ROADMAP TO 2030 FOR NEW DRUG EVALUATION IN OLDER ADULTS

PRESENTER BIOGRAPHIES

WELCOME & INTRODUCTION

SHIEW-MEI HUANG, PH.D., is currently Deputy Director, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration. She received her B.S. in Pharmacy from National Taiwan University, School of Pharmacy, in 1975 and her Ph.D. from the University of Illinois Medical Center, in Pharmacokinetics and Biopharmaceutics, in 1981. She has 15+ years of drug development experience (Ortho pharmaceutical Corp. and Dupont-Merck Pharmaceutical Company) before joining the FDA in 1996. She has over 160 publications focusing on topics in clinical pharmacology, drug metabolism/transport interactions, physiologically based pharmacokinetic modeling, and pharmacogenomics. She was an associate editor for a high-impact journal "Clinical Pharmacology and Therapeutics" from 2006-2019. She has received many awards, including an FDA Outstanding Achievement Award, an FDA Clear Communication Award, and an FDA Distinguished Service Award. Dr. Huang is an American Association of Pharmaceutical Scientists (AAPS) Fellow, a Japanese Society for the Study of Xenobiotics (JSSX) Fellow, and a diplomate of the American Board of Clinical Pharmacology. She has been an Adjunct Professor at the School of Pharmacy, University of Maryland, since 2010. She was President of the American Society for Clinical Pharmacology and Therapeutics (ASCPT) from 2009 to 2010. She also received the ASCPT Awards "Gary Neil Prize for Innovation in Drug Development" in March 2014 and "Henry Elliott Distinguished Service Award" in March 2016.

SESSION I PAST, PRESENT, AND CURRENT STATUS OF GUIDANCES FOR INCLUSION OF DATA ON OLDER ADULTS AND RESULTING ENROLLMENT

PATRICIA W. SLATTUM, PHARMD, PHD is a Professor Emeritus at the School of Pharmacy at the Virginia Commonwealth University (VCU) where she received her B.S. in pharmacy, PharmD in pharmacy, PhD in pharmaceutics, and Certificate in Aging Studies. She is a pharmacist and geriatric clinical pharmacologist applying clinical pharmacology principles to reduce medication-related problems among older adults with a particular interest in drug-induced cognitive and functional impairment. She serves as co-PI of the Geriatrics Workforce Enhancement Program at the Virginia Center on Aging at VCU and as faculty in the VCU Richmond Health and Wellness Program, an interprofessional teaching and care coordination program in low-income senior housing that she co-founded in 2012. Her role in these efforts is facilitating integration of age-friendly

practices into community-based care. She is also a visiting scholar at the Gerontological Society of America.

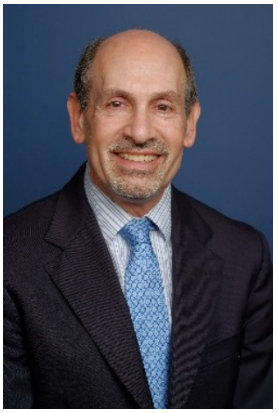
S.W. JOHNNY LAU, RPH, PHD is a senior clinical pharmacologist in the Office of Clinical Pharmacology of the Food and Drug Administration. He helps guide drug development through the review of the clinical pharmacology and biopharmaceutics studies for New Drug Applications, Biologics License Applications, Investigational New Drug Applications, Pediatric Study Plans, Proposed Pediatric Study Requests, and study protocols for metabolic, endocrine, bone, reproductive, urologic, pulmonary, rheumatologic, and nonmalignant hematologic drug products. He was formerly a clinical pharmacokineticist at Procter & Gamble Pharmaceuticals. He also worked for Norwich Eaton Pharmaceuticals as a clinical biopharmaceutics scientist. He received his B.S. (pharmacy) and M.S. (pharmacokinetics) from the University of Washington and Ph.D. (pharmaceutics) from the University of Houston. He is a diplomate of the American Board of Clinical Pharmacology. He founded and chairs the Geriatric Scientific Interest Group in his current position. He is a registered pharmacist in the state of Texas and Washington.

