amended to include all neurological diseases. Although H.R. 1362 passed the House, it was not taken up in the Senate. A companion bill (S. 1273) was introduced in the Senate in 2009 by Sen. Byron Dorgan (D-ND) but never passed out of Committee. The bill was re-introduced in both the House (H.R. 2595) and Senate (S. 425) in the 112th Congress, but no further action was taken.

H.R. 292 / S. 849 *Advancing Research for Neurological Diseases Act of 2015*

Provisions of the Legislation/Impact on NIH: This bill – similar to the version introduced in the 112th Congress - authorizes the Secretary of HHS to improve the collection of epidemiological and surveillance data on neurological diseases. The House version, which was included in the House-passed 21st Century Cures Act, specified that an integrated surveillance system shall be created to track neurological diseases. The Senate version, as amended and reported by the Senate Committee on Health, Education, Labor, and Pensions (HELP), would allow leveraging of existing surveillance activities and registries to achieve the same goal. While the House version specified that multiple sclerosis and Parkinson’s disease shall be tracked, the Senate version states that the HHS Secretary shall initially focus on five neurological diseases that are most prevalent or present a significant public health burden.

Status: On January 13, 2015, H.R. 292 was introduced by Rep. Michael Burgess (R-TX) and was referred to the House Committee on Energy and Commerce. H.R. 292 was included as part of the House-passed 21st Century Cures Act. Senator Johnny Isakson (R-GA) introduced S. 849 on March 24, 2015, which was referred to the Senate HELP Committee. S. 849 was reported by the Senate HELP Committee with an amendment in the nature of a substitute on February 9, 2016.

H.R. 2313 *Advancing Research for Hydrocephalus Act*

Provisions of the Legislation/Impact on NIH: This bill authorizes the Secretary of HHS, acting through the CDC, to enhance and expand infrastructure and activities to track the epidemiology of hydrocephalus, a condition in which fluid accumulates in the brain. This information would be incorporated into a National Hydrocephalus Surveillance System, which would be designed to facilitate further research on neurological disease.

Status: On May 13, 2015, the bill was introduced by Rep. Christopher Smith (R-NJ) and was referred to the House Committee on Energy and Commerce. No further action has occurred.

Tourette Syndrome

Background: The Collaborative Academic Research Efforts for Tourette Syndrome Act was introduced during the 112th and 113th Congresses by Representative Rep. Albio Sires (D-NJ) and Senator Robert Menendez (D-NJ); however, neither bill passed out of committee.

[H.R. 619](#) / [S. 276](#) *Collaborative Academic Research Efforts for Tourette Syndrome Act of 2015*

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: On January 28, 2015, H.R. 619 was introduced by Representative Rep. Albio Sires (D-NJ), and referred to the House Committee on Energy and Commerce and S. 276 was introduced by Senator Robert Menendez (D-NJ) and referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred.

Pending Legislation of Broad Interest to NIH

America COMPETES Reauthorization

Background: On August 9, 2007, President George W. Bush signed into law the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act of 2007 (America COMPETES Act), which authorized science programs and funding for agencies that are under the jurisdiction of the House Science, Space, and Technology Committee, including the National Aeronautics and Space Administration (NASA), National Oceanic and Atmospheric Administration (NOAA), National Science Foundation (NSF), the White House Offices of Science and Technology Policy (OSTP), the National Institute of Standards and Technology (NIST), and the Department of Energy's (DOE) science programs. In January of 2011, President Barak Obama signed into law the America COMPETES Reauthorization Act of 2010. Two reauthorization bills, America COMPETES 2014 and Frontiers in Innovation, Research, Science, and Technology (FIRST) Act of 2014, were introduced in the 113th Congress but failed to pass out of Committee.

[H.R. 1806](#) *America COMPETES Reauthorization Act of 2015*

Provisions of the Legislation/Impact on NIH: This bill would reauthorize funding for the NSF, OSTP, NIST, and the DOE's science programs for FY 2016 and 2017. A number of provisions would directly affect NIH or NIH grantees or may broadly affect federal science agencies. These provisions include:

Computing and Data Infrastructure

- Encourage NSF to coordinate with the Interagency Working Group on Neuroscience to determine how to use NSF's data infrastructure to facilitate research for the BRAIN InitiativeSM.
- Require the Comptroller General to submit a report on efficiencies that can be achieved by using shared scientific computing resources (hardware and software) and cost savings that could be achieved by potential sharing of scientific computing resources across all NSF grants.

Accountability and Transparency

- Require NSF to provide for each grant written justification that it is within the NSF mission and is in the national interest.
- Require NSF to establish procedures to prevent duplication of research, ensure preliminary research in grants applications does not include knowing misrepresentations of data, and address barriers to early career and new investigator applicants.
- Establish a working group within OSTP to make recommendations on minimizing regulatory burden on research institutions while maintaining accountability for Federal tax dollars and to identify and update specific regulations to refocus on performance-based goals rather than process.
- Direct the National Research Council (NRC) to provide a report assessing data reproducibility and replicability issues in interdisciplinary research and make recommendations to improve rigor and transparency in scientific research.

Alternative Funding Models/Scientific Prizes

- Direct the NSF Director to place a high priority on designing and administering pilot programs for scientific breakthrough prizes.
- Require the heads of Federal science agencies (defined as NASA, NSF, NIST, National Weather Service), in consultation with the OSTP Director, to conduct pilot programs to validate alternative research funding models, including scientific prizes and crowd source funding.
- Clarify and amend current law regarding prize competitions.

