



**NAEVR**

National Alliance For  
Eye And Vision Research

*Serving as Friends of the National Eye Institute*

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**[About NAEVR and List of Members on Last Page]**

**NAEVR 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**

**March 26, 2008**

**EXECUTIVE SUMMARY**

**NAEVR requests Fiscal Year (FY) 2009 NIH funding at \$31 billion, or a 6.6 percent increase over FY2008, to balance the biomedical inflation rate of 3.6 percent and to begin to restore NIH's purchasing power.** Although NAEVR commends the Congressional leadership's actions to significantly increase NIH funding above the Administration's budget request in FY2008 appropriations, the net 0.46 percent increase meant a net loss in NIH purchasing power. For five consecutive years, NIH funding has failed to keep pace with the biomedical inflation rate and NIH has lost more than 10 percent of its purchasing power. The Administration's FY2009 budget, which proposes to freeze the NIH budget at the FY2008 level, threatens to further hinder the momentum of discovery leading to treatments that are saving lives—as well as restoring the quality of life—and maintaining the nation's competitive edge in medical research. Secure and consistent funding for health and scientific research must be part of the nation's long-term strategies for sustained economic growth. NIH is a world-leading institution and must be adequately funded so that its research can reduce healthcare costs, increase productivity, improve quality of life, and ensure our nation's global competitiveness.

**NAEVR requests that Congress make vision health a top priority by funding the NEI at \$711 million in FY2009, or a 6.6 percent increase over FY2008.** The NEI was flat funded in FY2008, meaning that over the past five funding cycles it has lost 18 percent of its purchasing power, reducing the number of grants by 160, which threatens its impressive record of breakthroughs in basic and clinical research that have resulted in treatments and therapies to save and restore vision, as well as to prevent eye disease. Vision impairment/eye disease is a growing, major public health problem that disproportionately affects the aging and minority populations, costing the United States \$68 billion annually in direct and societal costs, let alone reduced independence and quality of life. 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.

**FY2009 NEI FUNDING AT \$711 MILLION ENABLES IT TO LEAD COLLABORATIVE RESEARCH REFLECTING THE NEW PARADIGM OF 21<sup>ST</sup> CENTURY HEALTHCARE THAT IS PREDICTIVE, PREEMPTIVE, PERSONALIZED, AND PARTICIPATORY**

NEI research addresses the NIH's overall major health challenges as set forth by NIH Director Elias Zerhouni, M.D.: an aging population; health disparities; the shift from acute to chronic diseases; and the co-morbid conditions associated with chronic diseases (e.g., diabetic retinopathy as a result of the epidemic of diabetes). NEI research responds to Dr. Zerhouni's vision for NIH research that is collaborative and cost-effective and meets the 21<sup>st</sup> century "P4Medicine" paradigm of predictive, preemptive, personalized, and participatory research and clinical practice. For example:

- One-quarter of all genes identified to date through NEI's collaboration with the Human Genome Project is associated with eye diseases, such as age-related macular degeneration (AMD), retinitis pigmentosa (RP), and glaucoma. NEI-funded researchers have discovered gene variants strongly associated with an individual's risk of developing AMD, the leading cause of blindness in older Americans. These variants, which are responsible for about 60 percent of the cases of AMD, are associated with the body's inflammatory response and may relate to other inflammation-associated diseases, such as Alzheimer's and Parkinson's disease. As NEI Director Dr. Paul Sieving has stated, "One of the important stories during the next decade will be how Alzheimer's disease and macular degeneration fit together."
- NEI is currently conducting the second phase of its Age-Related Eye Disease Study (AREDS), which follows up on initial findings that high levels of dietary zinc and antioxidant vitamins (Vitamins C, E and beta-carotene) are effective in reducing vision loss in people at high risk for developing advanced AMD—by a magnitude of 25 percent. The cost-effectiveness and public health consequences of this research are significant: 1.3 million Americans would develop advanced AMD if no treatment was given, and if all individuals at risk availed themselves of the AREDS supplement regimen, more than 300,000 of them would avoid advanced AMD and any associated vision loss during the next five years.
- NEI's collaborative research into factors that promote or inhibit new blood vessel growth has resulted in 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.

These examples primarily reflect NEI's trans-Institute research within NIH. The NEI has also collaborated with other Department of Health and Human Services (DHHS) agencies, specifically to share the results of its basic and clinical research which may impact the product approval and reimbursement processes. For example:

- In a March 2008 meeting, NEI collaborated with FDA's Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) to consider the appropriateness of new clinical endpoints in glaucoma clinical trials. Advances in visual imaging technologies—many of which emerged from collaborative research between the NEI and the National Institute of Biomedical Imaging and Bioengineering (NIBIB)—have enabled researchers to better detect structural changes in the nerve fiber layer of the retina and contours of the optic nerve head. These structural changes could potentially be used as a direct endpoint in a clinical trial, rather than a surrogate endpoint such as elevated intra-ocular pressure, when appropriately correlated to functional changes in vision to assure clinical significance of a new therapy. This meeting, which followed a November 2006 joint NEI-FDA/CDER meeting on clinical endpoints in AMD and DR clinical trials, represents the cost-effectiveness of NEI funding, as its research results may ultimately shorten the time and cost associated with clinical trials, as well as facilitate the approval of new diagnostics and therapies for patients.
- In collaboration with the Centers for Medicare and Medicaid Services (CMS), the NEI has launched the *Comparison of AMD Treatments Trial (CATT)*, which is a comparative effectiveness study of the two drugs that are used to block growth of the abnormal blood vessels in patients with the “wet” form of AMD. NEI's collaboration with CMS could guide clinical practice and reduce costs to the Medicare program.

