President’s Message

The New “Normal” in Vision Research Funding is Uncertainty

On a visit to Washington, D.C. this past weekend, uncertainty was the characteristic of the ongoing negotiations over the debt ceiling and deficit reduction. Clearly, these are challenging times that are creating a new “normal” for all of us involved in vision research, whether a federal agency employee without final funding guidance, a researcher awaiting grant approval or renewal who may need to rely on philanthropic bridge funding, or a company awaiting regulatory approvals. That new “normal” is uncertainty, and we are all learning how to operate within it and manage it as successfully as possible.

Related to that, recently NAEVR Executive Director James Jorkasky spoke at the EuroVisionNet meeting at the European Union (EU) in Brussels (see inside story). In presenting his perspectives on United States advocacy for federal funding, Jim shared two observations about the new “normal”—that the old rules for advocacy just may not apply anymore, and that, more than ever, it isn’t over until it’s over. I thought his message was on point, and I’d like to relate his observations to you.

That new “normal” is uncertainty, and we are all learning how to operate within it and manage it as successfully as possible.

Regarding the advocacy environment, as we saw in the Fiscal Year (FY) 2011 appropriations cycle, an eighth and final Continuing Resolution (CR) funding the government was not passed until mid-April 2012, seven months into the fiscal year. Although the President’s FY2012 budget proposal had already issued, it was difficult to focus Hill attention on an FY2012 funding level since FY2011 funding was still unknown—although the evergreen message about the return on investment at the National Institutes of Health (NIH) in terms of lives saved and jobs created always applies. Additionally, since the National Eye Institute (NEI), like other government agencies, was operating at the FY2010 level, it would be difficult to characterize what key research could or could not get funded. As reported herein, despite a $6.2 million cut, the NEI expects to fund the relatively same amount of Research Project Grants (RPGs) in FY2011 as it did in past years, as well as to retain its historically higher success rate than overall NIH. This did not just happen by chance, though. NEI Director Paul Sieving, M.D., Ph.D. and his team, especially Director of Extramural Research Lore Anne McNicol, Ph.D., invested the FY2009 and FY2010 “regular” appropriations increases and two-year American Recovery and Reinvestment Act (ARRA) funding wisely to minimize any impact of flat or reduced FY2011 funding. How long that the NEI will be able to maintain the momentum of research, especially in light of another contentious appropriations cycle in FY2012, is uncertain.

NAEVR takes its “Scorecard” issues very seriously, always wanting to facilitate additional federal funding for vision research so that it can demonstrate to constituents a return on their investment. In the “not over until it’s over” category, I am pleased that the FY2011 NEI funding reduction has been balanced by an FY2011 Peer Reviewed Medical Research-Vision (PRMR-Vision) appropriation of $4 million. As reported by the Department of Defense (DOD) representatives at the Association for Research in Vision and Ophthalmology (ARVO) 2011 Annual Meeting this past May, the final amount of FY2011 DOD funding could be higher if there is a transfer of funding from other DOD programs, as had occurred in the FY2009/2010 cycle. I encourage all interested researchers to seriously consider responding to this research funding opportunity when it issues.

Also in the “not over until it’s over” category, this edition reports on efforts by NIH Director Francis Collins, M.D., Ph.D. to implement the National Center for Advancing Translational Sciences (NCATS), which is the centralized translational research entity recommended last December by the NIH’s Scientific Management Review Board (SMRB). NIH is currently in the process of Congressional notification about budgetary and programmatic implications, especially its plans to abolish the National Center for Research Resources (NCRR). How and when NCATS is fully implemented remains to be seen. From my experience in 2002 as a member of the IOM’s Committee on the Organizational Structure of the NIH, I can assure you that changes at NIH have far-reaching consequences, and that Congress is wise to ensure that all analyses required by the NIH Reform Act of 2006 are completed. I am pleased that both NAEVR and AEVR are engaged in Hill education about NEI’s leadership in translational research. Dr. Sieving should also be commended for hiring NEI Senior Advisor for Translational Research Matthew McMahon, Ph.D. as NEI evaluates both potential challenges and opportunities as a result of NCATS. You will see Matt in several images as he has been actively engaged with the vision community.

I appreciate your commitment to the Alliances.

