Despair Morphs into Cautious Optimism—For Now!

When I last wrote to you in early April, President Trump had just released his Fiscal Year (FY) 2018 Budget Blueprint with a proposed devastating cut to National Institutes of Health (NIH) funding and a vague reference to changes to its structure and research prioritization process. I offered consolation to our community’s despair with the adage, “The President Proposes, the Congress Disposes.” And dispose it did! In early May, Congress approved an FY2017 Omnibus spending bill with a $2 billion NIH increase, as in FY2016, and a National Eye Institute (NEI) increase of $25.4 million, or 3.5 percent—one of the highest percentage increases of the Institutes and Center (I/Cs). That bill also funded the Department of Defense’s (DOD) Vision Research Program at $15 million for the first time—$5 million more than the $10 million in appropriated funding for each of fiscal years 2013-2016. That optimism of $40 million more for vision research in FY2017 soon turned to despair again in late May as the detailed FY2018 Trump budget emerged with proposals to cut NIH and its I/Cs even further, to reduce limits on reimbursement in NIH grants for Facilities and Administrative costs to ten percent, and to reduce the Extramural Salary Cap from Executive Level II to EL V. The only bright spot was the absence of language proposing I/C structural changes beyond the already-proposed elimination of the Fogarty International Center and move of the Agency for Healthcare Research and Quality (AHRQ) into the NIH.

Fast forward to mid-July, and the House Appropriations Committee approved a Labor, Health and Human Services, and Education ( LHHS) appropriations bill that not only rejects most of what the President proposed regarding indirect cost reimbursement limits, an Extramural Salary Cap reduction, and structural changes, it increases NIH funding by $1.1 billion and NEI by $1.3 billion. At the LHHS Appropriations Subcommittee’s July 12 markup, Chairman Tom Cole (R-OK) went as far as saying that he views the bill “as a floor and not a ceiling” and that he hopes the number can increase as the appropriations process continues—as it did in both FY2016 and FY2017, driven by the Senate and especially the leadership of Senate LHHS Appropriations Subcommittee Chair Roy Blunt (R-MO).

As you can see from this Report’s content, NAEVR has been on the Hill constantly, thanking Members for their past bipartisan efforts to increase biomedical research funding while requesting a sustained and predictable FY2018 NIH/NEI funding increase. From hosting private funding foundations in Hill advocacy in late April just as Congress released the FY2017 Omnibus bill to hosting Dry Eye researchers and clinicians in mid-July just as the House was releasing its LHHS spending bill, this advocacy has emphasized the value of biomedical research, especially vision research.

Tempering our optimism, much can still happen—or not happen—over the next several months. Without a Budget Resolution, the House and Senate have set different allotments for their spending bills, with the former adopting a defense spending cap at $70.5 billion over that in the Senate—at the expense of nondefense discretionary spending, which includes NIH. The House now plans “to pass a “Minibus” spending bill prior to August recess that includes FY2018 funding for the Departments of Defense, Veterans Affairs, and Energy, as well as to fund Congress and a portion of the Mexican Border Wall proposed by the President. The remaining bills would be combined into an Omnibus for consideration in September.

The Senate is further behind, with markup of its LHHS spending bill not expected until after its abbreviated August recess. As a result, Congress is likely to pass one or more short-term Continuing Resolutions (CR) and may even move to develop a bipartisan budget agreement—as it did for fiscal years 2016 and 2017—that could raise the Budget Control Act (BCA) caps and provide sequester relief that could pave the way for an NIH increase greater than the $11 billion “floor” proposed in the House. Of course, none of this could happen and Congress could default to a full-year CR at the FY2017 level, with a rescission that reflects the FY2018 BCA cap and sequestration. Other wild cards in the equation include a potential government shutdown, which is not favored by the rank-and-file from either party, as well as a potential Trump Administration veto of the Omnibus for consideration in September.