SHARON K. INOUYE, MD, MPH is an internationally recognized leader in geriatric medicine and aging research. She is a Professor of Medicine at Harvard Medical School, holder of the Milton and Shirley F. Levy Family Chair, and Director of the Aging Brain Center at the Marcus Institute for Aging Research, Hebrew SeniorLife. Dr. Inouye is board-certified in internal medicine and geriatric medicine and an expert in public health, health policy, and clinical epidemiology. Dr. Inouye's clinical and research work has focused on finding ways to improve the quality, safety, and outcomes of hospitalization for older adults. She developed a scientifically proven method for reducing delirium and functional decline in hospitalized older persons, the Hospital Elder Life Program (HELP), which has been implemented in hundreds of hospitals worldwide. She also created the Confusion Assessment Method (CAM), translated into over 20 languages, which is the most widely used method to identify delirium worldwide. She has dedicated her career to serving vulnerable and underserved populations; her clinical practice includes care of geriatric and homeless populations. A renowned scientist, Dr. Inouye has been continuously funded by the National Institutes of Health since 1989, with over 80 grants, including a current >$13 million P01 grant on the inter-relationship of delirium and dementia. She has published more than 350 articles, many in the highest impact journals (H-index =104), and was named by Thomson Reuters ScienceWatch (2014) as one of the World's Most Influential Scientific Minds of the decade. She serves as an Associate Editor at JAMA Network Open. She is an elected member of the National Academy of Medicine (2011), as well as the Association of American Physicians (AAP) and the American Society of Clinical Investigation (ASCI). She has received many awards, including the Henderson Award from the American Geriatrics Society (2013), and the M. Powell Lawton Award from the Gerontological Society of America (2015). She currently serves on the Board on Health Care Services (HCS), National Academies of Sciences, Engineering, and Medicine (NASEM), 2019-2022; President's Advisory Council, The National Academy of Medicine (NAM) Grand Challenge in Healthy Longevity, 2018-present; Advisory Board for the APHA-NAM Covid-19 Conversations series, 2020-present; and NASEM Committee Member for Improving the

Representation of Women and Underrepresented Minorities in Clinical Trials and Research, 2021- present. She served as a Health and Aging Policy Fellow and American Political Science Association Congressional Fellow in 2016-17 and an Encore Public Voices Fellow 2019-2020. She was recognized as a PBS-Next Avenue 2020 Influencer of Aging for her work in advocating for equitable COVID-19 vaccine testing and distribution for older and vulnerable populations.

FRANCESCA CERRETA, MSC, MPHARM is currently a Principal Scientific Officer of the European Medicines Agency (EMA) based in Amsterdam, the Netherlands. She qualified from the University of Florence (Italy) with a Masters in pharmaceutical chemistry and a Masters in Pharmacy. She worked as a research scientist at the CNRS laboratories in Caen (France) and subsequently for Merck in the field of molecular biology and for Eli Lilly in clinical research. In 1996 she joined the EMA. At the EMA she has covered different roles, as Senior Scientific Officer in the area of Quality of Medicines with a focus on innovative biotechnologies, in Scientific Advice, where she coordinated the establishment of the parallel scientific advice procedure with the FDA, and in the CNS section of the Safety and Efficacy of Medicines. She is the coordinator of the EMA geriatric medicines initiative, aiming to improve the assessment of the benefit/risk balance of drugs in the older population, and also coordinates the PRIME medicines initiative and the EMA group on digital therapeutics.

CAROLYN CHO, PHD is currently the Quantitative Pharmacology and Pharmacometrics Therapeutic Area lead for Immunology at Merck & Co., supporting quantitative decision-making on programs from discovery through registration and post-marketing development, programs for the treatment of asthma, chronic cough, auto-immune disease, and the prevention of shingles and CMV infection. She has previously held positions of Director of Systems Biology at Pfizer and Global Head of Computational Systems Biology at Novartis. She received her doctoral training in Biological Physics at the University of Toronto followed by post-doctoral research in Molecular Biology at Princeton University. Carolyn also leads an International Society of Pharmacometrics working group on the integration of Quantitative Systems Pharmacology and machine learning and serves as a journal and grant reviewer.



