



Novel Molecular Targets in Mood Disorders and Psychosis—A Virtual Workshop
March 8-9, 2021

Planning Committee Member Biographical Sketches

Linda Brady, Ph.D. (Workshop Chair), serves as the Director of the Division of Neuroscience and Basic Behavioral Science at the National Institute of Mental Health (NIMH). In this role, she provides scientific, programmatic, and administrative leadership for an extramural research program portfolio in basic neuroscience to support NIMH's mission of transforming the understanding and treatment of mental illnesses. Dr. Brady has directed programs in neuropharmacology, drug discovery, and clinical therapeutics and organized Consortia focused on ways to accelerate the development and clinical application of radiotracers in clinical research. She has provided leadership for the National Cooperative Drug/Device Discovery/Development Groups for the Treatment of Mental Disorders and First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders initiatives. Dr. Brady serves as co-chair of the Neuroscience Steering Committee of the Biomarkers Consortium, a 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 drug development, preventive medicine, and medical diagnostics. She serves as co-chair of the Steering Committee for the Accelerating Medicines Partnership – Schizophrenia, a public-private partnership to generate tools to improve success in developing early stage interventions for patients who are at risk of developing schizophrenia. She is also a member of the National Academies Forum on Drug Discovery, Development, and Translation. Dr. Brady was trained in pharmacology and neuroscience. She completed her Ph.D. at Emory University School of Medicine, followed by post-doctoral work and research positions at the Uniformed Services University of the Health Sciences and the NIMH Intramural Research Program. She is the author of more than 70 peer reviewed scientific publications and is a member of the Society for Neuroscience and a Fellow and President of the American College of Neuropsychopharmacology. Dr. Brady has received NIH Director's Awards and NIH Merit Awards in recognition of her activities in biomarker development and drug development for mental disorders.

Tiffany Farchione, M.D., is the Director of the Division of Psychiatry in the Office of Neuroscience at the US Food and Drug Administration. She received her medical degree from Wayne State University in Detroit, Michigan, and completed adult residency and child & adolescent fellowship training at the University of Pittsburgh's Western Psychiatric Institute and Clinic. Dr. Farchione is board certified in both general and child & adolescent psychiatry. Prior to joining FDA in 2010, Dr. Farchione was affiliated with the University of Pittsburgh Medical Center, and was on the faculty of the University of Pittsburgh. As the Director of the Division of Psychiatry, Dr. Farchione is involved in the oversight of new drug review for all psychiatric drug development activities conducted under investigational new drug applications, and the review of all new drug applications and supplements for new psychiatric drug claims.

David Gray, Ph.D., is the Vice President of Chemistry at Cerevel Therapeutics in Boston, MA. After obtaining a Ph.D. in organic chemistry at The Scripps Research Institute, he began his drug discovery career as a medicinal chemist at Pfizer where his early research focused on the discovery of novel compounds that leveraged developing concepts of functional selectivity and state-dependent activation to more precisely

modulate GPCRs and transporter targets. He then transitioned to leading research teams in CNS biology and clinical development. In support of compound identification efforts, his research group focused on physiological- and human-relevant assay development and translational neuroscience in the areas of depression, schizophrenia, Alzheimer's and Parkinson's. He has played a major role in advancing innovative and patient-centric clinical development strategies, including device-based clinical assessments, remote clinical assessments, and digital patient reported outcomes. Dr. Gray has become an advocate for effectively incorporating the patient voice into early research and for leveraging technology to increase the throughput of preclinical and clinical research efforts. He is active in several patient and research communities and has over 50 peer reviewed publications spanning a wide variety of scientific disciplines. During the past eight years, Dr. Gray has been spearheading clinical programs aimed to create improved motor symptom therapies in Parkinson's disease and treatments for specific cognitive and motivational deficits associated with schizophrenia and other CNS diseases. He led the early research and then the clinical development of a series of D1 partial agonists which include *tavapadon*, currently in Ph3. He joined the CNS-focused drug development company Cerevel Therapeutics to advance their portfolio of clinical and preclinical programs. Over the past eight years, Dr. Gray has advanced clinical-stage research programs based on highly selective modulation of dopaminergic circuitry in specific brain regions. He led the early research and clinical development of a series of D1 partial agonists, including *tavapadon*, which is currently in Phase 3 for Parkinson's Disease. Continual advances in the understanding of disease-relevant circuitry from the broader field of brain research suggest that pharmacotherapies with a high degree of receptor subtype and functional selectivity will lead to improved motor symptom therapies in Parkinson's disease, much needed advancements in the pharmacologic treatment of addiction, and strategies to alleviate specific cognitive and motivational deficits associated with CNS diseases. Dr. Gray joined the CNS-focused drug development company, Cerevel Therapeutics, to advance their portfolio of clinical and preclinical programs.

