Maintaining Momentum

Peter McDonnell MD, William Holland Wilmer Professor and Director, Wilmer Eye Institute, Johns Hopkins University School of Medicine

This edition of the Report details the Fiscal Year (FY) 2019 Labor, Health and Human Services, and Education (LHHS) spending bills proposed by the House and Senate. Due to strong bipartisan support, each bill includes National Institutes of Health (NIH) and National Eye Institute (NEI) funding increases for the fourth fiscal year—with the Senate bill providing larger increases due to a higher overall spending allocation. With a growing portion of any NIH increase going to special initiatives, including those specified in the 21st Century Cures Act such as the BRAIN Initiative, Cancer Moonshot, Precision Medicine, and Regenerative Medicine, NAEVR has commended the Senate LHHS Appropriations Subcommittee for ensuring that its bill provided greater-than-inflationary increases for all of NIH’s Institutes and Centers (I/Cs). NAEVR’s Capitol Hill advocacy, including a July 11 Dry Eye Awareness Month 2018 Advocacy Day, has been in support of the Senate bill.

Let’s make an accounting for vision in the FY2019 appropriations process: a Senate proposed $25 million NEI increase, and the House Defense bill’s proposed $20 million funding level for the Vision Research Program—a $5 million increase over the $15 million funding level in each FY2017 and FY2018. That yields a $30 million increase if these funding levels are included in final FY2019 appropriations. That is in addition to potential future funding from the BRAIN Initiative (about a third of funding awarded so far has been to vision researchers or brain researchers studying the brain through the visual route), the Regenerative Medicine Initiative, and the $500 million in FY2018 Opioid funding, with another $500 million proposed for FY2019. In recent meetings with researchers, NEI has advised that impending NIH-wide Opioid research funding announcements may provide an opportunity for ocular pain and dry eye researchers.

So, while there is a great deal of momentum for federally funded vision research, it all depends on the ability of Congress to finalize FY2019 appropriations in a timely fashion. Congressional appropriators have the will, and are proceeding with some semblance of “regular order”—meaning each chamber passing individual funding bills, conferencing those bills, and then finalizing, rather than one omnibus bill or a full-year Continuing Resolution. Although Congress has made great strides so far, the clock is ticking on time remaining before the September 30 end date for FY2018, especially with the August recess in the mix. The process could slow down or halt due to numerous factors—including Democrats holding up appropriations over the Immigrant Detention policy, Republicans holding firm on contentious policy riders in the bills, and Presidential veto threats.

NAEVR advocacy and AERV education continue unabated, especially in this year of NEI’s 50th anniversary and NAEVR/AEVR’s 25th anniversary. As you can see in the image to the right, I was pleased to join Prevent Blindness Board Chair Torrey DeKeyser at the July 18 Focus on Eye Health National Summit in presenting a plaque to the NEI recognizing its anniversary. NEI Acting Deputy Director Michael Steinmetz, PhD, who also directs the Extramural Program, graciously accepted that award on behalf of NEI Director Paul Sieving, MD, PhD. As you view this Report’s images, you will see that Dr. Steinmetz has been engaged in significant outreach with the vision community to emphasize NEI and NIH funding opportunities, often appearing on the same panels as NAEVR/AEVR Executive Director James Jorkasky, who speaks about all federal funding sources.

I’ll be joining Jim on September 27 at AEVR’s Fourth Annual Emerging Vision Scientists (EVS) Day Congressional Reception, which also recognizes the Alliances’ 25th anniversary. I look forward to meeting the 21 EVSs chosen this year and viewing their research posters. Inclusive of this year’s class, AEVR will have brought more than 100 early-stage investigators with MDs, ODs, and PhDs to the Hill in the past four years to discuss their careers and the importance of robust funding for vision research. I want to thank Research to Prevent Blindness for providing grant support for this “signature” annual event that occurs at such an important time in the appropriations process.

As always, thank you for your support.