JERRY H. GURWITZ, MD IS Executive Director of the Meyers Primary Care Institute, a joint endeavor of the University of Massachusetts Medical School, Reliant Medical Group, and Fallon Health. He also serves as Chief of the Division of Geriatric Medicine at the University of Massachusetts Medical School where he is the Dr. John Meyers professor of primary care medicine. He graduated from the University of Massachusetts School of Medicine Medical School in 1983, after which he completed a residency in internal medicine and a fellowship in geriatric medicine. Dr. Gurwitz's research has focused on improving medication use in older adults, especially those residing in long-term care settings. He has authored numerous original articles, reviews, commentaries, and book chapters in the area of geriatric

pharmacotherapy and is a respected teacher and public advocate for improving the care of older adults. He is currently principal investigator of the NIA-funded Advancing Geriatrics Infrastructure and Network Growth (AGING) Initiative, a joint endeavor of the Health Care Systems Research Network and the Older Americans Independence Centers. The AGING Initiative focuses on advancing the science of multiple chronic conditions in older adults.

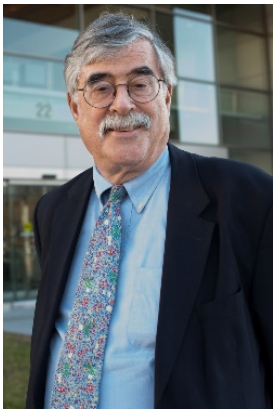
SARAH HILMER MBBS, FRACP, PHD is Professor of Geriatric Pharmacology, Northern Clinical School, Faculty of Medicine and Health, The University of Sydney; and Head of Department of Clinical Pharmacology and Senior Staff Specialist in Aged Care, Royal North Shore Hospital, New South Wales, Australia. She is currently Chair of the Geriatric Subcommittee of the Clinical Division, IUPHAR. She was a co-author in developing the Drug Burden Index and has been responsible for its validation and integration into clinical care in the Australian medical system. Her research focuses on the clinical pharmacology of frailty, reviewing polypharmacy, deprescribing, and developing animal models of polypharmacy to advance its study. She is an author of over 330 publications. She contributes to drug regulation and management through leadership of institutional and state committees, and membership of national committees in Australia. She is also an active practicing geriatric medicine clinician with most of her patients over the age of 85 years.

BINDU KANAPURU, MD is the Clinical Team Lead for the Multiple Myeloma team in the Division of Hematologic Malignancies 2 (DHM2) in the Office of Oncologic Diseases (OOD) at the FDA. Her areas of interest include the treatment of hematological malignancies, geriatric oncology, and novel trial designs. She also serves as the scientific liaison for geriatric oncology. Dr. Kanapuru joined the FDA in 2015. She is a board-certified hematologist-oncologist. Dr. Kanapuru completed her fellowship in hematology and oncology at the University of Maryland Medical Center in Baltimore. During her fellowship she did her research at the National Institute on Aging on mechanisms of unexplained anemia and cancer incidence in older adults and co-authored multiple publications and book chapters. She is board-certified in Hematology and Medical Oncology.

PHIL POSNER, PHD is a retired academic teacher and researcher (Cardiovascular and Neuroscience) and a current patient with multiple sclerosis, atrial fibrillation, and coeliac disease. He has been involved in research and teaching at several major medical institutions and has served as a patient representative for the FDA and the Patient-Centered Outcomes Research Institute for patients with multiple chronic conditions. He currently serves as a Patient-Centered Outcomes Research Institute Ambassador (for multiple chronic conditions) and was formerly on the Patient Engagement Advisory Panel. He is also a patient representative on several patient-centered research projects such as the AGING Initiative's Patient Caregiver Advisory Council (APCAC), a former co-chair of the National Coordinating Center-Beneficiary and Family Centered Care-Quality Improvement Organization, and a member of the iConquerMS research committee. Dr. Posner currently serves as chair of the Washington Metropolitan Area Transit Authority's Accessibility Advisory Committee.

