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Exploring Psychedelics and Entactogens as Treatments for Psychiatric Disorders: A Workshop

March 29-30, 2022

Planning Committee Member Biographical Sketches

Sarah Hollingsworth "Holly" Lisanby, M.D., (Co-chair), is Director of the Division of Translational Research at the National Institute of Mental Health (NIMH), which funds research on the discovery of preventions, treatments, and cures for mental illness across the lifespan. She founded and directs the NIMH Noninvasive Neuromodulation Unit which specializes in the use of brain stimulation tools to measure and modulate neuroplasticity. She is JP Gibbons Professor Emeritus at Duke University and was the first woman to serve as Chair of the Duke Department of Psychiatry and Behavioral Sciences. She founded and directed the Duke University and the Columbia University Divisions of Brain Stimulation, where she built interdisciplinary research programs specializing in the convergence of Psychiatry, Neuroscience and Engineering. She co-led the NIH BRAIN Initiative Team focused on large-scale neural recording and modulation devices. Dr. Lisanby's team pioneered magnetic seizure therapy (MST) as a novel depression treatment from the stages of animal testing, first-in-human, and now international trials. She has received international recognition including the Distinguished Investigator Award from the National Alliance for Research on Schizophrenia and Depression, the Max Hamilton Memorial Prize of the Collegium Internationale Neuro-Psychopharmacologicum, and the Eva King Killam Research Award from the American College of Neuropsychopharmacology.

Gerard Sanacora, M.D., Ph.D., (Co-chair), is the Gross Professor of Psychiatry at the Yale University School of Medicine, Director of the Yale Depression Research Program, and Co-Director of the Interventional Psychiatry Program at Yale-New Haven Hospital. He completed an NIH sponsored Medical Scientist Training Program at the State University New York at Stony Brook, earning his Ph.D. in Physiology and Biophysics in 1992 and his M.D. degree in 1994. He later completed the Clinical Neuroscientist Training Program Residency in the Department of Psychiatry, and an NIH funded Neuroimaging Scientist Training Program Fellowship at Yale University. For the past 25 years his work has employed both preclinical and clinical research methodologies in attempts to expand our understanding of the pathophysiology of mood disorders with the goal of using this information in developing new approaches for treating and preventing the disorders. He has served as PI on a broad range of NIH, foundation, and industry sponsored studies. At multiple levels these studies have helped highlight novel pathophysiological mechanisms in relation to mood disorders and contributed directly to the development, testing, and actual clinical application of novel treatment approaches for mood disorders. Most recently his interest has expanded to implementation science. In

attempts to more efficiently and cost effectively bring nascent, neuroscience informed treatment approaches to clinical practice he has worked on the creation and dissemination of educational resources and provided leadership on national and international consensus statements. Dr. Sanacora was elected a Fellow of the American College of Neuropsychopharmacology in 2012. He has also received the Anna-Monkia Stiftung international award for the investigation of the biological substrate and functional disturbances of depression in 2009 and the Joel Elkes Research Award for Outstanding contributions to Psychopharmacology from the American College of Neuropsychopharmacology in 2011.

Paul Appelbaum, M.D., is the Elizabeth K. Dollard Professor of Psychiatry, Medicine, and Law, and Director, Center for Law, Ethics and Psychiatry, Department of Psychiatry, Vagelos College of Physicians and Surgeons of Columbia University; a Research Scientist at the NY State Psychiatric Institute; and an affiliated faculty member, Columbia Law School. He directs Columbia's Center for Research on Ethical, Legal, and Social Implications of Psychiatric, Neurologic, and Behavioral Genetics, and heads the Clinical Research Ethics Core for Columbia's Clinical and Translational Science Award program. He is the author of many articles and books on law and ethics in clinical practice and research, including four that were awarded the Manfred S. Guttmacher Award from the American Psychiatric Association and the American Academy of Psychiatry and the Law. Dr. Appelbaum is Past President of the American Psychiatric Association (APA), and of the American Academy of Psychiatry and the Law. He has twice served as Chair of the APA Council on Psychiatry and Law, and of the APA Committee on Judicial Action, and now chairs the APA's DSM Steering Committee. He was a member of the MacArthur Foundation Research Networks on Mental Health and the Law and on Mandatory Outpatient Treatment, and was a Network Scholar for the Network on Neuroscience & Law. Dr. Appelbaum has received the APA's Isaac Ray Award for "outstanding contributions to forensic psychiatry and the psychiatric aspects of jurisprudence" and the APA's Adolph Meyer Award for career contributions to psychiatric research, was the Fritz Redlich Fellow at the Center for Advanced Study in the Behavioral Sciences, and has been elected to the National Academy of Medicine. Dr. Appelbaum is a graduate of Columbia College, received his M.D. from Harvard Medical School, and completed his residency in psychiatry at the Massachusetts Mental Health Center/Harvard Medical School in Boston.

