



NATIONAL
ALLIANCE
for EYE and
VISION
RESEARCH

National Alliance for Eye and Vision Research Executive Summary Talking Points

NIH Reauthorization Legislation

Advanced Medical Optics
Alcon Laboratories, Inc.
Allergan, Inc
American Academy
of Ophthalmology
American Academy
of Optometry
American Optometric
Association
Association for Research in
Vision and Ophthalmology
Association of University
Professors of Ophthalmology
Bausch & Lomb
Foundation Fighting
Blindness
Novartis
Pfizer Inc
Vistakon, Johnson & Johnson
Vision Care, Inc.

Association of Schools
and Colleges of Optometry
Eli Lilly and Company
Eyeteq Pharmaceuticals, Inc.
Inspire Pharmaceuticals, Inc.
ISTA Pharmaceuticals, Inc.
Santen, Inc.
Second Sight

American Association of
Ophthalmic Pathologists
American Association for
Pediatric Ophthalmology
and Strabismus
American Glaucoma Society
American Ophthalmological
Society
American Society of Cataract
and Refractive Surgery
American Society of Retina Specialists
American Uveitis Society
AMD Alliance International
Eye Bank Association
of America
Fight for Sight
Glaucoma Research Foundation
Juvenile Diabetes Research
Foundation International
Lighthouse International
Lions International
National Vision Rehabilitation Association
Ocular Microbiology and
Immunology Group
Prevent Blindness America
Prevention of Blindness
Society of Metropolitan
Washington
PXE International
Research To Prevent Blindness
The Cornea Society
The Glaucoma Foundation
The Macula Society
The Retina Society
Vision Share,
The Consortium of Eye Banks
Women in Ophthalmology
Women's Eye Health Task Force

NAEVR commends the Energy and Commerce Committee for its leadership in examining ways to modernize NIH management to most effectively and efficiently use federal research dollars. In that regard:

NAEVR supports changes that increase NIH transparency (e.g., formalizing the Office of Portfolio Analysis and Strategic Initiatives and improving health information technology/data collection/metrics).

NAEVR supports changes that provide the NIH Director greater authority over discretionary funds for activities that engage Institutes in an inter-disciplinary and collaborative manner.

NAEVR supports the NEI remaining as a free-standing Institute.

- Eye disease is a major public health problem that requires an Institute focused on basic and clinical research on that organ.
- The NEI is well-managed and directs more than 85 percent of its funding into extramural research on a range of blinding eye disorders.
- NEI's innovative collaborations with multiple NIH Institutes, other federal entities and the private sector are resulting in dramatic new treatments and therapies to not only stabilize vision loss but restore it, or ultimately prevent the onset of eye disease.

NAEVR opposes the budget cluster concept, in general, and opposes NEI being folded into a "Brain" cluster, specifically.

- In a budget cluster, larger Institutes could siphon dollars away from smaller Institutes; the potential for this is especially high if the NEI is folded into a "Brain" cluster with the NINDS and NIMH, in which it and the NIDCD would be "junior partners."
- "Front of the eye" research, which accounts for 50 percent of NEI's portfolio, may not have a home in a cluster focused on "back of the eye" retinal research, jeopardizing research on corneal diseases, cataracts and refractive errors which affect millions of Americans and cost billions of dollars.
- NEI's inclusion in a "Brain" cluster could limit its collaborations with seemingly unrelated NIH Institutes, other federal research entities and the private sector from which many new treatments and therapies are emerging.

NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH (NAEVR)

Comprehensive Comments on the Energy and Commerce Committee's Potential National Institutes of Health (NIH) Reauthorization Legislation June 30, 2005

Executive Summary

The National Alliance for Eye and Vision Research (NAEVR), on behalf of the 50 professional, consumer and industry member organizations representing the eye and vision research community and the millions of visually-impaired Americans they serve, is pleased to submit comments to the House of Representatives' Energy and Commerce Committee as it considers reauthorization legislation for the National Institutes of Health (NIH). NAEVR advocates for appropriate funding for the National Eye Institute (NEI) by educating about the value of federally-funded eye research for all Americans.

