

OPHTHALMIC DEVICES PANEL ROSTER

FEBRUARY 5-6, 2004 MEETING

CHAIR

JAYNE S. WEISS, M.D.

Dr. Weiss, a specialist in corneal and refractive surgery, is Professor of Ophthalmology and Pathology, Director of Refractive Surgery, and Director of Ophthalmic Pathology at the Kresge Eye Institute, Wayne State University in Detroit, Michigan. Dr. Weiss received her M.D. from the Mt. Sinai School of Medicine in New York with fellowships in ocular pathology at Harvard University's Massachusetts Eye and Ear Infirmary in Boston and in corneal disease and refractive surgery at Emory University in Atlanta. Dr. Weiss has served as a regular member of the National Institutes of Health Visual Sciences Study Section for the National Eye Institute and is Principle Investigator of an RO1 grant on Genetic Mapping of Schnyder's Crystalline Corneal Dystrophy. She is currently a member of the research committee of the Eye Bank Association of America as well as multiple American Academy of Ophthalmology Panels including the Preferred Practice Patterns Cornea/External Disease Panel, the Basic and Clinical Science Course (BCSC) on Cornea/External Disease and chairs the recently created BCSC on Refractive Surgery. She is a member of the editorial board of Cornea and is a reviewer for many other ophthalmology journals. Dr. Weiss is nationally and internationally recognized for her lectures and publications.

VOTING MEMBERS

ARTHUR BRADLEY, Ph.D.

Dr. Bradley is a Professor of Optometry and Visual Sciences and Adjunct Professor of Neural and Cognitive Science at Indiana University, Bloomington, IN. He is a graduate of Reading University, England, and has a Ph.D. in physiological optics from the University of California, Berkeley. He has been a principal investigator for the National Eye Institute (NIH), NASA, and USAF. His research interests include optics of the eye, spatial vision, assessment of night vision systems, and entoptic assessment of retinal vasculature. Dr. Bradley has authored over 100 publications in the field of visual optics and spatial vision. He consults on optics of the eye for the US Department of Defense and reviews research proposals and reports for several branches of the US government. Dr. Bradley is a recognized authority on the optics of the human eye and optical strategies for enhancing vision.

ANNE L. COLEMAN, M.D., Ph.D.

Dr. Coleman is an Associate Professor of Ophthalmology at the Jules Stein Eye Institute of the University of California at Los Angeles School of Medicine. In addition she is the Director of the Center for Eye Epidemiology at the Institute. Dr. Coleman is a graduate of Duke University and the Medical College of Virginia and completed her ophthalmology residence at the University of Illinois School of Medicine in Chicago and a fellowship in glaucoma at the Johns Hopkins School of Medicine in Baltimore. She received her Ph.D. in epidemiology from the University of California at Los Angeles, CA. Dr. Coleman currently serves as a reviewer for Ophthalmic Epidemiology, Current Eye Research, Ophthalmology, Journal of Glaucoma, Archives of Ophthalmology, and Investigative Ophthalmology and Research among others. She has published and lectured extensively and is internationally recognized for her expertise in the diagnosis and management of glaucoma

MICHAEL R. GRIMMETT, M.D.

Dr. Grimmatt is an Assistant Professor of Ophthalmology at the Bascom Palmer Eye Institute of the University of Miami School of Medicine. He graduated from Loyola Marymount University in Los Angeles, CA and received his M.D. from the University of California at Irvine. Dr. Grimmatt is board certified in both internal medicine and ophthalmology and completed his fellowship in corneal and external disease at the University of Minnesota in Minneapolis in 1993. He is a recognized expert on the medical/legal/ethical issues associated with refractive surgery, publishing *The Call of the Sirens, Ethically Navigating the Sea of Nonvalidated Therapies*, in the Journal of Refractive Surgery, the journal of the International Society of Refractive Surgery. He is a peer reviewer for the Journal of Refractive Surgery, the American Journal of Ophthalmology, and Cornea. Dr. Grimmatt has been actively involved in the Eye Bank Association of America since 1994, and contributes his expertise to the American Academy of Ophthalmology's continuing medical education (CME) program and the development of their CME website.

WILLIAM D. MATHERS, M.D.

Dr. Mathers is a Professor of Ophthalmology at the Oregon Health Sciences University, Casey Eye Institute in Portland, OR. He received undergraduate education at Allegheny College, and his medical doctorate at Stanford University. After a residency in ophthalmology at the University of Washington, he completed a fellowship in Cornea and External Disease at Georgetown University Medical School in Washington, DC. Dr. Mathers is very active in research and has been a principal investigator on many National Institutes of Health grants related to tear production and dry eyes, the molecular genetics of corneal dystrophys, and acanthamoeba keratitis. In addition, he has served on the NIH study section, multiple editorial boards and as president of CLAO (Contact Lens Association Organization and the Pan American Association for Contact Lenses and Refraction. Dr. Mathers has authored many publications and book chapters and is internationally recognized for his clinical expertise and scholarship.

TIMOTHY T. McMAHON, O.D., F.A.A.O.