Charma D. Dudley, Ph.D., FPPR, is the Second Vice President of the NAMI Board of Directors and serves as the Associate Director of Behavioral Health Services at Beacon Health Options in Pittsburgh. She is a member of NAMI Pittsburgh North where she has been active for more than 18 years. She has served on the national board for the last five years and is currently President for NAMI Keystone PA. With her work, she hopes to educate parents on mental health conditions and empower them to become advocates for their children when engaging with physicians and mental health professionals. She also hopes to dispel stereotypes and disparities in communities of color regarding mental illness. She previously worked at Family Resources where she was a clinical director. She is a licensed psychologist and has provided mental health services in a variety of settings, including outpatient, partial and inpatient hospitalizations, as well as social service agencies for children and adolescents. She has provided clinical oversight for intensive mental health services, conducted clinical supervision and trainings for mental health professionals. Her book, "Treating Depressed Children Utilizing Cognitive Behavioral Interventions," was published by New Harbinger Publications in 1997. She was nominated for Entertainment Industry Council's 3rd Annual Mental Health Media Awards and for TV Community Affairs Program of the Year WPXI-TV NBC

for the segment "The Effect of Violence and PTSD on Children." She earned her M.A. in Psychology and Ph.D. in Counselor Education and Psychology.

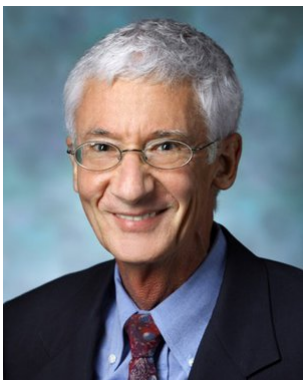
Allyson Gage, Ph.D., is a neuroscientist and drug development executive, who has over 20 years of

experience leading teams in all phases of clinical development. She has been responsible for the overall strategic and clinical development of small molecules, biologics, and cellular therapies for the treatment of central nervous system disorders, including depression, alcohol dependence, Alzheimer's dementia, neuropathic pain, traumatic brain injury, and spinal cord injury. Allyson has a proven track record in partnering with therapeutic area clinicians, US and International regulators, patient groups, and data scientists to translate pre-clinical information into human evaluation, to design informative clinical trial protocols, and ensure a regulatory path with approvable and clinically meaningful outcome measures. Prior to joining Cohen Veterans Bioscience, Allyson's most recent experience was focused in the field of regenerative medicine, working toward the development of a therapeutic for spinal cord injury. Allyson earned her BA from Rutgers College in New Brunswick, NJ and her MS and PhD in neuroscience from Albert Einstein College of Medicine, New York.

