

President's Message

NAEVR Seeks Every Possible Federal Dollar for Vision Research, Facilitates NEI/FDA Discussions about Product Approval

As the first story inside this edition summarizes, the National Eye Institute (NEI) and most National Institutes of Health (NIH) Institutes/Centers (I/Cs) were flat funded in the Fiscal Year (FY) 2008 appropriations process despite efforts by NAEVR and its networks, coalition partners, and Congressional supporters to increase funding.

I had the opportunity to join NAEVR Executive Director Jim Jorkasky and Legislative Counsel John Porter (Hogan & Hartson) in a January 9 meeting with NEI Director Dr. Paul Sieving. Despite NEI's funding limitations, Dr. Sieving remains committed to pursuing promising vision research through all appropriate funding mechanisms, including trans-Institute research and public-private partnerships. Regarding the former, NEI has a sterling reputation among the I/Cs for its level of collaboration, as documented in meetings that Jim has held with numerous I/C Directors as he works closely with coalition partners. Regarding the latter, we all anxiously await the results of the human gene therapy trials for Leber's congenital amaurosis (LCA), emerging from past joint funding by the Foundation Fighting Blindness (FFB) and NEI.

Having been briefed by Jim and John on NAEVR's FY2009 strategy, I can assure you that no other advocacy group has already worked as hard this year to seek FY2009 federal funding for vision research, whether at the NIH/NEI, the Department of Defense (DOD), or the Department of Veterans Affairs (VA).

Through ARVO's January 25 Advocacy Day, NAEVR's FY2009 NIH/NEI and DOD funding requests were made in 50 offices, with additional requests being made to more than 100 offices through the March 6 American Glaucoma Society Advocacy Day, being held on the first-ever World Glaucoma Day. NAEVR has not only already secured key bipartisan champions from the House and Senate Defense Appropriations Subcommittees for the FY2009 DOD vision research eligibility listing, the Alliance has also worked with the key Veterans' Service Organizations (VSOs) to recommend this listing in *The Independent Budget* that they develop and submit to Congress—which also urges Congress to authorize more VA-DOD research funding on eye trauma.

Unfortunately, we are never assured of any legislative victory, especially with respect to the budget and appropriations process, especially in this uncertain election year. That is why NAEVR has been working since 2005 to ensure that NEI's research findings are appropriately considered within the context of the Food and Drug Administration's (FDA) product approval process. With the November 2006 *Ophthalmic Clinical Trial Design and Endpoints* meeting, organized by NEI/FDA in conjunction with NAEVR and managed by ARVO, participants addressed the increased acceptance of Optical Coherence Tomography (OCT), for example, as an outcomes measure in clinical trials for age-related macular degeneration (AMD) and diabetic retinopathy.

Contributor Report



Left to right: Dr. Stephen Ryan, NEI Director Paul Sieving, M.D., Ph.D., and NAEVR Legislative Counsel John Porter

With the upcoming March 13-14 *Glaucoma Endpoints* meeting, glaucoma researchers will be able to consider new outcomes measures for glaucoma therapy clinical trials. NAEVR's leadership in facilitating these discussions have very real deliverables for all network members—whether researchers, practitioners, or patients—including reduced costs of clinical trials and the expeditious approval of new products. This also provides an opportunity for NIH Director Dr. Elias Zerhouni to highlight cost savings and benefits to vision patients through this NEI/FDA collaboration. We understand that the March 5 House Labor, Health and Human Services, and Education (LHHS) Appropriations Subcommittee hearing will focus on just that—how Department of Health and Human Services (DHHS) agencies are working together to save and improve lives reducing costs while in the healthcare system.

As always, thank you for your support.

