

PRESIDENT'S MESSAGE

SUMMER DOMINATED BY DEBT CEILING DEAL

I want to thank our members for their efforts this summer and prepare you all for a busy fall with the Alliances. The Alliances navigated a challenging political environment through the summer months and continued advocacy efforts with our partners to champion vision research and emphasize the vital work of the National Eye Institute (NEI). Our members' continued support has remained fundamental to advancing the Alliances' efforts.

Over the past few months, NAEVR has continued advocating for increased funding for the NEI. Our advocacy efforts have entailed meeting and submitting requests with every appropriations committee member, submitting testimony to the Labor Health and Human Services and Related Agencies Subcommittees, and submitting a sign-on letter with our partners. We've emphasized the need for increased support for vision research and highlighted how vision research is often leading efforts across medical science. We're working now on plans to elevate grassroots engagement with our members and stakeholders to help legislators better understand the far-reaching impact of NEI's work.

Even with these efforts, I would be remiss not to acknowledge the challenges that have emerged with the debt ceiling agreement. The deal reached in June inevitably cast a significant shadow on the federal spending landscape for 2024 and 2025 which we discuss in the legislative update on the following page. While we are steadfast in our efforts, proposed funding bills from the House and Senate indicate we are likely to see a break in the cycle of annual NIH increases that we've enjoyed since 2016.

In addition to NAEVR's advocacy efforts, AEVR has continued to increase awareness of vision research with the Alliance's Rare Eye Disease Briefing held in May and the Dry Eye Briefing held in July. These briefings are responsible for continuing to engage Congress on the important impact of vision research and have provided a platform for experts, patients, and stakeholders to present and champion the research needs to address a multitude of different vision conditions.

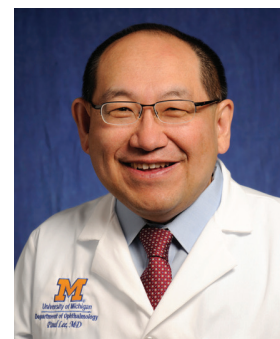
Our advocacy and awareness campaigns continue to showcase the collective strength and value of the vision research community. As we move forward, I encourage all of us to continue to stand together, amplify our voices, and advocate to elevate NEI-funded research.

I extend my deepest gratitude to each of you for your continued dedication and boundless commitment to the mission of the Alliances. It is through your continued support and engagement that we can have a lasting impact on vision science and vision health.

I wish you all an energizing fall and look forward to our continued successes ahead.

Sincerely,

Paul Lee, MD, JD
Executive Director, University of
Michigan Medical Group
Senior Associate Dean, Clinical
Affairs
Professor, Ophthalmology and
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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%	\$48.265 B +1.7%	\$44.6 B -6%	\$47.8 B +7%
NEI	\$835.71 M +1.4%	\$863.9 M +3.4%	\$896.55 M +3.8%	\$975 M +8.7%	\$896.5 M +0%	\$896.5 M +0%	\$896.5 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

DEBT CEILING IMPACT ON APPROPRIATIONS

On June 3, the President signed the “2023 Fiscal Responsibility Act,” an agreement to raise the nation’s debt ceiling while enacting concessions on current and future spending.

The agreement ultimately extends the borrowing limit for two years which gets the nation past the 2024 elections while effectively freezing domestic spending on non-defense programs for the next two years. The agreement also rescinds \$30 billion in unspent COVID-19 money that was intended for the COVID-19 response and to prepare for future pandemics, and several billion dollars from the IRS that was included as part of the Inflation Reduction Act to increase enforcement and customer service.

Essentially, the non-defense spending freeze represents an effective cut in real dollars when accounting for inflation over

the next two years and falls well short of the 7.3% increase the Biden Administration had sought for FY2024 in overall spending.

The agreement also seeks to limit the threat of a government shutdown for the next two years by requiring Congress to pass all twelve annual appropriations bills prior to January 1, 2024. If this is not achieved, the agreement stipulates that a continuing resolution would kick in that would cut discretionary spending for both defense and non-defense agencies by 1% until all the bills are passed. This provision is intended to incentivize lawmakers to pass each appropriations bill independently instead of in an omnibus, as both Democrats and Republicans want to avoid a cut to their key priorities. The same contingency would be in effect for 2025.

