FY2017 Funding Increases Are Still a Waiting Game

Although this issue of the Report documents activities primarily over a mere three months—from the early May 2016 ARVO Annual Meeting to the mid-July House Appropriations Committee approval of its Fiscal Year (FY) 2017 Labor, Health and Human Services, and Education (LHHS) spending bill—much has occurred, and the Alliances have been the leaders at every step of the way.

First, I want to acknowledge that the NAEVR and AEVR Board each have elected Gregory Skuta, M.D. (Dean McGee Eye Institute/University of Oklahoma) as a Director. A proven leader in academics and the ophthalmology profession, Greg brings tremendous knowledge and perspective to the Boards. Greg is the official representative from the American Academy of Ophthalmology which, along with ARVO and the Association of University Professors of Ophthalmology (AUPO), are the three founding members of the Alliances. For your information, I have listed the thirteen NAEVR/AEVR Directors in the Box to the right. I am pleased to work with such outstanding leaders in the vision community to ensure the adequate funding of the Alliances in their role as the “Friends of the National Eye Institute (NEI),” as well as the effectiveness of their voice, as led by NAEVR/AEVR Executive Director James Jorkasky.

Of course, the most newsworthy actions are those by Congress to significantly increase National Institutes of Health (NIH) and NEI funding for a second fiscal year, as well as House action to increase the Vision Research Program (VRP) in Defense appropriations by $5 million to $15 million.

Regarding NIH/NEI funding, NAEVR/AEVR Boards President pmcdonn1@jmi.edu

Peter J. McDonnell, M.D.
NAEVR/AEVR Boards President

Fall 2016 Events

September 14
AEVR Congressional Briefing: International AMD Awareness Week 2016
12 Noon-1:15 pm, House Rayburn B-338

September 15
NAEVR Emerging Vision Scientists Advocacy Day

September 22
Rally for Medical Research Advocacy Day (NAEVR co-sponsors, participates)
Emerging Vision Scientists Energize NAEVR Central at ARVO 2016

The NAEVR Central Booth at the 2016 ARVO Annual Meeting in Seattle, Washington enabled attendees to contact Congress regarding FY2017 NIH and NEI increases—requesting NIH funding to $34.3 billion and NEI to $770 million—which builds on the $2 billion NIH increase Congress passed in FY2016 appropriations (see funding chart inside). NAEVR wishes to thank the hundreds of ARVO members who visited the booth to support its advocacy efforts.

Booth traffic included many early-stage investigators who were interested in participating in AEVR’s Second Annual Emerging Vision Scientists (EVS) Day on Capitol Hill, scheduled for September 14, as well as those who have participated in past EVS events. NAEVR also assisted attendees in scheduling one-on-one meetings with representatives of the Department of Defense’s (DOD) Congressionally Directed Medical Research Programs (CDMRP), which manages the dedicated $10 million Vision Research Program.

From left: Brian Hofland, Ph.D., President of Research to Prevent Blindness; Jason Comander, M.D., Ph.D. (Massachusetts Eye & Ear/Harvard School of Medicine); and Greg Skuta, M.D. (University of Oklahoma/Dean McGee Eye Institute). Dr. Comander participated in AEVR’s 2015 EVS Day, while Dr. Skuta had just been elected to the NAEVR and AEVR Boards of Directors.

Prior to NAEVR’s session, on April 29 ARVO hosted a session on Vision and Traumatic Brain Injury, which focused on the outlook for therapeutics. Open to the public, the session featured the latest research into concussive and TBI-related injuries, emphasizing the parallels between visual dysfunction resulting from sports injuries and military deployment-related TBI. Dr. Hartwick also spoke at this session, relating his research into therapeutics for TBI-related photophobia.

Dr. Hartwick, O.D., Ph.D. (Ohio State University College of Optometry), who is studying TBI-related photophobia (light-sensitivity) and Joseph Ciolo, M.D. (Massachusetts Eye & Ear/Harvard Medical School), who is developing a drug-delivering contact lens.