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**Fall 2018 Events:**

**September 14**

Rally for Medical Research Advocacy Day  
(NAEVR as sponsor, Congressional Delegation Host)

**September 27**

AEVR Congressional Briefing:  
International AMD Awareness Week 2018  
12 Noon-1:15 pm, House Rayburn 2060

**AEVR Congressional Reception:**  
Fourth Annual Emerging Vision Scientists  
Day on Capitol Hill, also recognizing NAEVR/AEVR’s 25th Anniversary  
5:30 – 7:30 pm, House Rayburn Foyer  
(Supported by a grant from Research to Prevent Blindness)

**September 28**

NAEVR Advocacy:  
Emerging Vision Scientists Advocacy Day
ARVO ANNUAL MEETING

ARVO®
The Association for Research in Vision and Ophthalmology

James Jorkasky and David Epstein in front of the NAEVR Central Booth in the Honolulu Convention Center

ARVO's 2018-2019 President-elect W. Daniel Stamer, PhD (Duke University) with NAEVR's James Jorkasky

Tian Wang, PhD, the new Vision Program Manager at the Congressionally Directed Medical Research Programs (CDMRP), addresses the audience

NAEVR wishes to thank the hundreds of ARVO members who visited the NAEVR Central Booth, which served as the “Town Hall” for vision research funding advocacy and education. Many visitors contacted Congress thanking them for the FY2018 NIH $3 billion and NEI $41 million funding increases, while urging sustained increases in the FY2019 appropriations process.

At NAEVR’s April 30 session, new Department of Defense (DOD) Vision Research Program (VRP) Manager Tian Wang, PhD spoke to the vision research community for the first time. Dr. Wang also manages the Hearing Restoration Program within DOD’s Congressionally Directed Medical Research Programs (CDMRP), in addition to the VRP.

Dr. Wang reported that, since 2001 the CDMRP has funded $230 million in 189 awards, including Small Business Innovation Research (SBIR) awards. Within that total, and since it was created by Congress in FY2009 Defense appropriations and through FY2017, the VRP has been funded by Congress at $70.2 million and has made 83 awards for a total of $82 million. The VRP has also managed additional funds from “sister” DOD agencies, such as Traumatic Brain Injury (TBI), accounting for the difference between enacted funding and the total awarded.

Dr. Wang emphasized that, unlike NIH’s grant review process, the CDMRP uses a two-tier review process—Peer Review for scientific merit, and Program Review for military relevance, responding to DOD-identified research gaps. She announced that the FY2018 Program Announcement is expected in the July/August timeframe. Per an April 26 CDMRP Preliminary Announcement, FY2018 VRP funding will include Investigator Initiated Research Awards (IIRA) with maximum funding of $500,000 over three years and a new Focused Translational Team Science Award (FTTSA) mechanism, which seeks to support projects that are “highly collaborative” and would “fundamentally advance the understanding and treatment of military-relevant vision trauma.” This award would be funded over a period of four years for a maximum of $5 million and must have three-to-five distinct research teams addressing a specific trauma. Although the VRP is not funding a full Clinical Trial Award in FY2018 as it did in FY2017, the FTTSA may support a pilot clinical trial that would collect preliminary data.

Dr. Wang met one-on-one with researchers at a dedicated CDMRP booth from Monday through Wednesday. NAEVR wishes to thank her for participating in the session and her dedication to the soldiers who have experienced battlefield eye injuries and blindness.

See back page for more information on Defense-related Vision Research Funding

ARVO Advocacy and Outreach Committee Workshop

NAEVR’s James Jorkasky was honored to be included in the faculty of this May 1 Workshop, which brought together global experts on advocacy and education. He commented that, “While cautioning that I was not there to export ‘U.S.-style advocacy,’ I shared messaging that NAEVR is using on Capitol Hill to demonstrate the value of NIH/NEI funding. I learned a great deal about challenges and strategies throughout the world, and greatly respect the efforts of my international colleagues.”
Pathway for FY2019 Appropriations

Unlike recent past years, there is some semblance of “regular” order in the FY2019 appropriations process. The House Appropriations Committee has reported out all bills except for Homeland Security, while the Senate has reported out all twelve of its bills. At press time, the House has approved six of twelve spending bills, including Defense (with $20 million for the Vision Research Program—see back page), and with no announced plan for floor action on the contentious LHHS bill before the August recess. The Senate has approved three bills, and is preparing a package of four additional bills for floor action. Senate staff have signaled an intent to queue up both the Defense and LHHS bills in late July/early August, possibly as one “minibus” bill.

