

# FOCUS ON PUBLIC AFFAIRS

## AAI Holds Fourth Annual Public Policy Fellows Capitol Hill Day

Earlier this year, the 2014–2015 class of AAI Public Policy Fellows traveled to Washington, D.C., to participate in the fourth annual AAI Public Policy Fellows Capitol Hill Day.

The 10 AAI Fellows were joined by AAI Committee on Public

Affairs Chair Clifford V. Harding, M.D., Ph.D., and AAI Advocacy Programs Subcommittee Chair Susanna Greer, Ph.D. The program opened on the evening of March 10 with a working dinner. National Institute of Allergy and Infectious Diseases (NIAID) Principal Deputy Director Hugh Auchincloss, M.D. (AAI '83), was the special guest speaker for the fourth consecutive year. Auchincloss provided a behind-the-scenes perspective on NIH and



AAI Fellows, leaders, and staff gathered on Capitol Hill



(L-R): AAI Fellows Ryan Cummings and Heather Kling, AAI Director of Public Policy and Government Affairs Lauren Gross, AAI Fellow Sesquile Ramon, and Senator Elizabeth Warren

presentation focused on preparing the Fellows for their visits to Capitol Hill.

Each of the Fellows visited two or three offices of his or her own congressional delegation, as well as other congressional offices. The Fellows advocated for predictable and sustained funding for NIH, including a budget of at least \$32 billion for fiscal year 2016. They also distributed AAI materials, including a recently issued AAI statement on the safety and efficacy of vaccines (see [http://aai.org/Public\\_Affairs/Letters-Comments.html](http://aai.org/Public_Affairs/Letters-Comments.html)).

## AAI Launches Fifth Year of Public Policy Fellows Program

May 1 marked the beginning of the fifth year of the AAI Public Policy Fellows Program (PPFP). The PPFP is designed to engage eligible postdoctoral fellows and junior scientists in public policy and legislative activities that impact biomedical research. To date, 40 early-career scientists from 24 different states have completed the program.

AAI is pleased to welcome the following AAI members to the 2015–16 PPFP:

Tullia Bruno, Ph.D., *University of Colorado School of Medicine*

Jason Gigley, Ph.D., *University of Wyoming*

Nichol Holodick, Ph.D., *The Feinstein Institute for Medical Research*

David Larson, Ph.D., *University of Hawaii Cancer Center*

Jean Nepomuscene Manirarora, D.V.M., Ph.D., *FDA Center for Biologics Evaluation and Research*

Meghan Marré, Ph.D., *University of Pittsburgh*

Nicole Perry, Ph.D., *Seattle Children's Research Institute*

Erica Stone, Ph.D., *The Wistar Institute*

Joshua Vieth, Ph.D., *Child Health Institute of New Jersey/ Rutgers University*

Jessica Werner, Ph.D., *University of Michigan*

For more information about the AAI PPFP, please visit [http://aai.org/Public\\_Affairs/PPFP/index.html](http://aai.org/Public_Affairs/PPFP/index.html).

## Alternative Funding Sources Discussed during Public Affairs Session at IMMUNOLOGY 2015™

The AAI Committee on Public Affairs (CPA) hosted a session, entitled “Funding for Immunology Research: Non-Federal Opportunities and NIAID Program Update,” at the AAI annual meeting IMMUNOLOGY 2015™ in New Orleans. Due to fiscal constraints imposed by federal budget cuts and inflationary erosion, NIH paylines and success rates have been reduced significantly, jeopardizing the careers of many productive senior and emerging scientists. As a result, non-governmental sources are becoming an increasingly attractive way to support important biomedical research. The AAI session provided scientists with background on—and tips on how to acquire—these alternative

sources of funding. The session also included an update on the state of immunology research funded by National Institute of Allergy and Infectious Diseases (NIAID), the primary funder of basic immunology research.



(L-R): Bruce Walker, William Chambers, Gwen Nguyen, Daniel Rotrosen, Clifford Harding

The session, which was chaired by AAI CPA Chair Clifford V. Harding, M.D., Ph.D., featured four speakers: William Chambers, Ph.D., national vice president for extramural research at the American Cancer Society, who spoke about the role of charitable and patient advocacy groups in funding biomedical research; Gwen Nguyen, cause director at Indiegogo, who described how crowd-funding can be used for biomedical research projects; Bruce Walker, M.D., director of the Ragon Institute of MGH, MIT and Harvard, and professor at Harvard



Audience members asking questions of the public affairs session speakers

University, who discussed the role of philanthropy in supporting biomedical research; and Daniel Rotrosen, M.D., director of NIAID's Division of Allergy, Immunology, and Transplantation, who, among other things, provided an update on a new NIAID program that sets aside additional funding for basic immunology-focused projects. The symposium was very well attended. Following the speakers' talks, there was a lively question-and-answer session.

