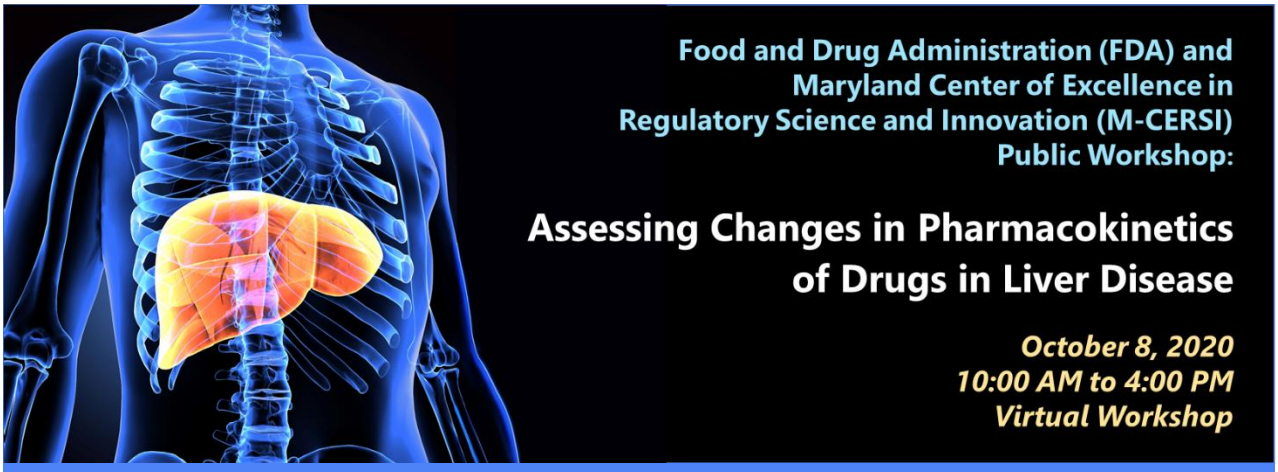
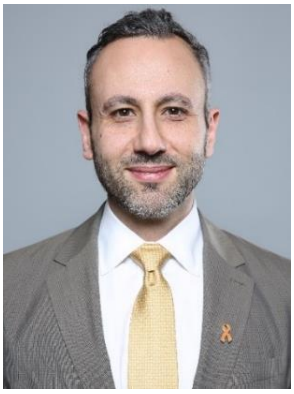


Welcome & Introduction



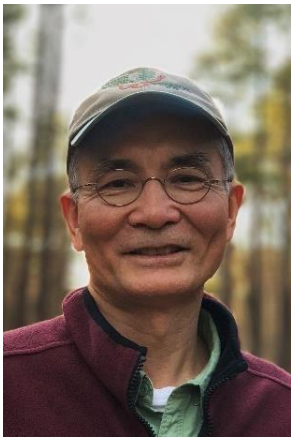
Issam Zineh, PharmD, MPH is the Director of the Office of Clinical Pharmacology (OCP) at the U.S Food and Drug Administration (FDA). He has held various leadership positions at FDA including Associate Director for Genomics in OCP (2008-2012) and Co-Director of the CDER Biomarker Qualification Program (2009-2015), and serves on the CDER Medical Policy Council. Dr. Zineh was formerly on faculty at the UF Colleges of Pharmacy and Medicine and Associate Director of the UF Center for Pharmacogenomics. He is a recognized expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of over 240 regulatory, research, program/project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.

Session 1- Current State: Liver Disease, Hepatic Impairment and Pharmacokinetics (PK)

Moderator: Martina Sahre, FDA

Martina Sahre, PhD is a Policy Lead in the Guidance and Policy Team within OCP/FDA. Her interests are related to the effects of intrinsic factors on drug disposition, such as renal and hepatic impairment, obesity, and age. Prior to that, she was a reviewer in OCP, reviewing cardiovascular and renal drug programs. She received her pharmacy degree from the Free University in Berlin, Germany, and obtained her PhD at the University of Florida.

