FALL 2023

CONTRIBUTOR REPORT

National Alliance For Eye And Vision Research | Alliance For Eye and Vision Research

PRESIDENT'S MESSAGE

I hope this letter finds all members of NAEVR and AEVR well. As we have navigated the intricate landscape of federal budget negotiations this fall, I wanted to take a moment to update you on the unique challenges we continue to face in advocating for funding the National Eye Institute (NEI) amid the evolving political climate.

The past few months have brought forth a set of challenges that have tested our advocacy efforts and resilience. The discussions in Congress surrounding the budget have been particularly complex, marked by a heightened sense of polarization and competing priorities which have even resulted in a change in the House Speaker. Amid these challenges, NAEVR/AEVR has worked to ensure that the importance of vision research funding and the NEI's critical role in advancing vision research is not lost in the shuffle.

The intricacies of the budget process and the various perspectives involved have made reaching a consensus more challenging than ever, starting with the debt limit deal earlier this year, up to the latest Continuing Resolution (CR) that was passed in mid-November. In these challenging budgetary environments, securing level funding for the NEI is an achievement, but still emphasizes the need for advocacy and educational efforts.

Level funding keeps NEI funding under inflationary adjustment, but when compared to a cut, ensures that the NEI can continue its vital work without significant disruption, providing researchers and scientists with the resources they need to make strides in vision research. This achievement is a testament to the dedication of our advocacy team and the support of our members.

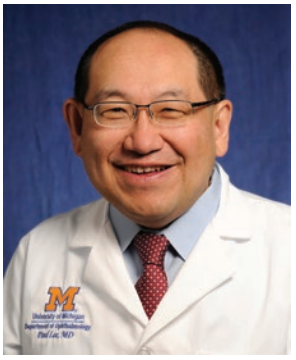
Looking ahead, we anticipate that passage of the latest CR that continues funding into January will provide an opportunity for Congress to pass a budget then. While this stability is welcomed, NAEVR/AEVR remains committed to advocating for increased support for vision research. Our ongoing efforts aim to emphasize the crucial role that the NEI plays in advancing scientific discovery, medical breakthroughs, and ultimately, improving the lives of people living with vision impairment and blindness.

As we navigate the coming months and move the organizations forward, NAEVR/AEVR will continue to engage with policymakers, cultivate relationships on both sides of the aisle, and underscore the importance of sustained investment in vision research. Your continued support and advocacy in coordination with the Alliances are invaluable as we work towards securing a brighter future for the National Eye Institute and vision science.

Thank you for your unwavering commitment to our mission, and I look forward to building and advancing our mission moving forward.

Sincerely,

Paul Lee, MD, JD
President, Board of Directors
National Alliance for Eye and Vision Research/
Alliance for Eye and Vision Research



NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH (NAEVR) LEGISLATIVE UPDATE

	FY2021 Final	FY2022 Final	FY2023 Final	FY2024 NAEVR Request	FY2024 President's Budget	FY2024 House Budget	FY2024 Senate Budget
NIH	$42.93 B +3%	$44.96 B +4.72%	$47.46 B +5.6%	$50.924 B +7.3%	$48.27 B +1.7%	$44.7 B -6%	$49.22 B +.7%
NEI	$835.71 M +1.4%	$863.9 M +3.4%	$896.55 M +3.8%	$975 M +8.7%	$896.14 M -0%	$896.55 M +0%	$896.55 M +0%

- The FY2023 budget includes funding for ARPA-H within NIH and includes an increase of $500 million to $1.5 B
- The House FY2024 budget proposal decreases ARPA-H by $1 B to $500 M while the Senate proposal keeps ARPA-H level funded
- The Fiscal Responsibility Act of 2023 (Debt Ceiling Agreement) put caps on federal spending for FY2024 and FY2025

The current House and Senate appropriations bills are likely to see comparable funding to FY2023 for the National Institutes of Health (NIH), with most institutes, including the National Eye Institute (NEI) being level-funded as well. The current Continuing Resolution that the government is operating on (more on that below) maintains FY2023 funding for NIH and NEI into January, however, the lack of full-year funding puts institutes in difficult positions to determine funding for new awards without knowing their final budgets.
NAEVR has partnered to support multiple lobby days in support of NEI and NIH, including our own Emerging Vision Scientists Lobby Day (more on pages 4-5), submitted testimony to the House and Senate, and submitted a sign-on letter from partner organizations to the Senate Appropriations Committee advocating for NEI.

On November 14th, the House passed an "innovative laddered" Continuing Resolution (CR) that (pending Senate action and the President's signature) keeps the government funded with a clean continuation of FY2023 levels for the government.

The CR was passed by a similar margin to the earlier CR that was passed in September that cost Speaker McCarthy his speakership with 336 in favor and 95 against.

On November 15th, the Senate voted to pass the measure by a vote of 87-11, clearing the CR to be signed before the previous CR shutdown deadline on November 17th. President Biden signed the CR into law on November 17th, marking the second CR that has been utilized for FY2024 funding.

The new CR will extend government funding to January 19 for some federal agencies and programs, and February 2 for the remainder. The first deadline consists of appropriations for less contentious agencies, including the Ag-FDA, Energy and Water, MilCon-CA, and THUD. Funding for the eight remaining spending bills (including for the Labor, Health and Human Services bill which includes funding for the National Institutes of Health and the National Eye Institute) will expire in February, hopefully giving Congress more time to secure funding for the remainder of FY2024 which started on October 1, 2023 and expires September 30, 2024.

The CR will extend funding through January 19 for several health programs that expired on September 30 and were extended through November 17 under the current CR:

- Community Health Center Fund, which provides the bulk of federal funding for community health centers

- National Health Service Corps, which provides scholarships and loans to medical students
- Teaching Health Center Graduate Medical Education Program
- Special Diabetes Program
- Special Diabetes Program for Indians
- Personal Responsibility Education Program
- Sexual Risk Avoidance Education Program

The House continues to debate its Labor-H bill, and the Senate is considering a proposal from Senator Susan Collins to pass over 70% of the discretionary spending bills in a package well before the CR deadlines.

Under the Debt Limit Agreement passed in May this year, annual appropriations levels for 2024 were capped at $6772.7 billion which is $1.3 billion above the FY2023 levels, however non-defense discretionary funding levels outside of Veterans' medical care was capped at $651.6 billion which is $1 billion below the FY2023 amount.

