

NAEVR Hosts Vision Research Community Meeting with FDA

On July 6, NAEVR hosted a meeting of representatives of the eye and vision research and patient communities with the leadership of the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), including Acting CDER Director Dr. Steven Galson. NAEVR requested the meeting so that FDA could provide an update on the status and implications of its reorganization of the Office of New Drugs, in which the Ophthalmology Group is being integrated into the Division of Anti-Infective Products. FDA reported that this process is complete, and the Ophthalmology Group now reports to Division Director Dr. Janice Soreth.

Within the context of this meeting, our community had an opportunity to educate FDA staff about the new drug therapies emerging from research, as well as

to highlight the unique mode of action of ophthalmic drugs (e.g., localized as compared to a systemic effect) that is a pivotal issue in the review process. Arising from these discussions, Dr. Soreth announced that the Division plans to proceed in the development of Guidance Documents to formalize more aspects of the review process, which can facilitate our community's constructive input.

NAEVR wishes to thank the following meeting participants: Dr. Allan Jensen and Norman Lanphear (representing the American Academy of Ophthalmology); Dr. James Boucher (representing the American Optometric Association); Daniel Garrett (representing Prevent Blindness America); Dr. Barrett Katz (Eyetechnopharmaceuticals, Inc.); Dr. Scott Whitcup (Allergan); Steven Grossman (EyeRX); and Dr. Pat Wilkinson, who served as the NAEVR spokesman with James Jorkasky. ■



CDER's Dr. Steven Galson and NAEVR spokesman Dr. Pat Wilkinson



Norman Lanphear, Dr. Barrett Katz and Dr. Scott Whitcup