PRESIDENT’S MESSAGE
It’s All About That (Discretionary) Base!

NAEVR’s advocacy messaging in the first quarter of 2016 and the beginning of the Fiscal Year (FY) 2017 appropriations cycle was very different than in past years and included:

- Thanking Congress for the FY2016 funding increases, including $2 billion for the National Institutes of Health (NIH) and $51 million for the National Eye Institute (NEI)—the latter after four years is now funded at a level greater than that in pre-sequester FY2012, albeit by a modest 0.8 percent.

- Supporting efforts by bipartisan Members in both chambers to ensure that the FY2016 funding increases begin a pattern of future sustained and predictable increases reflecting real growth above biomedical inflation.

- Joining bipartisan Members in both chambers in expressing concern about the President’s FY2017 budget request and its use of mandatory funding to supplant $1 billion of NIH discretionary funding, which also decreases NEI’s discretionary base. Mandatory funding is politically sensitive, outside the jurisdiction of the appropriators, and requires pay-fors.

As described within, this year’s recently-held appropriations hearings by the Labor, Health and Human Services, and Education (LHHS) Appropriations Subcommittees of the House Appropriations Committees of the House and Senate with Department of Health and Human Services Secretary Sylvia Burwell and NIH Director Francis Collins, M.D., Ph.D. (latter in the House to-date) regarding the President’s request have truly been “All about that base”—NIH discretionary, that is.

This will require appropriators to make some difficult decisions even if Congress adheres to the FY2017 budget framework set forth in the Bipartisan Budget Act of 2015 passed last October, which is not guaranteed. They must balance strong bipartisan support for NIH discretionary funding base increases against tight budget caps, which could mean cuts to other popular LHHS programs. And with their distaste for mandatory funding that supplants the NIH discretionary base rather than supplementing it, they will need to find a “path forward” to reach a goal of continued real growth above biomedical inflation. The House has already supported mandatory funding for specific NIH programs in the 21st Century Cures Act it passed in 2015 (supported by NAEVR), and as recently as the March 3 Senate LHHS hearing, Senate Health, Education, Labor and Pensions (HELP) Committee Chair Lamar Alexander (R-TN) stated that, perhaps, mandatory funding could be used as “surge” funding for new NIH initiatives, within a set timeframe with a specified amount.

Although Congress still intends to complete the appropriations process in regular order, pundit’s are already predicting an inevitable Continuing Resolution and completion of FY2017 appropriations post-election. Regardless, NAEVR will continue full-bore with its advocacy and AEVR with its education. I want to thank all of the researchers who have already assisted this quarter, and we have acknowledged them in the stories and images contained within this Report.

At the ARVO’s February 12 Advocacy Day engaged domestic and international research advocates from all stages of their careers, including Emerging Vision Scientists who are so vital to the future of vision research. ARVO Board President John Clark, Ph.D. (University of Washington) made the long flight from Seattle to Washington, D.C. twice this quarter, participating in the ARVO Advocacy Day regarding NIH/NEI funding, then on March 16-17 with Blinded Veterans Association (BVA) in support of the vision community’s request for $15 million funding for the Peer Reviewed Vision Research Program (VRP) to address traumatic eye injuries. I especially want to thank John for his support and commitment of time.

I want to conclude by thanking all of the organizations that have committed and paid NAEVR dues and AEVR contributions in 2016. The Alliances are fully funded and have many other activities planned for this year, including a second annual Emerging Vision Scientists Day on Capitol Hill, set for September 14-15 and made possible by a grant from Research to Prevent Blindness (RPB). Stay tuned for additional details!