Naga P. Chalasani, MD currently serves as the David W. Crabb Professor of Medicine and Interim Chair of the Department of Medicine at the Indiana University School of Medicine. He previously served as the Director of the Division of Gastroenterology and Hepatology at the same institution from 2007 to 2020. He completed his medical education in India and subsequently completed Internal Medicine Residency and Gastroenterology & Hepatology subspecialty training at Emory University in Atlanta. His research interests include CYP450 enzymes and liver disease and the hepatic safety of xenobiotics. His research 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 300 original papers, 3 Practice Guidelines, 47 book chapters/review articles, 31 editorials/commentaries, 16 symposium proceedings, and more than 500 abstracts. He is the lead author for the American Association for the Study of Liver Diseases (AASLD) Practice Guideline on the Diagnosis and Management of Nonalcoholic Fatty Liver Disease and is the lead author on the American College of Gastroenterology (ACG) Practice Guideline on the Diagnosis and Management of Drug Induced Liver Injury. He is an elected member of the American Society of Clinical Investigation (ASCI) and the American Association of Physicians (AAP).



Paul "Skip" H. Hayashi, MD, MPH, FAASLD recently joined the FDA and is an adult hepatologist and medical officer in the Division of Hepatology and Nutrition, Office of New Drugs (OND)/FDA. Prior to joining the FDA, he trained and held positions in academia, as well as public and uniformed services. He received his BA in microbiology at UCLA and medical degree at UC San Diego. After completing his residency and gastroenterology fellowship at UC Davis in Sacramento, California, he joined the public health service to complete a clinical research fellowship in the Liver Diseases Section, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH in Bethesda, Maryland. He then returned to California as Assistant Professor at the VA hospital in Loma Linda, California followed by serving in the US Air Force Medical Corp in Japan and Texas. While in the Air Force he continued clinical research, but fully returned to academia by completing a transplant fellowship at the University of Colorado in Denver and a Master of Public Health at Saint Louis University (SLU), St. Louis, Missouri. He was also an Assistant Professor and transplant hepatologists at SLU. In 2006, he became Medical Director of Liver Transplantation at the University of North Carolina (UNC), Chapel Hill, serving in that capacity as Associate and then full Professor before joining the FDA in 2020. His research interests include cirrhosis epidemiology and management, transplant outcomes, and drug-induced liver injury with the latter becoming his primary focus. He was Co-Principle Investigator for UNC's Drug-Induced Liver Injury Network (DILIN) site and remains Co-Chair of the DILIN's Causality Committee.

Tiffany Kaiser, PharmD received her Doctor of Pharmacy from The Ohio State University and completed a pharmacy practice residency at the University of Illinois at Chicago and a specialty residency in solid-organ transplantation at the University of Cincinnati. Currently, she is an associate professor of medicine in the division of digestive disease and an adjunct professor at the college of pharmacy at the University of Cincinnati. She practices as a transplant clinical pharmacist, Director of the Transplant Quality Program and Assistant Director of the PGY2 transplant residency program.

Guadalupe Garcia-Tsao, MD is a Professor of Medicine at Yale School of Medicine (Digestive Diseases), the Chief of the Section of Digestive Diseases at the Veterans Administration Connecticut Healthcare System and Director of the Clinical Core of the Yale Liver Center. Dr. Garcia-Tsao is a leading expert on cirrhosis, portal hypertension and related complications. Her research has been mainly patient-oriented research, and she has authored over 150 PubMed-verified original research publications that have been cited over 35,000 times, with an H-index of 86 (Google Scholar, August 2020). Dr. Garcia-Tsao served as the President of the American Association for the Study of Liver Diseases in 2012 and is currently Associate Editor for the New England Journal of Medicine. She has received numerous awards including the International Recognition Award (European Association for the Study of the Liver) and the Distinguished Clinician Educator and Mentor Award (American Association for the Study of Liver Diseases).