Magali Haas, M.D., Ph.D., M.S.E., is Chair, CEO and President of Cohen Veterans Bioscience, a non-profit brain research organization based in New York City whose mission is to fast-track diagnostics and therapeutics to advance precision brain health. Magali has over 15 years of pharmaceutical executive experience, predominantly at Johnson & Johnson, where she assumed broad end-to-end development leadership roles in early & late stage neuroscience clinical development, translational medicine, diagnostics and integrative solutions. To pioneer new approaches for precision therapeutics for brain health, she founded Orion Bionetworks in 2012, which was transformed to Cohen Veterans Bioscience in 2015, while also serving as founding Chief Science and Technology Officer for One Mind for Research. She serves on several advisory boards including Alto Neurosciences, Partnership for Assessment and Accreditation of Scientific Practice, VirtualBrainCloud, Krembil Centre for Neuroinformatics and IMEC for nanoelectronics. Magali earned her BS in bioengineering from the University of Pennsylvania, an MS in biomedical engineering from Rutgers University, and her MD and PhD in neuroscience with distinction from Albert Einstein College of Medicine.

Stuart Hoffman, Ph.D., is the Scientific Program Manager for the Brain Injury portfolio at the Department of Veterans Affairs, which includes traumatic brain injury (TBI) and stroke. Dr. Hoffman received his doctoral degree in behavioral and molecular neuroscience at Rutgers University in 1995 and completed his postdoctoral training in pharmacology at Virginia Commonwealth University's medical campus in 1997. Prior to accepting this position with VA, he was an assistant professor in the Department of Emergency Medicine at Emory University. Dr. Hoffman was also faculty in both the graduate and undergraduate neuroscience programs at Emory University, where he co-developed and directed a multidisciplinary course on neurotrauma. He was previously the Research Director for the

Defense and Veterans Brain Injury Center in Johnstown, Pennsylvania. Dr. Hoffman has more than 24 years of experience and has authored over 45 peer-reviewed publications in translational research on neuroprotection and recovery of function after brain injury. Dr. Hoffman has research experience in the following brain injury areas: in vitro TBI models, animal models of TBI, development of animal rehabilitation models, rodent brain ischemia models, translational drug development for neuroprotection, and clinical neurorehabilitation research.

John Krystal, M.D., is a leading expert in the areas of alcoholism, post-traumatic stress disorder, schizophrenia, and depression. His work links psychopharmacology, neuroimaging, molecular genetics, and computational neuroscience to study the neurobiology and treatment of these disorders. He is best known for leading the discovery of the rapid antidepressant effects of ketamine in depressed patients. He is a member of the U.S. National Academy of Medicine. He also serves in a variety of advisory and review capacities for NIAAA, NIMH, Wellcome Trust, Brain and Behavior Research Foundation, the Broad Institute, and the Karolinska Institutet. Dr. Krystal previously served on the National Alcohol Abuse and Alcoholism Advisory Council (NIAAA), the Department of Defense Psychological Health Advisory Committee, and the NIMH Board of Scientific Counselors (chair, 2005-2007). He has led the American College of Neuropsychopharmacology (president, 2012), and International College of Neuropsychopharmacology (president, 2016-2018). Currently, he is co-chair of the Neuroscience Forum (NeuroForum) of the National Academies of Sciences, Engineering, and Medicine, a member of the NIMH National Mental Health Advisory Council, and he edits the journal, *Biological Psychiatry* (impact factor: 11.982).

Carlos Larrauri, MSN, APRN, PMHNP-BC, FNP-BC, serves on the Board of Directors for the National Alliance on Mental Illness and NAMI Miami-Dade County. Diagnosed with schizophrenia at 23 years of age, access to affordable health care, community-based treatments, and early intervention afforded him the best opportunity for recovery. Mr. Larrauri is board certified as a Family Nurse Practitioner and Psychiatric Mental Health Nurse Practitioner, and formerly lectured at the University of Miami and Miami Dade College. Mr. Larrauri is currently pursuing a legal education at the University of Michigan. He aspires to interface clinical practice, health policy, and research, to reduce health inequities for people living with mental illness.