Peter J. McDonnell, M.D.
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NAEVR at the 2016 ARVO Annual Meeting

Saturday, April 30

ARVO’s Vision and Traumatic Brain Injury: The Outlook for Therapeutics Session
10:00 am - 1:00 pm in Skagit 4/5, Washington State Convention Center

Sunday, May 1 – Wednesday, May 4

NAEVR Central
9:00 am – 4:00 pm Daily, Skybridge, Washington State Convention Center

Monday, May 2

NAEVR’s Defense-Related Vision Research Opportunities Session
7:30 am – 8:30 am in Room 3AB, Washington State Convention Center
ARVO Advocates Thank Congress For FY2016 Increases, Urge FY2017 Growth

On February 12, NAEVR managed for ARVO’s Annual Meeting Planning Committee an Advocacy Day that engaged 23 domestic and international advocates who visited 40 Congressional offices early in the FY2017 appropriations process. The group included ARVO Board President John Clark, Ph.D. (University of Washington) as well as two Members-In-Training (MIT) and seven Emerging Vision Scientists (EVSs)—early-stage investigators who have not yet received an R01 grant and were nominated by Departments of Ophthalmology and Schools/Colleges of Optometry from around the country.

The ARVO advocates were among the first to thank Congress for approving the FY2016 NIH and NEI appropriations increases and to comment on the President’s FY2017 budget request that had issued February 9 (see details inside). Since NAEVR had expressed disappointment in the President’s proposal to replace $1 billion in discretionary funding with politically sensitive mandatory funding, it prepared the advocates to emphasize the importance of growing the discretionary base, as well as raising the budget caps to facilitate funding for priority programs.

The MIT and EVS delegation, which reflected clinicians, clinician-scientists, and basic researchers dealing with a wide range of eye diseases, added greatly to ARVO’s message, stressing the impact that the combination of past cuts, flat funding, and lack of an inflationary increase at NEI has had on their training and career paths. In most visits, these advocates were speaking with contemporaries who may also have been examining their own career paths.

The NAEVR and AEVR Alliances have focused on the plight of early-stage investigators. On October 7, 2015, AEVR hosted the first-ever Emerging Vision Scientists Day on Capitol Hill in which these investigators displayed posters of their breakthrough research, with a NAEVR Advocacy Day following. The second annual EVS event is scheduled for September 14-15, 2016.
Congress Increases Funding for NIH by $2 Billion, NEI by $31 Million

On December 18, 2015, President Obama signed into law the Consolidated Appropriations Act, 2016, which was facilitated by the earlier passage of the Bipartisan Budget Act of 2015 (signed by the President on November 2) that raised the debt limit through March 2017 and provided sequester relief equally to both nondefense discretionary and defense funding in fiscal years 2016 and 2017. The FY2016 omnibus spending bill funds NIH at $32.08 billion, a $2 billion or 6.5 percent increase over FY2015 funding—which is the largest dollar and percent increase since FY2003—and NEI at $715.9 million, a $31 million or 4.6 percent increase over its FY2015 appropriation of $684.2 million. NEI’s enacted level is reduced to a $708 million operating budget due to pass-throughs.

The bill maintains the Extramural Salary Cap at Executive Level (EL)II ($185,100 in FY2016), avoiding the House-proposed reduction to ELIII ($170,400 in FY2016). With respect to major NIH initiatives, the bill funds as follows:

- $200 million for the new Precision Medicine Initiative (PMI);
- $150 million for the Brain Research through Advancing Innovative Technologies (BRAIN) Initiative, or BI, an increase of $85 million (to-date, vision researchers and those studying the brain through the visual route have been awarded $31 million in the first two years of BI awards);
- $936 million (an increase of $350 million) for Alzheimer’s disease research; and
- $100 million increase for antimicrobial resistance research.

NAEVR issued a statement commending Congress for the increased funding as a first step in the rebuilding of the NIH and NEI budgets.

### NEI Budget Grows in FY 2016, still eroded by inflation

**NEI Budget Grows in FY 2016, still eroded by inflation**

The left graphic shows that the FY2016 NEI operating budget of $708 million has, for the first time in four years, exceeded the FY2012 level of $702 million—albeit by a modest 0.8 percent—after the devastating $36 million sequester cut in FY2015. The right graphic shows that biomedical inflation has continued to reduce NEI’s purchasing power by 25 percent since FY2003. NAEVR has used these graphics on Capitol Hill in urging Congress to support predictable and sustained increases in NIH/NEI funding.