HOUSE APPROPRIATIONS SUBCOMMITTEE FY2024 SPENDING BILL CUTS NIH \$2.8 BILLION, FLAT FUNDS NEI

On June 22, the House marked up the Labor, Health and Human Services and Related Agencies (LHHS) bill. The markup was very contentious, with Democrats strongly criticizing the bill for its severe cuts to social programs. The bill passed by a voice vote, clearing it for full Committee consideration. The bill would fund the National Institutes of Health (NIH) at a level of \$44.6 billion, a cut of \$2.8 billion compared with the final FY2023 spending levels, or 6%. The

National Eye Institute (NEI) would be funded at a level of \$896.5 million, the same amount as in FY2023.

Of the \$2.8 billion reduction in the NIH funding level, most of the proposed cuts are attributed to the National Institute of Allergy and Infectious Diseases (NIAID), which would be cut \$1.5 billion, the Office of the Director, which would be cut \$573 million, and the NIH Innovation Fund (21st Century

Cures Act) which would be cut \$678 million. Almost all the Institutes were flat-funded, with a couple of exceptions. In the House's proposed budget, none of the individual Institutes would see their funding increase over FY2023. In addition to the cut of \$2.8 billion to the NIH base, the Advanced Research Projects Agency-Health (ARPA-H) would be cut

by an additional \$1 billion.

NAEVR, along with the larger medical research advocacy community, had requested FY2024 NIH funding of \$50.924 billion. NAEVR had asked Congress to fund the NEI at a level of \$975 million, an increase of \$78.8 million over FY2023.

SENATE APPROPRIATIONS COMMITTEE FY2024 SPENDING BILL marginally INCREASING NIH FUNDING, FLAT FUNDS NEI

On July 27, the Senate Appropriations Committee passed its FY2024 LHHS spending bill.

The bill would fund the National Institutes of Health (NIH) at a level of \$47.8 billion, an increase of \$943 million over FY2023 (+.7%). This stands in contrast to the bill approved by the House LHHS Appropriations Subcommittee, which made severe cuts to the overall NIH funding level. The Senate bill funds the National Eye Institute at a level of \$896.5 million, the same amount as FY2023 and what the House bill provides.

The bill also funds the Advanced Research Projects Agency-Health (ARPA-H) at a level of \$1.5 billion, the same level it was funded at in FY2023. The House-passed bill proposes to cut ARPA-H funding by \$1 billion.

On June 22, the House Defense Appropriations Subcommittee approved its FY2024 spending bill which included \$20 million for the VRP, the sixth year that the VRP has been funded at that level.

Committee Chair Patty Murray (D-WA) opened the Senate mark by saying that the bills recognize the spending limits imposed by the debt limit bill negotiated between the

President and Congress earlier this year and that the bills are 'serious' and the product of bipartisan efforts.

In her opening remarks, Committee Vice Chair Susan Collins (R-ME) noted that this marks the first time in 5 years that the Committee has passed all 12 individual appropriations bills, and that she hopes that Majority Leader Charles Schumer (D-NY) will begin bringing packages of bills to the Senate floor in September. She also said she was proud of the funding increases for the NIH, noting the increases for research on Alzheimer's, Cancer, and Diabetes.

The significant differences between the House and Senate-passed LHHS spending bills will likely present a challenge for Conference Committee members from the two chambers who must meet to iron out differences between the bills before final passage before the September 30th deadline.

With less than a month to complete work on all 12 Appropriations bills before the start of the new fiscal year on October 1, Congress is already preparing for the possibility of a shutdown or short-term Continuing Resolution (CR). If all bills are not finalized and passed before January 1, 2024, an automatic 1% cut would be implemented across all federal spending.

