



Fall 2008

President's Message

NAEVR and AEVR Prepared with Strategies for New Administration and Congress

Articles herein describe the tangible results of NAEVR's advocacy: \$6.5 million more in vision research funding at the National Eye Institute (NEI) in Fiscal Year (FY) 2008; two rounds of FY2008 defense-related vision research funding opportunities; a first-ever dedicated line item for defense-related vision research, funded at \$4 million in FY2009; and the implementation of the new Vision Center of Excellence and Military Eye Injury Registry, managed within the Department of Defense (DOD) in coordination with the Department of Veterans Affairs (VA).

A key part of our strategy in 2009 is leading a year-long vision community celebration of the 40th anniversary of the creation of the NEI.

Regarding the latter, at the American Academy of Ophthalmology annual meeting in Atlanta, the NAEVR Board hosted Colonel Donald Gagliano, M.D., who was just named to serve as the Vision Center Director, with former NAEVR Board member Claude Cowan, Jr., M.D., as Deputy Director. NAEVR Executive Director Jim Jorkasky will host Dr. Gagliano in meetings with key vision community contacts over the next few weeks. I am pleased that Jim has worked effectively with NAEVR Legislative Counsel John Porter in pursuing DOD and VA support. Due to the uncertain nature of National Institutes of Health (NIH) funding, defense-related vision research has become a dedicated funding source. NAEVR estimates that the FY2009 Defense appropriations include \$20 million for vision-related research throughout the country.

The environment for NIH funding increases is changing. President-elect Barack Obama has vowed to double science funding over the next ten years. Congressional research champions have included a \$1 billion NIH increase in the economic stimulus package being considered, acknowledging the short—and long-term return on investment from medical research. As acting NIH Director Raynard Kington, M.D., Ph.D., has noted, each \$500 million increment of additional NIH investment translates into 1,400 grants and 9,000 jobs.

With the opportunities presented by the new Administration and Congress come challenges. Chief among these is the potential renewed effort to “cluster” Institute budgets at NIH, which NAEVR has opposed in the past to ensure the breadth of vision research. The Scientific Management Review Board (SMRB), which was established by the *NIH Reform Act of 2006* to advise on NIH management and structure, will meet initially in January 2009. It plans to issue an initial report within a year of the arrival of a new NIH Director, which could include a budget cluster recommendation. NAEVR is once again leading the effort to maintain the dedicated NEI budget line item and has initiated a preemptive strategy.

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Contributor Report



Colonel Donald Gagliano, M.D., (center) with NAEVR Board Member David Pyott (left), Chairman of the Board and Chief Executive Officer, Allergan, Inc., and NAEVR President Stephen Ryan, M.D.

seek a Congressional resolution that acknowledges NEI's 40 years of research to benefit patients and designates 2010–2020 as the *Decade of Vision (DOV)*. We will conduct a series of DOV-branded activities to ensure sustained awareness of the value of NEI-funded vision research. All will be accomplished through existing funding and the “sweat equity” contributions of members.

As we look to 2009 and close out 2008, we say goodbye and thank you to former NIH Director Elias Zerhouni, M.D. and offer our support to Dr. Kington. We also bid farewell to a year of activities acknowledging the 15th anniversary of NAEVR/AEVR, while preparing to take up the banner of the *Decade of Vision 2010–2020 Initiative*.

I thank you for your commitment to and support for the Alliances. I look forward to working with you in 2009.

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National Alliance For
 Eye And Vision Research
 Alliance For Eye
 And Vision Research

Significant Developments in Defense-Related Vision Research Funding

Peer Reviewed Vision Research Listed as Separate Line Item Funded at \$4 Million

FY2009 Defense appropriations include, for the first time, a separate line item for Peer Reviewed Vision Research, which is funded at \$4 million within the Department of Defense (DOD). The final FY2009 Defense, Military Construction/Veterans Affairs, and Homeland Security spending bills were included in the Continuing Resolution (CR) passed by Congress and signed by the President on September 30, which funded the remaining government operations at the FY2008 level (see NIH story inside). NAEVR advocated for this dedicated funding, having educated House and Senate Defense Appropriations Subcommittee members about the devastating eye injuries experienced by soldiers in Iraq and Afghanistan.

