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STATEMENT OF  
NAEVR PRESIDENT STEPHEN J. RYAN, M.D.  
AND  
NAEVR WRITTEN TESTIMONY IN SUPPORT  
OF INCREASED FY2005 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 21-22, 2004  
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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 21-22, 2004, hearing of the Labor, Health and Human Services, Education, and Related Agencies Subcommittee of the House Appropriations Committee.

NAEVR, on behalf of the more than 40 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 has strongly supported the doubling of the NIH budget from Fiscal Year (FY) 1998 to FY2003.

**NAEVR currently supports the Senate's efforts to increase the NIH budget by \$2 billion for a total of \$30 billion in FY2005.** NAEVR also supports the *NIH Roadmap for Medical Research* and commends NIH Director Dr. Zerhouni for fostering collaborative research that will result in cost-effective use of dollars. We are pleased with the NEI's involvement in the *Roadmap's* "Nanomedicine" and "Re-Engineering the Clinical Research Enterprise" Initiatives.

**NAEVR supports NEI funding of \$711 million in FY2005, which represents an 8% increase over FY2004.** NEI still lags behind the NIH overall and two-thirds of the other Institutes in terms of having its budget doubled since FY1998. On March 11, 2004, in introducing his amendment to increase NIH funding, Senate LHHS Subcommittee Chairman Specter specifically stated that, provided additional funding beyond that in the President's FY2005 budget request, the NIH [NEI] could launch an Age-related Macular Degeneration (AMD) Clinical Trials Network. Funding for projects such as these is vital, since:

**Eye and vision disease is now at epidemic proportions.** As of the year 2000 census, more than 119 million Americans age 40+ were at risk from age-related eye disease such as AMD, diabetic retinopathy, glaucoma, and cataracts. More than 35 million Americans age 40+ currently experience these diseases, with an expected 50 million by year 2020. A growing Hispanic and African American population is experiencing a disproportionate incidence of glaucoma and cataracts. And the epidemic of diabetes is significantly increasing the onset of diabetic retinopathy, the leading cause of blindness in individuals 25-74 in age. Conservatively stated, eye and vision impairment costs our country \$68 billion annually and growing, due to direct healthcare costs and lost productivity.

**Adequately funding NEI is a cost-effective investment.** NEI-sponsored research has resulted in effective treatments and therapies that reduce healthcare costs. NEI's Early Treatment Diabetic Retinopathy Clinical Trials Network, for example, has resulted in treatments that were 95% effective and save \$1.6 billion per year. Especially with an aging population, adequately funding eye and vision research now can delay, save, and prevent expenditures to the Medicare and Medicaid programs.

**Past NEI funding has successfully resulted in key basic and translational research findings that must be pursued in the future.** From slowing the progression of cataracts to using retinal implants to restore sight, and from controlling intraocular pressure in glaucoma to developing gene therapies, NEI-sponsored basic and translational research is culminating in treatments and therapies that restore vision and prevent the onset of disease.

**In summary, NAEVR supports FY2005 NIH funding at \$30 billion and NEI funding at \$711 million.** NEI-sponsored research, which results in therapies that reduce healthcare expenses and returns individuals to productive roles in society, is a cost-effective investment in maintaining the momentum of discovery and the ultimate vision health of all Americans.

**NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH (NAEVR)  
WRITTEN TESTIMONY IN SUPPORT OF INCREASED FY2005 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 21-22, 2004, hearings of the Labor, Health and Human Services, Education, and Related Agencies Subcommittee of the House Appropriations Committee.

**ABOUT NAEVR**

Founded in 1997, NAEVR is a non-profit advocacy organization comprised of a coalition of more than 40 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 SUPPORTS FY2005 NIH FUNDING AT \$30 BILLION TO  
MAINTAIN THE MOMENTUM OF DISCOVERY**

NAEVR believes that the NIH, generally, and the NEI, specifically, have made tremendous contributions to eye and vision research that have served to contain healthcare costs and improve the quality of life for millions of Americans. NAEVR is concerned about preserving the national commitment to medical research and, consequently, has strongly supported the doubling of the NIH budget that occurred from Fiscal Year (FY) 1998 to FY2003. NAEVR continues to support increases to the NIH budget that will serve to maintain the basic and translational research infrastructure and concomitant momentum of discovery. For example, the eye and vision research community recently supported Senate Amendment 2741, which resulted in an increase of \$2 billion for the NIH over FY2004, or a total of \$30 billion, in the FY2005 Senate Concurrent Budget Resolution. We strongly urge the Senate and House conferees to maintain this number in the conference bill.

