**President’s Message**

**NIH Reauthorization Will Fundamentally Change Research**

While NAEVR is leading our community on a number of issues relating to research, the most important current challenge relates to the National Institutes of Health (NIH) reauthorization legislation expected to be introduced shortly by the House Energy and Commerce Committee.

On July 12, I was in the midst of Capitol Hill visits with Committee members—joined by Dr. Dunbar Hoskins and Cathy Cohen of the American Academy of Ophthalmology (AAO) and NAEVR Executive Director Jim Jorkasky—when the initial “Discussion Draft” of legislation was issued. Joined by NAEVR Legislative Counsel John Porter, we prepared for our next day’s meeting with Committee chair Joe Barton (R-TX).

At that meeting, I shared my perspectives as a member of the Institute of Medicine (IOM) Committee that developed a set of recommended changes at NIH. Although stressing how pleased I was that 8 of 14 recommendations appeared in the draft, especially those to strengthen the Office of the Director and increase transparency, I expressed our community’s concern about the draft’s elimination of line item budgets for individual Institutes, such as the National Eye Institute (NEI). By grouping Institutes into one line item—such as the proposed grouping of 15 mission-specific Institutes that includes the NEI—the medical research advocacy community will lose an important “check and balance” that occurs through Congressional review of the extensively-revised internal NIH budget-development process.

Although our community supports NIH Director Dr. Elias Zerhouni’s leadership, especially his efforts to promote collaborative research, there are many concerns about the current draft’s impact on the NIH. In his comments during the Committee’s July 19 hearing on the draft, Dr. Zerhouni cautioned that changes need to be implemented gradually as not to cause a “disequilibrium.” I am pleased that his comments also acknowledged the discovery by NEI-funded researchers of a gene associated with age-related macular degeneration (AMD), which he has mentioned frequently since his participation in the ARVO Annual Meeting in May (see story inside).

NAEVR will continue to lead on this issue by engaging our community in advocacy—not only with the House authorizers and appropriators, but also with the Senate Health, Education, Labor and Pensions (HELP) Committee and Senate appropriators. In that regard, I want to thank a number of network members who have brokered their relationships with Members of Congress to share NAEVR’s message, including the AAO, ARVO, the American Optometric Association, Prevent Blindness America and the Foundation Fighting Blindness. We will need all members’ support when legislation is introduced.

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ARVO Annual Meeting Presents Opportunity for Dr. Zerhouni to Meet with Researchers and Postdocs on Value of Vision Research

On May 1, prior to his keynote address, Dr. Zerhouni met with ARVO-member researchers and NEI Director Dr. Paul Sieving in a session that addressed vision research's global role in scientific discovery and presented examples of exciting new research. Then-ARVO President Dr. Gary Abrams was joined by ARVO Executive Vice President Dr. Paul Kaufman, former ARVO President Dr. Sally Atherton and NAEVR President Dr. Stephen Ryan, who each provided a summary of their Institution’s activities that demonstrate the breadth of NIH/NEI sponsored research, as well as intra- and inter-Institution collaboration. Specific examples of research were provided by Dr. John Dowling (visual neuroscience), Dr. David Williams (imaging), Dr. Dusanka Deretic (cell biology), Dr. Martin Friedlander (angiogenesis), Dr. Gregory Hageman (AMD), and Dr. Edward Pugh (nanotechnology).

Incoming ARVO President Dr. Larry Takemoto concluded the meeting by reiterating the eye and vision research community's support for Dr. Zerhouni’s and Dr. Sieving’s leadership.

