



**NAEVR**

National Alliance For  
Eye And Vision Research

*Serving as Friends of the National Eye Institute*

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**WRITTEN TESTIMONY IN SUPPORT OF INCREASED  
FUNDING FOR THE NATIONAL INSTITUTES OF HEALTH (NIH)  
AND THE NATIONAL EYE INSTITUTE (NEI)  
LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED  
AGENCIES SUBCOMMITTEE OF THE U.S. HOUSE OF REPRESENTATIVES  
COMMITTEE ON APPROPRIATIONS**

**April 6, 2009**

**EXECUTIVE SUMMARY**

**NAEVR requests a Fiscal Year (FY) 2010 NIH funding increase of at least seven percent, to a level of \$32.4 billion, which represents a modest three percent increase plus the biomedical inflation rate, estimated at 3.8 percent in FY2009. This increase is necessary to keep pace with inflation and rebuild the base, since NIH has lost 14% of its purchasing power during the past six funding cycles.** NAEVR commends the Congressional leadership's actions in FY2008 and 2009 to increase NIH funding, including the \$150 million in the FY2008 supplemental dedicated to investigator-initiated grants, the \$10.4 billion in two-year stimulative NIH funding within the American Recovery and Reinvestment Act (ARRA), and the final FY2009 appropriations inflationary increase of 3.2 percent. However, NIH needs sustained and predictable funding to rebuild its base and support multi-year investigator-initiated research, which is the cornerstone of the biomedical enterprise. Annual increases of at least seven percent put NIH on a pathway to budget-doubling within the next ten years. Secure and consistent funding for biomedical research is integral to the nation's economic and global competitiveness. NIH is a world-leading institution that must be adequately funded so that its research can reduce healthcare costs, increase productivity, and save and improve the quality of lives.

**NAEVR requests that Congress make vision health a top priority by increasing NEI funding by at least 7 percent, to a level of \$736 million, in this year that NEI celebrates its 40<sup>th</sup> anniversary. Over the past six funding cycles, NEI lost 18 percent of its purchasing power.** Despite funding challenges, NEI has maintained its impressive record of breakthroughs in basic and clinical research that have resulted in treatments and therapies to save and restore vision and prevent eye disease. NEI will be challenged further, as 2010 begins the decade in which more than half of the 78 million Baby Boomers will turn 65 and be at greatest risk for developing aging eye disease. Adequately funding the NEI is a cost-effective investment in our nation's health, as it can delay, save, and prevent expenditures, especially to the Medicare and Medicaid programs.

**FY2010 FUNDING AT \$736 MILLION ENABLES NEI TO EXPAND ITS IMPRESSIVE RECORD OF BASIC AND CLINICAL COLLABORATIVE RESEARCH THAT HAS RESULTED IN TREATMENTS AND THERAPIES TO SAVE AND RESTORE VISION AND PREVENT EYE DISEASE**

Immediately after President Obama signed the ARRA, Acting NIH Director Raynard Kington, M.D., Ph.D., identified the major health challenges that NIH faces, especially when describing the potential emphasis of the newly created “Challenge Grants”: the shift from acute to chronic diseases, and the attendant co-morbid conditions; an aging population; health disparities; and prevention. Since its creation 40 years ago, the NEI has been directly addressing these issues as they apply to vision and has been a leader in what former NIH Director Elias Zerhouni, M.D., has described as the 21<sup>st</sup> century paradigm for healthcare research and clinical practice, or “P4 Medicine”— that which is predictive, preemptive, personalized, and participatory.

NEI continues to be a leader in basic research—especially that which elucidates the genetic basis of ocular disease—and in translational research, as those gene discoveries can lead to development of diagnostics and treatments. NEI Director Paul Sieving, M.D., Ph.D., has reported that one-quarter of all genes identified to date through NEI’s collaboration with the National Human Genome Research Institute (NHGRI) are associated with eye disease/visual impairment. Recent examples include:

- In 2005, NEI reported that gene variants of Complement Factor H (CFH), the protein product of which is engaged in the control of the body’s immune response, are associated with increased risk of developing age-related macular degeneration (AMD), the leading cause of vision loss. NEI-funded researchers are now working on potential therapies, including the manufacture and use of a 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. These same researchers are also conducting research in individuals with liver transplants, since most CFH is made in the liver, to see what happens when an individual receives a different form of CHF. The researchers hope that these studies 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. Researchers have also reported 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.
- In addition to gene-based approaches to develop AMD treatments, NEI’s collaborative research into factors that inhibit new blood vessel growth has in part fostered the first generation of ophthalmic drugs approved by the Food and Drug Administration (FDA) to inhibit abnormal blood vessel growth in “wet” AMD, thereby stabilizing and restoring vision, and NEI’s Diabetic Retinopathy Clinical Research (DRCR) Network is further evaluating these drugs for treatment of

macular edema associated with diabetic retinopathy (DR). In March 2008, NEI-funded researchers announced that damage from both AMD and DR was prevented and even reversed when the protein Robo4 was activated in mouse models that simulate the two diseases. Robo4 treated and prevented the diseases by inhibiting abnormal blood vessel growth and by stabilizing blood vessels to prevent leakage. Since this research into the “Robo4 Pathway” used animal models associated with these diseases that are already used in drug development, the time required to test this approach in humans could be shortened, expediting approvals for new therapies

- In late April 2008, researchers funded by the NEI and private funding organization Foundation Fighting Blindness reported on their use of gene therapy to restore vision in young adults who were virtually blind from a severe form of the neurodegenerative disease Retinitis Pigmentosa, known as Leber Congenital Amaurosis (LCA). Seven years earlier, the researchers shared on Capitol Hill results of a preclinical study of the same gene therapy, which at the time was successfully giving vision to dogs born blind with LCA. The subsequent human gene therapy trial validated the process of putting genes in the body to restore vision. Although the primary goal of the Phase I study was to ensure patient safety, the researchers reported through both objective and subjective testing that the patients were able to read several lines on an eye chart, had better peripheral vision, and better eyesight in dimly lit settings. In further research, the investigators will treat LCA patients as young as eight years old, since they believe the most dramatic results will be seen in young children
- In late 2008, NEI initiated its new NEI Glaucoma Human genetics collaBORation, known as NEIGHBOR, through which seven U.S. research teams will lead genetic studies of the disease. Glaucoma is called the “stealth robber of vision” as it often has no symptoms until vision is lost, and anywhere from 50-75 percent of individuals with it are undiagnosed. It is also the leading cause of preventable vision loss in African American and Hispanic populations. Previously, in a March 13-14, 2008, joint *Glaucoma Endpoints* meeting with the FDA, NEI-funded researchers acknowledged that glaucoma is a complex, neurodegenerative disease in which detectable changes within the eye may not progress linearly or in concert with functional changes, that is, vision loss. All of these factors emphasize the vital nature of determining the genetic basis of this disease.

### **FY2010 FUNDING AT \$736 MILLION ENABLES NEI TO FULLY FUND NEW INITIATIVES THAT MORE FULLY CHARACTERIZE EYE DISEASE**

NEI has been a leader in collaborative research, the use of networks to study diagnostics and treatments and their use in clinical settings, and in ocular epidemiology to characterize the nature and frequency of eye disease in diverse populations to better manage public health. In FY2008, NEI reported on/launched the initial phase of three important new programs to characterize eye disease that will require adequate future funding.

