Research and Funding Forecast

NAEVR/AEVR Report
2016 Alabama Vision Coalition Meeting
Birmingham, Alabama
October 28, 2016
About NAEVR and AEVR

NAEVR, a 501c4 “social welfare” advocacy organization, and AEVR, a 501c3 educational foundation, serve as the privately-funded “Friends of the National Eye Institute (NEI)”

• AEVR was founded in 1993 and NAEVR in 1997 by the American Academy of Ophthalmology (AAO), Association for Research in Vision and Ophthalmology (ARVO), and Association of University Professors of Ophthalmology (AUPO).

• NAEVR and AEVR’s goals are to achieve the best eye/vision care for all Americans through advocacy and public education about federal funding for vision research (NIH/NEI, DOD, VA, NSF, DOE, etc.).

• Comprised of 55 organizations, representing ophthalmic and optometric professional societies, patient and consumer groups, private funding foundations, and industry.

• Comments extensively to appropriators about the annual fiscal year funding process, as well as to authorizers (House E&C, Senate HELP) about NIH/NEI structure/management issues.

• Relates NIH research to FDA to foster “more progressive” product approval policies for ophthalmic drugs and devices. The ARVO-managed NEI/FDA Endpoints Symposia, held since 2006, emerged from AAO/NAEVR hosted meetings in 2005 of NEI and FDA staff.
NAEVR and AEVR each have a 15-member Board of Directors that reflects the diversity of the membership:

- Laurent Attias (Alcon Laboratories)
- Craig Crosson, Ph.D. (Medical College of South Carolina)  
  ARVO Rep.
- Steven Feldon, M.D. (Flaum Eye Institute/University of Rochester)  
  AUPO Rep.
- Yehia Hashad, M.D. (Allergan, Inc.)
- Linda Hazlett, Ph.D. (Kresge Eye Institute/Wayne State University)
- Joan Miller, M.D. (Harvard Medical School/Mass Eye and Ear Infirmary)
- Peter McDonnell, M.D. (Wilmer/Johns Hopkins)
- Bartly Mondino, M.D. (Jules Stein/UCLA), Boards Vice President
- Iris Rush, C.A.E. (ARVO Executive Director)
- William Schmidt, J.D. (Foundation Fighting Blindness), Boards Secretary
- Earl Smith, O.D., Ph.D. (University of Houston College of Optometry)
- Greg Skuta, M.D. (Dean McGee Eye Institute/University of Oklahoma)  
  AAO Rep.
- David Tanzer, M.D. (Abbott Medical Optics)
- Thomas Yorio, Ph.D. (UNT Health Science Center), Boards Treasurer
- Karla Zadnik, O.D., Ph.D. (Ohio State University College of Optometry)
FY2016 Vision Research Funding

Estimated Total of FY2016 US Vision Research: $2.86 B

Federal Components ($784 M):
- $680 M (NEI Extramural/Intramural portion of $708 M budget)
- $ 50 M (BRAIN, Other NIH I/Cs: aging, diabetes, imaging)
- $ 20 M (DOD/Vision Trauma Research, other programs)
- $ 20 M (VA Intramural Research, TBI centers)
- $ 10 M (Depts. of Energy/National Science Foundation)
- $  4 M (Vision Loss Prevention Research/CDC, HRSA)

Private Foundation Funding (estimate): $75 M
(excludes academic institution philanthropy)

Industry (estimate): $2 B

Takeaway: There is money to be had, the trick is how to get it!
FY2012-2016 NIH/NEI Funding; FY2017 Proposed

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<tbody>
<tr>
<td>NIH</td>
<td>$30.64 B .81%</td>
<td>$29.15 B -5.5%</td>
<td>$30.07 B +3.5%</td>
<td>$30.3 B +0.5%</td>
<td>$32.1 B +6.6%</td>
<td>$33.1 B +2.6%</td>
<td>$34 B +6.3%</td>
<td>$33.3 B +3.9%</td>
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<tr>
<td>NEI</td>
<td>$702.1 M +0.27%</td>
<td>Approp: $662.15 M -5.7%</td>
<td>Approp: $682.1 M +3%</td>
<td>Approp: $684.2 M +0.31%</td>
<td>Approp: $715.9 +4.6%</td>
<td>Approp: $708 M (Flat-funded)</td>
<td>$740.8 M +4.6%</td>
<td>$735.6 M +3.9%</td>
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* NEI appropriated amount is net of $36 M in sequester, cut and $3.9 M Secretary transfer.
  Operational Net reflects $5.8 M transferred back to NIH Central of the successful completed Studies of Ocular Complications of AIDS (SOCA) funding.

