NAEVR/AEVR and its Executive Director James Jorkasky are key contributors to our efforts to fund vision research. Participating in two recent events in Washington DC made it clear how critical our community’s involvement in educating our country’s leaders about the importance and exciting advances in vision research are for our ability to continue to do groundbreaking research. At both the September 5 National Institutes of Health (NIH) campus farewell event held for retiring National Eye Institute (NEI) Director Paul Sieving, MD, PhD, and the September 18-19 Fifth Annual Emerging Vision Scientists (EVS) Day, which is described in detail within this Report, the achievements and future potential of colleagues across our field were highlighted.

At the NIH event, on behalf of NAEVR/AEVR, we were delighted to have the opportunity to present to Dr. Sieving an Alliances’ plaque that read, “In appreciation for his leadership of the NEI and his commitment to the vision health of all Americans.” Several leaders in both vision research and the NIH highlighted the many ways in which vision researchers have pioneered advances in medical research. As you know, although Paul retired from the NIH, he is still fully committed to vision research through his leadership of a new Center for Ocular Regenerative Therapy at the University of California at Davis.

Acting NEI Director Santa Tumminia, PhD has met with Jim and ARVO Executive Director Iris Rush—who also serves as a NAEVR/AEVR Director—regarding ways to partner in communicating about the importance of good vision next year, a very apt 2020. At the October 4 National Advisory Eye Council (NAEC) meeting, Dr. Tumminia continued that spirit of partnership by announcing numerous staff changes and new initiatives that are driving the institute forward, especially encouraging vision community input on the latter when they are announced. Among the staff changes announced was that Mary Frances Cotch, PhD had been named NEI’s Acting Deputy Director. An epidemiologist by training, Dr. Cotch will be critical to NEI’s announced expanded opportunities for active member participation.

As part of NAEVR/AEVR’s expanded commitment to engaging broadly with our community, Jim organized a dinner meeting of nearly a dozen Alliances member organizations with a Washington presence to share insights and experiences on advocating for vision research. As the new Board President, I was pleased to see the easy rapport among the attendees, which is a reminder about how important face-to-face interactions are as we all work together on advocacy and education for vision research (more about that later). The EVS program is one of the most significant activities for our vision research community, and this year was a particularly strong showing. Starting with the outstanding presentation by NEI intramural researcher Kapil Bharti, PhD, about NEI’s first-in-human clinical trials for an induced pluripotent stem cell therapy for dry Age-related Macular Degeneration (AMD) at the International AMD Awareness Week Congressional Briefing, the entire program was impactful in both science and engagement of our government leaders. The AEVR Congressional Poster Reception and AEVR Advocacy Day provided our scientists with a tremendous opportunity to interact with Members of Congress and their staffs. Having heard directly from past Kellogg participants about the value of prior EVS events, the experiences gave all of us an invaluable opportunity to showcase the importance of continued robust funding for the NIH and NEI, especially to support the next generation of vision scientists.

Our Alliances Boards and Jim are fully committed to maximizing opportunities for active member participation, since being engaged first-hand is the best way to see the value of the Alliances’ efforts. In addition to Jim’s excellent update emails and this quarterly Report, as well as the recently launched redesigned Web site, the Boards and I want to engage members through upcoming quarterly Webcasts and a new Annual Town Hall so that there is an opportunity for two-way interaction. The Board has also created a Working Group to investigate Councils for sectors of the membership, such as Professional Societies, to ensure that the Alliances meet directly with the clinicians and researchers who directly benefit from the NIH/NEI-funded discoveries facilitated by NAEVR’s advocacy for increased funding for the NEI and special NIH initiatives, such as the BRAIN and Regenerative Medicine Initiatives.

Shortly, the Alliances will be issuing the 2020 renewal campaign, and I urge you to support NAEVR and AEVR during this next year of challenges for both the unfinished Fiscal Year (FY) 2020 and upcoming FY2021 appropriations processes. As always, if you have any comments, please feel free to email me!