In its advocacy, NAEVR has already been calling for an FY2018 bipartisan budget agreement that could pave the way for increased caps.

Fall 2017 Events:
September 13
AEVR Congressional Briefing: International AMD Awareness Week 2017 12 Noon-11:30 pm, House Rayburn G-2043

AEVR Congressional Reception: Third Annual Emerging Vision Scientists Day 5:30 – 7:30 pm, House Rayburn 2168 (Gold Room) (supported by a grant from RPB)

September 14
NAEVR Advocacy: Emerging Vision Scientists Advocacy Day, held in conjunction with the Rally for Medical Research Advocacy Day
Commenting on the Advocacy Day, RPB President Dr. Brian Hofland said:

“At a time when the federal funding for NIH is in a state of uncertainty, it was important for Research to Prevent Blindness and other foundations to visit the offices of key legislators and make the case for robust and sustained federally-funded research into vision loss and eye diseases.”

On April 25, as Congress was negotiating an FY2017 Omnibus spending bill, NAEVR hosted the third annual Advocacy Day for private funding foundations within the vision community, which had met the previous day under the auspices of a Research to Prevent Blindness (RPB) convening.

The participants from across the country met with key Congressional offices, including appropriations leaders directly engaged in Omnibus bill negotiations. The advocates reinforced NAEVR’s request for a $2 billion FY2017 NIH funding increase, as well as a $2 billion FY2018 NIH increase to continue the pattern of sustained funding to rebuild the NIH base. They also requested FY2018 NEI funding of $800 million to save sight and restore vision.

The foundation advocates also described their important role in the local economy and how they support researchers at academic institutions throughout the nation—including investigators in the early stage of their careers, as well as established researchers awaiting grant renewal who may need “bridge” funding to continue their work.

The Association for Research in Vision and Ophthalmology

ARVO

FY2017 OMNIBUS ADVOCACY AND APPRECIATION

NAEVR Leads Advocacy For FY2017 Omnibus NIH/NEI Funding Increases

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NAEVR Leads FY2017 Omnibus ‘Thanks’ at ARVO Annual Meeting

James Jorkasky and David Epstein host the NAEVR Central Booth in the Baltimore Convention Center at ARVO’s 2017 Annual Meeting.

In its NAEVR Central Booth, NAEVR assisted researchers in thanking Congress for the FY2017 Omnibus NIH/NEI funding increases, as well as expressing their concern about FY2018 in light of the Trump Administration’s March 28 Budget Blueprint proposal to cut NIH funding. Booth traffic included several early-stage investigators who participated in AEVR’s September 2016 Second Annual Emerging Vision Scientists Day on Capitol Hill, who expressed a sense of accomplishment in their successful advocacy efforts. AEVR began recruiting early-stage investigators for its Third Annual EVS Day, set for September 13-14, 2017.

NAEVR wishes to thank the hundreds of ARVO members who visited the booth to support the vision community’s advocacy efforts.

NAEVR Recognizes CDMRP’s Robert Read, Who Identifies FY2017 Funding Opportunities

NAEVR’s May 8 Defense-Related Vision Research Opportunities session at ARVO had an immediacy unlike past years, since the vision community was awaiting posting of the Program Announcement for the $15 million in FY2017 Vision Research Program (VRP) funding on the Department of Defense’s (DOD) Congressionally-directed Medical Research Programs (CDMRP) Web site (see back page for details).

