I recently enjoyed a dinner in Washington, D.C. with NAEVR Executive Director James Jorkasky and Association for Research in Vision and Ophthalmology (ARVO) Executive Director Joanne Angle. Although stories of the recent record snowfall dominated the conversation, we reviewed first-quarter advocacy activities and the legislative environment in which they are being conducted.

Despite the historic Fiscal Year (FY) 2009 funding of $230 million for vision research from “regular” and American Recovery and Reinvestment Act (ARRA) appropriations and defense funding, NAEVR has been engaged in Capitol Hill advocacy since the very first week of the year to maintain that momentum. NAEVR met with Hill champions for National Institutes of Health (NIH) funding to test messages about the need to fund NIH at $35 billion in FY2011—essentially the net level of funding in FY2009 and 2010 from “regular” and ARRA appropriations—to continue the stream of breakthroughs and fully leverage the significant ARRA investment.

NAEVR also met with its defense vision champions to test messages about the need to fund the dedicated Peer Reviewed Medical Research-Vision (PRMR-Vision) line at $10 million in defense appropriations. Since this dedicated line was just established in FY2009, NAEVR also educated staff in the offices of House and Senate defense appropriators that it is the only dedicated funding source for extramural vision research into immediate battlefield needs that is not currently being conducted by the National Eye Institute (NEI) and the Department of Veterans Affairs (VA). NAEVR member Blinded Veterans Association (BVA) has used its impressive influence to echo and amplify that message, especially garnering support from a wide range of Veterans Service Organizations (VSOs), and I want to express my deepest appreciation to them for their assistance and dedication.

NAEVR anticipates a very tough appropriations year due to Congressional concern about spending. As a result, NAEVR/AEVR followed these initial visits with a whirlwind of high-profile Capitol Hill events featured herein, ensuring that our issues remain in the spotlight. One overriding theme prevailed in all events—that, in 2009 through H. Res. 366 and S. Res. 209, Congress recognized the 40th anniversary of the NEI and designated 2010-2020 as the Decade of Vision. During this timeframe, vision research must be adequately funded, since investigators will be challenged to address the impact of aging eye disease, the disproportionate incidence of eye disease in minority populations, the visual implications of other chronic diseases, and the unprecedented impact of devastating eye injuries being incurred in Iraq and Afghanistan.

ARVO’s late January Advocacy Day set the tone, enabling both domestic and international researchers to discuss the broad reach of the U.S. biomedical research enterprise and why “going backwards” is not an option. In mid-February, and in its first defense vision Congressional briefing, AEVR addressed the potential for corneal wound sealing on the battlefield. In early March, AEVR joined with the entire vision community in recognizing the first-ever World Glaucoma Week in a Congressional briefing. AEVR’s efforts were amplified that same day when member Prevent Blindness America (PBA) held its Patient Advocacy Day and coordinated a Congressional Vision Caucus reception that evening. Jim Jorkasky has told me that our work is cut out for us, so I appreciate the commitments that members have made to support the Alliances in 2010. I especially want to thank those network members who highlighted our 2009 accomplishments in their late 2009 and early 2010 communications. This not only serves to educate broadly on the value of supporting our work, but emphasizes that we all have a stake in the future funding for and success of vision research.

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As in past years, ARVO researchers from the Annual Meeting Program Committee were among the first on Capitol Hill to advocate for increased NIH funding, generally, and NEI, specifically. In 35 visits, the 13 domestic and 9 international advocates urged Members of the 111th Congress, Second Session, to support FY2011 NIH funding at $35 billion to fully leverage and maintain the current momentum of research. In initial comments, the researchers thanked the offices for the $18.5 million increase in FY2010 NEI funding, as well as the $175 million two-year funding that NEI received of the $10.4 billion ARRA funding. They then emphasized that, due to the combination of “regular” and stimulus appropriations, the NIH biomedical research enterprise has been funded at a net level of $35 billion in FY2009 and FY2010, and that level is necessary to prevent a reduction in the number of grants.

The researchers shared a NAEVR fact sheet about ARRA-supported NEI research. Five of the domestic advocates had received ARRA funding, including John Ash, Ph.D., Joseph Carroll, Ph.D., Marc Kantorow, Ph.D., Leonard Levin, M.D., Ph.D., FARVO, and W. Daniel Stamer, Ph.D., FARVO. “For many Hill offices, this was the first opportunity to meet ARRA-funded researchers and learn about implications of their work to prevent blindness and restore vision, as well as to retain or hire staff,” said NAEVR’s James Jorkasky, who accompanied the researchers along with NAEVR Advocacy Manager David Epstein.