Additionally, NAEVR strongly supports the *NIH Roadmap for Medical Research*. We commend NIH Director Dr. Zerhouni for his leadership in eliminating roadblocks that prevent collaborative research and result in cost-effective use of research dollars. We are especially pleased with the NEI's important role in the "Nanomedicine" and "Re-Engineering the Clinical Research Enterprise" Initiatives. NAEVR is encouraged by Dr. Zerhouni's support for the NEI and the opportunities he feels that vision scientists and clinical investigators in the NEI Intramural and Extramural programs (which engage the leading academic and medical centers throughout the United States) can play in *Roadmap* initiatives.

**NAEVR SUPPORTS FY2005 NEI FUNDING AT \$711 MILLION TO  
COMPLETE THE DOUBLING OF NEI'S BUDGET**

As the eye and vision research community supports overall NIH funding increases, it also requests that Congress completes the doubling of the NEI's budget—requiring funding of NEI at \$711 million in FY2005—which would bring the NEI into parity with the budget-doubling that has occurred at NIH overall and in two-thirds of the Institutes.

Despite its net budget increase to \$653 million in FY2004 appropriations, NEI still remains in the bottom one-third of all Institutes in terms of having its budget doubled. Its FY2004 budget level is 1.84 times its FY1998 budget of \$355 million, which is still only 92% of its budget-doubling goal of \$711 million dollars. The \$711 million budget goal reflects an 8% increase over FY2004, compared to the President's budget proposal of \$672 million in FY2005, or a 2.9% increase.

To demonstrate the importance of funding eye and vision research at \$711 million in FY2005, one need look no further than Senate LHHS Subcommittee Chairman Specter's own words in introducing Senate Amendment 2741 on the floor of the Senate on March 11. In detailing NIH's "phenomenal progress against the most deadly diseases," he acknowledged the development of treatments for "deafness and other communications disorders, including glaucoma and macular degeneration." And, in stating why an increase in NIH funding is necessary if it is to proceed with very important research, he specifically stated that, "without this funding, the NIH [NEI] cannot launch a clinical trials network to test new therapies for Age-related Macular Degeneration", which is the leading cause of blindness in Americans age 60+. This Clinical Trial Network would build upon the past NEI-sponsored Age-related Eye Diseases Study (AREDS), which demonstrated that high levels of antioxidant nutrients (vitamins C, E, and beta-carotene) and zinc significantly reduce the risk of advanced AMD and associated vision loss.

To highlight how important the AMD Clinical Trials Network could be, similar NEI-sponsored studies, including both the Early Treatment Diabetic Retinopathy Study and Diabetic Retinopathy Study, helped to determine the best treatment strategies through diabetes control and laser photocoagulation. As a result, these treatments that delay or prevent the development of diabetic retinopathy are more than 95% effective and save an estimated \$1.6 billion per year. Most importantly, they enable patients to lead fully productive lives. Diabetic retinopathy is a condition that, just a little over 30 years ago, was considered untreatable and resulted in blindness. In fact, it is now the leading cause of blindness (if not properly treated) in the industrialized world in people between the ages of 25 and 74.

This last example encapsulates all of the reasons that support fully funding the NEI at \$711 million in FY2005 and enabling it to proceed with key research projects:

- Eye and vision disease is now at epidemic proportions, due to demographics (e.g., an aging population and growth in minority populations) and the impact of other diseases (e.g., diabetes);
- Eye and vision research is cost-effective, as it delays, saves, and prevents expenses to the healthcare system and returns individuals to productive lives; and
- Past NEI funding has successfully resulted in key basic and translational research findings that must be pursued to maintain the momentum of discovery.

### **THE EPIDEMIC OF EYE AND VISION DISEASE**

NEI currently estimates the economic and societal cost of eye and vision impairment as \$68 billion annually in the United States. This financial burden to the US is expected to increase dramatically, primarily due to an aging population and the growing prevalence of diseases that result in vision loss. For example, as of the year 2000 census, more than 119 Americans age 40+ were at risk from age-related eye disease such as AMD, glaucoma, and cataracts, and this number is expected to increase dramatically by 2020 as the population ages.