Nondefense discretionary (NDD) funding levels in the 2023 debt limit agreement

Comparing nondefense discretionary spending levels under the debt limit deal for fiscal year 2024 with the levels for fiscal year 2023.

	2023	2024	Difference
NDD Funding	$772.4B	$772.7B	+$0.3B
NDD base/cap*	$743.9B	$703.7B	-$40.2B
Agreed-upon adjustments:			
CHIMPs**	$15.0B	$25.0B	+$10.0B
Emergencies***	$13.5B	$23.0B	+$9.5B
Rescissions****		$21.0B	+$21.0B
Components of NDD			
Veterans Affairs (VA) medical care	$118.7B	$121.0B	+$2.3B
NDD outside VA medical care	$653.6B	$651.6B	-$2.0B

Note: The authors modified the 2023 funding level in the Center on Budget and Policy Priorities source to include emergency CHIPS and Science Act funding and to reflect Veterans Affairs medical care estimates from the congressional Appropriations committees.

*This refers to the statutory cap level for 2024 specified in the Fiscal Responsibility Act and the comparable level for 2023 at the time of the enactment of the bill.

** CHIMPs stands for "CHanges In Mandatory Programs" made in annual appropriations bills. The table reflects additional NDD funding offset by CHIMP savings.

*** Funding that is designated as an emergency is not subject to the caps.

**** Rescissions are provisions that repeal funding enacted in prior years that government agencies have not yet used. The table reflects additional NDD funding offset by rescissions.

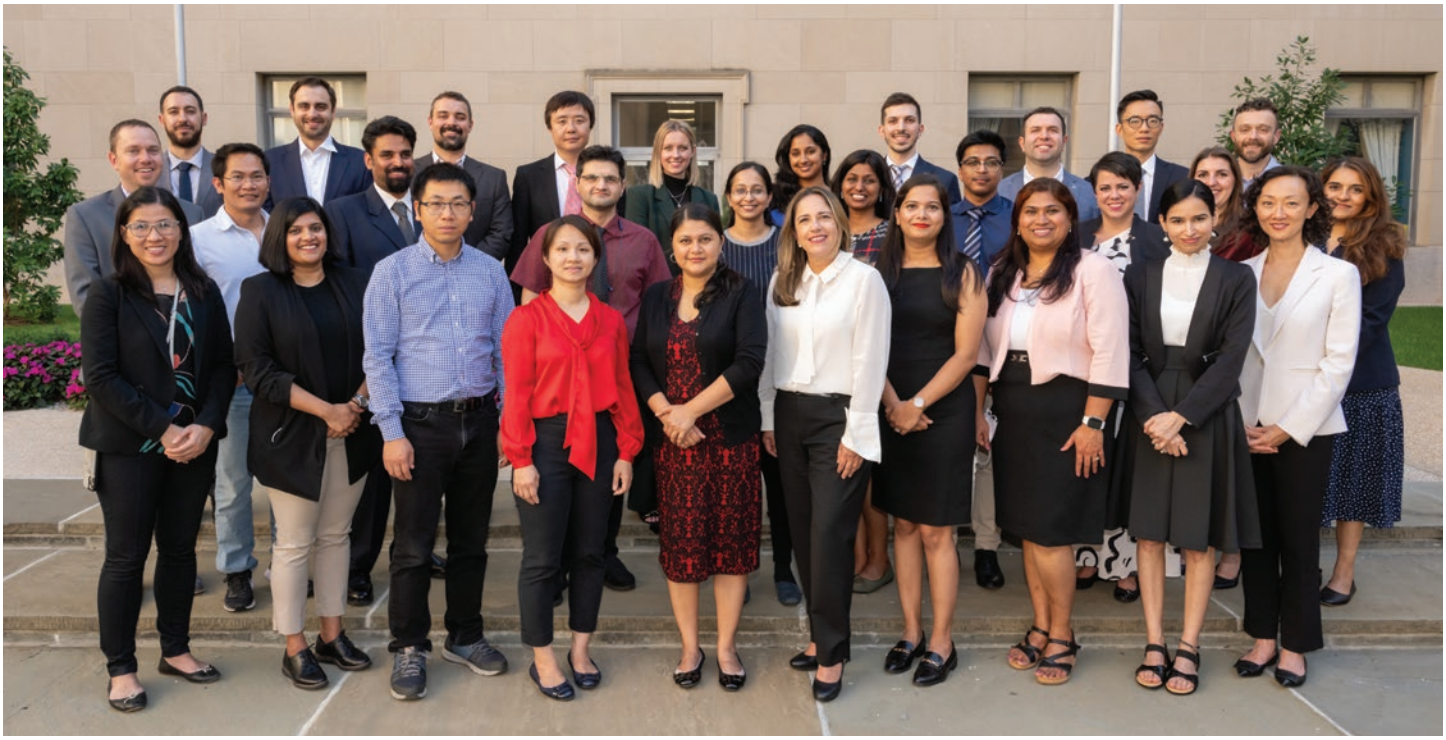
SENATE CONFIRMS MONICA BERTAGNOLLI AS DIRECTOR OF NIH

On November 7, the Senate confirmed Monica Bertagnolli, MD, as Director of the National Institutes of Health (NIH), two weeks after the Senate Health, Education, Labor and Pensions (HELP) committee approved her nomination. The vote was 62-36.

Dr. Bertagnolli had previously served as Director of the National Cancer Institute (NCI) before President Biden nominated her to lead the NIH. She will be the 17th NIH Director and replaces Francis Collins, MD, PhD, who served as Director from 2009 until December 2021. Lawrence A. Tabak, DDS, PhD, has been Interim Director since Dr. Collins left the NIH.

Before her arrival at the NCI, Dr. Bertagnolli was a surgeon at the Dana-Farber Brigham Cancer Center in Boston, where she was Chief of Surgical Oncology for a decade.

