ISCTM 7th Annual Scientific Meeting

21 - 23 February 2011
The Fairmont ~ Washington DC

PRESENTERS

Larry Alphs, MD, PhD

Therapeutic Leader, Psychiatry, Johnson and Johnson North America

Larry Alphs received his M.D. and Ph.D. from the University of Chicago Pritzker School of Medicine with a doctorate in neuropharmacology. In addition, he completed 2 years as a PRAT fellow at NIH and a residency in psychiatry at the University of Chicago Hospitals and Clinics. He worked for 10 years in academia as a researcher/clinician specializing in clinical research with persons with serious psychiatric disorders. His interests focused on nosology and treatment of schizophrenia and drug-induced movement disorders. For the past 15 years he has worked as a clinical scientist in the pharmaceutical industry where he as done Phase I-IV work in a variety of CNS disorders, including schizophrenia, bipolar disorder, suicidality, anxiety, depression, epilepsy, neuropathic pain, and traumatic brain injury. He currently is Therapeutic Leader, Psychiatry for Ortho-McNeil Janssen in Titusville, NJ and serves as the President for the International Society for CNS Clinical Trials and Methodology.

Ravi Anand, MD

Chief Executive Officer, Anand Pharma Consulting

Training
- University of Medical Sciences, Delhi

Current Areas of Research
- Clinical trial design
- Anti-psychotics
- Anti-depressants and anti-dementia drugs
- Drugs for neurological indications
- Global drug development
- Regulatory interactions
- Statistical issues

Anirban Basu, PhD

Associate Professor, Departments of Health Services and Pharmacy, University of Washington, Seattle
Faculty Research Fellow, National Bureau of Economic Research

Dr. Basu's research interests lie in revealing heterogeneity in clinical and economic outcomes in order to establish the value of individualized care. His work has focused on translating such information for public policy using innovative methods in comparative effectiveness and cost-effectiveness research. Dr. Basu has developed methods dealing with issues related to modeling health expenditure data, which is renowned for its idiosyncrasies and the difficulties it poses for applied health services researchers. He has also worked on methods used for making causal inferences using observational data. His applied work spans many dimensions that include analyzing the cost-effectiveness of prostate cancer treatments, establishing the value of individualized care based on patient preferences, developing models to predict quality of life of patients with multiple comorbidities, measuring the effect of patients' health on the quality of life of their partners, developing novel methods to estimate long-term costs of prostate cancer therapies, estimating the future value of research in diagnosing and finding a cure for Duchenne muscular dystrophy, developing simulation models for evaluating the cost-effectiveness of pharmacological treatment algorithms in schizophrenia, and comparative effectiveness research on the dynamic intensification of glucose lowering therapies in diabetes.

Dr. Basu is an Associate Editor for both Health Economics and the Journal of Health Economics and have taught courses on decision analysis, cost-effectiveness analysis and health services research methods. He has received numerous recognitions for his work throughout his career and for which he remains grateful to his mentors and peers: the NARSAD Wodecroft Young Investigator Award (2005), the Research Excellence Award for Methodological Excellence (2007) and the Bernie O'Brien New Investigator Award (2009) from the International Society for Pharmacoeconomics and Outcomes Research, the Alan Williams Health Economics Fellowship (2008) from the University of York, UK and the Labelle Lectureship in Health Economics (2009) from McMaster University, Canada.

Charles Bowden, PhD

Nancy U. Karren Clinical Professor, Department of Psychiatry and Professor, Department of Pharmacology, University of Texas Health Science Center at San Antonio

Dr. Bowden attended The University of Texas at Austin and earned his medical degree from Baylor College of Medicine in Houston, Texas. He completed his training in psychiatry at the New York State Psychiatric Institute and Columbia-Presbyterian Hospital in New York, New York.

Dr. Bowden was awarded the 2001 Gerald L. Klerman Senior Investigator Award by the Depression and Bipolar Support Alliance and received the 2006 Mind of America Scientific Research Award from the National Alliance for the Mentally Ill. Dr. Bowden is a Fellow of the American College of Neuropsychopharmacology and the Collegium Internationale Neuro-Psychopharmacologicum, a Corresponding

Member of the European College of Neuropsychopharmacology and a member of the Executive Committee of the International Society for CNS Clinical Trials and Methodology. He is Associate Editor for *Acta Psychiatrica Scandinavica* and a member of the editorial boards of *Bipolar Disorders* and *Depression and Anxiety*, Dr. Bowden is a reviewer for several journals including *Archives of General Psychiatry*, *Biological Psychiatry*, and the *Journal of the American Medical Association*. He has authored more than 370 publications. His research is principally on the symptomatic and biological characterization of bipolar disorders and the effectiveness and pharmacodynamics of mood stabilizing drugs. He has been principal investigator for 80 studies funded by pharmaceutical companies, NIMH, and various foundations. Dr. Bowden frequently serves as consultant to pharmaceutical companies and governmental agencies and is named in *Best Doctors in the US* in the area of mood disorders.

Linda Brady, PhD

Director, Division of Neuroscience and Basic Behavioral Science, National Institute of Mental Health, Bethesda

Dr. Linda Brady serves as the Director of the Division of Neuroscience and Basic Behavioral Science at the National Institute of Mental Health (NIMH). She has administered programs in the areas of neuropharmacology, drug discovery, and clinical therapeutics and served as a coordinator for the discovery and preclinical development of novel imaging agents and pharmacologic ligands as research tools for use in pathophysiological studies and in drug development. Dr. Brady has organized Consortia focused on ways to accelerate the development and clinical application of low mass, high specificity radiotracers in clinical research and drug development. She has spearheaded many programs, including: Development and Application of PET and SPECT Ligands for Brain Imaging Studies, National Cooperative Drug Discovery Groups for the Treatment of Mental Disorders, Drug or Alcohol Addiction, and has been actively involved in the MATRICS (Measurement and Treatment Research to Improve Cognition in Schizophrenia), and TURNS (Treatment Units for Research on Neurocognition in Schizophrenia) programs. Dr. Brady serves as co-lead for the Molecular Libraries Program, a trans-NIH roadmap initiative to provide biomedical researchers access to small organic molecules that can be used as chemical probes to study the functions of genes, cells, and biochemical pathways. In addition, she serves as a member of the Neuroscience Steering Committee for the Biomarkers Consortium, public-private research partnership of the Foundation for the National Institutes of Health (FNIH) that focuses on discovery, development, and qualification of biological markers to support new drug development, preventive medicine, and medical diagnostics and as a member of the Institute of Medicine Forum on Drug Discovery, Development, and Translation. Dr. Brady has received NIH Director's Awards and NIH Merit Awards in recognition of her activities in biomarker development, drug development for mental disorders, and the molecular libraries program.

Karl Broich, MD

Deputy Head of Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte)

Dr. Broich is professionally trained and board certified in Neurology, Psychiatry and Behavioral Psychotherapy. He completed a research fellowship at the Department of Nuclear Medicine at Hospital of the University of Pennsylvania. Dr. Broich was Vice Head in the Department of Psychiatry and Psychotherapy at the Hospital of the Martin Luther University in Halle Wittenberg. Dr. Broich held the position of Head of the Section Neurology Psychiatry at the Federal Institute for Drugs and Medical Devices (BfArM) in Germany, and since 2005 has operated as department head for that group. He is also the German alternate member of the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMEA).