Stephen J. Ryan, M.D.
President, NAEVR/AEVR Boards
sryan@doheny.org
Legislative Scorecard Issues

NEI Confirms $6.2 Million Reduction in FY2011 Funding

At its June 16 National Advisory Eye Council (NAEC) meeting, NEI confirmed that its Fiscal Year (FY) funding was reduced by $6.2 million to $700.8 million, or about one percent below the FY2010 level of $706.7 million (see funding chart). On April 14—seven months into the fiscal year—Congress passed final FY2011 funding through an eighth and final Continuing Resolution (CR) in which NIH received a 0.8 percent cut in funding in addition to an across-the-board 0.2 percent cut in all defense discretionary spending, as compared to FY2010. NIH was cut by a total of $322 million. Since this was not a “regular order” appropriations bill and required agencies to submit FY2011 spending plans for review, most did not receive confirmation of funding levels until much later.

Due to the series of CRs that funded the government at the FY2010 level throughout the first half of FY2011, NEI, as well as all other NIH Institutes and Centers (ICs), had to limit funding of grant commitments and was prohibited from starting new programs. With the final funding confirmation, NIH has also revised the noncompeting grant inflationary allowance policy to help ICs manage reduced budgets. NEI has stated that, since its number of

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* Net of Transfers/One-Time Expenses
** Absent ARRA Funding ($175M for NEI over two fiscal years)
^ $707.04M appropriation reduced by transfer of programs to National Library of Medicine
+ Percentage of change compared to FY2010

noncompeting Research Project Grants (RPGs) decreased under the regular cycle, it will be able to maintain relatively the same total number of RPGs and a success rate above the NIH average for FY2011.

Sebelius, Collins Testify About FY2012 Budget

On March 11 and 30, Department of Health and Human Services (DHHS) Secretary Kathleen Sebelius testified about the President’s FY2012 proposed budget (released on February 14) before the Labor, Health and Human Services, and Education (LHHS) Appropriations Subcommittees of the House and Senate, respectively. Secretary Sebelius echoed the President’s comments about the importance of innovation, generally, and NIH, specifically, in justifying the administration’s proposed $745 million, or 2.4 percent increase over FY2010, for NIH.

At the Senate hearing, Senate Ranking Member Richard Shelby (R-AL) cautioned against across-the-board cuts and urged Congress to sustain programs that are effective, where he cited NIH as “one of the most results-driven aspects of our entire federal budget” and stressed that its programs “consistently meet their performance and outcomes measures, as well as achieve their overall mission.” Senator Barbara Mikulski (D-MD) noted that a government shutdown, NIH cuts, or delayed appropriations, individually or in combination, will have far-reaching consequences, especially for academic Institutions across the country which receive funding.

On May 11, NIH Director Dr. Francis Collins testified before the Senate Subcommittee, where he reported examples of cost-savings resulting from NIH-driven improvements in health, as well as studies showing the impact of medical research on jobs and the economy. He and several Subcommittee members cited the just-released United for Medical Research (UMR) study entitled An Economic Engine: NIH Research, Employment, and the Future of the Medical Innovation Sector which reported that NIH directly and indirectly supported nearly 488,000 jobs and produced $68 billion in new economic activity in 2010 alone.

NAEVR Commends Shelby, Cites Comments in Testimony

On April 8, NAEVR and the EyeSight Foundation of Alabama delivered letters to Senator Shelby commending him for his comments about the importance of investing in the NIH. His comments and those of Senator Mikulski about the implications of delayed funding, formed the basis of NAEVR’s written testimony submitted on April 7 and May 12 to the hearing files of the House and Senate LHHS Appropriations Subcommittees, respectively, regarding FY2012 NIH appropriations. While acknowledging President Obama’s proposed $745 million, or 2.4 percent increase for the NIH overall as compared to FY2010, NAEVR requested that Congress increase NEI funding above the 1.8 percent proposed by the administration, stressing the vision impairment and eye disease challenges that NEI faces during the Decade of Vision 2010-2020.

NAEVR’s James Jorkasky (left) and Torrey DeKeyser, Executive Director of the EyeSight Foundation of Alabama (right), present Senate LHHS Subcommittee Minority Clerk Laura Friedel with the letter to Ranking Member Senator Shelby

Senators Urge Bipartisan Support for NIH

Senators Robert Casey (D-PA) and Richard Burr (R-NC) led a June 10 letter to the Senate Appropriations Committee and LHHS Subcommittee leadership in support of NIH funding in FY2012 appropriations. The letter, which was signed by a bipartisan group of 41 Senators, highlights NIH as “our best hope” for treating or curing debilitating disease. It also states that investments in NIH have “yielded an unprecedented number of scientific advances that have improved health outcomes and contributed significantly to the nation’s economic growth,” and that it is “essential to continue support for medical research.”
NAEVR Central at ARVO’s 2011 Annual Meeting drew a record number of visitors. In addition to contacting Congress to urge support for FY2012 NIH funding, researchers also visited with representatives from the Department of Defense’s (DOD) Telemedicine and Advanced Technology Research Center (TATRC) and the joint DOD/Department of Veterans Affairs (VA) Vision Center of Excellence (VCE). At NAEVR’s May 2 Defense-Related Vision Research Opportunities session (see back page), TATRC announced that it would shortly issue a Program Announcement seeking grant submissions for its Vision Research Program (VRP) funded through the dedicated $4 million line item in FY2011 defense appropriations.