### FY2016: President Issues FY2017 Budget Request that Relies on Mandatory Funding

On February 9, the President sent a $4.1 trillion FY2017 spending plan to Congress requesting NIH funding of $33.1 billion, an $825 million or 2.6 percent increase over FY2016. The budget request includes mandatory funding of $1.825 billion, reflecting 1 billion of that which was previously discretionary funding—essentially supplanting the discretionary base—and $825 million for new and existing trans-NIH initiatives (see below).

The proposal would fund NEI at $708 million—the same as its FY2016 operating budget. It would flat-fund all of the Institutes and Centers (I/C) at their FY2016 operating budget levels, except for the National Cancer Institute (NCI) and the Office of the Director (OD) due to new initiatives. The flat-funding relies, however, on mandatory funding—without it, I/Cs would be funded at the level proposed in the President’s FY2016 budget request. For NEI, that would be $687 million. The budget proposal essentially reduces the discretionary funding base for the I/Cs.

New and enhanced trans-NIH initiatives include:
- $100 million increase for the Precision Medicine Initiative Cohort Program, building on $150 million of funding for that portion of the PMI in FY2016; and
- $45 million increase for the BI, building on $150 million funding in FY2016.

NIH states that Research Project Grants (RPGs) remain a high priority, estimating that it will support 10,755 new and competing grants in FY2016—the largest amount since FY2003. Per NEI’s Congressional Justification, it will support a total of 1,119 RPGs in FY2017. Noncompeting RPGs will increase by 30 awards and $97 million, while competing RPGs will decrease by 25 awards and $15.5 million.

### FY2017: NAEVR Disappointed in President’s FY2017 Budget, Requests 7.5 Percent Appropriated Increases

On February 9, NAEVR issued a statement that read (in part):

“NAEVR is disappointed in the President’s reliance on mandatory funding in the FY2017 budget request, due to its politically sensitive nature and since it essentially reduces the discretionary base. We are especially concerned about the NEI budget. Although proposed to be flat-funded in FY2017 at its FY2016 operating level of $708 million, the budget essentially cuts the NEI base to $687 million and replaces the difference with mandatory funding.

NEI’s discretionary budget cannot go backwards, as it did with the devastating $36 million sequester cut in FY2013. It has taken four years for Congress to restore the NEI budget and grow it above the pre-sequester FY2012 level of $702 million—albeit minimally (0.8 percent). During that timeframe, the NEI continued to lose purchasing power due to biomedical inflation.

NAEVR is urging Congress to appropriate at least $34.5 billion for NIH and $770 million for the NEI in FY2017, a 7.5 percent increase over FY2016 for each that reflects five percent real growth above the projected 2.5 percent rate for biomedical inflation.”
**House and Senate Appropriators Hold Hearings without Budget Blueprint**

Despite the Bipartisan Budget Act’s framework for FY2017 spending, Congress has yet to arrive at a budget blueprint. That has not stopped the flurry of appropriations hearings, including those held by the Labor, Health and Human Services, and Education Subcommittees of each the House and Senate with Department of Health and Human Services Secretary Sylvia Burwell, who defended the President’s request and how it was structured to address priorities, which include the Zika virus, opioid abuse, Head Start, NIH, and the Affordable Care Act.

*DHHS Secretary Sylvia Burwell*

**House:**

At its February 25 hearing with Secretary Burwell, Subcommittee Chairman Tom Cole (R-OK) said in his opening statement:

“I was especially disappointed to see your proposed cut to the NIH. Your proposal to divert $1 billion of biomedical research funds to the mandatory side of the budget ledger and rely on new and, perhaps unlikely, authorizations to continue the advances that we have made in increasing research funding were disheartening.”

Full Appropriations Committee Chairman Hal Rogers (R-KY) joined Chairman Cole in expressing his concerns, along with their Republican colleagues, the most severe being expressed by Cong. Charlie Dent (R-PA) who called the proposal “completely unacceptable.” Citing his concern for extramural researchers, he noted that the budget only assumes mandatory funding for one year, resulting in a “cliff” due to the switch away from discretionary funding.