Dr. Broich is currently engaged in research in the areas of: Neuropharmacology, Neurodegenerative Disorders, Neuroimaging, Biomarkers in drug development, Clinical trial design.

Dr. Broich maintains membership in the following learned societies: German Society of Psychiatry; Psychotherapy and Neurosciences; German Society of Gerontopsychiatry; German Society of Biological Psychiatry; German Society of Neuropsychopharmacology; European College of Neuropsychopharmacology; International Psychogeriatric Association; American Society for Experimental Neurotherapeutics (ASENT); World Federation of Biological Psychiatry.

Dr. Broich is the author and co-author of more than 90 Publications (peer reviewed articles, reviews and book sections).

Adam Butler

Associate Vice President, Client Services, United Biosource Corporation

Mr. Butler works in United BioSource Corporation's Specialty Clinical Services group, which specializes in endpoint reliability services for clinical trials. Mr. Butler is responsible for all client activities at UBC, and is focused on development and support of new services for rater training and certification, ratings reliability and monitoring services, and computerized cognitive testing. Along with UBC's senior scientific staff, Mr. Butler supports all of UBC's research and publication efforts.

Mr. Butler has 7 years of experience working in the CNS pharmaceutical services industry. In his prior position as Associate Vice President, Creative Services, Mr. Butler led a group responsible for development of training materials for UBC's clinician and patient training and education programs. He led a team of clinicians, multimedia developers, producers, and filmmakers with experience in clinical and documentary video production. Under Mr. Butler's leadership, UBC has created thousands of hours of clinical training and education video, translated into more than 50 languages.

James Creeden, MD, PhD

Chief Medical Officer, Roche Diagnostics

Dr. Creeden is Chief Medical Officer for Roche Professional Diagnostics, the world's leading In-Vitro Diagnostics manufacturer with sales over CHF 5 billion. He holds a PhD in molecular toxicology from Rutgers University and an MD from Robert Wood Johnson Medical School.

Dr. Creeden joined Roche Pharmaceuticals in 2002 and worked in clinical development and the health economics of personalized healthcare before coming to Professional Diagnostics in 2007. His department is responsible for global clinical development strategy and execution. He lives in Switzerland with his wife and two boys.

Charles Curie

Principal and Founder, The Curie Group, LLC

THE CURIE GROUP, LLC, is a management and consulting firm specializing in working with leaders of the healthcare field, particularly the mental health services (MH) and substance use treatment and prevention (SU) arenas, to facilitate the transformation of services and to attain increasingly positive outcomes in the lives of people worldwide. Curie's professional experience spans 30 years in the mental health and substance use services fields. He was nominated by President George W. Bush and confirmed by the U.S. Senate from 2001 to 2006 to head the Substance Abuse and Mental Health Services Administration (SAMHSA). As SAMHSA Administrator, Curie led the $3.4 billion agency responsible for improving the accountability, capacity and effectiveness of the Nation's substance abuse prevention, addictions treatment and mental health services, including The President's New Freedom Commission on Mental Health, the Strategic Prevention Framework for substance use prevention, Access to Recovery, National Outcome Measures and work with post-conflict and war-torn countries MH and SU service systems, including Iraq and Afghanistan. From 1995 to 2001, Curie was appointed by Pennsylvania Governor Tom Ridge as Deputy Secretary for Mental Health and Substance Abuse Services and implemented a nationally recognized mental health and drug and alcohol Medicaid managed care program and a policy to reduce and ultimately eliminate the use of seclusion and restraint practices in the state hospital system which won the 2000 Innovations in American Government Award sponsored by Harvard University's John F. Kennedy School of Government, the Ford Foundation, and the Council on Excellence in Government. Currently, he serves on the Board of Directors of the Council on Social Work Education (CSWE) and the American Foundation of Suicide Prevention (AFSP).

David Daniel, MD

Senior Vice President, Chief Medical Officer, United BioSource Corporation

David G. Daniel, M.D. is Senior Vice President, Chief Medical Director and Practice Leader, United BioSource Corporation and Clinical Professor of Psychiatry and Behavioral Sciences, George Washington University. He was the founder of Bioniche Development Inc. and Global Learning, LLC and a founder and former principal of Best Practice, LLC. He served as Director of Clinical Trials for the Stanley Medical Research Institute. Dr. Daniel has received patent protection in the United States for processes for treatment of epilepsy, panic disorder and acute dystonic reactions.

Dr. Daniel graduated Phi Beta Kappa and Magna Cum Laude from Emory University. He received his medical education and residency training at Vanderbilt University where he served as Chief Resident and received the Marc Hollender Award. He was a senior staff fellow within the intramural program of the NIMH and served as Medical Director of the NIMH Neuroscience Center at Saint Elisabeths where he supervised all clinical research.

Rob Epstein, MD, MS

President, Advanced Clinical Science & Research and Chief Clinical Research & Development Officer, Medco Health Solutions, Inc.

As Medco's President of Advanced Clinical Science and Research, and Chief Clinical Research and Development officer, Dr. Robert Epstein is responsible for all of Medco's clinical research initiatives, including the Medco Research Institute™ and the United BioSource Research Divisions. In this role, Dr. Epstein oversees an extended research team that works to advance Medco's clinically ground-breaking and market-differentiating outcomes research initiatives. Additionally, Dr. Epstein is responsible for new and emerging clinical areas, including Personalized Medicine.

Prior to this role, Dr. Epstein was Medco's Chief Medical Officer for 13 years, where he oversaw formulary development, clinical guidelines, drug information services, accreditation oversight, personalized medicine services, and client analysis and reporting. In addition, Dr. Epstein was appointed President of the Medco Research Institute in 2009, where he led Medco's peer-reviewed research initiatives and collaborations in the areas of personalized medicine, comparative effectiveness and chronic conditions.

Dr. Epstein is a trained epidemiologist, and worked in public health and academia before joining the private sector. He is past elected President of the International Society of Pharmacoeconomics and Outcomes Research (ISPOR), and has served on the Board of Directors for the Drug Information Association. In 2008, Dr Epstein was nominated and elected to the Federal CDC EGAPP (Evaluation of Genomic Applications in Practice & Prevention) Stakeholder Committee, and the AHRQ CERT (Centers for Education and Research on Therapeutics) Committee. He has published more than 50 peer-reviewed medical articles and book chapters, and serves as a reviewer for several influential medical journals.

Larry Ereshefsky, PharmD, BCPP

Chief Scientific Expert, Paraxel International

Dr. Larry Ereshefsky provides specialist consulting services to clients for early and later phase drug development in the areas of neuropsychopharmacology and psychiatry. He is recognized as a leader in study design and research methodologies for CNS protocols, with experience serving on FDA and USP Advisory Boards/Special Panels.

