Leveraging Clinical Pharmacology to Optimize Drug Development for Nonalcoholic Steatohepatitis (NASH) and Cholestatic Liver Diseases

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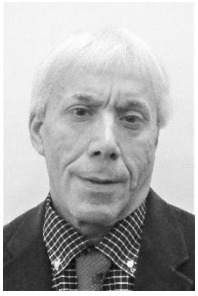
Speaker Biographies

Manal F. Abdelmalek is tenured Professor of Medicine in the Division of Gastroenterology and Hepatology and Director of the Nonalcoholic Fatty Liver Disease (NAFLD) Clinical Research Program at Duke University. She received training in Internal Medicine, Gastroenterology and Hepatology at the Mayo Clinic, Rochester, MN and obtained a MPH degree with emphasis in epidemiology, public health and clinical investigation at the University of Florida, Gainesville, Florida. Since first reporting on nonalcoholic steatohepatitis (NASH) as a cause of cryptogenic cirrhosis nearly 25 years ago, her clinical and research area of interest have been in the field of NAFLD, its associated risk factors for disease acquisition and progression and the discovery of novel approaches to treatment. She has expertise in the design and conduct of clinical trials in NAFLD/ NASH including investigator-initiated, industry sponsored and NIH-funded clinical studies evaluating new therapies and biomarkers for NASH. She collaborates extensively to translate new compounds to first-in-man clinical studies and translate clinic-to-bench and bench-to-clinic research to define pathogenic mechanisms underlying NAFLD acquisition and progression. Dr. Abdelmalek is a Fellow of American College of Physicians, American College of Gastroenterology and American Association for the Study of Liver Disease. She is a standing member of NASH Clinical Research Network (NASH CRN). She has over 150 publications authored publications in the field of liver disease, the majority of which are in the area of NAFLD/NASH.

Carol Addy joined GENFIT (Loos, France; Cambridge, MA) as Chief Medical Officer in September of 2019. In that position, she drives medical strategy of the company, including clinical development and medical affairs. She has spent over 20 years in the in the healthcare industry, including 15+ years spent in Diabetes and Endocrinology at Merck Research Laboratories where she lead early and late stage clinical programs for the development of novel therapeutics in obesity, diabetes and women's health. Prior to joining GENFIT, she was the Chief Medical Officer of HMR Weight Management Services, a subsidiary of Merck that provides intensive lifestyle-based behavioral intervention for the treatment of obesity. Carol earned her Doctor of Medicine (MD) degree and completed her Internal Medicine training at University of Massachusetts. She went on to complete a fellowship in Endocrinology & Metabolism at Brigham and Women's Hospital (Boston, MA) and to earn a Masters of Medical Science (MMSc) degree in clinical research from Harvard Medical School.

Varun Aggarwal holds a Bachelor of Technology in chemical engineering from the Indian Institute of Technology, a PhD in Chemical Engineering from the University of Florida, and trained as a post-doc at Shire Pharmaceuticals, where he remained employed as a scientist in the DMPK department. Varun is currently employed as the Scientific Director for Digital and Precision Medicine, as part of C-Path's Quantitative Medicine Program. He has extensive expertise in quantitative systems pharmacology, mechanistic modeling of cellular biology, and physiology-based pharmacokinetic modeling.

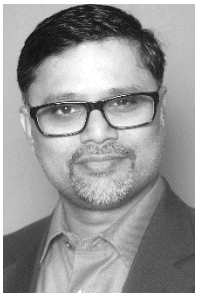
Frank Anania is currently an Acting Clinical Team Leader for hepatology products in the Division of Gastroenterology and Inborn Errors Products in the Office of New Drugs at the FDA. He joined the Agency in early 2018 as a medical officer after spending his entire career in academic medicine as a physician-scientist. Prior to joining the Agency, Frank held the R Bruce Logue Chair in Medicine and was the Director of the Division of Digestive Diseases at Emory University School of Medicine. Frank's basic research career focused on mechanisms of hepatic fibrogenesis particularly related to mechanisms in non-alcoholic fatty liver diseases (NAFLD). He also published other research related to the study and treatment of NAFLD, including an early paper in 2006 citing the beneficial use of glucagon-like peptides for the eradication of hepatic steatosis. In addition to liver research, Frank cared for pre- and post-liver transplant patients. He continues to teach trainees and care for patients at the NIH Clinical Center where he holds an appointment as a special volunteer in recognition of his many contributions to the field of Hepatology.