Javier González-Maeso, Ph.D., obtained his B.S. in Microbiology and Immunology and his B.S. in Biochemistry

and Molecular Biology at the University of the Basque Country in Bilbao - Spain, where as a Ph.D. student in the Department of Pharmacology his research interest was focused on neurotransmitter receptor function. He completed his postdoctoral training at Mount Sinai School of Medicine in New York City, where he proposed a molecular mechanism by which psychedelics such as psilocybin or LSD induce their unique behavioral effects in mice. Dr. González Maeso joined the faculty at Mount Sinai School of Medicine in 2008. He joined the Virginia Commonwealth University faculty in 2015. His research group studies the molecular mechanisms responsible for psychiatric disorders including schizophrenia, depression and alcoholism, as well as the basic signaling processes by which psychoactive drugs induce their therapeutic effects. Ongoing research projects employ the coordination of several interdisciplinary approaches ranging from computer structural modeling and biophysical methods in heterologous expression systems to mouse behavior assays and functional techniques in postmortem human brain samples.

Roland Griffiths, Ph.D., is Professor in the Departments of Psychiatry and Neurosciences at the Johns



Hopkins University School of Medicine. His principal research focus in both clinical and preclinical laboratories has been on the behavioral and subjective effects of mood-altering drugs. His research has been largely supported by grants from the National Institute on Health and he is author of over 400 journal articles and book chapters, and has trained more than 50 postdoctoral research fellows. He has been a consultant to the National Institutes of Health, to numerous pharmaceutical companies in the development of new psychotropic drugs, and as a member of the Expert Advisory Panel on Drug Dependence for the World Health Organization. He has conducted extensive research with sedative-hypnotics, caffeine, and novel mood-altering drugs. In 1999 he initiated a research program investigating the effects of the classic psychedelic psilocybin that includes studies in healthy volunteers, in beginning and long-term meditators, and in religious leaders. Therapeutic studies with psilocybin include treatment of

psychological distress in cancer patients, treatment of cigarette smoking cessation, and psilocybin treatment of major depression. Other studies have examined the effects of salvinorin A, dextromethorphan, and ketamine which produce altered states of consciousness having some similarities to psilocybin. Drug interaction studies and brain imaging studies (fMRI and PET) are examining pharmacological and neural mechanisms of action. The Hopkins laboratory has also conducted a series of internet survey studies characterizing various psychedelic experiences including those associated with acute and enduring adverse effects, mystical-type effects, entity and God-encounter experiences, and alleged positive changes in mental health, including decreases in depression and anxiety, decreases in substance abuse, and reductions in death anxiety.

Victoria Hale, Ph.D., is a pharmaceutical executive and social entrepreneur. She now serves in leadership

roles in several psychedelic medicine companies, as Board Chair of MAPS.org (MDMA for PTSD) and Founder and CEO of Sacred Medicines, PBC (Botanical Ayahuasca Tea). She is Founder and was CEO of OneWorld Health, the first nonprofit pharmaceutical company in the United States, that developed a new cure for visceral leishmaniasis and developed a synthetic biology platform technology to reduce the cost of artemisinin antimalarials by more than tenfold. Hale is also Founder and former CEO of Medicines360, a nonprofit pharmaceutical company that developed and obtained FDA approval of a hormonal IUD. She established her expertise in all stages of biopharmaceutical drug development at the FDA and at Genentech. She earned her PhD from the University of California, San Francisco, where she maintains an Adjunct Professorship in Bioengineering and Experimental Sciences. Her honors include being named a MacArthur Fellow, receiving the President's Award of Distinction from the American Association of Pharmaceutical Scientists and the Economist's Social and Economic Innovation Award, and being recognized as a Schwab Fellow of the World Economic Forum. She is a member of the National Academy of Medicine.

John Krystal, M.D., is the Robert L. McNeil, Jr., Professor of Translational Research; Professor of Psychiatry,

Neuroscience, and Psychology; and Chair of the Department of Psychiatry at the Yale University. He is also Chief of Psychiatry and Behavioral Health at Yale-New Haven Hospital. He is a graduate of the University of Chicago, Yale University School of Medicine, and the Yale Psychiatry Residency Training Program. He has published extensively on the neurobiology and treatment of schizophrenia, alcoholism, PTSD, and depression. Notably, his laboratory discovered the rapid antidepressant effects of ketamine in humans. He is the Director of the NIAAA Center for the Translational Neuroscience of Alcoholism and the Clinical Neuroscience Division of the VA National Center for PTSD. Dr. Krystal is a member of the U.S. National Academy of Medicine and a Fellow of the American Association for the Advancement of Science. Currently, he is co-director of the Neuroscience Forum of the U.S. National Academies of Sciences, Engineering, and Medicine; and editor of Biological Psychiatry (IF=13.38). He has chaired the NIMH Board of Scientific Counselors and served on the national advisory councils for both NIMH and NIAAA. Also, he is past president of the American College of Neuropsychopharmacology (ACNP) and International College of Neuropsychopharmacology (CINP).