From left: Colonel Donald Gagliano, M.D., President, Global Medical Innovation and former Director of the joint DOD/VA Vision Center of Excellence; Tim Hornik (U.S. Army, Ret); and Jeff Radel, Ph.D. (University of Kansas Medical Center). Mr. Hornik lost his vision while serving in Iraq and is now participating in a Ph.D. program at the University of Kansas, with Dr. Radel serving as his mentor.

Robert Read, DOD/CDMRP Vision Program Manager, speaks to the crowd.

NAEVR’s Defense Funding Session Complements ARVO’s Vision and Traumatic Brain Injury Session

At ARVO’s May 2 Defense-Related Vision Research Opportunities session focused on how researchers can be responsive to DOD-identified vision research gaps. DOD/CDMRP Vision Program Manager Robert Read spoke about funding opportunities from the VRP and other DOD programs. He noted that, since the VRP was created by Congress in FY2009 appropriations, the CDMRP has issued 67 awards totaling $35 million, and that shortly it would award another $18 million to researchers from the combined FY2015-2016 funding cycle. Since a new VRP funding announcement will not issue until FY2017 appropriations are finalized, he spoke about other DOD funding opportunities, including the Broad Agency Announcement (BAA) and the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. In discussion after Mr. Read’s comments, NAEVR Executive Director James Jorkasky reminded attendees that DOD funding opportunities were available to domestic and international researchers, and that those who navigate the VRP are more likely to apply for funding from other DOD programs with key words such as sensory and rehabilitation and diseases with a visual component.

Past VRP awardees—whom AEVR has featured in Congressional Briefings—spoke about their experiences in successfully navigating the VRP grant process in previous funding cycles. This included Andrew Hartwick, O.D., Ph.D. (Ohio State University College of Optometry), who is studying TBI-related photophobia (light-sensitivity) and Joseph Ciolo, M.D. (Massachusetts Eye & Ear/Harvard Medical School), who is developing a drug-delivering contact lens.

From left: Daniel Pelaez, Ph.D. (far left, Bascom Palmer Eye Institute/University of Miami Miller School of Medicine) and his colleagues—many of whom are early-stage investigators. Dr. Pelaez participated in AEVR’s first-ever 2015 EVS Day.

Andrew Hartwick, O.D., Ph.D. (Ohio State University College of Optometry)

Joseph Ciolo, M.D. (Mass Eye & Ear/Harvard Medical School)
SCORECARD LEGISLATIVE ISSUES

FY2016:

NEI Updates Funding Status at NAEC Meeting

At its June 16 National Advisory Eye Council (NAEC) meeting, NEI updated the status of its FY2016 appropriations as follows:

- Its $715.9 million Congressional appropriation was reduced to an Operational Net of $708 million due to the transfer of $7.9 million to NIH Central for the successfully completed Studies of the Ocular Implications of AID(SOCA) funding. NEI has transferred back $5.6 million in FY2015, $6.9 million in FY2014, and $7.4 million in FY2015.
- Starting with FY2016, its Operational Net includes “pass-through” funding for the Brain Research through Advancing Innovative Technologies (BRAIN) Initiative (BI) to map the human brain.

FY2017:

Senate and House Propose NIH/NEI Discretionary Funding Increases

Unlike the President’s FY2017 proposed budget—which relied upon $1.825 billion in mandatory funding—both the Senate and House have proposed FY2017 LHHS appropriations bills that increase discretionary funding for NIH and NEI—within the budget caps (see comparison chart below).

Comparison of FY2017 Senate and House LHHS Bills, FY2016 Omnibus

<table>
<thead>
<tr>
<th>Operational Net</th>
<th>FY2017 Senate</th>
<th>FY2017 House</th>
<th>FY2016 Omnibus</th>
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<td>National Institutes of Health</td>
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<td>Antibiotic Resistance</td>
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<td>Institutional Development Award (IDeA) Program</td>
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Senate:

On June 9, the Senate Appropriations Committee approved its FY2017 LHHS bill which had been marked up and approved by the LHHS Appropriations Subcommittee on June 7 with a $2 billion, or 6.3 percent, NIH Increase and a $32.8 million, or 4.6 percent, NEI increase. Praised by both Republicans and Democrats, it is the first bipartisan bill to come out of the Subcommittee in seven years.