Patrick S. Kamath, MD is a Professor of Medicine and Consultant in the Division of Gastroenterology and Hepatology, Department of Internal Medicine at Mayo Clinic. Dr. Kamath's research interests focus on acute-on-chronic liver failure, nonalcoholic fatty liver disease, polycystic liver disease, Budd-Chiari syndrome and hereditary hemorrhagic telangiectasia. Dr. Kamath also studies alcoholic hepatitis, cirrhosis and the complications thereof, including portal hypertension, variceal hemorrhage, ascites and hepatic encephalopathy. For patient care, Dr. Kamath works to improve understanding of the mechanisms and complications of liver disease, in the hopes of developing new strategies of prevention and treatment that will improve quality of life and overall outcomes for patients with various liver diseases. The Model For End-Stage Liver Disease (MELD) score that he helped develop is used worldwide as a prognostic score for liver disease. His current focus is on finding ways to improve survival in patients with acute-on-chronic liver failure. He is also dedicated to the education of the next generation of physicians, who will further advance this work.

Stacy S. Shord, PharmD, BCOP, FCCP is currently an Associate Director for Labeling in the Office of Oncologic Diseases at the FDA. Dr. Shord received her Doctor of Pharmacy from the University of Maryland School of Pharmacy in 1997. She then completed a Pharmacy Practice residency at the University of Pittsburgh Medical Center, an Oncology Pharmacy Practice residency at UNC Hospitals, and a fellowship in Oncology Pharmacotherapy at the UNC Eshelman School of Pharmacy. Dr. Shord joined the faculty at the University of Illinois at Chicago College of Pharmacy in 2001 as an assistant professor where her research focused on drug metabolism in patients with cancer and hematological diseases. She joined the FDA in 2009 and served as a primary reviewer and Lead Pharmacologist in OCP. Special interests included the clinical development of antibody drug conjugates and epigenome targeted drugs. Dr. Shord earned her Board Certification in Oncology Pharmacy in 2000. She has authored 51 peer reviewed papers and 12 book chapters. Dr. Shord is a member of the American College of Clinical Pharmacy and Hematology Oncology Pharmacists Association.

Lara Dimick-Santos, MD joined the FDA in 2009 and has been a major driver in the promotion of drug development for metabolic (fatty) liver disease since that time. Dr. Dimick was pivotal in the development of clinical benefit and surrogate endpoints for clinical trials in nonalcoholic steatohepatitis (NASH) that promoted the expansion of drug development for this disease. She was Co-chair for the joint public workshop with the FDA and the American Association for the Study of Liver Diseases (AASLD) entitled “Nonalcoholic Steatohepatitis, Liver Fibrosis and Cirrhosis Endpoints” meeting in 2013. She was a founding steering committee member with The Liver Forum when it was established in 2014 and continues to be actively involved on the steering committee. She was actively engaged in the development of the current draft FDA guidance on *Developing Drugs for Treatment for the Noncirrhotic NASH with Liver Fibrosis*. Dr. Dimick is also a member of the steering committee for the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) biomarker working group. She has been happy to see a large expansion in number of clinical trials for metabolic liver diseases over the last 10 years.

Session 2- New Insights on Identification and Classification of Hepatic Impairment for the Purpose of Assessing PK Changes in Liver Disease

Session Moderator: Insook Kim, FDA

Insook Kim, PhD is the clinical pharmacology team leader for gastroenterology and hepatology products in OCP/FDA. After joining the FDA as a clinical pharmacology reviewer in 2007, Dr. Kim has been heavily involved in IND and NDA reviews for gastroenterology, inborn errors, and non-viral liver products, providing regulatory and scientific guidance on drug development programs including pediatrics and rare diseases. Prior to joining the FDA, Dr. Kim earned a doctorate degree in Pharmaceutics from the University of Michigan and conducted post-doctoral research on nuclear receptors focusing on the roles of FXR on bile acid homeostasis at National Cancer Institute at NIH. She earned a master's degree in Pharmacy from Seoul National University, and a bachelor's degree in Pharmacy from Ewha Womens University in Korea. Dr. Kim's area of interest is the translational sciences for drug development.