“NAEVR Central continues to serve as the ‘Town Hall’ for questions on vision research funding and resources,” said NAEVR’s James Jorkasky. “With a net one percent cut to the NIH/NEI funding level in FY2011, researchers were especially interested in DOD funding opportunities and how their research could meet DOD-identified gaps in vision research, such as corneal healing, corneal and retinal protection, visual dysfunction associated with Traumatic Brain Injury (TBI), and the eye blast phenomenon. I especially want to thank TATRC Vision Portfolio Manager Robert Read for meeting with researchers for three days in our booth, as well as NAEVR’s David Epstein for responding to so many questions and adding researchers to his ‘DOD Interest Email List’ to receive announcements about funding opportunities.”

ARVO President Jeffrey Boatright, Ph.D., FARVO (Emory University School of Medicine), and Immediate-Past President J. Mark Petrack, Ph.D., FARVO (Rocky Mountain Lions Eye Institute/University of Colorado School of Medicine) meet with David Epstein after contacting Congress.

Left to right: DOD/TATRC’s Robert Read took a break from hosting researchers to meet in the Exhibit Hall with joint DOD/VA VCE Director Colonel Donald Gagliano, M.D. and NEI Director Paul Sieving, M.D., Ph.D. Colonel Gagliano sits on the NEI’s National Advisory Eye Council (NAEC), while NEI has a representative on the TATRC Programmatic Panel that oversees the Vision Research Program.

Left to right: James Jorkasky and 2009 ARVO President Nicolas Delamere, Ph.D., FARVO (University of Arizona) describe defense-related vision research to high school students.

Left to right: NEI’s Senior Advisor for Translational Research Matthew McMahon, Ph.D. with Allie Laban-Baker and Narinder Sharma from the AMD Alliance International.

Left to right: Joel Schuman, M.D., FARVO (University of Pittsburgh Medical Center) chats with Torrey DeKeyser and Shirley Hamilton of the EyeSight Foundation of Alabama. Dr. Schuman spoke on behalf of AEVER on Capitol Hill during World Glaucoma Week 2011.

Left to right: ARVO Executive Director Joanne Angle with 2008 ARVO President Martine Jager, M.D., Ph.D., FARVO (University of Leiden). Dr. Jager, the first international ARVO President and an advocacy champion, was the featured speaker at the Women in Eye and Vision Research (WEAVR) luncheon.
Translational Research

NIH Submits NCATS Budget and Program Plans to Congress

At its May 11 hearing (see previous page), Senate LHHS Appropriations Subcommittee members also asked Dr. Collins about a plan and budget amendment regarding the proposed National Center for Advancing Translational Sciences (NCATS)—the centralized translational research entity that was officially recommended for implementation by the NIH’s Scientific Management Review Board (SMRB) at its December 8, 2010, meeting. Due to timing, an NCATS budget line item was not included in the administration’s FY2012 budget proposal. Dr. Collins, who spoke with great enthusiasm for NCATS as a means by which to advance the discipline of translational research, responded that NIH would shortly provide program and budget details to ensure that NCATS was initially funded in the FY2012 budget process, rather than waiting for FY2013.

On June 6, Secretary Sebelius wrote to Congressional appropriators about plans to establish NCATS and abolish the National Center for Research Resources (NCRR), moving many of its programs into NCATS and various I/Cs. She requested that these changes be incorporated as the Appropriations Committee proceeds with its FY2012 funding bill, since DHHS intends to implement them within the President’s proposed budget. She attached a table that details the impact of the I/C-specific organizational and budgetary realignment, proposing an NCATS line item of $721.6 million, the majority of which reflects $479.7 million from the Clinical and Translational Science Awards (CTSA) program moved over from the NCCR. Other major NCATS components include the Cures Acceleration Network (CAN), proposed to be funded at $100 million in FY2012 (CAN was not previously funded in FY2011 since it was authorized during the appropriations process), the Therapeutics for Rare and Neglected Diseases (TRND) Program, and the Office of Rare Disease Research.