Mark Avigan is Associate Director for Critical Path Initiatives in the Office of Pharmacovigilance and Epidemiology at the Food and Drug Administration. As a clinical hepatologist with expertise both in drug safety science and cellular regulation, he served as a division director at FDA in drug safety and more recently as an expert consultant for the evaluation of risk surrounding drug-induced liver injury during the life-cycle of drugs and biological agents. Prior to joining FDA, Dr. Avigan served as a clinical staff fellow at the NIH and then became a faculty member at the Georgetown University Medical Center where he attended patients on the GI/Liver Service. At Georgetown he was the principal investigator and leader of a NIH-funded program to elucidate basic mechanisms in the transcriptional and post-transcriptional regulation of pathways critical for cellular growth and differentiation. He has been a long-standing member of the Drug Safety Oversight Board at the agency's Center for Drug Evaluation and Research. Dr. Avigan has authored or co-authored more than 140 scientific publications, book chapters and professional meeting abstracts. He continues to have an active role in public-private partnerships that support enhancement in the scientific and clinical analysis of hepatotoxicity associated with pharmaceuticals & biological agents.

Michael Badman is a Senior Translational Medicine Expert at Novartis Institutes of BioMedical Research, where he has led the FXR early clinical development program since 2012. Prior to joining Novartis, Michael was head of Acute Medicine at the Hammersmith Hospital, London, where he performed clinical research in peptide regulation of appetite. Michael obtained both his MA and DPhil in Physiological Sciences from the University of Oxford, UK and subsequently trained in Clinical Medicine at Newcastle and Imperial College London. During his post-doctoral fellowship, Michael defined the physiological role of Fibroblast Growth Factor 21 whilst working in the laboratory of Prof Maratos-Flier at Harvard. As a specialist in

Endocrinology, Diabetes and General Internal Medicine, Michael has a longstanding interest in obesity and metabolic liver disease.



Anand Balakrishnan is a clinical pharmacology reviewer in the Office of Clinical Pharmacology at FDA. In his current role he is responsible for the review of submissions relating to GI/Liver indications team covering both small molecules and biologics. Dr. Balakrishnan joined the Agency in November of 2015. Prior to joining the FDA, he spent 12 years in the pharmaceutical industry (Merck and Bristol-Myers Squibb) with experience in early discovery, preclinical development, and clinical development. Over his 15+ years career in pharmaceutical research and development, Dr. Balakrishnan has worked in multiple therapeutic areas (Neuroscience, GI and liver disorders, Oncology, Dermatology, Ophthalmic diseases) covering multiple therapeutic modalities (small molecules, oligonucleotides and therapeutic proteins). He received his Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore in 2005 with a research focus on drug transporters and prodrugs.

Abbas Bandukwala graduated from Vanderbilt University as a Biomedical Engineer. He then served 5 years as a United States Naval Officer. He completed his Masters Degree in Chemical Engineering from University of Maryland. He joined the FDA in 2009 in the Center of Devices and Radiological Health (CDRH), and reviewed pre-market applications for light based devices. In 2017, he moved from CDRH and became part of the Center Drug Evaluation and Research (CDER) Biomarker Qualification Program (BQP).

Art Bergman is a Senior Director of Clinical Pharmacology, Early Clinical Development at Pfizer, Inc. In this role, Art supports the early clinical development portfolio for the Internal Medicine Research Unit within Pfizer, specializing in metabolic diseases and NASH. Art has 20 years of experience in the pharmaceutical industry and has supported development programs across the gamut of the clinical development spectrum ranging from preclinical stages to post-marketing support. Art's areas of interest include designing phase 1 development strategies that integrate understanding of target engagement along with PK, safety and tolerability assessments to quantitatively inform design of phase 2 and 3 clinical studies, including patient and dose selection. Art is an advocate for model informed drug development, leveraging traditional PK/PD modeling, semi-mechanistic, quantitative systems pharmacology models and model-based meta analysis, as appropriate, to inform expected clinical response, study design and programmatic decisions.

