



NAEVR

National Alliance For
Eye And Vision Research

Serving as Friends of the National Eye Institute

12300 Twinbrook Parkway
Suite 250, Rockville MD 20852
240-221-2905 (PH); 240-221-0370 (FAX)
jamesi@eyerresearch.org
www.eyerresearch.org

(About NAEVR and List of Members at www.eyerresearch.org)

**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. SENATE
COMMITTEE ON APPROPRIATIONS**

April 23, 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 21st 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 21st 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 disease, 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, 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.
- 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. NEI estimates that 1.3 million Americans would develop advanced AMD if no treatment was given, and if all individuals at risk engaged in 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 "Robo4 Pathway" research used animal models from 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 drug and device Centers 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 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 and facilitate approval of new diagnostics/therapies.
- In collaboration with the Centers for Medicare and Medicaid Services (CMS), NEI has launched the *Comparison of AMD Treatments Trial (CATT)*, a comparative effectiveness study of the two drugs used to block growth of 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

Congress must adequately fund NEI so it can initiate promising new research, pursue results that have emerged from previous breakthroughs, and 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 for retinal degenerative diseases, in which nearly 200 gene defects have been implicated. Investigators supported by 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. Past NEI diabetes networks developed laser treatments for DR that save \$1.6 billion annually in federal disability payments.

- NEI funding for epidemiological studies is already limited, which jeopardizes future research into the basis/progression of eye disease in additional ethnic populations, such as Asian and Native Americans. Past NEI studies identified a three-fold greater risk of glaucoma in African Americans and glaucoma as 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 being incurred in record numbers by soldiers in Iraq and Afghanistan.

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.

EYE DISEASE IS A MAJOR PUBLIC HEALTH PROBLEM INCREASING HEALTH 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—the population most at risk for an age-related eye disease. The NEI estimates that more than 38 million Americans age 40 and older currently 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. Although the current annual cost of vision impairment and eye disease to the US is \$68 billion, it does not fully quantify the impact of direct healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. This 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 and cost-effective investment in the health, and vision health, of our nation as the treatments and therapies emerging from research can preserve and restore vision.

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