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National Alliance For
Eye And Vision Research

Alliance For Eye
And Vision Research

In March, Glaucoma Awareness and Research Take Center Stage on Capitol Hill, the NIH Campus, and Throughout the World

World Glaucoma Day

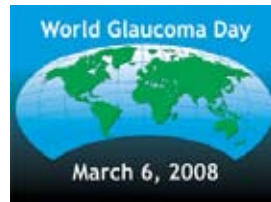
March 6 marks the first-ever World Glaucoma Day, and NAEVR is working with the World Glaucoma Patients Association and the American Glaucoma Society (AGS) to foster awareness of the incidence and economic burden of the disease, as well as to highlight breakthrough research being conducted by the NEI. In conjunction with the AGS, NAEVR has worked with the offices of Cong. Tammy Baldwin (D-WI) and Cong. Pete Sessions (R-TX) on a bipartisan House resolution recognizing this important day.



Left to right: On November 1, 2007, ARVO and NAEVR organized a planning session for the *Glaucoma Endpoints* meeting that involved Wiley Chambers, M.D. (FDA Center for Drug Evaluation and Research, CDER), Robert Weinreb, M.D. (Hamilton Glaucoma Center/University of California at San Diego) and Paul Kaufman, M.D. (University of Wisconsin at Madison)

AGS Advocacy Day and Congressional Briefing/Screening

Two of the more than 300 events being planned worldwide at 52 sites on March 6 include an Advocacy Day and a Congressional Briefing/Screening, both hosted by the AGS on Capitol Hill. At this time, the AGS has requested more than 100 appointments with Congressional offices to educate about glaucoma and to request increased FY2009 NIH/NEI funding, using NAEVR's position paper and fact sheets. The Congressional Briefing entitled *Glaucoma: Awareness and Early Detection Can Prevent Blindness* will feature real-time optic nerve and pressure evaluation of the eye.



NEI/FDA CDER Glaucoma Clinical Drug Trial Design and Endpoints Symposium

Both NAEVR and ARVO have worked with the NEI and the FDA to develop this meeting, to be held March 13-14 on the NIH campus, to explore how new outcomes measures may facilitate glaucoma therapy clinical trials. The meeting, which grew out of the successful November 2006 *Ophthalmic Clinical Trial Design and Endpoints* meeting that focused on AMD and diabetic retinopathy, had the participation of both drug and device approval staff within the FDA in initial planning sessions. For meeting details, visit www.arvo.org/endpoints



Left to right: On November 1, 2007, Pam Sample, Ph.D. (Hamilton Glaucoma Center/University of California at San Diego) joined Dr. Weinreb and Dr. Kaufman, along with Kesia Alexander, Ph.D. (FDA's Center for Devices and Radiological Health, CDRH) and NEI's Rick Ferris, M.D., in meeting planning

OCT Focus Highlights NEI and NIBIB Collaboration

The use of Optical Coherence Tomography (OCT) to evaluate physiological changes in the optic nerve head will be the focus of two upcoming events—a February 26 AEVER Congressional Briefing entitled *Visual Imaging: Revolutionizing the Diagnosis and Treatment of Eye Disease* featuring Alex Walsh, M.D. (Doheny Eye Institute/University of Southern California) and the March 13-14 *NEI/*

FDA CDER Glaucoma Clinical Drug Trial Design and Endpoints Symposium. The development of OCT can be traced to the collaborative efforts of two NIH Institutes—the NEI and the National Institute of Biomedical Imaging and Bioengineering (NIBIB). On January 7, NAEVR worked with the Coalition for Imaging and Bioengineering Research (CBIR, which serves as “Friends of NIBIB”), to engage NEI and NIBIB in discussions about these upcoming events.



Left to right: Renee Cruea (CIBR President), Belinda Seto, Ph.D. (NIBIB Deputy Director), Jack McLaughlin, Ph.D. (NEI Deputy Director) and NAEVR's James Jorkasky

NAEVR Scorecard ISSUES

Flat FY2008 NEI Funding Threatens Vision Research, Nation's Vision Health

On December 20, 2007, after Congressional passage of the FY2008 Consolidated Appropriations Act (HR 2764), NAEVR issued a statement expressing disappointment in the omnibus bill's flat funding for the NEI and most other Institutes/ Centers within NIH. NAEVR emphasized that this is actually a net 3.6 percent decrease in the NEI's purchasing power when biomedical inflation is factored in, and with the 14 percent loss in purchasing power experienced over the past four funding cycles, represents an almost 18 percent loss in purchasing power since the NIH budget doubling ended in FY2003.