Kim Brouwer is Associate Dean for Research and Graduate Education, UNC Eshelman School of Pharmacy, and Kenan Distinguished Professor in the School of Pharmacy and Curriculum in Toxicology at the University of North Carolina at Chapel Hill. Her research program (supported by NIH since 1991) is focused on hepatobiliary drug disposition, hepatic transport proteins, and development/refinement of in vitro models to predict in vivo hepatic drug disposition, drug interactions, and hepatotoxicity. Dr. Brouwer was founding Director of the UNC Pharmacokinetics/Pharmacodynamics Fellowship Program, and is Co-PI of an NIH-funded Postdoctoral T32 Training Program in Clinical Pharmacology. She has

mentored a diverse group of trainees (44 clinical pharmacology fellows, 28 postdoctoral fellows/visiting scholars, 35 PhD students, and numerous undergraduate/honors students), and published >235 research papers, reviews and book chapters. Dr. Brouwer is co-inventor of B-CLEAR® and co-founder of Qualyst Transporter Solutions, a UNC spin-off company recently acquired by BioIVT. She is a member of the International Transporter Consortium Steering Committee, a member of editorial advisory boards (Clinical Pharmacology and Therapeutics, Clinical and Translational Science, AAPS Journal), and has served as a member of the ASCPT Board of Directors (2014-2017), NIH Pharmacology Study Section (1998-2002), NIH Quantitative and Systems Pharmacology Working Group (2010-2012), and co-Chair of the NICHD Pediatric Transporters Working Group (2012-2015). Dr. Brouwer was recognized as an AAPS Fellow in 1998, received the 2001 PhRMA Foundation Award in Excellence in Pharmaceutics, and the 2018 ASCPT-FDA Abrams Award. In 2009, Dr. Brouwer was named a Kenan Distinguished Professor, one of the highest honors bestowed on UNC faculty. She was distinguished as the 2019 UNC Inventor of the Year.

Roberto Calle is Executive Director in the Clinical Research group at Pfizer - Internal Medicine Research Unit in Cambridge, MA. He is an endocrinologist with experience in early and late drug development, and translational medicine. Roberto received his medical degree from the University of Puerto Rico School of Medicine. He subsequently trained in Internal Medicine at the University of Michigan Health System and then completed a research fellowship in Endocrinology and Metabolism at Yale University School of Medicine. Roberto spent 10 years in academia before joining industry. Roberto is currently Industry Co-chair of the Metabolic Disorders Steering Committee of the Foundation for the National Institutes of Health Biomarkers Consortium, and Co-Chair of NIMBLE [Non-Invasive BioMarkers of MetaBolic Liver DiseasE], a pre-competitive consortium project for qualification of non-invasive biomarkers for NASH.

Patrizia Cavazzoni is the deputy director for operations at the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). Dr. Cavazzoni received her medical degree at McGill University and completed a residency in Psychiatry and a fellowship in mood disorders at the University of Ottawa. She subsequently joined the faculty of medicine at the University of Ottawa as an assistant professor, where she was engaged in clinical work, teaching, and research on genetic predictors of mood disorders, authoring numerous peer-reviewed scientific publications. Following this, Dr. Cavazzoni worked in the pharmaceutical industry for several years, and held senior leadership positions in clinical development, regulatory affairs and safety surveillance. Dr. Cavazzoni is certified by the American Board of Neurology and Psychiatry, a Fellow of the Canadian Royal College of Physician and Surgeons, a member of the Canadian College of Neuropsychopharmacology and recipient of the American College of Psychiatrists' Laughlin Fellowship.

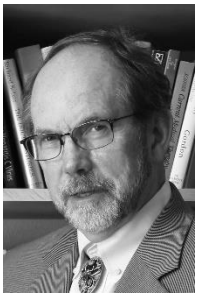
Naga Chalasani currently serves as David W. Crabb Professor of Medicine and Associate Dean for Clinical Research at Indiana University School of Medicine. He is the Director of the Division of Gastroenterology and Hepatology at the same institution. He completed his medical education in India and subsequently completed Internal Medicine Residency and Gastroenterology & Hepatology subspecialty training at Emory University in Atlanta. Dr. Chalasani is considered an authority in the fields of nonalcoholic fatty liver disease (NAFLD) and drug induced liver injury (DILI), two highly significant public health problems. He has been continuously funded by the National

Institutes of Health since 1999. He is currently the PI for three U01 awards and an R01 award from the National Institutes of Health. He published over 350 original papers, 3 Practice Guidelines, 47 book chapters/review articles, 31 editorials/commentaries, 16 symposium proceedings, and more than 500 abstracts. He has co-edited a textbook with Prof. Gyongyi Szabo titled 'Alcoholic & Nonalcoholic Fatty Liver Disease – Bench to bedside' (Springer 2015). He is an elected member of the American Society of Clinical Investigation (ASCI) and the American Association of Physicians (AAP).

