Iris M. Rush, CAE
Executive Director
Association for Research in Vision and Ophthalmology
irush@arvo.org; 240-221-2906

TESTIMONY SUPPORTING INCREASED FISCAL YEAR 2021 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 SENATE COMMITTEE ON APPROPRIATIONS
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EXECUTIVE SUMMARY

The Association for Research in Vision and Ophthalmology (ARVO), on behalf of the vision research community, thanks Congress, especially the House and Senate Appropriations Subcommittees on Labor, Health and Human Services, Education, and Related Agencies (LHHS), for the strong bipartisan support for the National Institutes of Health (NIH) funding increases from Fiscal Years (FY) 2016 through FY2020. The $11.6 billion NIH increase has helped the agency regain some of the ground lost after years of effectively flat budgets. ARVO also thanks Congress for the bipartisan agreements that provide supplemental appropriations for NIH as the research community responds to COVID-19.

ARVO urges Congress to continue this support and urges Congress to appropriate $44.7 billion for the NIH in FY2021, a $3 billion or 7.2 percent increase over the FY2020 program level and allowing for—

- meaningful growth above inflation in the base budget to support promising science across all NIH Institutes and Centers;
- funding from the Innovation Account established through the *21st Century Cures Act*, which would supplement NIH's base budget, as intended, through dedicated funding for specific programs and funding for early-stage investigators.

Due to the strain COVID-19 is placing on the research infrastructure and strict limits of the FY2021 discretionary spending caps, ARVO supports bipartisan proposals to exempt NIH from the FY2021 caps. ARVO also requests that the LHHS bill is structured to facilitate emergency funding, as necessary, to maintain the momentum of research emerging from past NIH investment such that the return-on-investment is fully realized with new diagnostics and therapies.

ARVO also urges Congress to appropriate $875 million for the National Eye Institute (NEI), a $51 million or 6.2 percent increase over enacted FY2020. The NEI is the world leader in sight-saving and vision-restoring research. Congress must ensure robust NEI funding to continue to address the challenges of *The Decade of Vision 2010-2020*—as recognized by Congress in H. Res. 366 in 2009—which include an aging population, disproportionate risk/incidence of eye disease in fast-growing minority populations, and the impact on vision from numerous chronic diseases and their treatments/therapies.

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Despite the total FY2016–2020 funding increases of $146 million, NEI's enacted FY2020 budget of $824.1 million is just 21 percent greater than the pre-sequester FY2012 budget of $702 million. Averaged over the eight fiscal years, the 2.6 percent annual growth rate is less than the average annual biomedical inflation rate of 2.8 percent, thereby eroding purchasing power, which in FY2019 was below that of FY2012 and equivalent to that in FY2000. Maintaining the momentum of vision research is vital to vision health, as well as overall health and quality of life. Since the U.S. is the world leader in vision research and training the next generation of vision scientists, the health of the global vision research community is also at stake.

ARVO recognizes that due to the pandemic, the NEI now faces additional challenges, as both the working-age population and students may potentially rely exclusively on electronic devices and e-learning platforms well into our new normal. As increased rates of myopia, dry eye, and eye strain are associated with lengthy exposure to these devices, NEI research will be instrumental in ensuring eye health is continually prioritized throughout the continuum of life.

NEI LEADS IN GENETIC AND REGENERATIVE MEDICINE RESEARCH

The NEI has been a leader in genetics/genomics research and regenerative medicine.

