



Spring 2008

President's Message

With this edition of the *Report*, we begin a celebration of the 15th anniversary of AEVR and NAEVR as the educational and advocacy voices for eye and vision research funding. In 1993, the American Academy of Ophthalmology (AAO), the Association for Research in Vision and Ophthalmology (ARVO), and the Association of University Professors of Ophthalmology (AUPO) founded AEVR, a 501c(3) foundation, to educate Congress about the value of federally funded vision research being conducted by the National Eye Institute (NEI) within the National Institutes of Health (NIH). Shortly thereafter, NAEVR was formed as a 501c(4) "social welfare" organization under which the vision research community could focus its advocacy efforts. AEVR/NAEVR now represents more than 50 contributing organizations reflecting the breadth of our community.

Although recognizing its rich history, AEVR/NAEVR plans to focus this year's anniversary celebration on the future, especially how past federal investment in the NEI is resulting in a continuous, dramatic stream of research findings changing the diagnosis and treatment of eye disease and saving and restoring vision.

NEI is accomplishing this, despite its funding challenges, due to its effective use of collaborations—within the NIH, with other Department of Health and Human Services (DHHS) agencies, and with private funding organizations. We commend NEI Director Dr. Paul Sieving for his leadership in that regard—in concert with NIH Director Dr. Elias Zerhouni—and the stories in this edition exemplify those efforts, including that

on the March 13-14 *Glaucoma Endpoints Symposium* in which the NEI collaborated with the Food and Drug Administration (FDA) to consider alternative endpoints for glaucoma clinical trials. This could have a major impact on new products for patients.

This meeting also reflects NAEVR's leadership, as it ultimately emerged from a NAEVR/AAO-initiated meeting with FDA in July 2005 to address ophthalmic drug approval issues, reflecting an expertise in regulatory issues brought to NAEVR by Executive Director James Jorkasky. Under Jim's leadership this past five years, NAEVR's scope has grown to include advocacy for defense-related vision research funding (see story on back page), fostering collaborations in which NEI study results may facilitate patient access to new treatments and therapies, and extensive collaborations with coalition partners.

NAEVR's focus will remain on NEI funding, as it serves primarily as the "Friends of the NEI." Medical research faces an enormous challenge with the President's Fiscal Year (FY) 2009 budget request that flat funds the NIH/NEI. Fortunately, medical research's champions Senator Tom Harkin (D-IA) and Senator Arlen Specter (R-PA), the respective Chair and Ranking Member of the Senate Labor, Health and Human Services, and Education (LHHS) Appropriations Subcommittee, have once again led a strong bipartisan effort to increase FY2009 funding. House champions, led by Cong. Ed Markey (D-MA), also coordinated a bipartisan letter signed by 179 Members to House appropriations leaders urging an increase.

Contributor Report



Photo courtesy of FFB

Dr. Ryan maintains ongoing communications with Senator Tom Harkin (D-IA), including congratulating him, on behalf of the eye and vision community, for receiving the *Visionary Award* from the Foundation Fighting Blindness at its February 13 gala

The vision community strongly supported these activities through email letters and direct visits, including more than 100 Capitol Hill visits by the American Glaucoma Society, coordinated with NAEVR on the first-ever World Glaucoma Day, as detailed herein.

As always, I thank you for your commitment and support. AEVR/NAEVR will announce a number of events reflecting this anniversary year!

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National Alliance For
 Eye And Vision Research

Alliance For Eye
 And Vision Research

Legislative Scorecard ISSUES

Advocacy Community Urges NIH Increase as House and Senate Pass FY2009 Budget Resolutions and Begin Appropriations Hearings

Budget Resolution

On March 13, the House passed its version of the \$3 trillion Budget Resolution, as did the Senate after rejecting an attempt to impose a year-long moratorium on earmarks. Earlier the Senate approved by a vote of 95-4 Amendment 4203, sponsored by Sen. Arlen Specter (R-PA) and Sen. Tom Harkin (D-IA) and co-sponsored by 29 bipartisan Members, which would add \$2.1 billion for NIH funding in FY2009 for a total increase of \$3 billion or 10.3 percent over the FY2008 appropriation. The overwhelming level of support for this non-binding amendment—which serves as a guideline for spending bills developed later—represented the advocacy by NAEVR and its coalition partners.