In an NEI-sponsored study, the Eye Disease Prevalence Research Group (a consortium of principal investigators who have conducted population-based eye disease studies) has recently reported that vision loss from eye diseases will increase as Americans age. The study notes 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, diabetic retinopathy, glaucoma and cataracts. This number is projected to increase to about 50 million by the year 2020.
- AMD is the leading cause of blindness in Americans age 60+. Although more than 1.8 million Americans currently have advanced AMD, this number is expected to grow to 3 million by the year 2020. Nearly 7.3 million Americans currently have intermediate-stage AMD. 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, which has an enormous impact on the quality of life and independence for many older Americans.
- 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.
- 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, along with cataracts, is the leading cause of blindness in the African American population.
- 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.

Although past investment in the NEI has resulted in an array of treatments for many of these conditions, the expanding population at risk for eye and vision disease will demand new and more effective treatments and therapies that restore vision or prevent the onset of disease. Adequate funding of the NEI now ensures that its basic and translational research "in the pipeline" comes to fruition in the form of appropriate treatments and therapies.

#### **FUNDING NEI AT \$711 MILLION IN FY2005 IS A COST-EFFECTIVE INVESTMENT**

As noted in the previous section, eye and vision disease represents a significant and expanding burden to society, due to the direct costs of healthcare associated with these conditions and the potential onset of other diseases (e.g., depression and its physical and emotional consequences), as well as the indirect

costs associated with social support services and lost productivity. Especially with an aging population, adequately spending now on eye and vision research can delay, save, and prevent expenditures to the Medicare and Medicaid programs. As a result, funding eye and vision research at the NEI is a cost-effective investment.

Below appear a few examples of the cost-effectiveness of adequately investing in eye and vision research:

- 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 95% effective.
- The NEI-sponsored Cryotherapy for Retinopathy of Prematurity (ROP) Study demonstrated the effectiveness of cryotherapy in halting the progression of the abnormal proliferation of blood vessels in the back of the eyes of very premature infants. This treatment results in \$38 million to \$65 million in annual savings. Most importantly, the 3,000 infants affected each year with this condition and successfully treated can be expected to experience 70-80 years of full and productive “sighted” lives.
- A recent, preliminary NEI-sponsored clinical trial found that an investigational treatment for uveitis—an immune therapy drug called Daclizumab—has fewer side effects and improves quality of life for patients. Uveitis, a chronic inflammation of the eye, results in 10-15% of blindness cases annually, and current steroidal treatments suppress the immune system and create multiple side effects, diminishing the quality of life. This treatment will save in terms of preventing blindness, as well as costs associated with side effects and lost productivity.

As a result of NEI-sponsored research to directly save healthcare expenses and return individuals to productive roles in society, funding the NEI at \$711 million in FY2005 is a cost-effective investment.

### **NEI ACCOMPLISHMENTS OVER THE PAST FIVE YEARS ARE IMPRESSIVE BUT FUTURE RESEARCH OPPORTUNITIES REQUIRE ADEQUATE FUNDING**

The NEI has an impressive record of accomplishment over the past five years, as documented in its *National Plan for Eye and Vision Research*. From slowing the progression of cataracts to using retinal implants to restore sight, and from controlling intraocular pressure in glaucoma to developing gene therapies, NEI-sponsored basic and translational research is culminating in treatments that restore vision and prevent the onset of disease. Provided a funding level of \$711 million in FY2005, and an appropriate funding level in future years, the Institute will have the opportunity to build upon past basic and translational research findings and develop effective treatments and therapies that will create and sustain healthy and productive lives for all Americans.

### **CONCLUSION**

NAEVR supports FY2005 NIH funding at \$30 billion to ensure that our nation’s medical research infrastructure can maintain its momentum of discovery. NAEVR also urges FY2005 funding of the NEI at \$711 million to ensure that promising discoveries lead to effective treatments and therapies. NEI’s basic and translational research advances come at a time when eye disease—especially in the elder population—has become a fast-growing but little-known epidemic that threatens vision health, further strains already-tight federal resources, and jeopardizes the ability of Americans to lead full and productive lives.