Ajit Dash is an Associate Medical Director at Genentech, where he oversees safety strategy for various programs across different therapeutic areas including non-alcoholic steatohepatitis (NASH), and leads cross-functional teams for hepatic safety and drug induced liver injury (DILI) biomarkers. He represents Genentech on IQ-DILI, a pharmaceutical industry consortium on drug induced liver injury where he currently serves as the co-chair elect. Prior to joining Genentech, Dr. Dash was a Senior Scientific Director at HemoShear Therapeutics, Charlottesville, VA, where he led the development of a translational human liver tissue platform for investigative toxicology, and drug discovery applications in NASH and rare inborn errors of metabolism. Ajit received his MD degree from KEM Hospital, Mumbai, India, and a Ph.D. in Molecular Toxicology from the Massachusetts Institute of Technology (MIT), Cambridge, MA.

Lara Dimick-Santos graduated Cum Laude from Eastern Virginia Medical School and completed a five-year general surgery residency at Eastern Virginia Graduate School of the Medical College of Hampton Road. Dr. Dimick then joined a private practice general surgery group in Norfolk. She became the managing partner of the clinical practice and Chairman of the Department of Surgery at DePaul Hospital in Norfolk. In 2005, Dr. Dimick moved to Maryland and assisted with the start of a general surgery hospitalist program at Anne Arundel Medical Center in Annapolis. This program was the second of its kind in the US at that time. Dr Dimick joined the FDA in 2009 and has been involved in the promotion of drug development for non-viral liver diseases since that time. She has been a Co-chair for three joint public workshops with the FDA and the American Association for the Study of Liver Diseases (AASLD): the Nonalcoholic Steatohepatitis, Liver Fibrosis and Cirrhosis Endpoints meeting in September 2013, the Trial Design and Endpoints for Primary Sclerosing Cholangitis meeting in March 2016, and the Trial Design and Endpoints for Alcoholic Hepatitis and Alcohol Associated Liver Disease in March 2018. She is participating in several working groups related to drug development in liver disease, including The Liver Forum, The PSC Forum and The NIMBLE biomarker working group. Dr. Dimick is participating in a committee to update the FDA guidance on drug-induced liver injury.

Jeffrey E. Edwards has over ten years of industrial experience in clinical and preclinical pharmacokinetics and pharmacology. He received a BS in Chemistry from James Madison University and then earned his Doctorate in Toxicology at University of Kentucky in the lab of Patrick J. McNamara. After completing his post-doctoral work at North Carolina State University, Dr. Edwards began his industrial career in pharmacokinetics and pharmacology at Arena Pharmaceuticals, Inc. followed by Amylin Pharmaceuticals, LLC. Most recently, Dr. Edwards serves as the Executive Director of Clinical Pharmacology at Intercept Pharmaceuticals, Inc.



Gregory T. Everson is an Emeritus Professor of Medicine and the former Director of Hepatology at the University of Colorado School of Medicine. Dr. Everson received his MD degree in 1976, from Weill-Cornell Medical College, New York, New York, had residency training in Internal Medicine at Creighton University School of Medicine, Omaha, NE, and fellowship training in Gastroenterology at the University of Colorado School of Medicine, Denver, CO. He is board-certified through the American Board of Internal Medicine in Internal Medicine, Gastroenterology, and Transplant Hepatology. Dr. Everson is an expert in Hepatology and Liver Transplantation. His research interests have encompassed the treatment of viral hepatitis, mechanisms of cholesterol gallstone formation, hepatic cholesterol metabolism, metabolic complications of liver transplantation, and quantification of liver function in humans. He has contributed more than 700 original manuscripts, reviews, chapters, abstracts, presentations and editorials in various scientific meetings and journals, including The New England Journal of Medicine, Hepatology, Gastroenterology, Liver Transplantation, and most major textbooks on liver diseases. With his patient, Hedy Weinberg, he published several books/editions to inform patients and families, such as Living with Hepatitis C: A Survivor's Guide. He was instrumental in starting patient advocacy groups, such as HepC Connection and PSC Partners. Dr. Everson has served on the editorial boards of numerous journals and is a member of several professional societies and boards. He is the inventor of the HepQuant technology, and with Randy Dietrich, co-manages HepQuant LLC with a goal to bring quantitative liver function testing to the clinic.