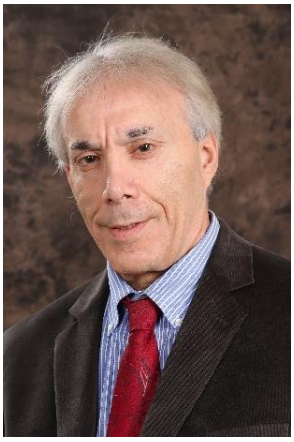
John Clarke, PhD is currently an Assistant Professor in the department of Pharmaceutical Sciences at Washington State University Health Sciences campus in Spokane, WA. Dr. Clarke received his PhD in Molecular and Cellular Biology from Oregon State University. He completed a five-year postdoctoral fellowship in the department of Pharmacology and Toxicology at the University of Arizona. His research interests and expertise are focused on elucidating the mechanisms of inter-individual variability in xenobiotic metabolism, disposition, and toxicity. This includes research with environmental contaminants and pharmaceuticals. He has been funded through the Department of Defense pre-doctoral fellowship program and through National Institute of Environmental Health Sciences (NIEHS)-funded Southwest Environmental Health Sciences Center pilot project and career development awards. Dr. Clarke is currently funded through an NIEHS-funded R00 focused on the mechanisms of microcystin disposition and toxicity in the context of nonalcoholic fatty liver disease and an NCCIH funded R21 elucidating the transporter mediated interactions perpetrated by goldenseal and green tea. He currently serves as Senior Councilor in the Society of Toxicology Mechanisms Specialty Section.

Cara H. Nelson, PhD is a Director of Clinical Pharmacology at Gilead Sciences, Inc., Foster City, CA. Dr. Nelson has more than seven years of industry experience in clinical pharmacology and has been involved in the design and analysis of numerous Phase 1 studies for small molecules, including several hepatic impairment studies. She has worked in a variety of therapeutic areas including oncology, cardiovascular disease, inflammatory diseases, and liver fibrosis. Dr. Nelson has recently joined the IQ Organ Impairment Working Group. Dr. Nelson received her MS in Nutrition from Iowa State University and her PhD in Pharmaceutical Sciences from University of Michigan. After receiving her PhD, Dr. Nelson was a post-doctoral research associate at the University of Washington in the Department of Pharmaceutics prior to joining industry.

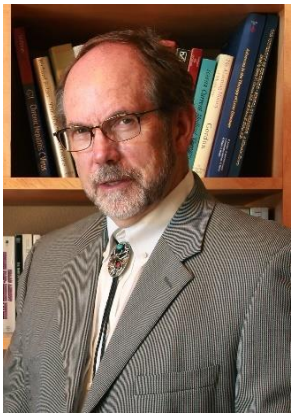
Nathan J. Cherrington, PhD is a Professor and 1885 Society Distinguished Scholar in the Department of Pharmacology and Toxicology. He is the Associate Dean for Research and Graduate Studies in the College of Pharmacy at the University of Arizona. He is also the Director of the Southwest Environmental Health Sciences Center and the Interim Director of the Arizona Board of Regents Center for Toxicology. He received a BS in Zoology from Brigham Young University and a PhD in Toxicology from North Carolina State University with an emphasis on xenobiotic metabolism. He then moved to the University of Kansas Medical Center to pursue postdoctoral training in drug metabolism and disposition. He has taught Drug Metabolism and Disposition, Systems Toxicology, Environmental Health Science, and Advanced Toxicology courses since joining the faculty at the University of Arizona in 2002. Nathan has published over 110 original research papers on the sources of inter-individual variability in drug response. He serves as an associate editor for Toxicological Sciences and is on the editorial board of Drug Metabolism and Disposition. He has served on numerous NIH study sections including chair of the NIEHS Environmental Health Sciences Review Committee and Severe Adverse Drug Reactions panel, as well as several committees for the Society of Toxicology and the International Society for the Study of Xenobiotics. He was awarded the Achievement Award by the Society of Toxicology and was made a fellow of the Academy of Toxicological Sciences. His current research is on the effect of underlying disease states on an individual's ability to metabolize and eliminate drugs.