Army's Dr. Donald Gagliano Named as Director of the Vision Center of Excellence

On November 6, Colonel Donald Gagliano, M.D., was named Director of the Vision Center of Excellence. Most recently, Dr. Gagliano served as Director of the Clinical Investigations Regulatory Office in the U.S. Army Medical Research and Materiel Command. Claude Cowan, Jr., M.D., a former NAEVR Board member, will serve as the Center's Deputy Director.

The Vision Center of Excellence and an accompanying Military Eye Injury Registry were provisions of the *Military Eye Trauma Treatment Act* (METTA) that were included in FY2008 *National Defense Authorization Act*, passed in early 2008 but not funded at that time. Subsequently, Congress included \$6.9 million in funding in the FY2009 Military Construction/Veteran Affairs appropriations bill passed in late September 2008, with an additional \$2 million for development of the Injury Registry.

Vision was previously one of 21 areas of research competing for a pool of \$50 million of funds in the Peer Reviewed Medical Research Program (PRMRP). In FY2009, vision researchers will compete against vision researchers for the \$4 million administered by the Army. A program announcement will likely issue in early 2009. Although vision researchers have competed successfully in the PRMRP in the past—for example, in FY2006, the first year of eligibility, vision researchers were awarded \$5.4 million—the competition had increased significantly due to a new structure for award mechanisms. FY2008 PRMRP awards are expected in late 2008/early 2009.

The Vision Center of Excellence will address the prevention, diagnosis, mitigation, treatment, and rehabilitation of military eye injuries, as well as coordinate work on the Injury Registry. The Center will also facilitate vision research, including research on prevention, visual dysfunction related to traumatic brain injury (TBI), and military eye injuries. Although the Vision Center of Excellence is a DOD program, it will coordinate with the VA.

NAEVR joined the vision community in strongly supporting the Center/Registry legislation, which was sponsored by Congressman John Boozman (R-AR). NAEVR was fortunate to have met with Dr. Gagliano on November 5, along with representatives of several Veteran Service Organizations (VSOs), and to host him a few days later at a meeting of the NAEVR Board of Directors held at the American Academy of Ophthalmology (AAO) annual meeting.



NAEVR Advocacy Manager David Epstein with Colonel Robert Mazzoli, M.D., Chief of Ophthalmology at Madigan Army Medical Center, at a September 2008 Schepens Eye Institute Symposium on Military Eye Trauma

In September, DOD announced additional FY2008 funds through the Deployment Related Medical Research Program (DRMRP), a \$92 million pool of funds created by the mid-year Supplemental Appropriations Act. The DRMRP has specifically requested grant proposals in the vision space, including visual/ocular trauma treatment and rehabilitation, traumatic brain injury (TBI), and wound infection. Awards are expected in first-quarter 2009.



Dr. Gagliano with Tom Zampieri, Ph.D., Blinded Veterans Association, who advocated strenuously for the creation and funding of the Vision Center/Injury Registry

Full details appear in the NAEVR Web site Advocacy Center's section on Defense-related Vision Research

Legislative Scorecard ISSUES

FY2008 NEI Research Funding Increases by \$6.5 Million

Although the NEI was flat-funded (as were most NIH Institutes) at \$667.1 million in initial FY2008 appropriations, the Supplemental Appropriations Act signed by the President on June 30, 2008, provided \$150 million in additional NIH funding, \$3.5 million of which was programmed to the NEI, which also received \$3 million for vision researchers from the NIH Director's Bridge Fund within the common fund. Despite this \$6.5 million increase in FY2008 over FY2007, NEI funding still did not keep pace with the biomedical inflation rate of 3.5 percent, which has resulted in an 18 percent loss of NEI purchasing power in

the last five funding cycles.

Congress has yet to finalize FY2009 Labor, Health and Human Services, and Education (LHHS) appropriations, which includes NIH/NEI funding. On September 30, the President signed a Continuing Resolution that flat-funds the NIH/NEI at the initial FY2008 funding level until March 6, 2009, by which time the 111th Congress must take action to finalize appropriations which were not already completed in the CR, as were the Defense, Military Construction/Veterans Affairs, and Homeland Security spending bills.