As stated by Subcommittee Chair Senator Roy Blunt (R-MO), the Subcommittee wants to establish a pattern of five percent annual increases plus inflation, and committing to that approximate funding level for a second year was necessary to the pattern.

Subcommittee Ranking Member Senator Patty Murray (D-WA) said in both markups, “I am especially proud that this bill doesn’t include a single new damaging policy rider.”

Subcommittee member Lamar Alexander (R-TN), who also chairs the Senate Health, Education, Labor and Pensions (HELP) Committee, noted that in addition to the discretionary increase he was still pursuing mandatory “surge” funding for key NIH initiatives (Precision Medicine, BRAIN, Cancer Moonshot, and early-stage investigators), similar to that in the House’s 21st Century Cures Act passed in July 2015 and which NAEVR supported.

Visit the NIH/NEI funding section of NAEVR’s Web site at www.eyeresearch.org for full details.
On July 14 and after a day-and-a-half marathon session, the House Appropriations Committee approved its FY2017 LHHS bill which had been marked up and approved by the LHHS Appropriations Subcommittee on July 7 with a $1.25 billion, or 3.9 percent, NIH increase and a $27.6 million, or 3.9 percent, NEI increase. In discussion, Subcommittee Chairman Tom Cole (R-OK) stated that, “I want to be clear that I view the mark we set today as a floor, not a ceiling, for biomedical research funding, and I am hopeful this number can increase as the process moves forward.” He noted that he would work with his Senate counterpart Subcommittee Chairman Blunt to do the best they could within the budget caps. He added, “And what we probably need to do in this area is have a sustained increase over a long period of time, so that the researchers know it, frankly some of the people coming into the field know it, so they can build a career knowing they’re going to have the opportunities to do what they want to and what they’re trained to do. And that’s what we’re trying to do in this bill, and that’s what we will continue trying to do, working with the Senate, because we want this to become a habit that we almost take for granted.” Unlike the bipartisan Senate bill, the House bill includes numerous policy riders that the Democratic members of the Subcommittee attempted to strike. Led by Ranking Member Cong. Rosa DeLauro (D-CT), Democratic members also offered several amendments in both the Subcommittee and Committee markups to restore funding to key programs in the bill. In one amendment during full Appropriations consideration, Cong. DeLauro proposed to increase NIH funding by $750 million—to match the Senate bill—by funding the Cancer Moonshot at $550 million and proportionately increasing funding within the Institutes and Centers—funding for which would have been offset by declaring the Opioid Abuse and Infectious Diseases Rapid Response Reserve Fund as emergency funding outside of budget caps. The amendment failed along party lines.

Since Congress adjourned on July 14 for the expanded Summer recess—due to the conventions—it has just a few weeks in September to conclude legislative business prior to the start of FY2017 on October 1. Although leadership has indicated a desire to complete appropriations, Congress will likely pass a Continuing Resolution (CR) to maintain government operations, which could be as long as a six-month duration.

**Private Funding Foundations Educate About their Role in Vision Research, Advocate for Increased NEI Funding**

On April 6, NAEVR hosted the second annual Advocacy Day for private foundations within the vision community which had met the previous day under the auspices of Research to Prevent Blindness (RPB).

The seven participants representing five organizations from across the country met with 16 Congressional offices in both the House and Senate—the latter in session that week. For most, it was an opportunity to build upon their initial visits conducted in late March 2015. In addition to describing their important role in the local economy, the advocates emphasized their support for researchers at academic institutions throughout the nation—often for investigators in the early stage of their careers or as bridge funding for established researchers.

Commenting on the day’s activities, RPB President Brian F. Hofland, Ph.D. said, “RPB is pleased to have participated in the second annual Private Funding Foundation Advocacy Day. We support both early-career and early-stage vision research to better nurture and position innovative ideas for follow-on federal support. These meetings with Congressional offices emphasized the urgency of finding and funding solutions to eye problems endured by millions.”

