Speaker Biographies

In order of presentations (refer to the Agenda)

Leonard Sacks, MD
Director
Clinical Methodologies | Office of Medical Policy
CDER | FDA

Leonard Sacks received his medical education in South Africa, moving to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa, and he joined the FDA in 1998 as medical reviewer in the Office of New Drugs. Subsequent positions included acting director of the Office of Critical Path Programs and associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research. In this capacity he has led efforts to support novel approaches to clinical trials including the use of electronic technology. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented on these topics. He holds academic appointments as Associate Clinical Professor of Medicine at George Washington University, and at the Uniformed Services University of the Health Sciences.

Karen A. Hicks, MD, FACC
Deputy Director
Office of Medical Policy (OMP)
CDER | FDA

Dr. Hicks came to the Division of Cardiovascular and Renal Products in 2003 and has led two large multi-stakeholder initiatives to standardize data collection for cardiovascular trials. In March 2018, the Standardized Data Collection for Cardiovascular Trials Initiative (SCTI) co-published cardiovascular and stroke endpoint definitions for clinical trials in the Journal of the American College of Cardiology (J Am Coll Cardiol 2018;71:1021-34) and Circulation (Circulation 2018;137:961-972). The data standards for these definitions were also co-published in 2015. In 2020, she became the Deputy Director of the Division of Nonprescription Drugs II, and in 2022, she became the Deputy Director in the Office of Medical Policy. Dr. Hicks received her undergraduate degree from Duke University, MS degree from Georgetown University, and MD degree from the Georgetown School of Medicine. She completed her internship and residency in Internal Medicine and fellowship in cardiovascular disease at Walter Reed Army Medical Center. She completed her Interventional Cardiology training at The Johns Hopkins Hospital and subsequently was Director of the Cardiac Catheterization Laboratory at Madigan Army Medical Center.

Lynne Yao, MD
Director
Division of Pediatric and Maternal Health (DPMH)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM)
Office of New Drugs (OND) | CDER | FDA

Lynne Yao, M.D., is the Director, Division of Pediatric and Maternal Health in the Office of New Drugs, Center for Drug Evaluation and Research. Dr. Yao received a B.S. degree in Biology from Yale University, and an M.D. degree from the George Washington University School of Medicine. She is board certified in both Pediatrics and Pediatric Nephrology. Prior to joining FDA, Dr. Yao was the Director of Dialysis and Associate Pediatric Residency Program Director at the Inova Fairfax Hospital for Children in Fairfax, VA. She has been with the FDA since 2008. The Division of Pediatric and Maternal Health oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve collection of data to support the safe use of drugs and biological products in pregnant and lactating individuals. She collaborates with numerous stakeholders both inside and outside of FDA to advance development of safe and effective therapies for children, and pregnant and lactating women.

Mark Levenson, PhD
Director
Division of Biometrics VII | CDER | FDA

Mark Levenson is currently the Director of the Division of Biometrics VII in the Center for Drug Evaluation and Research of the US Food and Drug Administration (FDA). At FDA, he has been the primary reviewer or secondary reviewer on many major pre-market and post-market drug safety problems. He contributes to statistical policy and guidance development in the areas of drug safety, real-world data, and regulatory evidence. He is a member of the CDER Medical Policy Program Review Committee and the FDA Real-World Evidence Committee. Dr. Levenson received a Ph.D. in Statistics from the University of Chicago and a B.A. from Cornell University in Mathematics and graduated from the Bronx High School of Science. Dr. Levenson is an elected fellow of the American Statistical Association.

Shabnam Naseer, DO, MMS
Medical Team Leader
Division of Anti-Infectives | Office of Infectious Diseases | Office of New Drugs | CDER | FDA

Dr. Shabnam Naseer is a Medical Team Leader at FDA in the Division of Anti-Infectives. She received a Master's in Medical Science from Drexel University and her Medical Degree at the Philadelphia College of Osteopathic Medicine in PA. Her post-graduate training included an Internal Medicine Residency at the Albert Einstein College of Medicine in NY and an Infectious Diseases Fellowship at the Georgetown University School of Medicine in DC. Prior to joining FDA in 2017, she served as an Infectious Disease physician at the University of Maryland, Upper Chesapeake Health and participated in clinical research. As a Medical Team Leader at FDA, she oversees a diverse application portfolio of products targeting various bacterial, viral, tick-borne, and fungal pathogens, and is an active member of many Agency committees.

