

President's Message

NAEVR Expands Its Advocacy Voice At Key Domestic and International Events

NAEVR's message about the value of vision research has resonated at numerous events here in the United States and at international venues.

NAEVR had a significant presence at this year's ARVO Annual Meeting with the NAEVR Central booth that was prominent in the exhibits area and the standing room-only defense vision session at which representatives of the Department of Defense's (DOD) Telemedicine and Advanced Technology Research Center (TATRC) announced \$10 million in awards. That level of funding is not only testimony to the quality of the proposals submitted by our community, but to NAEVR's advocacy efforts that got a dedicated Peer Reviewed Medical Research-Vision line item in defense appropriations, starting in Fiscal Year (FY) 2009. With the announcement of the awards, NAEVR has been educating its Capitol Hill champions about the unique nature of this research into immediate battlefield vision needs not addressed elsewhere in an effort to secure FY2011 funding at \$10 million. I wish to thank TATRC Director Colonel Karl Friedl, Ph.D. for having his team so accessible to researchers throughout the meeting such that they could learn more about this funding opportunity.

NAEVR's written testimony to Congressional appropriators supporting FY2011 funding increases for the National

During this tough appropriations cycle, Members of Congress and their staffs are especially responsive to tangible examples of the benefits of investment in research.

Institutes of Health (NIH) and National Eye Institute (NEI) was amplified when, shortly after ARVO, Neil Bressler, M.D. (Wilmer Eye Institute/Johns Hopkins) gave Citizen Witness testimony at a House Labor, Health and Human Services, and Education (LHHS) Appropriations Subcommittee hearing. As Chair of NEI's Diabetic Retinopathy Clinical

Research (DRCR) Network, Neil brought immediacy to the value of vision research by relating just-released results of a DRCR-funded comparative effectiveness study demonstrating better vision from a drug/laser treatment than with laser treatment alone for diabetic macular edema. During this tough appropriations cycle, Members of Congress and their staffs are especially responsive to such tangible examples of the benefits of investment in research.

NAEVR Executive Director James Jorkasky gave compelling testimony at two key NIH events. In May, at the meeting of NIH's Scientific Management Review Board (SMRB), he opposed merging or clustering of NIH Institutes and Centers and their budgets, emphasizing the importance of maintaining a dedicated NEI line item. NAEVR remains one of the few advocacy groups still vigilant on this issue. In June, he also spoke at the first Stakeholders Meeting of the NIH/Food and Drug Administration (FDA) Joint Leadership Council, describing the past collaborations between NEI and FDA that resulted in the series of *Endpoints Symposia* on age-related macular degeneration, diabetic retinopathy, glaucoma, and patient-reported outcomes. Thanks to the leadership of NEI Director Paul Sieving, M.D., Ph.D., this is just one of many examples of joint agency efforts.

At the World Ophthalmology Congress (WOC) in Berlin, Germany, Jim spoke

about the impact of the American Recovery and Reinvestment Act's (ARRA) stimulative funding on vision research. He also participated in a meeting of the European Vision Institute (EVI) in which he compared advocacy strategies and activities with researchers from a variety of European countries. Our European colleagues face a system that is

Contributor Report



Left to right: Dr. Ryan and Association for Research in Vision and Ophthalmology (ARVO) Executive Director Joanne Angle with NAEVR's James Jorkasky in the ARVO booth at the World Ophthalmology Congress. Dr. Ryan served as the Scientific Program Committee Chair for WOC 2010.

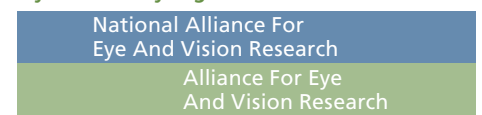
far more complex due to potential funding opportunities at the European Union, country, and state level, as well as varied cultural attitudes about the relationship between the private and public sectors. I share Jim's enthusiasm for future exchanges as the global research community seeks the funding necessary to address the vision impairment and eye disease challenges of the *Decade of Vision 2010-2020*.



James Jorkasky (second left) with European Vision Institute (EVI) representatives Eberhart Zrenner, M.D., Thomas Wheeler-Schilling, Ph.D., and Philipp Hunger, all from the Institute for Ophthalmic Research at the University of Tuebingen

I appreciate the commitments that members have made to support NAEVR and AEVR in 2010.