Prior to his current role as Chief Scientific Officer and Principal Investigator at California Clinical Trials, Dr. Ereshefsky worked for over twenty-six years at the University of Texas Health Science Centre (UTHSCSA) as Professor of Psychiatry and Pharmacology, and held the Regent's Chair in Psychopharmacology from the University of Texas at Austin (UTA). He helped to create the first State-funded Psychiatric Clinical Research Unit at the San Antonio State Hospital, where he was a clinical pharmacologist and Associate Director for Research. He was credentialed as a Clinical Pharmacy Specialist and PI at a number of institutions including the GCRC-NIMH unit at the Audie Murphy Veterans Administration Hospital. He Co-Directed the Advanced Psychopharmacology Evaluation and Pharmacogenetics Laboratory at the McDermott Clinical Science Building, UTHSCSA. He was Chairman, Post-doctoral Training Committee for the University of Texas' programs in Austin, El Paso, San Antonio, Temple, and Waco. He also held many Clinical Consultant positions during this time, including service on the Medical Executive Committee for the Center for Healthcare Services, Bexar County, Mental Health Authority.

Dr. Ereshefsky has experience spanning more than 30 years as a Principal Investigator for Phase I-IV and psychopharmacological evaluations of medications for the treatment of Schizophrenia, Bipolar, Anxiety, Sleep, and Major Depressive disorders, Alzheimer's Disease, ADHD, and Migraine. He has a proven track record to exceed expectations in performing studies in the target patient population where PK/PD (SAD, MAD, MTD) studies incorporate bio- and surrogate markers, and neuropsychiatric/cognitive evaluations. He provides translational CNS research expertise having conducted numerous experimental and proof of principle studies integrating continuous cerebral spinal fluid sampling, novel clinical assessment methodologies (QEEG, PSG), and analyte/pharmacogenetic and genomic targets. He also has extensive experience conducting ethnic sensitivity, bioequivalence, and drug interaction studies. He started his research career while an undergraduate at UCLA investigating the kinetics of organic cobalt complexes funded by the Atomic Energy Commission and was a pioneering researcher with clozapine, lithium, and depot antipsychotic therapies in the late 1970s-early 1980's. He has investigated almost every atypical antipsychotic and antidepressant candidate over his career. A portion of his work and program were supported by the NIMH, having participated in many grants over his academic career in pre-clinical, clinical, and psychosocial research.

Dr. Ereshefsky received his Pharm.D., and advanced practice residency in psychiatric pharmacy from the University of Southern California - LA County Medical Center (1977). He is BOARD CERTIFIED in Psychiatric Pharmacy (BCPP) by examination, December 1997 and 2005 (recertified). He has received numerous honours and awards, including: elected to the Executive Board of The International Society for CNS Clinical Trials and Methodology, 2006 – present; NIMH and NIAAA ad hoc Study Panel participation, 2002 – present; and Elected Presidential Officer, College of Psychiatric and Neurological Pharmacists, 2003-2006. He is a member of numerous professional bodies, including the American Association of Pharmaceutical Scientists (AAPS); the Collegium Internationale Neuro-Psychopharmacologicum (CINP), the American Society for Clinical Pharmacology and Therapeutics (ASCPT), the Drug Information Association (DIA), The American Association for the Advancement of Sciences (AAAS) and the American Society of Health-System Pharmacists (ASHP). He continues to serve on International psychiatry and neuropsychopharmacology advisory boards, and over the years has been a consultant for almost every major Pharma company.

Dr. Ereshefsky has been involved in under graduate and post graduate teaching for many years, including Director for one of the first accredited Post-graduate Residency Training Programs in Psychiatric Pharmacy Practice (since 1981) and the developer/graduate advisor of the Clinical Sciences Research program at the UTA/UTHSCSA. He also served as an attending on both clinical and research services for the Department of Psychiatry's residency training program at UTHSCSA.

He is frequently an invited presenter at International meetings, including:

- June 2008: Chair and presenter, "Strategies to Accelerate Drug Development For Schizophrenia", First Schizophrenia International Research Society Conference, Venice, Italy, June 2008.
- September 2007: Co-Chair and Presenter, "Global Clinical Trials: Opportunities and Challenges", and presenter "What is Causing the Reduced Drug-Placebo Difference in Our Recent Schizophrenia Trials and What Can We Do About It?", The 2007 Midyear Conference of ISCTM, Brussels, Belgium, September 2007.
- June 2007: "The Role of Biomarkers, Use of CSF Sampling, and Patient Phase IB Studies to Increase the Success Rate for CNS Drug Development", New Clinical Drug Evaluation Unit (NCDEU), symposium chair. Boca Raton, FL.
- April 2007: Keynote address: "New Possibilities in Understanding Antipsychotic Mechanisms of Action", College of Psyciatric and Neurologic Pharmacists (CPNP) 10th Annual Meeting, , Colorado Springs, Colorado

Dr. Ereshefsky has published more than 100 peer reviewed scholarly articles, and has held many editorial journal responsibilities over the years and serves as a journal referee for almost every major psychiatry, pharmacologic, and psychiatric pharmacy publications.

Douglas Feltner, MD

President, Douglas E Feltner, LLC, Biopharma Consulting
Adjunct Assistant Clinical Professor, Department of Psychiatry, University of Michigan

Dr. Doug Feltner is a graduate of the University of Michigan Medical School. He did his residency in Psychiatry at George Washington University and the National Institute of Mental Health, and then did a fellowship sponsored by the Howard Hughes Medical Institute in molecular genetics at the National Institute of Child Health and Human Development. He joined the pharmaceutical industry in 1997.

Dr. Feltner joined Pfizer (Warner-Lambert) in 1998 to work on phase 2 and 3 of the Lyrica® program. From 2001 to 2005 he led the Experimental Medicine group for neuroscience at the Ann Arbor site. This group contributed to moving three drugs past proof-of-concept, one for generalized anxiety disorder, one for insomnia, and one for peri-menopausal vasomotor symptoms. Since 2006, Dr. Feltner has served in several roles in the Pfizer Neuroscience group, including the disease area lead for depression/anxiety, the clinical lead for varenicline (Chantix®), the interim therapy area clinical lead for neuroscience, and the clinical lead for PD332334 for generalized anxiety disorder. Dr. Feltner is currently the Global Head of Translational Medicine for Pfizer and the Translational Medicine Lead for Neuroscience. He is a member of Pfizer's neuropsychiatric adverse event safety advisory council and co-chairs its suicidality workgroup. His primary scientific interest is in developing new treatments for patients with mental disorders.

Reuven Ferziger, MD

Scientific Affairs, J&J North American Pharmaceuticals

Reuven Ferziger is the Washington, DC, Scientific Liaison for CNS Medical Affairs at Johnson & Johnson. Before coming to Johnson & Johnson, Dr. Ferziger was the physician leader of behavioral health disease management for CareGroup, a network of academic medical centers and community hospitals in the Boston, Massachusetts region, and a member of the Department of Psychiatry at Beth Israel Deaconess Medical Center and Harvard Medical School. He received his undergraduate degree from Brown University and his medical degree from Albany Medical College in New York. He completed residency training in psychiatry at the New York Hospital-Cornell Payne Whitney Clinic and fellowships in psychopharmacology, at the Harvard Medical School Clinical Research Training Program, and in Medical Informatics, at the HMS Center for Clinical Computing.