EVS RECEPTION



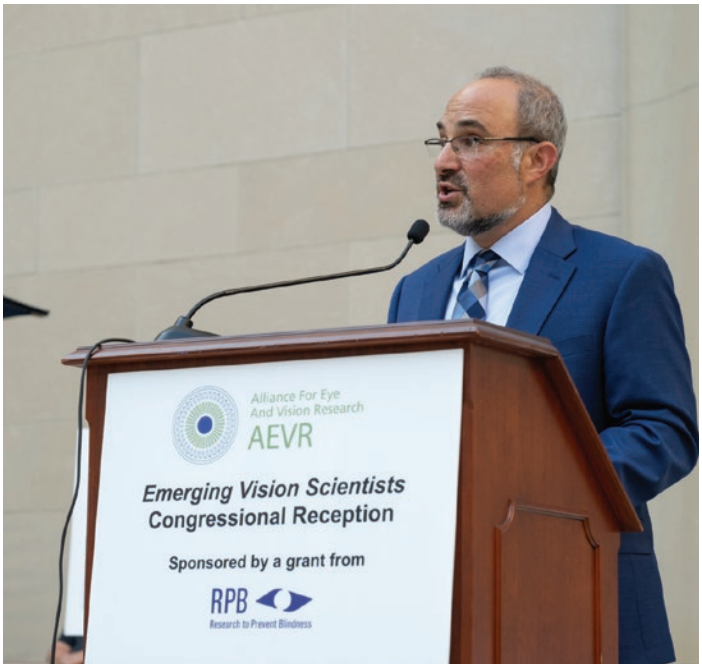
The 2023 EVS Participants included:

Louay Almidani, MD (Wilmer Eye Institute/Johns Hopkins University)
Sean Ashworth, PhD (New York University Langone Health)
Paulo Bispo, PhD (Massachusetts Eye and Ear/Harvard Medical School)
Pooja Chauhan, PhD (New York University Langone Health)
Holly Chen, PhD (University of Alabama at Birmingham)
Christopher Conrady, MD, PhD (University of Nebraska Medical Center)
Ananya Datta, PhD, BOptom (New England College of Optometry)
Antonio Escudero Paniagua, PhD (University of California Los Angeles)
Mohammad Eslami, PhD (Harvard Medical School)
TJ Hollingsworth, PhD (University of Tennessee Health Science Center)
Kirk Hou, PhD (University of California Los Angeles)
Sangeetha Kandoi, PhD (University of California San Francisco)
Deepayan Kar, PhD, BOptom (University of Alabama at Birmingham School of Medicine)
Shilpa Kodati, MD (Kellogg Eye Center/University of Michigan)
Sun Young Lee, MD, PhD (Roski Eye Institute/University of Southern California)
Shwetha Mangalesh, MD (Duke University)
Phuc Nguyen, PhD (University of Michigan)
Onur Olcucu, MD (Tufts Medical Center)
Anh Pham, PhD (Bascom Palmer Eye Institute/University of Miami)
Shaohua Pi, PhD (University of Pittsburgh)
Sriganesh Ramachandra Rao, PhD (State University of New York at Buffalo)
Neisha Rodriguez Ruiz, OD, PhD (Interamerican University of Puerto Rico School of Optometry)
Miranda Scalabrino, PhD (University of California Los Angeles)
Sneha Singh, PhD (Wayne State University School of Medicine)
Shreya Sirivolu, PhD (Keck School of Medicine/University of Southern California)
Whitney Stuard Sambhariya, MD, PhD (Wilmer Eye Institute/Johns Hopkins School of Medicine)
Pratima Suvas, PhD (Wayne State University School of Medicine)
Mala Upadhyay, PhD (Cole Eye Institute/Cleveland Clinic)
Cammi Valdez, PhD (Northeastern State University)
Mengyu Wang, PhD (Massachusetts Eye and Ear/Harvard Medical School)

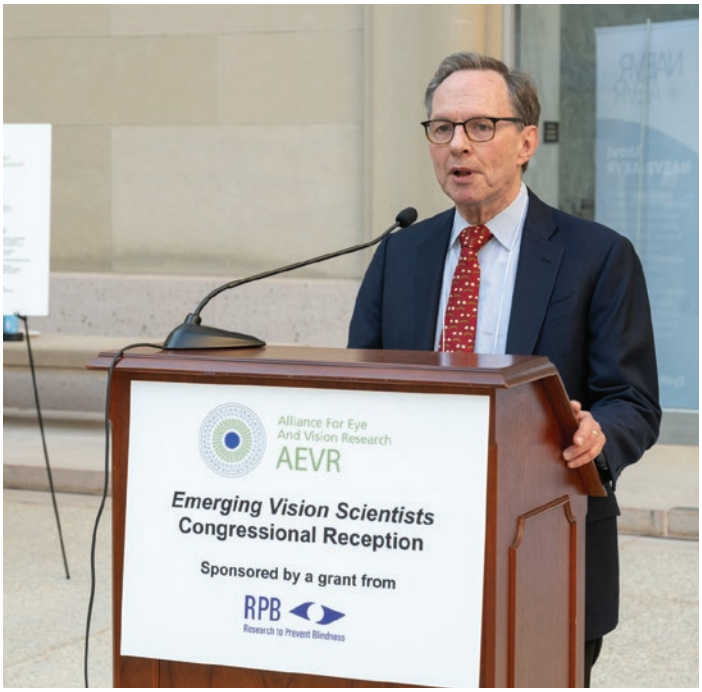
The 2023 class of *Emerging Vision Scientist* researchers (see names above) who participated in the AEVR and NAEVR events reflected the breadth of breakthrough vision research.

On September 20, AEVR's *Research Saving Sight, Restoring Vision Initiative* hosted the ninth annual *Emerging Vision Scientists (EVS)* Program, which was supported by a grant from Research to Prevent Blindness (RPB). The event, held during *Healthy Vision Month*, took place as Congress was working to finalize Fiscal Year (FY) 2024 appropriations before the start of the fiscal year on October 1.