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Artificial Retina Holds Promise for Restoring Vision to Millions



Lead Artificial Retina Researcher Mark Humayun, M.D., Ph.D.

Nearly 25 years ago, when Mark Humayun, M.D., Ph.D., first envisioned the development of a bionic retina to enable the blind to see, scientific pundits equated the undertaking to a “moon shot,” implying that the project might be overly

ambitious. However, thanks to sustained funding and innovative engineering by a team of engineers, scientists, and clinicians led by Dr. Humayun, 38 people with advanced retinitis pigmentosa, a vision-robbing retinal degenerative disease, are now successfully using implanted artificial retinas. Many of these individuals are participating in a clinical evaluation of the device, led by Second Sight Medical Products, Inc.

At an April 29 Congressional Briefing

To develop the artificial retina, we needed to merge the principles of biology with those of engineering. – Dr. Humayun

hosted by AEVR’s *Decade of Vision 2010-2020 Initiative* and the Foundation Fighting Blindness (FFB), Dr. Humayun, a professor of Ophthalmology and Biomedical Engineering at the Doheny Eye Institute of the University of Southern California and the lead investigator of artificial retina research, discussed how the device is enabling those who are otherwise completely blind to identify doors, crosswalks, and even utensils on a table. Many users of the device can also sort dark and light laundry. One woman with the artificial retina saw fireworks and the moon for the first time in decades.

The innovative device is a tiny computer array (i.e., chip) that is implanted on the retina in the back of the eye. A small, inconspicuous video camera placed in the nose bridge of a pair of sunglasses transmits images wirelessly back to the artificial retina. Dr. Humayun explained that the device needs to be very compact and survive the “hostile” environment of the human body for several years. “To develop the artificial retina, we needed to

merge the principles of biology with those of engineering,” adding that “and it wasn’t easy.”

The Department of Energy (DOE) Artificial Retina Program has played a major role in the project as both a funding source and developer of highly innovative technologies through its national laboratories. FFB provided funding to Dr. Humayun during the early stages of the device’s development.

A key goal of the project is to develop the artificial retina with more electrodes—the more electrodes, the more detailed vision the implant provides. The current version has 60 electrodes. Dr. Humayun and the DOE team plan to begin human testing of a 240-electrode array in the next few years. At 1,000 electrodes, Dr. Humayun said, users should be able to read large print and recognize the faces of loved ones. “It’s a big technological jump,” he explained, “but at that stage, the artificial retina will be a huge benefit to as many

as tens of millions of people with retinal degenerative diseases, including those who have lost their ability to see detail due to more prevalent conditions like age-related macular degeneration.”

Over the last seven years, the DOE has provided \$70 million in funding for the artificial retina project, which supports research at five of their national laboratories and four universities. Dr. Humayun said that another \$30 million is needed to develop the 1,000-electrode device and “finish the job.” He added that the innovative implantable technology being developed is not only applicable to the eye, it also has potential to improve existing therapeutic devices including the cochlear implant, cardiac pacemakers, and deep brain stimulators for Parkinson’s disease.

In addition to making a formal presentation to staff, Dr. Humayun met individually with several Members of Congress in key leadership positions to further educate them about the promise of the artificial retina.



Cong. Gene Green (D-TX), co-chair of the Congressional Vision Caucus, with AEVR’s James Jorkasky



FFB Chief Research Officer Stephen Rose, Ph.D., with FFB Board member Moira Shea



Dr. Humayun with Jenny Wing from the office of Senator Tom Harkin (D-IA)



David Brint, Vice President of the FFB Board of Directors, with Dr. Humayun and Tom Zampieri, Ph.D. of Blinded Veterans Association



NAEVR Advocacy Manager David Epstein and Marcia Knutson from the office of Cong. James Moran (D-VA)



FFB’s David Brint with Richard Fischer, Ph.D., Director of the National Eye Institute’s (NEI) Office of Program Planning and Analysis

Legislative Scorecard Issues

Dr. Collins Cites NEI-Funded Human Gene Therapy Research



Francis Collins, M.D., Ph.D.