While Democratic members expressed concern about the mandatory funding, they acknowledged that it was the result of austere budget caps and the reduced allocation for the LHHS bill.

*Said Cong. Rosa DeLauro (D-CT), the Subcommittee’s Ranking Member:*

“If we had received a more proportional investment in the LHHS bill, we could have had more than $5 billion for our allocation that would allow us to do important work within HHS.”

Full Appropriations Committee Ranking Member Nita Lowey (D-NY) also weighed in stating that, “The substantial mandatory funding is of concern. Without it, the budget amounts to a decrease in discretionary funding of 1.5 percent.”

**Senate:**

At its March 3 hearing with Secretary Burwell, LHHS Subcommittee Chairman Roy Blunt (R-MO) said in his opening statement:

“This is a precarious submission for the Department. The request leans heavily on new, mandatory spending proposals to bypass current budget caps. If this Subcommittee accepted the Department’s request, this would mean a $1 billion cut to the NIH.”

Full Appropriations Committee Chairman Thad Cochran (R-MS) expressed similar concerns, as did most Republican colleagues. Later, Chairman Blunt recognized past efforts by Subcommittee member Richard Durbin (D-IL) regarding predictable and sustained NIH funding increases: “If the funding goal was five percent real growth plus biomedical inflation, it would get us to where we need to be at NIH, per Senator Durbin. We did that last year and, if you want to develop a pattern, then the second year is not the time for a potential cut. FY2017 funding should be five percent plus biomedical inflation.”

*In her opening statement, Subcommittee Ranking Member Patty Murray (D-WA) said:*

“There is a lot to like in the bill which builds upon funding that was made possible through the budget framework in the Bipartisan Budget Act of 2015. We need to build on last year’s accomplishments by working together to handle the challenges that the request identifies. The Subcommittee needs an allocation that enables it to address these problems.”

Full Appropriations Committee Vice Chair Barbara Mikulski (D-MD) stated, “Like the Chairman, I am concerned about the mandatory funding and what could get cut.”

*Subcommittee member Senator Lamar Alexander (R-TN), who chairs the Senate Health, Education, Labor and Pensions (HELP) Committee on which Senator Murray also serves as Ranking Member, described the President’s budget request as “throwing a curve.” He offered a “path forward” that would provide bipartisan support for mandatory funding for key NIH initiatives (PMI, BI, Cancer Moonshot, and early-stage investigators) while continuing to grow its discretionary base, that is, supplemental mandatory funding as a “surge” with a defined timeframe and amount to address the initiatives. Recognizing his Committee’s work on a series of fifty proposals included in the Senate Biomedical Innovation bill—a companion to the House’s 21st Century Cures Act passed in June 2015, which NAEVR supported—he proposed that:

- With bipartisan support, the Senate approves the fifty proposals, while also developing consensus on the mandatory “surge” funding for key NIH initiatives, with a defined timeframe and funding amount.

- The Senate work with House colleagues to conference a bill that could pass and be signed by the President.*
World Glaucoma Week 2016
AEVR Congressional Briefing Addresses Public Health Challenges in Glaucoma

On March 9, AEVR held its World Glaucoma Week 2016 Congressional Briefing, co-hosted by all five major glaucoma societies and research organizations (see box below). Entitled Public Health Challenges in Glaucoma, the event focused on glaucoma incidence and prevention research funded by the NEI/NIH and the Centers for Disease Control and Prevention (CDC). Featured speaker David S. Friedman, M.D., M.P.H., addressed these issues, as he is an NEI and CDC-funded clinician-scientist who serves as the Alfred Sommer Professor at the Wilmer Eye Institute of Johns Hopkins University (JHU) School of Medicine, is a professor in the Department of International Health at the Johns Hopkins Bloomberg School of Public Health, and is the Director of the Dana Center for Preventive Ophthalmology—a leader in global and domestic research on blindness prevention and the only World Health Organization (WHO) collaborating center in the United States.

