

President's Message

Since my travel schedule has taken me to Washington, D.C. frequently this year, I have had the opportunity to both advocate and educate on Capitol Hill about the value of vision research within the National Institutes of Health (NIH). I have consistently heard in Hill offices—especially those of key committee leaders—about the quality and credibility of NAEVR's messages about the value of National Eye Institute (NEI)-funded research. As evidence, one of the stories contained herein describes the Report Language from both the Fiscal Year (FY) 2008 House and Senate Labor, Health and Human Services, and Education (LHHS) Appropriations bills, which was adopted verbatim from NAEVR's submissions.

NAEVR's messages are further supported by AEVR's educational briefings, which this quarter focused on the topics of *Visual Imaging* and *Children's Vision Research*. AEVR's Congressional briefings held so far this year have already drawn more than 200 attendees.



On July 10, Dr. Ryan met with Senate LHHS Appropriations Subcommittee Chair Sen. Tom Harkin (D-IA), thanking him for his leadership to increase FY2008 NIH funding by \$1 billion in the Senate bill

When Congress returns in September, they will have a busy legislative schedule. Although the House has acted on all of its FY2008 appropriations bills, the Senate has only acted on one. Despite both LHHS bills including increases for NIH/NEI, these are not guaranteed, due to the threat of a Presidential veto and a process that could result in an omnibus funding bill or one or more funding resolutions. NAEVR will continue to emphasize the need for both increased and timely appropriations and engage network members as appropriate in reaching out to Congress.

Even though NIH was funded in FY2007 through a Joint Resolution (JR) that maintained NEI appropriations at the FY2006 level of \$667 million, the NEI has netted \$12.7 million more for vision research. At the June 7 meeting of the National Advisory Eye Council (NAEC), NEI Director Dr. Paul Sieving announced that NEI received a total of \$4.2 million in NIH Director's Bridge Awards from the \$91 million pool contained in the JR. This is in addition to the \$8.5 million already available for NEI programs from the JR, since it directly funded the newly established NIH common fund (which was supported by NAEVR in the *NIH Reform Act of 2006*), obviating NEI's contribution.

The \$12.7 million NEI programmatic increase, coupled with the \$4.8 million awarded to vision researchers in 2007 through the Department of Defense's (DOD) Peer-Reviewed Medical Research



Dr. Ryan also met with Andrea Uckele in the office of Cong. James Walsh (R-NY), Ranking Member of the House LHHS Appropriations Subcommittee, who has strongly supported the House's \$750 million increase for NIH

Program (PRMRP), means that the vision community has netted an additional \$17.5 million for research in FY2007 over FY2006. This represents a greater than 30-fold return on the community's \$550,000 investment in NAEVR/AEVR this year.

Although this edition resembles a travelogue of images of my activities, I wanted you to see that we are working effectively with both sides of the aisle in both chambers to secure eye and vision research funding for our community from the NIH and other sources. I appreciate the efforts of NAEVR Executive Director James Jorkasky and Advocacy Manager David Epstein, in consultation with Legislative Counsel John Porter, to fully maximize my time with Members of Congress and their staffs.

Thank you for your support.

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National Alliance For
Eye And Vision Research

Alliance For Eye
And Vision Research

ARVO Advocacy Crucial to a Strong Vision Community Voice

Working through NAEVR, the Association for Research in Vision and Ophthalmology's (ARVO) members have lent their voices in emails, letters, and in personal visits with Congressional offices throughout the FY2008 appropriations process. At the early May Annual Meeting, ARVO members sent hundreds of letters in support of NIH/NEI funding increases from NAEVR's Contact Congress booth in the ARVO pavilion. They redoubled those efforts with hundreds of letters to support the July 19 passage of H.R. 3043, the House FY2008 LHHS funding bill, with an NEI increase of nearly \$10 million that is

threatened by a potential Presidential veto of major funding bills since they exceed his proposed budget [see story inside].