Prior to CDMRP Vision Program Manager Robert Read speaking about FY2017 plans, NAEVR’s James Jorkasky presented him with a plaque recognizing his dedication to defense-related vision trauma research. Mr. Read, who has managed the VRP since it was created by Congress in FY2009 as a result of NAEVR advocacy, will retire in September and will be succeeded by Ray Santullo, OD (Colonel, U.S. Army, retired).
**SCORECARD LEGISLATIVE ISSUES—NIH/NEI FUNDING**

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<tr>
<th>FY2018 House LHHS Bill Rejects Trump NIH Funding, Structure Proposals</th>
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<td>Without a Budget Resolution and setting spending caps for nondefense discretionary spending below that for FY2018 BCA levels, on July 19 the House Appropriations Committee approved an FY2018 LHHS funding bill with $156 billion in discretionary funding—$5 billion below the FY2017 enacted level. Despite that lower level, the House bill has proposed a $1.1 billion increase for NIH to a funding level of $35.2 billion. Details of the bill and their comparison to President’s Trump proposed budget appear below:</td>
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<td>• The $1.1 billion increase for NIH reflects a $943 million increase in base NIH funding—or 2.8 percent, which is slightly above the FY2018 biomedical inflation rate of 2.7 percent—and $144 million in increased funding for 21st Century Cures Act initiatives, raising it to the $496 million in FY2018 funding level designated by the Act. The House funding level is $8.6 billion above the President’s proposed NIH cut of $7.5 billion, or 21 percent, below enacted FY2017.</td>
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<td>• Funds the NEI at $743.9 million, which is an $11.3 million, or 1.5 percent, increase over the enacted FY2017 level of $732.6 million. I/C increases are essentially 1.5 percent across-the-board, except for special programs. The President proposed NEI funding of $549.8 million, a $187,000 cut.</td>
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<td>• Maintains the Extramural Salary Cap at EL II. The President proposed a reduction to EL V, which is $157,000 in FY2017.</td>
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<td>• Includes a provision requiring the NIH to continue reimbursing grantee research institutions for Facilities and Administrative costs—but would only apply to NIH in FY2018. The President proposed to limit these indirect costs to ten percent.</td>
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<td>• Retains the Fogarty International Center and cuts AHRQ funding (that supports the Affordable Care Act activities). The President proposed to eliminate Fogarty and move AHRQ into the NIH.</td>
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The bill reflecting the Republican leadership’s agenda, includes contentious policy riders dealing with fetal tissue research and abortion. Although NAEVR issued a statement expressing appreciation for the NIH/NEI funding increase, the vision community’s FY2018 funding request has been a $2 billion NIH increase and NEI funding of $800 million.

**FY2017 Omnibus Includes $2 B NIH Increase, $25.4 M NEI Increase**

On May 5, President Trump signed the FY2017 Omnibus appropriations bill that funds the NIH at $34.1 billion, a $2 billion increase that comes on the heels of a $2 billion FY2016 increase. The FY2017 funding level includes $352 million for implementation of the 21st Century Cures Act, which Congress passed in December 2016, meaning that the NIH base grows by $1,648 billion. Within the $352 million for Cures funding, the bill provides $300 million for cancer research, $40 million for the Precision Medicine Initiative, $10 million for the Brain Research through Advancing Innovative Technologies (BRAIN) Initiative, and $2 million for regenerative medicine research. Vision researchers and those studying brain function through the visual route have done well in the first three cycles of BRAIN funding—a total of $63.4 million in awards.

In addition, the bill maintains the Extramural Salary Cap at Executive Level (EL) II, which is $187,000 for FY2017. The NEI is funded at $732.6 million, a $25.4 million, or 3.5 percent, increase over its FY2016 Operating Budget of $708 million—one of the highest increases for I/Cs. Despite the FY2016 and 2017 funding increases, current NEI funding is just four percent more than the FY2012 pre-sequester funding level of $702 million—meaning that it has taken five fiscal years for NEI to experience any significant growth in its budget.

**Appropriations Leaders Comment on NIH Funding Increases**

NIH Director Francis Collins, MD, PhD appeared before hearings of the LHHS Appropriations Subcommittees—the House on May 17 and the Senate on 6/22. House Chairman Tom Cole (R-OK) and Senate Chairman Roy Blunt (R-MO) each expressed pride in the bipartisan support current NIH funding increases, their concern about the President’s proposal, and their hope to maintain sustained and predictable NIH funding.