STEM Education Kindergarten through Graduate School

- Direct the NSF Director and NRC to convene a workshop/roundtable to make recommendations for how federal support for STEM graduate students can be improved.
- Create an STEM Education Advisory Panel to develop recommendations for implementing the STEM strategic plan and improve STEM education, direct the Committee on STEM (CoSTEM) within OSTP to collaborate with the STEM Education Advisory Panel, and direct NSF to establish a STEM education coordinating office.
- Direct NSF to use existing programs to improve programs that engage underrepresented students at the K-8 level.
- Require NSF to establish a STEM grant program for Hispanic-serving institutions.
- Create state and regional workshops to train K-12 teachers in science and technology project-based learning to provide instruction in initiating robotics and other STEM competition team development programs.

New programs and positions within OSTP

- Require the OSTP Director to establish a body with the responsibility to identify and coordinate international science and technology partnerships.
- Create a Chief Technology Officer within OSTP.

Status: On April 15, 2015, Rep. Lamar Smith (R-TX) introduced H.R.1806. It was referred to the Committees on Education and the Workforce; Oversight and Government Reform; and Science, Space, and Technology. The Science, Space, and Technology Committee amended and passed the bill. Both the Education and the Workforce and Oversight and Government Reform Committees discharged the bill by unanimous consent. An amended version of the bill passed the House with a vote of 217 to 205 on May 20, 2015. The above summary is of the amended version of the bill. It was received in the Senate and referred to the Committee on Commerce, Science, and Transportation. No further action has occurred.

Clinical Data Registries

Background: In recent years, a number of bills have focused on ensuring the clinical trials are registered in clinicaltrials.gov, that data in clinical registries is searchable and available to the public, and that the privacy and human subjects protections of individuals participating in clinical trials is maintained. In addition to the below bills, a number of provisions in the [21st Century Cures](#) legislation address clinical trials registries and sharing clinical data.

H.R. 617 *Clinical Trial Cancer Mission 2020 Act*

Provisions of the Legislation/Impact on NIH: The bill would amend the PHS Act to clarify that the clinical trial registry data bank requirements apply regardless of the trial outcomes. The bill would also require the Department of Defense to have its grantees certify that funded trials have been registered and reported results as required under the Food and Drug Administration Amendments Act and restrict grantees from receiving additional federal funds if they do not remedy noncompliance and make them liable for repayment of grant funds received for the clinical trial.

Status: On January 28, 2015, Representative Tom Reed (R-NY) introduced H.R. 617, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

H.R. 965 *Facilitating Participation in Clinical Data Registries Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill would require the issuance of guidance on the application of the Federal policy for the protection of human subjects with respect to clinical data registries.

Status: On February 13, 2015, Representative Bill Pascrell, Jr. (D-NJ) introduced H.R. 965, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

Comparative Effectiveness Research

Background: Comparative Effectiveness Research (CER) is designed to compare the effectiveness of two or more interventions or approaches to health care, examining their risks and benefits. Patient-Centered Outcomes Research (PCOR) is a relatively new research field that considers patients' needs and preferences and focuses on outcomes most important to them. Both CER and PCOR are controversial research areas. The House version of the FY 2016 L-HHS-Ed Appropriations bill would prohibit funding for PCOR and rescind \$100 million from the PCOR Trust Fund, which was originally established by the Affordable Care Act (ACA).

S. 1718 *Four Rationers Repeal Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill would repeal the Center for Medicare and Medicaid Innovation established by the ACA, repeal the requirement for health plans to cover items or services recommended by the United States Preventive Task Force, repeal the Community Preventives Task Force established by the ACA, and prohibit data obtained from the conduct of CER to deny or delay coverage of an item or service under a Federal health care program. Of interest to NIH, the HHS Secretary would be required to ensure that CER conducted or supported by the Federal Government accounts for factors contributing to differences in the treatment response and treatment preferences of patients, including patient-reported outcomes, genomics and personalized medicine, the unique needs of health disparity populations, and indirect patient benefit.

Status: On July 8, 2015, Senator Pat Roberts (R-KS) introduced S. 1718, which was referred to the Senate Committee on Finance. No further action has occurred.

Federal Advisory Committees

Background: The Federal Advisory Committee Act (FACA), which first became law in 1972, is the legal foundation defining how the federal government receives advice and recommendations. The law has special emphasis on open meetings, chartering, public involvement, and reporting. In the 110th Congress, Representative Lacy Clay (D-MO) introduced the Federal Advisory Committee Act Amendments of 2008, which passed the House but was not taken up by the Senate. He reintroduced the bill in the 111th Congress, and it again passed the House but was not taken up by the Senate. He reintroduced the bill in the 112th and 113th Congresses, but it did not pass out of Committee.

H.R. 2347 *Federal Advisory Committee Act Amendments*

Provisions of the Legislation/Impact on NIH: The bill would require that all appointments to advisory committees be made without regard to political affiliation or political activity; extend all of the FACA requirements (except charters) to working groups; allow the public to make recommendations for committee members; require that advisory committee members be designated as a "special government employee" or "a representative"; and expand transparency requirements (for example, who nominated each member and why the selectee was appointed). The bill also contains a provision that would require the head of each agency to ensure that advisory committee advice and recommendations are the result of independent judgment. Further, when transmitting advice and recommendations, each advisory committee would be required to include a statement describing the process used in formulating its advice and recommendations.

Status: On May 15, 2015, Representative Lacy Clay (D-MO), introduced H.R. 2347, which was jointly referred to the House Committees on Oversight and Government Reform and Ways and Means. On October 9, 2015, the Committee reported the bill, which passed the House on March 1, 2016. The bill was received in the Senate and referred to the Committee on Homeland Security and Governmental Affairs. No further action has occurred.