With the House leaving for its summer recess in late July and the Senate potentially working through mid-August, the window for finalizing all or some portion of spending bills is closing—especially since the House has only 11 legislative days in September and the Senate 16 days until the end of the fiscal year on September 30. Anything can still happen, including a government shutdown. Stay tuned to NAEVR updates for the latest!

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<th>FY2014 FINAL*</th>
<th>FY2015 FINAL**</th>
<th>FY2016 FINAL**</th>
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<td>No change, but flat-funds all three agencies</td>
<td>No change, flat-funds ARHQ, modest increase for NIOSH, NIDILRR</td>
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AhRQ = Agency for Healthcare Research and Quality
NIOSH = National Institute for Occupational Safety and Health
NIDILRR = National Institute on Disability, Independent Living, and Rehabilitation Research

House:

Hearing: On April 11, the House held its hearing with NIH Director Francis Collins, MD, PhD and senior staff. Chairman Cole recognized the $3 billion FY2018 NIH increase as the second largest in NIH’s history and expressed concern about the President’s budget. Ranking Member Rosa DeLauro (D-CT) acknowledged that, despite the $7 billion in NIH increases over the past three fiscal years, its funding is still $5 billion below that of FY2003, when adjusted for inflation.

Markups: On June 15, the Subcommittee approved its LHHS bill under the flat-funded $177.2 billion spending allocation for all programs—the same as FY2018—increasing NIH funding by $1.25 billion (3.3 percent) to $38.3 billion (inclusive of Cures funding) and NEI by $9.2 million or 1.2 percent to $781.5 million, a less-than-inflationary increase. The House rejected the policy and structural changes proposed in the President’s budget. On July 11 in a marathon 13-hour session with more than 50 amendments offered, the House Appropriations Committee approved the bill. More than 20 of the amendments were related to the Trump Administration’s current Immigrant Detention policy, while several others related to contentious policy riders.

Senate:

Hearing: On May 17, the Senate held its hearing with Dr. Collins and his senior team. Chairman Blunt recognized the $7 billion total in NIH increases, noting his intent of a pattern of continued NIH increases. Ranking Member Patty Murray (D-WA) criticized the President’s proposed budget that would fund NIH below the FY2018 level and reduce the Extramural Salary Cap for researchers.

Markups: On June 26, the Subcommittee approved its LHHS bill under the $179.3 billion allocation for all programs—a $2.2 billion increase over FY2018. Recognized by Chairman Blunt as the third year of a bipartisan bill that avoided policy riders and authorizing provisions, the bill increases NIH funding by $2 billion or 5.4 percent to $39.08 billion (inclusive of Cures funding) and NEI by $24.6 million or 3.2 percent to $796.9 million. “Every Institute and Center receives an increase above FY2018 to continue investments in innovative research,” said Chairman Blunt. The Senate also rejected the policy and structural changes proposed in the President’s budget. On June 28, the Senate Appropriations Committee approved the bill.

Visit the NIH/NEI funding section of NAEVR’s Web site at www.eyeresearch.org for full details
NAEVR ADVOCACY

NAEVR Submits Testimony, Highlights Need for Robust NEI Funding

On April 23 and May 24, respectively, NAEVR submitted written testimony to the hearing files of the LHHS Appropriations Subcommittee of the House and Senate. NAEVR thanked Congress for the total $7 billion NIH and $96 million NEI increases in fiscal years 2016 through 2018 and requested NIH funding of $39.3 billion, reflecting a $2 billion increase plus the $215 million for the NIH Innovation Fund, as set forth in the 21st Century Cures Act to fund special initiatives.

Recognizing NEI’s 50th anniversary, NAEVR requested NEI funding at $800 million. Per the top graphic, NAEVR emphasized that, despite the recent increases, NEI’s FY2018 enacted funding of $772.3 million is just ten percent greater than the pre-sequester FY2012 funding level of $702 million. Averaged over six fiscal years, the 1.6 percent annual growth rate is less than the average annual biomedical inflation rate of 2.8 percent, thereby eroding purchasing power, as seen in the lower graphic. In terms of Research Project Grants (RPGs)—which at NEI are primarily R01 investigator-initiated awards—in FY2017 NEI had 130 fewer RPGs (1,157) than the 1,287 RPGs at the high-water mark in FY2004 (at the end of the NIH doubling effort).