On June 20, ARVO Trustee David Hunter, M.D., Ph.D., (Harvard University) visited the offices of the Massachusetts delegation, building upon visits made in October 2006. Although these Democratic offices have been supportive of NIH/NEI funding increases, the follow-up visits presented an opportunity to offer thanks and urge increased and timely FY2008 NIH/NEI appropriations.

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Huey Cai, M.D. (Columbia University), Steven Pittler, Ph.D. (University of Alabama at Birmingham), and Cynthia Ricard, Ph.D. (St. Louis University Eye Institute) contact Congress at the ARVO Annual Meeting

Making a Difference: One Researcher's Story

In addition to being politically active locally, Linda McLoon, Ph.D. (University of Minnesota) has communicated frequently through NAEVR's Contact Congress requests with her Members of Congress, including Cong. Betty McCollum (D-MN) who, in early 2007 with the start of the 110th Congress, was named to serve on the House LHHS Appropriation Subcommittee. Due to her past advocacy, Dr. McLoon's request to meet with the Congresswoman's office during her January 2007 trip to Washington, D.C. for an ARVO Program Planning Committee meeting was scheduled promptly. Dr. McLoon, an NEI-funded researcher, was joined by NAEVR's James Jorkasky in meeting with Cong. McCollum's staff to urge increased and timely FY2008 NIH/NEI appropriations, as well as to invite staff to visit. Just two months later, Cong. McCollum was an active participant in the Subcommittee's hearing with NIH Director Dr. Elias Zerhouni and

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Dr. Linda McLoon

subsequent Public Witness hearings, which included March 27 testimony by NAEVR's Dr. Stephen Ryan.

In early August and at her laboratory, Dr. McLoon hosted Joe Carlisle, educating him about her NEI-funded research and introducing him to fellow vision researchers. After the visit, Dr. McLoon commented to NAEVR that, "It is interesting how personalizing those 'form letter' emails to Capitol Hill can make a difference in terms of response. Sometimes all we need to do is invite our legislators to visit us." Dr. McLoon added that she had just heard from the office of Sen. Norm Coleman (R-MN) about an August recess visit.



Dr. David Hunter with John Phillips in the office of Sen. John Kerry (D-MA)



Joe Carlisle from the office of Cong. Betty McCollum (D-MN) and Dr. McLoon

NAEVR Scorecard ISSUES

Future Uncertain for House and Senate FY2008 Appropriations Bills Which Include NIH/NEI Funding Increases

Before its recess on August 5, the House passed all twelve of its FY 2008 appropriations bills, including H.R. 3043, the LHHS funding bill passed on July 19 that includes a \$750 million and \$9.9 million increase, respectively, for the NIH and the NEI over FY2007 [see funding chart]. Although the Senate Appropriations Committee has reported out S. 1710, the Senate's FY2008 LHHS funding bill that increases NIH and NEI funding by \$1 billion and \$14.8 million, respectively, it has yet to be considered on the Senate floor. Both bills were developed with strong bipartisan support.

Although by the recess the Senate had only passed the Homeland Security appropriations bill, Senate Majority Leader Sen. Reid (D-NV) has vowed an ambitious schedule for early September devoted to passing remaining bills. Critics remain skeptical of this timing, however, especially since the Senate LHHS bill debate could focus on a potentially controversial provision that would

make embryonic stem cell lines that existed prior to June 15, 2007, eligible for federally funded research, updating it from the August 9, 2001, date of the President's initial policy. Earlier this year, the House and Senate passed versions of *The Stem Cell Research Enhancement Act*—which NAEVR supported—but did not have sufficient votes to override a Presidential veto.

Congress must pass a Continuing Resolution (CR) to fund the government with the start of FY2008 on October 1 as it deals with finalizing appropriations and the threat of Presidential vetoes of most major bills since they exceed his budget proposal. At this time, it is appearing more likely that non-defense/homeland security appropriations may be wrapped into an omnibus bill, or major programs may be funded through a series of CRs or by a year-long resolution, as was done in FY2007. In its advocacy, NAEVR continues to emphasize the need for both increased and timely FY2008 NIH/NEI

appropriations, such that researchers do not have to rely on bridge or philanthropic funding in advance of grant awards.

