Although Fiscal Year (FY) 2008 began on October 1, Congress has yet to finalize any spending bills, other than Defense. It returns December 3 for a planned two-week session in an attempt to finalize FY2008 appropriations bills, either through an omnibus measure or year-long funding resolution. The current budget/spending battle, in which Congress plans to spend $22 billion more than the President’s budget proposal—much of it on domestic programs, such as medical research—is fraught with several good news/bad news stories for our community.

For the first time in five years, Congress passed a Labor, Health and Human Services, and Education (LHHS) appropriations conference bill with increased National Institutes of Health (NIH) funding that would match inflation. In that regard, the research value message is being heard. However, Congress could not override the President’s veto of the bill—based purely on politics, we are told, and not on a lack of appreciation for the NIH’s breakthrough research. As a result, the conference bill’s increase in NEI funding of $17 million will likely not occur, and NAEVR and its networks must work diligently to ensure even half that amount.

On a positive note, the Defense spending bill retained eye and vision research’s eligibility for funding. The bill also includes additional funding for Traumatic Brain Injury (TBI)-related research, including that into visually-related neurological conditions. NAEVR will fully inform all networks of the funding opportunities these initiatives present, which could be substantial and build upon the $4.8 million received by defense-related vision researchers in calendar year 2007 from FY2006 funding.

As noted in the stories contained within, throughout this complex legislative process the vision research message has been shared widely and in various contexts—ranging from Hill briefings on rare eye diseases, combat-related eye injuries, and release of the Silver Book: Vision Loss on aging eye disease, to NIH Director Dr. Elias Zerhouni acknowledging in multiple public venues NEI Director Dr. Paul Sieving’s leadership with respect to the genetic basis of eye disease and research into blood vessel inhibition in the eye. Dr. Sieving’s “plain English” explanation of the genetic basis of eye disease at the recent Congressional briefing on Rare Eye Diseases not only resulted in multiple requests from staff to view vision research on NIH campus and at extramural Institutions, but drew him praise from staffers for his simple-yet-dramatic examples of the value of research funding.

NAEVR Executive Director Jim Jorkasky and Legislative Counsel John Porter will not only continue to work for every possible dollar available for vision research in FY2008, they are already developing new strategies for the FY2009 legislative process. I look forward to working with them in that regard, as well as to report to you on their accomplishments for our community.

As always, thank you for your support and commitment.

Stephen J. Ryan, M.D.
Doheny Eye Institute
NAEVR/AEVR Boards President
sryan@doheny.org

Dr. Ryan (right) and Tom Harkin (D-IA)

Dr. Ryan and Philip Moore

See Special Insert:
NAEVR Releases Silver Book: Vision Loss

National Alliance For Eye And Vision Research
Alliance For Eye And Vision Research
On November 8, the NIH hosted an initial planning meeting of the newly established Council of Councils, a body created by the NIH Reform Act of 2006 to guide NIH on trans-Institute initiatives funded within a “common fund” that was also mandated in the legislation. The Council of Councils is composed of representatives from the existing advisory councils to the 27 NIH Institutes and Centers (ICs), including the NEI’s National Eye Advisory Council (NAEC) representative Lenworth Johnson, M.D., a neuro-ophthalmologist at the Mason Eye Institute (University of Missouri) involved in several research projects on disorders affecting the visual pathway and processing.

In introductory comments, NIH Director Dr. Elias Zerhouni stated that the Congressional intent in establishing the common fund and guiding Council was to ensure synergy in NIH’s scientific goals. “Congress wanted to build upon the initial NIH Roadmap initiative, which demonstrated NIH’s strategic vision for research,” said Dr. Zerhouni, noting such examples as: commonalities in biological systems; the movement from acute to chronic disease management, involving multiple diseases and NIH Institutes; and the tools that can predict, preempt, and prevent disease, such as the Human Genome Project. “The common fund is the glue for the ICs,” he stated, prior to challenging the Council to be bold and experimental in its guidance on research and creative in developing metrics used to evaluate scientific success.