On April 28 and May 5, respectively, the Labor, Health and Human Services, and Education (LHHS) Subcommittees of the House and Senate Appropriations Committees held hearings on Fiscal Year (FY) 2011 NIH funding, featuring primary witness NIH Director Francis Collins, M.D., Ph.D. Early in his testimony, Dr. Collins played a video entitled “Corey’s story,” which featured a recipient of human gene therapy for Leber Congenital Amaurosis (LCA) navigating a maze unsuccessfully prior to the procedure, then successfully after the procedure. This research, funded by the NEI in conjunction with private funding organization Foundation Fighting Blindness at Children’s Hospital of Philadelphia and featured in a June 2008 AEVR Congressional Briefing, received such prominence at the hearings that NAEVR has written to Dr. Collins thanking him for featuring it.

The April 28 House hearing is memorable as it was Dr. Collins’ first appearance as NIH Director (he appeared previously as Director of the National Human Genome Research Institute within NIH), and will likely be Chairman David Obey’s (D-WI) last with NIH since he has announced his retirement. Chairman Obey praised Dr. Collins as being “the right person in the right place at the right time” to lead NIH through the post-American Recovery and



Cong. David Obey (D-WI), who chairs both the House Appropriations Committee and LHHS Appropriations Subcommittee, presided over the Citizen Witness hearing at which many witnesses thanked him for his past dedication to biomedical research

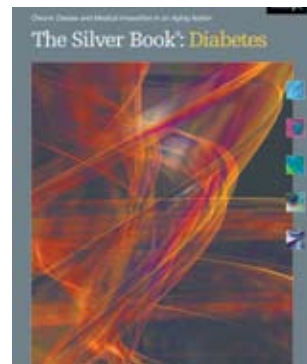
	FY 2008 Final	FY 2009 Final**	FY 2010 Final**	FY 2011 President's Request
NIH*	\$29.38 B	\$30.3 B +3.2%	\$31 B +2.3%	\$32.2 B +3.2%
NEI	\$670.7 M	\$688.5 M +3.2%	\$707.04 M +2.7%	\$724.36 M +2.5%

* Net of Transfers/One Time Expenses
** Absent ARRA Funding

Reinvestment Act (ARRA) timeframe and to expedite the translation of basic research into treatments. Dr. Collins stated that NIH has done the best job it could to prepare for possibly-reduced post-ARRA funding, while reiterating his top five priorities—genomics, translational research, global health, research that supports healthcare reform, and efforts to reinvigorate the biomedical research enterprise.

Both Democratic and Republican members praised NIH while noting that a funding increase would be tough (see funding chart). Both sides of the aisle questioned whether the Cures Acceleration Network (CAN), authorized by Congress at \$500 million in healthcare reform legislation but not yet appropriated funds, could assist NIH in “crossing the Valley of Death from bench to bedside,” that is, the rapid translation of basic research into treatments. Dr. Collins noted that the Institute and Center (I/C) Directors were to have a retreat the next day to address this issue. While commenting favorably on the great flexibility within the CAN model to alter research directions to address the most promising routes, he cautioned that it is “high risk, high reward” research that is not funded.

At the May 5 Senate hearing, Chairman Tom Harkin (D-IA) lamented the tight budget environment, stating that the Subcommittee will be forced to make “tough decisions...and some of our friends are not going to be very happy with some



Earlier on May 12, the Alliance for Aging Research held a Congressional Briefing to release *The Silver Book: Diabetes*, a compendium of the latest data about the incidence and economic impact of the disease. It also contains data about the impact of diabetic eye disease, building upon *The Silver Book: Vision Loss*, released in September 2007, which the Alliance developed with NAEVR.

of the decisions we make.” Senator Harkin also expressed his frustration over how CAN could be funded without taking funding away from I/Cs. Senator Arlen Specter (D-PA), the primary CAN sponsor, committed to finding the \$500 million in appropriations to fund it.

Vision Community Testifies at Citizen Witness Hearing



Neil Bressler, M.D.

At a May 12 House LHHS Appropriations Subcommittee Citizen Witness hearing, Neil Bressler, M.D. (Wilmer Eye Institute/Johns

Hopkins University School of Medicine), who represented the American Academy of Ophthalmology, urged Congress to fund NIH and NEI at \$35 billion and \$794.5 million, respectively, echoing NAEVR’s written testimony filed with the House and Senate on April 8. He reminded Members that May is *Healthy Vision Month* and that, in 2009, Congress passed H. Res. 366 and S. Res. 209 which recognized the 40th anniversary of the NEI and designated 2010-2020 as *The Decade of Vision*. He emphasized that the 2.5 percent “less-than-inflationary” NEI increase in the President’s budget proposal was inadequate to handle vision impairment and eye disease challenges.

