

PANEL ROSTER
NEUROLOGICAL DEVICES PANEL MEETING
January 27-28, 2011

Name	Affiliation	Role
Thomas G. Brott, M.D.	Mayo Clinic Jacksonville, FL	Temporary Non Voting Chair
Karen E. Anderson, M.D.	University of Maryland Baltimore, MD	Temporary Non Voting Member
Karen B. Domino, MD, MPH	University of Washington Seattle, WA	Temporary Non Voting Member
Kevin Duff, Ph.D.	University of Utah Salt Lake City, UT	Temporary Non Voting Member
Jonas H. Ellenberg, Ph.D.	University of Pennsylvania Philadelphia, PA	Temporary Non Voting Member
David C. Good, MD	Penn State Hershey, PA	Temporary Non Voting Member
Wayne K. Goodman, M.D.	Mount Sinai School of Medicine New York, NY	Temporary Non Voting Member
Mae O. Gordon, Ph.D.	Washington University St. Louis, MO	Temporary Non Voting Member
Scott Y.H. Kim, M.D.	University of Michigan Ann Arbor, MI	Temporary Non Voting Member
William M. McDonald, M.D.	Emory University Atlanta, GA	Temporary Non Voting Member
Jane S. Paulsen, Ph.D.	University of Iowa Iowa City, IA	Temporary Non Voting Member
Guerry M. Peavy, Ph.D.	University of California La Jolla, CA	Temporary Non Voting Member

PANEL ROSTER (Continuation)
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Name	Affiliation	Role
Christopher A. Ross, M.D., Ph.D.	The John Hopkins University Baltimore, MD	Temporary Non Voting Member
Glenn T. Stebbins, Ph.D.	Rush University Chicago, IL	Temporary Non Voting Member
Andrew Winokur, M.D., Ph.D.	University of Connecticut Farmington, CT	Temporary Non Voting Member
David H. Mueller, M.S.	Mueller & Associates Roseville, MN	Industry Representative
*Ms. Michelle Carras		Patient Representative
**E. Francine Stokes McElveen, J.D., M.S	Coppin State University Baltimore, MD	Consumer Representative
Olga I. Claudio, Ph. D.	Food and Drug Administration Silver Spring, M. D.	Designated Federal Officer

* Ms. Michelle Carras serves as a Patient Representative to the CDER Psychopharmacologic Drugs Advisory Committee.

** Ms. E. Francine Stokes McElveen, J.D., M.S serves as a Consumer Representative to the CDRH Gastroenterology-Urology Devices Panel

PANEL BIOGRAPHICAL SKETCH

Thomas G. Brott, M. D. (Temporary Non-Voting Chair)

Dr. Thomas G. Brott is Eugene and Marcia Applebaum Professor of Neurosciences, Mayo Clinic and James C. and Sarah K. Kennedy Dean for Research, Mayo Clinic in Florida. In addition, he is adjunct professor in the Department of Surgery at the University of Medicine and Dentistry of New Jersey in Newark, N.J. A pioneer in the field of stroke and cerebrovascular disease research, Dr. Brott was a leading investigator in the studies that identified tissue plasminogen activator (t-PA) as an effective acute treatment for ischemic stroke. He also played a key role in designing the National Institutes of Health Stroke Scale (NIHSS). Currently, Dr. Brott is principal investigator for the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) and national co-principal investigator of the Siblings with Ischemic Stroke Study (SWISS), both funded by NINDS. Dr. Brott received his M.D. from the University of Chicago and completed his residency at the Harvard Longwood Neurology Program. He has received many awards and honors and has held several national leadership positions, including chair of the Advisory Committee to the Neurological Devices Panel of the Food and Drug Administration and chair of the Stroke Council of the American Heart Association. He is a member of numerous professional societies and is widely published in the field.

