Focus on Public Affairs

Congress, President Obama Agree on Two-Year Budget Deal, Continuing Resolution

In late October, House and Senate leaders reached a two-year budget agreement with the White House that suspends the federal debt ceiling through March 2017, allowing the government to borrow money to pay its debts, and raises existing caps on discretionary spending, providing Congress with flexibility to provide funding increases for some of its priorities. The House passed the bill by a vote of 266-177 on October 28, while the Senate passed the measure the following day by a vote of 64-35. President Obama signed the bill into law on November 2.

The budget deal, officially known as the Bipartisan Budget Act of 2015, lifts the current caps on both nondefense and defense discretionary spending for fiscal years (FY) 2016 and 2017. In FY 2016, the nondefense discretionary spending cap is raised by $25 billion, providing appropriators with significantly more dollars to allocate to priority areas. AAI is hopeful that Congress will take this opportunity to restore funds lost to sequestration and provide a significant funding boost to the National Institutes of Health (NIH).

The budget agreement also suspends the federal debt ceiling through March 15, 2017, ensuring that the country will have the ability to meet its near-term fiscal obligations. It also eliminates a major procedural and budgetary impediment, allowing legislators to focus on a final appropriations agreement for FY 2016.

AAI President Dan Littman, M.D., Ph.D., joined with the president of FASEB and 20 other FASEB society presidents in co-signing a letter to leaders on Capitol Hill asking them "to expedite passage of the fiscal year (FY) 2016 spending bills that included proposed funding increases for these critically important research agencies" (NIH and the National Science Foundation).

Prior to the budget agreement, Congress had passed, and President Obama had signed, a resolution that funds the federal government through December 11, 2015. The resolution at least temporarily avoided a federal government shutdown which would have occurred if Congress and the President had not struck a deal by October 1.

The measure, also known as a Continuing Resolution (CR), funds the vast majority of federal agencies and programs at approximately FY 2015 levels. As a result, NIH is currently operating at roughly its FY 2015 funding level of $30.3 billion through December 11, or until another appropriations bill becomes law.

While passage of a CR is a much better outcome than a government shutdown, it is not ideal. Under a CR, NIH 1) cannot initiate new programs, 2) sets more conservative paylines, and 3) generally funds non-competing research grant awards at 90 percent of the previously committed level. In addition, under a CR, NIH will not receive the much needed funding increase approved by the House Appropriations Committee ($1.1 billion) or the Senate Appropriations Committee ($2 billion). Although a full-year budget agreement would not guarantee this additional funding, these previously-passed appropriations bills reflect strong bipartisan support for increased NIH funding.

Election of New House Speaker May Restore "Regular Order," Prevent Future Government Shutdowns

On October 29, Representative Paul Ryan (R-WI, 1st) was elected Speaker of the House of Representatives, replacing the outgoing Speaker, Rep. John Boehner (R-OH, 8th). In brief remarks after being sworn in, Ryan, the former chairman of both the House Budget Committee and House Ways and Means Committee, pledged to restore "regular order" to the House, letting committees "retake the lead in drafting all major legislation" and ensuing that all members, including those in the minority, are allowed to participate in the legislative process. He cautioned his colleagues that, "when we do not follow regular order—when we rush to pass bills a lot of us do not understand—we are not doing our job. Only a fully functioning House can truly represent the people." In the view of AAI, a return to regular order would reduce acrimony, enhance transparency, and significantly reduce the likelihood of future government shutdowns.

AAI Members Participate in National Rally for Medical Research Capitol Hill Day

AAI Cosponsors Effort For Third Year

AAI Committee on Public Affairs members Beth Garvy and David Chaplin joined almost 300 advocates from 40 states in visiting Congressional offices as part of the third annual Rally for Medical Research Capitol Hill Day (Rally Hill Day). Garvy, professor and chair of the

Department of Microbiology, Immunology and Molecular Genetics at the University of Kentucky, visited the offices of six members of the Kentucky congressional delegation, including Senate Majority Leader Mitch McConnell (R-KY); Sen. Rand Paul (R-KY), a member of the Senate Health Education Labor and Pensions (HELP) Committee (which authorizes NIH programs); and Rep. Harold (Hal) Rogers (R-KY, 5th), chair of the House Appropriations Committee (which funds NIH). She was accompanied by AAI Director of Public Policy and Government Affairs Lauren Gross, J.D. Chaplin, professor in the Department of Microbiology at the University of Alabama, Birmingham, visited with staff from eight members of the Alabama delegation, including the offices of Sen. Richard Shelby, a member of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies ("Labor-HHS Appropriations Subcommittee"), and Rep. Martha Roby (R-AL, 2nd), a member of the House Labor-HHS Appropriations Subcommittee.