Husseini Manji, M.D., is Global Head, Johnson & Johnson (J&J) Science for Minds. He previously was Global Therapeutic Head for Neuroscience at Janssen R&D, LLC, a J&J pharmaceutical company. Before joining J&J, Dr. Manji was Chief of the Laboratory of Molecular Pathophysiology at the National Institutes of Health (NIH) and Director of the NIH Mood and Anxiety Disorders Program, the largest program of its kind in the world. Dr. Manji's research has helped to conceptualize neuropsychiatric disorders as genetically influenced disorders of synapses and circuits and has prompted the investigation of novel therapeutics for refractory patients. His work led to the FDA, Canada and EC approval of the first novel antidepressant mechanism in decades, SPRAVATO® (esketamine) nasal spray for adults with treatment-resistant major depressive disorder. Dr. Manji has received numerous prestigious awards, is Visiting Professor at Duke University, Honorary Fellow at Oxford University, member of the World Dementia Council, member of the Scientific Advisory Board of the Stanley Center at the Broad Institute of MIT and Harvard, and member of the World Economic Forum, Global Futures Council and Board of Trustees, McLean Hospital.

Sharon Mates, Ph.D., has been the Chair of the board of directors, President and Chief Executive Officer of Intracellular Therapies Inc. (ITI) since June 2002. Dr. Mates co-founded ITI in May 2002. Prior to co-founding ITI, Dr. Mates was a co-founder of Functional Genetics, and served as its Chairman and Chief Executive Officer from December 2000 until August 2003. From 1989-1998 Dr. Mates was the President and a board

member of North American Vaccine Inc. and its predecessor companies. She has served on several boards, and recently completed a board membership and a two-year chairmanship of the Board of the New York Biotechnology Association. Dr. Mates has also served on the Advisory Council of the Center for Society and Health at the Harvard School of Public Health, the Board of Visitors of the Biotechnology Institute of the University of Maryland and the board of directors of Gilda's Club of New York. Earlier in her career, Dr. Mates spent several years as a research analyst and investment banker, and as an advisor to the life sciences industry. Dr. Mates received her BS from the Ohio State University and her Ph.D. from the University of Washington, and completed her postdoctoral fellowships at The Massachusetts General Hospital and Harvard Medical School.

Steven Paul, M.D., has over 40 years of experience in neuroscience, particularly in molecular neuropharmacology and CNS drug discovery and development. He first joined Third Rock in 2010 and returned in 2018 as a venture partner. Dr. Paul is the scientific co-founder of Sage Therapeutics and served as its interim start-up head of R&D. He is also the co-founder of Voyager Therapeutics, a CNS gene therapy company, and served as its president and CEO. Dr. Paul is currently the CEO and chairman of Karuna Pharmaceuticals, a company developing novel treatments for psychosis, cognition, and pain. Dr. Paul is the former director of the Appel Alzheimer Disease Research Institute at Weill Cornell Medical College and is currently an adjunct professor of psychiatry and neurology at Washington University of St. Louis School of Medicine. Prior to his appointments at Weill Cornell and Washington University, Dr. Paul spent 17 years at Eli Lilly and Company, during which time he held several key R&D leadership roles. Prior to Lilly, Dr. Paul spent 18 years at NIH and as the scientific director of the National Institute of Mental Health. Dr. Paul has been the recipient of many awards and honors and has served on numerous committees and advisory boards. He has also authored or co-authored more than 550 papers and book chapters. Dr. Paul is an elected fellow of the American Association for the Advancement of Science and a member of the National Academy of Medicine of the National Academy of Sciences. He is also an elected fellow emeritus of the American College of Neuropsychopharmacology (ACNP) and served as ACNP President (1999). Dr. Paul is also currently on the board of directors or is a trustee of several organizations, including serving as Chairman of the Board of the Foundation for the NIH (FNIH) and as a Director of Alnylam Pharmaceuticals, Sage Therapeutics, Voyager Therapeutics and Karuna Pharmaceuticals. Dr. Paul has also served as a member of the National Institute of General Medical Sciences (NIGMS) and the National Institute of Mental Health Advisory Councils and was appointed by the secretary of the Department of Health and Human Services (HHS) as a member of the Advisory Committee to the Director of the NIH from 2001-2006 as well as to the science board of the FDA (2012-2014).