	FY 2007 Final	FY 2008 Budget	FY 2008 House	FY 2008 Senate
NIH*	\$28.9 B	\$28.6 B -1.7%	\$29.6 B +2.6%	\$29.9 B +3.5%
NEI+	\$667.1 M	\$667.8 M +0.1%	\$677 M +1.5%	\$681.9 M +2.2%

* Program level, inclusive of transfers/one time expenses.
+ FY07 NEI excludes \$8.5 M for NEI programs due to direct appropriation to NIH common fund and \$4.2 M in NIH Director Bridge Awards.



House Appropriations Committee Chair Cong. David Obey (D-WI), who also serves as LHHS Subcommittee Chair, joins Subcommittee Clerk Cheryl Smith and NAEVR's James Jorkasky. Said Cong. Obey, "The medical research community will need to fight to hold onto the increases in the House bill."

NEI Director Dr. Sieving Testifies Before the Senate

On June 22, Dr. Sieving testified before the Senate LHHS Subcommittee in a hearing appropriately entitled *A New Vision for Medical Research*. This was the last in a series of hearings with NIH Institute/Center Directors, which were reinstated after an absence of several years as part of the FY2008 appropriations process led by Chair Sen. Tom Harkin (D-IA), in conjunction with Ranking Member Sen. Arlen Specter (R-PA). NAEVR has commended them for their leadership in this regard.

"NEI-funded research has resulted in remarkable advances to save and restore sight," stated Dr. Sieving, who in written and verbal testimony focused

his comments on the vision public health challenge resulting from the aging of the baby boom generation. Citing age-related macular degeneration (AMD), the leading cause of vision loss, as an example of NEI research that meets NIH goals of research that is preemptive/preventive, predictive, personalized, and participatory, he described NEI's identification of genes associated with an increased risk of developing AMD, NEI's demonstration that antioxidant vitamins and minerals can reduce the progression of moderate to severe AMD by 25 percent, and new Food and Drug Administration (FDA)-approved ophthalmic drugs that are stabilizing and restoring vision loss.



NAEVR network members, including Cathy Cohen (American Academy of Ophthalmology), have amplified the vision research message with key leaders such as Sen. Harkin



NAEVR's James Jorkasky congratulates Dr. Sieving on his testimony

NAEVR and AEVR Cite NEI Study on Protective Effect of Omega-3 Fatty Acids in Hill Advocacy and Education

In late June, NAEVR hand-delivered letters to all House and Senate appropriators citing a just-released NEI-funded study, published in *Nature Medicine*, which demonstrates the protective effect of omega-3 polyunsaturated acids against retinopathy in mice as an example of the types of groundbreaking research that must be adequately funded in FY2008. NAEVR wrote: "NEI is investigating low-cost and widely available nutrient-based treatment approaches to retinal disease such as Retinopathy of Prematurity (ROP) in infants, diabetic retinopathy, and AMD. This emphasis on disease preemption/prevention is a hallmark of the 21st century paradigm for research within the NIH, as described by Director Dr. Elias Zerhouni. With research ranging

from ROP in premature infants to AMD in seniors, the NEI affects and benefits Americans at all stages in life, ensuring productivity, independence, and quality of life."

On June 28, AEVR sponsored a *Children's Vision Research* Congressional Briefing. James Jorkasky's introductory comments stressed that NEI's research exemplifies NIH's larger goals for research—that which is collaborative (engaging ophthalmic and optometric researchers, as well as various NIH Institutes), community-based, and enrolls multi-ethnic patients. These comments were subsequently developed as a one-page *Characteristics of NEI Research* that was distributed on Capitol Hill.