Thirty early-stage investigators from around the country, reflecting a breadth of basic and clinical vision research and who have not yet received their first investigator-initiated (R01) grant from the NEI, displayed posters of their research



Shefa Gordon, Director of the Office of Program Planning and Analysis at the National Eye Institute (NEI), addresses the audience

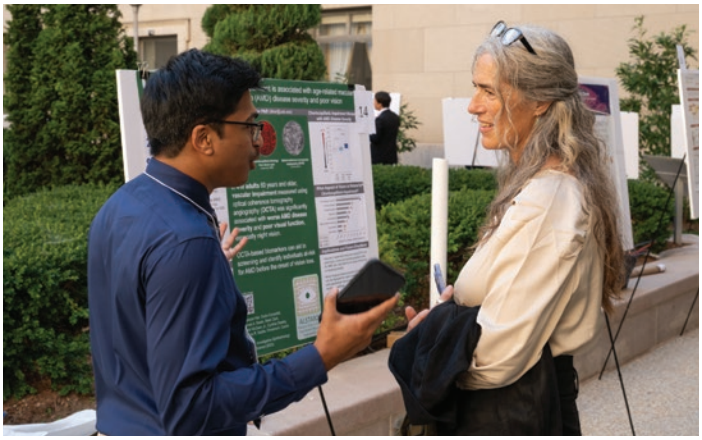


Brian Hofland, PhD, President of Research to Prevent Blindness

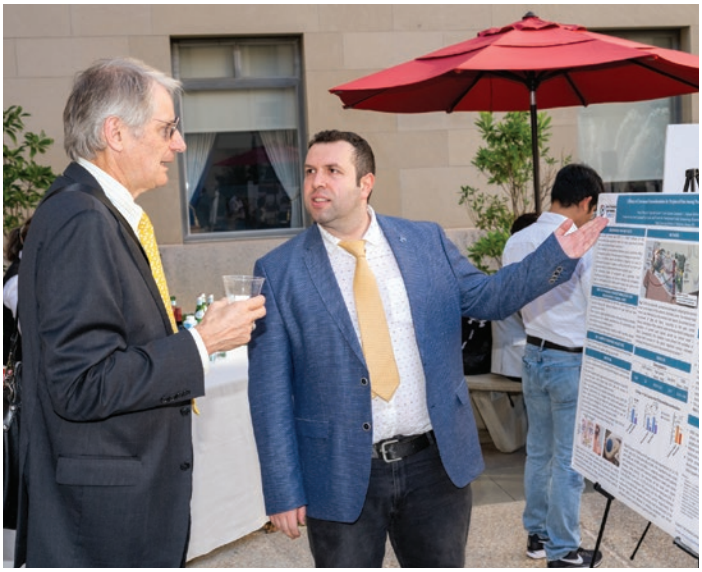
during an evening Congressional Reception held in the Rayburn House Office Building Courtyard. Earlier in the day, the EVS participants attended AEVR's annual *AMD* Congressional Briefing to learn how the Alliances effectively communicate the value and importance of vision research to a non-research, high-level lay audience meant for Congressional staff and policymakers.

AEVR Executive Director Dan Ignaszewski hosted a brief program that included comments from RPB President Brian Hofland, PhD and Shefa Gordon, PhD, Director of the Office of Program Planning and Analysis at the National Eye Institute (NEI).

Before the reception, AEVR staff conducted training for EVS participants on communication techniques and methods for effectively sharing their research. The training and reception focused on the importance of engaging with Congressional staff to help understand how federal support for basic science has led and continues to lead to advancements in the mitigation, diagnosis, and treatment of a range of conditions that lead to impaired vision and blindness.

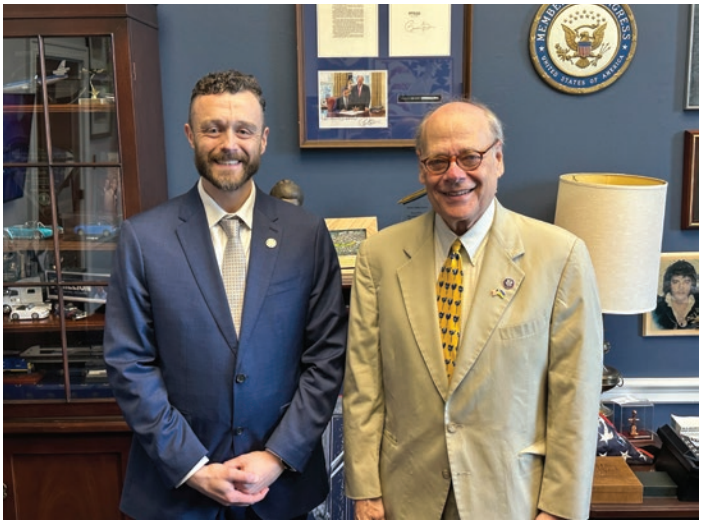


Deepyan Kar, PhD, University of Alabama at Birmingham speaks with an attendee)



John Graham (Senate Special Committee on Aging) with Onur Olcucu, MD (Tufts Medical Center)

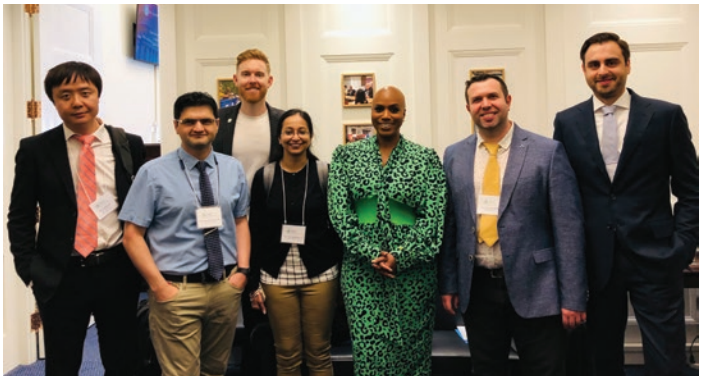
NAEVR EMERGING VISION SCIENTIST (EVS) ADVOCACY DAY



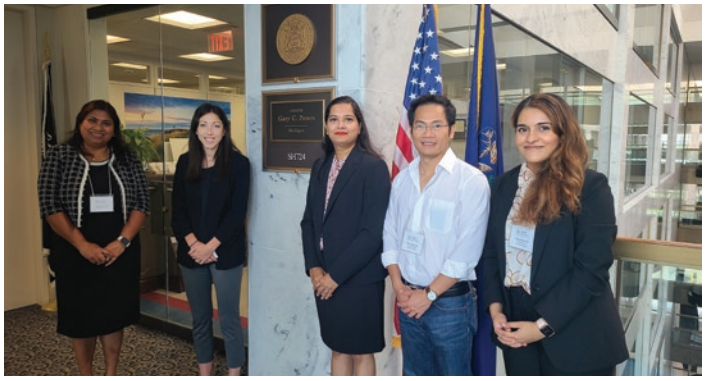
TJ Hollingsworth, PhD (University of Tennessee) with Congressman Steve Cohen (D-TN)

Following the September 20 AEVR events, on September 21 (see previous story) the thirty Emerging Vision Scientists (EVS) conducted 55 Congressional office visits, including several with Members of Congress, who wanted to hear directly about the concerns of early-stage investigators. NAEVR's Executive Director Dan Ignaszewski and Director of Government Relations David Epstein, along with Salewa Akintilo, Assistant Director, Science and Communications Initiatives from AVRO, each joined participants in their visits throughout the day.