Dr. McMahon is a Professor of Ophthalmology in the Department of Ophthalmology & Visual Sciences at the University of Illinois at Chicago College of Medicine. He received his Doctor of Optometry from the Illinois College of Optometry in 1980, and completed a residency at the Kansas City Veterans Administration Medical Center in 1981. He is a Fellow of the American Academy of Optometry and is a Diplomate in Cornea and Contact Lenses. He is a past Chair of the Academy's Research Committee and is a member of the AOA Council on Research. Dr. McMahon was appointed Secretary/Treasurer of the American Optometric Foundation in 2002. Recently the National Academies of Practice named him a Distinguished Clinical Fellow. Dr. McMahon is an investigator in several NIH and VA funded research projects, including the Collaborative Longitudinal Evaluation of Keratoconus Study, where he serves on the Executive Committee. He currently serves on the editorial boards of *Cornea* and *Eye & Contact Lens*. He has published extensively in the areas of contact lenses, corneal topography and the clinical course and therapeutic modalities of anterior segment diseases. He has lectured nationally and internationally. The breadth of his expertise in optometry and experience in clinical research methodology are widely recognized.

CONSULTANTS

KAREN BANDEEN-ROCHE, Ph.D.

Dr. Bandeen-Roche is a Professor of Biostatistics in the School of Hygiene and Public Health, The Johns Hopkins University, in Baltimore, MD. She graduated from the Andrews University in Berrien Springs, MI and received her master's and doctorate in Operations Research and Industrial Engineering from Cornell University in Ithaca, NY. Dr. Bandeen-Roche has contributed extensively to many publications including the American Journal of Epidemiology, Investigative Ophthalmology and Vision Science, and the Journal of American Statistical Association, Biometrika, and Statistics in Medicine. She is nationally recognized in the professional areas of multi-variate and longitudinal data analysis, quality of life assessment, and clinical study issues. She has authored journal articles on research related to ophthalmic issues, particularly with respect to the non-invasive assessment of the visual system, women's health, and aging. In 1997, Dr. Bandeen-Roche was awarded a Brookdale National Fellowship for excellence in research on aging. A paper she co-authored received the American Academy of Optometry's 1999 Garland Clay Award as the most cited paper in the preceding five years' issues of Optometry and Vision Science.

RICHARD CASEY, M.D.

Dr. Casey is the Interim Chairman of the Department of Ophthalmology at the Charles Drew University of Medicine and Science and Associate Professor of Ophthalmology at the Jules Stein Eye Institute in Los Angeles, CA. He is a graduate of Harvard Medical School and completed his residency and a fellowship in cornea and external disease at the Massachusetts Eye and Ear Infirmary in Boston, MA. The focus of his surgical profession is the management of ocular surface disease, anterior segment derangements, cataract, corneal transplantation and laser refractive surgery. His clinical research involves ocular allergy and ocular neovascularization, particularly the study of angiogenesis inhibitors. He has authored book chapters, published in many scientific journals and has lectured nationally and internationally on these topics.

ANDREW J. HUANG, M.D., M.P.H.

Dr. Huang is an Associate Professor and the Director of the Cornea and External Disease Service of the Department of Ophthalmology at the University of Minnesota in Minneapolis. He received his medical doctorate at National Taiwan University, a Masters of Public Health as well as a post-doctoral fellowship in the Division of Biophysics from The Johns Hopkins University School of Public Health. He completed a research fellowship at the Eye Research Institute and Massachusetts Eye and Ear Infirmary, Harvard Medical School and his ophthalmic residency training and clinical corneal fellowship at the Bascom Palmer Eye Institute, University of Miami. Dr. Huang has published numerous peer-reviewed journal articles as well as book chapters on the management of cornea and external diseases. He has lectured extensively to international organizations and is an active participant in Project Orbis, volunteering for numerous missions to provide ophthalmic education and clinical service to underdeveloped countries.

MARIAN S. MACSAI, M.D.

Dr. Marian S. Macsai is Chief of the Division of Ophthalmology at Evanston Northwestern Healthcare and Professor and Vice Chair of the Department of Ophthalmology at Northwestern University. She completed her medical education at Rush Medical College followed by a residency was at the University of Illinois and fellowship in cornea and external disease at the University of Iowa. In 1989, Dr. Macsai was recruited to West Virginia University where she was the Director of the Cornea External Disease and Refractive Surgery Service for ten years. During that period of time, Dr. Macsai also served as the Medical Director of the Medical Eye Bank of West

Virginia. She has served as the Chair of the Scientific Program Committee, the Research Committee and the Accreditation Committees of the Eye Bank Association of America. She has served on the Board of Directors for eight years and on the Certification Board for the past four. Dr. Macsai was recently awarded the Paton Award by the Eye Bank Association of America and will receive this award in November of 2003. Dr. Macsai has also served on the Board of Directors of the Cornea Society formerly known as the Castroviejo Society and has served as the Chair of the Scientific Program Committee for the Society for the past four years. In addition, she has served on many academies for the American Academy of Ophthalmology including the committee on eye banking. She is a former voting member of the FDA Ophthalmic Devices Panel. In 1996, Dr. Macsai co-edited the book, Eye and Skin Disease. She has authored 11 book chapters and published over 40 papers in peer review journals.