In citing examples of trans-Institute research, Dr. Zerhouni noted the collaborative effort of the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), and the NEI in identifying factors that inhibit angiogenesis (new blood vessel growth) that has resulted in the first generation of Food and Drug Administration (FDA)-approved drugs to treat the “wet” form of age-related macular degeneration (AMD) and are in clinical trials to treat diabetic retinopathy. In its September 22, 2006, letter to then-Chair of the House Energy and Commerce Committee Cong. Joe Barton (R-TX) supporting the NIH Reform Act of 2006, NAEVR acknowledged the opportunities for the NEI that the common fund presented. “NEI’s trans-Institute research efforts have resulted in numerous breakthroughs cited by Dr. Zerhouni, including the recent discovery of gene variants associated with AMD,” stated NAEVR President Dr. Stephen Ryan.

For the first time in the appropriations process, the common fund had a direct budget line in the FY 2007 Joint Funding Resolution, which funded it at $486 million. The FY 2008 LHHS appropriations conference report would fund it at $531 million, or 1.77 percent of the NIH budget (see inside story on status of the FY 2008 LHHS conference report.)

NEI’s Trans-Institute Research Praised, Vision Community Represented in Initial Meeting of Council to Guide NIH Common Fund

Dr. Lenworth Johnson with Alan Krensky, M.D., Director of NIH’s Office of Portfolio Analysis and Strategic Initiatives (OPASI), which is currently managing the Council of Councils as NIH organizes the legislatively mandated Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) that will have ultimate responsibility for the common fund

Left to right foreground: NIH Principal Deputy Director Raynard Kington, M.D., Ph.D., and NIH Director Dr. Zerhouni listen as Dr. Johnson provides comments

NAEVR’s James Jorkasky and Harold Shapiro, Ph.D., (Princeton University). Dr. Shapiro chaired the Institute of Medicine Committee which released a report in 2003 entitled Enhancing the Vitality of the National Institutes of Health that recommended a dedicated budget for trans-Institute research. NAEVR Board President Dr. Stephen Ryan served on that IOM Committee.
On November 15, just before Congress adjourned for the Thanksgiving recess, the House failed to override the President’s veto of the Fiscal Year (FY) 2008 Labor, Health and Human Services, and Education (LHHS) appropriations conference bill (H.R. 3043) by a vote of 277-141. A total of 51 Republicans voted with 226 Democrats for the override, while 141 Republicans voted to sustain the veto—many of whom are members of the conservative Republican Study Committee that vowed to sustain vetoes of bills that exceeded the President’s budget request. Congress will return on December 3 for a planned two-week session that may include action on an omnibus spending bill (including LHHS) which could split the $22 billion difference between the spending bills and the President’s request, as the current Continuing Resolution funding the government expires on December 14. As of the recess, only the Defense appropriations bill had been passed and signed (see separate story).

**NIH’s Dr. Zerhouni Expands Research Value Message at PhRMA/R!A Meeting**

At a November 16 meeting entitled *Transforming Health: Fulfilling the Promise of Research* sponsored by the Pharmaceutical Research and Manufacturers of America (PhRMA) and Research!America (R!A), NIH Director Dr. Zerhouni added new themes to his research value message. In addition to noting the importance of *P4 Medicine* (i.e., prediction, preemption, personalized, and participatory research) in managing the disease cycle, he emphasized the need to study the “software” of life (e.g., cellular mechanisms, signaling) in addition to the “hardware”. While recognizing the discovery of gene variants associated with age-related macular degeneration (AMD) in 2005 as a major breakthrough from the Human Genome Project, he presented a slide listing dozens of new gene discoveries that have occurred in 2007, demonstrating NIH’s accelerated knowledge about the basis of disease.