House Appropriations Hearings

On March 5, NIH Director Elias Zerhouni was among four Department of Health and Human Services (DHHS) agency heads who testified in a hearing entitled *Health Issues and Opportunities*. Dr. Zerhouni highlighted several NEI initiatives, including the *Comparison of AMD Treatments Trial (CATT)*, a comparative effectiveness study of the two drugs used to block growth of abnormal blood vessel growth in patients with

the “wet” form of age-related macular degeneration (AMD) that could guide treatment patterns and reduce costs to the Medicare program.

The Subcommittee held a Citizen Witness hearing, and although the vision community was not selected to testify as in 2007, NEI’s AMD research was lauded in testimony by Robert Palazzo, Ph.D., President of the Federation of American Societies for Experimental Biology (FASEB). NAEVR submitted written testimony that highlighted NEI’s recently released research results and its extensive collaborations within NIH, with other DHHS agencies, and with private funding organizations.

Senate Actions

On March 12, the Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing on the recently released report *A Broken Pipeline? Flat Funding of the NIH Puts a Generation of Science at Risk*, which was sponsored by seven academic research institutions.

On April 23, the Senate LHHS Appropriations Subcommittee plans a hearing with Dr. Zerhouni and several Institute Directors.

Research!America Forum On Future of Healthcare

On March 18, Research!America held a national forum entitled *Valuing Evidence and Enhancing Impact* which challenged speakers to identify fundamental changes that must be made now to impact healthcare 30-years out.



Left to right: Andrew von Eschenbach, M.D. (Commissioner, Food and Drug Administration), Elias Zerhouni, M.D. (Director, NIH), Garry Neil, M.D. (Corporate Vice President, Johnson & Johnson), Susan Dentzer (“The News Hour with Jim Lehrer”), Joel Kupersmith, M.D. (Chief R&D Officer, Department of Veterans Affairs), Carolyn Clancy (Director, Agency for Healthcare Quality and Research), William Novelli (CEO, AARP), and Julie Gerberding, M.D. (Director, Centers for Disease Control and Prevention)

Full details about these events appear in the NAEVR Web site Advocacy Center’s section on NIH/NEI Appropriations

	FY 2007 Final	FY 2008 Final	FY 2009 Budget	NAEVR Request
NIH*	\$28.9 B	\$28.9 B +.46%	\$28.9 B 0%	\$31.2 B +6.6%
	\$667.1 M	\$667.1 M 0%	\$677.8 M +0.1%	\$711 M +6.6%

* For FY 2009 NIH budget, equates to \$29.2 billion program levels with HIV/Global AIDS



In his supporting statement for Senate Amendment 4203, Sen. Specter (R-PA) detailed lost opportunities at NIH due to flat funding, including NEI’s ability to fund epidemiological studies in minority populations



In addition to lauding NEI research in his March 13 testimony, FASEB President Robert Palazzo, Ph.D., emphasized that flat NIH funding threatens an entire generation of young researchers, as well as new therapies



On March 31, NIH held the first official meeting of its Council of Councils, which was mandated by the *NIH Reform Act of 2006* to advise NIH on its common fund for trans-Institute research. National Advisory Eye Council representative to the Council, Lenworth Johnson, M.D. (University of Missouri-Columbia), joins Dr. Zerhouni, who has described the common fund as a primary route through which basic and applied science can converge to meet research goals.

NEI and FDA Collaborate on Clinical Trial Issues for Glaucoma Drug and Device Diagnostics and Therapies

On March 13-14, NEI and FDA held a *Glaucoma Clinical Drug Trial Design and Endpoints Symposium* with FDA's Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH), engaging investigators and clinicians to discuss how research studies can apply to clinical trials used to support new product approvals.

"This was a landmark meeting, and the glaucoma community made considerable progress. We learned from NEI how to improve clinical trial design, and heard a great deal of flexibility from the FDA regarding new outcomes endpoints used to support approvals of products," said Robert N. Weinreb, M.D. (Hamilton Glaucoma Center/University of California-San Diego), who served as Program Co-Chair with Paul Kaufman,

"This was a landmark meeting, and the glaucoma community made considerable progress." Robert N. Weinreb, M.D.