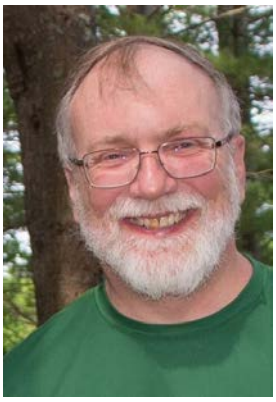
H. KEIPP TALBOT, MD, MPH got her medical degree from the Medical College of Georgia and trained in internal medicine and infectious disease at Vanderbilt University Medical Center (Nashville, Tennessee) where she also received her MPH and is currently Associate Professor of Medicine and Health Policy. The focus of her research is on viral respiratory illnesses in older adults with a special interest in the prevention of illness through immunization. She has studied both the epidemiology of and vaccine efficacy and effectiveness for influenza as well as studying respiratory syncytial virus and human metapneumovirus in older adults. She is the PI for the Vanderbilt site for the inpatient influenza vaccine effectiveness network. She is also a voting member of the CDC's Advisory Committee on Immunization Practices (ACIP) and is on the forefront of efforts on COVID vaccines.

SESSION II THE WAY FORWARD—POTENTIAL SOLUTIONS



DR. ROBERT TEMPLE, MD serves as CDER's Deputy Center Director for Clinical Science and Senior Advisor in the Immediate Office of the Office of New Drugs (OND). As the senior advisor, Bob is a consultant to the OND director and other FDA officials on matters related to clinical program objectives. Dr. Temple received his medical degree from the New York University School of Medicine in 1967. In 1972, he joined CDER as a Medical Officer in the Division of Metabolic and Endocrine Drug Products. He later moved into the position of Director of the Division of Cardio-Renal Drug Products. Before becoming Senior Advisor in OND, Dr. Temple was the Acting Deputy Director of OND's Office of Drug Evaluation-I (ODE-I) which is responsible for the regulation of cardiovascular and renal, neurology, and psychiatry drug products. He served in this capacity for more than 23 years—since the office's establishment in 1995. Dr. Temple has a long-standing interest in the design and conduct of clinical trials. He has written extensively on this subject, especially on the choice of a control group in clinical trials, evaluation and active control trials, trials to evaluate dose-response, and trials using "enrichment" designs. He has been involved in the development of many International Conference on Harmonization (ICH) guidelines and numerous FDA guidances, including ones on study enrichment and on issues related to the design and interpretation of non-inferiority studies.

RAJ MADABUSHI, PHD has 10 years of regulatory review experience as a Pharmacometrics Review and Team Leader in the Office of Clinical Pharmacology. He was predominantly involved in the application of quantitative clinical pharmacology approaches for regulatory decision-making and addressing various drug development issues in the areas of Cardio-Renal, Hematology, and Endocrinology drug products. Currently he is the Associate Director for Guidance and Scientific Policy in the Immediate Office of the OCP. He is involved in drug development, regulation, research, and policy from a clinical pharmacology perspective. He is also the CDER Point-of-Contact for the PDUFA VI MIDD Pilot Meeting Program.



JACK COOK, PHD is a Vice President in the Clinical Pharmacology Department of the Global Product Development unit at Pfizer, Inc. Dr. Cook holds adjunct faculty positions at the Universities of Michigan and Florida Colleges of Pharmacy. He received B.S. degrees in Applied Mathematics and Pharmacy from Ferris State College and his Ph.D. in Pharmaceutics from the University of Michigan. He has authored/co-authored over 70 peer-reviewed publications. He served as an industrial representative for the United States Food and Drug Administration's Pharmaceutical Science and Clinical Pharmacology Advisory Committees from 2012 to 2019. He is a fellow of the AAPS. His current interests include improving therapy by optimizing drug delivery and the use of modeling and simulation to make rational decisions in the development of drugs.

GÖTZ SEBASTIAN HAERTTER, PHD (SH) is currently a Clinical Pharmacology Expert at Boehringer Ingelheim (BI). He is also a member of the Cardiometabolism Therapeutic Area's leading bodies at BI (Clin Expert Committee, Ther Area Leading Committee). SH is also representative of Translational Science and Clinical Pharmacology in the BI Clinical Pediatric Expert Group, the Global Labeling and Risk/Benefit Committee, and Inlicensing expert groups. SH is a member of the IQ-Clin Pharm LG (CPLG) and chair of the IQ-CPLG Pediatrics WG and the Exploratory Trial Design WG. SH is a pharmacist by training and received his Ph.D. in pharm chemistry and a lecturing degree (German Habilitation) in Pharmacology & Toxicology. In the past, he has been an assistant professor at the University of Mainz (Germany), an Adjunct Professor at the Universities of Ulm (Germany), Connecticut, and Albany, NY and is author or co-author of > 100 peer reviewed publications. He served as the PhRMA deputy topic lead for the ICH M9-Working Group, is currently the EFPIA topic lead in the ICH M13 (Bioequivalence) Working Group, and is a member of the EFPIA expert group in support of ICH M12 – DDI.