Participants not shown in the images include: Leonard Levin, M.D., Ph.D., FARVO (University of Montreal/University of Wisconsin), John Ash, Ph.D. (University of Oklahoma Health Science Center), Muna Naash, Ph.D., FARVO (University of Oklahoma Health Science Center), and Motohiro Kamei, M.D. (Osaka University Graduate School of Medicine.)
NIH Director Francis Collins, M.D., Ph.D. has requested that medical research advocacy organizations briefly summarize their top concerns. In its March 15 submission, NAEVR initially acknowledged NEI’s 40 years of leadership in basic, translational, and clinical research, as well as in trans-NIH and trans-Department of Health and Human Services (DHHS) collaborations. NAEVR also cited NEI research that addresses Dr. Collins’ top five NIH priorities—genomics, translational research, comparative effectiveness research, global health, and empowering the biomedical research community—which NEI described in its FY2011 budget Congressional Justification.

NAEVR identified its top priorities as:

• Robust NIH/NEI funding, stating its support for FY2011 NIH funding at $35 billion and expressing concern about the proposed less-than-inflationary increase for NEI (see story above); and

• Potential NIH budget clusters, stating NAEVR’s ongoing opposition to “clustering” V/C budgets within NIH and support for maintaining a separate NEI budget line. NAEVR noted that it is tracking the activities of the NIH Scientific Management Review Board (SMRB), which is charged with making recommendations regarding NIH structure, and convenes meetings with “Friends” of other smaller Institutes to share strategies.

Per the funding chart, final FY 2010 appropriations, signed into law by President Obama on December 16, 2009, increased NIH funding to $31 billion, a $691.8 million or 2.3 percent increase over FY2009, and NEI funding to $707.04 million, an $18.5 million or 2.7 percent increase. Since NEI programmed $26.7 million of its ARRA funding for 2010, vision researchers will have a total of $45 million more than FY2009 NEI baseline funding.

## NAEVR Concerned About NEI Funding in President’s Proposed FY2011 Budget

Per the funding chart, the President’s FY2011 proposed budget released on February 1 would provide a 3.2 percent inflationary increase for the NIH, but only a 2.4 percent increase for the NEI, the second lowest of the NIH Institutes and Centers (I/Cs). In a statement, NAEVR stressed that now is not the time for a less-than-inflationary increase for NEI since it would result in a net loss in purchasing power, which had already declined by 18 percent in the FY2003-2008 timeframe. NAEVR noted that Congress spoke volumes in passing H. Res. 366 and S. Res. 209 in 2009, which acknowledged NEI’s 40th anniversary and designated 2010-2020 as the Decade of Vision. Year 2010 begins a decade in which more than half of the 78 million Baby Boomers will turn 65 years of age and be at greatest risk for developing aging eye disease.

NAEVR has called on Congress to improve upon the President’s proposed budget by supporting an FY2011 NIH funding level of $35 billion, per the previous story about ARVO Advocacy Day.

### Legislative Scorecard Issues

#### FY2010 NIH/NEI Appropriations Summary

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<thead>
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<th>FY 2008 Final</th>
<th>FY 2009 Final**</th>
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* Net of Transfers/one Time Expenses
** Absent ARRA Funding

### NAEVR Submits NIH Listens Comments to NIH Director Dr. Collins

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###Related Topics

- Establishing a joint NIH/FDA Leadership Council, co-chaired by Drs. Collins and Hamburg and consisting of six senior representatives from each agency, to ensure that regulatory considerations form an integral component of biomedical research planning and that the latest science is incorporated into the regulatory review process.

- A planned Stakeholders Meeting to seek input from interested parties, especially the manufacturer community whose products are regulated by FDA.

- A Request for Application (RFA) entitled Advancing Regulatory Science through Novel Research and Science-based Technologies to support research into regulatory science. Over a three-year timeframe, NIH will commit $6 million and the FDA $750,000 to this initiative, for a total of $6.75 million.
Vision Community Unites to Observe World Glaucoma Week on Capitol Hill

On March 11, AEVR’s Decade of Vision Initiative united the vision community in recognizing the first World Glaucoma Week (March 7-13), as well as the third World Glaucoma Day, held March 12, 2010.

Christopher Girkin, M.D., M.S.P.H., a tenured professor of Ophthalmology and director of the University of Alabama at Birmingham Glaucoma Service in the Department of Ophthalmology at Callahan Eye Foundation Hospital, described the NEI-funded African Descent and Glaucoma Evaluation Study (ADAGES), which is designed to identify factors accounting for differences in glaucoma onset and rate of progression between individuals of African and European descent. Dr. Girkin is one of the lead investigators in this multi-center collaboration that began in 2002 and is gathering clinical information from 1,200 African American and White Americans to determine which clinical techniques can best detect damage to the optic nerve related to glaucoma. The other ADAGES clinical sites include the University of California at San Diego’s Hamilton Glaucoma Center, at which study Principal Investigators Pamela Sample, Ph.D. and Linda Zangwill, Ph.D. are located, and New York Eye and Ear Infirmary, with Jeff Liebmann, M.D.