Steve M. Helmke, PhD is the Chief Scientific Officer for HepQuant and supervises their analytical Mass Spectrometry (MS) laboratory. He holds degrees in Biochemical Sciences (BA, Princeton University) and Biological Chemistry (PhD, UCLA) and has focused his research on protein biochemistry and quantitative MS in a wide variety of fields with publications in hepatology, pharmacology, neuroscience, cardiology, endocrinology, computer science and analytical chemistry. Dr. Helmke is an inventor on patents for methods to identify neuron growth factors and methods to evaluate liver function, and he has patents pending on a novel therapeutic target for heart failure, new biomarkers for thyroid cancer, and new ways to quantify protein isoforms. Dr. Helmke has developed novel MS techniques to identify and quantify motor protein isoforms, rare transcription factors, and phospho-oncoproteins. After joining Dr. Everson's laboratory, he developed methods to overcome isotopic envelope overlap and accurately quantify the stable isotope labelled cholates used in the HepQuant tests. Dr. Helmke has validated this technology to FDA standards and it has been used in studies of many types of liver disease in order to develop the Disease Severity Index.

Abhay Joshi, PhD is serving as a clinical pharmacology reviewer within the OCP/FDA. Dr. Joshi's training and research background are in the field of pharmacokinetics and its applications in translational and clinical pharmacology sciences. Since joining the FDA, he has contributed to the review of various IND, NDA, and BLA submissions across multiple therapeutic areas. Apart from the review work, he has contributed to various research projects and received recognitions and awards for his contributions at FDA. Additionally, he is serving as the clinical pharmacology subject matter expert on a team that provides oversight to the external research activities in the infectious diseases area. He has also participated in the review of internal regulatory research proposals and external research contracts in the infectious diseases area.



Mark Avigan, MD, CM is the Associate Director for Critical Path Initiatives in the Office of Pharmacovigilance and Epidemiology at the FDA. As a clinical hepatologist with expertise both in drug safety science and cellular regulation, he served as a Division Director at the 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 the FDA, Dr. Avigan served as a staff fellow at the NIH and then became a faculty member at the Georgetown University School of Medicine (GUMC) where he attended patients on the GI/Liver Service. During that period, he led an NIH-funded laboratory as principal investigator to elucidate basic mechanisms in the transcriptional and post-transcriptional regulation of pathways critical for cellular growth and differentiation. He received his medical degree from McGill University and was a medical resident and GI fellow in the Georgetown VA Medical Center. Dr. Avigan is currently an Adjunct Professor of Medicine at the GUMC and is a fellow of the American Association for the Study of Liver Diseases. He has authored or co-authored approximately 140 scientific publications, book chapters, and professional meeting abstracts. He has been a long-standing member of the Drug Safety Oversight Board at the FDA and continues to have an active role in national and international public-private partnerships that support enhancement in the scientific and clinical analysis of hepatotoxicity associated with pharmaceuticals and biological agents.



Gregory T. Everson, MD is the CEO of HepQuant LLC and an Emeritus Professor of Medicine at the University of Colorado Anschutz Medical Campus. He has been involved in clinical investigation related to chronic liver disease for 40 years. The topics covered by his research have included: mechanisms of gallstone formation, biliary and gastrointestinal motility, polycystic liver disease, therapy of chronic hepatitis C, liver transplantation, living donor liver transplantation, and noninvasive measurement of hepatic function. In his academic career, he joined the faculty of the Division of Gastroenterology as an Assistant Professor in 1982, became an Associate Professor in 1988, and became a full Professor with tenure in 1996. From 1987 to 1988, he, along with John Vierling, MD, initiated the program in clinical