Visit the NEW www.eyeresearch.org, with improved navigation, easier-to-read text, and compatibility with a variety of devices.
NEED TO KNOW:  
As the October 1 date for the start of FY2020 approached, Congress had yet to finalize any appropriations bills due to disagreement over top-line funding levels and policy riders. On September 27, the President signed into law the Continuing Resolution (CR) that funds the government in FY2020 until November 21. The CR funds at the FY2019 level, which limits an agency from beginning new programs or spending more in any one month in FY2020 than it did in FY2019. Although Congress is already discussing a potential second CR that would fund the government into March 2020 so as not to conflict with impeachment activities, options include a full-year CR—or even a government shutdown.

Whither FY2020 Appropriations?  
At this time last year, the Alliances were still thanking Congress for the minibus appropriations report that finalized prior to the end of FY2018 the FY2019 Department of Defense (DOD) and Labor, Health and Human Services, and Education (LHHS) spending bills—the latter with a $2 billion NIH increase.

Fast forward to now, with the government operating under a CR, and here’s where we stand:

• The House has passed ten of its twelve FY2020 spending bills, with the LHHS bill including a $2 billion NIH increase and a $39 million NEI increase. The bill funds the $492 million in 21st Century Cures Act special initiatives (BRAIN, Cancer Moonshot, Precision Medicine, and Regenerative Medicine) and maintains the Extramural Salary Cap at Executive Level II ($192,300 in FY2019).

• The Senate has not passed any of its spending bills, but introduced in mid-September an LHHS bill—which was not subject to Committee process—that includes a $3 billion NIH increase and $44 million NEI increase. As in the House, it funds 21st Century Cures initiatives and maintains the Extramural Salary Cap at EL II.

• Both the House and Senate LHHS bills contained language that emphasized the importance of inflation-plus-growth funding increases for the NIH Institutes and Centers (I/Cs), in addition to the various Congressionally-mandated special initiatives.

• Even prior to impeachment discussion, the ability of Congress to finalize appropriations was stymied by disagreement over top-line funding levels and policy riders. In addition to being a procedural distraction to appropriations, the impeachment inquiry also does not facilitate an atmosphere for agreement between the parties on spending and policy issues.

A series of CRs, or a full-year CR, all result in one thing—disruption of the research enterprise, as grant awards are delayed and researchers scramble to obtain private “bridge” funding to maintain their labs. Also, a full-year CR is essentially a cut, as agency funding levels would not increase but biomedical inflation would continue to eat away at purchasing power at the rate of 2.7 percent annually.

Since this is not the first time that appropriations have been “held hostage” by larger forces, NAEVR will continue to advocate along with its colleagues in medical research for Congress to take action on one of its primary responsibilities—the annual appropriations process.

### NAEVR Scorecard Legislative Issues

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>$50.07 B</td>
<td>$50.6 B</td>
<td>$51.1 B</td>
<td>$51.7 B</td>
<td>$52.3 B</td>
<td>$53.0 B</td>
<td>$53.8 B</td>
<td>$54.6 B</td>
</tr>
<tr>
<td>NEI</td>
<td>$675.4 M</td>
<td>$678.9 M</td>
<td>$682.1 M</td>
<td>$685.3 M</td>
<td>$688.5 M</td>
<td>$691.7 M</td>
<td>$694.9 M</td>
<td>$698.1 M</td>
</tr>
<tr>
<td>APPROP:�� punished OPERATIONAL NET:</td>
<td>$1750 M</td>
<td>$1760 M</td>
<td>$1770 M</td>
<td>$1780 M</td>
<td>$1790 M</td>
<td>$1800 M</td>
<td>$1810 M</td>
<td>$1820 M</td>
</tr>
</tbody>
</table>

**NEI Operational Net reflects $5.9 M transferred back to NIH Central of SOCA funding and Secretary transfer.**

**NEI Operational Net reflects $7.4 M transferred back to NIH Central of SOCA funding.**

Visit the NIH/NEI funding section of NAEVR’s Web site at www.eyeresearch.org for full details.