NAEVR commends the Committee for its leadership in examining ways in which to modernize NIH management to most effectively and efficiently use taxpayer dollars for medical research that can improve the quality of lives and contain healthcare costs.

NAEVR supports changes that will increase NIH transparency (e.g. formalizing the Office of Portfolio Analysis and Strategic Initiatives, improving health information technology and data collection, and developing uniform metrics).

NAEVR supports changes that provide the NIH Director greater authority over discretionary funds for activities that engage Institutes in an inter-disciplinary and collaborative manner (such as the *NIH Roadmap* and trans-Institute *Neuroscience Blueprint*) to address our nation's greatest health needs.

NAEVR supports the NEI remaining as a free-standing Institute. NEI is well-managed and directs more than 85 percent of its funding into extramural research on a range of eye disorders. Its research is responding to NIH's top priorities, as they relate to vision, in addressing chronic diseases, aging of the population, health disparities and co-morbidity of disease. Most importantly, its basic and clinical research is resulting in new treatments and therapies to not only stabilize vision loss but restore it, or ultimately prevent onset of disease.

NAEVR opposes budget clusters in general, as they can potentially siphon funding away from research performed by an Institute and will add a layer of bureaucracy (administration). NAEVR specifically opposes including the NEI in a budget cluster, especially a "Brain" cluster, as this could focus funding solely on "back of the eye" neurovision-related research at the expense of "front of the eye" research, which represents 50 percent of NEI's portfolio and addresses corneal diseases, cataracts and refractive errors. Folding NEI into a "Brain" cluster could also limit collaborations with seemingly unrelated NIH Institutes, other federal research entities and the private sector. NEI has been able to lead the nation's efforts in vision research by its focus on the diseases of the eye and visual system. This great advantage will be lost in any clustering effort.

As a Free-standing Institute Leading a Broad Portfolio of Basic and Clinical Eye Research, the NEI Has Facilitated Development of Treatments and Therapies to Stabilize and Restore Vision

In 1968, the NEI was created as a free-standing Institute separate from the then-National Institute of Neurological Diseases and Blindness (NINDB). Previously, the budget for eye research was less than 20 percent of the NINDB budget. Simply stated, if eye research had remained as part of the NINDB, the American people would not have benefited from the treatments and therapies for eye disease that have emerged from NEI-led and funded research, training and education.

The NEI is a well-managed and efficient Institute that maximizes funding by devoting 85 percent of its budget to extramural research that addresses the breadth of eye disorders, including “back of the eye” retinal disease and “front of the eye” diseases, such as corneal, lens and cataract, glaucoma, refractive errors and low vision. This research is more timely and valuable than ever since:

- Americans have consistently identified fear of vision loss as second only to fear of cancer in public opinion polls conducted over the past 40 years.
- Vision impairment and eye disease is a major public health problem. Currently, 38 million Americans age 40+ experience blindness, low vision or an age-related eye disease, and this number is expected to grow to 50 million by year 2020.
- Vision impairment and eye disease costs the United States \$68 billion annually in direct healthcare costs, lost productivity and diminished quality of life. This is expected to increase dramatically with the aging of the population.
- NEI-sponsored research results in therapies and treatments that can delay, save and prevent healthcare costs, especially to the Medicare and Medicaid programs.

NEI’s mission to protect and prolong the vision of the American people has resulted in research to advance our knowledge of both eye health and disease. Most recently, and post NIH-budget doubling, NEI-sponsored research has:

- Identified key genes associated with age-related macular degeneration (AMD), the leading cause of vision loss in older Americans, which can now lead to potential therapies and prevention.
- Demonstrated that nutritional supplements such as zinc and antioxidant vitamins can reduce vision loss in people at high risk of developing advanced AMD, thereby identifying a cost-effective preventive treatment.
- Demonstrated that pressure-reducing eye drops can delay or prevent the onset of glaucoma, an especially important finding for African Americans, who experience

this blinding disease at a rate three times that of White Americans. All of the new drug therapies and procedures for glaucoma introduced in the last decade have emerged from NEI-funded research.