Although the bill did provide a minimal increase for NIH—less than one percent—it fell far short of matching inflation. Congress had passed a bipartisan-

supported LHHS Conference Agreement (HR 3043) in early November that provided a \$900 million or 3.1 percent net increase for NIH and a \$17 million or 2.5 percent increase for the NEI. Unfortunately, Congress could not sustain this funding level as it was unable to override the President's veto of the bill, which exceeded the proposed FY2008 budget that essentially froze domestic spending.

Despite the outcome, NAEVR expressed its appreciation to the LHHS Appropriations Subcommittee Chairs—Cong. David Obey (D-WI) in the House and Sen. Tom Harkin (D-IA) in the Senate—for their leadership in championing increases for medical research in the face of competing priorities

Proposed FY2009 Budget to Flat Fund NIH, Provide Minimal Increase for NEI

On February 4, President Bush released the FY2009 budget proposal, which would flat fund the NIH at the FY2008 programmatic level of \$29.2 billion. The proposed number of competing research project grants (RPGs) in FY2009 will decrease by 14 to 9,757, but the total number of RPGs will increase by 18 to 38,257. The success rate is estimated to decrease by one percent to 18 percent, the lowest point in almost thirty years. The budget would continue to have a separate line item for the NIH "common fund" for trans-Institute research, funding it at \$534 million, an increase of \$34 million over FY2008 and representing 1.8 percent of the NIH budget.

The FY2009 budget would fund NEI at \$667.8 million, an approximate \$650,000 over the FY2008 level. In its Congressional Justification (CJ), the

NEI stated that it will fund RPGs at a total of \$417.7 million, providing no inflationary increases in noncompeting awards and no increase in average cost for competing RPGs. This reflects 1,039 RPGs in FY2009, with noncompeting RPGs increasing by 29 awards or \$15.3 million and competing RPGs decreasing by 44 awards or \$16 million. In the CJ, NEI cites key research in ocular genetics (including gene variants associated with AMD), the mechanism of lens transparency, and factors that prevent damage to the optic nerve.

On March 5, NIH Director Dr. Elias Zerhouni is scheduled to testify before the House LHHS Appropriations Subcommittee on the FY2009 NIH budget.

	FY 2007 Final	FY 2008 Final	FY 2009 Budget
NIH*	\$28.9 B	\$28.9 B +.46%	\$28.9 B 0%
NEI	\$667.1 M	\$667.1 M 0%	\$667.8 M +0.1%

* For FY2009 NIH, equates to \$29.2 billion program level with HIV/Global AIDS funding included.



At a February 4 briefing on the FY2009 budget, NIH Communications Director John Burklow released an updated compilation of all NIH fact sheets on the value of research, including those from NEI on Macular Degeneration, Glaucoma, Diabetic Retinopathy, and Amblyopia. These are posted on the NIH Web site's *Research Results for the Public* section.



NAEVR's James Jorkasky, who serves on the Steering Committee of the Ad Hoc Group for Medical Research (a special program of the American Association of Medical Colleges) joined colleagues in meetings with several Institute Directors—including NEI Director Dr. Sieving—to better understand research challenges. Left to right: Karen Hendricks (American Academy of Pediatrics), David Moore (Ad Hoc Group for Medical Research), Dr. Sieving, James Jorkasky, and Jon Retzlaff (Lewis-Burke Associates).

In a January 25 Advocacy Day, ARVO Researchers Make FY2009 NIH/NEI and Defense-related Vision Research Funding Requests to Congress

NAEVR hosted a January 25 Advocacy Day of the Association for Research in Vision and Ophthalmology's (ARVO) Program Committee, which engaged 20 participants in 50 Congressional visits in one of the earliest events in the second session of the 110th Congress. Using just-released NAEVR position papers and talking points, participants requested FY 2009 NIH and NEI funding at \$31 billion and \$711 million, respectively, an increase of 6.6 percent over FY2008—reflecting the

biomedical inflation rate of 3.6 percent plus 3 percent to begin restoring purchasing power. Participants emphasized the importance of timely appropriations, such that the continuity of research is not jeopardized by lay-offs of trained staff or lack of supplies for experimentation. The ARVO researchers also educated each office about the importance of defense-related vision research (see next page).



