NAEVR
National Alliance For
Eye And Vision Research
Serving as Friends of the National Eye Institute

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WRITTEN TESTIMONY TO THE SENATE APPROPRIATIONS COMMITTEE IN CONNECTION WITH THE APRIL 29, 2014, HEARING ENTITLED *DRIVING INNOVATION THROUGH FEDERAL INVESTMENTS*
April 18, 2014

EXECUTIVE SUMMARY

NAEVR thanks the Committee for the opportunity to submit these comments, which relate to biomedical research and innovation funded by the National Institutes of Health (NIH) and its National Eye Institute (NEI).

At the April 2 hearing of the Senate Labor, Health and Human Services, and Education (LHHS) Appropriations Subcommittee, NIH Director Francis Collins, M.D., Ph.D. stated that "nothing is worse for biomedical research than funding uncertainty. NIH needs a stable trajectory of an inflationary increase and growth to take advantage of the unprecedented scientific opportunity in biomedical research and innovation."

Since Fiscal Year (FY) 2003, NIH has lost 22 percent of its purchasing power, in terms of constant dollars. The number of Research Project Grants (RPGs) awarded in FY2013 was 20 percent less than in FY2003. R01s, or investigator-initiated grants, have been affected even more dramatically, as the number awarded fell by 24 percent between FY2003 and FY2013.

NIH-funded basic and clinical research has helped to understand the basis of disease, thereby resulting in innovations in healthcare to save and improve lives. Its research serves an irreplaceable role the private sector could not duplicate. As an economic driver, in FY2011NIH-funded research supported 432,000 jobs across the United States and generated more than $62 billion in new economic activity. Every $1 of NIH funding generates $2.21 in local economic growth. The U.S. must capitalize on previous investment to drive research progress, train the next generation of scientists, create new jobs, promote economic growth, and maintain leadership in the global economy.

Since FY2003, the NEI has lost 25 percent of its purchasing power, in terms of constant dollars. The FY2013 sequester cut resulted in NEI awarding 30 fewer grants−any one of which may have held the promise to save sight and restore vision.

In 2009, Congress spoke volumes in passing S. Res 209 and H. Res. 366, which designated 2010-2020 as *The Decade of Vision* and recognized NEI's 40th anniversary as the lead institute in funding research to save sight and restore vision. Congress can act upon its past resolutions regarding vision and ensure that NEI is adequately funded to meet these challenges with innovative diagnostics, therapies, and treatments.

AS NEI'S BUDGET DECREASES, THE INCIDENCE OF EYE DISEASE AND VISION IMPAIRMENT INCREASES, AS DOES THE ASSOCIATED COST, ESTIMATED AT $139 BILLION ANNUALLY IN THE UNITED STATES

The last ten years of flat funding and lack of an inflationary increase and growth, coupled with the drastic FY2013 sequester cut and increased internal Department of Health and Human Services (DHHS) transfers, have resulted in an FY2014 NEI budget of $674 million. That is well below NEI's highest appropriation−that of $707 million in FY2010 [prior to addition of American Recovery and Reinvestment Act (ARRA) funding.] Unfortunately, as NEI funding has decreased, the challenges it faces have grown, due to dramatic increases in the incidence and cost of vision impairment and eye disease.

The NEI estimates that more than 38 million Americans age 40 and older experience blindness, low vision, or an age-related eye disease such as age-related macular degeneration (AMD), glaucoma, diabetic retinopathy, or cataracts. This is expected to grow to more than 50 million Americans by year 2020. Much of this is being driven by the aging of the population, for example, the "Silver Tsunami" of the 78 million baby boomers who will turn age 65 this decade and experience the greatest risk for eye disease. Other demographic changes are also contributing to NEI's challenges, for example, African Americans and Hispanics which increasingly account for a larger share of the U.S. population and who experience a disproportionately greater prevalence of eye disease. Vision loss can also be a co-morbid condition of chronic disease, such as diabetes, which is at epidemic levels due to increased incidence of obesity.

In June 2013, Prevent Blindness America, in conjunction with the National Opinion Research Center (NORC) at the University of Chicago, released updated estimates of the cost of vision disorders−$139 billion annually, inclusive of direct and indirect costs. Most importantly, the direct medical costs associated with vision disorders are the fifth highest−only less than heart disease, cancers, emotional disorders, and pulmonary conditions.

NEI's FY2014 operational net funding of $674 million, as well as the President's FY2015 proposed funding of $675 million (a 0.15 percent increase), are each less than 0.5 percent of this $139 billion annual vision disorder cost burden. The U.S. is spending only $2.10 per-person, per-year for vision research at the NEI, while NORC estimates that the cost of treating low vision and blindness is $6,690 per-person, per-year.

In public opinion polls conducted over the past forty years, Americans have consistently identified fear of vision loss as second only to fear of cancer. In patients with diabetes, going blind or experiencing other vision loss rank among the top four concerns about the disease. These patients are so concerned about vision loss diminishing their quality of life that those with nearly perfect vision would be willing to trade 15 percent of their remaining life for "perfect vision," while those with moderate impairment willing to trade 22 percent and those legally blind willing to trade 36 percent, respectively, of their remaining life.