Morgan Sheng, MBBS, Ph.D., FRS, is a Core Institute Member, and Co-Director of the Stanley Center for Psychiatric Research, at the Broad Institute of MIT and Harvard; he is also Professor in the Dept of Brain and Cognitive Science at MIT. Previously (2008-2019), Sheng was Vice-President for Neuroscience at Genentech, a leading biotech company, where he was head of neuroscience research and drug discovery. Under his leadership, multiple innovative programs for treatment of serious diseases of the nervous system were advanced into clinical trials. Prior to joining Genentech, Dr. Sheng was the Menicon Professor of Neuroscience at MIT, as well as Investigator of the Howard Hughes Medical Institute. Sheng received a BA from Oxford University (UK), and obtained his medical degree and training in internal medicine at London University (UK). He also holds a PhD in molecular genetics from Harvard University. Following his postdoctoral work in neuroscience at the University of California, San Francisco, Dr. Sheng served on the faculty at Massachusetts General Hospital and Harvard Medical School before joining MIT. Elected as Fellow of the Royal Society (UK), Fellow of the Academy of Medical Sciences (UK), Fellow of the American Association for the Advancement of Science, and recipient of the 2020 Julius Axelrod Prize from the Society

for Neuroscience, Dr. Sheng is author of more than 200 peer-reviewed publications focused on the molecular cellular biology of brain synapses and the mechanisms of nervous system diseases.

Gregory Simon, M.D., M.P.H., is an investigator at Kaiser Permanente Washington Health Research Institute and a psychiatrist in Kaiser Permanente's Behavioral Health Service. He is also a Research Professor in the Department of Psychiatry and Behavioral Sciences at the University of Washington. Dr. Simon completed residency training in internal medicine at the University of Washington, residency training in psychiatry at the Massachusetts General Hospital, and fellowship training in the Robert Wood Johnson Clinical Scholars program at the University of Washington. Dr. Simon's research focuses on improving access to and quality of mental health care, especially for mood disorders and people at risk for self-harm and suicide. Specific areas of research include improving adherence to medication, increasing the availability of effective psychotherapy, personalization of treatment for mood disorders, evaluating peer support by and for people with mood disorders, prediction of suicidal behavior, population-based suicide prevention programs. Dr. Simon currently leads the Mental Health Research Network, an NIMH-funded cooperative agreement supporting population-based mental health research across 14 large health systems.

Ilna Singh, Ph.D., is a Professor of Neuroscience & Society at the University of Oxford, England, United Kingdom. She is also a co-director at the Wellcome Trust Centre for Ethics and the Humanities, and is a research fellow at the Oxford Research Centre. Singh obtained a Ph.D. from Harvard University. Dr. Singh leads the Neuroscience Ethics and Society group, based at the University of Oxford Department of Psychiatry (NeuroSec). There, she is involved in developing ethics research and guidance for a range of scientific and clinical studies in Oxford Psychiatry and Neuroscience, including projects in forensic psychiatry, bipolar disorder, psychosis, anorexia nervosa, and global child development. She also provides ethics advice and foresight analysis to projects involving “big neuro” and personalized mental health. Her research focuses on the social and ethical dimensions of innovations in neuroscience, psychiatry, and related areas – and she is particularly interested in translational impacts for children and families. She is an international policy-making board member with the Scatterhood Foundation Program for Behavioral Ethics, University of Pennsylvania Medical School, USA and the ELSA programme of the Norwegian Research Council. Dr. Singh serves as a consultant to health policy groups –including the United Kingdom National Institute for Clinical Excellence, and the National Institute of Health/Hastings Center Working Group on Drugs in Pediatric Psychiatry. She is a co-editor of the *Biosocieties* journal and an editorial board member of the *American Journal of Bioethics-Neuroscience* journal. She has contributed to various scientific and policy groups, including the US National Institutes of Mental Health and the Nuffield Council on Bioethics. Before joining at the University of Oxford, she was a Professor of Science, Ethics & Society at the Department of Global Health & Social Medicine at the King's College London (KCL), England, UK. Dr. Singh was a Reader at the London School of Economics and Political Science before joining KCL. Her current research focuses on the social and ethical side of neuroscience and psychiatry. She is interested in studying translational impacts for children and families, and in developing qualitative and quantitative methods of data collection & presentation. According to Scopus, Dr. Singh has published more than 88 research documents with over 2000 citations, and currently has an h-index of 23.