Participants in the Rally Hill Day, which took place on September 17, urged members of Congress to provide robust, sustained, and predictable funding increases for the National Institutes of Health (NIH). The Rally participants were able to visit 80 percent of all Senate offices and more than a third of House offices.

(L-R) Beth Garvy, former AAI Public Policy Fellow Jennifer (Lori) Blanchfield, David Chaplin, and Lauren Gross

Beth Garvy and other Hill Day participants with staffer for Rep. Hal Rogers

AAI served as a cosponsor of this year's effort, which was organized by the American Association for Cancer Research, for the third year. More than 300 other organizations, including professional societies, patient advocacy groups, and private industry, expressed their support for the rally by either sending representatives to the Hill Day or taking other actions in support of increased NIH funding.

In addition to visiting congressional offices, Garvy, Chaplin, and Gross attended a breakfast featuring keynote speaker Rep. Tom Cole (R-OK), Chairman of the House Labor-HHS Appropriations Subcommittee; and a reception, featuring remarks by Senator Richard Durbin (D-IL), the Assistant Senate Minority Leader; Senator Patty Murray (D-WA), Ranking Member on both the Senate Labor-HHS Appropriations Subcommittee and the Senate HELP Committee; Senator Jerry Moran (R-KS), a member of the Senate Labor-HHS Appropriations Subcommittee; Senator Amy Klobuchar (D-MN); and NIH Director Francis S. Collins, M.D., Ph.D.

Proposed Updates to Federal Policy Protecting Human Subjects

The Department of Health and Human Services recently released a Notice of Proposed Rulemaking for revisions to the Common Rule, which governs the standards, treatment, and protections for human subjects involved in research. AAI is working with the Federation of American Societies for Experimental Biology to develop comments to be submitted in response to these revisions. However, all individuals are invited to submit comments. If you would like to submit comments please visit www.regulations.gov and enter Regulation Identifier Number 0937-AA02. The deadline for responses is December 7, 2015.

AAI Responds to Request for Comments on NIH-wide Strategic Plan

AAI recently submitted comments to NIH in response to its "Request for Information (RFI): Inviting Comments and Suggestions on a Framework for the NIH-wide Strategic Plan." The NIH RFI resulted from a provision in the fiscal year 2015 federal budget, in which Congress requires NIH to develop and submit a strategic plan by December 2015.

NIH's proposed framework would include a review of its past and current situation, including why budget constraints hurt progress; a section describing its main priorities, which include fundamental science, health promotion and disease prevention, and treatments and cures; and a description of its overall priorities and stewardship plans. The RFI requested input on the following topics:

- "potential benefits, drawbacks/challenges, and areas of consideration for the current framework,
- compatibility of the framework with the broad scope of the NIH mission,
- additional concepts in ICO [Institute and Center Operations] strategic plans that are cross-cutting and should be included in this trans-NIH strategic plan,
- comprehensive trans-NIH research themes that have not been captured in the Areas of Opportunity that Apply Across Biomedicine,
- components of the Areas of Opportunity that Apply Across Biomedicine that are not applicable to an NIH-wide Strategic Plan, and
- future opportunities or emerging research needs."

The AAI comments (see www.aai.org > Public Affairs > Letters and Comments) applaud NIH's focus on basic research, and encourage further emphasis on the unexpected outcomes of fundamental science. AAI suggests that NIH address areas where Congress can assist NIH in achieving its mission, including providing predictable funding, allowing funds to be carried over at the end of the fiscal year, and lifting travel restrictions for government employee travel to scientific conferences. In addition, AAI recommends that the immune system be considered a cross-cutting theme, with vaccines and immunotherapeutics included as cross-cutting concepts.

Precision Medicine Initiative Recommendations Released

A detailed framework for building a one million person cohort for the Precision Medicine Initiative (PMI) was presented by the PMI Working Group at the NIH Advisory Committee to the Director meeting in late September (http://www.nih.gov/precisionmedicine/working-group.htm). The PMI, which was announced by President Obama in early 2015, aims to revolutionize medicine by accounting for individual variability in genes, environment, and lifestyle.