### NAEVR Hosted its Contact Congress Booth at the Recent American Academy of Optometry Annual Meeting in Orlando, Florida. Among those urging their Congressional delegations to finalize appropriations was Dean VanNasdale, Jr., OD, PhD (Ohio State University College of Optometry), who participated in AEVR’s Third Annual Emerging Vision Scientists Day in 2017. The Fifth Annual EVS Day held in September 2019 is featured inside this Report.
New Stem Cell-Based Therapies for AMD and Blast-Related Eye Injuries

On September 18, in recognition of both Healthy Aging Month and International Age-related Macular Degeneration (AMD) Awareness Week, AEVR’s Decade of Vision 2010-2020 initiative and co-sponsors (see box) held a Congressional Briefing entitled New Stem Cell-Based Therapies for AMD and Blast-Related Eye Injuries featuring tenured NIH intramural researcher Kapil Bharti, PhD. This event began AEVR’s Fifth Annual Emerging Vision Scientists Day on Capitol Hill, summarized in stories on the next two pages.

NEW TO KNOW:

On September 18, in recognition of both Healthy Aging Month and International Age-related Macular Degeneration (AMD) Awareness Week 2019, AEVR’s Decade of Vision 2010-2020 Initiative and co-sponsors (see box) held a Congressional Briefing entitled New Stem Cell-Based Therapies for AMD and Blast-Related Eye Injuries featuring tenured NIH intramural researcher Kapil Bharti, PhD. This event began AEVR’s Fifth Annual Emerging Vision Scientists Day on Capitol Hill, summarized in stories on the next two pages.

AEVR President Dr. Paul Lee provided a welcome to the Briefing that featured Dr. Bharti, who serves as a Senior Investigator in the Ocular and Stem Cell Translational Research Section at the NEI. He has also received funding from the Department of Defense’s (DOD) Psychological Health/ Traumatic Brain Injury (PH-TBI) Program for new stem cell approaches to treat blast-related eye injuries, complementing his NIH Common Fund and NIH intramural-funded AMD and blast injury research.

Dr. Bharti explained that tremendous strides in the treatment of patients with wet AMD have resulted from Food and Drug Administration (FDA)-approved anti-Vascular Endothelial Growth Factor (VEGF) therapies—which emerged from initial NIH funded research—that stabilize vision loss and may improve lost vision. Although research to develop new therapies to treat geographic atrophy or the dry form of AMD has lagged behind that for wet AMD, he described the Phase I first-in-human clinical trial that will test the safety of using an induced pluripotent stem cell (iPSC)-based therapy to treat AMD. The study, in which he serves as Lead Investigator, had recently been submitted to the FDA for review.

The therapy involves taking a patient’s blood cells and, in a lab, converting them into IPS cells, which can become any type of cell in the body. The IPS cells are programmed to become Retinal Pigment Epithelium (RPE), the type of cell that dies early in the geographic atrophy stage of AMD. RPE cells nurture photoreceptors, the light-sensing cells in the retina. In geographic atrophy, once RPE cells die, photoreceptors eventually also die, resulting in blindness.

“Although it could be another 10 years until we have an approved therapy, we are one step closer to providing hope for patients with vision loss.”—Dr. Bharti

The therapy is an attempt to shore up the health of remaining photoreceptors by replacing dying RPE with patient’s own iPSC-derived RPE.

Through dramatic multi-dimensional graphics that documented prior work in animal studies, Dr. Bharti demonstrated how, before they are transplanted, the iPSC-derived RPE are grown in tiny sheets one cell thick, replicating the natural structure within the eye. This monolayer of iPSC-derived RPE is grown on a biodegradable scaffold designed to promote the integration of the cells under the retina. A specifically designed surgical tool was built for the task of inserting the patch of cells under the retina. Proof of concept in the initial animal studies focused on the structural and functional assessment of the transplanted tissue and the RPE injury. For example, imaging studies confirmed that the lab-made cells had integrated within the animal eye, while electrical responses recorded from photoreceptors “rescued” by RPE patches were closer to normal, whereas photoreceptors treated with a control empty scaffold had died.

In describing the types of stem cell-derived tissues that may be needed at different stages of retinal disease or retinal injury to various structures in the eye—including the choroid, which is the vascular layer that provides nutrients to the RPE—Dr. Bharti spoke about his complementary DOD-funded research to develop an RPE patch, an RPE/choroid patch, or retina/RPE/choroid patch, depending on the extent of blunt or blast injury that can lead to complex tears and tissue loss in the retina.