**Chairman Tom Cole**

“Our need to continue to build upon the $2 billion increases provided in last year’s Omnibus, and indeed $2 billion the year before, and I view this mark as a floor for biomedical research funding. I am hopeful that this number can increase as the process goes on, as it did the last two years that we’ve done this.”

- July 13 House LHHS Subcommittee Markup of the LHHS appropriations bill

**Chairman Roy Blunt**

“The President’s budget request proposes to cut $7.5 billion from the NIH, and according to an analysis from United for Medical Research it would cost 90,000 jobs nationwide and result in $15.3 billion loss in economic activity. A cut to NIH is not a cut to Washington bureaucracy; it is a cut to life-saving treatments and cures, affecting research performed all across the country.”

- June 22 Senate LHHS Subcommittee Hearing with Dr. Collins

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

Dry eye is one of the most frequent causes of patient visits to eye care providers. This disease has an important impact on healthcare policy since it affects more than 30 million Americans and costs the U.S. healthcare system $3.8 billion, with a $55.4 billion cost to society, with an estimated 2 million workers missing work days that they sleep, wear contact lenses, or work on computer each day—noting that all are dry eye risk factors. He described dry eye's impact on quality of life in graphic terms, stating that, “Imagine if every day you woke up and were aware of your eyes, like a broken windshield wiper on a car.”

The July 2017 Dry Eye Awareness Month activities were especially poignent, due to the impending July 20 publication of the TFOS Dry Eye Workshop II™ Report (TFOS DEWS II™) in The Ocular Surface journal. In this first re-examination of the topic since the initial TFOS DEWS™ report issued in 2007, TFOS DEWS II™ updates the definition, classification, and diagnosis of dry eye; critically evaluates the epidemiology, pathophysiology, mechanism, and impact of the disease; addresses its management and therapy; and develops recommendations for the design of clinical trials to assess pharmaceutical interventions.

The Briefing faculty reflected experts engaged in development of the TFOS DEWS II™ Report. They highlighted that, although researchers have long known about age, sex, and gender as factors, they are now discovering ethnic and racial differences and the fact that dry eye impacts younger patients. Dry eye can have many causes, including environmental exposure; side-effects from medications; eye surgery; (such as laser correction surgery); lid disorders; immune system diseases such as Sjögren's Syndrome, lupus, or rheumatoid arthritis; contact lens wear; cosmetic use; aesthetic procedures; and an increasingly common cause—staring at computer or video screens for too long without blinking. Speaker highlights include:

**Paul Karpecki, OD, FAAO (Director, Cornea Services, Kentucky Eye Institute),** who served as moderator, began by asking attendees about the number of hours that they sleep, wear contact lenses, or work on computer each day—noting that all are dry eye risk factors. He described dry eye's impact on quality of life in graphic terms, stating that, “Imagine if every day you woke up and were aware of your eyes, like a broken windshield wiper on a car.”

**TFOS Founder David A. Sullivan, MS, PhD, FARVO (Senior Scientist, Schepens Eye Research Institute, and Associate Professor, Department of Ophthalmology, Harvard Medical School)** addressed the pathophysiological mechanism of dry eye and how it may be induced unintentionally through medical treatment by a physician—called iatrogenic Dry Eye—resulting from drug therapies, ophthalmic surgeries, and several other causes. He also addressed quality of life issues, noting that the impact of moderate-to-severe dry eye is comparable to dialysis and severe angina. He concluded by presenting the updated TFOS DEWS II™ Report definition of dry eye:

“Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hypersmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.”

**Susan Vitale, PhD, MHS (NEI)** described the work of the TFOS DEWS II™ Epidemiology Subcommittee in assessing the prevalence of dry eye and identifying risk factors. “Non-Modifiable” risk factors include age, female sex, Asian race, meibomian gland (oil glands in eyelids) dysfunction, connective tissue diseases, and Sjögren's Syndrome. “Modifiable” risk factors include: androgen deficiency, computer use, contact lens wear, hematopoietic stem cell transplantation, environmental factors (pollution, low humidity, and sick building syndrome), and medications (antihistamines, antidepressants, anxiolytics, and isotretinoin).