OLIVER D. SCHEIN, M.D., M.P.H.

Oliver Schein, M.D., M.P.H. is the Grossman Professor of Ophthalmology at the Wilmer Eye Institute, Johns Hopkins University School of Medicine. He holds a joint appointment in the Department of Epidemiology at the Johns Hopkins University School of Public Health and Hygiene. His clinical expertise is in the medical and surgical management of patients with corneal disease and problems involving the anterior segment of the eye. Research interests have centered on the application of epidemiologic and public health principles to the study of eye disease, the practice of ophthalmology, and the evaluation of ophthalmic technology. The focus of recent publications has been on the assessment of outcomes of cataract surgery using a variety of research methodologies including randomized clinical trials, longitudinal cohort studies and case-control studies. Another major focus has been the development of standardized questionnaires to measure the functional impact of common ophthalmic interventions (eg. cataract surgery, refractive surgery) from the patient perspective. Dr. Schein is an author of the American Academy of Ophthalmology's (AAO) Preferred Practice Pattern on management of cataract in the adult and is a member of the AAO's Quality of Care Committee.

JANINE A. SMITH, M.D.

Dr. Smith is the Deputy Clinical Director of the National Eye Institute (NEI) and works within the Clinical Trials Branch of the Division of Epidemiology and Clinical Research. She received her medical doctorate from Howard University College of Medicine and completed an ophthalmology residency at the Medical College of Virginia in Richmond. She pursued sub-specialty training and completed fellowships in Cornea and External Disease at the Wilmer Ophthalmological Institute at Johns Hopkins University and in Ocular Immunology at the National Eye Institute. The focus of her basic science research has been immune-based diseases of the ocular surface. Dr. Smith is integrally involved with the NEI Institutional Review Board and Data Safety Monitoring Committee and represents NEI on several NIH committees. The focus of her clinical research is the identification of outcome measures for ocular surface disease clinical studies and is a key contributor to the research, education and consultation responsibilities of the NEI intramural clinical research program.

WOODFORD S. VAN METER, M.D.

Dr. Van Meter is Associate Clinical Professor, Department of Ophthalmology, University of Kentucky School of Medicine in Lexington, KY and is in private practice. He is a graduate of Davidson College in North Carolina and Vanderbilt University School of Medicine. He completed a residency in Ophthalmology at the Mayo Graduate School of Medicine and a fellowship in Corneal and External Disease at Emory University, Atlanta, GA. Dr. Van Meter, an internationally recognized expert on cornea and external disease is on the Board of Directors of the Castroviejo Cornea Society and the Eye Bank Association of America, and is assistant treasurer of the EBAA. He has published and lectured extensively on cataract surgery, corneal transplantation, and contact lenses.

CONSUMER REPRESENTATIVE

GLEND A V. SUCH, M.Ed.

Ms. Such is the Director of Computer Training Program, Department of Career Services, Lighthouse International in New York, NY. She received her Bachelor of Arts in Psychology and Pre-Law at Norwich University in Montpelier, VT and a Master of Education in Education of the Visually Impaired at the Pennsylvania College of Optometry in Philadelphia, PA. She is a recognized expert in the field of adaptive technology for visual impairments and the functional implications of visual disabilities, particularly low vision. In addition to teaching students who are visually impaired, she lectures at Temple University Graduate School, Harcum College, and Saint Joseph's University Graduate School in areas relating to working with clients who are visually impaired. She served for four years as a board member of the Council of Citizens with Low Vision International and was a member of the Institutional Review Board of Pennsylvania College of Optometry.

INDUSTRY REPRESENTATIVE - February 5, 2004 (Acting)

ANDREW K. BALO

Mr. Balo is the Vice President for Regulatory and Clinical Affairs with DEXCOM, Inc. in San Diego, CA. He also serves as the Industry Representative on the Neurological Devices Advisory Panel. Mr. Balo has a Bachelor of Science in microbiology and chemistry from the University of Maryland and has done graduate work in business and executive management at the University of California in Los Angeles, and Stanford University, respectively. He has over twenty years of experience in regulatory and clinical affairs with both domestic and international device firms.

INDUSTRY REPRESENTATIVE - February 6, 2004

RONALD E. McCARLEY

Mr. McCarley is President, CEO and founder of Ophtec USA, Inc. an ophthalmic medical device firm that manufactures cataract, refractive and iris reconstruction implants in Boca Raton, FL. He has over 19 years experience in domestic and international business operations and extensive knowledge in the areas of regulatory affairs, clinical studies and quality assurance. Mr. McCarley has participated in bringing a wide range of ophthalmic devices to market through positions he has held with small manufacturers as well as large firms. In addition, he has demonstrated leadership within the device industry through his participation in the International Standards Organization and American National Standards Institute standards development working groups.