

# Examining the Working Definition for Long COVID

## Committee

### Kevin M. Alexander

#### Member

Kevin Alexander, M.D., is an advanced heart failure and transplant cardiologist and an Assistant Professor of Medicine at Stanford University. He completed internal medicine residency training at Johns Hopkins Hospital and a cardiology fellowship at Brigham and Women's Hospital. He then completed an advanced heart failure fellowship at Stanford Hospital. Dr. Alexander's clinical and research interests include heart failure, cardiac amyloidosis, and heart transplantation. His primary interest lies in cardiac amyloidosis, in particular unraveling the molecular determinants of transthyretin amyloid cardiomyopathy to improve diagnosis and treatment. He has co-authored many publications on cardiac amyloidosis and has received research grants from the National Institutes of Health and the American Heart Association. During the COVID-19 pandemic, he developed an interest in the interaction between cardiovascular disease and COVID-19 infection. He published several articles on the effect of COVID-19 on heart transplants and left ventricular assist patients (Trans-Co-V registry) as well as served as a member of the Association of Black Cardiologists COVID Task Force. Dr. Alexander indicated that he serves on an ongoing advisory board for Arbor Biotechnologies, and in the past served as consultant for Alnylam, Bristol Myers Squibb, Eidos, Ionis, Novo Nordisk, and Pfizer.

### Jerry Krishnan

#### Member

Jerry Krishnan, M.D., Ph.D., is a physician-scientist with clinical experience caring for people with asthma, chronic obstructive pulmonary disease (COPD), and Long COVID. He is a Professor and Associate Vice Chancellor for Population Health Sciences at the University of Illinois Chicago with research expertise in clinical trials, real-world evidence, and guideline development. He is an investigator in the National Institutes of Health (NIH) and Patient-Centered Outcomes Research Institute-funded research networks. Dr. Krishnan previously served as a member of the Pulmonary-Allergy Drugs Advisory Committee for the U.S. Food and Drug Administration (FDA) from 2007-2012 (Chair, 2011-2012), the National Committee for Quality Assurance (NCQA) Respiratory Measurement Advisory Panel (2010- 2015), and the National Heart, Lung, and Blood Institute's Clinical Trials Review Committee (2012- 2017; Chair 2016-17). He has authored more than 275 peer-reviewed publications in major medical journals, including JAMA, the New England Journal of Medicine, and the American Journal of Respiratory and Critical Care Medicine. Dr. Krishnan received his medical degree from the Baylor College of Medicine, completed his clinical training in Internal Medicine and Pulmonary/Critical Care Medicine at Johns Hopkins, and a Ph.D. in Clinical Investigation from the Hopkins Bloomberg School of Public Health. Dr. Krishnan currently receives consulting fees for the following organizations: AstraZeneca, CereVu Medical, Propeller and ResMed, and BData, Inc: Consultant.

# Harvey V. Fineberg

## Chair

Harvey Fineberg is president of the Gordon and Betty Moore Foundation. He previously served as president of the Institute of Medicine from 2002 to 2014 and as provost of Harvard University from 1997 to 2001, following 13 years as dean of the Harvard School of Public Health. Fineberg devoted most of his academic career to the fields of health policy and medical decision-making. His past research has focused on the process of policy development and implementation, assessment of medical technology, evaluation and use of vaccines, and dissemination of medical innovations. Fineberg serves on the boards of the Carnegie Endowment for International Peace and the China Medical Board. He helped found and served as president of the Society for Medical Decision Making, previously served on and chaired the board of the William and Flora Hewlett Foundation, and chaired the committee to review the performance of the World Health Organization and the functioning of the International Health Regulations (2005) during the 2009 H1N1 influenza pandemic. Fineberg is co-author of the books *Clinical Decision Analysis*, *Innovators in Physician Education*, and *The Epidemic That Never Was*, an analysis of the controversial federal immunization program against swine flu in 1976. He has co-edited several books on such diverse topics as AIDS prevention, vaccine safety, understanding risk in society, and global health. He has also authored numerous articles published in professional journals. Fineberg chaired the National Academies committee that produced the 2019 report on Reproducibility and Replicability in Science. He earned his bachelor's and doctoral degrees at Harvard and is the recipient of several honorary degrees.