M.D. (University of Wisconsin-Madison). Dr. Kaufman added, "This was an excellent opportunity for investigators to understand from FDA what is involved in the testing of new drugs on new sites in ways we have never treated before. The approval process can be faster due to FDA's receptivity to new endpoints for clinical trials. This will enable researchers to "telescope" clinical trials and potentially reduce the cost and time of getting new therapies to patients."

As researchers noted, glaucoma is a complex disease in which detectable structural and functional changes may not progress linearly or in concert, that is, early disease may be detected and characterized primarily by observable structural change, middle-stage by both, and end-stage primarily by measurable functional change. As a result, the regulatory process should be flexible to reflect this disparity between detectable structural and functional changes,

especially when considering, for example, a new class of neuro-protective drugs that could mitigate damage to the optic nerve before it is manifested in visual function change. Much of the meeting's discussion focused on how these new structural endpoints—which would be a direct endpoint, rather than a surrogate endpoint such as intraocular pressure—are incorporated into clinical trials and, as appropriate, correlated to visual function and concomitant quality of life indicators to ensure clinical significance and ultimate benefit to patients.

"The development of an exciting new generation of treatments for glaucoma will require close collaboration between researchers and the FDA if we are to be able to demonstrate that the treatments are safe and effective in

the shortest time possible," said NEI Clinical Director Rick Ferris, M.D. He was joined by symposium co-sponsors Wiley Chambers, M.D. (CDER/Acting Director, Division of Anti-Infective and Ophthalmic Products) and Malvina Eydelman, M.D. (CDRH/Director, Division of Ophthalmic and ENT Devices) in predicting a new generation of glaucoma drugs and devices, including combinations of products that deliver drug therapies directly into the eye.

The *Glaucoma Endpoints* meeting, developed by NAEVR and ARVO, is the second collaborative meeting between the NEI and FDA, following up on the November 2006 *Ophthalmic Clinical Trial Design and Endpoints Symposium*, which focused on new treatments for AMD and diabetic retinopathy.



Program Co-Chairs Robert N. Weinreb, M.D. (left) and Paul Kaufman, M.D. (right) with NEI Director Paul Sieving, M.D., Ph.D.



FDA co-sponsors Malvina Eydelman, M.D. (CDRH) and Wiley Chambers, M.D. (CDER)



Anne Coleman, M.D. (Jules Stein Eye Institute/University of California-Los Angeles), with NEI co-sponsor Rick Ferris, M.D.



Murray Fingeret, O.D. (VA NY Health System), Scott Christensen (The Glaucoma Foundation), and speaker Christopher Girkin, M.D. (University of Alabama at Birmingham)



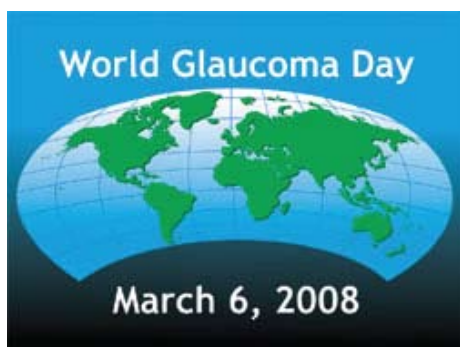
Rohit Varma, M.D. (Doheny Eye Institute/University of Southern California) presented findings from the NEI-funded Los Angeles Latino Eye Study (LALLES)

AGS Advocates for Glaucoma Awareness/Research in Capitol Hill Visits/Screening Event on the First-ever World Glaucoma Day

On March 6, members of the American Glaucoma Society (AGS) visited nearly 100 Capitol Hill offices to educate Congress about the incidence of glaucoma and the need for increased vision research funding. This first-ever AGS Advocacy Day—held on the first-ever World Glaucoma Day and in conjunction with NAEVR—was accompanied by a luncheon screening that included real-time optic nerve and pressure evaluation of the eye. These events represented two of the more than 300 events being held globally to expand awareness of the disease, which can damage the optic nerve and lead to vision loss. The glaucoma specialists and researchers focused on three important messages:

- **Increasing glaucoma awareness**
- **Urging support for House Resolution 981, sponsored by Cong. Tammy Baldwin (D-WI) and Cong. Pete Sessions (R-TX), which recognized March 6 as the first-ever World Glaucoma Day**
- **Urging FY2009 funding for the NIH and NEI of \$31 billion and \$711 million, respectively, a 6.6 percent increase over FY2008 to match inflation and to begin to restore purchasing power lost over the past five funding cycles**