## House Passes 21st Century Cures Act Includes New Mandatory Funding for NIH

In early July, the House of Representatives approved the *21st Century Cures Act*, a bipartisan bill designed "to accelerate the discovery, development, and delivery of 21st century cures," by a vote of 344-77. About two months earlier, the bill was unanimously approved by The House Energy & Commerce Committee (by a vote of 51-0). Among its many NIH and FDA provisions is a new \$8.75 billion NIH and Cures Innovation Fund.

The *21st Century Cures Act* is the product of more than a year of work by the House E&C Committee, most notably by Committee Chair Fred Upton (R-MI, 6th) and former Ranking Member Diana DeGette (D-CO, 1st). The first draft of the bill, which was released by Upton in January 2015, did not have the support of his Democratic colleagues. The version of the bill that was approved by the full House was at least the 6th iteration of the bill.

Unlike the original draft bill, the *21st Century Cures Act* would both permit and require new funding for NIH. The bill authorizes (but does not require) appropriators to increase the regular NIH budget by \$1.5 billion per year over the next three years. However, the bill requires new funding for NIH by establishing the NIH and Cures Innovation Fund. If the bill becomes law, NIH would receive an additional \$8.75 billion in "mandatory" funding over the next five years through this Fund.

The bill does place restrictions on how NIH Innovation Fund dollars may be used. For example, each year, at least \$500 million of Fund dollars must be allocated to another new program called the Accelerating Advancement Program (AAP). Under the AAP, the NIH Director would partner with NIH Institutes and Centers "to accomplish important biomedical research objectives." Every dollar that the NIH Director provides to an NIH Institute or Center would have to be matched by that Institute or Center. The bill would also require that a significant percentage of NIH Innovation Fund dollars be allocated to high-risk, high-reward research and early stage investigators.

Other NIH provisions of interest in the bill include:

- a requirement that NIH develop a strategic plan for fiscal years 2016-2020, and a new strategic plan once every five years;
- the establishment of 5-year terms for NIH Institute and Center Directors, though it does not place a limit on the number of terms that may be served;

- a requirement that NIH reduce administrative burden by implementing the recommendations of several groups that have already addressed this issue;
- the creation of a new Capstone Award “to facilitate the successful transition or conclusion of research programs.” This is very similar to an idea recently floated by NIH, tentatively entitled the NIH Emeritus Award.

In order for the bill to be considered on the House floor, the managers of the bill had to agree on a way to pay for it. According to the Congressional Budget Office, the House-passed version of the bill would actually reduce federal deficits over the next decade after accounting for the offsets in the bill, which include selling 70 million barrels of oil from the Strategic Petroleum Reserve

The Senate Health, Education, Labor, and Pensions (HELP) Committee is in the early stages of developing its own proposal. AAI recently signed a community letter (see <https://www.aamc.org/download/437064/data/communitylettertosenatehelpcommitteeonmedicalinnovation.pdf>) to HELP Committee Chair Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA), which offers a number of recommendations regarding potential NIH provisions in the bill. The HELP Committee has also held numerous hearings and is engaging the biomedical research community in an effort to understand the issues at play and determine some possible solutions. In particular, in multiple hearings, Alexander has asked NIH Director Francis Collins, M.D., Ph.D., to provide him with a list of steps that Congress can take to reduce the administrative burden of NIH researchers.

AAI will continue to actively follow the *21st Century Cures Act* and the companion innovation effort now underway in the Senate.

## AAI Submits Comments on Policies to Optimize NIH Funding

AAI recently submitted comments in response to the NIH “Request for Information (RFI): Optimizing Funding Policies and Other Strategies to Improve the Impact and Sustainability of Biomedical Research.” This RFI sought input on issues that could increase the efficacy and sustainability of the biomedical research enterprise despite tight fiscal conditions. AAI offered recommendations on a wide range of topics, including evaluating the allocation of the NIH budget, reviewing the efficacy of various NIH pilot initiatives, and reconsidering how grant applications are evaluated.

The NIH solicited information on four topic areas:

1. issues that limit the impact and sustainability of NIH-funded research
2. suggested adjustments to current funding policies
3. ideas for new policies that would increase impact and sustainability of NIH-funded research
4. other relevant issues

In its response (see [www.aai.org](http://www.aai.org) > Public Affairs > Letters and Comments), AAI recommended that NIH evaluate ongoing and future large projects/contracts, indirect cost reimbursements, and the percentage of salary charged to NIH grants, as well as identify ways to reduce administrative burden. AAI also recommended that NIH reduce the number of Requests for Applications, evaluate the efficacy of increased review for well-funded individuals, consider wider implementation of successful pilot programs, and adopt an expedited review process similar to that used for AIDS and AIDS-related applications. Finally, AAI suggested that new policies be geared toward expanding the role of staff scientists and extending funding advantages to those seeking their first R01 renewal. AAI also identified and recommended solutions to several current laws and regulations that impede the sustainability of the biomedical research enterprise, including NIH’s inability to carry over funding from one fiscal year to the next and travel restrictions for government scientists.