**Susan Stone, JD (left) and Maria Zanardo (right), both from Allergan, with Ali Manson (American Optometric Association).**
TearLab Conducts “Test Your Tears” Dry Eye Screening

Prior to and after the Briefing, Michael Berg and Benjamin Sullivan, PhD of TearLab conducted the “Test Your Tears” screening using the TearLab Osmolarity System, which measures osmolarity of human tears to aid in the diagnosis of dry eye disease, in conjunction with other methods of clinical evaluation. Osmolarity is an important biomarker of ocular surface health.

Research Advocates Present Posters, Join Speakers in Congressional Office Visits

Prior to and after the Briefing, four clinicians and researchers engaged in TFOS DEWS II™ Report development presented posters on different aspects of dry eye as follows:

• “Why Is the Tear Film Important?” Carolyn Begley, OD, MS, FAAO (Professor, Indiana University School of Optometry)
• “Why is Dry Eye Disease Painful?” Anat Galor, MD (Staff Physician, Surgical Services, Miami Veterans Administration Medical Center and Associate Professor of Clinical Ophthalmology, Bascom Palmer Eye Institute/University of Miami)
• “Why is Dry Eye a Problem for Doctors?” Victor Perez, MD (Professor of Ophthalmology, Microbiology, and Immunology, Bascom Palmer Eye Institute/University of Miami)
• “Can the Use of Cosmetics Affect Dry Eye?” Laura Periman, MD (Private Practice, Redmond Eye Clinic, Redmond, Washington)

TFOS Executive Director Amy Gallant Sullivan and Briefing Moderator Dr. Karpecki joined the research advocates in meetings with their Congressional delegations, joined by NAEVR’s James Jorkasky and David Epstein. While describing dry eye’s impact on quality of life and productivity, the advocates emphasized the importance of research into its causes and treatments which is supported by the NEI.

Congressional Recognition of Dry Eye Awareness Month

The Congressional Record editions of July 12 and July 17 included Dry Eye Awareness Month recognition statements by Cong. Pete Sessions (R-TX) and Senator Tammy Baldwin (D-WI), respectively. In 2009, Cong. Sessions and then-Cong. Baldwin were co-sponsors of the successfully passed H. Res. 366, which recognized the NEI’s 40th anniversary and designated 2010-2020 as the “Decade of Vision.” Long-time advocates for the NEI and vision research, Cong. Sessions is Chair of the House Rules Committee and Senator Baldwin is a member of the Senate LHHS Appropriations Subcommittee, with jurisdiction over NIH/NEI funding, and the Senate Health, Education Labor & Pensions (HELP) Committee, with oversight jurisdiction over NIH.

Vision community/coalition partners that supported Dry Eye Awareness Month educational activities include:

Alliance for Eye and Vision Research
American Academy of Ophthalmology
American Academy of Optometry
American Optometric Association
Association for Research in Vision and Ophthalmology
HealthyWomen
Prevent Blindness
Research to Prevent Blindness
Sjögren’s Syndrome Foundation
Tear Film & Ocular Surface Society
University of Alabama at Birmingham School of Optometry
Women’s Eye Health
Women in Ophthalmology

TFOS thanks the following industry partners who supported TFOS DEWS II™ with unrestricted donations, including: Novartis Pharmaceuticals Corporation and Alcon, a division of Novartis, Shire, Allergan, Bausch+Lomb, Akorn, CooperVision, Dompé, Horizon Pharma, LQbris Biopharma, Oculeve, TearLab, Laboratoires Théa, SIFI, Johnson & Johnson Vision Care, Quint Health, Scope Ophthalmics, Sun Pharma, Carl Zeiss Meditec, Inc. ZEISS Group, and Senju.