Hepatology, and with our surgical and anesthesiology colleagues, Igal Kam, MD, Frederick Karrer, MD, and Charles Laughton, MD, began the second era of liver transplantation at the University of Colorado Denver. When Dr. Vierling left Colorado in 1990, he assumed the dual role of Director of Hepatology and Medical Director of Liver Transplantation. Under his leadership, in conjunction with talented colleagues within Hepatology and Transplant Surgery, the Hepatology and Liver Transplant program rose to become one of the strongest in the United States. While he had continuous NIH funding throughout most of his academic career, in more recent years, his research program shifted more towards clinical trials and industry sponsorship of hepatitis C virus (HCV) disease therapy (Research Support). He has published or presented over 700 papers, chapters, editorials, books, and abstracts related to my research and clinical interests. More recently his studies have focused on the development of quantitative tests of liver function, like the SHUNT and STAT tests and the DISEASE SEVERITY INDEX (DSI), and their use in the assessment of liver disease severity and measurement of liver disease progression and regression. His experience in the use of stable isotopes of bile acids to probe hepatic physiology spans over three decades. In the HALT-C trial, we applied the dual stable isotope labeled cholate clearance test to measure changes in the portal circulation and to quantify portal-systemic shunt. Three papers published in Aliment Pharmacol Ther in 2007, 2008, and 2009 describe the performance characteristics of the dual cholate test, which became the HepQuant SHUNT Test. Most significantly, this test was superior to the gold standard, biopsy histology, and also to other liver function tests in predicting which patients would have future liver-related clinical outcomes. The promise of this new technology led him to found HepQuant, LLC in 2007 with the goal of bringing accurate convenient quantitative liver function testing to the clinic. Although he remains connected to the CU programs in Hepatology and Liver Transplantation (Emeritus Professor of Medicine), he has now transitioned from his academic career to being the full time CEO of HepQuant, LLC to lead the effort toward introduction of HepQuant quantitative liver function testing into the clinic.

Session 3- Current Status of the Role of Physiologically Based Pharmacokinetic (PBPK) Modeling in Characterizing the PK of Drugs in Hepatic Impairment

Moderator: Xinyuan (Susie) Zhang, FDA

Xinyuan (Susie) Zhang, Ph.D. is a physiologically based pharmacokinetic (PBPK) co-lead in the Division of Pharmacometrics (DPM)/ OCP/FDA. She shares responsibility for scientific oversight of PBPK review activities and provides leadership in PBPK-related research in OCP. Dr. Zhang has conducted clinical pharmacology reviews for numerous INDs and NDAs. Prior to joining OCP, Dr. Zhang was a scientific lead for absorption modeling in the Office of Research and Standards (ORS)/ Office of Generic Drugs (OGD)/FDA where she focused on applying PBPK absorption modeling and simulation to address issues in Abbreviated New Drug Application (ANDA) reviews, controlled correspondences, citizen petitions, and bioequivalence guidance development. She received her PhD from the University of Michigan, Ann Arbor.

Ying-Hong Wang, PhD is a senior reviewer in DPM/OCP/FDA. Dr. Wang received her BS in Biochemistry from NanKai University in China, PhD in Molecular and Cellular Biology from Oregon Health Science University in Portland, Oregon, and Clinical Pharmacology Fellowship training in the Division of Clinical Pharmacology at the Indiana University-Purdue University Indianapolis. Before joining the FDA in January 2020, she spent over fourteen years at Merck, where she was responsible for preclinical and clinical development of numerous compounds in multiple therapeutic areas. In addition, she focused her research on the use of PBPK modeling and simulations for the prediction of clinical drug interactions and PK in organ impairment and pediatrics. These activities led to internal guidelines for quantitative prediction of CYP-mediated drug-drug interactions (DDIs), prospective simulations for pediatric trial design, waiver of clinical DDI studies and addressing regulatory questions during IND and NDA submissions. She also represented Merck in the IQ Organ Impairment PBPK Working Group and performed the data analysis for the group.

Stephen D. Hall, PhD is a Senior Research Fellow in the ADME function at Eli Lilly and Co. in Indianapolis. In this role he is responsible for developing new, quantitative preclinical and clinical translational models and has led several PBPK initiatives in the Translational and ADME Leadership Group of IQ. Prior to joining Lilly, Dr. Hall was Professor of Medicine and of Pharmacology and Toxicology at Indiana University School of Medicine and Associate Director of the Division of Clinical Pharmacology and the NIH supported Clinical Pharmacology Training Program. Dr. Hall received a PhD in Pharmacology from the University of Manchester and completed a fellowship in Clinical Pharmacology at Vanderbilt University. Dr. Hall has published over 200 peer-reviewed articles in the fields of pharmacokinetics, drug metabolism and drug-drug interactions.