Karen E. Anderson, M. D. (Temporary Non-Voting Member)

Dr. Karen Anderson is a neuropsychiatrist at the University of Maryland. Her undergraduate and medical degrees are both from the University of Chicago. She completed residency training in psychiatry at Columbia University and the New York State Psychiatric Institute. Following this, she stayed at Columbia to do a dementia and brain imaging fellowship at the Gertrude Sergievsky Center. She moved to the University of Maryland in 2001, where she has appointments as an Assistant Professor in both the Department of Psychiatry and the Department of Neurology. She is the founder and Director of the University of Maryland Huntington's Disease Clinic, the psychiatrist for the Maryland Parkinson's and Movement Disorders Center, and a member of the Deep Brain Stimulation Team at the University of Maryland. She is also a member of the Operation Iraqi Freedom/Operation Enduring Freedom Traumatic Brain Injury Program at the Baltimore VA Medical Center. Dr. Anderson is currently the PI on a VA Merit project studying exercise and cognitive training for executive dysfunction in Parkinson's Disease.

Karen B. Domino, MD, MPH (Temporary Non-Voting Member)

Dr. Karen Domino is Professor and Vice Chair for Clinical Research in the Department of Anesthesiology and Pain Medicine, University of Washington School of Medicine, Seattle. Dr. Domino is also Associate Chief of Anesthesia and Director of Operating Room at University of Washington Medical Center in Seattle. Dr. Domino has extensive experience with continuous quality improvement, risk management, and patient safety. She is Chair of the American Society of Anesthesiologists' (ASA) Professional Liability Committee, a consultant to the Anesthesiology and Respiratory Therapy Devices Panel at the Food and Drug Administration, and a senior examiner for the American Board of Anesthesiology. She has been a member of several ASA Task Forces to develop practice advisories and guidelines. She is a past president of the Society for Neuroscience in Anesthesia and Critical Care (SNACC). Dr. Domino is internationally recognized as an expert on anesthesia patient safety and a popular invited lecturer around the world. She is author of over 80 peer-

reviewed journal articles (12 accompanied by editorials), over 40 book chapters, and 40 other publications.

Kevin Duff, Ph. D. (Temporary Non-Voting Member)

Dr. Duff is an Associate Professor in the Department of Neurology and a Neuropsychologist for the Center for Alzheimer's Care, Imaging and Research (CACIR), at the University of Utah. He completed his undergraduate work at the University of Massachusetts-Dartmouth, and received an MA in Psychology at the University of Northern Colorado. He obtained his PhD in Clinical Psychology from the State University of New York at Albany. He completed his neuropsychology internship at the Southern Arizona Healthcare System in Tucson, AZ, and his post-doctoral fellowship at the University of Oklahoma Health Sciences Center in Oklahoma City. He has extensive teaching experience and had clinical and research experience working with patients with dementia, Huntington's disease, and a variety of other neuropsychiatric conditions. He currently conducts research in clinical neuropsychology, aging and dementia. His primary areas of interest include longitudinal cognitive assessment, practice effects as an indicator of cognitive plasticity, and cognitive decline in normal aging, mild cognitive impairment, and dementia. Dr. Duff's extensive work with Huntington's disease has focused on psychiatric and cognitive functioning, particularly psychiatric and cognitive changes that occur in individuals before they develop Huntington's. Dr. Duff's research has been widely published in scientific journals and he has lectured nationally and internationally on his areas of expertise.

Jonas H. Ellenberg, Ph. D. (Temporary Non-Voting Member)

Dr. Ellenberg is a Professor of Biostatistics and Associate Dean for Research Program Development, University of Pennsylvania SOM. His statistical research has focused on issues affecting validity and inferential viability/generalizability in clinical research, including bias arising from patient selection and subjects lost to follow-up, uniformity of methods of assessment across centers in multicenter studies, missing data and completeness of reporting, barriers to access to enrollment pools in observational studies, and intention to treat analysis in clinical trials. His medical interests include the etiology and prognosis of cerebral palsy (CP), convulsive disorders, and other neurological disorders in children, neurodegenerative disorders, and the treatment and prognosis of HIV in adolescents. He is an elected fellow of the American Statistical Association, the International Statistical Institute and the AAAS, and is past President of the American Statistical Association and of the International Biometric Society.