Lei Xu, MD, PhD
Branch Chief
General Medicine Brach 2 (GMB2) | DCEPT | OTAT | CBER | FDA

Lei Xu serves as the Chief of General Medicine Brach 2 in the FDA's Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) of Office of Tissue and Advanced Therapies (OTAT) at Center for Biologics Evaluation and Research (CBER). Her Branch is responsible for reviewing clinical trial protocols, overseeing clinical trial conducts and evaluating trial data of investigational biologics (e.g., gene therapy, cellular therapy and plasma-derived products) in several clinical areas, including Neurology, Ophthalmology, Pulmonology, Dermatology, and burn and wound care. Her Branch reviewed all the clinical data that led to FDA-approval of the first two adeno associated virus-based gene therapy products: voretigene neparvovec (Luxturna) for the treatment of retinal dystrophy due to RPE65 mutation, and onasemnogene abeparvovec (Zolgensma) for the treatment of spinal muscular atrophy. In addition to the regulatory responsibilities, she is actively involved in FDA guidance development, including the Guidance for Industry: Expedited Programs for Serious Conditions, Guidance for Industry: Human Gene Therapy for Retinal Disorders, and draft Guidance for Industry: Human Gene Therapy for Neurodegenerative Diseases.

Dr. Xu received her M.D. from Central South University Xiangya School of Medicine in China, and her Ph.D. in neuroscience from Yale University. She completed residency training in Neurology at Loyola University Chicago. She is board-certified in Neurology by the American Board of Psychiatry and Neurology.

Lianne Hu, MD, PhD, MPH, MS
Clinical Analyst
DCEPT | OTAT | CBER | FDA

Dr Lianne Hu is a clinical analyst/clinical reviewer at the Oncology Branch (OB) within the Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) under Office of Tissues and Advanced Therapies (OTAT) of Center for Biologics Evaluation and Research (CBER). Dr Hu has been trained in many branches of medicine including clinical medicine, neurophysiology, biostatistics, epidemiology, and biomedical informatics. She joined the FDA in July 2020, bringing her unique interdisciplinary skills and expertise to the review of IND submissions for treatment of solid tumors. Prior to joining the FDA, she was a clinical researcher at a contract research organization for 9 years and a bench scientist at the National Institute of Health for 7 years.

Kassa Ayalew, MD, MPH
Branch Chief
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI)
CDER | FDA

Dr. Ayalew is a Director the Division of Clinical Compliance Evaluation in the Office of Scientific Investigation in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). He oversees verification of the reliability, integrity of efficacy and safety data submitted to the FDA in support of new drug and biologic applications and the protection and assurance of the rights and welfare of human research subjects. At his current position, he directs the scientific oversight for CDER-assigned bioresearch monitoring (BIMO) activities including compliance programs of clinical investigators, sponsors, and contract research organizations. He also leads the international collaboration with global regulatory counterparts in good clinical practice (GCP) initiatives. Dr. Ayalew has experience in clinical trials including designing, implementing clinical studies, and analyzing trial data and publishing study results.

Prior to this position, Dr. Ayalew served as Good Clinical Practice Assessment Branch Chief in the Office of Scientific Investigations. Dr. Ayalew began his tenure at FDA as a Medical Officer in CBER. Prior to joining the Office of Compliance, he served as a Medical Officer and Team Leader both in CBER and CDER. While serving in these positions, he was involved in multi-center, agency level programs dealing with policy and regulatory decisions related to development of biologic, antibacterial, antiviral, oncologic, hematologic and immunosuppressant products.

Dr. Ayalew obtained his M.D. from Haile Selassie University Medical Faculty in Addis Ababa, Ethiopia (also called Addis Ababa University Medical Faculty). He then worked as an assistant professor in the Department of Pediatrics at the Gondar University of Medical Sciences in Ethiopia and completed post-graduate training in pediatrics and child health at Leipzig University in Germany. He also completed a pediatrics residency at the Long Island College of Hospital (State University of New York)
followed by a fellowship program at Children's National Medical Center/George Washington University.