Fetal Tissue Research

Background: Research involving transplantation of human fetal tissue is governed by Section 498A of the Public Health Service Act, 42 USC §[289g-1](#) and [289g-2](#). NIH grantees are bound by the NIH Grants Policy Statement, based on the statute:
<http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

H.R. 3171 *A bill to prohibit certain research on the transplantation of human fetal tissue obtained pursuant to an abortion*

Provisions of the Legislation/Impact on NIH: The bill would require that only human fetal tissue obtained from stillbirth could be used for transplantation research.

Status: On July 22, 2015, Representative James Sensenbrenner (R-WI) introduced, H.R. 3171, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

H.R. 3215 *End Trafficking of the Terminated Unborn Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill would prohibit research on fetal tissue obtained pursuant to an induced abortion. Only human fetal tissue obtained from stillbirth could be used for transplantation research.

Status: On July 27, 2015, Representative Doug Lamborn (R-CO) introduced H.R. 3215, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

H.R. 3429 *Prohibiting the Life-Ending Industry of Fetal Organ Exchange (Pro-LIFE) Act*

Provisions of the Legislation/Impact on NIH: Current law prohibits the exchange of “valuable consideration” for fetal tissue. This bill would define “valuable consideration” to include (a) any payment or debt incurred; (b) any gift, honorarium or recognition; (c) any price, charge or fee which is waived, forgiven, reduced or indefinitely delayed; (d) cancellation of any loan or debt; (e) the transfer of any item from one person to another or provision of any service or granting of any opportunity for which a charge is customarily made, without charge or for a reduced charge; and (f) any payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

Status: On July 29, 2015, Representative Kevin Yoder (R-KS) introduced H.R. 3429, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

S. 1917 *A bill to prohibit the provision of Federal funds to an entity that receives compensation for facilitating the donation of fetal tissue derived from an abortion*

Provisions of the Legislation/Impact on NIH: The bill would prohibit the provision of Federal funds to an entity that receives compensation for facilitating the donation of fetal tissue derived from an abortion.

Status: On August 3, 2015, Senator Susan Collins (R-ME) introduced S. 1917, which was referred to the Senate Committee on Health, Education, Labor, and Pensions. No further action has occurred.

[HR 3729](#) *Safe Responsible Ethical Scientific Endeavors Assuring Research for Compassionate Healthcare (Safe RESEARCH) Act*

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: On October 8, 2015, Representative James Sensenbrenner (R-WI) introduced H.R. 3729, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

Funding for NIH

Background: In addition to the authorization of NIH funding increases included in the [21st Century Cures](#) legislation, several stand-alone bills to authorize funding increases up to a certain amount have been introduced recently. However, even if these bills are enacted, NIH would not receive funds unless they are appropriated through the annual appropriations bill. Of the below bills, only two bills (S. 2624, the National Biomedical Research Act; H.R. 777, the Permanent Investment in Health Research Act) would appropriate funds to NIH. The American Cures Act, Accelerating Biomedical Research Act, and Permanent Investment in Health Research Act were also introduced in the 113th Congress, but they never passed out of Committee.

[H.R. 531](#) / [S. 318](#) *Accelerating Biomedical Research Act*

Provisions of the Legislation/Impact on NIH: The bill would authorize funding increases of up to 10% per year for FY 2016 – 2021 for NIH. This purpose of the bill is to prioritize funding for NIH to discover treatments and cures, to maintain global leadership in medical innovation, and to restore the purchasing power the NIH had after the historic doubling campaign that ended in FY 2003.

Status: On January 26, 2015, and January 29, 2015, Representative Rosa DeLauro (D-CT) and Senator Barbara Mikulski (D-MD) introduced H.R. 531 and S. 318, respectively. H.R. 531 and S. 318 were referred to the House and Senate Committees on the Budget. No further action has occurred.

[H.R. 2104](#) / [S. 289](#) *American Cures Act*

Provisions of the Legislation/Impact on NIH: The bill would authorize additional investment at a rate of GDP-indexed inflation plus five percent annually for NIH, CDC, Department of Defense Health Program, and Veterans Medical & Prosthetics Research Program. Appropriations under the American Cures Act would be exempt from sequestration.

Status: On January 28, 2015, Senator Richard Durbin (D-IL) introduced S. 289, which was referred to the Senate Committee on the Budget. On April 29, 2015, Representative Anna Eshoo (D-CA) introduced H.R. 2104, which was referred to the House Committee on the Budget in addition to the House Committees on Energy and Commerce, Armed Services, and Veterans' Affairs.

[H.R. 744](#) / [S. 320](#) *Medical Innovation Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill would authorize the collection of supplemental payments from pharmaceutical companies who settle with the government after committing certain illegal activities to invest additional money into the NIH and FDA. Drug

companies (1) who sell at least one drug whose annual net sales exceed \$1 billion, (2) where that drug can be traced at least in part to federally funded research, and (3) who enter into a settlement agreement of at least \$1 million with the government after committing certain types of wrongdoing, would be required to pay an additional fine of 1% of the company's profits each year for five years on top of the value of their settlement. These funds would be in addition to regular appropriations for the NIH and FDA.

Status: On January 29, 2015, Senator Elizabeth Warren (D-MA) introduced S. 320, which was referred to the Senate Committee on Health, Education, Labor and Pensions. On February 4, 2015, Representative Chris Van Hollen (D-MD) introduced H.R. 744, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

H.R. 777 *Permanent Investment in Health Research Act*

Provisions of the Legislation/Impact on NIH: This bill would amend the Public Health Service Act to make appropriations to the NIH of \$32 billion for FY2016 and for FY 2017-FY 2025, appropriations would increase at the rate of GDP-indexed inflation. The bill would add NIH to the list of programs and activities exempt from sequestration.