## AAI Submits Comments to USDA on Reducing Regulatory Burden

On May 18, AAI submitted comments in response to a U.S. Department of Agriculture (USDA) “Request for Information (RFI): Identifying and Reducing Regulatory Burdens.” The RFI sought to understand how current regulations could be streamlined or improved and to determine if any regulatory requirements are outdated or could benefit from flexibility.

In its comments (see [www.aai.org](http://www.aai.org) > Public Affairs > Letters and Comments), AAI provided two suggestions to reduce regulatory burden for researchers and oversight committees. First, AAI recommended that “the USDA should exempt from AWA [Animal Welfare Act] registration certain nonagricultural biomedical research procedures that occur in an agricultural research setting.” Exemption under certain circumstances would potentially reduce the number of animals used in biomedical research. AAI also recommended that

the USDA reduce the number of yearly inspections required, as multiple inspections per year impose an administrative burden on Institutional Animal Care and Use Committees without improving the health or safety of the research animals.

## AAI Responds to Petition on Alternatives to Animal Research

On May 29, AAI submitted comments to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regarding the use of animal alternatives in biomedical research. In response to this "Notice of Petition: Petition to Define Alternatives to Procedures That May Cause Pain or Distress and To Establish Standards Regarding Consideration of These Alternatives," AAI urged APHIS to refrain from creating additional definitions for the term "alternative" or from supplanting the current role of Institutional Animal Care and Use Committees (IACUCs) in the evaluation of whether alternatives to animal models have been thoroughly considered (see [www.aai.org](http://www.aai.org) > Public Affairs > Letters and Comments).

The "Notice of Petition" was posted by APHIS in response to a petition submitted by the Physicians Committee for Responsible Medicine, which requested that APHIS amend the Animal Welfare Act to provide definitions of "alternative" and "painful procedure," specify what investigators must do when considering alternatives to animal models, and standardize the consideration and evaluation of alternatives in animal research. The AAI comments argue, however, that the measures suggested in the petition would increase the regulatory and administrative burden on investigators and IACUCs without tangibly improving animal welfare.

## Senators Durbin, Graham Create NIH Caucus

Senators Richard Durbin (D-IL) and Lindsey Graham (R-SC) recently joined forces to create a Senate NIH Caucus. A congressional caucus is a coalition of members of Congress who meet to pursue common objectives. Durbin and Graham will serve as co-chairs of the caucus.

According to a report in the Washington, D.C., newspaper, *The Hill*, "[t]he caucus will focus on the agency's waning ability to fund research after losing 25 percent of its purchasing power since 2003...." Durbin and Graham "attribute the decline to 'sequestration

and flat budgets'" (see <http://thehill.com/policy/healthcare/242483-senators-create-new-caucus-on-nih-funding>).

Senators formally announced the caucus at a May 19 event attended by several representatives from NIH, including NIH Director Francis Collins, M.D., Ph.D.; National Center for Advancing Translational Sciences Director Christopher Austin, M.D.; National Institute of Mental Health Director Tom Insel, M.D.; and National Institute on Drug Abuse Director Nora Volkow, M.D.

The caucus is open to all senators. Thus far, Durbin and Graham have been joined by Senators Tammy Baldwin (D-WI), Richard Blumenthal (D-CT), Ben Cardin (D-MD), Robert Casey (D-PA), Christopher Coons (D-DE), Joe Donnelly (D-IN), Al Franken (D-MN), Angus King (I-ME), Amy Klobuchar (D-MN), Edward Markey (D-MA), Claire McCaskill (D-MO), Gary Peters (D-MI), Brian Schatz (D-HI), Debbie Stabenow (D-MI), Thom Tillis (R-NC), Tom Udall (D-NM), and Roger Wicker (R-MS).

## NIGMS Announces Pilot Program to Fund Early Investigators

On June 3, the National Institute of General Medical Sciences (NIGMS) announced a new funding opportunity, entitled "Maximizing Investigators' Research Award (MIRA) for New and Early Stage Investigators (R35)" (see <http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-16-003.html>). Applicants may request up to \$250,000 in direct costs per year for five years, with an opportunity for renewal. This award is intended to provide junior investigators with increased flexibility in their research by eliminating the need for specific aims and reducing the time spent on grant applications. Applications can be submitted between August 9 and September 9.

This Request for Applications follows the first pilot MIRA program for established investigators, which was announced on January 27. Both programs fund individual investigators, not specific projects, and aim to improve the distribution of funds by requiring that no additional NIGMS grants be awarded to MIRA recipients (with the exception of pre-existing K awardees). This pilot comes in response to concerns raised after the MIRA program was first announced that this funding mechanism might be biased against young investigators. As a result, NIGMS launched this new initiative, whose "purpose...is to test the feasibility of this grant mechanism for New and Early Stage Investigators through a pilot program with restricted eligibility."