Researchers Awarded \$4.8 Million for Defense-related Vision Research

In early July, the Department of Defense's (DOD) Peer-Reviewed Medical Research Program (PRMRP) finalized its awards from the FY2006 appropriations process, and five researchers received a total of \$4.8 million. These researchers included Balamurali Ambati, M.D. (Medical College of Georgia), Michelle Callegan, Ph.D. (University of Oklahoma), Lu Chen, Ph.D. (Schepens Eye Research Institute), Shelley Fried, Ph.D. (Harvard Medical School), and Joseph Rizzo III, M.D. (Massachusetts Eye and Ear Infirmary), and their awards reflect 10 ten percent of the \$50 million pool of funds in this program. The PRMRP program was not funded in the FY2007 appropriations process.

In its advocacy, NAEVR is urging that FY2008 defense appropriations retain the eligibility of eye and vision research for PRMRP funding since 16 percent of

Iraq war injuries involve vision, usually traumatic eye injury. On July 10, NAEVR President Dr. Stephen Ryan delivered to defense-related vision research champions Sen. Kay Bailey Hutchison (R-TX) and Sen. Barbara Boxer (D-CA) letters from ophthalmology chairs and optometry deans in those states in support of vision research's continued eligibility.

"The responsiveness of the vision community to this new and additional source of funding was dramatic," said NAEVR's James Jorkasky, who added that 52 of all 651 grants submitted for PRMRP funding, or eight percent, came from this community. He noted that, if successful in retaining eligibility in FY2008, NAEVR will work in future years for a direct earmark that would obviate competition for funds with the 28 other areas of research within the PRMRP.



Lynn Cyert, Ph.D., O.D. (Northeastern University/Oklahoma College of Optometry) spoke about the NEI-funded *Vision in Preschoolers (VIP) Study*. She was joined by Cong. Gene Green (D-TX), co-chair of the Congressional Vision Caucus, who attended the event.



Michael Repka, M.D., (Wilmer Eye Institute/ Johns Hopkins University School of Medicine) spoke about the *Pediatric Eye Disease Investigator Group (PEDIG)*, which he co-chairs. Dr. Repka also discussed ROP and the recent NEI basic research on the protective effect of omega-3 fatty acids against retinal disease that will be translated into clinical practice in a follow-up study in premature infants, to be conducted at Children's Hospital Boston.



Dr. Stephen Ryan and James Jorkasky with Kevin Kane (center), an Iraq war veteran handling defense issues in the office of Sen. Kay Bailey Hutchison (R-TX)

AEVR Educates Capitol Hill on Visual Imaging Technologies Changing the Diagnosis and Treatment of Blinding Eye Disease

At an April 17 AEVR Congressional Briefing entitled *Vision for the Future: Eye Imaging to Save and Restore Sight*, Dr. Stephen Ryan described how optical coherence tomography (OCT) is changing the way vision disorders are diagnosed and treated. The latest OCT technology, which reveals the retina three-dimensionally and in color through sophisticated computer software, can be used to identify early changes in potentially blinding diseases and to subsequently monitor the effectiveness of treatments emerging from research.

“This new OCT technology will transform and improve the way we diagnose AMD, diabetic retinopathy, and glaucoma. The major asset is that it creates a quantitative measurement of retinal changes which, when coupled with a functional measurement of vision, can maximize the use of evidence-based medicine in eye care.”



Since retinal changes often precede improvements or losses in vision detected functionally by the eye chart, he emphasized that treatments for individual patients can begin earlier, before permanent retinal damage sets in. He added that

This new OCT technology will transform and improve the way we diagnose AMD, diabetic retinopathy, and glaucoma.

the quantitative basis of OCT will impact clinical trials of new treatments, since this research will require fewer patients, take less time, and be far less costly. “This OCT technology facilitates in eye care the goal described by NIH Director Dr. Elias Zerhouni for research and clinical practice in the 21st century—that which is predictive, preemptive/preventive, personalized, and participatory.”

Dr. Ryan stated that it is hard to overemphasize the value of this new technology.