- Genetics/Genomics: Vision researchers worldwide participating in NEI's Glaucoma Genetics Collaboration Heritable Overall Operational Database (NEIGHBORHOOD) Consortium have identified 133 genetic variants that predict within 75 percent accuracy a person's risk for developing glaucoma related to elevated intraocular pressure (IOP). Among the 133 variants, 68 had not been previously linked to IOP, and their loci point to cellular processes, such as lipid metabolism and mitochondrial function, that contribute to IOP. By understanding these cellular processes that can increase IOP and cause optic nerve damage, clinicians may be able to make an earlier diagnosis and researchers may be able to develop neuroprotective therapies to potentially halt disease progression.
- NEI-funded research has also made discoveries of dozens of rare eye disease genes possible, including the discovery of RPE65, which causes congenital blindness called Leber congenital amaurosis (LCA). As of late 2017, NEI's initial efforts led to a commercialized, Food and Drug Administration (FDA)-approved gene therapy for this condition. These gene-based discoveries are forming the basis of new therapies that treat the disease and potentially prevent it entirely. Success in this field is driving now similar promising research for the most common blinding diseases, such as Age-related macular degeneration (AMD).
- Regenerative Medicine: NEI is at the forefront of regenerative medicine with its Audacious Goals Initiative (AGI) for Regenerative Medicine, which launched in 2013 with the goal of restoring vision. Initially asking a broad constituency of scientists within the vision community and beyond to consider what could be done if researchers employed this new era of biology, the AGI currently funds

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major research consortia that are developing innovative ways to image the visual system. Researchers can now look at individual nerve cells in the eyes of patients in an examination room and learn directly whether new treatments are successful. Another consortium is identifying biological factors that allow neurons to regenerate in the retina. In addition, the AGI is gathering considerable momentum to develop disease models that may result in clinical trials for therapies within the next decade.

- In late 2019, NEI began a first-in-human clinical trial that tests a stem cell-based therapy from induced pluripotent stem cells (iPSC) to treat geographic atrophy, also known as the "dry" form of Age-related Macular Degeneration (AMD), the leading cause of vision loss among people age 65 and older. This trial converts a patient's own blood cells to iPSCs, which are then programmed to become retinal pigment epithelial (RPE) cells. RPE cells nurture and keep alive the photoreceptor cells necessary for vision but die in geographic atrophy causing the loss of photoreceptors and vision and cannot be replaced by the retina itself. The new therapy replaces dying RPE with iPSC-derived RPE cells keeping remaining photoreceptors alive and thereby stopping the loss of vision.

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]

CONGRESS MUST ROBUSTLY FUND THE NEI AS IT ADDRESSES THE INCREASING BURDEN OF VISION IMPAIRMENT AND EYE DISEASE

NEI's FY2020 enacted budget of $824.1 million is less than 0.5 percent of the $167 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 vison impairment by year 2050, 41 percent will be borne by the federal government as the Baby-Boom 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 costs associated with heart disease, cancers, emotional disorders, and pulmonary conditions. The U.S. is spending only $2.50 per-person, per-year for vision research, while the cost of treating low vision and blindness is at least $6,680 per-person, per-year. [http://costofvision.preventblindness.org/]

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In a May 2016 *JAMA Ophthalmology* article, NEI-funded researchers reported that the number of people with legal blindness will increase by 21 percent each decade to 2 million by 2050, while best-corrected visual impairment will grow by 25 percent each decade, doubling to 6.95 million people—with the greatest burden affecting those 80 years or older. [http://jamanetwork.com/journals/jamaophthalmology/article-abstract/2523780?resultClick=1]

Investing in vison health is an investment in overall health. NEI's breakthrough research is a cost-effective investment, since it leads to treatments and therapies that may delay, save, and prevent health expenditures. It can also increase productivity, help individuals to maintain their independence, and generally improve the quality of life—as vision loss is associated with increased depression and accelerated mortality.

In summary, ARVO requests FY2021 NIH funding of at least $44.7 billion and NEI funding of $875 million. We also thank the Subcommittee for the opportunity to submit this written testimony, especially as it assesses current and future challenges associated with the COVID-19 pandemic.

The Association for Research in Vision and Ophthalmology (ARVO) is the largest eye and vision research organization in the world. Members include nearly 12,000 eye and vision researchers from over 75 countries. ARVO advances research worldwide into understanding the visual system and preventing, treating and curing its disorders.