Although Dr. Zerhouni avoided comment on the previous evening’s failed House override of the Presidential veto of the FY2008 LHHS conference bill, PhRMA President and CEO Billy Tauzin, a former Republican House member from Louisiana and a cancer survivor, did remark. “Don’t misinterpret the vote, as it is just politics,” he said, stating that there is a lot of support for the NIH in Congress. “Researchers in the district need to make the connection between NIH funding and the extramural research being conducted at the institutions in the district, as well as the new diagnostics and treatments that are emerging for constituents.”
The FY2008 Defense appropriations bill signed by the President on November 13 (Public Law 110-116) continues eye and vision research’s eligibility for funding within the Department of Defense’s (DOD) Congressionally Directed Medical Research Program (CDMRP). Eye and vision research is one of 21 fields of research that can compete for funds within the CDMRP’s Peer Reviewed Medical Research Program (PRMRP), which was funded at $50 million.

“This is the third year that eye and vision research has been listed, which reflects both the applicability and importance of defense-related vision research,” said NAEVR’s James Jorkasky, who noted that 16 percent of all Iraq war injuries affect the eye, with optic nerve trauma the most severe. In its first year of listing (FY2006), the vision research community submitted 52 of the 651 total grant requests, or eight percent, and received five of the 48 awards, or ten percent, representing $4.8 million. Although eye and vision research was listed in FY2007, PRMRP funding was not included in the year-long Joint Funding Resolution due to jurisdictional issues, which have subsequently been resolved.

The bill also contained the Wounded Warriors Act’s $70 million funding for a variety of research and rehabilitation programs, including research on visually-related neurological conditions associated with Traumatic Brain Injury (TBI). NAEVR will track the stream through which these funds may be available, as well as those in the CDMRP/PRMRP programs, and report to the networks.

On November 7, prior to final passage, NAEVR commended the House and Senate Defense conferees for the inclusion of vision research and sent a letter of appreciation to House Defense Appropriations Subcommittee Ranking Member C.W. “Bill” Young (R-FL) and to Members who submitted letters of support, including Cong. James Walsh (R-NY), Cong. Pete Sessions (R-TX), and Cong. John Boozman (R-AR).

Vision Community Supports Military Eye Trauma Treatment Act

On October 29, under the auspices of the Congressional Vision Caucus, NAEVR network members American Academy of Ophthalmology, American Optometric Association, Blinded Veterans Association, and Prevent Blindness America joined NAEVR in supporting a Congressional briefing entitled Through the Eyes of a Soldier. The briefing, featuring representatives of the DOD and Department of Veterans Affairs (VA), was held to educate staff about the extent of eye injuries in Iraq and Afghanistan and to summarize provisions in the Military Eye Trauma Treatment Act (H.R. 3558/S. 1999) that would improve coordination of care between the DOD and VA. The legislation would create a Military Eye Injury Registry to track the diagnosis and treatment of combat-related injuries, as well as create a joint DOD/VA program to coordinate on all aspects of visual dysfunction related to TBI, including screening, diagnosis, rehabilitative management, and research.

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.
At an October 31 Congressional briefing sponsored by the Foundation Fighting Blindness (FFB) and AEVR, top leaders from the vision research community spoke about the critical need for research funding to eliminate retinal diseases that affect more than nine million Americans.

In his welcome, Cong. Pete Sessions (R-TX) stated that, “Today the message is very clear: There is much that can and must be done to overcome these blinding conditions. It is our responsibility through good public policy to recognize that we have the ability to find cures for these diseases.” Cong. Sessions, who has a teenage son affected by retinitis pigmentosa (RP), added, “When you have a 16-year old son who wants to be a physician and has a great life ahead of him, you’re crushed when you learn he is losing his eyesight to RP.” He also stated that it is in the public’s best interest to ensure that the best, most-promising research technologies are investigated and employed, including the potential of stem cell therapies for treating vision loss. “We need to find out what stem cells can do for us in order to make wise public policy,” he said.