Status: On February 5, 2015, Representative Kathy Castor (D-FL) introduced H.R. 777, which was referred to the House Committee on Energy and Commerce, in addition to the Committees on the Budget and Appropriations. No further action has occurred.

H.R. 1360 *America's Fund for Future Opportunities and Outcomes in the United States (America's FOCUS) Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill would establish a separate account in the U.S. Treasury to be known as the America's FOCUS Fund, into which the following would be deposited: (1) revenue generated by civil and criminal fines and penalties for violations or alleged violations of federal law; (2) revenue generated by legal settlements reached between corporations and the federal government for violations or alleged violations of federal law; and (3) gifts, bequests, or donations to the Fund from private entities or individuals. The bill would require that of the total revenue in the Fund: (1) up to a third be used to award grants for youth mentoring via Department of Education and STEM education via NASA; (2) up to a third be used to award grants to fund evidence-based justice reinvestment projects as part of the Justice Reinvestment Initiative and programs established under the Second Chance Act within the Department of Justice; (3) up to a third be used to award grants and prizes for innovations in medical research and development; and (4) the remaining revenue be used to reduce the federal budget deficit or, if there is no deficit, to reduce the federal debt. Of interest to NIH, the bill would require the NIH Director to use the revenue designated for medical innovation to fund entities that conduct innovative medical research and development and authorize the NIH Director to use up to 15 percent of those funds to award monetary prizes to entities that have used their own funding and research facilities to produce innovative results.

Status: On March 13, 2015, Representative Chaka Fattah (D-PA) introduced H.R. 1360, which was referred to the House Committee on the Judiciary, in addition to the Committees on Education and the Workforce, Energy and Commerce, and Science, Space, and Technology. No further action has occurred.

H.R. 2653 *American Health Care Reform Act of 2015*

Provisions of the Legislation/Impact on NIH: This bill includes a number of provisions focused on repealing Obamacare, establishing patient-centered reforms, and developing free-market solutions for America’s health care sector. Of interest to NIH, the bill would establish a Medical Breakthrough Fund including \$15 billion in total in FYs 2017 – 2024. These funds would have to be appropriated and used for Alzheimer’s disease, cancer, heart disease, stroke, or diabetes research. The bill would require the NIH Director to award a Cures and Vaccine Prize of \$1 billion to the first applicant to develop a cure or vaccine for Alzheimer’s disease. The bill also would require the NIH Director to ensure that scientifically based strategic planning is implemented in support of research priorities of the Medical Breakthrough Fund and appoint 18 members to an advisory council for this fund. The bill would offset costs for this fund and other provisions by reducing the non-defense discretionary spending caps. Provisions of the bill would limit indirect costs for research programs or projects to 50% of the direct costs.

Status: On June 4, 2015 Representative David Roe (R-TN) introduced H.R. 2653, which was referred to the House Committee on Energy and Commerce in addition to the House Committees on Ways and Means, Education and the Workforce, the Judiciary, Natural Resources, House Administration, Rules, Appropriations, Veterans' Affairs, and the Budget. No further action has occurred.

S. 2624 *National Biomedical Research Act of 2016*

Provisions of the Legislation/Impact on NIH: The bill would establish a Biomedical Innovation Fund within the Treasury and direct the Treasury Secretary to transfer \$5 billion not later than September 1, 2016, and each year through 2025. As long as the discretionary appropriations increase, the fund allocates money for the BRAIN Initiative; Precision Medicine Initiative; Cancer Moonshot Initiative; research that fosters “disruptive innovation”; research related to diseases that disproportionately account for Federal healthcare spending; early career scientists; and research efforts that increase the potential for breakthrough discoveries across a diverse set of investigators, research groups, and institutions.

Status: On March 3, 2016, Senator Elizabeth Warren introduced S. 2624, which was referred to the Senate Health, Education, Labor, and Pensions Committee. During committee markups of bills related to NIH and FDA on March 6, 2016 and April 9, 2016, Senator Warren offered then withdrew the bill as an amendment. No further action has occurred.

Reducing Administrative Burden

Background: During the 113th Congress, the Research and Development Efficiency Act (H.R. 5056), which would create a working group within OSTP to identify ways to reduce administrative burden on research institutions, passed the House but was never taken up by the Senate. The [America Competes Reauthorization Act of 2015](#) includes the Research and Development Efficiency Act as well as additional language directing the working group to identify and update regulations to refocus on performance-based goals rather than process. The [21st Century Cures Act](#) also includes language on reducing administrative burden but would not create a working group to develop recommendations. Instead the bill would require the NIH Director to implement measures to reduce the administrative burden on grantees, taking into account recommendations, evaluations and plans researched by the Scientific Management Review Board, the National Academy of Sciences, the 2007 and 2012 Faculty Burden Survey conducted by the Federal Demonstration Partnership, and recommendations from the Research Business Models Working Group.

H.R. 1119 *Research and Development Efficiency Act*

Provisions of the Legislation/Impact on NIH: The bill would require the Director of the Office of Science and Technology Policy (OSTP) to establish a working group under the authority of the National Science and Technology Council, to include the Office of Management and Budget (OMB). The working group would be responsible for reviewing Federal regulations affecting research and research universities and to make recommendations to 1) harmonize, streamline, and eliminate duplication of Federal regulations and reporting requirements; and 2) minimize the regulatory burden of U.S. Institutions of higher education performing federally funded research while maintaining accountability of Federal tax dollars. The working group would be required to engage stakeholders including federally funded and non-federally funded researchers, institutions of higher education, scientific disciplinary societies and associations, non-profit research institutions, industry, and others with a stake in ensuring effectiveness and efficiency in the performance of scientific research. The bill would also require a report on the steps taken to carry out the recommendations of the working group.