On June 15, House LHHS Appropriations Subcommittee Chair Denny Rehberg (R-MT) wrote to Secretary Sebelius expressing several concerns about the NCATS proposal, including how abolishing the NCCR may impact management of the CTSA and Institutional Development Award (IDeA) programs. Chairman Rehberg also noted that his office had not yet received a formal budget amendment from the President, especially if NCATS is to be implemented in FY2012, nor answers to questions posed at the March 11 Subcommittee hearing. He also expressed concern that NIH has already taken steps to start searching for an NCATS director in advance of resolution of these issues. At press time, NAEVR understands that DHHS plans to respond. NIH has sought input on the NCATS proposal through its Feedback.NIH.gov Web site.

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

NEI and FDA Hold Endpoints Symposium

On May 6 on the NIH Campus, the NEI and the Food and Drug Administration (FDA) jointly held the fifth in the series of Joint Endpoint Symposia, which are managed by ARVO. Entitled Use of Functional Visual Endpoints in Visual Prosthesis Product Development, the meeting addressed how functional vision-related endpoints for clinical trials of visual prostheses will be analyzed and correlated with objective measures of visual acuity, visual fields, and contrast sensitivity. The FDA currently has draft guidance for industry and FDA staff entitled Investigational Device Exemption (IDE) Guidance for Retinal Prostheses.

Previous joint symposia, which bring together regulators, researchers, and industry representatives, have focused on research into Age-related Macular Degeneration (AMD), Glaucoma, and Diabetic Retinopathy, as well as Patient Reported Outcomes. The symposia grew out of NAEVR-initiated meetings between NEI and FDA and exemplify NEI’s leadership in facilitating the translation of its basic research—an NIH priority.

Dr. Collins Comments on NCATS

As recently as the June 28 NIH Council of Councils meeting, at which the vision community was represented by Mae Gordon, Ph.D. (Washington University School of Medicine), Dr. Collins described the potential transformative power of NCATS. In a July 6 commentary published in the journal Science Translational Medicine and posted on the Director’s section of the NIH Web site, Dr. Collins described the goals and functions of NCATS as it strives to reengineer the process of developing drugs, diagnostics, and devices. NCATS will seek to generate innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions with the goal of significantly shortening what currently takes about 15 years from molecular discovery to new therapy.
Capitol Hill Education
Congressional Briefing Highlights NIH’s Drug Discovery Technology

Finding a vision-saving drug can take years because scientists need to screen tens or hundreds of thousands of compounds before they find one that might work. But thanks to advanced screening technology and a research collaboration involving the Foundation Fighting Blindness (FFB), the NIH’s Chemical Genomics Center (NCCG), and Johns Hopkins University (JHU), the search for drugs to combat retinal diseases has been accelerated. The NCCG is a component of the

DECADE OF VISION
an initiative of the Alliance For Eye And Vision Research

2010-2020

Now, new screening technology enables us to more quickly identify promising compounds and move them into animal studies. —Dr. Rose

Molecular Libraries Program destined for inclusion in NCATS (see previous page).

At a June 9 Capitol Hill briefing hosted by AEV’s Decade of Vision 2010-2020 Initiative and FFB, Donald Zack, M.D., Ph.D., a clinician-scientist at the Wilmer Eye Institute at JHU, spoke about how the NCCG’s high-throughput drug screening systems have greatly accelerated his search for retinal disease treatments. In a research project funded in part by FFB, Dr. Zack and his NCCG colleagues were able to identify several molecules with vision-saving potential in a period of weeks. Without NCCG’s expertise and technology, that same effort would have taken several years.

“Years ago, because technology and access were limited, this part of the process took exponentially more time,” said FFB Chief Research Officer Stephen Rose. “Now, new screening technology enables us to more quickly identify promising compounds and move them into animal studies, which help researchers better understand the compounds’ safety, efficacy, and clinical potential.”

Dr. Rose noted the availability of advanced high-throughput screening systems is limited, because of their expense. “Most research institutions can’t afford screening systems as powerful and sophisticated as NCCG’s. To have such a resource available to FFB-funded researchers greatly accelerates our drive for vision-saving treatments,” says Dr. Rose.

High-throughput systems combine robotics and computers to quickly screen large numbers of compounds. In grid-like plates containing divots, or wells, a variety of compounds are mixed with biological materials — proteins or cells, for instance — to determine if they promote cell health and function. What the latest technology enables researchers to do, via an automated process that involves the incubation and analysis of multiple plates simultaneously, is screen tens of thousands of compounds daily.

As Dr. Zack stressed, speeding up the drug-development process not only increases the quality of life, it is also cost-effective. Rare retinal degenerative diseases including retinitis pigmentosa (RP), Usher syndrome (combined deafness and blindness), and Stargardt disease (juvenile macular degeneration) affect 200,000 Americans, while more common retinal diseases, such as age-related macular degeneration (AMD), affect more than 10 million Americans. Dr. Zack’s research is enabling him to develop new paradigms for the diagnosis, prevention, and treatment of these blinding eye conditions.