ARVO Advocacy Participants included (from left to right): Front Row: Carol Toris, Ph.D. (University of Nebraska Medical Center); Muna Naash, Ph.D. (University of Oklahoma Health Science Center); Janey Wiggs, M.D., Ph.D. (Harvard Medical School); Thomas Millar, Ph.D. (University of Western Sydney/Australia); Filippo Drago, M.D., Ph.D. (University of Catania/Italy); Second Row: Rajiv Mohan, Ph.D. (University of Missouri-Columbia); ARVO Executive Director Joanne Angle; Neeru Gupta, M.D., Ph.D. (University of Toronto/St. Michael's Hospital/Canada); Claude Burgoyne, M.D. (Devers Eye Institute); Third Row: Lenworth Johnson, M.D. (University of Missouri-Columbia); Erik van Kuijk, M.D., Ph.D. (University of Texas Medical Branch /Galveston); Ron Adelman, M.D., Ph.D. (Yale University School of Medicine); Debra Nickla, Ph.D. (New England College of Optometry); Fourth Row: Michael Kirby, Ph.D. (Loma Linda University); Michael Robinson, Ph.D. (Miami University); Not Pictured: Linda McLoon, Ph.D. (University of Minnesota); Todd Margolis, M.D., Ph.D. (University of California at San Francisco); and Dong Chen, M.D., Ph.D. (Schepens Eye Research Institute).



Dr. McLoon with Ryan Crowley in the office of Sen. Amy Klobuchar (D-MN). Recently, Dr. McLoon hosted in her laboratory staff from the offices of Sen. Norm Coleman (R-MN), a member of the Special Aging Committee, and Cong. Betty McCollum (D-MN), an LHHS appropriator.



Dr. Steinemann, Dr. Adelman, and Dr. Johnson met with Elizabeth Lee in the office of Sen. Hillary Clinton (D-NY)



Maryam Khan from the office of Sen. Kay Bailey Hutchison (R-TX), an LHHS and Defense appropriator, met with Dr. van Kuijk. Ms. Khan had previously conducted vision research at Northwestern University.



Dr. Kirby, Dr. Margolis, and Dr. Millar (far right, one of three ARVO international members participating) met with Kristin Wikelius from the office of Sen. Dianne Feinstein (D-CA). The group also met with House Speaker Nancy Pelosi's (D-CA) staff in the U.S. Capitol.



Tim Steinemann, M.D., and Dr. Johnson (far right) met with Philip Young, a DOD Fellow in the office of Sen. Kit Bond (R-MO) and a former Special Operations soldier in Iraq. Dr. Johnson, a constituent and member of the National Advisory Eye Council (NAEC) and the NIH Council of Councils that manages the NIH common fund, requested that Defense appropriator Sen. Bond champion the continued listing of eye and vision research in DOD peer reviewed funding. Dr. Steinemann (Case Western Reserve University), who chairs the American Academy of Ophthalmology's (AAO) Research, Regulatory, and External Affairs Committee, joined in visits prior to the next day's AAO Federal Secretariat meeting.

FY2008 Defense Appropriations and Authorization Bills Address Combat-related Eye Injuries, Include Vision Research Funding Opportunities

DOD/PRMRP:

The FY2008 Defense Appropriations bill (HR 3222) listed “eye and vision research” as eligible for the pool of \$50 million of peer-reviewed funding available under the DOD’s Peer Reviewed Medical Research Program (PRMRP) within the more-expansive Congressionally Directed Medical Research Program (CDMRP). On February 13, DOD released a preliminary notice on its Web site stating that, by April 2008, it would issue an announcement of the award mechanisms available to the 21 areas of eligible research, including eye and vision research. The award mechanisms include a combination of basic research, through Investigator-initiated Research Awards, and translational research, through Translational Research Awards, Advanced Technology/Therapeutic Development Awards, and Clinical Trial Awards. NAEVR will monitor the Web site and report to its networks on the release of the final announcement and all applicable deadlines. Contact NAEVR’s David Epstein at depstein@eyersearch.org to be added to NAEVR’s update list.