“As of June 2006 and for the first time in history, we have an FDA-approved ophthalmic drug that improves vision in people with AMD. OCT can track changes that will help us make the best diagnoses for our patients and tell us when

to initiate or follow-up with injections of the drug,” said Dr. Ryan, who predicted that the same will apply to glaucoma and diabetic retinopathy within the next five years. “The level of federal investment in medical research to deal with the growing and costly public health problem of eye disease and vision impairment will play a large part in determining the progress in implementing treatments for blinding eye diseases.”

Dr. Ryan speaks, then meets with Cong. Darrell Issa (R-CA), who has supported NIH/NEI funding increases, and joins John Porter in meeting with Sean McCluskie in the office of Cong. Xavier Becerra (D-CA), who represents the USC campus and is on the House Democratic leadership team

Dr. Ryan Challenges Vision Community to Quantify the Value of Vision Research

In April 18 keynote comments at a symposium sponsored by Prevent Blindness America to release its study entitled *The Economic Impact of Vision Problems: The Toll of Major Adult Eye Disorders, Visual Impairment, and Blindness on the U.S. Economy*, Dr. Ryan challenged the vision community to build upon the study to develop cost-effectiveness data on the value of federally funded vision research conducted by the NEI, Centers for Disease Control and Prevention (CDC), and other government agencies. ARVO is taking the lead by sponsoring a mid-September initial meeting on the methodology involved in such a study, in which NAEVR will participate



Symposium speaker Paul Lee, M.D. (Duke University) is joined by ARVO Executive Director Joanne Angle and American Academy of Ophthalmology Executive Vice President H. Dunbar Hoskins, Jr., M.D.

FY2008 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:

AMD

"The Committee commends the NEI for its trans-Institute research into the cause, prevention, and treatment of AMD. The Committee also applauds NEI for initiating the second phase of its Age-related Eye Diseases Study (AREDS), in which additional dietary supplements are being studied to determine if they can demonstrate or enhance their protective effects against progression to the advanced form of AMD."

Diabetic Retinopathy

"The Committee applauds NEI for the collaborative efforts of the Diabetic Retinopathy Clinical Research Network to test innovative treatments for diabetic eye disease. The Institute is encouraged to consider expanding and extending the network by increasing the number of clinical trials with new drugs and therapeutics."

National Ophthalmic Disease Genotyping Network (eyeGene)

"The Committee congratulates NEI on its progress in identifying many of the genes involved in some of the most devastating eye diseases, including AMD, retinitis pigmentosa, and glaucoma, and the progress that has been made in understanding the underlying disease mechanisms and in developing appropriate treatments. The eyeGene Network will help accelerate application of these new approaches to medicine."

Vision Community Urges Further FDA Collaboration with the NEI

In a May 2 letter, NAEVR's Dr. Stephen Ryan thanked FDA Commissioner Andrew von Eschenbach, M.D., for his recent public mention at a National Health Council meeting about the collaborative research between the NEI and National Cancer Institute (NCI) that resulted in the first generation of FDA-approved ophthalmic drugs to treat the "wet" form of AMD. NAEVR used this letter to commend FDA's Janice Soreth, M.D., director of the Division of Anti-Infective and Ophthalmology Products within the FDA's Center for Drug Evaluation and Research (CDER), for working with NEI Director Dr. Paul Sieving on the

November 2006 NEI/FDA *Ophthalmic Clinical Trial Design and Endpoints* Meeting, which was managed by ARVO. That meeting addressed outcomes variables and clinical trial strategies for evaluating new treatments for AMD and diabetic retinopathy (DR).

"The vision research community looks forward to further collaborations between the NEI and FDA to consider how the latest research can be applied to ophthalmic product approvals, not only for retinal diseases such as AMD and DR, but also complex neurodegenerative diseases such as glaucoma," wrote Dr. Ryan.



Dr. von Eschenbach

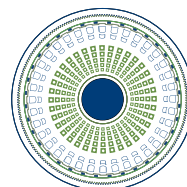


NAEVR Legislative Counsel John Porter with Cong. Pete Sessions (R-TX), who submitted language in support of eyeGene

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