NAEV Speaks at the EU
On June 22, NAEVR’s James Jorkasky presented the United States perspective on vision research funding advocacy at the EuroVisionNet’s Parliamentary Evening at the European Parliament (EU) in Brussels entitled Finding New Treatments for Blinding Disorders. EuroVisionNet, which is managed by the European Vision Institute (EVI) with which NAEVR has a strategic relationship, works to coordinate vision research activities and policies in Europe in order to overcome national fragmentation. The event was hosted by Member of the European Parliament (MEP) Charles Tannock from London.

“Although I spoke about NAEVR’s activities in the United States to advocate for increased vision research funding at the NEI and DOD, I was careful to offer these as just an example of how to influence governmental entities,” said Jorkasky. “Having worked with EVI in the past, I know what it faces in terms of the complexity of coordinating research policies and funding opportunities at the EU, country, and even state level.” He reminded attendees that NAEVR has written a document entitled International Advocacy Handbook: Tools to Influence Vision Research Funding for ARVO, which is posted on its Web site. As with NAEVR’s comments at the meeting, the ARVO Handbook is sensitive to varied cultural differences and attitudes.

NAEVR’s international outreach was also enhanced in a profile in the May 2011 edition of International Innovation, a United Kingdom publication.

James Jorkasky with speaker and Incoming ARVO President Peng Khaw, M.D., Ph.D. and Anthony Moore, M.D., both of whom are from the Moorfields Eye Hospital/University College London Institute of Ophthalmology. Dr. Moore coordinated the EuroVisionNet’s EU event.

Left to right: Member of the European Parliament (MEP) and host Charles Tannock with speaker Eberhart Zrenner, M.D. (Institute for Ophthalmic Research at the University of Tuebingen, Germany). Dr. Zrenner also serves as Chairman of the European Vision Institute (EVI).
Defense Related Vision Research

DOD Announces Plans to Issue an FY2011 Funding Program Announcement

At press time, the DOD’s Telemedicine and Advanced Technology Research Center (TATRC) was finalizing a Program Announcement seeking grant proposals for its FY2011 Vision Research Program (VRP), which it announced on May 2 at NAEVR’s Defense-Related Vision Research Opportunities session at the ARVO Annual meeting (see inside cover page). The VRP is funded by the dedicated Peer Reviewed Medical Research-Vision (PRMR-Vision) line item in defense appropriations. In the final CR that funded the government through the end of FY2011, PRMR-Vision was funded at $4 million.

TATRC Vision Portfolio Manager Robert Read has noted that the amount of funding available for researchers could be greater than the appropriated $4 million, as it was in the FY2009/2010 cycle. Although Congress appropriated $4 million and $3.75 million in FY2009 and FY2010, respectively, for PRMR-Vision, it was increased by another $4.1 million transferred over from TATRC’s “sister” agency within the U.S. Army’s Medical Research and Materiel Command (MRMC), the Clinical and Rehabilitative Medicine Research Command (CRMRP). As a result, a total of $11 million was awarded to twelve researchers—many of whom were in the audience—in the FY2009/2010 cycle.

Mr. Read identified current DOD-identified vision research gaps, some or all of which may appear in the Program Announcement. These include:

- diagnosis, treatment, and mitigation of TBI-related visual dysfunction
- treatments for traumatic injuries (e.g., blasts, burns)
- vision restoration
- epidemiological studies on sight-injured patients
- ocular diagnostics
- vision rehabilitation strategies
- inadequate computational models of battlefield injuries
- vision care education/training

The joint DOD/Department of Veterans Affairs (VA) Vision Center of Excellence (VCE) Director Donald Gagliano, M.D., who serves as the co-chair of the TATRC Programmatic Panel, emphasized how the quality of the past submissions from vision researchers has caught the attention of various funding entities within the DOD. “Vision researchers have certainly raised awareness among DOD agencies for both the quality and responsiveness of their grant submissions to the current needs of our military.” The VCE, which does not have extramural research funding, is coordinating military vision care from diagnosis through rehabilitation, including development of a Congressionally-mandated Defense and Veterans Eye Injury Registry (DVEIR). The latter may identify the most significant future research needs.

Contact NAEVR’s David Epstein at depstein@eyeresearch.org to be added to the “DOD Interest Email List” and notified when the TATRC/VRP Program Announcement issues.

Visit the Defense-related Vision Research section of NAEVR’s Web site for more details