On May 2, Dr. Zerhouni was joined by fellow keynote speaker Dr. Peter Agre in meeting with ten Post Doctoral fellows. After the two-hour meeting, participant Dr. Joe Carroll (University of Rochester) commented that, “The fact that a Nobel laureate and the NIH Director placed training as one of the markers of success impressed many of us, and reiterated to us how serious Dr. Zerhouni is in wanting to improve the training that young scientists receive.”
AEVR Briefing Features NEI-Funded Research to Improve Detection Techniques for Glaucoma

At an April 21 Congressional Briefing sponsored by the Alliance for Eye and Vision Research (AEVR), NEI-funded researcher Dr. Christopher Girkin (University of Alabama at Birmingham, UAB) announced that research into the physiology of the optic nerve in African Americans is resulting in better techniques to detect glaucoma, which will impact current and future screening programs and subsequent treatment strategies. Providing an update of the NEI-sponsored African Americans with Glaucoma Study about one-and-one-half years into the five-year study, Dr. Girkin stated that, “Improved detection techniques can determine at-risk characteristics of the optic nerve and better define the progressive changes that occur in the disease. Earlier detection results not only in earlier diagnosis, but will also have an impact on the clinical practice patterns in treatment of the disease.” He noted that the NEI-funded Ocular Hypertension Treatment Study has already shown that pressure-reducing drops can delay or prevent the onset of disease.

UAB colleague Cassandra Page spoke about the importance of outreach to the African American churches in the Birmingham area to recruit study participants, as prior research into physiological differences in the optic nerve have not been conducted in as large of a study population.

Cong. Davis provides a welcome

Congressman Artur Davis (D-AL) provided an introduction to the event and emphasized the importance of Congressional support for medical research generally, as well as that into health disparities, specifically. “You spend money on what you value, and our nation needs to invest in the health of all of its citizens,” said Cong. Davis. AEVR Executive Director James Jorkasky concluded by noting NEI’s leadership on health disparities research in relation to vision, citing studies NEI has co-sponsored with the National Center for Minority Health and Health Disparities.

AEVR plans a September 21 Congressional Briefing on AMD, featuring Dr. Greg Hageman (University of Iowa). Visit www.eyeresearch.org for more details.
House NIH Reauthorization Bill Expected in September

When Congress returns after the Labor Day recess, the House Energy and Commerce Committee is expected to introduce bipartisan legislation to reauthorize the NIH, which has not been reauthorized since 1993. On July 12, the Committee released a “Discussion Draft” of legislation that would greatly expand the authority of the NIH Director and authorize only a four line item budget for the NIH—the Office of the Director; a new Division of Program Coordination, Planning and Strategic Initiatives; a cluster of 15 mission-specific Institutes (including the NEI); and a cluster of 9 science-enabling Institutes/Centers—as opposed to the current 27 line item budget.

On July 19, the Committee held a hearing at which it questioned NIH Director Dr. Elias Zerhouni about various aspects of NIH’s potential implementation of the “Discussion Draft.” Both Republican and Democratic Committee members expressed concerns about the extensive nature of the changes proposed, including the elimination of line item budgets for individual Institutes. This has been a major concern of the eye and vision research community, as presented in two sets of NAEVR comments submitted to the Committee, which were developed in conjunction with an ARVO NIH Working Group that represented the breadth of eye and vision research. Although NAEVR generally supports many of the 2003 IOM report’s recommendations to strengthen the Office of the Director and increase transparency that are included in the draft legislation, NAEVR opposes the elimination of line item budgets since Congressional review of individual Institute line item budgets provides an important “check and balance” to the proposed extensively-revised internal NIH budget development process driven by the NIH Director.

At press time, the July 12 draft was the subject of negotiations between Republican and Democratic leaders on various aspects, in addition to the authorizing amounts and line item budgets, such as how to establish a “common fund” for trans-NIH collaborative projects and any increase to the current one percent cap in the NIH Director’s authority to transfer funds from an Institute. Working with its network members, NAEVR will analyze revised draft legislation, develop appropriate comments and alert our community about messages to send to the Committee/Congress through the NAEVR Web site at www.eyeresearch.org.

"Congressional review of line item budgets is an important check and balance to the internal NIH budget process."