Early on September 21, NAEVR picked up on the training from AEVR the day before to train EVS participants on how to combine the communications skills they learned with talking points and an ask to effectively advocate for vision research funding.

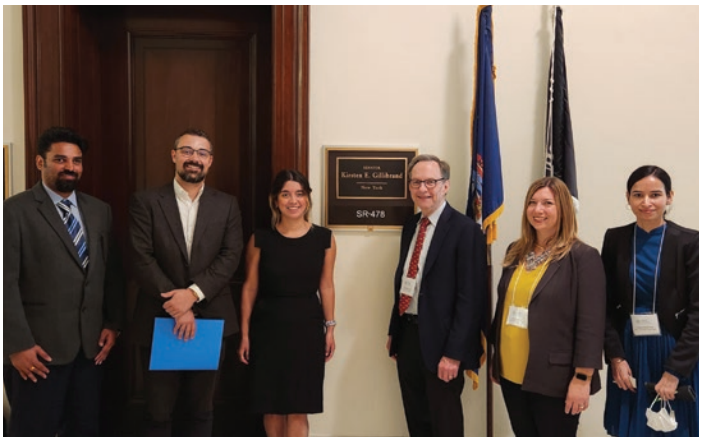


From left: Mengyu Wang, PhD, Harvard Medical School, Mohammed Eslami, PhD, Harvard Medical School, Ananya Datta, BOptom, PhD, New England College of Optometry, Cong. Ayanna Pressley (D-MA), Onur Olcucu, MD, Tufts University Medical Center, and Paolo Bispo, PhD, Harvard Medical School

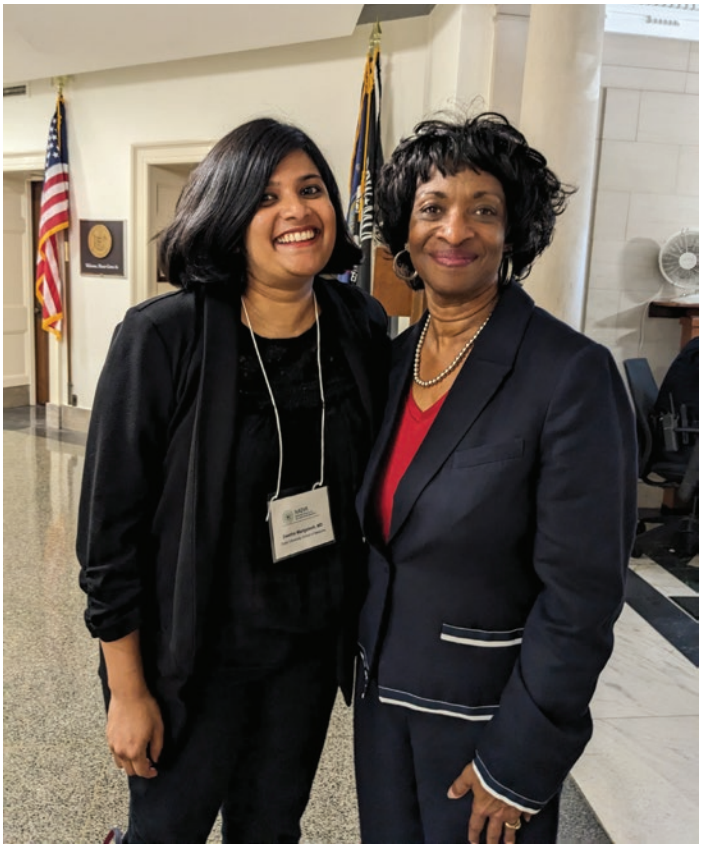


From left: Pratima Suvas, PhD (Wayne State University), Sarah Shapiro, office of Senator Gary Peters (D-MI), Sneha Singh, PhD (Wayne State University), and Phuc Nguyen, PhD and Shilpa Kodata, MD, both from the University of Michigan

In their meetings, the EVS advocates thanked Congress for NIH/NEI funding increases between FY2016 and FY2023 and asked that Congress finalize FY2024 appropriations before the start of the fiscal year on October 1. They also cautioned about the detrimental impact that Continuing Resolutions (CRs) can have on research, including delaying awards or requiring researchers to seek "bridge" funding while awaiting funding. Advocates emphasized that if CRs are necessary, it's vital that Congress work to pass full-year funding as soon as possible.

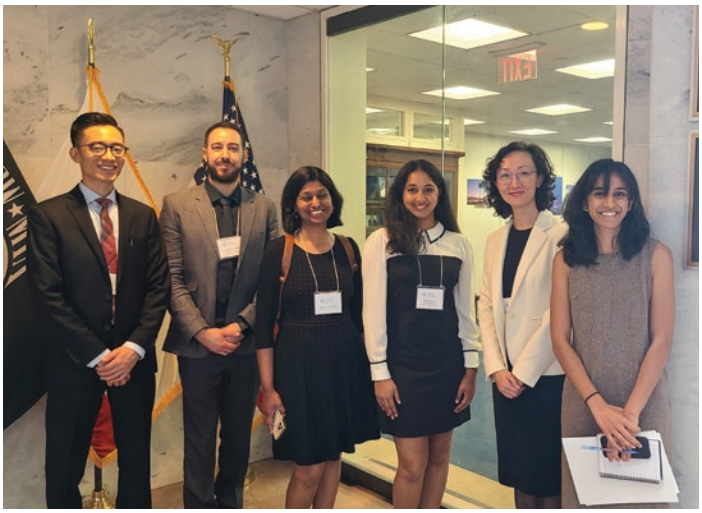


From left: Sriganesh Ramachandra Rao, PhD, SUNY Buffalo, Sean Ashworth, PhD, New York University Langone Health, Jasmin Palomares, office of Senator Kirsten Gillibrand (D-NY), Brian Hofland, PhD and Diana Friedman, both from Research to Prevent Blindness, and Pooja Chauhan, PhD, New York University Langone Health

