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The State of the Science of the Use of Biomarkers
to Establish Presence and Severity of Impairments: A Workshop

Speaker Biosketches

Joan Bathon, M.D., is a rheumatologist, Professor of Medicine, Chief of the Division of Rheumatology, at Advisory Dean for Clinician Scientist Faculty, at Columbia University Medical Center. Prior to that, she was Deputy Director of Rheumatology and Director of the Arthritis Center at Johns Hopkins Medical Institutions. Her career has focused on understanding the pathogenesis and functional consequences of inflammation in rheumatoid arthritis (RA). Her group is particularly interested in understanding the effects of chronic rheumatoid inflammation on the extraarticular phenotype of RA, as manifested by accelerated atherosclerosis, myocardial dysfunction and adverse body composition. Her work has consistently been funded by NIH-NIAMS, the Rheumatology Research Foundation, and other sources. Dr. Bathon has also been the PI or co-investigator on many RA and osteoarthritis clinical trials, both industry and NIH sponsored. She has authored over 200 scientific publications and book chapters. Dr. Bathon is currently a member of the NIAMS Advisory Council. She previously served as a standing member of both the NIH ACTS and the NIH-NIAMS AMSCT study sections. She is past Editor-in-Chief of Arthritis & Rheumatology, past member of the FDA Arthritis Advisory Committee, and a past member of the Board of Directors of the American College of Rheumatology. Her dedication to advancing the careers of women faculty and trainees is reflected by her past roles while at Johns Hopkins as Director of the Dean's Office of Women in Science and Medicine, Co-Chair of the Women's Leadership Council, and Chair of the Department of Medicine's Task Force on Academic Careers of Women in Medicine.

Jerome Bickenbach, Ph.D., LL.B is a permanent visiting professor at the Department of Health Sciences and Medicine at the University of Lucerne and professor in the Department of Philosophy and Faculties of Law and Medicine at Queen's University. He is the author of Physical Disability and Social Policy (1993) and the co-editor of Introduction to Disability (1998), Disability and Culture: Universalism and Diversity (2000), A Seat at the Table: Persons with Disabilities and Policy Making (2001), Quality of Life and Human Difference (2003) and numerous articles and chapters in disability studies, focusing on the nature of disability and disability law and policy. He is a content editor of Sage Publications' proposed 5 volume Encyclopaedia of Disability. Since 1995 he has been a consultant with the World Health Organization (WHO) working on the revision of the ICIDH to the final draft leading to the ICF. Prof. Bickenbach has participated in nearly all revision activities, and continues to consult with WHO on ICF dissemination and international disability social policy. His research is in disability studies, using qualitative and quantitative research techniques within the paradigm of participatory action research. Most recently his research includes disability quality of life and the disability critique, disability epidemiology, universal design and inclusion, modelling disability statistics for population health surveys, the relationship between disability and health, and the ethics and the application of ICF to monitoring the implementation of the UN

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Convention on the Rights of Persons with Disabilities. As a lawyer, Prof. Bickenbach was a human rights litigator, specializing in anti-discrimination for persons with intellectual impairments and mental illness.

Daniel J. Clauw, M.D is a Professor of Anesthesiology, Medicine (Rheumatology) and Psychiatry at the University of Michigan. He attended undergrad and medical school at Michigan, and then did his internal medicine residency and rheumatology fellowships at Georgetown University, where he eventually held roles including Chief of Rheumatology and Vice Chair of Medicine. While at Georgetown he assembled an interdisciplinary team who began to study the central nervous system contributions to a number of chronic pain disorders, including fibromyalgia, interstitial cystitis, low back pain, and Gulf War Illnesses. This group of investigators, the Chronic Pain and Fatigue Research Center, moved to the University of Michigan in 2002. In addition to bringing this group to the University of Michigan, Dr. Clauw was also asked to lead the meager existing clinical research infrastructure serving UM at that time. With strong support from UM leadership he helped grow clinical and translational research infrastructure dramatically, becoming the first Assistant and then Associate Dean for Clinical Research (through 2009). He was also the first PI of the University of Michigan Clinical and Translational Sciences Award and founding director of the unit at Michigan that supports translational research – the Michigan Institute for Clinical and Health Research. He currently is co-PI of three NIH center grants studying the mechanisms underlying chronic pain in urological and musculoskeletal disorders and is an active mentor of clinical and pain researchers.