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.

Tristan McClure-Begley, Ph.D., joined The Defense Advanced Research Projects Agency (DARPA) as a

Program Manager in October 2017. His scientific pursuits at the agency involve novel chemical biology approaches to treating disease and injury, and developing methods to accelerate and protect learning and executive functions. Dr. McClure-Begley came to DARPA from the University of Colorado, Boulder, where he was a Research Assistant Professor in the Department of Molecular, Cellular and Developmental Biology. His academic studies focused on molecular mechanisms of perturbations to complex biological systems, particularly drugs of abuse, toxins and neurodevelopmental disorders. Prior to his faculty appointment at CU, Dr. McClure-Begley was a postdoctoral fellow in the Department of Psychiatry at the Yale University School of Medicine, and an alumnus of the Yale/NIDA Neuroproteomics Center. He received his Doctor of Philosophy degree in Integrative Physiology and a Graduate Certificate in Behavioral Genetics from the University of Colorado, Boulder.

Javier Muñiz, M.D., is the Associate Director for Therapeutic Review in the Division of Psychiatry, Office of

New Drugs at the Food and Drug Administration (FDA). Dr. Muniz has supported the clinical review of psychiatry and other CNS products at the FDA for over seven years, and served as a Medical Officer for the Commissioned Corps of the U.S. Public Health Service for thirteen years. Prior to these roles, Dr. Muniz was Chief of Psychiatry at the Kimbrough Ambulatory Care Center in the US Army, and has held several leadership roles as a psychiatrist with the US Air Force. Dr. Muniz received his medical degree from the Universidad Central del Caribe. He then completed medical residencies in psychiatry at Thomas Jefferson University and Mount Sinai School of Medicine of New York University.

Srinivas Rao, M.D., Ph.D., is the Chief Scientific Officer at atai Life Sciences AG. Dr. Rao has over 19 years of professional experience in the pharmaceutical and biotechnology industries. Prior to atai, Dr. Rao has held the titles of Chief Scientific, Medical, or Executive Officer at companies ranging from venture backed startups to vertically-integrated, publicly traded pharmaceutical companies. Dr. Rao completed an internship in Internal Medicine at Yale-New Haven Hospital. He received his Ph.D. in neurobiology from Yale Graduate School and his M.D. from Yale School of Medicine. He holds both a Bachelor of Science and Master of Science degree in Electrical Engineering from Yale College and Yale Graduate School, respectively.

Rita Valentino, Ph.D., is the Director of the Division of Neuroscience and Behavior at the National Institute on Drug Abuse (NIDA). She received her Ph.D. in Pharmacology from the University of Michigan and did postdoctoral fellowships at the University of North Carolina and The Salk Institute. Her career spans 30 years of academic, research, and leadership experience in neuropsychopharmacology, substance abuse, stress neurobiology and viscero-cognitive processing. She held faculty positions at George Washington University, Hahnemann University and was a Professor at the University of Pennsylvania School of Medicine prior to joining NIDA. Dr. Valentino is recognized for her research on stress neurobiology and the impact of sex, age and coping style on behavioral and cognitive health, and how this can determine vulnerability to substance use. She is a Fellow and current Secretary of the American College of Neuropsychopharmacology, Fellow of the American Society of Pharmacology and Experimental Therapeutics and a member of the Scientific Advisory Board of the Brain Behavior Foundation. She is also the Founding Editor-in-Chief of Neurobiology of Stress.