“The AGS members were articulate and effective advocates with a powerful message.” NAEVR’s James Jorkasky



“Although many of the AGS members had not previously visited Capitol Hill, they were articulate and effective advocates with a powerful message,” said NAEVR’s James Jorkasky who, with NAEVR Advocacy Manager David Epstein, accompanied the participants in meetings the entire day. “Members and their staffs were especially interested in how glaucoma is a ‘sneak thief’ of vision loss, often undetected until there is significant vision loss. That is why the accompanying screening event was so important in emphasizing the message about early diagnosis and treatment.”

Cong. Pete Sessions, a sponsor of HR 981, provided a welcome. “We need to be concerned about vision loss around the world. Even though the United States is a leader in eye and vision research, we still have many challenges in getting individuals diagnosed and treated for blinding eye diseases.” Cong. Gene Green (D-TX), a co-chair of the Congressional Vision Caucus, also attended the two-hour event, which drew a steady stream of staff.

NAEVR has posted events related to World Glaucoma Day in a dedicated section of its Web site at eyersearch.org



AGS President Robert N. Weinreb, M.D., Cong. Pete Sessions (R-TX), and Program Co-Chair Anne Coleman, M.D.



Foreground: Cong. Sessions participates in the screening



Dr. Weinreb and Dr. Coleman with Cong. Gene Green (D-TX), Co-Chair of the Congressional Vision Caucus



Arthur Sit, M.D. (Mayo Clinic College of Medicine), Sen. Amy Klobuchar (D-MN), and Thomas Samuelson M.D. (University of Minnesota)



Advocacy Day Program Co-Chair Ted Krupin, M.D. (Northwestern University)



NAEVR Executive Director James Jorkasky and Scott Christensen, President of the World Glaucoma Patient Association, which initiated World Glaucoma Day

Using Real-time OCT, AEVR Educates Capitol Hill on Visual Imaging Technologies Revolutionizing the Diagnosis and Treatment of Eye Disease

The next generation of Optical Coherence Tomography (OCT), a powerful diagnostic imaging technology that has emerged from collaborative research between the NEI and the National Institute of Biomedical Imaging and Bioengineering (NIBIB) within NIH is already revolutionizing an eye care practitioner's ability to diagnose and monitor treatment of major eye diseases faster, more accurately, at lower cost, and with less discomfort for the patient than ever before, Alexander Walsh, M.D., told members of Congress and staffers in a February 26 Capitol Hill briefing.

"OCT has changed everything we do in ophthalmology," said Walsh, an assistant professor of ophthalmology at the University of Southern California and director of the Doheny Eye Institute's Imaging Exploration and Software Engineering Laboratory. "It represents an objective, standardized method for making a diagnosis and a quantitative way to monitor treatment progress and outcomes." Walsh spoke at this briefing sponsored by AEVR and held in conjunction with the Coalition for Imaging and Bioengineering Research (CIBR), the American Institute for Medical and Biological Engineering (AIMBE), ARVO, and the Ad Hoc Group for Medical Research.

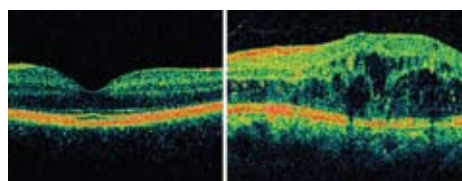
OCT is a non-invasive, high-speed, high-resolution imaging technology that can



Normal vs. Diabetic Retinopathy (traditional fundus photography images) Early diagnosis is critical in patients with diabetic retinopathy since those with healthy retinas (left) who receive timely laser treatments have a better chance of visual preservation than patients with diagnoses that are missed (right) and who often become legally blind.

now display a three-dimensional, cross-sectional view of the retina, not just the superficial view of its surface provided by conventional imaging technologies. Layers of the retina can then be separated on the computer screen to visualize and diagnose eye diseases, such as AMD, diabetic retinopathy, and glaucoma. "With OCT, we can now see minute tissue layers deep inside the eye to determine what might well have been missed before. Quantifying the state of the eye's interior leaves less to subjective judgment and helps both practitioners and patients understand the disease and measure treatment progress," said Walsh, who demonstrated the speed and simplicity of an OCT scan with a live demonstration using a next-generation system provided by Topcon Medical Systems.