AEVR thanks Shire for a grant to support the Briefing/Screening event management.
DEFENSE-RELATED VISION FUNDING

Vision Research Program Funding Scorecard

Since it was created by Congress in FY2009 in Defense appropriations through NAEVR advocacy, the Department of Defense’s (DOD) Peer Reviewed Vision Research Program (VRP) within the Congressionally-directed Medical Research Program (CDMRP) will have awarded 79 grants totaling $68.4 million (including FY2015/2016 awards).

FY2017: Program Announcement Released
The FY2017 Omnibus Appropriations included $15 million for the VRP—$5 million greater than in FY2016 and the first time at that increased level after being funded at $10 million in each FY2013-2016. On May 15, the CDMRP released the VRP Program Announcement with two funding mechanisms: Clinical Trial Awards, with a maximum funding of $5.25 million per award, and Technology and Therapeutic Development Awards, with a maximum funding of $2.1 million per award. The Clinical Trials funding maximum is higher than the previous year due to feedback that the previous maximum was too low to properly conduct a clinical trial. Pre-Applications were due July 12, and full grant applications are due October 25.

FY2018: NAEVR Requests Funding at $15 M
On June 29, the House Appropriations Committee reported out its FY2018 DOD Appropriations bill which included $15 million in VRP funding, the second year at that level. The Senate Appropriations Committee has not marked up its companion bill. Typically, the Senate bill does not contain detailed funding for most areas of research within Defense Health Programs, but instead accepts the House’s numbers when the two bills are conferenced.

FY2019 and Beyond: AEVR Updates the 2012 Cost of Military Eye Injury Study

To justify an FY2019 VRP funding increase to $20 million, AEVR has begun an update of NAEVR’s 2012 Cost of Military Eye Injury study, which estimated total costs from 2010-2020 at $25.1 billion (see box right). Once again, AEVR has hired Kevin Frick, PhD (Carey Business School/ Johns Hopkins) to conduct the study, and he is guided by a Working Group that includes representatives of the DOD, VA, joint DOD/VA Vision Center of Excellence (VCE), Blinded Veterans Association (BVA) and Eric Singman, MD, PhD (Wilmer/Johns Hopkins), who will author an article for publication with Dr. Frick.

In its initial call, the Working Group discussed the planned review of all relevant published literature since the 2012 study’s 2011 cut-off date, as well as the potential use of data from the Defense and Veterans Eye Injury and Vision Registry (DVEIVR), which is managed by the VCE. The Group also addressed a number of considerations not included in the 2012 study, including:

- More robust data on visual dysfunction implications from Traumatic Brain Injury (TBI), such as double vision, light-sensitivity, and dry eye.
- Economic data regarding the re-training and replacement of soldiers with eye injuries, especially those from the highly-trained Special Forces, since eye-injured soldiers have only a 20 percent return-to-duty rate as compared to an 80 percent rate for other battle trauma injuries.
- Economic implications of vision loss and polytrauma, such as loss of limb.
- Data on lost wages for eye-injured soldiers as opposed to that from general population studies.

AEVR plans completion of an initial assessment of data resources by late August, with a recommendation for the analysis and report development associated with Phase II.

NAEVR released its study entitled Cost of Military Eye Injury study in May 2012 at the ARVO Annual Meeting. It used published data from 2000-2010 and widely accepted economic conventions to characterize the incidence numbers and concomitant costs associated with eye injuries, which ranged from superficial to one-eye or two-eye (bilateral) blindness, as well as visual dysfunction associated with TBI. The study report estimated total incident cost of eye injury each year had been $2.28 billion, yielding a total cost to the economy over the 2000-2010 timeframe of $25.1 billion, reflecting $24.3 billion in present value costs to the economy and society (Social Security benefits, lost wages and family care). This was not surprising, as 97 percent of visual injuries occur in male soldiers age 20-24 who have a potential 50-70 years of life remaining.

More photos...