

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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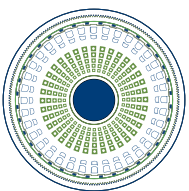


Left to right: The meeting was moderated by Jesse Goodman, M.D., M.P.H., FDA's Chief Scientist and Deputy Commissioner for Science and Public Health, and Kathy Hudson, Ph.D., NIH Chief of Staff, with meeting management provided by Vicki-Seyfert-Margolis, Ph.D., Senior Advisor in the FDA Office of the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

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