—NAEVR Comments to Energy and Commerce Committee

Dr. Zerhouni testifies at July 19 hearing, at which he announced as a major breakthrough the discovery by NEI-funded investigators of a gene associated with AMD

Steven Grossman (EyeRx), Norman Lanphear (AAO), NAEVR Counsel John Porter, Dr. Stephen Rose (FFB) and David Danielson (AOA) were among those participating in an August 10 NAEVR-sponsored vision community strategy session on NIH reauthorization
NAEVR Commends Senate Appropriations Leadership for FY2006 LHHS Spending Bill That Includes $1 Billion Increase for NIH, $24 Million for NEI

On July 14, the full Senate Appropriations Committee unanimously approved an FY2006 Labor, Health and Human Services, and Education (LHHS) spending bill that includes a $1.05 billion increase over FY2005 (or 3.7 percent) for the NIH, for a total of $29.4 billion, and a $24 million increase for the NEI, also a 3.7 percent increase, for a total of $693.6 million. The Committee sent the bill to the Senate floor for action, which is not expected until after Labor Day. In drafting the bill, the Senate LHHS Appropriations Subcommittee proposes to fund the increase in NIH and other programs by moving the last Supplemental Security Income (SSI) payment of FY2006 into FY2007. NAEVR President Dr. Stephen Ryan wrote to Subcommittee chair Arlen Specter (D-PA) and Ranking Member Tom Harkin (D-IA) commending them for their leadership and dedication to the health—and vision health—of all Americans through this funding increase. Note that NAEVR had requested FY2006 funding for the NIH and NEI at $30 billion and $711 million, respectively.

Assuming that the Senate bill is passed, it is likely to find opposition from the House in conference, as the House-passed bill (HR 3010) maintained the funding levels in the President’s FY2006 budget request, which are significantly lower than that in the Senate bill. The House conferees may also challenge the Senate’s underlying funding mechanism of moving the SSI payment, which was attempted and failed in last year’s conference.

Prior to the passage of the House bill, both ARVO and NAEVR represented the eye and vision research community in public witness testimony before the House LHHS Subcommittee, chaired by Cong. Ralph Regula (R-OH). On April 14, then-ARVO President Dr. Gary Abrams testified, focusing primarily on the recent breakthroughs from NEI-sponsored research, noting that “vision research is on the cutting edge of scientific discovery.” On April 21, NAEVR President Dr. Stephen Ryan testified, focusing on the impact of eye disease and requesting that Congress “make this nation’s vision health a top priority.” In addition to testifying, both also made extensive Capitol Hill visits with House and Senate appropriators.
NAEVR Requests FY2006 Funding for Defense-related Eye and Vision Research

NAEVR has formally requested that “Eye and Vision Research” be added to categories eligible for peer-reviewed funding within the Congressionally-directed Medical Research Program (CDMRP) within the Department of Defense (DOD). In FY2005, for example, the CDMRP program provided $50 million of funding for research in autism, epilepsy and osteoporosis.

The CDMRP program is funded through the Military Quality of Life appropriations bill in the House, which was passed in May but did not include the list of approved research categories. The program is funded in the Senate through the DOD appropriations bill, which was not marked up by the Subcommittee prior to the August recess and will likely be considered in September. From past practice, new CDMRP research categories are often not added until the conference process between the House and Senate bills. The practical implication of the addition of “Eye and Vision Research” to the CDMRP program will be the opportunity for defense-related vision researchers to submit competing grants for funding. With greater experience with this process, grantees may then seek direct earmarks from Congress in future DOD spending bills.

A working group of ARVO members was pivotal to the development of a funding justification document, which cites three major areas of vision research most applicable to defense applications: visual acuity, eye trauma and infection, and vision health disparities. NAEVR’s case was strengthened by a Senate Committee on Veterans Affairs finding that 15 percent of current wartime injuries relate to the eye, with optic nerve trauma the most grave condition.

