Contribution Report

President’s Message

NAEVR Uses Recess to Thank Members and Build Relationships, with AREDS 2 Release Highlighting the Value of NEI’s Trans-Institute Research

I recently spent two days in Capitol Hill visits with NAEVR Executive Director Jim Jorkasky and Advocacy Manager David Epstein. I was delighted with the generous amount of time provided by staff in key offices to discuss the vision community’s issues. NAEVR has used this election recess time wisely—through my visits, as well as the 40-plus visits conducted by the ARVO Board of Trustees during its October 20 Lobby Day, detailed inside.

My priority on the Hill this year has been National Institutes of Health (NIH) reauthorization. I was pleased to thank key staff of House Energy and Commerce (E&C) Committee Members from both sides of the aisle for their responsiveness in significantly improving the legislative draft that resulted in the House bill passed with strong bipartisan support just prior to the election recess. This includes Cheryl Jaeger and Katherine Martin from E&C Committee Chairman Joe Barton’s (R-TX) staff, and John Ford of Ranking Member Cong. John Dingell’s (D-MI) staff. NAEVR endorsed this bill, but only after the controversial budget clusters were eliminated and its provisions were aligned with the Institute of Medicine’s (IOM) recommendations.

The bill’s improvements were a direct result of advocacy by the medical research community, and NAEVR should be proud of the tenacity of Jim Jorkasky and Legislative Counsel John Porter in urging appropriate changes. To demonstrate Jim’s and John’s leadership in this regard, the majority of my recent visits were spent with Republican and Democratic Members of the Senate Health, Education, Labor, and Pensions (HELP) Committee, which has Senate jurisdiction over NIH. As noted in the next story, although the Senate may not take up NIH reauthorization this session, NAEVR has already been in key offices building relationships and offering its assistance in post-election legislative actions.

We also spent time with Senate Appropriators, since NIH champions Sen. Arlen Specter (R-PA) and Sen. Tom Harkin (D-IA) will feel strongly about any Senate bill.

The National Eye Institute (NEI) had just announced the second phase of its Age-Related Eye Diseases Study (AREDS), building upon the first study which demonstrated that high-dose antioxidant vitamins and minerals reduced the risk of progression to advanced age-related macular degeneration (AMD) by 25 percent. I emphasized to staff how this research meets so many of the goals of NIH reauthorization, such as trans-Institute research, as well as NIH Director Dr. Zerhouni’s goals, such as prevention research. I commend NEI Director Dr. Paul Sieving and his team for communicating the value of NEI research via-a-vis NIH’s larger goals. And I wish to recognize Jim Jorkasky, too, as he recently received a letter of commendation from Dr. Zerhouni for NAEVR/AEVR efforts to amplify that NEI value message broadly.

I appreciate your commitment to NAEVR/AEVR and look forward to working with all network members.

—Stephen J. Ryan, M.D.
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On October 20, members of the Board of Trustees of the Association for Research in Vision and Ophthalmology (ARVO) held a Capitol Hill Lobby Day. With the elections looming, the 40-plus visits to Members on both sides of the aisle enabled these researchers to educate their Senators and Representatives from work/home districts about the importance and broad implications of NEI-funded vision research being conducted locally. Participants also visited House Appropriators and Energy and Commerce Committee Members from neighboring districts. As with NAEVR Board President Dr. Stephen Ryan’s October 10-11 Congressional visits (see front page), NAEVR placed an emphasis on meetings with Senate HELP Committee Members regarding the NIH reauthorization issue, now that the House has passed a bill.

ARVO Trustees Educate Key Congressional Offices About Their Vision Research

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House Passes NIH Reauthorization Bill; Senate Timetable Uncertain

On September 26, the House passed HR6164, the National Institutes of Health Reform Act of 2006, by an overwhelmingly bipartisan vote of 414-2. NAEVR immediately commended the House, as it was one of 51 organizations that endorsed the bill, formalized in a September 22 letter to E&C Committee Chairman Cong. Joe Barton (R-TX). At press time, and after NAEVR visits with leadership and ranking staff, the Senate HELP Committee was uncertain of timing for Senate action. Even if this issue is not taken up this session, the current House bill serves as the “floor” for further legislative action.

Readers of past Contributor Reports know that NAEVR’s number one priority has been to ensure that any NIH reauthorization bill does not jeopardize the ability of the NEI Director to lead the nation’s vision health commitment with a dedicated budget. In that regard, the final House bill eliminated the budget clusters proposed in previous drafts that were strongly opposed by NAEVR and the medical advocacy community. Additionally, the final bill aligned its provisions regarding expanded transparency, increased NIH Director discretion and establishment of a “common fund” for trans-Institute research with the recommendations issued by the IOM in its 2003 report entitled Enhancing the Vitality of the National Institutes of Health.