Judith A. Cook, Ph.D., is an internationally recognized authority on mental health services research, specifically the study of clinical and rehabilitation outcomes of children and adults receiving community-based care. She directs a federally funded research center along with numerous grants focused on intervention science and psychiatric epidemiology. She designs and implements innovative programs to enhance health and behavioral health of vulnerable populations. She works with federal, state and local authorities on behavioral health service system redesign and alternative financing strategies. Her recent work focuses on randomized controlled trials of evidence-based practice treatments for serious mental illness, and outcomes of individuals with co-occurring mental illness and chronic medical conditions. She consults with federal agencies including the National Institutes of Health, Social Security Administration, Department of Labor, Government Accountability Office, Substance Abuse and Mental Health Services Administration, and Veteran's Administration. She is currently the Principal Investigator for the first national study of the prevalence of psychiatric and substance use disorders among women living with HIV/AIDS. She was a member of the NIMH Study Section on Mental Health Services in Specialty Settings from 2006-2009.

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Amit Etkin, M.D., Ph.D., is the Founder, CEO and Chairman of Alto Neuroscience, as well as a Professor in the Department of Psychiatry and Behavioral Sciences at Stanford and a member of the Wu Tsai Neuroscience Institute at Stanford. He has received multiple awards, most notably the NIH Director's Pioneer Award in 2017, for groundbreaking work in clinical psychiatry and neuroscience. Dr. Etkin is trained as both as a neuroscientist and psychiatrist, with scientific experience ranging from molecular biology through machine learning and human clinical trials. The overarching aim of the Dr. Etkin's work has been understanding the neural basis of emotional disorders and their treatment, and leveraging this knowledge to better understand how the brain works and to develop novel treatment interventions. Alto builds on this work in order to advance precision psychiatry with respect to actionable, real-world, clinical and commercial outcomes.

Philip D. Harvey, Ph.D., is Leonard M. Miller Professor of Psychiatry and a VA Senior Health Scientist. He is the author of over 1,000 scientific papers and abstracts and he has written over 60 book chapters. He has been designated annually by Thompson-Reuters since 2010 as the being in the top 1% of all mental health researchers in citations. He has received a number of awards, including the first SIRS Clinical Scientist Distinguished Contributions award in 2012, the 2014 Alexander Gralnick Schizophrenia Research award from the American Psychiatric Foundation, the 2014 Department of Veterans affairs John Blair Barnwell award, and he will receive the Stanley Dean Award from American College of Psychiatrists in 2021. He has received continuous Federal funding since 1985. His research has focused on cognition and everyday functioning across neuropsychiatric conditions, with a special focus on severe mental illness. His research has also recently focused on technology in mental health and aging, including novel assessment strategies using ecological momentary assessment and various passive measurement strategies and technology-based interventions.

Kristi L. Kirschner, M.D., is a Clinical Professor in the University of Illinois College of Medicine (UICOM) Department of Medical Education, with a secondary appointment in the Department of Neurology and Rehabilitation. She is currently the subtheme leader for Health Humanities for the UICOM curriculum taskforce and overseeing the development and enhancement of Health Humanities Programs within the University of Illinois College of Medicine. Dr. Kirschner's academic interests include medical humanities and bioethics with a particular focus on disability issues and marginalized populations; the training of health care professionals about health humanities, bioethics and disability; and health care access for people with disabilities including reproductive health services. She also is an adjunct faculty member in the Department of Disabilities and Human Development at UIC where she worked with Carol Gill PhD and Teresa Savage PhD RN, to create the Certificate in Disability Ethics in 2003. As background, she is a physician specializing in Physical Medicine and Rehabilitation with particular interest in the needs of patients with complex neurological disabilities, including adults with spina bifida, neuromuscular diseases and cerebral palsy.

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Virginia Byers Kraus, M.D., Ph.D., is Professor of Medicine, Pathology, and Orthopaedic Surgery, and a faculty member of the Duke Molecular Physiology Institute in the Duke University School of Medicine. She is a practicing Rheumatologist with 20 years' experience in Osteoarthritis research. Dr. Kraus is past president of the Osteoarthritis Research Society International (OARSI); the premier organization focused on the prevention and treatment of osteoarthritis through the promotion and presentation of research, education, and the worldwide dissemination of new knowledge. In 2019, she was elected to the Association of American Physicians and awarded the Lifetime Achievement Award from OARSI. She is co-PI of the OARSI/Foundation for NIH Osteoarthritis Biomarkers Consortium Project, which advances the validation and qualification of biomarkers for OA diagnosis, prognosis, and clinical trials. She also directs the Duke Biomarkers Shared Resource under the management of Janet Huebner. This facility assists investigators with the design and implementation of molecular and protein assays to evaluate biochemical and inflammatory markers. Dr. Kraus is also the Director of the Molecular Measures Core in the Center for the Study of Aging and Human Development. This has led to long time collaboration of the Kraus lab with the Stedman Nutrition Center that has culminated in the housing of these labs under the Duke Molecular Physiology Institute.