Traumatic Brain Injury (TBI):

HR 3222 also funded provisions of the *Wounded Warriors Act*, including several that relate to TBI, which require the DOD and VA to conduct TBI research and establish a Traumatic Brain Injury Veterans Health Registry. One area of research is that of visually-related neurological conditions associated with TBI. The DOD may post TBI-related grant requests on its CDMRP Web site in early 2008, and NAEVR will inform all networks of that notice.

Full details about the stories on these pages appear in the NAEVR Web site Advocacy Center’s sections on NIH/NEI Appropriations and Defense-related Vision Research

Military Eye Trauma:

The FY2008 Defense Authorization bill (HR 4986) included provisions of the *Military Eye Trauma Treatment Act* (HR 3558), which create a Center of Excellence within the DOD that would collaborate with the VA on a comprehensive approach to the prevention, diagnosis, mitigation, treatment, and rehabilitation of eye injuries and trauma, including a Military Eye Injury Registry to track the diagnosis and treatment of each significant eye injury incurred by a member of the armed forces while on active duty.

Armed Forces Institute of Pathology:

HR 4986 retained key functions of the Armed Forces Institute of Pathology (AFIP), including its education, consultation, and research services, as part of a newly created Joint Pathology Center located at the National Naval Medical Center in Bethesda, Maryland. The AFIP, which was set to be abolished by the Defense Base Realignment and Closure Commission, houses a world-renowned Tissue Repository and provides educational training programs in ophthalmic pathology



NAEVR’s James Jorkasky and Nicole Brown from the Senate Special Committee on Aging, chaired by Sen. Herb Kohl (D-WI), a defense appropriator. NAEVR has requested that Sen. Kohl champion the FY2009 listing of eye and vision research in the DOD/PRMRP.



Major General Gale Pollock, U.S. Army Deputy Surgeon General and Chief, Army Nurse Corps, met with NAEVR’s James Jorkasky to discuss her concerns about combat-related eye injuries, especially those that result in “low vision/no vision.”



Cong. John Boozman (R-AR), sponsor of the *Military Eye Trauma Treatment Act*, and NAEVR’s James Jorkasky

Cong. Tammy Baldwin (D-WI) sponsored the successfully-passed *Blinded Veterans Paired Organ Act* (HR 797) which makes it easier for veterans who are legally blind to qualify for additional disability compensation payments

NAEVR Joins Vision Community in Celebrating PBA Centennial

On January 10, NAEVR was joined by many of its contributor organizations in celebrating Prevent Blindness America's 100th anniversary in New York City. Actress Jane Seymour and Chicago Cubs' first baseman Derrek Lee were presented with the 2008 Visionary Awards. Seymour's "Don't Lose Sight"

campaign focused on awareness of macular degeneration, while Lee—whose daughter was diagnosed with LCA, a neurodegenerative eye disease—has raised more than \$1 million for research through his Project 3000.



Willard Scott, PBA President and CEO Hugh Parry, Derrek Lee, Jane Seymour, and comedian Tom Sullivan



Cathy Cohen (American Academy of Ophthalmology) and Paul Lee, M.D. (Duke University Eye Center)



Torrey Smitherman (Eye Sight Foundation of Alabama), Jane Seymour, and Lindsay Knox (University of Alabama at Birmingham School of Medicine)

NAEC Welcomes Three New Members

At its January 24 meeting, the National Advisory Eye Council welcomed three new members: Ronald Gardner, J.D. (National Federation for the Blind); Charles Gilbert, M.D., Ph.D. (Rockefeller University); and Scott Cousins, M.D. (Duke University Eye Center).

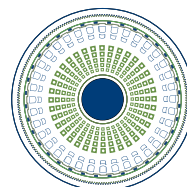


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Educating about the Value of Vision Research