He added his unique perspectives from his roles as Chair of the Food and Drug Administration’s (FDA) Ophthalmic Devices Panel and as Chair of the Diabetic Retinopathy Clinical Research (DRCR) Network, the NEI-funded collaborative, multi-center network dedicated to facilitating clinical research into diabetic retinopathy, diabetic macular edema, and associated conditions. He cited recently reported results of a DRCR Network comparative effectiveness trial which confirmed that laser treatment for diabetic macular edema, when combined with injections of the FDA-approved drug Lucentis, is more effective than laser treatment alone, the latter of which has been the standard of care for the past 25 years. “Nearly 50 percent of patients who received this new treatment experience substantial visual improvement, and fewer than 5 percent experience substantial vision loss,” said Dr. Bressler. “The investment by Congress to the NIH to make studies such as these possible is an example of the huge successful impact that these funding increases can have on the quality of life and productivity of America.”

Visit the dedicated NIH/NEI and ARRA funding sections of NAEVR’s Web site for full details

NAEVR Central Draws Largest Number of Visitors Ever

Prominently situated next to ARVO Central at the entrance to the Exhibit Hall, NAEVR Central, which serves as the vision research community's "Town Hall," drew its largest number of visitors ever at the 2010 ARVO Annual Meeting. In addition to contacting Congress to urge increased FY2011 NIH/NEI funding, researchers could also visit with representatives of 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).

"There was a palpable energy at NAEVR

Central this year, much of which I attribute to the unprecedented \$230 million increase in FY2009 vision research funding, driven primary by the \$175 million in NEI ARRA funding, as well as FY2009 and 2010 increases in "regular" NEI appropriations," said NAEVR's James Jorkasky, who added that many researchers dropped by to describe to him their ARRA-funded research.

"Of course, the presence of the TATRC representatives for three days at NAEVR Central attracted many additional researchers who had heard about funding opportunities—not only at TATRC, but at other "sister" agencies within the



DOD—that relate to traumatic injury to the eye and other sensory organs. NAEVR Advocacy Manager David Epstein and I answered dozens of questions about these opportunities and alerted researchers to an FY2010 Program Announcement expected shortly from the FY2010 Traumatic Brain Injury (TBI) program."



ARVO President J. Mark Petrash, Ph.D., FARVO (Rocky Mountain Lions Eye Institute/University of Colorado School of Medicine) contacts Congress



Left to right: ARVO President-Elect Jeffrey Boatright, Ph.D., FARVO (Emory University School of Medicine) and Erik van Kujik, M.D., Ph.D. (University of Texas) speak with NAEVR's James Jorkasky after contacting Congress



Lois Schoenbrun, C.A.E., F.A.A.O., Executive Director of the American Academy of Optometry, visits the booth. The Academy also hosts a NAEVR Contact Congress booth at its meeting each year.



NAEVR's James Jorkasky and Rajiv Mohan, Ph.D. (Mason Eye Institute/University of Missouri-Columbia), whom NAEVR has hosted during ARVO Advocacy Days in Washington, D.C.



Left to right: DOD/TATRC representatives Francis McVeigh, O.D., F.A.A.O., Marc Mitchell, Lt. Colonel Michael Mines, M.D., D.V.M., and Robert Read speak with Stephen Tsang, M.D., Ph.D., a recipient of FY2008 DOD funding through its Tuberculous Sclerosis Complex Research Program (TSCR)

NAEVR Seeks FY2011 PRMR-Vision Funding at \$10 Million

With TATRC's recent announcement of its awards, NAEVR has tangible examples of vision research to share with its Capitol Hill champions. NAEVR has been working closely with Blinded Veterans Association (BVA) to secure House and Senate "Dear Colleague" letters from non-defense appropriators in support of FY2011 PRMR-Vision funding at \$10 million.