Status: On February 26, 2015, Representative Barbara Comstock (R-VA) introduced H.R. 1119, which was referred to the House Committee on Science, Space, and Technology. The bill was marked up by the House Committee on Science, Space, and Technology on March 4, 2015 and passed the House on May 19, 2015. On May 20, 2015, H.R. 1119 was received in the Senate and referred to the Senate Commerce, Science and Transportation Committee. No further action has occurred.

Rehabilitation Research

Background: After suffering a stroke in 2012 and crediting much of his recovery to intensive rehabilitation, Senator Mark Kirk (R-IL) has shown a strong interest in rehabilitation research and return to work. During the 113th Congress, he introduced the Return to Work Act of 2013 ([S. 1026](#)) to assist survivors of stroke and traumatic brain injury, the Preserving Rehabilitation Innovation Centers Act of 2013 ([S. 1220](#)) to increase Medicare payments to certain rehabilitation centers that also conduct research, and a bill to improve, coordinate, and enhance rehabilitation research at the National Institutes of Health ([S. 1027](#)), none of which passed out of Committee.

[S. 800/H.R. 1469/H.R. 1631](#) *Enhancing the Stature and Visibility of Medical Rehabilitation Research at NIH Act*

Provisions of the Legislation/Impact on NIH: The identical bills would direct the National Center for Medical Rehabilitation Research (NCMRR) Director to develop a comprehensive research plan in consultation with the coordinating committee and update it not less than every five years. The NCMRR Director would be required to develop an annual report for the coordinating committee and advisory board describing and analyzing the progress during the preceding fiscal year, including IC expenditures for carrying out the Research Plan, recommendations for revising and updating the Research Plan, and an assessment by the NIH Director. The bill would direct the Coordinating Committee to host a scientific conference or workshop not less than every five years. The NCMRR Director would be required to develop guidelines governing the funding for medical rehabilitation research, and the Secretary and heads of Federal agencies would jointly review programs and enter into agreements to prevent duplication. The bill would also define medical rehabilitation research according to the World Health Organization in the International Classification of Function, Disability and Health.

Status: On March 19, 2015, Senator Mark Kirk (R-IL) and Representative Jim Langevin (D-RI) introduced S. 800 and H.R. 1469, which were referred to the Senate Committee on Health, Education, Labor, and Pensions (HELP) and House Committee on Energy and Commerce, respectively. On March 25, 2015, Representative Langevin also introduced H.R. 1631, an identical bill, which was referred to the House Committee on Energy and Commerce. On February 9, 2016, the Senate HELP Committee reported an amended version of the bill. The summary above reflects provisions in both the original and amended version of the bill.

Science Prizes

Background: The America COMPETES Reauthorization Act of 2010, signed into law on January 4, 2011, granted all agencies broad authority to conduct prize competitions to spur innovation, solve tough problems, and advance their core missions. In addition to the stand alone bill described below, the [America COMPETES Reauthorization Act of 2015](#) has several provisions encouraging the use of prize authority by Federal science agencies, the [21st Century Cures Act](#) would require NIH to establish a prize competition program, the America's FOCUS Act of 2015 would set aside funds for science prizes, and one provision of the American Health Care Reform Act of 2015 would establish a \$1 billion prize for the first applicant to discover a cure or vaccine for Alzheimer's. (Summaries of the America's FOCUS Act of 2015 and the American Health Care Reform Act of 2015 can be found in the [Funding for NIH](#) section.)

[H.R. 1162](#) *Science Prize Competitions Act*

Provisions of the Legislation/Impact on NIH: This bill would clarify that agencies may partner with both nonprofit and for-profit entities in the private sector to support competitions and require that notification of the competitions be made publicly available on a government website. The bill also would allow agencies that sponsor prize competitions to waive a requirement that participants in such competitions obtain liability insurance to protect the government against claims by third party entities, making the federal government potentially responsible for paying the cost of successful claims.

Status: On February 27, 2015, Representative Donald Beyer Jr. (D-VA) introduced H.R. 1162. The bill was referred to the House Committee on Science, Space, and Technology, which reported an amended version of the bill on March 4, 2015. The bill passed the House on May 19, 2015. On May 20, 2015, H.R. 1162 was received in the Senate and referred to the Senate Commerce, Science and Transportation Committee. No further action has occurred.

[S. 2113](#) *Crowdsourcing and Citizen Science Act*

Provisions of the Legislation/Impact on NIH: This bill would authorize each federal agency, or multiple federal agencies working cooperatively, to use crowdsourcing and citizen science approaches to conduct activities designed to advance the agency's mission or the joint mission of the group of agencies. "Citizen science" means a form of open collaboration in which individuals or organizations participate in the scientific process in various ways, including developing technologies and applications and making discoveries. "Crowdsourcing" means a method to obtain needed services, ideas, or content by soliciting voluntary contributions from a group of individuals or organizations, especially from an online community.

Status: On September 30, 2015, Sen. Christopher Coones (D-DE) introduced S. 2113, which was referred to the Senate Committee on Commerce, Science, and Transportation. No further action has occurred.

Sex Differences Research

Background: In 1993, the NIH Revitalization Act required the inclusion of women in NIH-funded clinical research, and currently just over half of clinical research participants in NIH-funded studies are women. However, balancing the inclusion of both male and female animals and cells in preclinical, laboratory-based research has received little attention until recently. In May of 2014, NIH published a [policy statement](#) outlining steps NIH would take to address sex differences in preclinical research. In the 113th Congress, Representative Jim Cooper (D-TN) introduced the Research for All Act of 2014, which is identical to the current bill, but it failed to pass out of Committee.