He concluded by stating, “Although the timeline for development of an approved stem cell therapy for dry AMD is lengthy, we have successfully completed the preclinical work in animals and are now ready to embark on the Phase I safety trial in humans.”

AEVR wishes to thank its co-sponsors:

Research to Prevent Blindness
American Macular Degeneration Foundation
Association for Research in Vision and Ophthalmology
European Vision Institute
Lighthouse Guild
Macular Degeneration Partnership

AEVR also thanks Regeneron for their support for event management.

AMD, which is one of the leading causes of blindness and low vision in the United States and the developed world, destroys central vision through proliferation of new blood vessels in the “wet” form of the disease or gradual breakdown of cells in the retina. The light-sensitive tissue at the back of the eye, in the “dry” form of the disease, also called geographic atrophy. Vision loss from AMD makes it increasingly difficult to read, drive, and perform other everyday tasks.
Since 2015, AEVR has hosted more than 120 early-stage investigators on Capitol Hill. Summaries of the 2015-2018 events—including brief documentary videos—are posted at www.eyeresearch.org

The 20 early-stage investigators—reflecting the breadth of basic and clinical vision research and who have not yet received their first investigator-initiated (R01) grant from the NIH or NEI—displayed posters of their research in an evening Congressional Reception and provided on-camera interviews about their research for a documentary video. Both the educational and advocacy activities were built around one question—"How will the breakthrough research being conducted by these EVSs prevent, delay, and treat vision disorders—which will grow to an annual United States cost burden of $717 billion in inflation-adjusted dollars by year 2050, as projected by Prevent Blindness in its 2014 study entitled The Future of Vision: Forecasting the Prevalence and Costs of Vision Problems.

A number of the EVSs presented research into therapies and technologies that are in development by a team in which they participate at their academic institution led by an NEI-funded Principal Investigator. The posters not only described the research, but also presented “public health” data about the incidence/impact of the disease and its cost as a means to fully explain benefit of the research investment.

Dr. Lee hosted a brief program that included comments from Michael Steinmetz, PhD, NEI’s Director of Extramural Science Programs, who described the Institute’s commitment to the next generation of vision scientists. He was joined by NEI’s Shefa Gordon, PhD and Nora Wong, MPH from NEI’s Office of Program Planning and Analysis and Dustin Hays from NEI’s Office of Communications. The NEI team visited each poster and spoke with the researchers, as did Dr. Lee and Dr. Hofland. Cong. Scott DesJarlais, MD (R-TN) and Cong. Steve Cohen (D-TN) visited the posters after also attending AEVR’s AMD Congressional Briefing earlier that day.

The class of the Fifth Annual Emerging Vision Scientists Day who participated in the AEVR and NAEVR events reflecting the breadth of breakthrough vision research and were nominated by their Departments of Ophthalmology or Schools/Colleges of Optometry from across the nation.

Stephanie Adams, OD, PhD  (Illinois College of Optometry)
Ava Bittner, OD, PhD  (UCLA/Stein Eye)
Kinga Bujakowska, PhD  (Mass Eye & Ear/Harvard Medical School)
Florence Cabot, MD  (University of Miami/Bascom Palmer)
Vicki Chen, MD  (Tufts Medical Center)
Daniel Coates, PhD  (University of Houston College of Optometry)
Ross Collery, PhD  (Medical College of Wisconsin)
Susana da Silva, PhD  (University of Pittsburgh)
Irina De La Huerta, MD, PhD  (Vanderbilt University)
Abigail Fahim, MD, PhD  (University of Michigan)
Muneeb Faq, PhD  (NYU/Langone)
Ian Han, MD  (University of Iowa)
Lynn Hassman, MD, PhD  (Washington University)
Ajay Kurian, MD  (Flaum Eye/University of Rochester)
Jesson Martin, PhD  (Kentucky College of Optometry)
Sangeetha Metlapally, PhD  (New England College of Optometry)
Sumit Sharma, MD  (Cleveland Clinic/Cole Eye Institute)
Jessica Steen, OD  (NOVA Southeastern College of Optometry)
An-Jey Su, PhD  (University of Colorado)
Jia Yin, MD, PhD  (Mass Eye & Ear/Harvard Medical School)
Emerging Vision Scientists to Congress: Finalize FY2020 Spending Bills Since Delayed Appropriations Hurt

**NEED TO KNOW:**
On September 19 and under the auspices of NAEVR, the EVSs visited their Congressional delegation offices where they requested final, robust FY2020 NIH/NEI appropriations.