In reauthorizing the NIH for three years, the bill also authorizes funding increases of five percent for each year of fiscal years (FY) 2007-2009. In the September 20 markup, Cong. Ed Markey (D-MA) introduced amendments to increase funding by five percent above the biomedical inflation rate for each year, but this was voted down along party lines. In its letter to Chairman Barton, NAEVR offered its full support in urging Congressional leadership and appropriators to ensure these NIH funding increases.

Former E&C staff member Cheryl Jaeger, now in the office of Cong. Roy Blunt (R-MO), presents the final legislative draft on which she has worked for three years. She is joined by Dr. Jeff Allen of Friends of Cancer Research, with which NAEVR worked closely in advocacy.

NAEVR Board Director Cary Rayment (Alcon Laboratories) and E&C Chairman Joe Barton (R-TX) at an AdvaMed-sponsored session in which NAEVR participated. This was one of several NAEVR meetings with Chairman Barton this past year.
In the post-election “lame duck” session, Congress will conference FY2007 health-related Department of Defense (DOD) spending, which is contained in the House Military Quality of Life and Senate Defense appropriations bills. This includes NAEVR’s request that eye and vision research remain eligible for funding under the Peer-Reviewed Medical Research Program (PRMRP). NAEVR is working closely with the offices of House champion Cong. Jim Walsh (R-NY) and Senate champion Sen. Kay Bailey Hutchison (R-TX). At press time, FY2006 awards were announced, which included at least two vision-related grants. NAEVR will report further on the status of the FY2007 listing and FY2006 awards. Full details appear in the NAEVR Web site Advocacy Center’s dedicated section on defense-related vision research.
On September 29, just prior to the election recess and start of FY2007, the Senate passed the Defense appropriations conference report (approved earlier by the House) that included a Continuing Resolution (CR) to fund non-defense, non-homeland security government operations at the FY2006 level until November 17. This includes Labor, Health and Human Services, and Education (LHHS) programs, such as the NIH/NEI. Congress is scheduled to return the week of November 13 for a “lame duck” session. Although House and Senate Appropriations Committee Chairs Jerry Lewis (R-CA) and Thad Cochran (R-MS) have expressed their intent to pass the remaining spending bills individually, Congress may act on a comprehensive omnibus spending bill.

NAEVR has urged House and Senate Members to follow through on their respective Budget Resolution commitments to increase LHHS programs by the full, additional $7 billion over the President’s budget request (same as House bill). Although the House LHHS bill added $4.1 billion, no additional funds were committed to NIH. The Senate added $5 billion, with an NIH increase of $220 million over the FY2006 funding level, which would negate the proposed 0.8 percent cut to the NEI budget and increase it $600,000 over the FY2006 level.

NAEVR joined medical advocacy colleagues in urging all Senators to support a “Dear Colleague” letter from Senators Specter (R-PA) and Harkin (D-IA) to fully fund LHHS programs. NAEVR also urged moderate House Republicans to sign onto a similar letter from Cong. Mike Castle (R-DE). Full details appear in the NAEVR Web site Advocacy Center’s dedicated section on NIH/NEI appropriations.
James Jorkasky (left) scrambles among September 19 Energy and Commerce Committee hearing witnesses to inform Dr. Zerhouni about AEVR’s Congressional Briefing Collaboration in Diabetic Retinopathy Research held earlier that day.

“I greatly appreciate your efforts to increase awareness of and support for research on eye diseases and disorders of vision. The efforts of NAEVR/AEVR to highlight both the great need and unparalleled opportunity to develop new or improved treatments for these conditions offer hope to those who are visually impaired.”
—August 24 Dr. Zerhouni commendation letter to James Jorkasky

“NAEVR is confident of the opportunities that the newly created common fund presents for the NEI, especially due to its strong track record of trans-Institute, collaborative research. In that regard, you should be aware that, at a September 13 briefing on the bill, Energy and Commerce staff solely cited NEI research as examples of trans-Institute research potentially supported by the common fund.”
—September 27 James Jorkasky letter to Dr. Zerhouni, upon passage of the House NIH reauthorization bill
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FY2007 LHHS Appropriations Bills Laud NEI Trans-Institute Research

Report Language in the House and Senate LHHS appropriations bills, recommended by NAEVR, recognizes the importance of NEI’s collaborative research, as follows:

House
“The Committee applauds NEI for the collaborative efforts of the Diabetic Retinopathy Clinical Research Network to test innovative treatment for diabetic eye disease. The Institute is encouraged to expand and extend the network by increasing the number of clinical trials with new drugs and therapeutics that can reverse or prevent diabetic retinopathy.”