Claudia Filozof is Vice President and Liver Therapeutic Area Head in Covance LabCorp. She is board certified in Nutrition and Metabolism and has 20 years of experience in academic roles in metabolic disorders. She served as director of the postgraduate course of obesity in the John F Kennedy University in Buenos Aires, was Vice president of the Argentine Society of Obesity (SAO) and the Editor-in-Chief of the SAO Journal. She was a member of the IASO (International Association for the Study of Obesity) award Committee, member of the first WHO Task Force in obesity and a member of the initial editorial board of the prestigious international journal "Obesity Reviews". Dr Filozof started Pharma career in 2004 leading development programs in obesity, diabetes and most recently NAFLD/NASH. She has been actively involved with the NASH community since 2011, being an active member of the Liver Forum. Dr Filozof joined Covance in 2014 and is currently consultant and responsible for the scientific and medical oversight of 15 ongoing NAFLD/NASH projects. Dr Filozof has published multiple manuscripts in obesity and metabolism, most recently 4 review articles on drug development in NASH.

John Franc has served as Vice President External Scientific Affairs and Global Project Lead for Madrigal Pharmaceuticals since September 2016. Prior to joining Madrigal, Mr. Franc served as Senior Director Project Management of VIA Pharmaceuticals from 2007 to 2011, and Director Global Project Management of Daiichi Sankyo from 2011 to 2016. In those positions, Mr. Franc oversaw Phase I and II proof of concept NASH clinical trials and global Phase III registrational trials and development for several cardiovascular and metabolic disease projects, including the Factor Xa inhibitor, edoxaban, and platelet inhibitor, prasugrel. Mr. Franc has more than 35 years of experience in the biopharmaceutical industry leading cross-functional development teams. From 1986 through 2007, Mr. Franc worked at Bristol-Myers Squibb, in a variety of positions of increasing responsibility, including Process Chemistry, Drug Metabolism and Pharmacokinetics, Clinical

Pharmacology, Global Project Management and Corporate Strategy. Mr. Franc received his B.S. in Chemistry from Carnegie Mellon University and M.B.A. from Syracuse University.

Saurabh Gupta is a translational medicine expert with more than 10 years of experience in drug development and clinical biomarker strategies across multiple therapeutic areas specifically fibrosis, stem cell therapies, cardiovascular-metabolics, CNS, rare diseases and endocrinology. Presently he is leading translational medicine and biomarker strategies in GI, and number of rare disease programs at Takeda Pharmaceuticals International Co., Boston, USA. He has successfully identified and implemented target engagement, MOA, disease, safety, patient stratification biomarkers for in different phases of clinical trials. His research experience expands both in industry and academics across continents in diverse working environments. He has more than 40 peer-reviewed publications, numerous invited talks and presentations in international congresses. He has been reviewer/guest editor for number international journals including Nature Reviews Neuroscience, British Journal of Pharmacology, Cephalalgia, Headache, Journal of Cardiovascular Pharmacology and Vascular Pharmacology.

Dilara Jappar is a clinical pharmacology reviewer at the FDA in the Office of Clinical Pharmacology under the Office of Translational Science. She has obtained her Ph.D. degree in Pharmaceutical Sciences from the University of Michigan in 2009. Since then, she has joined the FDA and reviewed numerous IND and NDA drug application in gastrointestinal, liver and in-born error disease therapeutic areas. Her daily responsibilities include evaluating scientific approaches and methodologies used for clinical pharmacology studies and providing scientific and regulatory advices and guidance to address a variety of questions related to clinical pharmacology issues during drug development.