Since FY2004, the difference between what NEI was able to fund and the cumulative number of projects it would have funded if it had maintained 1,287 grants each year is 1,970 project years (this number treats each year of a project individually, even though average length of an NIH grant is four years). NAEVR concluded that “any one of these projects could have held the promise to save sight or restore vision.”

NAEVR Comments on House and Senate LHHS Bills

After the House LHHS Subcommittee’s June 15 markup, NAEVR commended leaders for the $1.25 billion NIH increase, which was especially significant in light of the inadequate spending allocation the Subcommittee received. NAEVR expressed concern that the $9.2 million or 1.2 percent NEI increase did not keep pace with inflation, resulting in a loss of purchasing power. NAEVR’s concern echoed that of Ranking Member DeLauro, who acknowledged in the markup that more than twenty I/Cs would receive increases of 1.2 percent or less.

After the Senate LHHS Subcommittee’s June 28 markup, NAEVR commended leaders for the $2 billion NIH increase and for the greater-than-inflationary $24.6 million or 3.2 percent NEI increase. In subsequent advocacy, NAEVR has urged Congress to finalize FY2019 appropriations at the Senate’s proposed numbers.

Focus on Research

NAEVR’s James Jorkasky was pleased to participate in member organizations’ sessions that focused on vision research funding opportunities.

On July 9, the American Optometric Association Council on Research held an Optometric Research Summit entitled A Vision for the Future of Optometric Research, the goal of which was to develop a five-year plan to broaden participation in and promotion of research within the profession.

The July 18 Prevent Blindness Focus on Eye Health National Summit featured a panel entitled Promising Practices Emerging from NEI Partnerships, since the meeting honored 50 years of NEI leadership.

NAEVR recognizes John Brabyn, PhD, Executive Director of the Smith Kettlewell Eye Research Institute, for his written testimony opposing the President’s proposed move of the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) from the Administration for Community Living (ACL) in the Department of Health and Human Services to the NIH. In his comments, Dr. Brabyn emphasized that NIDILRR, which supports more than $2 million in vision research, “has an applied research focus with model programs to address and help the population of people with existing disabilities, while the NIH is organized to foster basic research. This different focus, target population, and program structure is fundamentally incompatible with the NIH model, and the practical impacts on people with disabilities would inevitably be diluted if not lost altogether.” The House and Senate LHHS bills reject this move.

Image far left, left to right: Jinan Saaddine, MD (Centers for Disease Control and Prevention, CDC); Felix Barker, OD (Joint DOD/VA Vision Center of Excellence); NEI’s Michael Steinmetz, PhD, Anne Schaffner, PhD, and Don Everett, MA; Leon Rozenblit, JD, PhD (Prometheus Research); and James Jorkasky

Image left, left to right: Cynthia Toth, MD (Duke University Eye Center) and member of ARVO’s “Telling the Story of Optical Coherence Tomography (OCT)” Steering Committee, spoke about public/private partnerships expanding OCT development and patient applications; Chief Scientific Officer Stephen Rose, PhD (Foundation Fighting Blindness) spoke about how the private sector leverages NEI discoveries; James Jorkasky moderated the panel; and NEI’s Dr. Michael Steinmetz spoke about NEI partnerships within the NIH and with federal agencies.
**AEVR Education**

**Speakers Urge More Dry Eye Disease Research at Capitol Hill Briefing**

On July 11, AEVR and the Tear Film & Ocular Surface Society (TFOS) joined with the vision community and coalition partners in recognizing July 2018 as Dry Eye Awareness Month—the second year of this re-formalized and expanded event that included a Congressional Briefing and “Test Your Tears” Dry Eye Screening, along with Congressional delegation visits managed by NAEVR. The Briefing focused on the TFOS Dry Eye Workshop II™ Report (TFOS DEWS II™), published in *The Ocular Surface* journal in July 2017, and how it has impacted clinical practice and research. TFOS DEWS II™ was the first re-examination of the topic since the initial TFOS DEWS™ report issued in 2007, updating the definition, classification, and diagnosis of dry eye; critically evaluating the epidemiology, pathophysiology, mechanism, and impact of the disease; addressing its management and therapy; and developing recommendations for the design of clinical trials to assess pharmaceutical interventions.