HOUSE APPROPRIATIONS SUBCOMMITTEE FY2024 SPENDING BILL FLAT FUNDS DEPARTMENT OF DEFENSE VISION RESEARCH PROGRAM

On June 22, the House included \$20 million in funding for the Vision Research Program funded within the Congressionally Directed Medical Research Programs (CDMRP) within the Department of Defense (DOD). This represents the sixth consecutive year the program has been level funded.

**Read the Sign-On Letter from the Vision
Research Community for FY2024
NEI Funding Here:**



NAEVR ATTENDS AND PRESENTS SESSION AT ARVO ANNUAL MEETING

ARVO ANNUAL MEETING

At the 2023 ARVO Annual Meeting in New Orleans, the NAEVR Booth served as the “Town Hall” for vision research funding advocacy and education. NAEVR wishes to thank the many ARVO members who visited, including those who contacted Congress to express appreciation for the past years’ increases in National Institutes of Health (NIH) and National Eye Institute (NEI) funding and requested continued robust increases in FY2024.

NAEVR answered questions from researchers about the Department of Defense’s (DOD) Vision Research Program (VRP) funding, which was the focus at NAEVR’s April 24 *Defense Related Vision Research Opportunities* session at which Vision Program Manager Q. Tian Wang, PhD was the primary speaker.



NAEVR’s Dan Ignaszewski and David Epstein spoke with interested researchers about how to increase federal funding for the NEI.

DEFENSE RESEARCH SESSION AT ARVO

In addition to attending and exhibiting at ARVO, NAEVR presented on April 24 the *Defense-Related Vision Research Opportunities* session at the ARVO Annual Meeting. The session featured Department of Defense (DOD) Vision Research Program (VRP) Manager Q. Tian Wang, PhD, who spoke about the history and priorities of the VRP and the expected Fiscal Year (FY) 2023 VRP Program Announcement. Over 100 researchers attended the session, including National Eye Institute (NEI) Director Michael Chiang, MD.

The VRP is one of 38 medical research programs managed by the DOD’s Congressionally Directed Medical Research Programs (CDMRP). Since its establishment by Congress in FY2009 and through FY2021, the VRP has funded 154 projects for a total of \$151 million, with FY2022 awards currently being negotiated with researchers whose projects have been selected for funding.

In her presentation, Dr. Wang emphasized that, unlike the National Institutes of Health (NIH) grant review process, CDMRP uses a two-tier review process—Peer Review first for scientific merit, and then Programmatic Review for military relevance. The Programmatic Review is especially interested in proposals that respond to DOD-identified research gaps identified in the Program Announcement.

Dr. Wang noted that the Pre-Announcement for the FY2023 VRP funding cycle was released on March 28 shortly before the ARVO Annual Meeting, and that a full Program Announcement was expected by late May. For FY2023, the VRP is funded at a level of \$20 million, the fifth year that the program is funded at that level. Per the Pre-Announcement, the VRP will employ five award mechanisms:

- the Investigator-Initiated Research Award (IIRA, with two funding levels),
- the Translational Research Award (TRA),
- the Focused Translational Team Science Award (FTTSA),
- the Clinical Trial Award (CT),
- and the Mentored Clinical Research Award (MCRA)



Tian Wang, PhD, VRP Program Manager addresses the audience.

Applications submitted to the FY23 VRP must address one or more of the following Research Focus Areas:

- Understanding and treatment of eye injury or visual dysfunction as related to military exposure.
- Diagnosis, stabilization, and treatment of eye injuries in austere environments and prolonged field care settings.
- Restoration of visual function after military exposure-related vision loss or severe visual impairment.

In addition to discussing the VRP, Dr. Wang discussed other DOD funding opportunities, such as the Joint Warfighter Program (JWP), which funds projects that have previously received DOD funding and would benefit from additional funds to further the research. She also highlighted the NEI-DOD Vision Research Collaborative (VRC), under which the NEI may provide additional funding opportunities for selected VRP proposals, enhance current NEI Program portfolios, expand the scope of research supported by the NEI, and provide support for high-quality projects addressing critical gaps in civilian and military vision research. The VRC was established in 2018 and was renewed in 2021 for 10 years. To date, the VRC has funded 6 projects for a total of \$4.65 million.