^ NEI Operational Net reflects $6.9 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.

+ Includes $1.825 B in mandatory funding.

- FY2016:
  - NIH increase of $2 B to $32.1 B, the largest increase since FY2003
  - NEI increase of $31.2 M to $708 M restores to pre-sequester FY2012 level
- NEI Director Dr. Paul Sieving reports:
  - FY2016 NEI Success rate of 25% (18% for NIH overall)
  - NEI is still funding 100 less investigators than FY2012
FY2016 NEI Funding Versus Purchasing Power

FY2016 NEI funding has minimal growth (0.8%) after four years...

...while losing purchasing power due to biomedical inflation
Medical Research Funding from NIH/NEI To Alabama

In FY2015, 24 Alabama Institutions received NIH funding:
- 650 grants totaling $307 M
- UAB is the largest recipient at $243.2 M
- Alabama received $7.7 M in NIH grants to train the next generation of scientists

In FY2015, the NEI awarded 32 Grants totaling $3.6 M, all to UAB
- Reflect the breadth of NEI research:
  - Retinal
  - Glaucoma
  - Corneal
  - Lens and Cataract
  - Strabismus, Amblyopia, and Visual Processing
  - Low Vision
Major Areas of NEI Research/Education

Genetic Basis of Eye Disease
• NEI supports domestic and international consortia to study.
• Reflects move to “Precision Medicine,” a major NIH initiative—one once you know genetic basis, can develop diagnostics and tailored treatments.

Audacious Goals Initiative: Regenerating Neurons and Neural Connections in the Eye and Visual System
• Initial awards in novel imaging technologies, FY2016 awards in factors involved in regenerating the visual system.
• Awards are “cross-walked” with other grants in NEI’s profile to ensure no redundancy, research findings shared.
• Annual workshops at the ARVO and Society for Neuroscience annual meetings.

BRAIN Initiative
• Grew out of the Neuroscience Blueprint, in which NEI participates.
• Although NIH-wide, vision researchers have done well—in the FY2014 and 2015 cycles, vision researchers and those studying brain connections through the visual route have been awarded $31 M total.
• NIH just announced $150 M in FY2016 awards—NEI analyzing vision share.
FY2017 NIH/NEI Funding Status Unclear

Congress was unable to finalize FY2017 Appropriations before the start of FY2017 on October 1, so government currently operating under a short-term Continuing Resolution (CR) through December 9.

- Funded at FY2016 level minus 0.5% during the 10-week CR.
- NEI cannot begin new initiatives, cannot spend more in any one month than it did in same month in FY2016.
- Chilling affect on research—delays NEI awarding grants, may require lab to seek institution philanthropic funding or “bridge” funding from private foundations.

Congress to act (?) in post-election lame duck session—options include another short-term or year-long CR, several appropriations bills combined into several “mini-buses,” or all combined in one omnibus bill.

- Full-year CR would have an even more chilling impact on research—community has requested that Congress finalize FY2017 appropriations by year-end.
- Will Congress increase NIH by another $2 B, as proposed by the Senate Appropriations Committee, to maintain sustained and predictable funding?
- Will Congress increase NIH funding by cutting other programs to stay within the budget caps?
Since FY2001, the Department of Defense (DOD) has funded $137 M+ in vision research. To-date in the Peer Reviewed Vision Research Program (VRP), created in FY2009 by Congress through NAEVR advocacy, and through FY2016, DOD will have awarded 79 grants totaling $68.4 M.

The first two VRP funding cycles have generated 80 published papers advancing the field of vision trauma research.

- House proposes to fund at $15 M in FY2017 after four years at $10 M funding.
- If Congress finalizes FY2017 before year-end, DOD will issue a Program Announcement in first-quarter 2017.
- Grant submissions must respond to vision research gaps as identified by DOD.
- Desire is to get product applications into the battlefield:
  - Kardon: I-Phone TBI Diagnostic
  - Humayun: corneal patch
  - Weiland: vision enhancement system in rehabilitation
  - Nguyen: computational model of eye to study blast injuries
In 2016, NAEVR held four advocacy days during the peak timeframe for funding requests.

**ARVO Advocacy Day (2/12)**
- Included an *Emerging Vision Scientist* track” of seven pre-R01 researchers reflecting ophthalmology/optometry.

**RPB Private Funding Foundation Advocacy Day (4/6)**
- Foundations’ importance as business in district and state, role in complementing federal funding, especially for young investigators, as well as providing bridge funding.

**Second Annual *Emerging Vision Scientists* Advocacy Day on Capitol Hill (9/15)**
- 22 pre-R01 investigators, reflecting breadth of vision research in ophthalmology and optometry.