- In early 2009, the NEI and the National Aeronautics and Space Administration (NASA) reported on the use of a compact fiber optic probe developed for the space program that has proven valuable as the first non-invasive early detection device for cataracts, the leading cause of vision loss worldwide. Using a laser light technique called dynamic light scattering (DLS), which was developed to analyze the growth of protein crystals in a zero-gravity environment, the probe measures the amount of light scattering by an anti-cataract protein called alpha-crystallin. This protein binds to other proteins when they become damaged, thus preventing them from bunching together to form a cataract. Since humans are born with a fixed amount of alpha-crystallin, if it is depleted due to radiation exposure, smoking, diabetes, or other causes, a cataract can result. The probe senses protein damage due to oxidative stress, a key process involved in many medical conditions including age-related cataract and diabetes, as well as Alzheimer's and Parkinson's disease
- In late 2008, NEI launched a new research network, the Neuro-Ophthalmology Research Disease Investigator Consortium, or NORDIC. There is a broad spectrum of neuro-ophthalmic disorders that collectively affect millions of people. However, since many of the visual disorders associated with other systemic and neurologic conditions fit the definition as "rare" diseases, they have not been adequately studied. NORDIC will initially lead multi-site observational and treatment trials, involving nearly 200 community and academic practitioners, to address the risks, diagnosis, and treatment of two such "rare" diseases: idiopathic intracranial hypertension (visual dysfunction due to increased intracranial pressure) and thyroid eye disease (also called Graves' disease, in which muscles of the eye enlarge and cause bulging of the eyes, retraction of the lids, double vision, decreased vision, and irritation). The network's structure enables it to study additional conditions. The NEI and NORDIC's Principal Investigator have already begun coordinating with the Department of Defense's (DOD) newly established Vision Center of Excellence (VCE) about the applicability of NORDIC research to combat-related eye injuries, especially those associated with Traumatic Brain Injury (TBI), which is being experienced in record numbers in Iraq and Afghanistan.
- There is currently almost no information on the prevalence, risk factors, and genetic determinants in Asian Americans—one of the fastest growing racial groups in the US. Studies from East Asia have suggested that Asians have a spectrum of eye diseases different from that of White Americans, African Americans, and Hispanics. In late 2008, NEI launched the Chinese American Eye Study to characterize the extent of eye disease in Chinese Americans, the largest Asian sub-group in the US. Participants 50 years and older will be evaluated for blindness, visual impairment, and eye disease. The observations will add to the expanding body of knowledge about aging eye disease. Past NEI-funded studies have yielded dramatic findings—the Ocular Hypertension Treatment Study (OHTS) reported that African Americans have a four-fold greater risk of developing glaucoma than White Americans, and the Los Angeles

Latino Eye Study (LALES) found increased incidence of glaucoma and diabetic retinopathy in individuals of Mexican descent. All of these studies assist in developing public health policy, especially in relation to education, prevention, rehabilitation, and eye care services.

## **VISION IMPAIRMENT/EYE DISEASE IS A MAJOR PUBLIC HEALTH PROBLEM THAT INCREASES HEALTHCARE COSTS, REDUCES PRODUCTIVITY, AND DIMINISHES QUALITY OF LIFE**

The NEI estimates that more than 38 million Americans age 40 and older experience blindness, low vision, or an age-related eye disease such as AMD, glaucoma, diabetic retinopathy, or cataracts. This is expected to grow to more than 50 million Americans by year 2020. The economic and societal impact of eye disease is increasing not only due to the aging population, but to its disproportionate incidence in minority populations and as a co-morbid condition of chronic disease, such as diabetes.

Although the NEI estimates that the current annual cost of vision impairment and eye disease to the US is \$68 billion, this number does not fully quantify the impact of direct healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. The continuum of vision loss presents a major public health problem and financial challenge to the public and private sectors.

In public opinion polls over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer. As recently as March 2008, the NEI's *Survey of Public Knowledge, Attitudes, and Practices Related to Eye Health and Disease* reported that 71 percent of respondents indicated that a loss of their eyesight would rate as a "10" on a scale of 1 to 10, meaning that it would have the greatest impact on their day-to-day life.

In 2009, the NEI will celebrate its 40<sup>th</sup> anniversary as the NIH Institute that leads the nation's commitment to save and restore vision. During the next decade, more than half of the 78 million Baby Boomers will celebrate their 65th birthday and be at greatest risk for developing aging eye disease. As a result, sustained, adequate federal funding for the NEI is an especially vital investment in the health, and vision health, of our nation as the treatments and therapies emerging from research can preserve and restore vision. Adequately funding the NEI can also delay, save, and prevent health expenditures, especially those associated with the Medicare and Medicaid programs, and is, therefore, a cost-effective investment.

**NAEVR urges FY2010 NIH and NEI funding at \$32.4 billion and \$736 million, respectively, reflecting an at-least seven percent increase over FY2009.**

### **ABOUT NAEVR**

The National Alliance for Eye and Vision Research (NAEVR) is a 501(c)4 non-profit advocacy coalition comprised of 55 professional, consumer, and industry organizations involved in eye and vision research. Visit the Web site at [www.eyersearch.org](http://www.eyersearch.org).