Baruch Fischhoff, PhD

Professor, Departments of Social and Decision Sciences and Engineering and Public Policy, Carnegie Mellon University

Baruch Fischhoff, Ph.D., is the Howard Heinz University Professor in the departments of Social and Decision Sciences and of Engineering and Public Policy at Carnegie Mellon University, where he heads the Decision Sciences major. A graduate of the Detroit Public Schools, he holds a BS in mathematics and psychology from Wayne State University and an MA and PhD in psychology from the Hebrew University of Jerusalem. He is a member of the Institute of Medicine of the National Academy of Sciences and currently chairs the National Research Council Committee on Behavioral and Social Science Research to Improve Intelligence Analysis for National Security. He also chairs the Food and Drug Administration Risk Communication Advisory Committee. He is a member of the Department of Homeland Security's Science and Technology Advisory Committee, the World Federation of Scientists Permanent Monitoring Panel on Terrorism, and the Department of State Global Expertise Program. He is past President of the Society for Judgment and Decision Making and of the Society for Risk Analysis, and recipient of its Distinguished Achievement Award. He was a member of the Eugene, Oregon Commission on the Rights of Women and the Environmental Protection Agency Science Advisory Board, where he chaired the Homeland Security Advisory Committee. He is a Fellow of the American Psychological Association, the Association for Psychological Science (previously the American Psychological Society), and the Society for Risk Analysis. He has co-authored or edited four books, Acceptable Risk (1981), A Two-State Solution in the Middle East: Prospects and Possibilities (1993), Elicitation of Preferences (2000), and Risk Communication: A Mental Models Approach (2002).

George Grossberg, MD

Samuel W. Fordyce Professor and Director of Geriatric Psychiatry, Saint Louis University School of Medicine

Dr. Grossberg earned his medical degree at SLU and completed an internship at St. John's Mercy Medical Center in St. Louis. Dr. Grossberg completed a residency, subsequently becoming chief resident, in the Department of Psychiatry also at SLU.

Dr. Grossberg is Past President of the American Association for Geriatric Psychiatry and the International Psychogeriatric Association. As well, he is a distinguished fellow in the American Psychiatric Association.

Dr. Grossberg has authored or coauthored more than 400 scientific meeting abstracts, book chapters, and journal articles and edited eight textbooks. His articles have been published in peer-reviewed journals such as Dementia and Geriatric Cognitive Disorders, Neurology, the American Journal of Geriatric Psychiatry, the Journal of the American Medical Association, the Journal of Clinical Pharmacology, and Medical Clinics of North America. Dr Grossberg is on the editorial boards of the Journal of the American Medical Directors Association and Dementia Today, and is section editor (Geriatric Psychiatry) for Current Psychiatry.

Dr. Grossberg has participated in numerous clinical trials investigating mild, moderate, and severe dementia of Alzheimer's type with additional research interest in the treatment of major depressive disorder in the geriatric population.

Dr. Grossberg has received many honors and awards including being the first recipient of the Robert Lerner, MD, Memorial Award for National Contributions to the Field of Geriatrics from the University of Wisconsin; receiving the George Dyck Endowed Lectureship in Geropsychiatry by the University of Kansas School of Medicine; and the Fleischman-Hilliard Award for contributions to Geriatrics from the Jewish Center for Aging in St Louis. He has been listed as one of the Best Doctors in America since its inception, America's Top Docs since inception, and was named one of America's Top 327 Mental Health Experts by Good Housekeeping Magazine.

Dr. Grossberg's work relative to Alzheimer's disease has been featured in national publications including People magazine, USA Today, the Wall Street Journal and the New York Times. He has appeared on CNN, Lifetime Television, Web-MD, and hosts the internet medical education program: Alzheimer's Answers.

Harald Hampel, MSc

Director and Head, Dept. Psychiatry, Psychosomatics and Psychotherapy, Johann Wolfgang Universität

Dr. Hampel obtained his MD at the University of Munich. He also holds an MSc in hospital management from Cologne University and an MA from Trinity College, University of Dublin. After training at the University of Munich, he moved to Washington D.C. in 1995 for a post-doc fellowship at the NIH/NIA Laboratory of Neurosciences in Bethesda on structural & functional neuroimaging of the Alzheimer brain. In 1997 he became director of the Alzheimer Memorial Center at the University of Munich where he was appointed as Professor of Psychiatry in 2005. In 2006 he moved to Dublin and was appointed as Professor and Chair of Psychiatry at Trinity College, University of Dublin. In 2010 he was appointed as Chair and Head of Department of Psychiatry, Psychosomatic Medicine & Psychotherapy and Co-Director of the Brain Imaging Center (BIC) at the University of Frankfurt, Germany. Dr. Hampel has published more than 200 peer-reviewed original research papers, 150 review articles and is editor of 6 books. He won the Bernhard-von-Gudden Award, The German Brain Foundation Research Award, the Alois Alzheimer Award, the Kraepelin-Alzheimer-Medal and the Katharina Hardt-Foundation Research Award. Recently he was elected as Professorial Fellow of Trinity College, University of Dublin. He holds several national, European & international research grants and is PI of international research consortia. His research focuses on brain health & disease, cognition, neuronal coordination and networks, neurophysiology and neuroimaging of the brain (MRI, DTI, fMRI, EEG, MEG, PET), multi-modal biomarker & therapy development in Alzheimer disease. He served as an academic expert at various dementia & Alzheimer's disease meetings of the European Medicines Agency (EMA), London, UK.

Recent key publications

Out of > 200 peer-reviewed original articles, 175 invited reviews and bookchapters, 6 books (Editor), >500 conference proceedings:

1. Hampel H, Wilcock G, Andrieu S, Aisen P, Blennow K, Broich K, Carrillo M, Fox NC, Frisoni GB, Lovestone S, Nordberg A, Prvulovic D, Sampaio C, Scheltens P, Weiner M, Winblad B, Coley N, Vellas B (2010) Biomarkers for Alzheimer's disease therapeutic trials. Progress in Neurobiology, accepted

2. Ewers M, Sperling RA, Klunk WE, Weiner MW, Hampel H. Neuroimaging Biomarkers of Cognitive Decline in Preclinical and Prodromal Alzheimer's Disease (2010) Trends in Neuroscience, accepted

3. Hampel H, Frank R, Broich K, Teipel SJ, Bokde ALW, Herholz K, Hardy J, Hoessler Y, Jessen F, Katz RG, Woodcock J, Zetterberg H, Blennow K (2010) Biomarkers for diagnosis and as endpoints for clinical trials in Alzheimer's disease. Nature Reviews Drug Discovery, Jul;9(7):560-74.

4. Blennow K, Hampel H, Weiner M, Zetterberg H. (2010) Cerebrospinal fluid and plasma biomarkers in Alzheimer's disease. Nature Reviews Neurology, 6(3):131-44. Epub 2010 Feb 16.

5. Buschert M, Bokde A, Hampel H (2010) Cognitive Intervention in Alzheimer's Disease. Nature Reviews Neurology, Sep;6(9):508-17. Epub 2010 Aug 17.

6. Harold D, ..., Hampel H, et al. (2009) Genome-wide association study identifies variants at CLU and PICALM associated with Alzheimer's disease. Nature Genetics, 41(10):1088-93.