- Demonstrated through the Los Angeles Latino Eye Study (LALES), the largest eye health epidemiological study on Latinos, that this fastest-growing segment of the US population has a higher incidence of diabetic retinopathy, glaucoma and low vision than other segments. One in five individuals with diabetes was newly diagnosed during the clinical exam, and 25 percent were found to have diabetic retinopathy.

NEI Can Best Achieve Its Mission as a Free-standing Institute That Leads Eye Research in Active Collaboration

NEI's status as a free-standing Institute has enabled it to pursue numerous clinical trials (55 to date) not previously considered a priority when eye research was part of the NINDB and to collaborate with seemingly unrelated Institutes. These collaborations have resulted in measurable health improvements and cost-effective treatments, such as therapies that have enabled individuals to see that didn't see before, as well as substantial progress in the professional practice of vision care. Three dramatic examples include:

- NEI's original Diabetic Retinopathy Study established the efficacy and value of laser treatments. NINDB did not consider this research a priority, and did not have the expertise in clinical trial design. NEI collaborated with colleagues at the National Heart, Lung and Blood Institute (NHLBI) on trial design and with the National Institute for Diabetes and Digestive and Kidney Disorders (NIDDK), since retinal vessels respond differently to diabetes than do brain vessels in response to diabetes. As a practical matter for treatment, retinal vessels and "back of the eye" are readily accessible to laser treatment, whereas brain vessels are not. Thus, one can understand that neurologists and brain researchers did not support the clinical trial that demonstrated the efficacy of laser treatment and has saved the vision of millions of Americans. This laser therapy is cost effective for the federal government.
- The subsequent NEI-sponsored Diabetic Retinopathy Clinical Trial Network helped to determine the best treatment strategies through diabetes control (in conjunction with NIDDK) and laser photocoagulation. As a result, these treatments that delay or prevent the disease are effective and save an estimated \$1.6 billion per year in costs of blindness and vision impairment to the federal government.
- NEI has funded research, along with that of the National Cancer Institute (NCI) and the NHLBI, into factors that promote new blood vessel growth (such as Vascular Endothelial Growth Factor, or VEGF). This has resulted in anti-VEGF factors that have been translated into the first generation of ophthalmic drugs to inhibit abnormal blood vessel growth in "wet" AMD, thereby stabilizing vision loss. Current research is focused on improving vision that has already been lost in AMD, as well as applying these drugs to treatment of diabetic retinopathy.

The NEI is an important participant in the *NIH Roadmap* (leading the Nanomedicine initiative) and the trans-Institute *Neuroscience Blueprint*, since eye research is at the cutting edge of scientific discovery. NEI is engaged in various forms of collaborative research with most other NIH Institutes and Centers, since:

- Eye diseases affect Americans of all ages and races, are most often chronic diseases and can be a co-morbidity of another disease.
- The eye can often be used as a diagnostic tool for disease. As noted in the previously-cited LALES study, many individuals are initially diagnosed with diabetes only after an eye care professional detects retinal damage associated with diabetic retinopathy.
- The eye is a unique site to study cellular mechanisms and pathways, as it offers accessibility and an organ in which to measure an effect of a treatment.
- Most blinding eye diseases require research expertise from a wide range of fields, including neurobiology, genetics, physiology, cellular mechanisms, biophysics, membrane transport, microbiology, virology, immunology, bacteriology, parasitology and optics.

Additionally, because the NEI staff has a thorough understanding of the eye and works closely with a large community of support for eye research, including other federal entities, academic institutions, ophthalmic and optometric professional societies, private research organizations, patient advocacy organizations and industry, it can fully leverage federal research dollars with the private sector. Examples of two groundbreaking public-private relationships include:

- Bioengineering research partnerships, one of which is engaging the National Science Foundation, Department of Energy, an academic institution and private companies in developing a retinal chip implant that has enabled individuals who have been blind for decades to perceive visual images.
- A collaborative research program with Foundation Fighting Blindness, a privately funded research organization, which anticipates conducting a human clinical trial later this year of a gene therapy to treat neurodegenerative eye diseases, such as 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.

NEI must remain as a free-standing Institute, leading research focused on the eye, if it is to take full advantage of such productive collaborations among NIH Institutes and with other federal entities and the private sector.