"The need for OCT grows all the time," said Walsh, who added that ongoing collaborations among the NEI, NIBIB, academic researchers, and industry are leading to further refinements in the technology. "Although currently used primarily in a retinal specialist's office, OCT has widespread potential as a cost-effective tool to screen for AMD, diabetic retinopathy, and glaucoma," he said, while also acknowledging that the technology is just beginning to expand into other medical fields, such as cardiology, dermatology, and gastroenterology.



Normal vs. Diabetic Retinopathy (OCT images) Retinal swelling (right) is a common cause of visual blurring in patients with diabetic retinopathy. The quantitative measurement of retinal thickness by OCT can improve management of therapies and decrease unnecessary or costly treatments.



Attendees view real-time OCT images



Topcon Medical Systems' Aaron Graham performs a retinal scan



CIBR President Renee Cruea offered a welcome and commented that, with respect to medical imaging, "We can be proud of the state of the science now, but we also have to be aware of how much further we have to go."



Prior to the briefing, Dr. Walsh met with Melissa Bez in the office of Cong. Henry Waxman (D-CA) of the House Energy and Commerce Committee, with authorization jurisdiction over the NIH



NAEVR's James Jorkasky and Dr. Walsh also met with Sean McCluskie (right) in the office of Cong. Xavier Becerra (D-CA), whose district includes the USC campus

Legislative Scorecard ISSUES

House Investigates Incidence and Care for TBI-Related Vision Disorders

On April 2, the Subcommittee on Oversight and Investigations of the House Committee on Veterans' Affairs held a hearing to investigate the incidence of combat-related eye injuries, particularly those associated with Traumatic Brain Injury (TBI). Testimony was provided by two veterans—Bryan Pearce (U.S. Army Staff Sergeant, retired), accompanied by his wife Angela, and Glen Minney (U.S. Navy Petty Officer, retired)—coordinated by NAEVR contributor Blinded Veterans Association (BVA, which also testified), as well as by representatives of the Department of Defense (DOD) and Department of Veterans Affairs (VA).

After dramatic testimony by the veterans, who detailed their injuries, the aftermath of DOD and VA care, and the ongoing impact on their families, BVA's Tom Zampieri summarized concerns that include:

- Seamless transition from DOD to VA care, especially the current lack of portability of medical records

- Lack of accurate numbers on combat-related eye injuries, especially visual disorders associated with TBI that can be short- and long-term

- The need for Congress to fund the Military Eye Trauma Center of Excellence and Eye Trauma Registry, which were provisions of the *Military Eye Trauma Treatment Act* authorized in the FY2008 Defense Authorization Act but not funded

The VA representatives described the creation of four national Polytrauma Treatment Centers, in which research is being conducted to improve the diagnosis and treatment of TBI-related visual disorders. DOD representatives stated that work had begun on the Eye Trauma Registry, and that future DOD research would focus increasingly on TBI-related visual disorders and not just on eye disease.



Left to right: Cong. Eric Cantor (R-VA), who introduced constituent witnesses Angela and Bryan Pearce, Tom Zampieri (Blinded Veterans Association), and Glen Minney. In addition to significant visual impairment from TBI, both Mr. Pearce and Mr. Minney experience cognitive disorders



NAEVR's James Jorkasky and Cong. David Hobson (R-OH), who introduced constituent Mr. Minney, who now serves as an advocate for veterans issues

NAEVR at ARVO Annual Meeting 2008:

NAEVR Advocacy Breakfast, Monday, April 28, in Room 301-302 of the Ft. Lauderdale Convention Center, 7:30-8:30 am

**Contact Congress Booth in Hall B/C (next to ARVO Booth)
Sunday-Wednesday**

DOD Issues PRMRP Funding Opportunities Notice and Deadlines

On March 28, the DOD released a notice on its Web site for FY2008 Peer Reviewed Medical Research Program (PRMRP) funding opportunities in the 21 areas of eligible research, which includes eye and vision research, for

a funding total of \$50 million in the program. The pre-application submission deadline is June 4, 2008, and the proposal deadline is July 2, 2008. The award mechanisms include a combination of basic and translational research.

Details appear in the NAEVR Web site section on Defense-related Vision Research

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