## **Donald M. Berwick**

### **Member**

Donald M. Berwick is President Emeritus and Senior Fellow at the Institute for Healthcare Improvement (IHI), an organization he co-founded and led as President and CEO for 19 years. He is one of the nation's leading authorities on healthcare quality and improvement. In July 2010, President Obama appointed Dr. Berwick to the position of Administrator of the Centers for Medicare and Medicaid Services (CMS), which he held until December 2011. A pediatrician by background, Dr. Berwick has served as a Clinical Professor of Pediatrics and Health Care Policy at the Harvard Medical School, Professor of Health Policy and Management at the Harvard School of Public Health, and as a member of the staff of Boston's Children's Hospital Medical Center, Massachusetts General Hospital, and the Brigham and Women's Hospital. He has also served as vice chair of the U.S. Preventive Services Task Force, the first "Independent Member" of the Board of Trustees of the American Hospital Association, and chair of the National Advisory Council of the Agency for Healthcare Research and Quality. He is an elected member of the American Philosophical Society, the American Academy of Arts and Sciences, and the National Academy of Medicine (formerly the Institute of Medicine). Dr. Berwick served two terms on the IOM's governing Council, was a member of the IOM's Global Health Board, and currently chairs the NAM Board on Health Care Services. He served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. His numerous awards include the 2007 William B. Graham Prize for Health Services Research, the 2006 John M. Eisenberg Patient Safety and Quality Award, and the 2007 Heinz Award for Public Policy. In 2005, he was appointed Honorary Knight Commander of the British Empire by Her Majesty Queen Elizabeth II, the highest honor in the UK for non-UK citizens. He is the author or co-author of over 200 scientific articles and six books. He also serves now as a Lecturer in the Department of Health Care Policy at Harvard Medical School. Dr. Berwick indicated that he is a member of the Board of Directors of LumiraDx and has been a member of the advisory group to the COVID Patient Recovery Alliance organized by Leavitt Partners, which has been considering the consequences of Long COVID and has made several public statements and drafted a bill.

## **Karyn Bishof**

### **Member**

Karyn Bishof, B.S., is the Founder & President of the COVID-19 Longhailer Advocacy Project (C19LAP), a nonprofit whose mission is to advance the understanding of Long COVID and expedite assistance and solutions to Longhailers and their families through advocacy, education, research, and support. Karyn is a former Firefighter/Paramedic due to Long COVID & Associated Conditions (LCAC) and currently serves on the NIH RECOVER Initiative Ancillary Studies Committee and sits on the Executive Committee of the Long COVID Alliance. In 2022, Karyn received the Amelia Moore Sparkle Award for Compassionate Advocacy from Dysautonomia International. Karyn holds a Bachelor of Science in Exercise Science and Health Promotion.

## **Lily Chu**

### **Member**

Lily Chu, M.D., M.S.H.S., is the Vice President of the International Association for Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis. She has a background in internal medicine, geriatric medicine, and health services research. Her career took a detour in 2006 when she became ill with myalgic encephalomyelitis/ chronic fatigue syndrome (ME/CFS). Since then, she has investigated various aspects of ME/CFS, including its epidemiology and the unusual symptom of post-exertional malaise. During 2014-2015, she served as a member of the NAM Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, which created new, evidence-based criteria. From 2012-2021, she was a member of the Community Advisory Board for the Stanford University ME/CFS Initiative. She has also collaborated with the CDC, FDA, NIH, and Cochrane. Dr. Chu hopes to bring her perspectives as a patient, physician, and researcher to this project.

## **Betty A. Diamond**

### **Member**

Betty Diamond, M.D., received her MD from Harvard Medical School, performed a residency in Internal Medicine at Columbia Presbyterian Medical Center, and then trained in immunology at the Albert Einstein College of Medicine. Her research has focused on the induction and pathogenicity of autoantibodies in SLE, especially in the brain. Most recently, she has become interested in the anti-inflammatory effects of C1q. In recent years, she has also become involved in clinical trials in SLE and has led several clinical trials of novel therapeutics. She has received the Outstanding Investigator and the Mentoring awards of ACR. She is a member of the National Academy of Medicine and the National Academy of Sciences. She is a past president of the American Association of Immunologists. In the past, Dr. Diamond served as a consultant for Pfizer and Moderna.

## **Abigail Dumes**

### **Member**

Abigail Dumes, Ph.D., is an assistant professor in the Department of Women's and Gender Studies at the University of Michigan. She is a medical and cultural anthropologist with research interests in gender, infectious disease, contested illness, and environmental health. She is currently conducting qualitative research on Long COVID. She received her Ph.D. in sociocultural anthropology from Yale University. Between December 2021 and August 2022, she conducted seven recorded interviews with Long COVID patient advocates that are archived on the University of Michigan's Global Feminisms Project website for research and educational purposes. Since 2022, Dr. Dumes has been conducting a collaborative qualitative pilot study on Long COVID through the University of Michigan's Michigan COVID-19 Recovery Surveillance Study (MI CReSS).