7. Mattsson N, ..., Hampel H, Scheltens P, Pirttilä T, Wallin A, Eriksdotter Jönhagen M, Minthon L, Winblad B, Blennow K (2009) CSF biomarkers and incipient Alzheimer disease in patients with mild cognitive impairment. JAMA, 302(4):385-93.

8. Bokde ALW, Ewers M, Hampel H (2009) Assessing neuronal networks: understanding Alzheimer's disease. Progress in Neurobiology, 89(2):125-33.

9. Hampel H, ..., Basun H (2009) Lithium trial in Alzheimer's disease: a randomized, single-blinded, placebo-controlled multicentre 10-week study. Journal of Clinical Psychiatry.

10. Visser PJ, ..., Hampel H, Buerger K, Pirttila T, Soininen H, Olde Rikkert M, Verbeek M, Spiru L, Blennow K (2009) Prevalence and prognostic value of CSF markers of Alzheimer's disease pathology in patients with subjective cognitive impairment or mild cognitive impairment in the DESCRIPA study: a prospective cohort study. Lancet Neurology, 8(7):619-27.

Virginia Haynes, PhD

Director of Medical and Scientific Affairs, i3 Global

Dr. Haynes received her PhD and master's degree in statistics and master's degree in mathematics from Baylor University. She has over twelve years of clinical research experience in the pharmaceutical industry, primarily with Eli Lilly and Company (Lilly).

During her nine years at Lilly, Dr. Haynes collaborated on several successful FDA submissions for Zyprexa, two in schizophrenia, and was a research partner in bipolar disorder, Alzheimer's disease, and Parkinson's disease. She also gained extensive experience designing positive phase IIIB and IV clinical trials in ADHD and data mining efforts that fueled Strattera's launch, the most successful in neuroscience pharmaceutical history at that time. She was recognized for technical, therapeutic, and administrative leadership, concurrently serving as a scientific reviewer for the U.S. CNS protocol review committee and publications efforts and lead statistician and group leader for the U.S. Zyprexa statistics team in the latter part of her tenure.

Dr. Haynes continues to actively publish and present at international meetings as part of her role within the i3 medical and scientific affairs team. She serves in the International Society for CNS Clinical Trial Methodology as a member of the scientific and publication committees and chairs the adaptive design working group. As scientific advisor for psychiatry and neurology, Dr. Haynes provides critical therapeutic and scientific guidance in the design and operation of clinical trials. She is also a strategic statistical and scientific consultant for internal i3 scientists, external sponsors, and key opinion leaders.

Dr. Haynes's special areas of interest include ADHD, bipolar disorder, MDD, placebo response, and schizophrenia.

David Henley, MD

Senior Medical Advisor, Alzheimer's Disease Team, Eli Lilly and Company

David Henley, M.D. is Senior Medical Advisor of the Alzheimer's Disease Team at Eli Lilly and a volunteer Clinical Associate Professor of Psychiatry at Indiana University (IU) School of Medicine. He completed a medical degree from IU School of Medicine and a psychiatry residency at IU Department of Psychiatry. Before joining Lilly, Dr. Henley provided general adult/geriatric psychiatric inpatient, nursing home and outpatient care at a community mental health center. At Lilly, he worked in pharmacovigilance and represented Lilly in a Council for International Organizations of Medical Sciences (CIOMS) and Medical Dictionary for Regulatory Activities (MedDRA) working group developing Standardized MedDRA Queries (SMQs). As Senior Medical Advisor for the Alzheimer's Disease Team, he has led the protocol development and implementation of semagacestat phase 3 (IDENTITY) studies and has published a review article on the development of semagacestat.

Thomas Insel, MD

Director, National Institute for Mental Health

Thomas R. Insel, M.D. directs the component of the National Institutes of Health charged with generating the knowledge needed to understand, treat, and prevent mental disorders. His tenure at NIMH has been distinguished by groundbreaking findings in the areas of practical clinical trials, autism research, and the role of genetics in mental illnesses.

Prior to his appointment as NIMH Director in the Fall 2002, Dr. Insel was Professor of Psychiatry at Emory University. There, he was founding director of the Center for Behavioral Neuroscience, one of the largest science and technology centers funded by the National Science Foundation and, concurrently, director of an NIH-funded Center for Autism Research. From 1994 to 1999, he was Director of the Yerkes Regional Primate Research Center in Atlanta. While at Emory, Dr. Insel continued the line of research he had initiated at NIMH studying the neurobiology of complex social behaviors. He has published over 250 scientific articles and four books, including the Neurobiology of Parental Care (with Michael Numan) in 2003.

Dr. Insel has served on numerous academic, scientific, and professional committees and boards. He is a member of the Institute of Medicine, a fellow of the American College of Neuropsychopharmacology, and is a recipient of several awards including the Outstanding Service Award from the U.S. Public Health Service. Dr. Insel graduated from the combined B.A.-M.D. program at Boston University in 1974. He did his internship at Berkshire Medical Center, Pittsfield, Massachusetts, and his residency at the Langley Porter Neuropsychiatric Institute at the University of California, San Francisco.

Amir Kalali, M.D.

Vice President, Medical and Scientific Services, and Global Therapeutic Team Leader CNS, Quintiles Inc.

Dr. Kalali is currently focusing on developing novel compounds for the treatment of disorders of the central nervous system. He is globally responsible for development programs in psychiatry and neurology. He is also Professor of Psychiatry at University of California San Diego

Dr. Kalali is a member of the Executive Committee, and Chair of the Publication Committee of the International Society for CNS Clinical Trials and Methodology (ISCTM), as well as a member of the Scientific Committee. He was the Founding Chairman of the Executive Committee of the International Society for CNS Drug Development (ISCDD), and currently the Executive Secretary. In these roles he is active in facilitating scientific collaboration between academia, government, and pharmaceutical industry scientists.

Dr. Kalali has been an academic investigator in over 70 psychopharmacological clinical trials and at Quintiles has had medical and scientific responsibility for over 300 clinical trials.

He is an expert in CNS clinical trial methodology, including clinical rating scales, and has trained investigators from over forty countries.

Dr. Kalali is the Editor of the journal Psychiatry, and is on the editorial board of several other journals. He has published widely in journals such as the Archives of General Psychiatry, The American Journal of Psychiatry, and the British Journal of Psychiatry.

Dr. Kalali regularly presents at national and international scientific meetings, and lectures frequently on psychopharmacological and drug development topics. He is particularly interested in educating clinicians worldwide, and is facilitating this currently by being the Chairman of the Educational Committee of the Collegium Internationale Neuro-Psychopharmacologicum (CINP).

Dr. Kalali is an active member of many professional societies including the American College of Neuropsychopharmacology, the American Society for Clinical Psychopharmacology, the American Psychiatric Association, the Canadian College of NeuroPsychopharmacology, the Collegium Internationale Neuro Psychopharmacologicum, the Drug Information Association, the International Society for CNS Drug Development, the International Society for CNS Clinical Trials and Methodology, the Royal College of Psychiatrists, United Kingdom, and the Society for Neuroscience.