Hosted vision researchers during the fourth annual *Rally for Medical Research* Advocacy Day (9/22).
AEVR hosts/co-hosts five Congressional Briefings each year on key vision topics (glaucoma, AMD, Diabetic Retinopathy, Defense vision, uveitis, dry eye, and uncorrected refractive errors).

- Speakers are basic and clinical researchers, and each presentation is documented in a summary posted on the Web site, in the quarterly Contributor Report, and shared with Congressional offices.

- AEVR uses its Briefings to support NAEVR advocacy efforts—the annual Glaucoma and Defense Vision Briefings are held in March in conjunction with appropriations request cycle.

- AEVR’s Briefings are well-respected on the Hill as they feature one speaker presenting in “plain English”—AEVR has a core of interested Congressional office staff as attendees.

An annual $50,000 grant from Research to Prevent Blindness has enabled AEVR to greatly expand its educational deliverables.

- In 2014 under the RPB grant, AEVR released its public opinion poll about the attitudes about vision and vision loss among American’s four major racial/ethnic groups at a National Press Club event in Washington, D.C.

- The survey was published in the August 4 edition of JAMA Ophthalmology’s Online First section and subsequently cited in the NASEM report and multiple press outlets.
FY2016 AEVR Educational Activities

2016 Congressional Briefings:

- March 2016  World Glaucoma Week 2016
- March 2016  Defense Vision Research
- June 2016  Chronic Dry Eye
- September 2016  International AMD Awareness Week
- October 2016  World Sight Day-NASEM Study

Based on the reception to Dr. Nichols’ June Dry Eye presentation, AEVR is working with the vision community to establish July as Dry Eye Month, with major awareness activities planned for July 2017 with release of the “DEWS II” report expanding the definition of Dry Eye and its comorbidity with many chronic diseases and their treatments. Stay tuned!!
Emerging Vision Scientists Activities

Since 2015, AEVR has conducted an annual *Emerging Vision Scientists Day* on Capitol Hill, recognized as an important development tool for early-stage investigators.

- Under AEVR, EVSs attend a Congressional Briefing to learn how to present research in “plain English”), conduct spokesman training about their research/why funding EVSs is important, and exhibit research posters at a Capitol Hill reception. Under NAEVR, they visit Congressional delegation offices to address the plight of early-stage investigators.

- Since 2015, AEVR/NAEVR have engaged almost 60 EVSs in Capitol Hill activities, between AEVR’s EVS Day and the *EVS Track* at the annual ARVO Advocacy Day.

EVSs have “cachet” on Capitol Hill, since most advocacy organizations do not engage them. Of the recent 50 Congressional office visits, 10 were with the Member. NAEVR emphasize the need for increased federally funding for researchers at all stages of their careers by featuring EVSs, since they are the most extreme example of that need.
On 9/15, NAEVR was hosting 22 Emerging Vision Scientists in 50 Congressional visits as NASEM released its report. NAEVR issued a statement supporting the report’s recommendations, and all 2017 NAEVR/AEVR activities will complement the recommendations:

- NAEVR will use each visit with the 115th Congress to inform about the NASEM report recommendations.
- NAEVR will support Prevent Blindness activities with the Congressional Vision Caucus as it reaches out to colleagues to inform about the report.
- As appropriate, NAEVR advocacy will support appropriations or authorization activities that affect NEI and CDC activities, the “Call to Action,” and the coordination of federal activities.
- AEVR will support the “Awareness Campaign” recommendation through Congressional briefings, publications, and other educational activities.
2017 Challenges

The new 115th Congress and new Administration—not only President, but heads of the various Department of Health and Human Services agencies (NIH, CDC, FDA, CMS, etc.)—will present challenges:

- If FY2017 appropriations are not finalized before year’s end, they may be addressed in the 115th Congress.
- Could another CR or delay in FY2017 appropriations impact research support, causing labs to seek bridge funding?
- Committee leadership is likely to change—not only if the opposing party wins, but also due to term limits even if current leadership is maintained.
- FY2018 appropriations will be subject to the sequester in the Budget Control Act—FY2016 and 2017 had sequester relief due to the two-year Bipartisan Budget agreement, passed in late 2015.
- Will advocates be able to maintain the bipartisan support for NIH funding?
- Will Congress want to continue a pattern of sustained and predictable funding increases for the NIH?
- Will a new NIH Director propose different priorities and initiatives?
- How can the vision community best advocate for and educate about the NASEM study recommendations?
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Visit our Web site!
www.eyeresearch.org

Visit us at ARVO 2017 in Baltimore!
May 7-11, 2017

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