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for EYE and
VISION
RESEARCH

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Vision Share,
The Consortium of Eye Banks
Women in Ophthalmology

**STATEMENT OF
NAEVR PRESIDENT STEPHEN J. RYAN, M.D.
AND
NAEVR WRITTEN TESTIMONY IN SUPPORT
OF INCREASED FY2006 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 6, 2005
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STATEMENT OF NAEVR PRESIDENT STEPHEN J. RYAN, M.D.

The National Alliance for Eye and Vision Research (NAEVR) is pleased to submit the attached written testimony to the file of the April 6, 2005, hearing of the Labor, Health and Human Services, Education and Related Agencies Subcommittee of the Senate Appropriations Committee.

NAEVR, on behalf of the nearly 50 professional, consumer and industry member organizations representing the eye and vision research community, recognizes the valuable contribution that the National Institutes of Health (NIH) has made to medical research, generally, and the National Eye Institute (NEI) to eye and vision research, specifically. NAEVR strongly supported Congress' bipartisan doubling of the NIH budget from Fiscal Year (FY) 1998 to FY2003.

NAEVR requests FY2006 NIH Funding at \$30 billion, or a 6 percent increase over FY2005, to maintain the momentum of discovery. NAEVR commends Dr. Zerhouni for fostering collaborative, cost-effective research through such initiatives as the *NIH Roadmap for Medical Research* and the trans-Institute *NIH Neuroscience Blueprint*. However, his efforts to maximize the return on research dollars are jeopardized by the proposed FY2006 funding increase of less than 1 percent, which does not keep pace with the biomedical inflation rate. Congress should ensure that NIH's gains are not eroded.

NAEVR requests that Congress make vision health a "top priority" among many priorities by funding the NEI at \$711 million in FY2006, or a 6 percent increase over FY2005. This "Citizens Budget" represents the eye and vision research community's judgment as that necessary to advance NEI's basic and clinical research that result in treatments and therapies to prevent eye disease and restore vision. Congress should adequately fund NEI in FY2006 because:

- Eye and vision research responds to the nation's top public health challenges of an aging population, chronic diseases, health disparities, emerging diseases and biodefense.
- The eye is a unique biological system offering exceptional experimental advantages in which to conduct genetic, neuroscience and cellular mechanism research.
- Vision impairment and eye disease is a major public health problem that is growing and which disproportionately affects the aging and minority populations. By 2020, more than 50 million Americans will experience blindness, low vision or age-related eye disease unless NEI research can result in treatments and therapies to reverse this trend.
- The annual economic and societal cost of vision impairment and eye disease of \$68 billion in the United States is significant and growing. 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.
- Past NEI-funded basic and translational research is resulting in treatments and therapies to slow the progression of vision loss and restore vision.

In summary, NAEVR supports FY2006 NIH funding at \$30 billion and NEI funding at \$711 million. NEI's research, which results in therapies that reduce healthcare costs and returns individuals to independent and productive roles in society, is a cost-effective investment in maintaining the momentum of discovery and vision health for all Americans.

**NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH (NAEVR)
WRITTEN TESTIMONY IN SUPPORT OF INCREASED FY2006 FUNDING
FOR THE NATIONAL INSTITUTES OF HEALTH (NIH)
AND THE NATIONAL EYE INSTITUTE (NEI)**

The National Alliance for Eye and Vision Research (NAEVR) is pleased to submit this written testimony to the file of the April 6, 2005, hearings of the Labor, Health and Human Services, Education and Related Agencies Subcommittee of the Senate Appropriations Committee.

ABOUT NAEVR

Founded in 1997, NAEVR is a non-profit advocacy organization comprised of 50 professional, consumer and industry organizations (see list on cover sheet) 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 National Institutes of Health (NIH), the National Eye Institute (NEI) and other federal research entities.

**NAEVR REQUESTS FY2006 NIH FUNDING AT \$30 BILLION TO
MAINTAIN THE MOMENTUM OF DISCOVERY**

Although NAEVR realizes that Congress faces an expanding set of challenges at home and abroad, we join the community of support for medical research in requesting Congress to fund the NIH at \$30 billion in FY2006, or a 6 percent increase over the FY2005 level, to maintain the momentum of discovery. NAEVR believes that the NIH has made tremendous contributions that have served to improve the quality of lives for millions of Americans and contain healthcare costs.