## **E. Wesley Ely**

### **Member**

Wesley Ely, M.D., M.P.H., is a physician-scientist and tenured Professor of Medicine and Critical Care at Vanderbilt University and the Associate Director of Aging Research for the TN Valley VA Geriatric Research Education Clinical Center. He has been continuously NIH and VA funded for over 20 years and was the principal architect of multiple landmark trials (NEJM, JAMA, Lancet) that have transformed ICU medicine and improved the survival of critically ill patients with and without COVID-19. In the ICU, Dr. Ely's evidence-based ABCDEF safety bundle is translated into over 35 languages and is part of daily care for critically ill patients globally. His work defined ICU-acquired delirium and dementia as major public health problems that ruin lives and cost society billions annually. During the COVID pandemic, Dr. Ely conducted the largest international cohort study of acute brain dysfunction that established risk factors for COVID-induced delirium. Dr. Ely is an academic member of NAM's Forum on Traumatic Brain Injury (TBI). He is a leader in studies focused on reducing the risk of Post Intensive Care Syndrome (PICS), which is particularly relevant to Long COVID since both syndromes lead to rapidly acquired forms of disabling cognitive impairment. Dr. Ely hopes to draw on these experiences to improve survivorship for millions of people suffering from the cognitive, physical, and mental health disabilities of Long COVID. Dr. Ely was an unfunded investigator for Eli Lilly who designed the COV-Barrier study of Baricitinib. Likewise, he is conducting a combined pilot and phase III investigation of baricitinib for Long COVID, and Eli Lilly is providing study drug for this investigation, which will be called the REVERSE-Long COVID clinical trial. He provided educational lectures (approved CME activities) within the past 5 years to medical audiences about topics related to clinical outcomes of ICU care and severe COVID-19 infection that were sponsored by Pfizer.

## **Dennis Kolson**

### **Member**

Dennis Larry Kolson, M.D., Ph.D., is a Professor of Neurology and Vice Chair for Faculty Affairs in the Department of Neurology at the University of Pennsylvania. He is the past Chair of the Neurological Complications of HIV sub-committee of the Program Committee for the International Conference on Retroviruses and Opportunistic Infections (CROI), and he continues to serve as a reviewer of the HIV and COVID-19 neurological complications program. His laboratory research (NIH-funded) is focused on the neuropathogenesis of HIV infection and simian immunodeficiency virus (SIV) infection in the rhesus macaque model. He is the co-founder and co-Director of the Penn NeuroCOVID clinic. His clinical areas of expertise include HIV-associated neurocognitive disorders (HAND), the use of immunomodulating therapies for the treatment of multiple sclerosis, and the diagnosis and management of neurological complications of COVID-19. He is a member of the American Academy of Neurology and the American Neurological Association, and he serves as Associate Editor for Neurology: Neuroimmunology & Neuroinflammation. He completed his M.D. and Ph.D. degrees at the University of Pittsburgh, his neurology residency at Duke University Medical Center, and his post-doctoral fellowship in Neurovirology at the University of Pennsylvania. He joined the University of Pennsylvania faculty in 1992.

# Peter Palese

## Member

Peter Palese, Ph.D., received his Ph.D. from the University of Vienna in 1969. After completing a postdoctoral fellowship at The Roche Institute of Molecular Biology in Nutley, NJ, he was recruited to the Mount Sinai School of Medicine as an Assistant Professor. Palese was the Chair of the Department of Microbiology at the Icahn School of Medicine at Mount Sinai from 1987 to 2023 and he continues his research as Professor of Microbiology and of Medicine. His interest is in the area of RNA-containing viruses with a special emphasis on influenza viruses. Specifically, he established the first genetic maps for influenza A, B, and C viruses, identified the function of several viral genes, and defined the mechanism of neuraminidase inhibitors (which are now FDA-approved antivirals). He was also a pioneer in the field of reverse genetics for negative strand RNA viruses, which allows the introduction of site-specific mutations into the genomes of these viruses. This technique is crucial for the study of the structure/function relationships of viral genes, for the investigation of viral pathogenicity, and for the development and manufacture of novel vaccines. An improvement of this technique has been effectively used by him and his colleagues to reconstruct and study the pathogenicity of the highly virulent, but extinct, 1918 pandemic influenza virus. Work in collaboration with Adolfo García-Sastre has revealed that most negative strand RNA viruses possess proteins with interferon antagonist activity, enabling them to counteract the antiviral response of the infected host. In recent years most of the efforts by Palese and by his collaborators at Mount Sinai, Adolfo García-Sastre and Florian Krammer, have been directed at developing a Universal Influenza Virus Vaccine. Since the beginning of the pandemic, there has been a shift in direction as work on COVID-19 has become central to the efforts by Palese. At present, a major focus is the development of COVID-19 vaccines. In collaboration with Adolfo García-Sastre and Florian Krammer, Palese has developed a vaccine to combat COVID-19. These vaccines are based on Newcastle Disease Virus (an avian virus) as a vector expressing the spike protein (S) of SARS-CoV-2. Clinical trials using these SARS-CoV-2 vaccines are going on in five different countries. Palese is a Member of the National Academy of Sciences, a Member of the National Academy of Medicine, a Fellow of the American Academy of Arts and Sciences, and a Fellow of the National Academy of Inventors. Palese is also a corresponding Member of the Austrian Academy of Sciences and a Member of the German Academy of Sciences (Leopoldina).