**NAEVR Advocacy Day**
The 20 EVSs conducted Congressional office visits in which they thanked Congress for robust NIH/NEI funding increases in the FY2016-2019 timeframe, as well as for passing the Bipartisan Budget Act of 2019 in late July that increases the FY2020 and 2021 spending caps. In requesting that Congress finalize FY2020 appropriations in a timely fashion with continued robust increases, they also cautioned about the detrimental impact that Continuing Resolutions can have on research, including delaying awards or requiring researchers to seek “bridge” funding while awaiting funding. That same day, however, the House did pass a CR funding the government in FY2020 until November 21, as the House and Senate were in disagreement over appropriation bills’ top-line funding levels and policy riders.

In House visits, the EVSs also requested that the Member become a co-sponsor of H.R. 2620, the Faster Cures and Treatments for Eye Diseases Act, which would authorize and implement the “Eye Bond” program of private funding to speed translational vision research.

**Sponsor RPB Comments**
For the fifth year, RPB provided a grant to support AEVR’s events. RPB President Dr. Brian Hofland commented:

“The Fifth Annual EVS Day was important—the cost of biomedical research goes up significantly each year with the rapid rate of medical inflation, and it’s essential that we educate members of Congress and their staffs on the need to provide robust funding for cutting-edge vision research. It’s also important to help early-career scientists bring their real-life research experiences to the Hill. Through this event we’re empowering participants to make an immediate difference in the future of our field and, hopefully, setting up a life-long commitment to science advocacy.”

**EVS Impressions/Development**
The Alliances designed this program to be an important component of an EVS’s professional development and to train the next generation of vision research advocates. This year’s participants commented...

“My visit to Capitol Hill really opened my eyes to the process of advocacy for research funding, as well letting me communicate my desire and ability to help those suffering from vision loss and eye disease. I felt lifted away from test-tubes and pipettes to appreciate the bigger picture as I met with legislators to discuss research and development that comes from NEI funding.” — Dr. Collery

“I could feel the enthusiasm as I described the tremendous impact of NIH funding and the importance of my research to help people with vision loss as I spoke to the Congressional staff. They were extremely positive and engaged, and I had the opportunity to drive home the message that robust increases in NIH/NEI funding are critical to support our work that has direct, meaningful impact on visually impaired patients and has great potential to substantially improve clinical care nationwide. It is truly an exciting time to be a young clinician-scientist who will help shape the future of vision research.” — Dr. Bittner

“As an early-career clinician scientist trying to balance the rigors of clinical care, starting and maintaining a lab, and investing in teaching and mentorship, it is easy to overlook the importance of advocacy on local and national levels. The day highlighted for me the importance of dedicating time and effort to interact with influential leaders in our government to ensure continued support for the things we do daily—provide excellent clinical care, teach the next generation, and advance our ability to diagnose and treat eye disease.” — Dr. Han
World Sight Day 2019 Congressional Briefing Focuses on the Promise of Artificial Intelligence for Vision and Eye Health

NEED TO KNOW:
The October 17 World Sight Day Congressional Briefing, held by VISION 2020 USA and supported by 18 vision organizations, including AEVR (see box right), focused on the promise of Artificial Intelligence (AI), Information Technology (IT), and Big Data for vision and eye health. The Briefing featured speaker Michael F. Chiang, MD, Knowles Professor of Ophthalmology & Medical Informatics and Clinical Epidemiology at Oregon Health & Science University (OHSU), and Associate Director of the OHSU Casey Eye Institute.

From Left: Victoria Sheffield of the International Eye Foundation, VISION 2020 USA Chair Mitchell Brinks, MD, MPH, and featured speaker Michael F. Chiang, MD, both from the NEI with Dr. Brinks. Dr. Cotch serves as the NEI’s Acting Deputy Director.

From left: Maria Zacharias and Mary Frances Cotch, PhD, both from the NEI, with Dr. Brinks. Dr. Cotch provides further information on the NEI's Acting Deputy Director.