Russell Katz, MD

Professor Director, Division of Neurology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Dr. Katz joined the FDA as a medical officer in 1983, where he is currently the Director of the Division of Neurology Products (previously called the Division of Neuropharmacological Drug Products). He has lectured extensively on the various aspects of neurologic drug development as well as written numerous articles on the same issues. He received his BA in mathematics from Queens College in New York City and his medical degree from Albert Einstein College of Medicine in New York City. He completed his residency in neurology in 1982 at the Einstein-affiliated hospitals in New York.

Frank LaFerla, PhD

Chancellor's Professor, Department of Neurobiology and Behavior, University of California, Irvine
Director, Institute for Memory Impairments and Neurological Disorders
Fellow, Center for the Neurobiology of Learning and Memory

Dr. LaFerla received his B.S. in Biology from St. Joseph's University in Philadelphia. His graduate training was completed at the University of Minnesota where he earned his Ph.D. in the field of virology in 1990. He subsequently was a postdoctoral fellow at the Holland Laboratory of the American Red Cross before moving to Irvine as an assistant professor in late 1995.

Dr. LaFerla has received several honors for his research accomplishments including the Ruth Salta Junior Investigator Achievement Award from the American Health Assistance Foundation, Zenith Fellows Award from the Alzheimer Association, UCI Chancellor's Fellow, Distinguished Mid-career Faculty Research Award, UCI Innovation Award and the Promising Work Award from the Metropolitan Life Foundation for Medical Research. He serves on the Scientific Advisory Board for the Orange County Alzheimer's Association and the Medical and Scientific Advisory Boards for Sonexa Therapeutics, Akeso Health Sciences, and Signum Biosciences. He is also the associate editor for Current Alzheimer Research and a member of the editorial board of the Neurobiology of Aging and Neurobiology of Disease.

Dr. LaFerla's research is focused on understanding the pathogenesis of Alzheimer disease, the most common form of dementia among the elderly. His laboratory has developed several transgenic mouse models of neurodegenerative disorders including the first transgenic mouse model of Alzheimer disease that recapitulates the two major neuropathological lesions, plaques and tangles. This mouse model, referred to as the 3xTg-AD mice, has been widely distributed to researchers throughout the USA and over 20 countries throughout the world. His laboratory has used this model to understand the relationship between plaques and tangles and how each affects the development of the other, and more significantly, this model has proven to be invaluable for the pre-clinical evaluation of novel therapeutic compounds.

His research group was also among the first to show that stem cell transplantation could be useful for the treatment of cognitive dysfunction. Findings from his lab show that stem cells promote repair not via a cell replacement mechanism but by performing a "nursing" function. Work in his lab shows that the transplanted neural stem cells produce high amounts of the neurotrophic factor, BDNF, which promotes synaptogenesis. Recently, the lab was awarded $3.6 million from CIRM as part of the Early Translation Grant Program to develop an Alzheimer's disease therapy involving human neural stem cells.

Thomas Laughren, MD

Division Director, Division of Psychiatry Products, Center for Drug Evaluation and Research, FDA

Dr. Laughren is currently Division Director for the Division of Psychiatry Products, Center for Drug Evaluation and Research at FDA. Prior to coming to FDA in September 1983, Dr. Laughren was affiliated with the VA Medical Center in Providence, RI, and was on the faculty of the Brown University Program in Medicine. He received his medical degree from the University of Wisconsin in Madison, Wisconsin, and he also completed residency training in psychiatry at the University of Wisconsin. Dr. Laughren is board certified in general psychiatry.

As Division Director for the Division of Psychiatry Products, Dr. Laughren oversees the review of all psychiatric drug development activities conducted under INDs and the review of all NDAs and supplements for new psychiatric drug claims. He has authored and co-authored many papers on regulatory and methodological issues pertaining to the development of psychiatric drugs, and is a frequent speaker at professional meetings on these same topics. Dr. Laughren has received numerous awards from FDA for his regulatory accomplishments.

Ramy Mahmoud, MD, MPH

Chief Operating Officer, Optinose US, Inc.

OptiNose is an entrepreneurial start up with offices in the US, UK, and Norway, which is developing a technology platform for improving the efficacy and safety of drugs through a novel form of nasal drug delivery. As Chief Operating Office, Doctor Mahmoud is responsible for directing all daily operations of the company, including planning and execution of corporate strategy, device technology development, manufacturing and supply chain, clinical research, finance, staffing and human resource system development.

Immediately prior to joining OptiNose, Doctor Mahmoud worked as a member of the Global Management Board at Ethicon, a multibillion dollar multinational Johnson & Johnson company. At Ethicon, Doctor Mahmoud served for 3 years as Chief Medical Officer and Worldwide Vice President of Evidence-Based Medicine, leading Pre-Clinical Research, Clinical Development, Medical Affairs, and Health Economics & Reimbursement.

Ramy is an accomplished public health physician and organizational leader, holding a Masters in Healthcare Management & Policy from the Harvard School of Public Health and an M.D. from the first Honors Program in Medical Education at the University of Miami. Doctor Mahmoud has been board certified in both Public Health/Preventive Medicine and in Internal Medicine. He spent over 20 years, including 10 years on active duty, as an officer in the United States Army. As a military officer, he served in diverse roles including battalion surgeon

and flight surgeon, earning the rank of Lieutenant Colonel and a number of commendations and decorations. His government service also included various academic, patient care, and research positions, culminating as head of the Department of Epidemiology at the Walter Reed Army Institute of Research and inaugural leader of a policy research and analysis activity in support of the Assistant Secretary of Defense (Health Affairs). Subsequent to his government service Doctor Mahmoud spent 14 years in the private sector, where he held successive U.S. and global leadership positions at Johnson & Johnson companies in R&D, Outcomes Research, and Medical Affairs. Ramy is an accomplished international scientist and researcher, having published more than 50 peer-reviewed papers and served in leadership roles in multiple professional organizations.

Ron Manderscheid, PhD

Director of Mental Health and Substance Use Programs, Global Health Sector, SRA International

Ronald W. Manderscheid, Ph.D., has served as the Director of Mental Health and Substance Use Programs at the Global Health Sector of SRA International since 2006. In this capacity, he is developing new demonstration and research projects around mental health and substance use services, programs, and systems, using a public health framework. Areas of focus include transformation of financing, human resources, evidence-based practices, information technology, statistical data, performance measures, and quality report cards. Consumer and family concerns pervade all of this work. Concurrently, he is Adjunct Professor at the Department of Mental Health, Bloomberg School of Public Health, Johns Hopkins University, and a Member of the Secretary of Health and Human Services Advisory Committee on Healthy People 2020. Dr. Manderscheid serves on the boards of the Employee Assistance Research Foundation, the American College of Mental Health Administration, the Danya Institute, and the Public Manager. Previously, Dr. Manderscheid served as Branch Chief, Survey and Analysis Branch, for the federal Center for Mental Health Services (CMHS), SAMHSA.

Dr. Manderscheid is currently on the Governing Council of the American Public Health Association (APHA), current President of the Federal Executive Institute Alumni Association (FEIAA) Foundation, Past President of FEIAA, and past Chair of the APHA Mental Health Section. He has also served as the Chairperson of the Sociological Practice Section of the American Sociological Association, and as President of the Washington Academy of Sciences and the District of Columbia Sociological Society.