Senate
“The Committee was pleased to hear of the recent discovery of a second gene which can increase the risk of developing age-related macular degeneration. The identification of these genes creates the opportunity to predict and preempt the disease, thus preserving independence and mobility for millions of Americans. The Committee urges the Institute to move on an expedited basis to translate this finding into treatment for those suffering from this condition.”
Collaboration was the watchword at the September 19, Alliance for Eye and Vision Research (AEVR) Congressional briefing on the impact of research partnerships at the NEI in the fight against diabetic retinopathy. The briefing, held in conjunction with the American Diabetes Association (ADA) and the Juvenile Diabetes Research Foundation International (JDRF), featured Dr. Thomas Gardner, a diabetes researcher and clinician from the Pennsylvania State University Milton S. Hershey Medical Center, a site within the Diabetic Retinopathy Clinical Research (DRCR) Network, www.DRCR.net.

The DRCR, funded by NEI in partnership with JDRF, is a collaboration of clinicians and researchers from different specialties throughout the nation and at the NIH who are combining their skills and assets to accelerate discoveries about the causes of diabetic retinopathy and to develop preventions, treatments and cures for this potentially blinding condition. NIH estimates that 21 million Americans have diabetes, and most of these individuals will experience vision problems related to this condition.

“The eye is a complex structure, so the collaborative nature of the Network enables it to quickly respond with basic and clinical research into the most promising new findings,” said Dr. Gardner, who added that, in its first four years, the Network has grown to include 545 experts at 163 clinical sites (many community-based) in 43 states seeing more than 1,700 patients—many of whom would not have otherwise had access to this care.

Dr. Gardner acknowledged that he understands diabetes and its consequences from a personal and professional perspective, due to both of his brothers having the disease. That personal experience with diabetes was also expressed by Cong. Gene Green (D-TX), who introduced Dr. Gardner. Cong. Green, a co-chair of the Congressional Vision Caucus and a Member of the House Energy and Commerce Committee with oversight over the NIH, represents a largely Hispanic district in which the incidence of diabetes and diabetic retinopathy is disproportionately high. Since the Committee was preparing for an afternoon hearing on an NIH reauthorization bill that would establish a “common fund” for collaborative research, he commented that, “It’s fitting that we’re here on this particular day, as I can’t emphasize trans-NIH research too much as a way to lift the disease burden on the American people. Disease doesn’t occur in isolation, nor should the research.”

The DRCR is just one of several networks which NEI has funded over the past 30 years in collaboration with the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) to study diabetic retinopathy, which have resulted in treatments that have reduced blindness by 90 percent and save $1.6 billion annually in healthcare costs.

NEI has also collaborated with the National Cancer Institute (NCI) on research into factors that inhibit blood vessel growth in tumors that is now being applied to diabetic retinopathy and AMD therapies. NEI collaborative research with the National Human Genome Research Institute (NHGRI) has resulted in the discovery of gene variants in the body’s inflammatory response associated with increased risk of AMD that may also relate to diabetic retinopathy.
NEI Discusses Upcoming Clinical Endpoints Meeting with the Vision Community

At a September 21 meeting sponsored by the EyeRX, NEI Clinical Director Dr. Rick Ferris spoke to the vision community about plans for the joint NEI/Food and Drug Administration (FDA) Ophthalmic Clinical Trial and Endpoints meeting, to be held November 28-29 at the L’Enfant Plaza Hotel in Washington, D.C. The meeting will focus on aspects relevant to clinical trials for both neovascular and atrophic AMD, endpoints in diabetic retinopathy and post-marketing drug surveillance mechanisms.

This educational event emerged from July 2005 and February 2006 meetings, convened by NAEVR in conjunction with the EyeRX and the American Academy of Ophthalmology, with FDA’s Dr. Janice Soreth, the Director of the Center for Drug Evaluation and Research’s (CDER) Division of Anti-Infective Products, in which the Ophthalmic Review Group is housed. The community wanted to ensure the timely approval of new products emerging from NEI-sponsored research.

“NEI’s collaboration with FDA is especially important, as the recently-passed House reauthorization bill requires NIH to report on outreach with other federal entities, such as the FDA. As with trans-Institute research within NIH, NEI is also a leader in this regard,” stated NAEVR’s James Jorkasky.
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NAEVR Participates in AMD Awareness Week Roundtable

One of the many events held worldwide during the September 19-23 AMD Awareness Week was a roundtable entitled Prioritizing the Patient: a Holistic Approach to AMD Case Management, sponsored by the National Association for Visually Handicapped (NAVH) and the Am Eye Healthy? campaign. NAEVR was pleased to participate in this discussion, which included network members AMD Alliance, Foundation Fighting Blindness, Lighthouse International, Macular Degeneration Partnership, Novartis and Prevent Blindness America, as well as the NEI.

“Learning more about the daily challenges of individuals with AMD has enhanced NAEVR’s message about the importance of adequately funding research into its treatment and prevention,” said NAEVR’s James Jorkasky after the event.

Dr. Lorraine Marchi (NAVH Founder/CEO), Dr. Robert Vitti (Novartis Medical Director) and NAEVR’s James Jorkasky