Glucoma, the second leading cause of preventable blindness in the United States, is a neurological disease affecting the optic nerve, causing loss of peripheral vision and ultimately blindness. Certain characteristics such as age, ethnicity, high intraocular pressure (IOP), and the appearance of the optic nerve are associated with disease development. Called the “sneak thief” of vision, it is frequently not associated with disease development. Called

Dr. Friedman also addressed the challenges of daily living for those with glaucoma, twice as likely to slow down while reading, and those with the severe form of the disease are four-times more likely to be reading-impaired.

Ongoing research will improve glaucoma detection, increase our understanding of the ways in which the disease impacts individuals, and result in better rehabilitation and preventive strategies to allow people to live healthy, independent lives.”
—Dr. Friedman

Glucoma severity is also associated with driving cessation, with the restriction of driving increasing with visual field loss. About one percent of older adults are not driving due to glaucoma.

Glucoma also impacts mobility (gait, strength of steps, orientation) and the level of physical activity, which is important as lower activity levels are associated with increased mortality and greater incidence of chronic diseases, such as heart disease, diabetes, and osteoporosis.

Falls are a significant public health issue, as they are the leading cause of accidental deaths in older adults. Vision loss increases the risk of falls, and initial research has shown that there is a two-to-four times greater risk of falls among glaucoma patients. NIH has initiated the Falls in Glaucoma Study to assess a cohort with glucoma for falls and to determine when and why individuals with glucoma fall.

The first World Glaucoma Day was held on March 6, 2008, and the U.S. House of Representatives passed H.R. 981, which recognized the event and supported NEI’s efforts to research the causes of and treatments for glucoma. Since 2010, the day has expanded into a week of events held worldwide, with all major glucoma professional societies and research organizations co-sponsoring AEVR’s 2016 event, including:

From left: AEVR Executive Director James Jorkasky, Dr. Friedman, and Anthony Nguyen from the office of Cong. Scott Peters (D-CA), who has submitted a Programmatic Request for FY2017 NEI funding of $770 million, the vision community’s request.

AEVR Congressional Briefing:
June 8
Dry Eye: Today’s Research, Tomorrow’s Solutions
12 Noon – 1:15 pm, House Rayburn B-339

AEVR Congressional Briefing:
International AMD Awareness Week 2016
12 Noon-1:15 pm, House Rayburn B-338

AEVR Congressional Reception:
Second Annual Emerging Vision Scientists Day
5:00 – 7:00 pm, House Rayburn 2168 (Gold Room)
(supported by a grant from RPB)

Emerging Vision Scientists

’ll be held at the 2016 AEVR Congressional Briefing, which will be held on June 8, 2016, at the U.S. House of Representatives Rayburn Room. The event will feature presentations by emerging vision scientists on the latest research in the field of vision science.

Research to Prevent Blindness (RPB) and AEVR have partnered to sponsor this event, which will bring together the next generation of vision scientists with policymakers and advocates to discuss the challenges and opportunities in the field of vision science.

The event will include a keynote address by Dr. David S. Friedman, who will discuss the latest research in glaucoma and its impact on public health.

AEVR Congressional Briefing:
Emerging Vision Scientists Day
5:00 – 7:00 pm, House Rayburn 2168 (Gold Room)

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5:00 – 7:00 pm, House Rayburn 2168 (Gold Room)

(supported by a grant from RPB)
DEFENSE VISION FUNDING

Since it was created by Congress in FY2009 in Defense appropriations through NAEVR advocacy, the DOD’s Peer Reviewed Vision Research Program (VRP) within the Congressionally-directed Medical Research Program (CDMRP) has awarded 71 grants totaling $56 million.

NAEVR Requests FY2017 VRP Funding at $15 Million

For the second year, NAEVR has been working with Capitol Hill champions to increase VRP funding to $15 million. Although funded at $10 million in each of fiscal years 2013-2016, the final amount awarded to vision researchers has been greater each year due to transfers from other CDMRP programs:

- **FY2013:** $10 M appropriated, $16 M awarded
- **FY2014:** $10 M appropriated, $18.1 M awarded
- **FY2015:** $10 M appropriated, $14.8 M awarded
- **FY2016:** $10 M appropriated, Awards will be made under the FY2015 Program Announcement

The FY2015 Program Announcement combines FY2015 and 2016 appropriations—which total $20 million minus administrative costs—and will make awards through two separate funding mechanisms:

- A Technology/Therapeutic Development Award (TTDA), expected to fund four awards for a total of $6 million; and
- Clinical Trial Award (CTA), expected to fund four awards for a total of $12 million.