David C. Good, M. D. (Temporary Non-Voting Member)

Dr. David Charles Good is Professor and Chair of Neurology and Director of Neurorehabilitation at the Milton S. Hershey Medical Center of the Penn State College of Medicine. Dr. Good received his MD degree from the University of Wisconsin at Madison and subsequently completed his Neurology residency and stroke fellowship at the University of Minnesota Hospitals. He has served as a consultant or advisor to a number of organizations, including the National Institutes of Health, the Food and Drug Administration and the National Multiple Sclerosis Society. He has served on a number of national study sections, and has held leadership positions in a variety of organizations, including the American Society of Neurorehabilitation, the World Federation for Neurorehabilitation, and the United Council for Neurologic subspecialties. Dr. Good is author or co-author of numerous journal articles, book chapters, and has edited three books. His research focuses on stroke recovery, particularly techniques to enhance motor recovery. Dr. Good is an accomplished teacher and has received a number

of teaching awards. He is also an active clinician and is consistently listed in the Best Doctors of America. Dr. Good is frequently invited to speak nationally and internationally on topics related to Neurorehabilitation.

Wayne K. Goodman, M. D. (Temporary Non-Voting Member)

Dr. Goodman is Professor and Chairman of the Department of Psychiatry at the Mount Sinai School of Medicine in New York City. Prior to joining Mt. Sinai, he served as Director, Division of Adult Translational Research and Treatment Development (DATR), at the National Institute of Mental Health in Bethesda, Maryland. A graduate of Columbia University with a BS in electrical engineering, Dr. Goodman received his medical degree from Boston University and completed his internship, residency, and a research fellowship at Yale University School of Medicine where he remained on faculty as an Associate Professor. He joined the University of Florida (UF) in Gainesville where he served as Chairman of the Department of Psychiatry for nine years. Dr. Goodman has published more than 200 articles in scientific journals. Dr. Goodman is an expert psycho-pharmacologist and has served as Chair of the Food and Drug Administration's (FDA's) Psychopharmacologic Drug Advisory Committee. With respect to neurological devices, he has conducted research on Deep Brain Stimulation (DBS) for intractable OCD.

Mae O. Gordon, Ph. D. (Temporary Non-Voting Member)

Mae O. Gordon, Ph.D., is a Professor at the Department of Ophthalmology and Visual Sciences and Division of Biostatistics, Washington University School of Medicine, St. Louis, MO. Dr. Gordon's expertise includes the design and implementation of randomized clinical trials and observational studies, risk modeling and psychometrics. She is PI and Director of the Coordinating Center for the Ocular Hypertension Treatment Study (OHTS), a multi-center NIH randomized trial of the safety and efficacy of topical ocular hypotensive medication to prevent glaucoma. The study received the New York Academy of Medicine prize and the International Glaucoma Society Award for the most outstanding glaucoma research published in 2002. This study identified central corneal thickness as a risk factor for glaucoma, a finding which resulted in CPT1 coding by Medicare in 2004. Dr. Gordon was PI and Director of Coordinating Center for The Collaborative Longitudinal Evaluation of Keratoconus Study, the first multi-center study in Optometry. Surveys and measurement protocols developed by Dr. Gordon include the Glaucoma Symptom Questionnaire, corneal scarring grading system and Pediatric Cerebral Palsy Visual Function Questionnaire. Her studies on patient adherence to glaucoma medication using an unobtrusive electronic eye drop monitor are considered "landmark" studies. Dr. Gordon has served on numerous scientific review panels, chaired numerous Data and Safety Monitoring committees including the Beaver Dam Eye Study, the Baltimore Eye Study and The Prism Adaptation Randomized Trial. She has authored more than 100 peer reviewed publications. She has served on the National Advisory Eye Council (2007-2010) and the NIH Council of Councils (2009-2012).

Scott Kim, MD, Ph. D. (Temporary Non-Voting Member)

Dr. Kim is an associate professor in the Department of Psychiatry and Co-Director, Center for Bioethics and Social Sciences in Medicine at the University of Michigan. He is a graduate of Harvard Medical School, received his PhD in philosophy from the University of Chicago, and trained in psychiatry at the Massachusetts General Hospital. His work addresses a variety of ethical issues in neuropsychiatric research. He has written extensively on the ethics of research involving the decisionally impaired, on surrogate consent for dementia research, on the ethics of gene transfer

research for neurodegenerative disorders, including the ethics of sham surgery trials, and on ethical design of research protocols in neuropsychiatry. Dr. Kim's work has been supported by grants from NIMH, NINDS, NIA, Michael J. Fox Foundation, and the American Association for Geriatric Psychiatry. He is a former Greenwall Faculty Scholar in Bioethics.

