

**TESTIMONY SUPPORTING INCREASED FISCAL YEAR 2022 FUNDING FOR THE
NATIONAL INSTITUTES OF HEALTH (NIH) AND NATIONAL EYE INSTITUTE (NEI)**

**LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED
AGENCIES SUBCOMMITTEE OF THE HOUSE COMMITTEE ON APPROPRIATIONS
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EXECUTIVE SUMMARY

The Association for Research in Vision and Ophthalmology (ARVO), on behalf of the eye and vision research community, thanks Congress, especially the House and Senate LHHS Appropriations Subcommittees, for the strong bipartisan support for the National Institutes of Health (NIH) funding increases from Fiscal Year (FY) 2016 through FY2021.

This past investment in NIH has improved our understanding of fundamental life and health sciences and prepared the nation to combat unprecedented health threats, including COVID-19. To maintain this momentum in FY2022, ARVO strongly supports \$51 billion in NIH funding as proposed by President Biden, including no less than \$46.1 billion for NIH's base program level budget (absent proposed funding for the Advanced Research Projects Agency–Health [ARPA-H]), an increase of at least \$3.177 billion or 7.4%, which would allow NIH's base budget to keep pace with the Biomedical Research and Development Price Index (BRDPI) and allow for 5% growth. This increase will support promising science across all Institutes and Centers (ICs), ensure continued Innovation Account funding established through the *21st Century Cures Act* for special initiatives, and support early-stage investigators.

Along with partners and other scientific societies, ARVO also urges one-time emergency funding for federal agency “research recovery” investment to enable NIH to mitigate pandemic-related disruptions without foregoing promising new science. ARVO

supports the bipartisan *Research Investment to Spark the Economy (RISE) Act* (H.R. 869/S. 289) which includes \$10 billion for NIH.

ARVO also urges Congress to fund the NEI at \$900 million, a \$64.3 million or 7.7% increase over FY2021 that reflects both biomedical inflation and growth. Despite NEI's total \$160 million funding increases in the FY2016-2021 timeframe, its enacted FY2021 budget of \$835.7 million is just 19% greater than the pre-sequester FY2012 funding of \$702 million. Averaged over those nine fiscal years, the 2.1% annual growth rate is still less than the average annual biomedical inflation rate of 2.7%, thereby eroding purchasing power. In fact, NEI's FY2021 purchasing power is less than that of FY2012.

The NEI currently faces an increasing burden of vision impairment and eye disease due to an aging population, the disproportionate risk/incidence of eye disease in minority populations, and the impact on vision from numerous chronic diseases, such as diabetes. NEI also faces additional challenges with the COVID-19 pandemic, as both the working-age population and students have relied almost exclusively on electronic devices and e-learning platforms, which research has shown correlates to increased rates of myopia, dry eye and eye strain.

Maintaining the momentum of eye and vision research is vital to vision health and to overall health and quality of life and would secure the U.S. as the world leader in eye and vision research and training the next generation of eye and vision scientists.

NEI-FUNDED RESEARCH SAVES SIGHT AND RESTORES VISION

Historical federal investment has led to landmark advances in the prevention of vision loss as well as the restoration of vision, including:

- **Audacious Goals Initiative:** The NEI has been at the forefront of regenerative medicine with its Audacious Goals Initiative (AGI), launched in 2013 with the goal of restoring vision. AGI-funded consortia have developed innovative ways to image the visual system such that researchers can now look at individual nerve cells in the eyes of patients to learn directly whether new treatments are successful. Another consortium has identified biological factors that allow neurons to regenerate in the retina, and current AGI proposals may result in clinical trials for therapies within the next decade.
- **Retinal Diseases:** The NEI has been at the forefront of research into retinal diseases. NEI-funded researchers helped to show that the Vascular Endothelial Growth Factor (VEGF) protein stimulates abnormal blood vessel growth that occurs in the advanced stages of the “wet” form of age-related macular degeneration (AMD) and diabetic retinopathy. Food and Drug Administration (FDA)-approved anti-VEGF drug therapies that slow the development of blood vessels in the eye delay vision loss and may improve vision for patients. NEI has funded comparison trials of anti-VEGF drugs to provide clinicians and patients with information they need to choose the best treatment options. With respect to the “dry” form of AMD, also known as geographic atrophy and is the leading cause of vision loss among individuals age 65+, since 2019 NEI has been performing a first-in-human clinical trial that tests a stem cell-based therapy from induced pluripotent stem cells (iPSC) to treat geographic atrophy. This trial converts a patient’s own blood cells to iPS cells which are then programmed to become retinal pigment epithelial (RPE) cells, which nurture the photoreceptors necessary for vision and which die in geographic atrophy.