The working group recommended ways to guide the development of the cohort, including making inclusion in the cohort broadly accessible by enabling any American to join and by partnering with healthcare providers to recruit participants, and emphasized the need to keep cohort participants engaged and informed over the course of what is expected to be a long-term study. The working group also offered recommendations regarding data collection, storage, and use, including the central storage of data which would later be moved to multiple coordinating centers that would serve as contact points for other institutions.

NIH Director Francis Collins immediately accepted the recommendations and appointed Josephine Briggs, current director of the National Center for Complementary Integrative Health, to be the acting director of the PMI.

NIH Working Group Recommends Ways to Improve Grants Process

The NIH Grant Review, Award, and Management Process (GRAMP) Working Group recently released its recommendations on ways to optimize the grants process. The GRAMP working group, a subgroup of the NIH Scientific Management Review Board (SMRB), was tasked by the SMRB with "further optimizing the process of reviewing, awarding, and managing grants in a way that maximizes the time researchers can devote to research while still maintaining proper oversight." The working group specifically focused on streamlining the application and awarding process so that grantees can receive their funds sooner, while also reducing the burden on administrative staff, reviewers, and council members.

In July, GRAMP released ten recommendations to improve the grant process, including: 1) fast-track awards for high priority, top scoring applications, 2) share best practices for speeding the award process between institutes and centers, 3) award partial funding early in the fiscal year, with the remaining paid after passage of a final appropriations bill, 4) pilot test a pre-application process, 5) deepen and diversify the peer review pool, 6) consider pilot testing a continuous submission policy, 7) provide review staff with needed resources to handle additional volume of applications, 8) enhance just-in-time procedures, 9) consult with outside experts on improving efficiency of administrative aspects of grants process, and 10) consider prize competitions to generate innovative ideas to improve the grant process.

The working group was created by the SMRB in response to a 2014 request by NIH Director Francis Collins for SMRB to advise NIH on ways to optimize the grants process. To date, however, Collins has not indicated whether any of the recommendations will be implemented.

NIH Appoints New Deputy Director for Extramural Research

Michael Lauer

NIH Director Francis Collins has appointed Michael Lauer, M.D., to be the new NIH deputy director for Extramural Research. He replaces Sally Rockey, Ph.D., who had served in this position since 2008.

Lauer, who most recently was the director of the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute (NHLBI), was previously the director of the Division of Prevention and Population Science and the director of the Division of Cardiovascular Sciences at NHLBI. He was recently appointed as the NIH co-chair for the President's Precision Medicine Initiative.

Prior to joining NIH in 2007, Lauer was a professor of Medicine, Epidemiology, and Biostatistics at the Cleveland Clinic's Lerner College of Medicine of Case Western Reserve University.

A board-certified cardiologist, Lauer received his M.D. from Albany Medical College. After an internship and residency in medicine at Massachusetts General Hospital and Harvard Medical School, he served as a clinical fellow in medicine (cardiology) at Harvard Medical School and Beth Israel Hospital.

NIH Appoints Inaugural Director of NIH Division of Biomedical Research Workforce Programs

NIH Director Francis Collins, M.D., Ph.D., appointed Kay Lund, Ph.D., to be the inaugural director of the NIH Division of Biomedical Research Workforce Programs ("Workforce Programs Division"). Lund, who was previously a professor of cell biology and physiology with joint appointments in pediatrics and nutrition at the University of North Carolina, Chapel Hill, will lead the implementation of programs that strengthen and sustain the nation's biomedical workforce.

The Workforce Programs Division was created as a result of recommendations made by the NIH Advisory Committee to the Director Working Group on the Biomedical Research Workforce. It is charged with providing "ongoing analysis of the biomedical research workforce and evaluation of NIH policies to enable NIH to sustain and grow the biomedical research workforce at all levels to assure the most productive biomedical research endeavors and most effective use of taxpayer dollars."

AAI Responds to USDA "Notice of Petition" to Modify Animal Welfare Act Regulations

The United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) recently received a petition from the National Anti-Vivisection Society (NAVS) seeking to amend the Animal Welfare Act Regulations. NAVS called upon APHIS to require research facilities to include additional information in their annual reports about the animals being used in research, including the genetic background of the animals; what each animal is specifically being used for; the location of the facility housing the animals; and the origin of the animals (e.g. bred in-house or purchased).