Viera Lukacova, PhD is Chief Scientist at Simulations Plus, Inc. Over the last decade she has been contributing to the research in the area of mechanistic absorption and PBPK modeling and the development of GastroPlus™, DDDPlus™, and MembranePlus™ software packages widely used throughout the pharmaceutical industry in early drug development, formulation, pre-clinical, and clinical research. She also contributes to modeling studies helping companies with their drug development programs ranging from early discovery stage, through formulation development, and up to clinical pharmacology and interactions with regulatory agencies. She authored a number of papers in computational chemistry, basic research of transport of small molecules through artificial membranes, and pharmacokinetic and pharmacodynamic modeling in peer-reviewed journals and served as a reviewer of publications in the same areas.

Frank A. Anania, MD is currently the Deputy Director of the Division of Hepatology and Nutrition at the FDA. He holds an MD degree from the University of Pittsburgh School of Medicine. He was trained as an Internist at the Hospital of the University of Pennsylvania in Philadelphia, after which he pursued training as a post-doctoral fellow in Gastroenterology and Hepatology at the Johns Hopkins University School of Medicine. Upon completing his training, Anania remained at Hopkins for five additional years as a junior hepatologist in which he pursued research interests to decipher mechanisms of liver fibrosis in the laboratory. He also was trained during this period as a transplant hepatologist and throughout his career cared for patients with all types of liver diseases. Before leaving Hopkins, he published a widely-cited paper in which he and his colleagues described how the adipocytokine hormone leptin played a pivotal role in the deposition of collagen in injured liver. This set the stage for his research interests throughout his career in studying various hypotheses concerning non-alcoholic steatohepatitis, or NASH. Dr. Anania became an Assistant Professor of Medicine at the University of Maryland, Baltimore, School of Medicine from 1999 to late 2003, after which he joined the faculty at Emory University School of Medicine in Atlanta, where he was recruited as an Associate Professor of Medicine and the Director of Hepatology. Anania rose through the ranks at Emory having been awarded numerous federal research grants. He also was one of the first hepatologists to publish the benefits of glucagon-like peptide 1 (GLP-1) analogues for treatment of NASH in 2006. Because of his important research contributions as a physician-scientist, Anania was inducted into the American Society of Clinical Investigation in 2009. Dr. Anania became a full professor with tenure at Emory in 2011, at which time he also became the Director of the Division of Digestive Diseases. In 2013 he became the R. Bruce Logue Chair of the Division. Anania has served on numerous committees for both the American Gastroenterological Association (AGA) and the American Association for the Study of Liver Diseases (AASLD). He carries the distinction of “fellow’ in both organizations reflecting his longstanding contributions to the broad fields of Gastroenterology and Hepatology. In 2017, Dr. Anania was recruited to the Office of New Drugs (OND) by the leadership of the Division of Gastroenterology and Inborn Errors Products (DGIEP) at the FDA. He joined the FDA in early 2018 after which he served as a primary medical reviewer until September 2019 when he was promoted to clinical team leader, a position that became permanent in spring 2020.

Closing Remarks

Joga Gobburu, PhD, MBA is a Professor with the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD, USA. He held various positions at the FDA between 1998 and 2011. He has experience with overseeing the review of thousands of INDs, over 250 NDAs/BLAs, and numerous FDA guidances and policies pertaining to drug approval and labeling. At the FDA, he was part of the committee responsible for 21st Century Review Process and provided input into PDUFA planning. He received numerous FDA awards such as the Outstanding Achievement Award and was recognized with the Senior Biomedical Research Scientist appointment. He also received the Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology (2008) and Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics (2019). He is also a Fellow of AAPS and ACCP. Dr. Gobburu is on the Editorial Boards of several journals. He has published over 100 papers and book chapters.

Acknowledgements

We would like to acknowledge the following people in the planning, organization and participation in this workshop:

- **US FDA:** Daphne Guinn, Martina Sahre, Anuradha Ramamoorthy, Insook Kim, Ruby Mehta, Shirley Seo, Mehul Mehta, Shiew-Mei Huang, Rajanikanth Madabushi, Xinyuan (Susie) Zhang, Lauren Milligan, Kim Bergman, Colleen Kuemmel, & Kirk Roy
- **M-CERSI:** James Polli & Ann Anonsen
- **UMD:** Joga Gobburu
- **All the Speakers, Moderators and Panelists**
- **Registrants and Participants**