Dr. Girkin stated that clinical observations demonstrate that Primary Open Angle Glaucoma (POAG), the most common form of the disease, appears ten years earlier in African Americans and progresses more rapidly. He noted that ethnicity is one of several risk factors for developing the disease, which include advancing age, a family history of glaucoma, long-term elevated ocular pressure, and access to healthcare—most importantly, regular eye exams. Chronic diseases, such as hypertension and diabetes, are likely to play a role as well, while the impact of environmental factors is not yet clearly understood.

Dr. Girkin explained that basic research is helping to understand the clinical observations, especially when using advanced imaging techniques, such as Optical Coherence Tomography (OCT), that can reveal damage to the optic nerve head, which is the delicate structure of ganglion cells at the very back of the optic globe. He predicted that developments in imaging will one day enable researchers to view individual cells in the eye and to determine physiological changes that could be associated with disease progression and visual impairment far earlier than currently possible. He concluded by stating that, “However, for the new technologies to be useful to provide more efficient and high quality care to at-risk minority populations, it is critical that long-term studies using these devices continue in order to determine how best to detect progressive injury in this chronic blinding disease.”

In closing comments, AEVR’s James Jorkasky directed attendees to a March 3 statement issued by the NEI for World Glaucoma Week in which its Director Paul Sieving, M.D., Ph.D., noted that NEI currently funds 181 glaucoma research projects at a total of $82.6 million.

On March 11, AEVR member Prevent Blindness America (PBA) held its Eyes on Capitol Hill Patient Advocacy Day. That evening, the vision community joined the Congressional Vision Caucus (CVC) in hosting a Capitol Hill reception.

Several medical research advocacy colleagues attended the briefing, including (left) Martha Nolan (Society for Women’s Health Research) and (right) Renee Cruea (Coalition for Imaging and Bioengineering Research), with AEVR’s James Jorkasky.

Accompanied by James Jorkasky, Dr. Girkin and Ms. Smitherman made visits with Alabama delegation offices. Left: Senator Jeff Sessions (R-AL) greeted them in the hallway prior to a visit with his staff.

Christopher Girkin, M.D., M.S.P.H., speaks.
Vision Research Meeting Battlefield Needs: Corneal Wound Sealing/Healing and Protection

On February 18, AEVR’s Decade of Vision Initiative sponsored a Congressional briefing to describe research that addresses the devastating nature of traumatic eye injuries being experienced by the nation’s troops in Iraq and Afghanistan.

Colonel Donald Gagliano, M.D., M.H.A., who commanded troops in the early years of Operation Iraqi Freedom, provided an initial description of how traumatic eye injuries are diagnosed and treated in battlefield conditions. Col. Gagliano serves as the Director of the Vision Center of Excellence (VCE), a joint Department of Defense (DOD) and Department of Veterans Affairs (VA) initiative with the primary task of coordinating the Defense and Veterans Eye Injury Vision Registry (DVEIVR).

Short-term, with more complete data on eye injuries, the VCE can update in-theater vision protocols to ensure early intervention to avoid ocular cell death. Long-term, the registry can identify the most significant future research needs. The VCE is coordinating with an existing civilian eye injury registry to ensure that what is learned from treatment and research is shared broadly.

Featured speaker Irene Kochevar, Ph.D., (Wellman Center for Photomedicine, Massachusetts General Hospital), who is a photochemist, described herself as a basic researcher who has focused on the light activation of tissue sealing agents. After consulting with clinical ophthalmologist Colonel Anthony Johnson, M.D. (Ophthalmology/Cornea Service, Brooke Army Medical Center, San Antonio, Texas), the pair combined their skills to submit and receive jointly an Advanced Technology/Therapeutic Development Award from the DOD’s Deployment Related Medical Research Program (DRMRP) to study the sealing of penetrating eye injuries using photo-activated bonding, as well as a joint DOD Peer Reviewed Medical Research Program (PRMRP) Translational Research Award to study corneal protection in burn patients.

Dr. Kochevar, who has studied photochemical tissue bonding on skin and peripheral nerves, tendons, and blood vessels in animal research, emphasized its benefits for wound sealing and healing in that it is sutureless, thereby reducing inflammation and scarring; creates a water-tight seal, which guards against fluid loss and infection; and is simple and rapid, with potential direct battlefield application. In summary, a nontoxic, non-inflammatory Rose Bengal dye is applied to lacerated or damaged tissue, a light source is applied (green laser or LED), and the tissue is sealed. The activation of the dye, which is already Food and Drug Administration (FDA)-approved for diagnostic purposes, promotes linking of the collagen fibers, which she describes as “nanosutures.”