H.R. 2101 *Research for All Act of 2015*

Provisions of the Legislation/Impact on NIH: The bill would direct the FDA to ensure that the design and size of clinical trials for products granted expedited approval under any program within Sec. 506 of the Federal Food, Drug, and Cosmetic Act are sufficient to determine the safety and effectiveness of such products for both men and women. The bill would also provide for increased communication with the FDA and rolling review of applications for new drugs and biologics that will treat women or men in light of clinical information about sex differences. In terms of NIH, the bill would amend 492B of the PHS Act by adding a section titled “(b) Inclusion of Sex Differences in Basic Research.” H.R. 2101 would require the Director of NIH, within a year of enactment of the Act, to determine when it is appropriate for basic research projects to include both sexes and issue guidelines to ensure that inclusion of both sexes and the analysis of sex differences, as appropriate; and require NIH’s biennial report on inclusion demographics to track statistics on the use of male and female animals, cells, and tissues in basic research, and codifies NIH’s existing Special Centers of Research on Sex Differences. The bill would also direct GAO to update its 2000 report: “Women’s Health: NIH Has Increased Its Efforts to Include Women in Research” and its 2001 report “Women’s Health: Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement.”

Status: On April 29, 2015, Representative Jim Cooper (D-TN) introduced H.R. 2101, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

Small Business Innovation

Background: The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grant programs at the NIH and similar programs at other Federal agencies provide a funding source for U.S. small businesses. These programs require that any federal agency that provides more than \$100 million in research funding set aside a certain percentage of the agency budget for SBIR/STTR. Authorization for these programs ends in 2017, and lawmakers are seeking to reauthorize and increase funding for the programs. Current set asides for these programs are not less than 3.0% for SBIR and 0.45% for STTR in FY 2016. Some research advocates are concerned these increases would leave less funding available for traditional research grants, while proponents of the increase note that these programs help draw attention to the need for more basic research funding and help small business owners plan for the future.

H.R. 4783 *Commercializing on Small Business Innovation Act of 2016*

Provisions of the Legislation/Impact on NIH: This bill would authorize the SBIR and STTR programs through FY 2022. The bill would also raise the SBIR set aside by 0.26 percent each FY starting in 2018 through 2022, ending at 4.50 percent, and the STTR set aside by 0.05 percent in FYs 2017, 2019, and 2022, ending at 0.60 percent. The bill would establish deadlines for some reporting requirements and allows the SBA Administrator to adjust Phase I and Phase II award amounts in accordance with inflation.

Status: On March 17, 2016 Representatives Steve Chabot (R-OH) and Nydia Velazquez (D-NY) introduced H.R. 4783, which was referred to the House Committees on Small Business and Science, Space, and Technology. On March 23, 2016, it was amended and reported by the Committee on Small Business.

S. 2812 *A bill to amend the Small Business Act to reauthorize and improve the SBIR and STTR Programs, and for other purposes*

Provisions of the Legislation/Impact on NIH: This bill would make both the SBIR and STTR programs permanent and incrementally increase the SBIR set aside from 3.5 percent in FY 2018 to 6.0 percent in FY 2028 and the STTR set side from 0.55 percent in FY 2018 to 1.00 percent in FY 2024 for agencies other than DOD. The bill would also update references to NIH as HHS, because other OPDIVS might also participate in these programs; make the commercialization pilot program for civilian agencies permanent; require agencies to put in place a goal for Federal research and R&D with small business of not less than 10 percent by FY 2018; allow costs for seeking intellectual property protections for SBIR/STTR technologies as indirect cost expenses; replace annual agency self-reports with GAO audits of key commercialization goals; directs HHS to shorten application review and decision to less than 10 months. The bill would also extend through FY 2021 a pilot program at SBA to provide grants to regional, multi-state collaboratives to address the needs of small business concerns in States receiving relatively little SBIR support and reauthorize the Federal and State Technology Partnership (FAST) program. The bill would require agencies to contribute 15 percent of their administration funds

to SBA for to carry out these two programs and deploy outreach initiatives in a coordinated and streamlined way. During markup by the Senate Committee on Small Business and Entrepreneurship, several amendments were added and adopted, including some that would require the Small Business Administration to increase outreach and awards to women and minority-owned businesses.

Status: On April 18, 2016, Senator Jeanne Shaheen (D-NH) introduced S. 2812, which was referred to the Senate Committee on Small Business and Entrepreneurship, which reported an amended version of the bill on May 11, 2016.

STEM Education and Health Workforce Development

Background: STEM education programs are spread across 13 federal agencies and are coordinated by the Committee on STEM Education (CoSTEM) within the White House Office of Science and Technology Policy (OSTP). According to the [2011 Federal Science, Technology, Engineering, and Mathematics \(STEM\) Education Portfolio](#) report, the majority of STEM education funding among Federal agencies comes from the NSF (34%), the Department of Education (29%), and the Department of Health and Human Services (17%). In addition to the below bills, a number of provisions in the [America Competes Reauthorization Act of 2015](#) address STEM education, and the [America's FOCUS Act of 2015](#) would set aside funds for STEM education.

H.R. 467 *STEM Opportunities Act of 2015*

Provisions of the Legislation/Impact on NIH: Among the provisions, the bill would (1) require OSTP to provide federal science agencies with guidance on establishing specified policies to accommodate the needs of researchers who are caregivers; (2) require each federal science agency to annually collect and submit to the NSF institution-level data on a number of items including demographics, primary field, award type, and review rating (as practicable); (3) direct OSTP, in collaboration with NSF, to identify and disseminate to federal science agencies information and best practices useful in educating program officers and members of standing peer review committees at federal science agencies about research on implicit gender, race, or ethnic bias; and methods to minimize the effect of such bias in federal research grant reviews; and (4) require federal science agencies to maintain or develop and implement policies and practices to minimize the effects of implicit bias in federal research grant reviews.