Champions Emphasize Power of Medical Research to Stimulate the Economy

The \$100.3 billion economic recovery package introduced by the Senate on November 18 included \$1 billion for NIH. Whether an economic stimulus package that includes NIH funding moves in the lame duck session, early in 2009, or in concert with final FY2009 spending bills, it acknowledges the value of medical research to stimulate the economy both short- and long-term.

This was emphasized at a November 18 session held by the Society for Neuroscience, at which former NIH Director Harold Varmus, M.D. (President and CEO, Memorial Sloan-Kettering Cancer Center, and science advisor to the Obama campaign), said that Congress now understands the short-term value of research grants—including salaries, indirect expenses with universities, supplies and equipment—to stimulate the economy, as well as the long-term return on investment, cited at 150 percent. Dr. Varmus was joined by Wendell Primus, Ph.D., Senior Policy Advisor to House Speaker Nancy Pelosi (D-CA), and John Porter (Hogan & Hartson). Dr. Primus predicted that “research would be treated

well in the next Administration and Congress,” adding that Speaker Pelosi “is a true believer.” This was echoed by Mr. Porter, who previously served as Chair of the House LHHS Appropriations Subcommittee on which Speaker Pelosi formerly sat. Dr. Primus cautioned, however, that he was uncertain when potential NIH funding increases would be enacted, predicting that it would likely be when FY2009 appropriations are finalized.

Mr. Porter stated that, in addition to increases to “bring NIH back to where it should be after the impact of five cycles of flat funding and biomedical inflation,” NIH needs sustainable annual increases of 3 percent, plus the biomedical inflation rate (currently 3.5 percent). When asked about potential NIH reauthorization (NIH was reauthorized for three years by the *NIH Reform Act of 2006*), Dr. Varmus noted that it was unlikely in 2009, as the Scientific Management Review Board (SMRB) that was created by the *Act* to make recommendations on the structure of NIH was just formed and had yet to meet.

	FY 2008* Final	FY 2009 Budget	FY 2009 House	FY 2009 Senate
NIH	\$29.38B	\$29.2B +0%	\$30.4B +3.9%	\$30.2B +3.5%
NEI	\$670.7M	\$667.8M +0.1%	\$690.7M +3.5%	\$687.3M +3.0%

* FY2008 figures include original appropriation sums of \$29.2B NIH / \$667.1M NEI plus Supplemental Appropriations of \$150M NIH / \$3.5M NEI. FY2009 Budget, House and Senate percent increases based on initial FY2008 appropriations.

Final FY2008 NEI excludes \$3 million from Director's Bridge Fund in NIH Common Fund



In late October, at the American Academy of Optometry annual meeting in Anaheim, California, then AAOptom Board President-elect Mark Eger, O.D., F.A.A.O., was the first attendee to contact Congress about vision research funding from NAEVR's booth



Left to right: John Porter, Wendell Primus, Ph.D., and Harold Varmus, M.D., speak about the value of biomedical research



Elias Zerhouni, M.D., greets farewell reception attendees



“The Directors” (a band of NIH senior staff) plays such favorites as “Taking it E.Z.,” “King of the Road(map),” and “Run, Run, Run-away”

NIH Acting Director Dr. Raynard Kington Testifies On Economic Impact of Research



Raynard Kington, M.D., Ph.D.

On October 31, former NIH Principal Deputy Director Raynard Kington, M.D., Ph.D., began serving as Acting NIH Director. On November 13, he testified at a House Energy and Commerce Committee Health Subcommittee hearing, chaired by Cong. Frank Pallone (D-NJ) and entitled *Treatments for an Ailing Economy: Protecting Health Care Coverage and Investing in Biomedical Research*. Dr. Kington addressed the short- and long-term economic impact of NIH grants, noting that any economic stimulus funds made available to the NIH could be administered quickly with little

overhead. In response to questions, he stated that each \$500 million increment of additional NIH funding translates into 1,400 grants and 9,000 jobs. During questions, Subcommittee member Michael Burgess, M.D., (R-TX) stressed that the *NIH Reform Act of 2006* had authorized funding increases which had not translated into appropriations. He reiterated the Committee's intention in that legislation for sustained increases and expressed his desire that NIH receives these, whether through an economic stimulus bill or final FY2009 appropriations.