During the Clinton National Health Care Reform debate, Dr. Manderscheid served as Senior Policy Advisor on National Health Care Reform in the Office of the Assistant Secretary for Health at the U.S. Department of Health and Human Services. At that time, Dr. Manderscheid was also a member of the Mental Health and Substance Abuse Work Group of the President's Task Force on Health Care Reform.

Dr. Manderscheid served as principal editor for eight editions of Mental Health, United States. He has also authored numerous scientific and professional publications on services to persons with mental illnesses. Each month, he prepares the Manderscheid Report for Behavioral Healthcare.

Dr. Manderscheid is the recipient of both federal and professional awards, including the 1995 National Sociological Practice Award; Substance Abuse and Mental Health Services Administration (SAMHSA) Administrator's Award for Meritorious Achievement, 1995; SAMHSA Administrator's Award for Meritorious Achievement (Group Award to Branch) 1995; 1st Annual Going to Bat Award, National Association for Rural Mental Health, 1996; Friends of Case Management Award, National Association of Case Management, 1996; Quality of Work Life SAMHSA Partnership Award, 1997; SAMHSA Outstanding Teamwork Award, 1997; Loras College Distinguished Alumni Award, 1998; Federal Executive Institute Alumni Association's Meritorious Service Award, 1999; HHS Secretary's Distinguished Service Award, 1999, 2004, 2005, 2006, and 2008; American Public Health Association's Mental Health Section Award, 2000; Mental Health Statistics Improvement Program's National Leadership Award, 2001; American Association for Psychosocial Rehabilitation's Irving T. Blumberg Humanitarian Award, 2002; American College of Mental Health Administration's Saul Feldman Lifetime Achievement Award, 2003, and Distinguished Service Award, 2006; National Association of State Mental Health Program Directors Career Distinguished Service Award, 2006; National Council of Community Behavioral Healthcare Distinguished Public Service Award, 2006; and 50th Anniversary Award, Southern Regional Conference on Mental Health Statistics, 2008.

Dr. Manderscheid worked in a variety of positions with the National Institute of Mental Health (NIMH). While there, he served as NIMH's Chief, Statistical Research Branch, where he provided strong leadership in implementing the National Reporting System (NRP) and the Mental Health Statistics Improvement Program (MHSIP).

Dr. Manderscheid received a B.A. degree (with highest honors) in Sociology from Loras College; a M.A. degree in Sociology-Anthropology from Marquette University; and a Ph.D. in Sociology, with a specialization in Social Psychology and Statistics from the University of Maryland. He is also a graduate of the Federal Executive Institute.

Stephen Marder, MD

Director, Department of Veterans Affairs, VISN 22 Mental Ilness Research, Education and Clinical Center Professor, Psychiatry, David Geffen School of Medicine, UCLA

Dr. Marder's research has focused on improving the long-term treatment of individuals with schizophrenia through pharmacological and psychosocial strategies. He was the Principal Investigator for the NIMH MATRICS initiative to improve neurocognition in schizophrenia as well as the leader of a trials network to study candidate drugs for enhancing cognition.

Dr. Marder has received the Exemplary Psychiatrist Award from the National Alliance for the Mentally Ill, the Stanley Dean Research Award of the American College of Psychiatry, the Alexander Gralnick Award for Schizophrenia Research from the American Psychiatric Association, and the APIRE/Kempf Fund Award for Research Development is Psychobiological Psychiatry He is listed in The Best Doctors in America and America's Top Doctors.

Laysha Ostrow, MD

NIMH Pre-doctoral Training Fellow, Johns Hopkins Bloomberg School of Public Health

Ms. Ostrow's research focuses on consumer-directed mental health care and the organization, financing, and service delivery of peer-run organizations. Ms. Ostrow was previously a Policy Analyst at Human Services Research Institute (HSRI) in Cambridge, Massachusetts, where she worked on projects related to recovery and resilience, systems change, and quality of mental health care.

Ms. Ostrow holds a Master of Public Policy (M.P.P.) from the Heller School for Social Policy and Management at Brandeis University, and a B.S. in Psychology from Lesley University. Ms. Ostrow's Master's capstone was a case study of a mental health consumer organization, and her undergraduate thesis looked at issues surrounding the experience of mental illness.

Ms. Ostrow provides consulting expertise and technical assistance to consumer groups on planning and implementing peer-run crisis respites—a consumer-operated alternative to psychiatric hospitalization. Ms. Ostrow has consulted for state, county, and federal governments and consumer groups on crisis alternatives, recovery measurement, and person-centered approaches to treatment.

Ms. Ostrow is the Project Director for a contract from the Substance Abuse and Mental Health Services Administration (SAMHSA) to write educational guides on person-centered planning in behavioral health treatment for consumers, providers, administrators, and families of youth. Ms. Ostrow is part of the evaluation of a peer-run crisis respite, funded by the SAMHSA Mental Health Transformation Grant program, in Santa Cruz County, CA. She is also currently working with the Temple University Collaborative on Community Inclusion of Individuals with Psychiatric Disabilities to survey and study the financing and costs of evidence-based practices, including peer support, in counties and states.

Ms. Ostrow is a mental health consumer in recovery, and a family member of a person with mental illness. These experiences help inform and guide her approaches to research, evaluation, and technical assistance.

Eva Petkova, PhD

Director of the Division of Biostatistics, NYU Child Study Center

Dr. Petkova's primary interest is the development and application of statistical methods for psychiatric research. Her technical expertise is in statistical modeling and design of clinical experiments, which includes regression methods for clustered longitudinal, categorical and survival data, finite mixture modeling, causal inference and models for missing data. Dr. Petkova also has extensive experience in designing, monitoring, and analyzing data from large single-site and multi-site psychiatric clinical trials in the areas of treatment and services research.

The nature of psychiatric disorders poses numerous statistical methodological challenges for design and analysis of studies. Dr. Petkova has been at the forefront of new methodological advances that seek to address these obstacles. Dr. Petkova has established a Division of Biostatistics at the Department of Child and Adolescent Psychiatry to provide statistical expertise to clinical researchers.

Dr Petkova is a recognized leader in the field of Biostatistical methods for mental health research. She is a one of the founders of the Annual Symposium on Statistics in Psychiatry, which is in its 11th year. She has been involved in the administration of the Biometrics section of the American Statistical Association and its annual Statistical Meetings jointly with the Institute of Mathematical Statistics, International Biometrics Society and the Statistical Association of Canada.

Dr. Petkova graduated with a degree in Mathematics from the Sofia University in Bulgaria in 1982, where she also obtained a Masters degree in Mathematics in 1984 and a Ph.D. in Physics in 1987. She then obtained a second Ph.D. in Statistics from Pennsylvania State University in 1992. She completed her Postdoctoral Fellowship in Biostatistics at Harvard University in 1994. Prior to joining the Department of Child and Adolescent Psychiatry and NYU, for twelve years she worked at the Departments of Biostatistics and Psychiatry at Columbia University, where she directed the Division of Biostatistics at the New York State Psychiatric Institute.