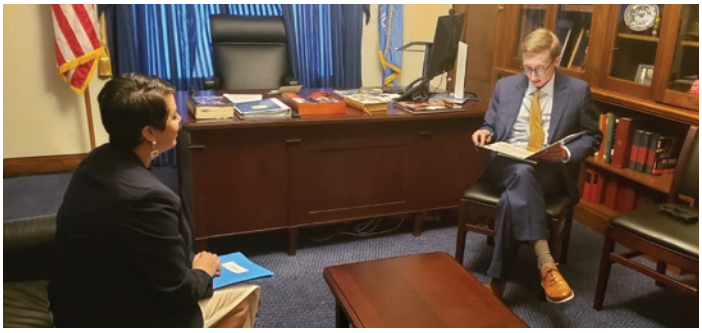


Shwetha Mangalesh, MD, Duke University, with Congresswoman Valerie Foushee (D-NC)

The advocates reiterated NAEVR's request for FY2024 NIH funding of $50.1 billion and NEI funding of $975 million, which is necessary to rebuild the NEI's base funding level after years of increases that have failed to keep pace with inflation. They also expressed that although the



From left: Kirk Hou, MD, PhD and Antonio Paniagua, PhD, both from the University of California Los Angeles, Sangeetha Kandoi, PhD, from the University of California San Francisco, Shreya Sirivolu and Sunny Lee, MD, PhD, both from the University of Southern California, with Priya Amilineni, office of Senator Alex Padilla (D-CA)

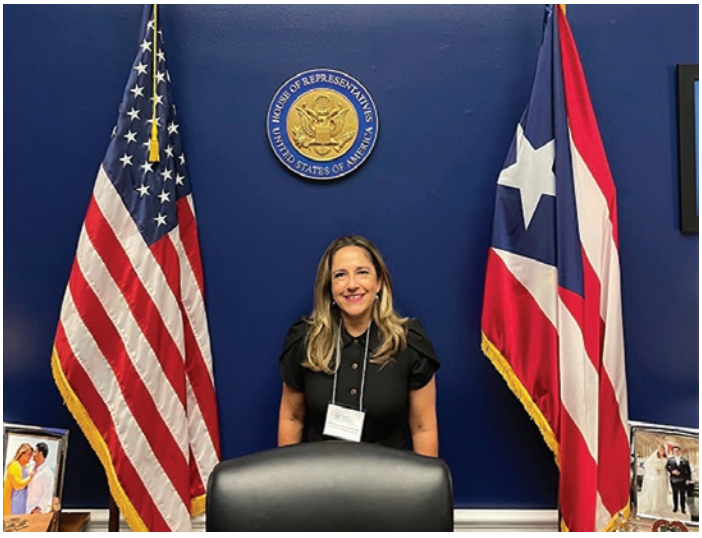


Cammi Valdez, PhD, Northeastern State University, with Christian Gentile, office of Cong. Josh Brecheen (R-OK)

Senate-passed funding level of $896.5 million—the same level as in FY2023— is still short of what is needed, it is preferable to the House bill. While the House bill also flat-funded the NEI, the bill makes severe cuts of over $3 billion to the NIH funding level that would impact the ability of the NIH to conduct its mission to support the larger medical research community.

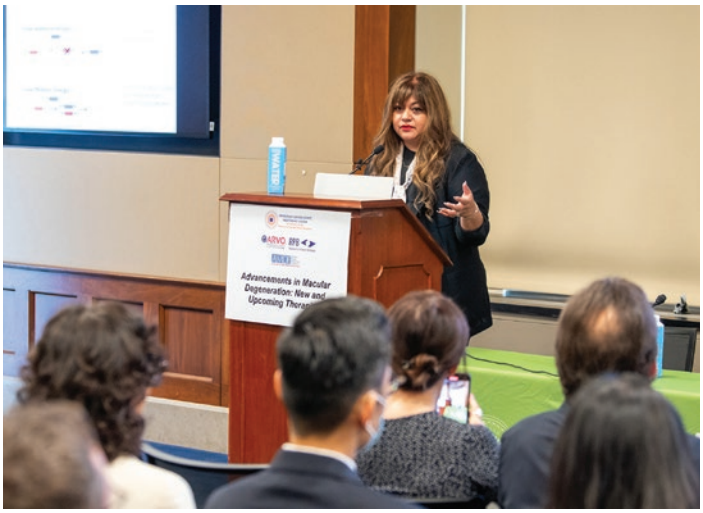
Several of the EVS participants shared a one-page graphic of their research emphasizing the potential benefit and return on the federal investment. Some participants were also able to share experiences through a virtual reality eye disease simulator in meetings to help Congressional staff understand what patients with vision loss experience.

All the participants also offered to serve as a reference on vision issues for their Congressional offices and invited Members and staff to visit their departments or School/College for lab tours.



Neisha Rodriguez Ruiz, OD, PhD, Inter-American University of Puerto Rico

AEVR HOSTS AMD WEEK CONGRESSIONAL BRIEFING FOCUSING ON NEW THERAPIES



Neena Haider, PhD, Addresses the Audience

On September 20, AEVR partnered with the American Macular Degeneration Foundation (AMDF) to host its fourth *Research Saving Sight, Restoring Vision* Congressional Briefing of 2023, entitled *Advancements in Macular Degeneration: New and Upcoming Therapies*. The briefing was held as part of *Healthy Aging Month*.

The briefing featured speakers Neena Haider, PhD, who is an Associate Professor at Harvard Medical School and has been involved in the field of genetics and retinal disease for over 15 years, and Mark Roser, an engineer and researcher who developed an at-home vision evaluation tool to provide early identification of vision loss and has been living with AMD since he was diagnosed at 25 years old.