Bolstering remaining photoreceptors, the therapy replaces dying RPE with iPSC-derived RPE.

- **Genetics/Genomics:** The NEI has been at the forefront of genetics/genomics and gene therapy approaches to various eye and vision disorders—both common and rare. The causes of AMD and glaucoma remain elusive, although most cases are not inherited, genetics does play a role. While NEI-funded researchers have identified many genetic risk factors for AMD and glaucoma, further study of these genes is helping to understand disease biology and the promise for improved therapies. NEI-funded research has also made discoveries of dozens of rare eye disease genes possible, including the discovery of RPE65, which causes congenital blindness known as Leber congenital amaurosis (LCA). As of late 2017, NEI’s initial efforts led to a commercialized FDA-approved gene therapy for this condition. These gene-based discoveries form the basis of new therapies that treat and may prevent the disease.
- **Front-of-Eye Research:** The NEI has launched an Anterior Segment Initiative (ASI) studying clinically significant, front-of-eye problems such as ocular pain and Dry Eye Disease (DED), especially in terms of pain and discomfort sensations and disruptions in the tearing process. Using multi-disciplinary approaches, the ASI plans to elucidate relevant anterior segment innervation pathways that contribute to normal or abnormal functioning of the neural circuits related to the ocular surface.

NEI FUNDING DEMONSTRATES SIGNIFIGANT RETURN ON INVESTMENT

Optical coherence tomography (OCT) is a technology developed with federal research funding through the NIH, which has led to significant cost savings by helping to

diagnose conditions that lead to vision loss among patients more efficiently. In 2017, ARVO shared the story of OCT, including the significant associated cost savings:

- \$9 billion: Medicare savings from clinicians using OCT to optimize the injection schedule of anti-VEGF drugs for patients with wet-AMD
- \$2.2 billion: Wet-AMD patient savings from reduced spending on drug copays
- \$0.4 billion: Total investment over 20 years made by NIH and NSF to invent and develop the technology
- 2,100%: Return on taxpayer investment

[[http://www.ajo.com/article/S00029394\(17\)30419-1/fulltext](http://www.ajo.com/article/S00029394(17)30419-1/fulltext)]

NEI RESEARCH ADDRESSES INCREASING BURDEN OF EYE DISEASE

NEI's FY2021 enacted budget of \$835.7 million is less than 0.5% of the \$177 billion annual cost (inclusive of direct and indirect costs) of vision impairment and eye disease, which was projected in a 2014 Prevent Blindness study to grow to \$317 billion—or \$717 billion in inflation-adjusted dollars—by year 2050. Of the \$717 billion annual cost of vision impairment by year 2050, 41% will be borne by the federal government as the “Baby Boomer” generation ages into the Medicare program. A 2013 Prevent Blindness study reported that direct medical costs associated with vision disorders are the fifth highest—only less than heart disease, cancers, emotional disorders, and pulmonary conditions. The U.S. is spending only \$2.53 per person, per year for eye and vision research, while the cost of treating low vision and blindness is at least \$6,680 per person, per year. [<http://costofvision.preventblindness.org/>]

Investing in vision health is an investment in overall health. In summary, ARVO requests FY2022 NIH funding of at least \$51 billion and NEI funding of \$900 million.

The Association for Research in Vision and Ophthalmology (ARVO) is the largest eye and vision research organization in the world. Members include approximately 10,000 eye and vision researchers from over 75 countries.