William M. McDonald, M. D. (Temporary Non-Voting Member)

William M. McDonald, MD graduated from Duke University Medical School and was a member of the clinical faculty before moving to Emory. Dr. McDonald is the Fuqua Chair for Late-Life Depression and Professor of Psychiatry and Behavioral Sciences at Emory. He is Chief of the Division of Geriatric Psychiatry and oversees the extensive inpatient and outpatient geriatric psychiatry services. His research has been supported by funding from the National Institute of Mental Health, the National Institute of Neurological Disease and Stroke, the Fuqua Foundation, National Association for Research in Schizophrenia and Depression and a number of private funding agencies. Dr. McDonald is a member of the American Psychiatric Association's (APA) Research Council on Research, the APA Taskforce on the Guidelines for Electroconvulsive Therapy and the Food and Drug Administration's Neurological Devices Panel. He is President of the Georgia Psychiatric Association and in 2009 he was appointed the Special Advisor on Mental Health to Governor Perdue of Georgia.

Jane S. Paulsen, Ph. D. (Temporary Non-Voting Member)

Dr. Paulsen is a professor at the University of Iowa. Her research uses tools on neuropsychology and cognitive psychology to examine behavioral correlates of brain dysfunction. Topics of current interest include subtypes of Alzheimer's disease, preclinical cognitive deficits associated with gene-carriers of Huntington's disease and clinical/imaging correlates of cognitive measures. Functional MR and PET are used to examine frontal-striatal circuitry dysfunction in these disorders.

Guerry M. Peavy, Ph. D. (Temporary Non-Voting Member)

Guerry M. Peavy, PhD is a neuropsychologist at the University of California, San Diego, Shiley-Marcos Alzheimer's Disease Research Center, Project Scientist in the Department of Neurosciences, and Health Sciences Assistant Clinical Professor in the Department of Psychiatry. Her primary research focus is on the effects of chronic stress on cognitive change and cellular aging in older adults at risk for dementia, with an emphasis on specific, stress-related factors that contribute to change in level of functional independence. She also conducts research to characterize cognitive loss associated with Huntington's disease in an effort to identify appropriate criteria for diagnosing dementia in this population. Clinically, she is a member of a team that provides predictive testing for individuals at risk for Huntington's disease.

Christopher A. Ross, M. D., Ph. D. (Temporary Non-Voting Member)

Dr. Ross is Professor of Psychiatry, Neurology and Neuroscience and he is the Director of the Division of Neurobiology at the John Hopkins University, The Solomon H. Snyder Department of Neuroscience. His research focuses in the study of neuropsychiatric disorders, using a wide range of techniques, with an ultimate goal of illuminating normal human brain function. Huntington's disease (HD) and Parkinson's disease (PD) are models which may provide methods for approaching the more complex psychiatric disorders such as schizophrenia.

Glenn T. Stebbins, Ph. D. (Temporary Non-Voting Member)

Dr. Stebbins is Professor of Neurological Sciences at Rush University Medical Center in Chicago, Illinois. His research interests center on the effects of normal and pathological aging on cognitive function in humans. Using advanced neuroimaging (e.g., fMRI, Diffusion Tensor Imaging, SPECT) and behavioral techniques, studies are designed to assess the relationship between structural and functional changes in the CNS and age-related behavioral changes. Specific areas of interest include the contribution of white matter microstructural integrity to cortical and subcortical gray matter function during executive and declarative memory performance. Current research focuses on four areas: 1) Dissociation of cortical and sub-cortical contributions of executive working memory impairments in patients with movement disorders. 2) Delineation of medial temporal lobe functional activity during declarative memory performance in patients with Alzheimer's disease, mild cognitive impairment, 3). Examining the contribution of "normal appearing" white matter integrity to perceptual motor processing speed and executive working memory performance in patients with ischemic stroke. 4). Decomposing the influence of lesion pathology on cognitive function in patients with multiple sclerosis.