After Dr. Wang's presentation, two researchers who have received funding from the VRP participated in a panel discussion on their experiences with the program. Joe Ciolino, MD (Schepens Eye Research Institute/Mass Eye and Ear) and Kimberly Gokoffski, MD, PhD (University of Southern California) answered questions about how they first learned about research opportunities at the DOD and their experiences applying for funding.

NAEVR Director of Government Relations David Epstein emphasized to the audience that DOD funding opportunities are available to domestic and international researchers and that those who navigate the VRP are more likely to apply for funding from other DOD programs with keywords such as "sensory" and "rehabilitation" and for diseases with a vision impact. In addition to the VRP, eye and vision researchers have been extremely successful with other DOD research programs, receiving over \$286 million in funding from 17 separate programs.

In addition to her appearance at NAEVR's session, Dr. Wang, along with VRP Science Officer Colleen LaVinka, attended the ARVO Annual Meeting and met one-on-one with researchers from Sunday through Wednesday at a dedicated CDMRP booth. These meetings allowed researchers to discuss their ideas for projects and gauge the potential interest of the VRP.



Joe Ciolino, MD (Schepens Eye Research Institute/Mass Eye and Ear) and Kimberly Gokoffski, MD, PhD (University of Southern California) joined Dr. Wang on the panel.



The standing-room-only crowd included NEI Director Michael Chiang, MD, who was interested in learning more about DOD research.

AEVR RARE EYE DISEASE BRIEFING

On May 25, AEVR held a Congressional Briefing that focused on rare eye disease entitled: Rare Eye Disease: Research Bringing Treatments to Patients. The briefing featured topics around rare retinal disease and Thyroid Eye Disease (TED). Ben Shaberman, Vice President of Science Communications for the Foundation Fighting Blindness provided insight into research advancements that have been supported by the National Eye Institute (NEI) in rare retinal disease, and AEVR Executive Director, Dan Ignaszewski, shared information about the impacts of TED. In addition, patients who are living with Usher Syndrome and TED shared their experiences living with these diseases.

Classified as diseases that affect less than 200,000 Americans annually, rare diseases represent an area where significant research advancements are being made by NEI-funded research, private foundation-funded research, and the pharmaceutical and biotechnology industries.

Mr. Shaberman began the briefing with an overview of the retina and how various retinal degenerative diseases affect the ability of the retina to detect light and transmit information to the brain for processing. He detailed the individual impacts of rare retinal diseases present differently and how they can lead to progressive vision loss and blindness. He explained how private foundations, the NEI, and the industry play important roles in advancing research to bring treatments to patients.

Mr. Shaberman shared the advancements being made in gene therapy and emphasized the potential of currently funded research at NEI that seeks to use pluripotent stem cells that are derived from a patient's own blood that could be utilized to grow RPE cells that could be transplanted subretinally to provide future treatments to patients.

Patient Advocate Peggy Borst discussed her experience living with Usher Syndrome and Retinitis Pigmentosa and how the progressive vision loss she's experienced since her twenties has impacted her and her family. She shared that she knows there is likely a day when she will progress to full vision loss beyond the tunneling and

spotty vision she currently has, but that she hopes to see advancements that can stave off more vision loss and potentially restore vision in the future.

AEVR Executive Director, Mr. Ignaszewski, shared that in addition to rare retinal disease, TED is also considered a rare eye disease. Mr. Ignaszewski explained how TED is an immune system disorder resulting in hyperthyroidism causing the tissue around the eye to become inflamed resulting in swelling of eyelids, eye bulging, double vision, and additional vision loss. Like some of the advances in the retinal space, researchers have been able to draw on NEI-funded research to develop targeted therapies that help treat TED resulting in new treatments for patients beyond the pre-existing steroids and surgical interventions most used.

Natalie Roberts and LaQuilla Harris, two individuals living with TED shared their experience and how it has significantly impacted their lives, and how important research advancements have been in bringing new treatments to market that have helped improve their outcomes.