NAEVR's David Epstein (left) and James Jorkasky have updated lead House champion James Moran (D-VA, third left) and staff member Chris Gaspar (second left) about the unique "gap filling" nature of the vision research awards recently announced by DOD's TATRC



BVA member Glen Minney (U.S. Navy Petty Officer, retired, center), who serves as a Patient Advocate at the Chillicothe, Ohio, VA Hospital, joined BVA's Tom Zampieri, Ph.D. (left) in meeting with Brady Van Engelen of the office of Senator John Kerry (D-MA) to support a Senate "Dear Colleague" letter for FY2011 PRMR-Vision funding



Dr. Zampieri (left) and Mr. Minney (third left) also visited with Doug Babcock (second left) in the office of Senator Sherrod Brown (D-OH) with NAEVR's James Jorkasky to support a Senate "Dear Colleague" letter. A Veterans Affairs Committee member, Senator Brown has been a strong supporter of VA Blind Rehabilitation services.

DOD Announces \$10 Million in Vision Research Portfolio Grants

At a May 3 standing room-only session held by NAEVR at the ARVO Annual Meeting, representatives from DOD's TATRC announced \$10 million in grant awards to vision researchers from its Vision Research Program (VRP). The net total of these awards reflects the total of FY2009 and 2010 Congressional appropriations of \$4 million and \$3.75 million, respectively, from the Peer Reviewed Medical Research-Vision (PRMR-Vision) program line item in defense funding plus \$3.2 million provided by TATRC's "sister" agency within the U.S Army's Medical Research and Materiel Command (MRMC), the Clinical and Rehabilitative Medicine Research Program (CRMRP), minus administrative costs.

In announcing the awards, TATRC Vision Portfolio Manager Robert Read exhibited a poster describing the grant awards, noting recipients, amounts, and applicability of the awards to the five critical areas identified in the June 2009 Program Announcement that called for submissions. Mr. Read commented that it was the quality of the proposals and their emphasis on research that fills "knowledge gaps" in understanding the impact of traumatic eye injury that have made Research Area Directors in other DOD programs, such as the CRMRP, interested in funding such projects. Mr. Read stated that, "there were initially more excellent proposals than there were dollars to spend—12 submissions scored between 1.1 and 1.8 on a scale of 1.0 to 5.0" [with one being highest score] in the peer review process conducted by the American Institute of Biological Science (AIBS)."

Vision Center of Excellence Director Donald Gagliano, M.D., who serves as the co-chair of the TATRC Programmatic Panel, echoed Mr. Read's remarks, noting that "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." Dr. Gagliano also presented a Powerpoint presentation about how the VCE, which is a joint DOD and Department of Veterans Affairs (VA) program, is coordinating military vision care from diagnosis through rehabilitation, including development of a Congressionally-mandated Defense and Veterans Eye Injury Vision Registry (DVEIVR). The latter may identify the most significant future research needs.

Since TATRC has combined its FY2009 and 2010 funding, there will be no program announcement issued in calendar year 2010. In the interim, other DOD agencies are issuing Program Announcements that request grant submissions into visual and sensory research needs. Earlier this year, the Defense Medical Research and Development Program (DMRDP) requested grants for FY2010 under three mechanisms—Applied Research and Advanced Technology, Clinical Trials, and Basic Research—that solicited research into "Treatment of Sensory System Traumatic Injury (Vision, Hearing and Balance)" and "Diagnosis and Treatment of Traumatic Brain Injury (TBI)". NAEVR understands that, shortly, a Program Announcement will issue for the FY2010 TBI program.



TATRC Vision Portfolio Manager Robert Read announces defense vision awards



Joint DOD/VA VCE Director Colonel Donald Gagliano, M.D., informs attendees about the Center's activities to coordinate military vision care from diagnosis through rehabilitation



Left to right: Colonel Robert Mazzoli, M.D., (retired), former U.S. Army ophthalmology consultant, joins TATRC representatives Robert Read, Marc Mitchell, Lt. Colonel Michael Mines, and Dr. Fran McVeigh

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



Mr. Read with Michael Steinmetz, Ph.D. from the NEI's Division of Extramural Research, who served on the TATRC Programmatic Panel



NAEVR's David Epstein with VRP awardee Tonia Rex, Ph.D. (University of Tennessee)