ARVO Board member Dr. Bob Barlow and AUPO member Dr. John Hoepner of Syracuse College of Medicine/SUNY have advocated for NAEVR’s position with their representative, Cong. James Walsh (R-NY), chair of the Military Quality of Life and Veterans Affairs Appropriations Subcommittee. Dr. Christopher Girkin of the University of Alabama at Birmingham (see AEVR Briefing story) has advocated with Senator Richard Shelby, a member of the Senate Defense Appropriations Subcommittee. Although Hill contacts have indicated that NAEVR has made a strong case, there have been an inordinate number of similar requests as various research communities seek alternative funding sources.

NAEVR is soliciting additional examples of defense-related vision research to enhance its justification, which appears on the Web site at www.eyeresearch.org.
Senator Frist’s Support for Expanding Embryonic Stem Cell Research May Break Senate Logjam

Senate Majority Leader Bill Frist’s (R-TN) July 29 announcement of support for expanding the Administration’s current embryonic stem cell policy could facilitate a post-Labor Day vote on S 471, the *Stem Cell Research Enhancement Act*, co-sponsored by Senator Arlen Specter and Senator Tom Harkin. S 471 is the Senate version of HR 810, which was passed by the House in late May and expands the number of embryonic stem cell lines available for federal funding beyond those specified in the Administration’s August 2001 policy. NAEVR network members sent hundreds of letters of support for HR 810.

In an August 2 letter, NAEVR President Dr. Stephen Ryan praised Dr. Frist’s leadership and requested that the Senate bring S 471/HR 810 with no amendments to the floor for a vote as soon as possible upon the return from the August recess. The Senate still needs to resolve the issue of six other stem cell bills that could siphon away support from S 471.

NAEVR has actively participated with nearly 100 other research advocacy organizations in the Coalition for the Advancement of Medical Research (CAMR), which has taken the lead in educating Congress. NAEVR will alert our community about a Senate vote and appropriate messages of support to send through the NAEVR Web site at [www.eyeresearch.org](http://www.eyeresearch.org).
NAEVR Hosts Vision Research Community Meeting with FDA

On July 6, NAEVR hosted a meeting of representatives of the eye and vision research and patient communities with the leadership of the Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER), including Acting CDER Director Dr. Steven Galson. NAEVR requested the meeting so that FDA could provide an update on the status and implications of its reorganization of the Office of New Drugs, in which the Ophthalmology Group is being integrated into the Division of Anti-Infective Products. FDA reported that this process is complete, and the Ophthalmology Group now reports to Division Director Dr. Janice Soreth.

Within the context of this meeting, our community had an opportunity to educate FDA staff about the new drug therapies emerging from research, as well as to highlight the unique mode of action of ophthalmic drugs (e.g., localized as compared to a systemic effect) that is a pivotal issue in the review process. Arising from these discussions, Dr. Soreth announced that the Division plans to proceed in the development of Guidance Documents to formalize more aspects of the review process, which can facilitate our community’s constructive input.

NAEVR wishes to thank the following meeting participants: Dr. Allan Jensen and Norman Lanphear (representing the American Academy of Ophthalmology); Dr. James Boucher (representing the American Optometric Association); Daniel Garrett (representing Prevent Blindness America); Dr. Barrett Katz (Eyetech Pharmaceuticals, Inc.); Dr. Scott Whitcup (Allergan); Steven Grossman (EyeRX); and Dr. Pat Wilkinson, who served as the NAEVR spokesman with James Jorkasky.
ARVO Members Contact Congress Regarding NIH/NEI Funding

Once again, ARVO members attending the ARVO Annual Meeting demonstrated their strong support for funding eye and vision research by sending hundreds of email letters to their elected representatives at a booth sponsored by NAEVR. The emails went to both the House and Senate requesting FY2006 NIH and NEI funding at $30 billion and $711 million, respectively.