Patient Advocates Natalie Roberts and Peggy Borst, Dr. Shaberman, and AEVR Executive Director Dan Ignaszewski

AEVR thanks its sponsoring Member organizations for their support for the briefing:



AEVR DRY EYE DISEASE BRIEFING

On July 20, the AEVR partnered with the Tear Film & Ocular Surface Society (TFOS) to recognize July as Dry Eye Awareness Month, hosting its third *Research Saving Sight, Restoring Vision* Congressional Briefing of 2023, entitled: *A Lifestyle Epidemic: Ocular Surface Disease: Researching the Impact of Cosmetics on Eye Health*.

The Briefing featured international experts in dry eye disease (DED) and dry eye research including:

- David Sullivan, MS, PhD, FARVO, Founder of TFOS, recent past Associate Professor, Department of Ophthalmology, Harvard Medical School and Senior Scientist, Schepens Eye Research Institute
- Kathy Hammitt, Vice President of Medical and Scientific Affairs at Sjögrens Foundation
- Bridgitte Shen Lee, OD, FAAO, FBCLA, FEAOO, Dipl ABO, Founder, Vision Optique & Ocular Aesthetics
- Shane Swatts, OD, Founder, Eastern Virginia Eye Associates and OD Immersion
- Amy Gallant Sullivan, BS, Executive Director TFOS, CEO & Founder, ESSIRI Labs

The briefing began by highlighting that more than forty million Americans are living with dry eye disease and that dry eye disease is the leading cause of patient visits to eye care practitioners. Dry eye disease is estimated to have a \$3.84 billion impact on the US healthcare system and is estimated to exceed \$55 billion annually due to diminished productivity.

Dr. Sullivan then discussed the findings of the latest TFOS Report on dry eye disease which focuses on the impact of cosmetics on eye health. The report details the significant number of ingredients in today's cosmetics that act as allergens, carcinogens, endocrine disrupters, immunosuppressants, irritants, mutagens, toxins, and/or tumor promoters. Additionally, Dr. Sullivan highlighted the impacts of eye makeup ingredients that affect the ocular surface and/or adnexa, including benzalkonium chloride,

chlorphenesin, formaldehyde-releasing compounds, parabens, phenoxyethanol, phthalates, prostaglandin analogues, vitamin A metabolites (retinoids), salicylic acid, and tea tree oil.

The panel discussed the significant impact each can have on eye health. Since cosmetics are largely unregulated in the United States, it was also explained that ingredients can often be significantly in excess of what are considered safe levels for human corneal, conjunctival, and meibomian gland cells which, when negatively impacted, can severely increase the risk and effects of dry eye disease.

Each of the panelists detailed their experiences with DED. Ms. Hammitt shared her experience as a patient with severe dry eye disease and its impact on her quality of life. She discussed how she regularly must utilize eye drops and that due to the severe nature of her dry eye disease, she can no longer form tears to moisten her eyes or develop tears to cry as a person without severe dry eye would be able to do. Dr. Shen Lee and Dr. Swatts noted the significant challenges they see with more patients coming into their offices with dry eye symptoms and they have to explain how cosmetics are playing a significant role in their discomfort. Ms. Sullivan highlighted the importance of regular eye exams and the need to educate eye care practitioners and patients about the medical risks associated with eye products and procedures and emphasized the importance of addressing regulations on cosmetic products. Finally, she stated that more research is needed to determine the effects of cosmetics and procedures on the ocular surface.

Ultimately, the panel concluded with the TFOS Report finding that the widespread nature of these ingredients in cosmetic products — Parabens are included in over 22,000 cosmetic products in the US— is making the use of cosmetics a significant lifestyle challenge. Further, it was found that these products and/or procedures may cause harm and/or procedures may be associated with multiple adverse effects and that they may lead to or exacerbate dry eye disease.

AEVR thanks its partner and sponsoring Member organizations for their support for the briefing:



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SPECIAL THANKS TO MEMBERS AND SUPPORTERS OF THE ALLIANCES

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MEMBERS