GILBERT BURCKART, PHARMD is presently Associate Director for Pediatrics, Office of Clinical Pharmacology, U.S. Food and Drug Administration. Dr. Burckart has served on the faculties of four universities (Buffalo, Tennessee, Pittsburgh, Southern California) as a Professor of Pharmacy, Pediatrics, and Surgery for 33 years prior to coming to the FDA. He has previously served as President of the American College of Clinical Pharmacy and as President of the American College of Clinical Pharmacology. He moved to the US FDA in 2008, and his duties include the direction of the Pediatric Clinical Pharmacology program within the Office of Clinical Pharmacology, and participation in the FDA's Pediatric Review Committee. His present educational and research program focuses on pediatric drug development studies.

JANICE SCHWARTZ, MD, FACC, ASGF, is a Professor of Medicine at the University of California, San Francisco. She graduated from Tulane Medical School and is a board-certified internist, cardiologist, and geriatrician with significant experience in clinical pharmacology. She has been on the faculty of Stanford Medical School, Baylor College of Medicine, UCSF Schools of Medicine, Nursing, and Pharmacy, and was Professor of Medicine and Chief of Clinical Pharmacology and Geriatric Medicine at Northwestern University Medical School until 2000 when she returned to the San Francisco Bay area to launch a Research Program at the Jewish Home of San Francisco. She has been funded by the National Institute on Aging since 1985 to elucidate the changes with aging that determine responses to therapeutic medications and ways to optimize medication use. Her research has involved basic laboratory research, clinical trials, and population research and she is the author of over 200 publications including scientific articles, reviews, and book chapters. She has been named one of the Best Doctors in the U.S. (geriatric medicine) and received the 2012 William B. Abrams Award in Geriatric Clinical Pharmacology from the American Society of Clinical Pharmacology and Therapeutics and the 2019 Award for Excellence in Clinical Pharmacology from PhRMA, Foundation, Inc. She was an ORISE Visiting Professor in the Office of Clinical Pharmacology from October 2019-November 2020. Her current work focuses on improving medication use in the very oldest people and inpatient groups receiving polypharmacy, as well as the translation of new therapies into clinical use

ROBERT M. CALIFF, MD, MACC, is the Head of Clinical Policy and Strategy for Verily and Google Health for Verily and Google Health. Previously, Dr. Califf was the vice chancellor for health data science for the Duke University School of Medicine; director of Duke Forge, Duke's center for health data science; and the Donald F. Fortin, MD, Professor of Cardiology. He served as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration (FDA) from 2015-2016 and as Commissioner of Food and Drugs from 2016-2017. A nationally and internationally recognized leader in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf is a graduate of Duke University School of Medicine. Dr. Califf was the founding director of the Duke Clinical Research Institute and is one of the most frequently cited authors in biomedical science.

JAMIE GAMERMAN, JD is a Regulatory Counsel in the Office of Medical Policy within FDA's Center for Drugs Evaluation and Research. Jamie has worked extensively on clinical trial diversity issues, including broadening eligibility for older adults in clinical trials. Jamie received her JD from the University of Maryland School of Law and her bachelor's degree from the University of Maryland.

PAUL GOLDSMITH, PHD, is a Clinical Pharmacology Research Fellow within the Exploratory Medicine and Pharmacology department at Lilly working primarily on early phase clinical trials in the Neuroscience and Diabetes diseases areas and is based in the UK. Prior to Paul's current position, he completed his Ph.D. with Professor Malcolm Rowland in Manchester and has held various positions of seniority in Discovery, Pharmacokinetic, and Clinical Pharmacology departments at SB, GSK, Novartis and Takeda with a primary focus on neuroscience, respiratory, and immunology. Immediately prior to his appointment at Lilly, Paul was heading up early development activities at BenevolentAI, a biotech company utilizing AI technologies.