Dr. Haider explained that there are two types of AMD—dry AMD which is more common, and wet AMD which, although less common, usually causes faster vision loss. AMD is a common condition that can lead to blurring and loss of central vision, typically in older adults. AMD is diagnosed through regular eye exams which are vital to be able to intervene early to avoid as much vision loss as possible.

Worldwide, over 196 million people have AMD with that number expected to grow to 288 million people by 2040. In the United States, 15 million Americans are living with AMD with that figure expected to double to 30 million by 2050. Additionally, 200,000 cases of wet AMD are diagnosed every year in the United States.

Dr. Haider highlighted how research for new treatments to address AMD is often initiated by NEI-funded projects and then picked up by industry to further develop and bring new treatments to market.

Dr. Haider emphasized that exciting things are happening in the treatment of AMD mentioning the newest FDA-approved therapy to market for AMD, Syfovre, which is an injection to treat Geographic Atrophy (GA), an advanced form of dry AMD. Anti-VEGF (Vascular Endothelial Growth Factor) injections have often been used to mitigate additional vision loss for patients with AMD, and new treatments are looking at other avenues to improve outcomes and potentially restore vision.

In addition to Syfovre, Dr. Haider mentioned Izervay which is also an injection that targets a different component of the immune system and is the latest to receive FDA approval for GA. She shared that the pharmaceutical industry continues to advance new treatments for AMD with multiple research studies and clinical trials in development and that a new focus on gene

Patient-Advocate Mark Roser Shares His Experiences with AMD

therapy was providing encouraging results. Dr. Haider detailed the growth in gene therapy research and the potential that it has for AMD by identifying genes that may impact AMD to replace a "mutant gene" with a normal gene, cut out the mutant gene, or correct the mutated gene. Dr. Haider described how new studies have shown novel genes and pathways that are linked to AMD which have focused on the Retinal Pigment Epithelium (RPE) — the outermost layer of the retina— and the macula.

Dr. Haider summarized that AMD is a complex disease affected by both genetics and the environment and everyone's experience with AMD is unique. Genetic components of AMD arise from multiple genetic perturbations and there are several clinical trials underway for wet and dry AMD. Dr. Haider again highlighted the two innovative FDA-approved treatments for dry AMD, and that OCU410 has been approved for trials for Stargardt disease and Dry AMD.

Finally, Dr. Haider shared the importance of NEI funding in research implications for AMD. Emphasizing that NEI-funded research is often foundational to advancing new treatments and therapies and is often the groundwork needed for industry partners to move forward, explaining that expanding grant mechanisms with additional funding for research could further support NEI researchers as they work on new and novel approaches.

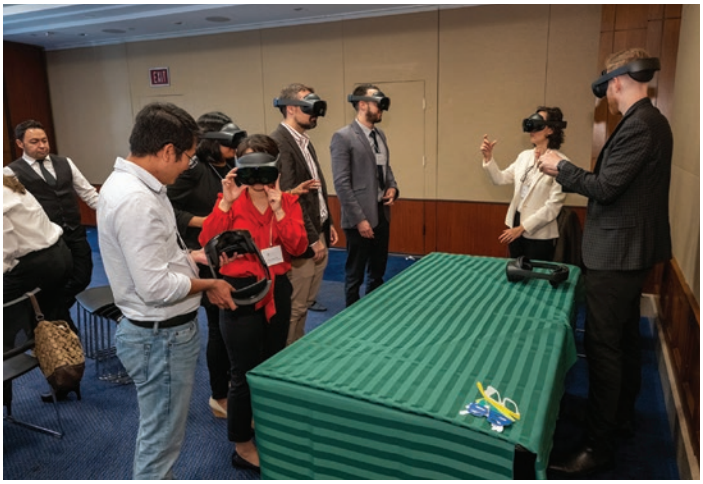
After Dr. Haider spoke, AMDF and Prevent Blindness patient advocate Mark Rosen spoke about his experience living with AMD and the importance of early detection and intervention. Mark shared how he was diagnosed with AMD in his 20s and received laser eye surgery which was one of the early treatments for AMD before the development of anti-VEGF injections and the newest therapies.

Mark explained how important early detection is and how, as an engineer and researcher himself, he helped develop an approved early detection tool that is available through AMDF for patients to track and identify AMD from home which can encourage individuals to go to an eye doctor if changes are noticed. With vision loss impacting Mark throughout his adulthood, he emphasized how important vision research is and the NEI is to develop a better understanding and ultimately new treatments and therapies to treat AMD and other vision loss.

In addition to the presentation from its speakers and partners, AEVR expressed its appreciation to VisionAid for providing a mixed-reality experience for attendees and provided attendees with an NEI virtual reality experience to help in understanding what a patient experiences when they have AMD. Through the VisionAid virtual reality goggles and NEI's VR app "*See What I See*," attendees were able to experience AMD in different settings. The NEI app can also be downloaded from the Apple App Store and Google Play Store for an at-home experience.