Andrew Winokur, M. D., Ph. D. (Temporary Non-Voting Member)

Dr. Winokur received his M.D. from Tufts University School of Medicine and his Ph.D. in Pharmacology from the University of Pennsylvania. He did an internship in Medicine at the Boston Veterans Administration Hospital, and his residency training in Psychiatry at the University of Pennsylvania School of Medicine. Dr. Winokur was a faculty member in the Department of Psychiatry at the University of Pennsylvania for 20, and he has held the position of Professor of Psychiatry at the University of Connecticut Health Center since 1998, where he serves as Director of Psychopharmacology. Dr. Winokur also holds the Manfred J. Sakel Distinguished Chair in Psychiatry at the University of Connecticut Health Center. Dr. Winokur has been involved in basic and clinical research in the area of psychopharmacology throughout his academic career. He has published over 100 original scientific articles and 40 book chapters on selected topics related to psychopharmacology. He has served on several study sections for NIH and for the VA Behavioral Sciences Division, and was a member of the Advisory Committee for the Psychopharmacological Drugs Division of the FDA from 200-2003. Since that time, Dr. Winokur has served as a Special Government Employee and has participated in several Advisory Committee meetings as a consultant to the FDA.

David H. Mueller, M. S. (Industry Representative)

David H. Mueller, M. S. is the Industry Representative to the FDA Neurological Devices Advisory Panel. Mr. Mueller has 25 years of medical device industry experience including 3M, Medtronic and St. Jude Medical. He is currently the owner and principal of Mueller and Associates Consulting, providing clients with regulatory affairs, clinical, quality and toxicology/ biocompatibility expert advice. Mr. Mueller has extensive experience in Class I, II and III neurological and cardiovascular devices as well as international biocompatibility and clinical standards and bovine spongiform encephalitis (BSE). Mr. Mueller also teaches medical device regulatory affairs class at Anoka-Ramsey (MN) College and St Cloud State University (MN).

Ms. Michelle Carras (Patient Representative)

Michelle Colder Carras is a graduate student in public health and a freelance writer. She has lived with a diagnosis of bipolar disorder for decades, and hopes to focus her future career on comparative effectiveness research in psychiatry, defining recovery from mental illness, and ensuring that people who use mental health services have access to complete and accurate information about treatments. She began her service as a mental health advocate in New York in the mid 1990's by helping to found the first New York chapter of the Federation of Families for Children's Mental Health, and has worked with NAMI, the National Alliance on Mental Illness, providing recovery education since 2006. She has also worked as a medical library reference specialist and is a peer reviewer for the Cochrane Consumers and Communication Group. In 2010 she received the Individual Leadership Award from the Howard County Commission on Disability Issues for her work in the community. She holds a BA in Psychology from Johns Hopkins University.

E. Francine Stokes McElveen, J. D., M. S. (Consumer Representative)

Ms. Stokes McElveen serves as the Senior Advisor to the President for Legal Affairs at Coppin State University, a constituent institution of the University System of Maryland. She provides legal advice and counsel to executive officers, directors and other senior academic and administrative leaders regarding a broad range of laws, regulations, risk and policies that impact the institution. Prior to coming to Coppin State University, Ms. Stokes McElveen served as an assistant to the President of Morgan State University for government and state relations. She is also a former assistant State's Attorney for Baltimore City.

Olga I. Claudio, Ph. D. (Designated Federal Officer)

Dr. Claudio obtained a B.S in General Sciences and a Ph. D. in Pharmacology and Toxicology from the University of Puerto Rico. She performed her post doctoral work on electrophysiology at the Albert Einstein College of Medicine Neurology Department. She has five years experience in regulated industry environment (Amgen Manufacturing Limited and Abbott Laboratories Inc. Diagnostics Division) and before joining the FDA, she was Director and Assistant Professor of the Biochemistry and Pharmacology Department, San Juan Bautista School of Medicine, Caguas, Puerto Rico.