# Caitlin Pedati

## Member

Caitlin Pedati, M.D., M.P.H., F.A.A.P., is the Public Health District Director of the Virginia Beach Department of Public Health. She is a board-certified pediatrician and started her career working in public health at the Centers for Disease Control and Prevention in the Epidemic Intelligence Service and then in state public health as a medical epidemiologist for the Nebraska Department of Health and Human Services and then as the Medical Director and State Epidemiologist for the Iowa Department of Public Health. Dr. Pedati has been a member of the Council of State and Territorial Epidemiologists (CSTE) since 2015 and has served as co-chair of the Healthcare Associated Infections subcommittee and a State Epidemiologist, contributing to a variety of workgroups, case definitions, and position statements, including the CSTE COVID-19 case definition and CSTE's current long COVID workgroup. During her career in applied governmental public health at the federal, state, and local levels across the United States, she has served as a leader through infectious disease responses, natural disasters, behavioral health crises, and more. Dr. Pedati has several peer-reviewed publications in basic science HIV research, clinical pediatrics, and public health. She is a Fellow of the American Academy of Pediatrics and a member of the Gold Humanism Honor Society and the Delta Omega Honorary Society in Public Health. Dr. Pedati earned her M.D./M.P.H. from George Washington University and completed a pediatric residency with a Certificate in Global Child Health at Children's National Hospital in Washington D.C. Dr. Pedati conducts consulting work for the Council of State and Territorial Epidemiologists Healthcare Associated Infections Committee (editing and compiling resources).

## **Mark S. Smolinski**

### **Member**

Mark Smolinski currently serves as President of Ending Pandemics. Dr. Smolinski brings 25 years of experience in applying innovative solutions to improve disease prevention, response, and control across the globe. Mark is leading a well-knit team—bringing together technologists; human, animal, and environmental health experts; and key community stakeholders to co-create tools for early detection, advanced warning, and prevention of pandemic threats. Since 2009, Mark has served as the Chief Medical Officer and Director of Global Health at the Skoll Global Threats Fund (SGTF), where he developed the Ending Pandemics in Our Lifetime Initiative in 2012. His work at SGTF created a solid foundation for the work of Ending Pandemics, which branched out as an independent entity on January 1, 2018. Prior to SGTF, Mark developed the Predict and Prevent Initiative at Google.org, as part of the starting team at Google’s philanthropic arm. Working with a team of engineers, Google Flu Trends (a project that had a tremendous impact on the use of big data for disease surveillance) was created in partnership with the U.S. Centers for Disease Control. Mark has served as Vice President for Biological Programs at the Nuclear Threat Initiative, a public charity directed by CNN founder Ted Turner and former U.S. Senator Sam Nunn. Before NTI, he led an 18-member expert committee of the National Academy of Medicine on the 2003 landmark report “Microbial Threats to Health: Emergence, Detection, and Response.” Mark served as the sixth Luther Terry Fellow in Washington, D.C., in the Office of the U.S. Surgeon General and as an Epidemic Intelligence Officer with the U.S. Centers for Disease Control and Prevention. Mark received his B.S. in Biology and M.D. from the University of Michigan in Ann Arbor. He is board-certified in preventive medicine and public health and holds an M.P.H. from the University of Arizona.