Jeffrey A. Lieberman, M.D., is the Lawrence C. Kolb Professor and Chairman, Department of Psychiatry, Columbia University College of Physicians and Surgeons; Director, New York State Psychiatric Institute; and Psychiatrist-in-Chief, Columbia University Medical Center of the New York-Presbyterian Hospital. Columbia University Department of Psychiatry is among the top ranked in the nation in psychiatric research funding from the National Institutes of Health and for Psychiatry in the U.S. News & World Report Best Hospital rankings. Dr. Lieberman's work at Columbia has advanced the understanding of the neurobiology and treatment of schizophrenia and related psychotic disorders, and led to the transformative mental health care strategy for the early detection and prevention of schizophrenia. He has authored or co-authored over 600 articles published in scientific literature and wrote or edited 11 books on mental illness, psychopharmacology and psychiatry. In recognition of this work, he has received many national and international honors and awards, and in 2000 was elected to the National Academy of Sciences Institute of Medicine and in 2013 as president of the American Psychiatric Association. More recently, Dr. Lieberman's work has extended into public policy and advocacy for enhancing awareness of mental illness and improving mental health care, as well as reducing the stigma associated with mental illness. In this context, Dr. Lieberman has actively contributed to government policy and federal legislation including the Mental Health Parity and Addiction Equity Act, The Patient Protection and Affordable Care Act and the Helping Families in Mental Health Crisis Act, and is a visible spokesperson to the media on mental illness and psychiatry. This motivated him to write the critically acclaimed book *Shrinks the Untold Story of Psychiatry* and deliver a TED Talk on Stigma and Mental Illness.

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Joseph P. Menetski, Ph.D., is Associate Vice President of Research Partnerships and Director of the Biomarkers Consortium at the Foundation for the National Institutes of Health. Dr. Menetski received his Ph.D. from Northwestern University Medical School with Dr. Stephen Kowalczykowski and completed his post-doctoral training at the Laboratory of Molecular Biology, National Institutes of Health (NIH/NIDDK) with Dr. Martin Gellert. He then started his career in industry in 1993 in the Immunopathology Department at Parke-Davis (later Pfizer), where he established a discovery research program in cellular inflammation that eventually transitioned to the molecular study of osteoarthritis. Joseph moved to Merck in 2004. His first position was in the department of Immunology where he was involved in the osteoarthritis new targets and biomarker program. While at Merck he was a member of the Molecular Profiling group, the Knowledge Discovery and Knowledge Management group and finally a Director in Global Competitive Intelligence. Over the years, he has been a key contributor to many basic research and clinical programs in the areas of arthritis, sarcopenia, osteoporosis and asthma. He has served as a core research team member on several external basic research projects for identification of new targets and molecular biomarkers. His industry research and development experiences include target identification, compound selection, translational biomarker identification, clinical study design and analysis, and external scientific collaborations. In the commercial space, he has been intimately involved in opportunity and asset identification and qualification, and in assessing the competitive landscape of disease areas that he is supporting. During this time, he has been recognized by multiple research and development awards for his contributions.

Andrew Peterson, Ph.D., is an Assistant Professor in the Institute for Philosophy and Public Policy at George Mason University, a Guest Researcher (in residence) at the National Institutes of Health Department of Bioethics (2019-Present), and a Greenwall Faculty Scholar (2018-2021). Previously, he was a Crest Fellow at the Potomac Institute for Policy Studies in Washington D.C. (2017) and a Vanier Canada Graduate Scholar in the Rotman Institute of Philosophy and The Brain and Mind Institute at the University of Western Ontario, Canada (2013-2016). Dr. Peterson's research centers on bioethics and the philosophy of neuroscience, with specialization in ethical and epistemological issues related to the scientific study of consciousness. This work has been funded by the Vanier CGS program, the Canadian Institutes for Health Research, and the Greenwall Foundation.