Stephen Rose, Ph.D., Chief Research Officer for FFB, which is the largest source of non-governmental funding for retinal degenerative research in the world, and NEI Director Paul Sieving discussed why partnerships between government and the private sector are beneficial to advancing research. For example, both Dr. Rose and Dr. Sieving noted that an FFB-NEI partnership helped to advance a treatment called Encapsulated Cell Technology (ECT), which is now in Phase II/III studies across the country for treatment of a variety of retinal degenerative conditions, including RP, the “dry” form of AMD, and Usher syndrome (combined blindness and deafness). “In an FFB-funded lab study, ECT showed promise for saving vision, so the NEI subsequently conducted Phase I safety studies of it,” said Dr. Rose. During the Phase I trial, ECT saved and in some cases restored vision. More than 150 people are now enrolled in the Phase II/III studies, which are funded in part by FFB.

Dr. Sieving, who showed the tiny ECT to attendees added, “What is learned in treating the eye may translate into benefits for treating other neurodegenerative diseases such as ALS, Parkinson’s disease, and Alzheimer’s disease. One of the advantages of working in the eye is that it is easier to get the device into the eye than into the skull.” In addressing the genetic basis of eye disease, Dr. Sieving noted that of the 25,000 genes in the body, about 10 percent or 2,000 of those have been cloned, and about one-quarter of these have been found to cause eye disease.

Though many retinal diseases are considered to be rare or “orphan”—meaning that they affect less than 200,000 people—research for orphan diseases is a critical public health issue. Collectively, 25 million Americans are affected by some orphan disease. Dr. Sieving said that, over time, many common conditions will be subdivided into smaller, genetically related groups. “Heart disease, diabetes, and cancer are all genetically driven diseases. We are finding that all common diseases in fact splinter into groups of rare genetic diseases, and we are beginning to treat these conditions based on their genetic profile.”

Dr. Rose remarked that it is an extraordinarily promising time in vision research because of the numerous human studies emerging and underway to save and restore vision. He said, “Ten years ago, a person with a retinal degenerative disease was told ‘There’s nothing we can do for you, go home and learn Braille, you will go blind.’ Today, thanks to funding from the NEI and FFB, there are clinical trials underway to eradicate these diseases. There is a lot of hope.”
ARVO and NAEVR Develop New Global Tools to Assess/Advocate on Vision Loss

On September 17 in Vancouver, Canada, members of the Association for Research in Vision and Ophthalmology (ARVO) and guests, including NAEVR’s James Jorkasky, met to develop a methodological model to assess the costs of vision loss and impairment regionally, nationally, and worldwide. This international group included representatives from the World Health Organization (WHO), blindness prevention organizations, and health economics researchers. Participants considered epidemiological evidence, direct medical costs, societal costs, productivity, and impact on well-being. Since most participants had published papers on the burden of vision loss in their own countries, they offered useful and varied considerations.

ARVO members Kevin Frick, Ph.D., Paul Lee, M.D., J.D., and Hugh Taylor, M.D., will coordinate follow-up activities, including a paper on the group’s recommendations and a course and symposium at the 2008 ARVO Annual Meeting. At the meeting, NAEVR will also release an International Advocacy Handbook and an accompanying section of the ARVO Web site that will provide resources to enable researchers to advocate for increased vision funding from governmental agencies and private funding sources.

Dr. Rao Receives 2007 Pisart Vision Award

At a November 15 dinner, Gullapalli Rao, M.D. of the Prasad and Hyderabad Eye Institutes in India, received the 2007 Pisart Award in recognition of his contribution to the prevention, cure, or treatment of severe vision impairment or blindness. Dr. Rao (left) is joined by Lighthouse International President and CEO Tara Cortes, Ph.D., R.N., and Board member Donald D’Amico, M.D. (Weill Cornell Medical College). NAEVR’s James Jorkasky serves as a Pisart jurist.