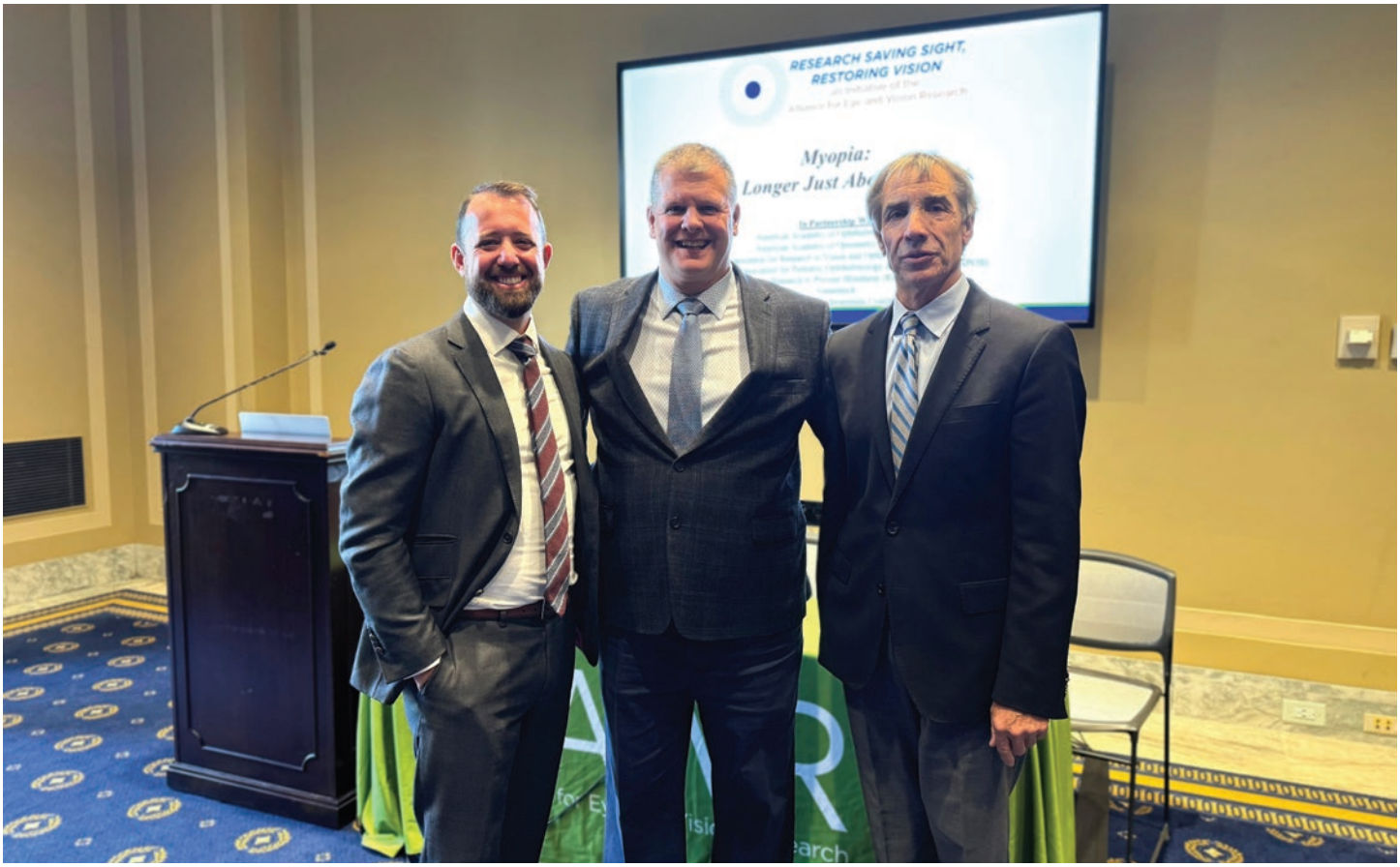
AEVR was pleased to be able to host this Congressional Briefing and thanks AMDF for partnering in raising awareness about AMD. AEVR also thanks its supporters who helped make this event possible, including:

- American Macular Degeneration Foundation (AMDF) (partner and lunch sponsor)
- Association for Research in Vision and Ophthalmology (ARVO)
- Research to Prevent Blindness
- Apellis
- Genentech (event support)



Briefing Attendees Experience Vision with AMD Using VisionAid's Virtual Reality Technology

MYOPIA CONGRESSIONAL BRIEFING



Myopia is a prevalent vision condition affecting millions of people worldwide that is expected to affect more than half of the global population by 2050. As the global prevalence of myopia continues to rise, researchers are diligently working to understand and manage this vision impairment effectively. To bring awareness to the importance of myopia management research, AEVR partnered with the American Academy of Ophthalmology (AAO) and the American Academy of Optometry (AAOptom) as part of its *Research Saving Sight, Restoring Vision Initiative* to conduct its Myopia Briefing on October 19 entitled *Myopia: It No Longer is Just About Glasses*.

The briefing featured Michael Repka, MD, MBA, from Johns Hopkins University who serves as Medical Director for Government Affairs for AAO, and Paul Walline, OD, PhD, from Ohio State University who serves as the President-Elect for AAOptom, each of whom has made significant contributions to understanding research management of myopia.

Dr. Repka began by emphasizing the projected growth of high myopia and his research into the risk factors for myopia development and progression in children which include parental myopia, ethnicity, use of electronic devices, low light levels, low time outdoors, education, family income, high-pressure educational system, reading at close distance, urban environments, and gender, with females seeing a higher incidence. Dr. Repka also highlighted research that investigates the link between outdoor activities and myopia which finds that increased time spent outdoors may play a protective role against the onset and progression of myopia in children.

Dr. Walline shared research into strategies that slow down the progression of myopia, particularly in children. These studies investigated the effectiveness of multifocal contact lenses in

controlling myopia compared to contact lenses that reshape the cornea (Orthokeratology) with data showing that both treatments work equally effectively and are safe in helping slow myopia progression and eye growth.

Dr. Repka then shared research into the use of low-dose atropine eyedrops which have shown promise and limited side effects, but the conclusion is that more data is needed and the long-term outcomes of patients who have undergone treatment need to be clarified.

Finally, Dr. Walline shared additional research on the future of myopia control, including red light, spectacles, delaying myopia onset, and a broader combination of treatments. Dr. Walline shared that while red light myopia control has shown some positive benefits, it may also cause retinopathy and additional data is needed. Concerning spectacle control, Dr. Walline emphasized that spectacles still play an important role in effective management and further emphasized how low-dose atropine eye drops may delay the onset of myopia. In looking at a combination of treatment methods, Dr. Walline explained that progress is being made but more research is needed to establish effective methods that may be available and emphasized many of these still need to go through the regulatory process for effectiveness and safety.

Both Dr. Walline and Dr. Repka's work underscores the importance of a multi-disciplinary approach to myopia management. Their research not only provides valuable insights into effective interventions but also emphasizes the need for continued collaboration between researchers, clinicians in optometry and ophthalmology, and educators to address the growing global burden of myopia.

In addition to partnering with AAO and AAOptom with our featured speakers, AEVR also thanks member supporters of its Myopia briefing which included:

- Association for Research in Vision and Ophthalmology
- Research to Prevent Blindness
- American Association for Pediatric Ophthalmology and Strabismus
- American Optometric Association
- Global Myopia Awareness Coalition
- Genentech

As the prevalence of myopia continues to rise globally, the impact of myopia research extends beyond the laboratory, influencing clinical practice and public health strategies. With ongoing collaborative efforts and innovative research, the future holds promising prospects for enhanced myopia management strategies that can benefit individuals of all ages.

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