NAEVR commends Chairman Specter's leadership in introducing Senate Amendment 173 to the FY2006 Senate Budget Resolution that would add \$1.5 billion to the NIH beyond that proposed in the administration's budget, to a level of approximately \$30 billion. NAEVR also recognizes the leadership demonstrated by the full Senate in successfully passing the amendment and Senate Budget Resolution, and we strongly urge the Senate and House conferees to maintain this number in the conference bill.

Congress' past bipartisan leadership in doubling the NIH budget from FY1998 to FY2003 has had a profound impact on the health care of all Americans, in terms of earlier, more accurate diagnosis of disease; more targeted, effective treatment options; more comprehensive, cost-effective prevention strategies; and the transformation of acute diseases to chronic, manageable diseases. With this basis, NIH has plans to further transform how basic and clinical research is conducted through initiatives such as the *NIH Roadmap for Medical Research* (the NEI is a lead Institute on the *Nanomedicine* project) and *NIH Neuroscience Blueprint*, in which 15 Institutes are engaged, including the NEI.

NAEVR commends NIH Director Dr. Zerhouni for his leadership in eliminating roadblocks that prevent collaborative research and using NIH-directed dollars in a cost-effective manner. However, his efforts to maximize the return on medical research dollars can only go so far. For example, in the FY2006 funding process, NIH would need an increase of at least 3.5 percent just to keep pace with the Biomedical Research and Development Price Index (BRDPI). Since the FY2006 funding level in the administration's budget proposal would represent the third year in which the NIH would not keep pace with inflation, the gains realized from the past investment in the NIH will be jeopardized.

In summary, to ensure that NIH's momentum is not eroded further, and to continue the fight against diseases and disabilities that affect millions of Americans, NAEVR requests that Congress seek an NIH budget of at least \$30 billion in FY2006.

NAEVR REQUESTS FY2006 NEI FUNDING AT \$711 MILLION AS VISION HEALTH IS A "TOP PRIORITY" AMONG MANY PRIORITIES

NAEVR requests that Congress fund the NEI at \$711 million in FY2006, or a 6 percent increase over FY2005. This "Citizens Budget" for the NEI represents the eye and vision research community's judgment as the level necessary to advance the breakthroughs resulting from NEI's basic and clinical research that will result in treatments and therapies to prevent eye disease and restore vision.

In presenting this request, NAEVR asks Congress to make this nation's vision health a "top priority" among the many priorities it faces in the FY2006 funding cycle for the following reasons:

- Eye and vision research responds to the nation's top public health challenges and touches the lives of all Americans.
- The eye is a unique biological system offering exceptional experimental advantages in which to conduct genetic, neuroscience and cellular mechanism research.
- Vision impairment and eye disease is a major public health problem that is growing and which disproportionately affects the aging and minority populations.
- The economic and societal costs of vision impairment and eye disease are significant and growing; adequately funding the NEI is a cost-effective investment in our nation's health.
- Past NEI-funded basic and translational research is resulting in treatments and therapies to slow the progression of vision loss and restore vision.

EYE AND VISION RESEARCH RESPONDS TO THE NATION'S TOP PUBLIC HEALTH CHALLENGES AND TOUCHES THE LIVES OF ALL AMERICANS

Dr. Zerhouni has identified the NIH's top public health challenges as an aging population; chronic diseases; health disparities; emerging diseases (primarily co-morbidities); and biodefense. NEI is responding to all of these challenges as they relate to eye and vision research:

- Not only has the NEI sponsored studies to characterize the incidence of age-related eye diseases such as age-related macular degeneration (AMD), glaucoma, diabetic retinopathy and cataracts, it sponsors extensive research into the cause and potential prevention of and treatments for these chronic diseases.
- Working with the National Center on Minority Health and Health Disparities (NCMHD), the NEI has sponsored studies to characterize vision impairment and eye disease disparities to direct further research—whether into the underlying physiological cause and potential concomitant therapy, or to the socio-economic or access issues that may enable it to focus its public health education programs.
- NEI has taken its basic research on diabetic retinopathy, a co-morbidity of diabetes, and tested treatments through a Clinical Trials Network. This optimal example of translating basic

research “from bench to bedside” has resulted in treatments that are more than 95% effective and save the United States \$1.6 billion annually.