In the DRMRP awards, the researchers are directly applying this technology to the sealing and healing of wounds to the cornea, especially to ensure its continued transparency, as well as to the sclera, the white part of the eye, and eyelid lacerations. For more complex, penetrating eye wounds, Dr. Kochevar seals amniotic membrane over the cornea, similar to a patch on a tire. The membrane, which is the innermost layer of the placenta, has numerous benefits in that it has a high collagen content that promotes nanosuture cross-linking, it is already used in corneal surgery, and it contains healing properties.

Building on the initial research into the membrane patch, in the PRMRP awards, the researchers are studying how it can be made stronger to create a long-lasting protective eye covering in patients who cannot blink due to scarring after burns and grafts that cause skin contraction around the eyes. Current treatments include eye drops and an amniotic membrane ring, but the latter is often degraded by enzymes in the eye within a day or two. The researchers are studying how to fortify the membrane patch by photo-bonding multiple layers of the amnion together to create a highly cross-linked structure which is more resistant to degrading enzymes.

In both sets of these animal studies, the researchers are looking at multiple variables, such as amount of dye and efficacy of light source, to determine optimal sealing and healing conditions and their relationship to a battlefield application. Dr. Kochevar estimates that the research could be ready for human clinical trials within a year, but that separate, additional funding would be necessary.

This corneal sealing research could be ready for human clinical trials within a year. – Dr. Kochevar

See back page for details about PRMR-Vision funding
As DOD Finalizes FY2009 Awards, NAEVR Advocates for FY2011 Peer Reviewed Medical Research-Vision Extramural Funding at $10 Million

TATRC on Track to Issue FY2009 PRMR-Vision Awards by First-Quarter 2010

On February 16, DOD’s Telemedicine and Advanced Technology Research Center (TATRC), which manages the dedicated Peer Reviewed Medical Research-Vision (PRMR-Vision) line in defense appropriations, held a meeting of its Programmatic Committee to make final recommendations regarding FY2009 extramural research awards. TATRC has proposed to combine the FY2009 appropriated funding level of $4 million—plus its internal additional funding of $1.2 million—with the FY2010 appropriated level of $3.75 million, for a $9 million total. In 2009, TATRC issued a Program Announcement in June, receiving 120 pre-proposal submissions that were reviewed in August. Full proposals, due in October, received peer reviewed in early December. TATRC will notify awardees, and NAEVR will post links to abstracts once information is publicly available.

The Committee, co-chaired by the VCE’s Colonel Donald Gagliano and TATRC Director Colonel Karl Friedl, Ph.D., is composed of ophthalmologists and optometrists from the various branches of the U.S. military and the VA, in addition to representatives from the NEI and FDA. ARVO Executive Director Joanne Angle, as well as NAEVR Executive Director James Jorkasky and Advocacy Manager David Epstein, serve as “stakeholder” representatives.

NAEVR Advocates for FY2011 PRMR-Vision Funding of $10 Million

NAEVR has educated staff of the House and Senate Defense Appropriations Subcommittees that the PRMR-Vision line is the only dedicated funding source for extramural research into battlefield needs that is not conducted by the VA or NEI. NAEVR also stressed that Defense Secretary Robert Gates has identified “Restoration of Sight and Eye-Care” as one of four top defense research priorities. The BVA has used its significant influence to assist as follows:

• Ensuring that the Independent Budget, an annual set of recommendations to Congress by close to 60 Veterans Service Organizations (VSOs) and other supporters, urged FY2011 PRMR-Vision funding at $10 million

• Organizing letters to Congressional leaders from seven VSOs supporting the funding

• Testifying at a March 4 joint session of the House and Senate Committees on Veterans Affairs, identifying PRMR-Vision as a top priority for funding

Organizations (VSOs) and other supporters, urged FY2011 PRMR-Vision funding at $10 million

• Working to secure House and Senate “Dear Colleague” letters from non-defense appropriators in support of PRMR-Vision funding

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

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Senator Sherrod Brown (D-OH), center, was presented BVA’s National Legislative Recognition Award on March 2 by Dr. Tom Zampieri (left) and BVA President Roy Kekahuna, Ph.D. Sen. Brown sponsored a bill that provides scholarships for future VA Blind Rehabilitation specialists. He also made a January 26 statement on the Senate floor regarding the importance of non-military vision rehabilitation and the need for Medicare coverage of professionals providing these services. NAEVR member Lighthouse International is leading advocacy on the latter issue.