About VISION 2020 USA
VISION 2020 USA has been organized to better coordinate the efforts of the many US organizations working in the field of blindness prevention, both nationally and internationally. VISION 2020 USA is committed to assuring the right to sight for all peoples both within the US and countries outside the US. Launched in 2009, nearly 40 organizations have come together under the VISION 2020 USA umbrella, which is the national entity within the International Agency for the Prevention of Blindness (IAPB) and its VISION 2020: The Right To Sight initiative.

WSD Briefing Sponsors included:
Alliance for Eye and Vision Research
American Academy of Optometry
American Optometric Association
Association for Research in Vision and Ophthalmology
Casey Eye Institute
Helen Keller International
Himalayan Cataract Project
International Eye Foundation
Kellogg Eye Center for International Ophthalmology
Lighthouse Guild
Lions Club International
One Sight
Orbis International
Pacific University College of Optometry
Prevent Blindness
R. Ramchandran, Flaum Eye Institute
Seva Foundation
Vision Impact Institute

EXECUTIVE DIRECTOR
James F. Jorkasky
240-221-2905 | jjames@eye research.org

Director, Government Relations and Education
David H. Epstein
240-221-2902 | depstein@eye research.org

1801 Rockville Pike, Suite 400
Rockville, Maryland 20852-1606
www.eyeresearch.org

NEED TO KNOW:
The October 17 World Sight Day Congressional Briefing, held by VISION 2020 USA and supported by 18 vision organizations, including AEVR (see box right), focused on the promise of Artificial Intelligence (AI), Information Technology (IT), and Big Data for vision and eye health. The Briefing featured speaker Michael F. Chiang, MD, Knowles Professor of Ophthalmology & Medical Informatics and Clinical Epidemiology at Oregon Health & Science University (OHSU), and Associate Director of the OHSU Casey Eye Institute.

From Left: Maria Zacharias and Mary Frances Cotch, PhD, both from the NEI, with Dr. Brinks. Dr. Cotch serves as the NEI’s Acting Deputy Director.

Since Dr. Chiang’s specialty is pediatric ophthalmology, he initially described the potential to harness AI to better diagnose and treat such visual conditions as Retinopathy of Prematurity (ROP, a blinding eye condition in premature babies), as well as Diabetic Retinopathy (DR, the leading cause of vision loss in the working age population) and AMD (the leading cause of vision loss in individuals age 65 and older). Stating that ophthalmology has taken the lead in the use of AI, he recognized that the first FDA-cleared autonomous AI system in any field of medicine was approved in 2018 for the automated detection of clinically significant DR. He then described some of the implications for how AI might be used in screening for eye disease in the future, whether at a Primary Care Physician office versus that of an ophthalmologist, or how it could be managed by the private sector, such as at a retail store.

Stating that AI holds the potential to diagnose eye disease earlier and better, he acknowledged that it may also help to predict systemic health issues, such as cardiovascular disease. However, AI is only as good as the Big Data that is used to develop it. In that regard, he emphasized that ophthalmology again has taken the lead, with the American Academy of Ophthalmology’s IRIS® Registry not only being the first national registry but the largest specialty-specific registry in any field of medicine, with information on 253 million eye exams to-date. The Big Data gleaned from registries such as IRIS®, facilitate the development of population-based medicine, which then leads back to more personalized health care approaches.

He concluded by identifying some of the barriers for Big Data, such as Electronic Health Records (EHR) that do not fully reflect the information collected during an eye exam (for example, the complex images that show changes in the eye) or that lack interoperability with other EHR systems.

Prior to Dr. Chiang’s presentation, Victoria Sheffield of the International Eye Foundation spoke about the recently issued World Health Organization (WHO) Report, which estimates that there are 2.2 billion people globally experiencing vision impairment, and how it can be used as a roadmap to guide the vision community’s research and educational activities in the next decade.

Executive Director
James F. Jorkasky
240-221-2905 | jjames@eye research.org

Director, Government Relations and Education
David H. Epstein
240-221-2902 | depstein@eye research.org

1801 Rockville Pike, Suite 400
Rockville, Maryland 20852-1606
www.eyeresearch.org