SIR MUNIR PIRMOHAMED, MB CHB, PHD, FRCPE, FRCP, FBPHS, FMEDSCI is David Weatherall Chair in Medicine at the University of Liverpool and a Consultant Physician at the Royal Liverpool University Hospital. He is Director of the MRC Centre for Drug Safety Sciences and Director of the Wolfson Centre for Personalised Medicine. He is also Director of HDR North. He is an inaugural NIHR Senior Investigator, Fellow of the Academy of Medical Sciences in the UK, Commissioner on Human Medicines, a non-executive director of NHS England, and has been appointed as President of the British Pharmacological Society. He was awarded a Knights Bachelor in the Queen's Birthday Honours in 2015. His research focuses on personalised medicine, clinical pharmacology and drug safety.

BARBARA RADZISZEWSKA, PHD, MPH is a Program Officer in the Clinical Trials Branch of the Division of Geriatrics and Clinical Gerontology (DGCG) at the National Institute on Aging, NIH. Her educational background is in developmental psychology (Ph.D., University of Utah, 1987) and in public health (MPH, Johns Hopkins University, 1995). She has worked at NIH since 1996, focusing on scientific, programmatic, and regulatory aspects of clinical trials and epidemiological studies. Throughout her career at NIH, Dr. Radziszewska has provided oversight and direction to clinical trials focusing on primary and secondary prevention and treatment of age-related conditions, including cardiovascular disease and functional decline. She has been involved in DGCG programmatic initiatives on the role of chronic, low-grade, age-related inflammation in aging and disease and exploring potential interventions aimed at modulation of chronic inflammation. Dr. Radziszewska has also been

actively involved in NIH-wide initiatives aimed at enhancing inclusion in clinical research studies of historically under-represented populations, with special emphasis on strategies for enrolling older adults, including those with multiple comorbidities and frailty.

PIET VAN DER GRAAF PHARMD, PHD is Senior Vice President of Quantitative Systems Pharmacology at Certara and Professor of Systems Pharmacology at Leiden University. He was Director of Research of the Leiden Academic Centre for Drug Research (LACDR) from 2013-2016 and held various research leadership positions at Pfizer from 1999-2013 in Discovery Biology, Pharmacokinetics and Drug Metabolism, and Clinical Pharmacology. He was the founding Editor-in-Chief of *CPT: Pharmacometrics & Systems Pharmacology (PSP)* from 2012-2018 before becoming Editor-in-Chief of *Clinical Pharmacology & Therapeutics (CPT)*. He received his doctorate training in quantitative pharmacology and Ph.D. in Clinical Medicine with Nobel laureate Sir James Black at King's College London and a Pharm.D. from the University of Groningen (The Netherlands). He is a Fellow of the *British Pharmacological Society*.

CLOSING REMARKS

QI LIU, PHD, MSTAT, FCP is a Senior Science Advisor in the Office of Clinical Pharmacology (OCP), CDER, FDA. During her career at the FDA, Dr. Liu contributed to over 200 NDA/sNDA reviews, 20 BLA/sBLA reviews, and numerous IND reviews to support drug development. She has also worked on many research projects and built collaborations to advance regulatory sciences and promote innovations. She co-authored about 50 manuscripts and presented on many topics at FDA Advisory Committee meetings and scientific conferences. She worked on several working groups for FDA guidance documents and Manual of Policies & Procedures (MAPP) development. She also leads OCP's Innovative Data Analytics program. Dr. Liu is a Fellow of the American College of Clinical Pharmacology. She is also on the editorial board of the American Association of Pharmaceutical Scientists Journal, Clinical Pharmacology and Therapeutics, and Clinical and Translational Science. Dr. Liu is interested in the application of clinical pharmacology principles, innovative tools (e.g., modeling/simulation, machine learning, digital health tools), big data and real-world evidence to facilitate drug development and advance precision medicine. Before joining FDA, Dr. Liu was a senior pharmacokineticist at Merck & Co. Inc. She obtained her Ph.D. degree in Pharmaceutics and a concurrent Master's degree in Statistics from the University of Florida. In addition, she has a Master's degree in Pharmaceutics and a Bachelors' degree in Clinical Pharmacy from West China University of Medical Sciences.