Insook Kim is a clinical pharmacology team leader in the Office of Clinical Pharmacology at FDA and is responsible for gastroenterology and hepatology products. Since Dr. Kim joined FDA as a clinical pharmacology reviewer in 2007, Dr. Kim has been involved in numerous IND and NDA reviews of clinical pharmacology information for gastroenterology, inborn errors of metabolism, and non-viral liver products. Prior to joining FDA, Dr. Kim earned a doctorate degree in Pharmaceutics from the University of Michigan and conducted post-doctoral research on the roles of FXR on bile acid homeostasis using transgenic animal models at National Cancer Institute at NIH. Dr. Kim's area of interest is the translational sciences for drug development.

Shen (Steven) Li is currently a Clinical Pharmacology Reviewer in the Division of Inflammation and Immune Pharmacology (DIIP), Office of Clinical Pharmacology (OCP) at the US Food and Drug Administration (FDA). Dr. Li has over 14 years of regulatory and industry experience in clinical drug development. Since 2015, he has been the clinical pharmacology reviewer in OCP, while focusing on the reviews of IND, NDA, and BLA submissions for the liver, gastroenterology, and in-born error drug products as well as carrying out related research in the Center for Drug Evaluation and Research (CDER)/FDA. Dr. Li received his Ph.D. in Pharmaceutical Sciences from the University of Tennessee, College of Pharmacy. He also obtained M.D. and M.S. in Clinical Medicine from Tianjin Medical University in China.

Ruby Mehta is a medical officer in the Division of Gastroenterology and Inborn Errors Products (DGIEP) at FDA's Center for Drug Evaluation and Research where she performs clinical reviews of products intended for the treatment of liver diseases such as nonalcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), pediatric & rare liver diseases etc. She is board certified in Pediatrics, Pediatric Gastroenterology, and Pediatric Transplant Hepatology. Her prior clinical experience includes being an Assistant Professor and staff physician at University of Tennessee and LeBonheur Children Hospital and staff physician at St. Jude's Medical Center, Memphis, TN, where she was involved in the diagnosis and management of patients with gastrointestinal, pancreatic and liver disorders. Her current work encompasses the clinical review and regulation of medical products for liver diseases and engagement with external stakeholders including industry, academia, and patient groups to facilitate and accelerate drug development for rare diseases with unmet medical needs.

John Michael Sauer is a toxicologist by training with over 15 years of experience in drug discovery and development. He has been responsible for leading multiple functional areas across several pharmaceutical companies. He is dedicated to bringing quantitative translational science approaches to safety assessment, as well as transforming the way we use nonclinical safety data to drive clinical study design and data interpretation. John Michael has over 100 scientific publications in the areas of toxicology, drug metabolism, clinical pharmacology, pharmacokinetics, pharmacology and translational science. Prior to joining C-Path in 2013, John Michael had the opportunity to play an individual contributor role at Eli Lilly where he participated in the development, registration, and commercialization of Strattera for the treatment of ADHD in children and adults, as well as supported many other discovery and development teams. He also played a pivotal leadership role in the transformation of Elan Pharmaceutical's discovery and development strategies including the incorporation of several quantitative translational science approaches. John Michael also gained operational and management experience in the Contract Research Organization environment as the Site Scientific Head for the Covance Chandler site in Arizona. John Michael received his undergraduate and Master's degree in Biomedical Sciences at Western Michigan University and his Doctorate degree in Pharmacology and Toxicology from The University of Arizona. Currently, John Michael is the Program Officer of Biomarkers Program at the Critical Path Institute, as well as an Adjunct Research Professor in the Department of Pharmacology at the University of Arizona, College of Medicine.

Robert Schuck is a Clinical Pharmacologist in the Division of Translational and Precision Medicine at the FDA. In his current position, Dr. Schuck contributes to regulatory review of investigational new drug (IND), new drug (NDA), and biologic licensing (BLA) applications to effectively utilize genomic- and biomarker-based strategies in drug development and regulatory evaluation. He is also involved in regulatory policy development and translational research projects that advance the FDA's mission to protect and promote public health. Prior to joining the FDA in 2013, Dr. Schuck received his Pharm.D. from the University of Michigan College of Pharmacy in 2008 then completed his Ph.D. in Pharmaceutical Sciences at the University of North Carolina Eshelman School of Pharmacy in 2013.