## **Linda Sprague Martinez**

### **Member**

Linda Sprague Martinez, Ph.D., is an associate professor at the Boston University School of Social Work, faculty affiliate with the BU Center for Emerging Infectious Diseases Policy and Research, and co-director of the BU Clinical Translational Science Institute Community Engagement Program. Her research is focused on community collaborative projects designed to advance health equity. Dr. Sprague Martinez’s scholarly impact has been in the area of community engagement and participatory research approaches. She has been recognized locally and nationally for her work to advance health equity and community engagement. In 2017, she was named a Resident Empowerment Honoree by the Boston Housing Authority, Center for Community Engagement and Civil Rights, and Resident Empowerment Coalition. In 2023 she received the NIH HEAL Director’s Award for community partnerships. Dr. Sprague Martinez was also named a Society for Social Work Research Fellow in 2023.

# Andrea Troxel

## Member

Andrea B. Troxel, Sc.D. is a Professor of Population Health and Director of the Division of Biostatistics at NYU Grossman School of Medicine, leading a growing group of over 60 faculty, staff, and trainees conducting methodological and collaborative research in medicine and population health. Dr. Troxel has extensive experience in the design, conduct, and analysis of all phases of clinical studies and has published on missing data, sensitivity analyses, and statistical methodology for the analysis of clinical trials. She is the author of over 300 peer-reviewed publications in the literature of statistical methodology, behavioral research, and other areas of medicine, and is an expert on randomized trials of behavioral interventions and on adaptive trial designs, with a special focus on pragmatic trials and hybrid effectiveness/implementation studies. She currently serves as MPI for three Data Coordinating Centers - the NEI-funded multi-center international randomized Zoster Eye Disease Study, the NHLBI-funded multi-center Pulmonary Embolism - Thrombus Removal with Catheter-Directed Therapy Trial, and the NIH HEAL Initiative's Data Coordinating Center for the Early Phase Pain Investigation Clinical Trials Network - and is MPI of the Clinical Science Core for the NIH's RECOVER Initiative to study Long COVID. She is an elected Fellow of the American Statistical Association and has served on Data Safety Monitoring Boards for randomized trials in cancer, cardiac devices, smoking cessation, and behavioral therapies. She earned her undergraduate degree in Applied Mathematics at Yale University and her doctorate in Biostatistics at Harvard University. Dr. Troxel is statistical editor for the New England Journal of Medicine. She is also on DSMBs for the NIH's Roybal Centers, for an NIA trial being run by investigators at U Penn, for a trial of CAR-T cell therapy sponsored by Cellectis, Inc, and for an NIMS knee osteoarthritis trial being run by investigators at Johns Hopkins.

# Monica Verduzco-Gutierrez

## Member

Monica Verduzco-Gutierrez, M.D., is an academic physiatrist and professor and chair of the Department of Rehabilitation Medicine at the Joe R. and Teresa Lozano Long School of Medicine at UT Health in San Antonio, TX. She also is currently the clinical chief of physical medicine and rehabilitation at the University Hospital System and the medical director of Critical Illness Recovery and Neurorehabilitation at Warm Springs Rehabilitation Hospitals in San Antonio. She previously served as the medical director of the Brain Injury and Stroke Program at TIRR Memorial Hermann, Houston TX. Her area of clinical expertise is traumatic brain injury, stroke rehabilitation, interventional spasticity management, and now Post-Acute Sequelae of SARS-CoV-2 (PASC). She is currently directing a COVID-19 Recovery Clinic, the first in South Texas, which aligns with her mission to increase access to interdisciplinary care, optimize function, and improve quality of life for survivors with long COVID. She is a co-PI at one of NIH's RECOVER Initiative sites. As a member of the American Academy of Physical Medicine and Rehabilitation's (AAPM&R's) Multi-Disciplinary Post-Acute Sequelae of SARS-CoV-2 infection (PASC) Collaborative, Dr. Verduzco-Gutierrez is a coauthor on all six of the Collaborative's current published guidance statements. She is an associate editor of the American Journal of PM&R. Dr. Verduzco-Gutierrez has current consultancies with AbbVie, Merz, Ipsen, Medtronic, and Piramal, related to her work in interventional spasticity management, and a past consultancy with ReNeuron. She also is an uncompensated consultant to AstraZeneca, addressing outcomes data for patients with cancer and immunodeficiencies. Dr. Verduzco-Gutierrez has testified twice in front of Congress on issues pertaining to long COVID. She has received the Top 25 Women in Healthcare Award from the National Diversity Council and Healthcare Diversity Council and the Distinguished Member Award from the AAPM&R. Dr. Verduzco-Gutierrez indicated that she serves as a consultant for AbbVie, Ipsen, Merz, Piramal, Medtronic.