National Institute of Neurological Disorders and Stroke

LEGISLATIVE UPDATE:

Overview of Legislation from the 114th Congress

May 2015

NINDS OFFICE OF SCIENCE POLICY & PLANNING

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Appropriations Update

FY 2016

The President's FY 2016 budget was released on February 2, 2015. The budget reflects the Administration's priority to invest in basic research and technology in order to remain economically and globally competitive.

	FY 2016 Budget Request	FY 2015 Enacted	Change in Dollars (%)
NIH	$31.31 billion	$30.31 billion	+ $1 billion (1%)
NINDS	$1.66 billion	$1.60 billion	+ $55 million (1%)

In particular, the budget prioritizes biomedical research by proposing $135 million for NIH's contribution to the multi-agency Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative[SM], which is an increase of $70 million from FY 2015. This request for BRAIN allocates $23 million each for NINDS and NIMH. In addition, $200 million is proposed for the Precision Medicine Initiative at NIH. The budget includes an increase of $50 million for research on Alzheimer's disease. Additional priorities for NIH include Ebola research and vaccine development, combating antibiotic resistance, continued support for the Accelerating Medicines Partnership (AMP), and the Big Data to Knowledge program.

In spring 2015, Dr. Collins, accompanied by several institute directors, testified at two hearings related to the FY 2016 budget – one before the House Appropriations Subcommittee on Labor, HHS, Education and Related Agencies and one before the Senate Appropriations Subcommittee on Labor, HHS, Education and Related Agencies. His written testimony can be found at the following links: House; Senate. In the opening statements, Dr. Collins highlighted progress in developing vaccines for Ebola and influenza, incentives for young and early-stage investigators, The BRAIN Initiative, the Precision Medicine Initiative, and the NIH-wide strategic plan. This plan was mandated by the FY2015 budget legislation and will define the overarching strategies for NIH. It will include the individual plans of each IC and will be submitted to Congress in December, 2015. In addition to asking for details on these topics, members of Congress expressed interest in research on Alzheimer's disease, multiple sclerosis, opioid addiction and overdose, and mental health. The inclusion of both sexes in preclinical and clinical research and prioritization of funding by disease burden were also discussed.

This spring the House and Senate passed a concurrent budget resolution for FY 2016 (S. Con. Res. 11), marking the first time since 2009 that both chambers agreed to a budget resolution. This budget resolution adheres to the spending caps as established in the Budget Control Act of 2011 (also known as the sequester), though the amounts laid out in the document are not binding. While the resolution does not specify funding levels for NIH, it includes a policy statement stating: "Thanks to the visionary and determined leadership of innovators throughout America, including industry, academic medical centers, and the National Institutes of Health (NIH), the United States has led the way in early discovery. The United States leadership role is being

threatened, however, as other countries contribute more to basic research from both public and private sources."

FY 2015

President Obama signed the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) into law on December 16, 2014. This was an omnibus budget for FY 2015 that provided $30.3 billion for NIH, an increase of $240 million from the FY 2014 funding level, and allocated $1.605 billion for NINDS, which represents an increase of $17 million or 1.1% from the FY 2014 funding level.

Pending Legislation Directly Relevant to NINDS

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

Background: In April of 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. The Initiative 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. After substantial revisions and another hearing on the effect of this legislation on the NIH and FDA, the third version of the bill was marked up by the House Energy and Commerce Health Subcommittee on May 14th. Although the bill was passed by the subcommittee, many of the provisions were still bracketed, meaning that they have not yet been finalized. As of the writing of this report, a fourth version of the bill is scheduled to be marked up by the full Energy and Commerce Committee on May 21, 2015.

The Senate Health, Education, Labor and Pensions (HELP) Committee is conducting a separate, parallel and complementary effort through a bipartisan working group led by Senator Lamar Alexander (R-TN) and Sen. Patty Murray (D-WA). The Senate Committee does not plan to vote on legislation from the House. Rather, they will write separate legislation, and conference the bills from the two chambers of Congress. 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.

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

Provisions of the Legislation/Impact on NIH: The 302-page 21st Century Cures bill includes three titles. Title 1: Discovery is largely focused on the National Institutes of Health. Provisions in this title would:

- Authorize $1.5 billion increases in NIH funding for each of the next 3 years and create the NIH Innovation Fund, which would be funded by an additional $2 billion in mandatory spending for each of the next five years. 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.
- Establish a Capstone Grant Program to facilitate lab closures at the end of a scientist's career.
- 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 and antibiotic 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".

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, and outreach to the patient and scientific communities. 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.

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 as amended. As of the writing of this report, the amended text is not yet available.

Autism

Background: Since 2006, five 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.

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 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.

Hereditary Hemorrhagic Telangiectasia

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 guideline 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 that 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 the NINDS, the 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 System

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 made it out of Committee. The bill was re-introduced in both the House (H.R. 2595) and Senate (S. 425) in 2011 (the 112th Congress), but no further action was taken. The bill is also included in the 21st Century Cures Act.

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

Provisions of the Legislation/Impact on NIH: This bill – identical to the version introduced in the 112th Congress - authorizes the Secretary of HHS, acting through the CDC, to enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, such as multiple sclerosis and Parkinson's disease. This information would be incorporated into a National Neurological Diseases Surveillance System, which would be designed to facilitate further research on neurological disease.

Status: The bill was introduced on January 13, 2015, by Rep. Michael Burgess (R-TX) and was referred to the House Energy and Commerce Committee. Senator Johnny Isakson (R-GA) introduced the bill on March 24, 2015, which was referred to the Senate Committee on Health, Education, Labor, and Pensions. 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 would:

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 Initiative℠.
- 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 the engage underrepresented students at the K-8 level.

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. As of the writing of this report, the full amended text is not yet available.

America's FOCUS Act

Background: During the 113th Congress, Congressman Chaka Fattah (D-PA) introduced an identical bill, the America's FOCUS Act of 2013, but it failed to pass out of Committee.

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.

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.

Funding for the 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 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.

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 of 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.

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 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.

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, which is currently being considered by the House of Representatives, has several provisions encouraging the use of prize authority by Federal science agencies, and the America's FOCUS Act of 2015 would set aside funds for science prizes.

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.

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[1] 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.

[1] Clayton JA, and Collins FS. "Policy: NIH to balance sex in cell and animal studies." Nature. 2014 May 15;509(7500):282-3.

STEM Education

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.

Recent Hearings of Interest

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

Hearing on President Obama's Proposed Fiscal 2015 Budget Request for the NIH
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.

House Appropriations Subcommittee on Commerce, Justice, and Science

Federal Investments in Neuroscience and Neurotechnology
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.

House Energy and Commerce Health Subcommittee

Legislative Hearing on 21st Century Cures
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.

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

Hearing on President Obama's Proposed Fiscal 2015 Budget Request for the NIH
April 30, 2015
Witnesses included Francis Collins, NIH Director; Tony Fauci, NIAID Director; Gary Gibbons, NHLBI Director; Thomas Insel, NIMH Director; Doug Lowy, NCI Acting Director; and John Lorsch, NIGMS Director.

Senate Committee on Health, Education, Labor, and Pensions

Continuing America's Leadership in Medical Innovation for Patients
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
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
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
Witnesses included Francis Collins, NIH Director; Karen DeSalvo, National Coordinator for Health Information Technology; and Jeffrey Shuren, FDA Center for Devices and Radiological Health.

Senate Special Committee on Aging

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