Status: On January 22, 2015, Representative Eddie Bernice Johnson (D-TX) introduced H.R. 467, which was referred to the House Committee on Science, Space, and Technology. No further action has occurred.

S. 1183 *STEM Gateways Act*

Provisions of the Legislation/Impact on NIH: The bill would direct the Department of Education to award competitive grants for STEM elementary and secondary school programs that encourage interest in the STEM fields; motivate engagement in the STEM fields by providing relevant hands-on learning opportunities; support classroom success in the STEM disciplines; support STEM workforce training and career preparation for secondary school students; or improve the access of secondary school students to STEM career and continuing education opportunities.

Status: On May 4, 2015, Senator Kirsten Gillibrand (D-NY) introduced S. 1183, which was referred to the Senate Committee on Health Education and Pensions. No further action has occurred.

[H.R. 2468](#) *Minority Inclusion in Clinical Trials Act of 2015*

Provisions of the Legislation/Impact on NIH: This bill would require that the Secretary, acting through NIH, CDC, and AHRQ, award grants to expand existing opportunities for scientists and researchers; and promote the inclusion of underrepresented minorities in health professions. The bill also contains provisions to build the health workforce in underrepresented communities, eliminate disparities in maternity health outcomes, and establish a health disparities education program. Section 2 of the bill contains a sense of Congress that NIMHD should include within its strategic plan ways to increase representation of underrepresented communities in clinical trials. This section is similar to language in the 21st Century Cures Act.

Status: On May 20, 2015, Representative Bobby Rush (D-IL) introduced H.R. 2468, which was referred to the House Committee on Energy and Commerce. No further action has occurred.

[H.R. 2762](#) *GIRLS STEM Act*

Provisions of the Legislation/Impact on NIH: This bill would amend the Elementary and Secondary Education Act of 1965 to provide grants to eligible local educational agencies to encourage female students to pursue studies and careers in science, mathematics, engineering, and technology.

Status: On June 12, 2015, Representative Jerry McNerney (D-CA) introduced H.R. 2762, which was referred to the House Committee on Education and the Workforce. No further action has occurred.

[H.R. 2773](#) *21st Century STEM for Girls and Underrepresented Minorities Act*

Provisions of the Legislation/Impact on NIH: This bill would amend the Elementary and Secondary Education Act of 1965 to provide grants to local educational agencies to encourage girls and underrepresented minorities to pursue studies and careers in science, mathematics, engineering, and technology. This bill is similar to H.R. 2762 except that it targets underrepresented minorities as well as females.

Status: On June 15, 2015, Representative Joyce Beatty (D-OH) introduced H.R. 2733, which was referred to the House Committee on Education and the Workforce. No further action has occurred.

Recent Hearings of Interest

Appropriations Hearings

[Senate Hearing on President Obama's Proposed Fiscal 2017 Budget Request for NIH](#)

April 7, 2016

Witnesses included Francis Collins, Director, NIH; Douglas Lowy, Acting Director, NCI; Walter Koroshetz, Director, NINDS; Richard Hodes, Director, NIA; Christopher Austin, NCATS; and Nora Volkow, Director, NIDA.

Summary: Members raised concerns about the President's request for mandatory funding for NIH. Dr. Collins highlighted ten areas in which we could make major advancements in the next ten years if given sustained funding, including the Precision Medicine, BRAIN, and Cancer Moonshot Initiatives. In addition to these topics, witnesses described efforts in particular areas such as opioid abuse, big data, and Zika. Dr. Koroshetz emphasized the importance of supporting basic research as well as targeted research, noting that we could not have predicted where our current advances would come from.

[House Hearing on President Obama's Proposed Fiscal 2017 Budget Request for NIH](#)

March 16, 2016

Witnesses included Francis Collins, Director, NIH; Anthony Fauci, Director, NIAID; Richard Hodes, Director, NIA; Doug Lowy, Acting Director, NCI; and Nora Volkow, Director, NIDA.

[Senate hearing on the NIH: Investing in a Healthier Future](#)

Senate Appropriations Subcommittee on Labor, Health and Human Services, Education

October 7, 2015

Witnesses included Francis Collins, NIH Director; Nora Volkow, NIDA Director; Griffin Rodgers, NIDDK Director; Walter Koroshetz, NINDS Director; Jon Lorsch, NIGMS Director; and Douglas Lowy, NCI Acting Director.

Summary: Chairman Blunt asked the witnesses to talk about their research programs and how to increase research opportunities and training for young investigators. Dr. Collins emphasized the importance of NIH's long-term investment in basic biomedical research, and he highlighted advances including increased longevity, declining cancer rates, and the realistic prospect of an AIDS-free generation. Broad themes included what NIH would do if its annual budget were increased by \$2-3 billion, and the potential impact of a Continuing Resolution. Witnesses responded that caps on innovation would decrease opportunities for young scientists, efforts such as the BRAIN Initiative and Precision Medicine Initiative would stall, and access to treatments would be reduced.

[House Hearing on President Obama's Proposed Fiscal 2016 Budget Request for the NIH](#)

House Appropriations Subcommittee on Labor, Health and Human Services, Education

March 3, 2015

Witnesses included Francis Collins, NIH Director; Anthony Fauci, NIAID Director; Thomas Insel, NIMH Director; Jon Lorsch, NIGMS Director; Nora Volkow, NIDA Director; and Gary Gibbons, NHLBI Director.