### **THE NEI'S DIMINISHED PURCHASING POWER JEOPARDIZES ITS ABILITY TO FOLLOW UP ON RESEARCH BREAKTHROUGHS FROM PAST INVESTMENT**

The NEI must be adequately funded to initiate promising new research, to pursue results that have emerged from previous breakthroughs, and to offer up its “fair share” of funding in its extensive collaborations. The number of NEI grants has declined by 160 over the past five years, from 1,214 in FY2004 to 1,054 in FY2008, representing myriad “lost opportunities”—any one of which could have been the key to curing eye disease or restoring vision. Examples of such lost opportunities include:

- Ocular gene therapy holds great promise, especially for retinal degenerative diseases in which nearly 200 gene defects have been implicated. Investigators supported by the NEI and private-funding organization Foundation Fighting Blindness (FFB) have begun human clinical trials of a gene therapy to treat Leber

Congenital Amaurosis (LCA), a rapid retinal degeneration that blinds infants in the first year of life. Previous research has restored vision in dogs with LCA, and the results of the human clinical trials are forthcoming. Although the NEI could expand this program to target more diseases, current budget realities limit further research.

- Promising protocols proposed within the Diabetic Retinopathy Clinical Research Network will not be funded. The DRCR Network is a large, multi-center study that engages ophthalmologists and optometrists, many in community health centers, in basic and clinical research into diabetic eye disease. Past NEI diabetes networks developed laser treatments for DR that save \$1.6 billion annually in federal disability payments.
- NEI funding for new epidemiology studies has already become limited, which jeopardizes future research into identifying the basis and progression of eye disease in additional ethnic populations, such as Asian and Native Americans. Past NEI studies have identified a three-fold greater risk of glaucoma in African Americans, as well as glaucoma being the leading cause of irreversible vision loss in African Americans and Hispanics.
- NEI will not be able to fund proposed new Clinical Research Networks for AMD and for neuro-ophthalmic disorders. The latter could assist in understanding visual disorders associated with Traumatic Brain Injuries (TBI), especially those currently occurring in record numbers by soldiers in Iraq and Afghanistan.

In addition, NEI research into other significant eye disease programs such as cataract will be threatened, along with quality of life research programs into low vision and chronic dry eye. This occurs at a time when the US Census cites significant demographic trends that will increase the public health problem of vision impairment and eye disease, such as the first wave of 78 million Baby Boomers celebrating their 65th birthday in 2010, with about 10,000 Americans turning 65 each day for 18 years afterward.

**VISION IMPAIRMENT/EYE DISEASE IS A MAJOR PUBLIC HEALTH PROBLEM THAT IS INCREASING HEALTHCARE COSTS, REDUCING PRODUCTIVITY, AND DIMINISHING QUALITY OF LIFE**

The 2000 US Census reported that more than 119 million people in the United States were age 40 or older, which is the population most at risk for an age-related eye disease. The NEI estimates that, currently, 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. As a result, federal funding for the NEI is a 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 delay, save, and prevent expenditures, especially those associated with the Medicare and Medicaid programs, and is, therefore, a cost-effective investment.

**NAEVR urges FY2009 NIH and NEI funding at \$31 billion and \$711 million, respectively.**

**ABOUT NAEVR**

Founded in 1997, NAEVR is a non-profit advocacy organization comprised of a coalition of more than 50 professional, consumer, and industry organizations (see list below) involved in eye and vision research. NAEVR's goal is to achieve the best vision for all Americans through advocacy and public education about the value and cost-effectiveness of eye and vision research sponsored by the NIH, NEI, and other federal research entities.

Advanced Medical Optics	Juvenile Diabetes Research Foundation Intl
Alcon Laboratories, Inc.	Lighthouse International
Allergan, Inc.	Lions Clubs Intl. Foundation
AMD Alliance International	Macular Degeneration Partnership
American Academy of Ophthalmology	Novartis
American Academy of Optometry	Ocular Microbiology and Immunology Group
American Association for Pediatric Ophthalmology and Strabismus	Pfizer Inc
American Association of Ophthalmic Pathologists	Prevent Blindness America
American Glaucoma Society	Prevention of Blindness Society of of Metropolitan Washington
American Ophthalmological Society	Research to Prevent Blindness
American Optometric Association	Santen, Inc.
American Society of Cataract and Refractive Surgery	Second Sight
American Society of Retina Specialists	Sjogren's Syndrome Foundation
American Uveitis Society	Tear Film and Ocular Surface Society
Association for Research in Vision and Ophthalmology	The Cornea Society
Association of Schools and Colleges of Optometry	The Glaucoma Foundation
Association of University Professors of Ophthalmology	The Macula Society
Association of Vision Science Librarians	The Retina Society
Bausch & Lomb	Vision Council of America
Blinded Veterans Association	Vision Share, The Consortium of Eye Banks
Discovery Eye Foundation	Vistakon, Johnson & Johnson Vision Care, Inc.
Eye Bank Association of America	Women in Ophthalmology
EyeSight Foundation of Alabama	Women's Eye Health Task Force
Fight for Sight	
Foundation Fighting Blindness	
Genentech, Inc.	
Glaucoma Research Foundation	
Inspire Pharmaceuticals, Inc	
ISTA Pharmaceuticals, Inc	