Dr. Ayalew is a Pediatric Infectious Disease physician and holds an active license to practice medicine in Virginia. He continues to provide clinical care in pediatrics and pediatric infectious diseases. He has given numerous didactic lectures and case presentations and has published article in peer review journals. He holds several awards and credentials from the FDA, where he has over two decades of regulatory medicine and work experience.

Ann Meeker-O'Connell, MS
Director
Office of Clinical Policy | Office of Clinical Policy and Programs | Office of the Commissioner | FDA

Ann Meeker-O'Connell is the Director of the Office of Clinical Policy in the Office of the Commissioner at FDA. Ms. Meeker-O'Connell has more than 20 years of experience in biomedical research and development in government, academic, and industry settings, including FDA efforts related to clinical trial modernization and clinical quality by design. She received an M.S. in Pharmacology and was an NIH Integrated Toxicology Fellow at Duke University.

John Concato, MD, MS, MPH, BE
Associate Director
Office of Medical Policy | Immediate Office | CDER | FDA

As Associate Director for Real-World Evidence (RWE) Analytics, Dr. Concato's responsibilities include developing internal Agency processes, interacting with external stakeholders, coordinating demonstration projects and guidance development, and serving as Chair of the RWE Subcommittee. John joined FDA after a 27-year career at Yale School of Medicine and the U.S. Department of Veterans Affairs (VA), where he was a Professor of Medicine and one of two founding principal investigators of the VA Million Veteran Program genomic mega-biobank. He has a B.E. degree from The Cooper Union, M.D. & M.S. degrees from New York University, and an M.P.H. degree from Yale University.

Paresma Patel, PhD
Division Director
Division of New Drug API | Office of New Drug Products
OPQ | CDER | FDA

Paresma Patel, Ph.D. is a Division Director for the Division of New Drug API in CDER's Office of New Drug Products, Office of Pharmaceutical Quality. She started at the FDA in 2015 as a review chemist supporting the oncology divisions. She has worked across multiple clinical divisions as a drug substance and drug product chemistry, manufacturing, and controls (CMC) reviewer and served as a Quality Lead for two years prior to transitioning to a role as Branch Chief in 2021. Prior to FDA, she worked as a medicinal chemist at the National Institutes of Health with a focus on target validation and lead optimization of small molecule kinase inhibitors. Dr. Patel completed her Ph.D. in organic chemistry at The Scripps Research Institute in 2010 and completed a postdoctoral fellowship at the California Institute of Technology in 2012.

Matthew Thompson, PhD, MPH
Supervisory Pharmacologist
Division of Hematology Oncology Toxicology | Office of Oncologic Diseases | Office of New Drugs | CDER | FDA

Dr. Thompson is a Supervisory Pharmacologist in the Division of Hematology Oncology Toxicology supporting the Division of Oncology 3 in the Office of Oncologic Diseases at the US Food and Drug Administration. Prior to joining the FDA, Dr. Thompson was a fellow at the National Cancer Institute at the National Institutes of Health. Dr. Thompson received his PhD from the Medical College of Wisconsin and his MPH from the Johns Hopkins Bloomberg School of Public Health.

Shirley K. Seo, PhD
Director, Division of Cardiometabolic and Endocrine Pharmacology
Office of Clinical Pharmacology
OTS | CDER | FDA

Shirley Seo is the director of the Division of Cardiometabolic and Endocrine Pharmacology in the Office of Clinical Pharmacology at the FDA. Dr. Seo obtained her Ph.D. in pharmaceutics at the University of Texas at Austin in 2004 where her main areas of research focus were drug metabolism, pharmacokinetics, and immunopharmacology. That same year, she began her FDA career in the Office of Generic Drugs, and in 2007, joined the antivirals teams as a reviewer in the Office of Clinical Pharmacology. In 2012, Dr. Seo became the clinical pharmacology team leader for antiviral products, a position she served in for almost 6 years. In her current role as a division director, she is actively engaged in guiding the development of regulatory policy and overseeing regulatory decision-making for drugs in the following disease areas: cardiology, nephrology, non-malignant hematology, diabetes, dyslipidemia, general endocrinology, bone, reproduction, and urology. Her areas of scientific interest and regulatory expertise include pediatric clinical pharmacology, complex drug interactions, antiviral drug development, and drugs being developed for medical countermeasures. In 2019, she became an associate editor for the journal, Clinical Pharmacology & Therapeutics. Shirley also has a passion for mentoring.