Left to right: Vision Research Program award winners included Randy Kardon, M.D., Ph.D. (University of Iowa), Stacy Choi, O.D., Ph.D. (New England College of Optometry), James Weiland, Ph.D., (Doheny Eye Institute/ University of Southern California), and Gregory Schultz, Ph.D. (University of Florida)

NAEVR Testifies Against Merging Institutes at SMRB Meeting

On May 18-19, the NIH's Scientific Management Review Board (SMRB) held its fourth meeting to address NIH management and structure issues, per its charter as set forth by the *NIH Reform Act of 2006*. The meeting focused on status reports from three Working Groups—Deliberating Organizational Change and Effectiveness (DOCE); Substance Use, Abuse, and Addiction (SUAA), which is considering the merger of the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA); and Intramural Research Program (IRP), which is also considering changes to how the NIH Clinical Center is funded and interacts with the extramural research community.

Due to NAEVR's long-standing opposition to merging Institute and Center budgets and support for maintaining the NEI's budget line item, James Jorkasky urged the SMRB to fully examine the potential impact on the actual research that is being conducted by NIDA and NIAAA should a structural change be recommended. NAEVR likened the concern expressed by liver function researchers that "targeted organ research" could be minimized in a combined Drug/Alcohol Institute to the concern previously expressed by vision researchers that "front of the eye" corneal research could be minimized if NEI was clustered into a "Brain" Institute that may maximize "back of the eye" retinal research.

Late on the second day, NIH Director Dr. Collins requested that the SMRB



NIH Director Dr. Collins speaks to the SMRB

take on a new project—recommending to NIH how to integrate the numerous initiatives to translate basic research more rapidly into treatments and therapies. He included the newly formed NIH-FDA Joint Leadership Council (see story below) as one such example, and noted that the NIH was uniquely positioned to demonstrate leadership to Congress in accelerating therapies for patients.

NAEVR Comments at First NIH/FDA Joint Leadership Council Stakeholders Meeting

On June 2, the NIH/FDA Joint Leadership Council held the first of what is expected to be several Stakeholders Meetings. The Council, which was announced on February 24 by Department of Health and Human Services (DHHS) Secretary Kathleen Sebelius, will work to ensure that regulatory considerations form an integral component of biomedical research planning and that the latest science is integrated into the regulatory review process. Chaired by Dr. Collins and FDA Commissioner Margaret Hamburg, M.D., the Council will consist of six senior representatives from each of the two agencies.

The purpose of the meeting was to elicit public comments on how the NIH and FDA could collaborate to enhance the translation of biomedical research discoveries into new preventatives, diagnostics, therapies or devices for clinical use and what issues/mechanisms

need to be addressed to facilitate that process. Medical research advocates representing a variety of disease conditions offered recommendations. NAEVR, which submitted written comments to the meeting docket, also commented verbally, stressing the importance of the past collaboration between the NEI and FDA. "In its 40-year history, the NEI has had an ongoing collaboration with the FDA on ophthalmic drug and device issues, especially clinical trial design and the identification of new clinical endpoints" said James Jorkasky. "We need to look no further than the ongoing series of joint NEI/FDA *Endpoints Symposia*, including a September 2009 session on *Patient-Reported Outcomes*, a March 2008 session on *Glaucoma Clinical Drug Trial Design*, and a November 2006 *Ophthalmic Clinical Trial Design* session that focused on new treatments for age-related macular degeneration and diabetic retinopathy."

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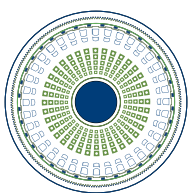


Left to right: The meeting was moderated by Jesse Goodman, M.D., M.P.H., FDA's Chief Scientist and Deputy Commissioner for Science and Public Health, and Kathy Hudson, Ph.D., NIH Chief of Staff, with meeting management provided by Vicki Seyfert-Margolis, Ph.D., Senior Advisor in the FDA Office of the Chief Scientist



Left to right: Medical research advocacy colleagues attending the session included Jennifer Ayers (American Institute for Medical and Biological Engineering, AIMBE), Martha Nolan (Society for Women's Health Research), and Keith Kerneklian (Coalition for Imaging and Bioengineering Research, CIBR), who joined NAEVR's James Jorkasky

Visit the [NAEVR Web site home page's NAEVR in ACTION](http://NAEVR.org) section to obtain these comments



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