Gwendolyn Sowa, M.D., Ph.D., is the Endowed Professor and Chair of the Department of Physical Medicine and Rehabilitation at the University of Pittsburgh/UPMC. Dr. Sowa also serves as the Co-Director of the Ferguson Laboratory for Orthopaedic and Spine Research, and Medical Director of UPMC Total Care- Musculoskeletal Health. She holds joint appointments in the Departments of Orthopaedic Surgery and Bioengineering. Dr. Sowa completed her PhD in Biochemistry and Medical Degree at the University of Wisconsin-Madison and her PM&R residency at the Rehabilitation Institute of Chicago, Northwestern University. She has served as

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a clinician scientist in the Department of Physical Medicine and Rehabilitation for over 15 years, where she has been active in developing new models of care for patients with low back pain. As Co-Director of the Ferguson Laboratory, which has a rich history in musculoskeletal research, she leads a diverse group of scientists including engineers, physiatrists, molecular biologists, orthopaedic surgeons, and neurosurgeons working together to develop innovative and individualized treatments for spine conditions and low back pain. The ultimate goal of her research program is to apply the growing knowledge of the biology and mechanobiology of the spine to the development of biomarkers to facilitate precision medicine approaches for low back pain treatment.

Madhukar H. Trivedi, M.D., is a Professor in the Department of Psychiatry at UT Southwestern Medical Center. He serves as Chief of the Division of Mood Disorders and the founding Director of the Center for Depression Research and Clinical Care, where he holds the Betty Jo Hay Distinguished Chair in Mental Health and the Julie K. Hersh Chair for Depression Research and Clinical Care. He specializes in treating depression. Dr. Trivedi is an internationally recognized translational researcher focusing on developing and validating biosignatures of depression. He also conducts research on pharmacological, psychosocial, and nonpharmacological treatments for depression. Dr. Trivedi has authored more than 500 peer-reviewed research publications, and he is currently the President of the American Society of Clinical Psychopharmacology (ASCP). Dr. Trivedi earned his medical degree at Baroda Medical College in India, where he also completed a residency in psychiatry. He performed a second residency in psychiatry at Henry Ford Hospital in Detroit, Michigan, and received advanced training in functional brain imaging and psychopharmacology through a research fellowship at UT Southwestern.

Amy K. Wagner, M.D., is a tenured Professor, Vice-chair Faculty Development, and Endowed Chair for Translational Research in the Department of Physical Medicine and Rehabilitation at the University of Pittsburgh. She holds a secondary appointment in the Department of Neuroscience and is Associate Director for Rehabilitation Research at the Safar Center for Resuscitation Research. Dr. Wagner's research program uses biomarkers as tools for developing and optimizing personalized treatments and outcomes for individuals with disability, particularly with traumatic brain injury (TBI) and with cardiac arrest. Dr. Wagner's research focus includes the TBI Rehabilomics Research Model, identifying biomarkers relevant for assessing pathology and prognosis as well as for assessing clinical risk and use in clinical decision making. Her experimental research also focuses on how agents commonly used during rehabilitation impact recovery. Her experimental research also focuses on the neurobiology of neuroplasticity and recovery after TBI, immunotherapies after neurological injury, and how commonly used therapeutic agents impact neurobiological and neurobehavioral processes associated with neuroplasticity and recovery. She is especially focused on dopaminergic systems and brain injury recovery, and her experimental TBI work also includes the study of rehabilitation relevant cognitive training paradigms to better understand the substrates and mechanisms of learning and memory recovery.

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Mark Warshawsky, Ph.D., is Deputy Commissioner for Retirement and Disability Policy at the Social Security Administration (SSA). He is in charge of a policy, research and administration component (about 520 employees), identifying issues, assuring quality, responsiveness of policy development, analysis and data for agency leadership, and the Administration. In particular, he is leading efforts to modernize the disability programs, and to improve the vehicles that educate the public on program features. His interests include social security, employer-sponsored pension and retirement programs, financial planning, health and long-term care financing, public finance, and macroeconomics. He has testified before Congress and administrative agencies many times, and was recently a Senior Research Fellow at the Mercatus Center of George Mason University, as well as a visiting scholar at the MIT Golub Center for Finance and Policy. Mark is the author of over 150 published articles and four books. From 2006 to 2013, he was Director of Retirement Research at Towers Watson, a global human capital consulting firm.

Mark was a member of the Social Security Advisory Board from 2006 through 2012 and was Vice Chairman of the Federal Commission on Long-Term Care in 2013. From 2004 to 2006, Mark served as Assistant Secretary for Economic Policy at the U.S. Department of the Treasury, playing a key role in the development of the Pension Protection Act of 2006.

He is the inventor of the life care annuity, a product integrating the immediate life annuity and long-term care insurance benefits, and a developer of planning software. Mark has held senior-level positions at the Federal Reserve Board, the Internal Revenue Service, and the Teachers Insurance and Annuity Association – College Retirement Equities Fund. He received a Ph.D. in economics from Harvard University and a B.A. with highest distinction from Northwestern University.