Dr. Kington Briefs NIH Council of Councils on NIH Priorities

During November 20 comments to the NIH Council of Councils—the entity created by the *NIH Reform Act of 2006* to guide NIH on trans-Institute initiatives funded by the common fund—Dr. Kington commented on impending NIH actions.

The Scientific Management Review Board will meet initially in January 2009 to determine NIH management/structural issues it will address. Dr. Kington predicted that the SMRB would issue a report within a year of the arrival of a new

NIH Director, noting that the Institute of Medicine (IOM) issued its 2003 report entitled *Enhancing the Vitality of the NIH* about a year after Dr. Zerhouni was confirmed (NAEVR Board President Dr. Ryan was a member of the IOM Committee that issued the report).

The Department of Health and Human Services plans to issue an Advanced Notice of Proposed Rulemaking (ANPR) to solicit public comment in advance of modifying regulations governing financial

conflicts of interest among extramural investigators receiving grant support from NIH. He could not predict timing, especially with the change in Administration. NAEVR will work with ARVO to coordinate a vision community response.

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

Dr. Zerhouni Urges Predictable and Sustained Funding in Last Hill Appearance

NAEVR commended the testimony presented by NIH Director Elias Zerhouni, M.D., at a September 9 hearing of the House Energy and Commerce Committee's Health Subcommittee on the status of implementation of the *NIH Reform Act of 2006*. Dr. Zerhouni acknowledged that, although the law has helped NIH to streamline governance and to better plan short-term, its ability to plan medium-to-long term is limited by the lack of predictable and sustained funding increases. He cited the latter as the primary cause of NIH's biggest challenge—workforce issues, specifically those related to the training

and retention of new investigators and clinician-scientists.

“Invest in the talent pool first to ensure a pathway to success,” he said, adding that this requires stabilizing the NIH success rate for grant awards, which he recommended at least 30 percent. Currently, NIH projects the FY2009 success rate at 18 percent, the lowest level in 40 years. Dr. Zerhouni also emphasized the importance of “high risk, high reward” research, noting various funding mechanisms to support such research within the NIH common fund established by the 2006 law.



Dr. Kington and Lana Skirboll, Ph.D., who was named on November 4 as the Acting Director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), which is the entity created by the *NIH Reform Act of 2006* to coordinate trans-Institute initiatives, including the NIH common fund



Dr. Skirboll with Lenworth Johnson, M.D., (Mason Eye Institute, University of Missouri/Columbia), who serves as the National Advisory Eye Council's (NAEC) representative to the Council of Councils. At the meeting, Dr. Johnson reported on an early October 2008 conference that addressed the science of science management.

On October 30, NAEVR's James Jorkasky attended the farewell event for NIH Director Dr. Elias Zerhouni, at his invitation. Previously, NAEVR Board President Dr. Stephen Ryan sent a letter of appreciation, thanking Dr. Zerhouni for his exemplary leadership in navigating the NIH through a period

of significant scientific breakthroughs and a challenging funding environment. At the event, Mr. Jorkasky offered NAEVR's full support to incoming Acting NIH Director Raynard Kington, who has had significant past outreach with the advocacy community.

AEVR Congressional Briefing Highlights AMD Awareness Week 2008



On September 16, AEVR sponsored a Congressional briefing in recognition of *International AMD Awareness Week 2008*. Researcher Gregory Hageman, Ph.D. (University of Iowa, UI), described dramatic advances in age-related macular degeneration (AMD) research that have occurred since 2005, when his and three other research teams first identified a gene variant strongly associated with increased risk for developing AMD. This research, funded by the NEI and the National Human Genome Research Institute (NH-GRI) within NIH, was initially described by Dr. Hageman at a September 2005 AEVR briefing. In this update, he announced new findings that could change the way AMD is treated—and potentially cured.

The identified gene Complement Factor H (CFH) and its protein product are normally engaged in the control of a portion of the body's immune system. Variants in the gene result in poor regulation of this system and can lead to the development of AMD. In the United States, approximately 15 million people have AMD and, world-

“The recent scientific and translational progress in AMD research is nothing short of spectacular.” Dr. Gregory Hageman

wide, it affects vision and the concomitant productivity, independence, and quality of life of more than 30 million people.