Shirley K. Seo is currently the director of the Division of Cardiometabolic and Endocrine Pharmacology in the Office of Clinical Pharmacology at the FDA. She obtained her Ph.D. in pharmaceutics at The University of Texas at Austin where her research focus was in drug metabolism and immunopharmacology. Dr. Seo began her career at the FDA in 2004 in the Office of Generic Drugs. In 2007, she joined the Office of Clinical Pharmacology and in 2012, she was selected as a team leader for antiviral products. In her previous role as a team leader and currently as division director, Dr. Seo has been involved in IND and NDA analysis and review, interpreting regulations, and providing guidance on drug development programs. Her areas of scientific and regulatory interest include: complex drug interactions, pediatric clinical pharmacology, women's health issues, and drugs being developed for medical countermeasures. She also has a passion for mentoring.

Scott Q. Siler is the Chief Scientific Officer of DILIsym Services, Inc. and Co-Director of the DILI-sim Initiative. Dr. Siler graduated with a Ph.D. in Nutrition from the University of California, Berkeley and worked for more than 12 years integrating physiology and mathematics and applying quantitative systems pharmacology (QSP) models to pharmaceutical drug development with the company Entelos. As a Principal Scientist at Entelos, he oversaw and contributed to the development of the Metabolism PhysioLab. Moreover, he led multiple projects with pharmaceutical partners, evaluating potential treatments for type 2 diabetes. Also during his time with Entelos, Dr. Siler oversaw the early development efforts of what would become the current DILIsym software. Upon leaving Entelos in 2011, Dr. Siler became Co-Director of the DILI-sim Initiative and later the Chief Scientific Officer of DILIsym Services. Over this time, he has continued working on advancing the DILIsym software in both oversight and technical roles. Dr. Siler has also overseen and contributed to the development of three other QSP models for DILIsym Services, MITOsym®, NAFLDsym®, and IPFsym™. Dr. Siler has given numerous presentations (public and proprietary) about the QSP efforts in addition to co-authoring numerous publications. Combining these experiences, Dr. Siler has a unique combination of expertise in metabolic diseases, liver physiology and hepatocyte health, bioenegertics, and quantitative systems pharmacology that lends itself to the study of drug-induced organ diseases, non-alcoholic fatty liver disease (NAFLD), and metabolic diseases like type 2 diabetes.

Yaning Wang is the Director of the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA. Before joining FDA, Dr. Wang received his Ph.D. in Pharmaceutics and master's degree in Statistics from the University of Florida from 1999 to 2003. He also obtained a master's degree in Biochemistry (1999) from National Doping Control Center and a bachelor's degree in Pharmacy (1996) from Peking University in China. Dr. Wang oversees reviews, research projects, and policy development within the Division of Pharmacometrics for all disease areas. During his sixteen years of service at FDA, Dr. Wang received numerous awards, including Award of Merit and FDA Outstanding Service Award. Dr. Wang is an Adjunct Professor in the Department of Pharmaceutics at the University of Florida and an invited lecturer in the College of Engineering and College of Pharmacy at the University of Michigan. Dr. Wang is a regulatory expert lecturer for American Course on Drug Development and Regulatory Sciences (ACDRS) organized by University of California at San Francisco (UCSF), European Course in Pharmaceutical Medicine (ECPM) organized by University of Basel, and Chinese Course on Drug Development and Regulatory Sciences (CCDRS) organized by Peking University Clinical Research Institute in collaboration with University of Basel and UCSF. Dr. Wang served as a committee member for multiple Ph.D. candidates from various

universities. He mentored more than fifty former research fellows (visiting scholars, post-doctoral scholars, and Ph.D. candidates) at FDA. Dr. Wang has published over 70 papers and given over 200 presentations at various national and international meetings. He served as a board member of the International Society of Pharmacometrics (ISoP) and is a fellow of ISoP. He is a member of the Advisory Committee for Chinese Pharmacometrics Society and a member of the Editorial Advisory Board for the Journal of Pharmacokinetics and Pharmacodynamics.

Duke-Margolis Moderator

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Margolis Center for Health Policy at Duke University. He is a physician economist who focuses on quality and value in health care including payment reform, real-world evidence and more effective drug and device innovation. He is former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration, where he developed and implemented major reforms in health policy. He was previously Senior Fellow at the Brookings Institution and a faculty member at Stanford University.

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