**NAEVR Comments on Senate and House Proposed NIH/NEI Funding Increases**

NAEVR, which had requested FY2017 NIH funding of $34.5 billion and NEI funding of $770 million, commended the Senate and House actions to increase biomedical research funding for the second year. But NAEVR also recognized the importance of adequately funding the Institutes and Centers, including the NEI, as follows: “NAEVR is disappointed that the bill’s NEI funding level falls short of the $770 million requested. The Alliance will continue to impress upon Congress the importance of robust funding for the Institutes and Centers. In addition to the funding of new NIH initiatives. After all, vision health is critical to the productivity, independence, and quality of life of all Americans.”

**LHHS Appropriations Leaders Also Champion Defense Vision Funding**

In addition to proposing FY2017 NIH/NEI funding increases, both LHHS Subcommittee Chairman Blunt and Chairman Cole have championed a $5 million increase in FY2017 funding for the dedicated Vision Research Program in Defense appropriations to $15 million.

**NASEM (IOM) Study to Issue in September**

At the Fifth Annual Focus on Eye Health National Summit, hosted by Prevent Blindness and sponsored by AEVR, the National Academies of Sciences, Engineering, and Medicine (NASEM), formerly the Institute of Medicine (IOM), announced that its study entitled Public Health Approaches to Reduce Vision Impairment and Promote Eye Health would issue on September 15. NAEVR and other study sponsors (see box below) will work with NASEM to disseminate study results widely to legislators, policy makers, and the media.

NAEVR’s James Jorkasky with Prevent Blindness President and CEO Hugh Parry

For the third year, RPB organized a meeting of private funding foundations to seek collaborative solutions in addressing big questions in vision research. Among the 25 participating organizations were key federal agencies, including the NEI, represented by Director Paul Sieving, M.D., Ph.D., the Centers for Disease Control and Prevention (CDC), represented by Jinan Saaddine, M.D., M.P.H., Team Lead for the Vision Health Initiative, and the Food and Drug Administration (FDA), represented by Malvina Eydelman, M.D., Director of the Division of Ophthalmic, and Ear, Nose and Throat Devices within FDA’s Center for Devices and Radiological Health (CDRH). NAEVR Executive Director James Jorkasky participated and provided an update on federal funding for vision research.
that, when considering an area of research for her doctoral studies, she chose dry eye since it is such a common condition yet little had been known about its diagnosis and treatment at the time. She has subsequently focused her research on all aspects of dry eye, including meibomian gland dysfunction, blepharitis (inflammation of the eyelids), other types of inflammation, impact of menopause on dry eye, tear proteomics and lipidomics, dry eye diagnostics and therapies, and quality of life.

Dr. Nichols described the three layers of the tear film and the important role of each from cornea outward: the mucin layer, which adheres tears to the eye; the aqueous or water layer, produced by the lacrimal gland and which nourishes and protects the cornea; and the lipid or oil layer, produced by meibomian glands and which lubricates and prevents evaporation and provides the smooth refractive surface needed for optimal vision. Although the tear film includes 200-plus different lipids and 500-plus unique proteins, science does not yet know which are the most important for proper protection and lubrication of the eye and the absence or insufficiency of which results in dry eye. As a result, proteomics and lipidomics are one of the main areas of research within the 30-plus dry eye basic, translational, and clinical projects being funded by the NEI/NIH in fiscal years 2015 and 2016 and among the more than 50 scientific papers displayed a timeline which showed progress over the past twenty years, including the first consensus dry eye definition in 1995 to a second in 2007 through the Tear Film and Ocular Surface (TFOS) Dry Eye Workshop, often called the DEWS Report, and potential research direction is greatly accelerating and will result in advances in clinical care.”

–Dr. Nichols

Dry eye is one of the most common of all eye conditions, primarily affecting adults 45 years and older, with an estimated six million Americans over age 65 with severe dry eye—the majority of which are women. Although researchers have long known about age and gender as factors, they are now discovering ethnic and racial differences, and that dry eye impacts younger and younger patients. Dry eye can have many other causes including environmental exposure, medications, eye surgery (such as laser correction surgery), immune system disorders such as Sjögren’s syndrome, lupus, or rheumatoid arthritis, and an increasingly common cause—staring at computer or video screens for too long without blinking. Therapies have been developed or are in the drug-development pipeline to treat dry eye—some of which affect the lacrimal glands while others affect the meibomian glands—research is vital to develop more focused and potentially personalized treatment approaches.