**About Dry Eye**

Moderator and TFOS Founder David A. Sullivan, MS, PhD, FARVO (Senior Scientist, Schepens Eye Research Institute, and Associate Professor, Department of Ophthalmology, Harvard Medical School) noted that Dry Eye Disease (DED) is one of the most frequent causes of patient visits to eye care providers and has a significant impact on healthcare policy as it affects more than 30 million Americans and costs the United States healthcare system $3.8 billion annually, with a $35.4 billion annual cost to society from diminished productivity. There is no cure for DED—at best, eye care professionals manage the disease.

A panel of four experts, several of whom were among the 150 experts from 23 countries who participated in the development of TFOS DEWS III™, spoke about various aspects of DED.

**DED and Comorbidities**

Since dry eye is an important area of vision research funded by the NIH/NEI, Janine Austin-Clayton, MD (NIH Associate Director for Research on Women’s Health and Director, Office of Research on Women’s Health, NIH) addressed more fully the causes and comorbidities of DED—including autoimmune diseases, thyroid disease (especially Graves’ disease), diabetes, Graft versus Host disease (after a bone marrow transplant), viral infections (such as Human Immunodeficiency Virus and Epstein-Barr virus) and blepharitis (eyelid inflammation). She emphasized that two-thirds of those with DED are women, in part due to the greater incidence of autoimmune diseases.

**DED and Cosmetics Use**

Leslie O’Dell, OD, FAAO (Wheatlyn Eye Care, York, Pennsylvania) spoke about the use of cosmetics and the incidence of OSD and DED. She reported that the average woman exposes herself to 167 different chemicals on her body and face during her daily regimen. There are ingredients in commonly used eye makeup and beauty products that can exacerbate dry eye symptoms by affecting how the meibomian glands function and lubricate the tear film, increasing the inflammation-inducing evaporative load of patients with OSD. She also recognized that cosmetics include carcinogens, endocrine disruptors, neurotoxins, and reproductive toxins—many of which are banned in the European Union but not in the United States. This has resulted in Congressional proposals to update the Federal Food, Drug, and Cosmetic Act to require manufacturers to register ingredients of personal care products and any adverse reactions with the Food and Drug Administration (FDA).

**DED and Contact Lenses**

Clinician-scientist Penny Asbell, MD (Professor of Ophthalmology/Icahn School of Medicine at Mt. Sinai) reported that, while contact lens wearers are more likely to have symptoms of DED, research is needed as to whether contact lenses cause dry eyes or does underlying DED lead to contact lens discomfort. Regarding the latter, she described the potential role that meibomian gland dysfunction (MGD) may play. These exocrine glands at the rim of the eyelids supply meibum, the oily substance that prevents evaporation of the eye’s tear film, and when not functioning properly may result in alteration of the tear film, symptoms of eye irritation, inflammation, and ocular surface disease (OSD).

**DED and Digital Device Use**

Scott Schachter, OD (Vision Source, Pismo Beach, California and Adjunct Clinical Professor, Marshall B. Ketchum University) spoke about the increasingly common relationship between digital eye strain and DED. He presented numerous statistics about digital device use—including that 83 percent of Americans use digital devices for more than two hours per day and that 60 percent report experiencing symptoms of digital eye strain. He noted that the quality of blinks and their frequency diminishes when viewing a digital device versus hard copy, which promotes DED. He concluded by reporting that, by three years of age, 68 percent of children regularly use a digital device, resulting in an amplified population of younger patients affected by dry eye.

**TearLab Conducts “Test Your Tears” Dry Eye Screening**

Prior to/after the Briefing, TearLab’s Chief Scientific Officer Benjamin D. Sullivan, PhD conducted the “Test Your Tears” screening using the TearLab Osmolarity System, which measures osmolarity of human tears to aid in the diagnosis of DED, in conjunction with other methods of clinical evaluation. Osmolarity is an important biomarker of ocular surface health.