On August 21, AAI submitted comments (see www.aai.org > Public Affairs > Letters and Comments) in response to this petition. While affirming support for the humane care and use of animals in research, AAI expressed concern that the proposed changes would impose increased costs and administrative burden without tangibly improving the welfare of research animals. Specifically, research facilities and investigators would need to implement new tracking mechanisms and develop tools to properly report research protocols and techniques, which would require additional personnel and resources. In addition, AAI cautioned APHIS about the potential danger posed by animal rights organizations, which could "target" institutions and investigators if specific animal locations were required to be reported.

New Federal "Dual Use Research of Concern" Policy in Effect

A new "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)" became effective on September 24, 2015. The DURC policy describes the practices and procedures that are required for the use of pathogens or toxins whose use could potentially be misapplied to pose a threat to public health or safety.

Research is considered DURC if it meets three conditions. First, one of the following agents or toxins must be used: highly pathogenic avian influenza, *Bacillus anthracis,* Botulinum neurotoxin, *Burkholderia*

mallei, Burkholderia pseudomallei, Ebola virus, foot-and-mouth disease virus, *Francisella tularensis,* Marbug virus, reconstructed 1918 influenza virus, rinderpest virus, toxin-producing strains of *Clostridium botulinum,* variola major virus, variola minor virus, and *Yersinia pestis.* Second, the experiments must fall into at least one of the following seven categories: "1) enhances the harmful consequences of the agent or toxin, 2) disrupts immunity or the effectiveness of an immunization against the agent or toxin, 3) confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies, 4) increases the stability, transmissibility, or the ability to disseminate the agent or toxin, 5) alters the host range or tropism of the agent or toxin, 6) enhances the susceptibility of a host population to the agent or toxin, or 7) generates or reconstitutes an eradicated or extinct agent or toxin listed above." If the first two conditions are met, then principal investigators (PIs) must have their research evaluated by their institution's Institutional Review Entity (IRE), which will determine if the research qualifies as DURC. Regardless of the IRE decision, the institution must report this research to the funding agency within 30 days of the IRE decision. If the research is considered DURC, then the PI and IRE must develop a risk mitigation plan within 90 days, to be submitted for approval by the funding agency.

Questions about this policy can be answered by each institution's designated "Institutional Contact for Dual Use Research (ICDUR)."

NSABB Discusses Recommendations on Gain-of-Function Research

On September 28, the National Science Advisory Board for Biosecurity (NSABB) met to hear updates on the development of recommendations that would govern Gain-of-Function (GOF) research. The meeting followed the federal government's October 2014 research funding pause on GOF research involving selected experiments on influenza, Middle East Respiratory Syndrome (MERS), and severe acute respiratory syndrome (SARS) viruses, due to biosafety and biosecurity concerns. At the recent meeting, NSABB heard progress reports from the its Working Group on Evaluating Risks and Benefits of GOF Studies Involving Pathogens with Pandemic Potential, and from Gryphon Scientific, a consulting firm hired to conduct a risk-benefit analysis for GOF studies. NSABB expects to release draft recommendations at the end of the year, and final recommendations in the spring of 2016.

National Academies Release Report on Reducing Regulatory Burden

The National Academies of Sciences, Engineering, and Medicine (NAS) recently released a report entitled "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century, Part I." The report reviews the regulations that research universities must follow and considers undue burdens that some of these requirements impose. It also recommends ways to reduce such burdens, including the creation of a public-private board to streamline research policies and specific actions that can be taken by Congress, the White House Office of Management and Budget, research institutions, and federal agencies.

The report was written by the NAS Committee on Science, Technology, and Law and its Board of Higher Education and Workforce, which were tasked with identifying the federal regulations and reporting requirements that had the most significant negative impact on research universities. The report, which was congressionally mandated, was released early due to a request from Senator Lamar Alexander (R-TN), chair of the Senate Health, Education, Labor, and Pensions Committee, who hopes to incorporate some of its recommendations in legislation he is currently drafting. The second part of the report will be released in the spring of 2016.

AAAS Soliciting Stories on the Benefits of Scientific Conferences to Science, Technology, and Society

Strict new federal regulations on government employee travel and conference spending were implemented in May 2012. As a result, it has been difficult for federal employees, including but not limited to those working at NIH, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Science Foundation, to participate in – or attend – scientific meetings and conferences.

Many groups, including AAI, have been asking both the Obama Administration and Congress to exempt from these restrictions federal employees who want to attend scientific or technical conferences. To support this effort, the American Association for the Advancement of Science (AAAS) is collecting stories describing how professional interactions at conferences, particularly with government employees, have led to valuable and productive collaborations. To submit your story, visit www.aaas.org/yourstory.