In addition to directing the Cell Biology and Functional Genomics Laboratory at UI, Dr. Hageman is also the Scientific Founder and Chief Scientific Officer of a newly formed company Ophtherion, Inc., which is working on developing AMD treatments based on the latest gene discoveries. With funding from the NEI and UI, and additional support from Ophtherion, he and colleagues around the world are moving toward commercializing a therapy for replacing CFH in patients with AMD

and possibly in genetically-susceptible individuals.

His work over the past 25 years has focused on understanding the cellular pathways leading to AMD, which could lead to discoveries of potential therapies, including the manufacture and use of the protective version of the CFH protein in an augmentation strategy similar to that of treating diabetes with insulin. This therapy is under development and expected to enter Phase I clinical safety trials in summer 2009.

He also announced preliminary, unpublished findings in patients with liver transplants that support the direction and scope of his research. Normal levels of healthy CFH protein protect against AMD. Since most of the CFH is made in the liver, liver transplant recipients offer an opportunity to study what occurs when an individual receives a different form of CFH following transplantation. Researchers hope that these studies will reinforce the concept of providing AMD patients with doses of the protective protein or, in

the future, with gene therapy approaches that would allow the liver to produce the protein on its own. Dr. Hageman also noted newly published observations of possible relationships between CFH and obesity, coronary artery disease, myocardial infarction, and stroke, among other conditions—the findings of which facilitate new opportunities for trans-NIH research.

For more information about AMD and other aging eye diseases, refer to *The Silver Book: Vision Loss*, published by the Alliance for Aging Research in partnership with NAEVR at: www.silverbook.org/visionloss



AEVR Executive Director James Jorkasky joins Gregory Hageman, Ph.D., in discussing the dramatic implications of his AMD research



Left to right: Tara Cortes, Ph.D., R.N., Carl Tuvin (Tuvin Associates), Cynthia Stuen, Ph.D., and David Moore (Ad Hoc Group for Medical Research). Drs. Cortes and Stuen represented co-sponsor Lighthouse International.



Dr. Hageman and Cong. Bruce Braley (D-IA), who attended the briefing



Dr. Hageman met Cong. Dave Loebsack (D-IA), in whose district the University of Iowa is located, during a break in a hearing by the House Armed Services Committee



Erik Fatemi, who works for Senator Tom Harkin (D-IA), Chair of the Senate LHHS Appropriations Subcommittee, hears about Dr. Hageman's translational research

AEVR's Co-sponsors for this event included:

AMD Alliance International
Association for Research in Vision and Ophthalmology (ARVO)
Lighthouse International
Alliance for Aging Research
Ad Hoc Group for Medical Research

NEI Research Highlighted in *NIH MedlinePlus Magazine*

The Summer 2008 edition of the *NIH MedlinePlus Magazine* contains a six-page summary about NEI research that impacts Americans of all ages and races. The story features an interview with actor Ernest Borgnine, who stars in an NEI video that educates about the dangers of AMD and offers advice on regular eye exams. Appropriately, this edition's cover features medical research champion Senator Arlen Specter (R-PA), Ranking Member of the Senate LHHS Appropriations Subcommittee, who has

been waging his own battle with a form of lymphoma. In the cover story, Sen. Specter offers advice to others diagnosed with serious illness, including never giving in, which coincides with his recent book entitled *Never Give In: Battling Cancer in the Senate*.

These articles are available at:
www.medlineplus.gov



The NEI Posts Redesigned Web Site

In late November, NEI launched a major redesign of its Web site, www.nei.nih.gov that features new sections including:

- A dynamic *Highlights* section that showcases vision research findings, scientific meetings, clinical trials, and publications
- An update service to which visitors can subscribe that informs them of new Web site content
- A featured eye health topic
- A text tool size that allows visitors to change font size with a single click

Upcoming NAEVR/AEVR Events in early 2009:

January 23:	ARVO Program Committee Advocacy Day, hosted by NAEVR
January 28:	NAEVR <i>Welcome Reception for the 111th Congress</i>
February 5:	AEVR Congressional Briefing on <i>Usher Syndrome</i>
March 10:	AEVR Congressional Briefing on <i>Glaucoma</i> , in recognition of the second annual <i>World Glaucoma Day</i> , celebrated March 12

Visit www.eyeresearch.org for additional details.

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