[Senate Hearing on President Obama's Proposed Fiscal 2016 Budget Request for the NIH](#)

Senate Appropriations Subcommittee on Labor, Health and Human Services, Education
April 30, 2015

Witnesses included Francis Collins, NIH Director; Anthony Fauci, NIAID Director; Gary Gibbons, NHLBI Director; Thomas Insel, NIMH Director; Doug Lowy, NCI Acting Director; and John Lorsch, NIGMS Director.

[Federal Investments in Neuroscience and Neurotechnology](#)

House Appropriations Subcommittee on Commerce, Justice, and Science
March 26, 2015

Witnesses included Jo Handelsman, Associate Director for Science OSTP; James Olds, Assistant Director for Biological Sciences NSF; Zack Lynch, Executive Director of the Neurotechnology Industry Organization; and Steven Hyman, Director of the Stanley Center for Psychiatric Research at the Broad Institute of MIT and Harvard.

21st Century Cures Initiative (House) / Continuing America's Leadership in Medical Innovation for Patients (Senate) Hearings

[Legislative Hearing on 21st Century Cures](#)

House Energy and Commerce Health Subcommittee
April 30, 2015

Witnesses included Kathy Hudson, NIH Deputy Director for Science, Outreach, and Policy; Janet Woodcock, FDA Center for Drug Evaluation and Research; and Jeffrey Shuren, FDA Center for Devices and Radiological Health.

[Continuing America's Leadership in Medical Innovation for Patients](#)

Senate Committee on Health, Education, Labor, and Pensions
March 10, 2015

Witnesses included Francis Collins, NIH Director and Margaret Hamburg, FDA Commissioner.

[Continuing America's Leadership: Advancing Research and Development for Patients](#)

March 24, 2015

Senate Committee on Health, Education, Labor, and Pensions

Witnesses included Bruce Sullenger, Duke Translational Research Institute; Alexis Borisy, Third Rock Ventures; Michael Mussallem, Edwards Lifesciences; and Allan Coukell, Pew Charitable Trusts.

[Continuing America's Leadership: The Future of Medical Innovation for Patients](#)

April 28, 2015

Senate Committee on Health, Education, Labor, and Pensions

Witnesses included Roderic Pettigrew, NIBIB Director; Christopher Austin, NCATS Director; Janet Woodcock, FDA Center for Drug Evaluation and Research; and Jeffrey Shuren, FDA Center for Devices and Radiological Health.

[Continuing America's Leadership: Realizing the Promise of Precision Medicine for Patients](#)

May 5, 2015

Senate Committee on Health, Education, Labor, and Pensions

Witnesses included Francis Collins, NIH Director; Karen DeSalvo, National Coordinator for Health Information Technology; and Jeffrey Shuren, FDA Center for Devices and Radiological Health.

Other Hearings and Roundtables Relevant to NINDS

Broad Review of Concussions: Initial Roundtable

House Energy and Commerce Oversight and Investigations Subcommittee
March 14, 2016

Participants included Grant Baldwin, CDC; David Cifu, Virginia Commonwealth University; Michael Collins, University of Pittsburgh Medical Center; Captain (Dr.) Mike Colston, Defense Centers for Excellence for Psychological Health and Traumatic Brain Injury (DCoE/DOD); Gerard Gioia, Children's National Health System; Colonel Dallas Hack, consultant retired from DOD; Brian Hainline, Indiana University School of Medicine and New York University School of Medicine; Walter Koroshetz, NINDS; Geoffrey Manley, UCSF; Michael McCrea, VA Medical Center in Milwaukee, WI; Lisa McHale, Concussion Legacy Foundation; Ann McKee, Boston University; Jeff Miller, National Football League (NFL).

Summary: The meeting was convened to raise awareness on concussions and set the stage for potential future events sponsored by the Committee. The discussion raised a number of issues related to the current understanding and recent advances in how to prevent, diagnose, and treat brain injury. Topics spanned concussion, traumatic brain injury, and CTE in both youth and professional contact sports.

Follow up: On May 13, 2016, the Committee held a second event, a hearing entitled [Concussions in Youth Sports: Evaluating Prevention and Research](#). Witnesses were from sports organizations, advocacy groups, and academia. The discussion focused on concussions in youth sports and ways to improve safety. In particular, the participants discussed the current knowledge around concussion in youth, need for more attention on this large population group, guidelines for practice and game situations, educational and training policies, and the role of culture in youth sports.

The Fight Against Alzheimer's Disease: Are We on Track to a Treatment by 2025?

Senate Special Committee on Aging
March 25, 2015

Witnesses included B Smith, former model, diagnosed with early onset AD; Dan Gasby, husband and caretaker of B Smith; Richard Hodes, NIA Director; Ron Peterson, Mayo Clinic and Chair of Advisory Council on Alzheimer's Research, Care, and Services for NAPA; Kim Stemley, caregiver; and Heidi Weirman, MaineHealth Geriatrics.

What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?

House Energy and Commerce Oversight and Investigations Subcommittee
May 1, 2015

Witnesses included Nora Volkow, NIDA Director; Mike Botticelli, Office of National Drug Control Policy Director; Richard Frank, HHS Assistant Secretary for Planning and Evaluation; Doug Throckmorton, FDA Deputy Center Director for Regulatory Affairs; Debra Houry, Director of CDC National Center for Injury Prevention and Control; Pamela Hyde,

Administrator, Substance Abuse and Mental Health Services Administration; and Patrick Conway, Deputy Administrator, Innovation and Quality and CMS Medical Officer.

[Cannabidiol: Barriers to Research and Potential Medical Benefits](#)

Senate Caucus on International Narcotics Control

June 24, 2015

Witnesses included Nora Volkow, NIDA Director; Doug Throckmorton, FDA Deputy Director for Regulatory Programs; and Joseph Rannazzisi, DEA Deputy Assistant Administrator