Projects funded with FY2015 dollars must be negotiated by September 30, 2016, and those funded with FY2016 dollars by September 30, 2017.

DOD-Funded Researcher Develops Drug-Delivering Contact Lens

On March 17, AENV hosted its seventh military eye trauma Congressional Briefing entitled Deployment-Related Vision Trauma Research: Development of a Contact Lens for Drug Delivery featuring Joseph Ciolino, M.D. (Mass Eye & Ear/ Harvard Medical School). Funded through a Translational Research Award in the VRP’s FY2013/2014 cycle, his research addresses a major DOD-identified gap: improved treatments for traumatic eye injuries, war-related injuries, and diseases to ocular structures and visual system by developing novel drug-delivery systems for the eye. The briefing was co-sponsored by Research to Prevent Blindness (RPB), Blinded Veterans Association (BVA), and ARVO.

Dr. Ciolino is a corneal specialist and clinician-scientist who treats patients with serious eye diseases and conducts research to develop new and better therapies for treating those conditions. He is also an Emerging Vision Scientist who has yet to receive his first investigator-initiated (R01) grant from NIH, although he has been awarded two grants from the DOD, a K08 Career Development Award from the NIH, and a Career Development Award from RPB.

He described why a new method for delivering drugs to the eye is a critical need by citing the limitations of other means, such as oral therapeutics and topical eye drops—the latter requiring repeated applications that can be inefficient at delivering therapeutically appropriate levels of drugs, having unpleasant side effects as a result of preservatives used, and often resulting in significant waste due to difficulty in getting drops into the eye which can also negatively impact patient compliance with a therapy regimen. Although a drug-delivering contact lens could, if successful, address these challenges, its development raises its own set of challenges: the lens must deliver drugs over an extended period of time or it would not be much more successful than repeated applications of drops; it must release a controlled amount of drug throughout its application on the eye; it must be clear so as to not impede normal vision; and it must be comfortable for the patients to wear.

A DOD-identified need in treating eye trauma is the difficulty of delivering steroids to corneas that are at risk of inflammation due to trauma from combat operations, from eye diseases such as uveitis, and from post-operative complications. Using a special polymer that is infused with medication and placed within the periphery of a contact lens, Dr. Ciolino’s project has been able to test the efficacy of the lens in delivering Ciprofloxacin, an antibiotic used to reduce ocular infections, and Dexamethasone, a corticosteroid used to reduce inflammation. The results of his work so far indicate that this corticosteroid-releasing therapeutic contact lens (TCL) is more effective than conventional eye drops at delivering drugs to the eye with fewer complications and side effects, opening the door for greatly expanded treatment options, simplified treatment regimens, and better patient compliance.

The goal of this project, Dr. Ciolino added, is to develop the lens as a platform technology that can also be used in civilian applications, treating such diseases as glaucoma and diabetic retinopathy.

Dr. Ciolino concluded by discussing his other DOD-funded grant which seeks to improve the success rate of artificial corneas. Artificial corneas are composed of a tissue carrier that contains a plastic optic. These tissue carriers often ‘melt,’ resulting in a failure of the artificial cornea and can lead to blindness. Dr. Ciolino’s project uses collagen cross-linking that aims to strengthen the carrier tissue, preventing melting and thereby improving the success rate of artificial corneas, which can be necessary when troops suffer eye trauma in combat.

From left: Dr. Zampieri, First Sergeant (Ret.) Wallace, Senator Claire McCaskill (D-MO), and Dr. Clark

From left: Dr. Zampieri, Senator Roy Blunt (R-MO), First Sergeant (Ret.) Wallace, and Dr. Clark. Senator Blunt is a defense appropriator.