- Going beyond the traditional focus on battlefield visual acuity, NEI’s biodefense research has resulted in new therapies to treat infectious eye diseases and promote corneal healing.

While addressing the nation’s top public health challenges, NEI research also touches all Americans, whether directly or through loved ones. NEI research has the potential to ensure the best vision health of individuals at all stages of life—from newborns to the most elderly—thereby ensuring their independence, productivity and quality of life.

THE EYE IS A UNIQUE BIOLOGICAL SYSTEM OFFERING EXCEPTIONAL EXPERIMENTAL ADVANTAGES IN WHICH TO CONDUCT GENETIC, NEUROSCIENCE AND CELLULAR MECHANISM RESEARCH

As the entire medical research community gains a better understanding of the genetic basis of disease, the eye emerges as a unique biological system in which to study cellular mechanisms and pathways. The eye and vision community is at the forefront of genetic research, as the eye offers accessibility and a system in which one can measure the potential effect from a treatment. For example, NEI-sponsored researchers have recently announced the discovery of a gene strongly associated with a person’s risk of developing AMD, which is the leading cause of vision loss in older Americans. This may enable researchers to develop tests for the disease before symptoms begin to appear and when drug therapies might help slow its progress.

Since the retina is a direct outgrowth of the brain and nerve cells underlie the ability to process vision, the eye also serves as an important system in which to study neurodegenerative diseases. For example, NEI-funded researchers have recently announced the regeneration of the optic nerve in mice, which could potentially result in treatments for Americans blinded by glaucoma or other injuries that destroy the optic nerve, as well as for other Central Nervous System disorders.

VISION IMPAIRMENT AND EYE DISEASE IS A MAJOR PUBLIC HEALTH PROBLEM THAT DISPROPORTIONATELY AFFECTS THE AGING AND MINORITY POPULATIONS

Over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer in public opinion polls. In recent NEI-sponsored research, patients with advanced AMD equated that condition to the gravest chronic diseases. These societal implications of vision impairment and eye disease are important since, as of the year 2000 census, there were more than 119 million Americans age 40+ who are most at risk from age-related eye disease such as AMD, glaucoma, diabetic retinopathy and cataracts.

In 2004, an NEI-sponsored study reported that vision loss from eye diseases will increase as Americans age. Also in 2004, the NEI reported on an African American subset analysis in its Ocular Hypertension Treatment Study (OHTS) and initial findings from its Los Angeles Latino Eye Study (LALES), both of which were co-sponsored by the NCMHD. Combined, these three studies reported that:

- Blindness or low vision currently affects 3.3 million Americans age 40+, or one in 28, and is projected to reach 5.5 million by year 2020.
- Age-related eye diseases currently affect more than 35 million Americans age 40+, and include intermediate-to-advanced AMD, glaucoma, diabetic retinopathy and cataracts. This number is projected to increase to about 50 million by the year 2020.

- More than 1.8 million Americans currently have advanced AMD, and this number is expected to grow to 3 million by the year 2020. Another 7.3 million Americans currently have intermediate-stage AMD. Currently, 200,000 Americans each year develop advanced AMD, and this number is expected to double by 2020. Because AMD affects the part of the eye called the macula, which is necessary for central vision, it affects a person's ability to read and drive. This has an enormous impact on quality of life and independence for older Americans.
- Glaucoma, a chronic potentially blinding disease that requires life-long treatment to control it, currently affects 2.2 million Americans, with 3.3 million expected to develop it by the year 2020. Glaucoma is now the leading cause of blindness in the fast-growing Hispanic population age 65+. Glaucoma is almost three times as common in African Americans as in White Americans and is the leading cause of blindness in the African American population.
- Diabetic retinopathy is the leading cause of blindness in the industrialized world in people between ages 25 and 74. It currently affects 4.1 million Americans age 40+, or one out of 12 Americans with diabetes in that age group, and is expected to increase to 7.2 million by the year 2020. Although successfully treatable in more than 95% of cases, many people do not know they are diabetic until symptoms, such as vision loss, occur. And with estimates of 50 million Americans having diabetes by the year 2020 at a yearly cost of \$1 trillion, and one-third of all American children born in year 2000 developing it in their lifetimes, there will be increasing demand for research into new treatments and prevention therapies.
- Cataracts, which are the leading cause of low vision, currently affect nearly 20.5 million Americans age 65+, which is projected to increase to 30.1 million Americans by the year 2020. In the US, a cataract is widely treatable by removing the natural lens and implanting an intraocular lens (IOL). However, in the rest of the world, cataracts are the leading cause of blindness due to lack of access to adequate care.