AEVR and TFOS thank the vision community organizations that supported Dry Eye Awareness Month 2018 educational activities, including Shire for a grant to support event management.
DEFENSE-RELATED VISION FUNDING

Vision Research Program Funding Scorecard

FY2017: VRP Finalizing Awards
The VRP Program Committee is making final decisions on FY2017 grants, with the program funded for the first time at $15 million. NAEVR will post awardee abstracts on its Web site when released by CDMRP.

FY2018: VRP Finalizing Program Announcement
The VRP Program Committee expects to issue the Program Announcement in the July/August timeframe. For the second year, the VRP was funded at a level of $15 million.

FY2019: House Appropriation Bill Funds VRP at $20 Million
For the first time, Congress proposed FY2019 VRP funding at $20 million—$5 million more than in each FY2017 and 2018—per the House Defense Appropriations bill which passed on June 28. The Senate’s bill, reported out of the Senate Appropriations Committee on June 28, is silent on most funding levels within the Defense Health Programs section. After each chamber passes its respective bill they will be conferenced, with the program usually accepting the House bill’s funding levels. NAEVR had requested the $20 million funding level, including the following updated information in its advocacy messaging:

- With assistance from VRP Vision Program Manager Tian Wang, PhD, NAEVR revised the number of published papers that emerged from VRP funding since FY2009 to 153 and patents received/applied for to 15. NAEVR emphasized that VRP-funded research has been instrumental to the development of the field of military eye trauma care.

- An updated $45.5 billion cost of deployment-related eye injuries and blindness in the 2000-2017 timeframe, as estimated by AEVR consultant Kevin Frick, PhD (Johns Hopkins Carey School of Business) in his 2017 update of NAEVR’s 2012 Cost of Military Eye Injury Study. Of that total, $44.4 billion reflects the present value of a lifetime of long-term benefits, lost wages, and family care. (The 2017 AEVR update is being prepared as a manuscript for journal submission in 2018.)

- VRP Holds Stakeholders Meeting
On April 17, NAEVR’s James Jorkasky and David Epstein were guest attendees at the VRP Program Panel’s “Stakeholders” meeting. The Panel heard from speakers describing the status of research funded by other federal institutions (NEI, Department of Veterans Affairs) and by private vision research funding foundations, as well as the economic cost of military eye injuries and vision loss to society. The Panel then reviewed the adequacy of the current DOD-identified vision trauma research gaps in advance of developing the FY2018 Program Announcement.

- Steven Fliesler, PhD (SUNY-Buffalo/VA Medical Center-Buffalo), the Research Stakeholder Representative to the VRP Program Panel, spoke about the state of science in vision research. Dr. Fliesler is the 2018-2019 President of the ARVO Board of Trustees and a NAEVR/AEVR Director.

- DOD Funded Researcher Examines Whole Eye Transplantation
On March 29, AEVR hosted its ninth Defense-related Vision Research Congressional Briefing entitled Whole Eye Transplantation—From Experimental Model to Clinical Translation, co-sponsored by RPB, ARVO, and Blind Veterans Association (BVA). The Briefing featured clinician-scientist Kia Washington, MD, an assistant professor at the University of Pittsburgh School of Medicine in the VA Pittsburgh Healthcare System and was recently named Director of a newly-established interdisciplinary research program that focuses on the science of Whole Eye Transplantation (WET).

Funded by an NIH training grant originally at the Starzl Transplant Institute at the University of Pittsburgh, Dr. Washington began working with rodents as an animal model for facial transplants, and that work formed the basis for her later work on the DOD-funded WET—the goal of which is to restore form and function of a transplanted eye. Although such efforts date back to the 1880s, they have been unsuccessful due to three major impediments; inadequate blood flow to keep the organ alive; immune system rejection of the transplanted tissue; and lack of nerve function past the point of where the optic nerve was severed. Overcoming these three challenges has been the focus of Dr. Washington’s research, which has had success in meeting the first two. But if a transplanted eye is going to restore vision, it is the third barrier that is essential to overcome. Her team is testing a number of different techniques to preserve the optic nerves and encourage them to regenerate. One therapy has introduced the use of a “wrap” infused with special drugs that holds the two severed ends of the optic nerve together to allow the two ends to knit to the other. Also being evaluated for effectiveness are gene therapy strategies, which tap into the innate ability of our body to regenerate after injury.