Steven Potkin, MD

Professor, University of California, Irvine

Dr. Potkin received his medical degree from Washington University in St. Louis. Trained as a psychiatrist at Duke University, Dr. Potkin spent nine years at the National Institute of Mental Health (NIMH) as a clinical research psychiatrist before coming to UCI in 1985. Dr. Potkin's career has been devoted to understanding the causes of, and development of new treatments for, schizophrenia, bipolar disorder, Alzheimer's disease, and other neuropsychiatric diseases.

Dr. Potkin is the author of more than 200 peer reviewed scientific articles and book chapters. He serves on several editorial boards and is a member of numerous neuropsychiatric organizations, including the Collegium Internationale Neuropsychoparmacologicum (CINP), the largest international neuropsychopharmacology organization, as well as the American College of Neuropsychopharmacology (ACNP), and is a Distinguished Fellow of the American Psychiatric Association (APA). From 1981 to 1983, he was the first US exchange scientist on the bilateral exchange of science and technology between the People's Republic of China and the United States.

Dr. Potkin is the recipient of numerous awards, including the A.E. Bennett Award from the Society of Biological Psychiatry for psychiatric research; the Michtell Balter Award; the Outstanding Psychiatrist Award from the California Alliance for the Mentally Ill; and the Riley Public Service Award from the Mental Health Association of Orange County, a rare distinction for a research psychiatrist. Dr. Potkin has twice been awarded the Exemplary Psychiatrist Award by the National Alliance for the Mentally Ill (NAMI), the most influential familybased organization advocating for the mentally ill, in recognition of the outstanding clinical care he has provided to individuals suffering from mental illness and, most specifically, to those with schizophrenia.

In addition to communicating to the general public, family members, and patients with schizophrenia, he has made many presentations to the California Legislature to educate legislators on mental illness and advocate for the needs of the mentally ill. Dr. Potkin played a key

role in passing legislation which allowed treatment-resistant patients to receive new treatments and provided funding for model integrated service programs, such as the Village. He has served on numerous Task Forces, including the Lieutenant Governors' Task Force on Mental Illness (California).

Dr. Potkin has approached decreasing stigma for those suffering from mental illness in a variety of ways. His brain imaging, biological and genetic studies provide evidence that schizophrenia and bipolar disorder are brain illnesses. Dr. Potkin directs two interdisciplinary research consortia. The Biomedical Imaging Research Network (BIRN) is a national consortium of computer scientists, physicist, cognitive scientist and physicians developing tools and the associated infrastructure needed for multi-site neuroimaging studies. He also directs the Transdisciplinary Imaging Genetics (TGIC) that develops new methods for combining imaging and genetic data to leverage the power of these disciplines as a gene discovery tool for neuropsychiatric illness.

Steven Romano, MD

Vice President of Medical Affairs, Pfizer Inc.

Steven has been in the pharmaceutical industry for nearly 15 years, and has been involved in clinical drug development phases 1 through 4. Recent positions held at Pfizer include Development Head, Neurosciences and Vice President, Global Medical, Neuroscience, Pain and Inflammation. He is a board certified psychiatrist and currently holds an academic appointment as Clinical Associate Professor of Psychiatry at the New York University Medical School in New York City. He serves on the scientific advisory boards or committees of a number of professional organizations, including The International Society for CNS Clinical Trials and Methodology (ISCTM).

After receiving his Bachelor of Arts degree at Washington University in St. Louis, Dr. Romano obtained his medical degree at the University of Missouri in Columbia, Missouri. He completed his internship, residency in psychiatry, and psychiatry fellowship at The New York Hospital-Cornell Medical Center, New York City and Westchester Divisions. Dr. Romano continued on the faculty of Cornell University Medical College for approximately 6 years prior to joining industry, and was Director of the Outpatient Eating Disorders Clinic and Partial Hospitalization Program at the New York Hospital-Cornell Medical Center-Westchester Division in White Plains, New York. His main areas of clinical and research focus at Cornell included the treatment and management of anorexia, bulimia, and obesity, and the psychopharmacology of major psychiatric conditions, including schizophrenia, bipolar disorder, and severe personality disorders.

Lon Schneider, MD

Professor, USC Keck School of Medicine

Training
- Sarah Lawrence College
- Hahnemann Medical College
- American Board of Psychiatry & Neurology
- ABPN
- University of Southern California

Significant Lifetime Achievements and Affiliations
- Tsai Memorial Lecture
- The Best Doctors in America
- America's toTop Docrs
- First Annual Dorothy Kirsten French Memorial Lecture
- The French Foundation for Alzheimer Research
- 11th Annual Research Award, Los Angeles Alzheimer's Association
- American Association for Geriatric Psychiatry Senior Investigator Award
- 21st Annual Research Award, Los Angeles Alzheimer's Association
- Senator Mark Hatfield Award for Clinical Research, Alzheimer's Association
- More than thirty peer-reviewed articles and publications
- Jay L. Foster Memorial Lecture in Alzheimer's Disease. Univ. of Pittsburgh Graduate School of Public Health

Holly Soares, PhD

Director, Clinical Biomarkers Neruoscience, Bristol-Myers Squibb

Michelle Stewart, PhD

Director, Pfizer, Inc.

Michelle received her Ph.D. in psychology from the University of Arizona and a M.A. in clinical psychology from the University of Colorado at Colorado Springs. Michelle joined Pfizer's Outcomes Research group in 2002 and has extensive experience supporting development programs in a variety of therapeutic areas. She is currently the Outcomes Research therapeutic area lead for Neurosciences within Pfizer's Specialty Care Business Unit working on indications including schizophrenia and cognitive impairment associated with schizophrenia, and also supports marketed products in the inflammation and multiple sclerosis therapeutic areas. She is a member of Pfizer's internal Suicidality Assessment Working Group and is on the MATRICS-CT industry-academic partnership subcommittee that is validating an intermediate functional measure for cognition in schizophrenia. Prior to joining Pfizer, Michelle conducted research as part of a federally funded grant at the University of Arizona to study psychosocial interventions for persons with serious mental illness in the Arizona public mental health system.

Marc Walton, MD, PhD
Medical Officer, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

Dr. Woodcock has led many of FDA's drug initiatives. She introduced the concept of risk management in 2000 as a new approach to drug safety. Since 2002, she has led the "Pharmaceutical Quality for the 21st Century Initiative," FDA's highly successful effort to modernize drug manufacturing and its regulation. In 2004, she introduced FDA's "Critical Path" Initiative, which is designed to move medical discoveries from the laboratory to consumers more efficiently.

Most recently, Dr. Woodcock launched the "Safety First" and "Safe Use" initiatives designed to improve drug safety management within and outside FDA, respectively.

Dr. Woodcock previously served as FDA's deputy commissioner and chief medical officer. She also led CDER as director from 1994–2005. Prior to joining CDER, Dr. Woodcock oversaw approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis in her position as director of the Office of Therapeutics Research and Review in FDA's Center for Biologics Evaluation and Research (CBER).

Dr. Woodcock received her medical degree from Northwestern University Medical School, and her undergraduate degree from Bucknell University. She has held teaching appointments at Pennsylvania State University and the University of California at San Francisco. She joined FDA in 1986.