The past investment in the NEI's basic research has yielded breakthrough discoveries in the potential cellular mechanisms that result in these diseases, and its clinical research has resulted in an array of treatments for these conditions. However, the expanding population at risk for eye and vision disease will demand new and more effective therapies that restore vision or ultimately prevent the onset of these diseases. Adequately funding the NEI now ensures that its basic and clinical research "in the pipeline" comes to fruition and can be responsive to this growing public health problem.

THE ECONOMIC AND SOCIETAL COSTS OF VISION IMPAIRMENT AND EYE DISEASE ARE SIGNIFICANT; FUNDING NEI IS A COST-EFFECTIVE INVESTMENT

Although the NEI estimates that the current annual cost of vision impairment and eye disease to the United States is \$68 billion, this number does not fully quantify the impact of lost productivity and diminished quality of life. And as noted above, this financial burden to both the public and private sector is expected to increase dramatically, primarily due to an aging population and the growing prevalence of eye diseases that result in vision loss.

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. For example:

- As previously cited, the NEI-sponsored Early Treatment Diabetic Retinopathy and Diabetic Retinopathy studies have saved as much as \$1.6 billion per year in costs of blindness and vision impairment and resulted in treatments that are more than 95% effective.
- NEI-funded researchers have developed treatments for Retinopathy of Prematurity (ROP), a blinding complication in premature babies. As a result, more than 1,500 infants born this year with the most serious form of this condition can experience sighted lives, which would have cost the government \$1 million in benefits and lost taxes over the lifetime of each child.
- Economists estimate that cataract surgery provided Americans over \$300 billion in benefits in 2003 alone.

Funding the NEI at \$711 million in FY2006 is a cost-effective investment, as it will directly save healthcare expenses and return individuals to productive roles in society.

PAST NEI-FUNDED RESEARCH IS RESULTING IN TREATMENTS AND THERAPIES TO SLOW THE PROGRESSION OF VISION LOSS AND RESTORE VISION

The NEI has an impressive record of accomplishment over the past five years, as documented in its *National Plan for Eye and Vision Research*. Some of the most exciting developments that have widespread implications for Americans of all ages and races include:

- NEI is conducting additional clinical trials on nutritional supplements that may slow the progression of AMD, following previous research demonstrating that zinc and three antioxidant vitamins are effective in reducing vision loss in people at high risk for developing advanced AMD.
- An NEI-sponsored study has found that eye injections of bone-marrow derived stem cells prevented vision loss in two rodent models of Retinitis Pigmentosa (RP), a family of eye diseases that cause vision loss. This study raises the possibility that patients could receive an injection of their own bone marrow stem cells to preserve central vision.
- NEI-supported investigators are moving closer to human clinical trials of a gene therapy to treat neurodegenerative eye diseases, including Leber Congenital Amaurosis (LCA), which is a rapid retinal degeneration that blinds infants in the first year of life. Previous research has restored vision in dogs with LCA. This gene therapy not only has direct implications for the 9 million Americans affected by AMD, RP, Usher Syndrome and the entire spectrum of retinal degenerative diseases, but can potentially lead to therapies for glaucoma, diabetic retinopathy and cataracts.

CONCLUSION

NAEVR supports FY2006 NIH funding at \$30 billion to ensure that our nation's medical research infrastructure can maintain its momentum of discovery. NAEVR also requests that Congress make our nation's vision health a "top priority" among many priorities by funding the NEI at \$711 million in FY2006. NEI-funded research results in therapies that reduce health expenses and return individuals to productive lives. It is a cost-effective investment in maintaining the momentum of discovery and vision health for all Americans.