In expressing hope for the future, Dr. Nichols displayed a timeline which showed progress over the past twenty years, including the first consensus dry eye definition in 1995 to a second in 2007 through the Tear Film and Ocular Surface (TFOS) Dry Eye Workshop, often called the DEWS Report, to a third anticipated in 2017 (TFOS DEWS II), which will assist in further refining clinical and research efforts. Concurrently, treatments have developed from over-the-counter topical lubricants to topical prescription drugs approved by the Food and Drug Administration (FDA), with many more in the development pipeline to treat dry eye—some of which affect the lacrimal glands while others affect the meibomian glands—research is vital to develop more focused and potentially personalized treatment approaches.

AEVR wishes to thank the following member organizations and coalition partners for their co-sponsorship of this event:

Research to Prevent Blindness
Association for Research in Vision and Ophthalmology
Women in Ophthalmology
Women’s Eye Health
Society for Women’s Health Research
Sjögren’s Syndrome Foundation

AEVR also wishes to thank Shire for funding to support event management.
Since it was created by Congress in FY2009 in Defense appropriations through NAEVR advocacy, the DOD’s Peer Reviewed Vision Research Program (VRP) within the Congressionally-directed Medical Research Program (CDMRP) has awarded 67 grants totaling $50 million.

2015/2016: USAMRAA and CDMRP To Issue Awards
For the FY2015/2016 VRP funding cycle, the US Army Medical Research Acquisition Activity (USAMRAA) and CDMRP are expected to award approximately $18.4 million to twelve researchers. An additional five investigators have been recommended as alternates should dollars become available. For the Technology/Therapeutic Development Awards, amounts of $1.5 million for a maximum period of performance of three years are being negotiated, and for the Clinical Trial Awards, amounts of $3 million for a maximum period of performance of four years are being negotiated.

2017: Per NAEVR Request, House Proposes FY2017 VRP Funding at $15 Million
On May 17, the House Appropriations Committee passed its FY2017 Defense bill, which includes $15 million for the VRP—$5 million greater than in FY2016 and the first time at that increased level. The Senate Appropriations Committee passed its FY2017 Defense bill May 26 which did not include VRP funding. Traditionally the House takes the lead in funding many DOD Defense Health Programs and the Senate defers to its priorities.

Although funded at $10 million in each of fiscal years 2013-2016, the final amount awarded to vision researchers has been greater each year due to transfers from other CDMRP programs.

NAEVR Joins Advocates in Opposing Onerous NDAA Provisions
In early June, NAEVR, in partnership with the Defense Health Research Coalition—a group that advocates for medical research programs within the DOD—supported an amendment offered by Senator Richard Durbin (D-IL) that nullified language in the FY2017 National Defense Authorization Act (NDAA) bill that would have imposed two burdensome new requirements on DOD research programs. The first provision would have subjected every single DOD medical project grant to a very laborious and challenging level of review by senior DOD leadership who may not have the level of expertise to adequately assess the merits of the grants. The second provision would have imposed new contracting requirements on funded projects that could slow down the process to get money to researchers. NAEVR was one of 143 organizations that signed on to a letter that was delivered to the Chair and Ranking Member of the Senate Armed Services Committee urging that the two provisions be nullified in the final bill. In addition, NAEVR enlisted the support of individual researchers in sending letters to their Senators asking them to vote in support of the Durbin amendment.

While the effort to amend the NDAA succeeded, because the Durbin amended only nullified—rather than deleted—the two provisions, there is concern that when the House and Senate meet to conference their two versions of the legislation these provisions could be resurrected.

In mid-July at the National Press Club, NAEVR’s James Jorkasky encountered former Cong. James Moran (D-VA), who as a member of the House Defense Appropriations Subcommittee championed the creation of the dedicated VRP funding line in FY2009 Defense appropriations and supported it until his retirement from Congress in 2014. When informed that the FY2017 House Defense appropriations bill increases VRP funding to $15 million, he gestured a “thumb’s up” and expressed his ongoing support for NAEVR’s efforts.

Visit the Defense-related Vision Research section of NAEVR’s Web site for full details