CONGRESS MUST ADEQUATELY FUND THE NEI SO THAT IT CAN PURSUE ITS PRIMARY "AUDACIOUS GOAL" OF RESTORING VISION

NEI has lost 25 percent of its purchasing power since FY2003. The FY2013 sequester cut resulted in NEI awarding 30 fewer grants, and the President's FY2015 proposal would result in 23 fewer awards. Any one of those missed funding opportunities could have held the promise to save sight and restore vision−goals that would have seemed unattainable just a few short years ago.

The NEI has long been a leader in biomedical research. As NIH Director Francis Collins, M.D., Ph.D. stated in February 2013:

> "It's often, it seems to me, that vision research is a couple of steps in front of things that are happening in biomedical research. It's clear that vision research has played a disproportionately large share in scientific breakthroughs."

Dr. Collins made his comments at NEI's *Audacious Goals Development* meeting, where more than 200 attendees reflecting every sector of the vision community, including government scientists and regulators from various disciplines, discussed topics built around the ten winning submissions from a pool of nearly 500 entries selected through NEI's *Audacious Goals in Vision Research and Blindness Rehabilitation Challenge*. This initiative, conducted by NEI with its National Advisory Eye Council (NAEC) and through *The America Competes Act,* yielded such ideas as restoring light sensitivity to the blind through gene-based therapies and visual prosthetics, pinpoint correction of defective genes, and growing healthy tissue from stem cells for ocular tissue transplants.

In consultation with the NAEC, the NEI converged on its primary Audacious Goal for vision research: **To Regenerate Neurons and Neuronal Connections in the Eye and Visual System."** In terms of what this would mean for some common eye diseases:

- For AMD, it could mean the development of light-sensitive photoreceptor cells and their placement into the retina of individuals who are blind from the disease.
- For glaucoma, it could mean the development of new retinal ganglion cells which would then be transplanted into the retina of individuals with vision loss.

As NEI Director Paul Sieving, M.D., Ph.D. stated in February 2014:

> "The goals are bold but achievable. They are beyond what medicine currently can do. We are planning for a 10-12-15 year effort to reach these endpoints. Success would transform life for millions of people with eye and vision diseases. It would have major implications for medicine of the future, for vision diseases, and even beyond this, for neurological diseases."

As NEI works to achieve this goal, it will build upon its breakthrough research funded through past federal investment. For example, NEI has been a leader in determining the genetic basis of disease−the research it has funded has identified more than 500 genes

associated with both common and rare eye diseases, which is 7.5 percent of all disease-causing genes discovered to-date. Understanding the genetic basis of the disease and underlying mechanisms will lead to better diagnostics and therapies. In the last year, NEI has announced that:

- The AMD Gene Consortium, a network of international investigators representing 18 research groups, has discovered seven new regions of the human genome−called loci−that are associated with increased risk of AMD. They also confirmed 12 loci already identified in previous studies. These loci implicate a variety of biological functions, including regulation of the immune system, maintenance of cellular structure, growth and permeability of blood vessels, lipid metabolism, and atherosclerosis. AMD is the leading cause of vision loss overall, as well as the leading cause in individuals are 60-plus.

- The NEI Glaucoma Human Genetics Collaboration (NEIGHBOR) Consortium, which involves clinicians and geneticists at multiple institutions throughout the U.S. who are studying genetic variants associated with Primary Open Angle Glaucoma−the most common form of the disease−has identified the first common genetic risk factors for normal pressure glaucoma. NEIGHBOR, unique because it is the largest Genome-Wide Association Study to-date, will generate new insights into the molecular pathogenesis, effective screening and prevention strategies, and more rational treatment approaches for this disease. Glaucoma is three-to-four times more prevalent in African Americans than non-Hispanic Whites and is the leading cause of blindness in the Latino population.

These are ambitious goals that require increased−not decreased−funding. Our nation's investment in vision health is an investment in its overall health. NEI's breakthrough research is a cost-effective investment, since it is leading to innovative treatments and therapies that can ultimately delay, save, and prevent health expenditures, especially those associated with the Medicare and Medicaid programs. It can also increase productivity, help individuals to maintain their independence, and generally improve the quality of life, especially since vision loss is associated with increased depression and accelerated mortality.

The very health of the vision research community is also at stake with the decrease in NEI funding. Not only will funding for new investigators be at risk, but also that of seasoned investigators, which threatens the continuity of research and the retention of trained staff, while making institutions more reliant on bridge and philanthropic funding.

ABOUT NAEVR

NAEVR, which serves as the "Friends of the NEI," is a 501(c)4 non-profit advocacy coalition comprised of 55 professional (ophthalmology and optometry), patient and consumer, and industry organizations involved in eye and vision research. Visit NAEVR's Web site at www.eyeresearch.org.