Including the NEI in a Budget Cluster, Especially a “Brain” Cluster, Could Jeopardize the Future of Eye Research

NAEVR understands that the Committee may be considering clustering currently free-standing Institutes within a budget line item. NAEVR opposes the budget cluster concept, in general, as it could siphon funding away from an Institute (dramatically affecting its portfolio of research), as well as add an additional layer between the Institute Director and the NIH Director. This increased bureaucracy could decrease an Institute’s responsiveness and efficiency, while offering little benefit in relation to research.

NAEVR also understands that the Committee may be considering a “Brain” cluster that could include the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Mental Health (NIMH), the National Institute of Deafness and Other Communications Disorders (NIDCD) and the NEI. NAEVR opposes this “Brain” cluster concept as it will siphon funding away from eye research funded by the NEI and adversely affect the balance of its portfolio of research, especially with respect to “front of the eye.”

Since the FY2006 budgets of the NINDS and NIMH are each approximately \$1.5 billion, and that of the NEI and NIDCD substantially less (\$674 and \$397 million, respectively), the NEI and NIDCD would be “junior partners” in this cluster. The NEI’s budget would represent only 17 percent of the budget cluster total. Since eye research has already served as a “junior partner” prior to 1968 (representing 20 percent of the NINDB budget), NAEVR is concerned about several potential consequences, including:

- Larger Institutes could potentially (and would probably) siphon away dollars from smaller Institutes.
- Since 50 percent of NEI-funded research relates to “front of the eye,” it would represent only 7 percent of the total “Brain” cluster budget presented above. Future funding for this research could be jeopardized, as dollars might be redirected to larger Institutes or re-prioritized to “back of the eye” neurovision-related research. Since “front of the eye” research relates to corneal diseases, cataracts and refractive errors that affect millions of Americans and cost tens of billions of dollars annually, any action that impacts upon funding of this portfolio of research could have devastating consequences for the public’s health and quality of life, as well as productivity and healthcare costs.
- If “front of the eye” research is not adequately funded, our community could permanently lose key investigators in this important area of eye research.
- Eye researchers and clinicians are uniquely qualified to understand and treat eye disease. Neurologists from the NINDS or NIMH are not well-acquainted with eye disease and would not have any more of a basis to understand corneal disease or cataract than would individuals in the NCI or other Institutes. There is no significant commonality for “front of the eye” in a “Brain” cluster, and this vital research may not have a home in such a cluster.

- As noted previously, NEI's successful collaborations with seemingly unrelated Institutes such as the NCI, NHLBI or NIDDK could potentially be limited by a "Brain" cluster, jeopardizing further research into such major blinding eye diseases as AMD and diabetic retinopathy.

NAEVR also notes that, in its 2003 report entitled *Enhancing the Vitality of the National Institutes of Health*, the Institute of Medicine (IOM) did not recommend that the NEI be folded into a "Brain" or "Neuroscience" cluster.

Conclusion

NAEVR commends the Energy and Commerce Committee for engaging in a review of NIH management and budget practices as it considers reauthorization legislation and the most efficient use of the public's dollars for research. However, as recommended in the IOM report, any changes to consolidate or centralize functions at the NIH should be considered only after careful study of the impact on research and training programs, and that a public process should be established to evaluate scientific needs, opportunities and consequences of any proposed changes. NAEVR urges the Committee to fully consider both the intended and unintended consequences of changes made in reauthorizing legislation.

In summary, NAEVR supports reauthorization legislation that would increase transparency and provide the NIH Director greater authority over discretionary funds for activities that engage Institutes in an inter-disciplinary and collaborative manner.

NAEVR strongly supports the NEI remaining as a free-standing Institute but opposes its inclusion in a budget cluster, especially a "Brain" cluster. NAEVR is specifically concerned that such a cluster could jeopardize funding for NEI's current balanced portfolio of "back" and "front" of the eye research that is addressing the major and still growing public health problem of eye disease and vision impairment.

NAEVR would be pleased to assist the Committee in any way as it addresses this issue so important to the health, and eye health, of our nation.