Pediatric Developmental Safety Assessment and New Approach Methodologies

A Virtual Workshop sponsored by the U.S. Food and Drug Administration and the Triangle Center of Excellence in Regulatory Science and Innovation

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Speaker, Moderator and Panelist Biographies

Kristin Ardlie, PhD is director of the GTEx Laboratory Data Analysis and Coordination Center at the Broad Institute of MIT and Harvard, where she is an institute scientist. She was responsible for the generation, QC, and analysis of RNA sequence data from up to 20,000 tissues, with a goal towards characterizing the relationship between genetic variation and the regulation of gene expression across multiple human tissues. She is currently working on several projects to characterize these samples at the single cell level. Ardlie completed a fellowship with the Harvard Society of Fellows in 1998 and worked at the Whitehead Institute/MIT Center for Genome Research for two years. She then worked for six years in a leadership role at Genomics Collaborative Inc., a commercial large-scale biological sample repository. Ardlie earned her B.S. in zoology from the Australian National University and her Ph.D. in population genetics from Princeton University.

Dr. **Gilbert Burckart** is Associate Director for Pediatrics in the Office of Clinical Pharmacology at the U.S. Food and Drug Administration. He received his B.S. in Pharmacy from the University of Pittsburgh, Pharm.D. from the University of Kentucky, and completed a pediatric residency at the UK Medical Center and Norton Children's Hospital. Dr. Burckart previously held faculty positions at the State University of New York at Buffalo, University of Tennessee, and University of Pittsburgh, where he was Professor of Pharmacy, Pediatrics, and Surgery, and Director of Research for the Division of Cardiothoracic Surgery. His research focused on drug therapy in organ transplantation and was supported by NIH grants in liver and lung transplantation. He later served as Chairman of the Department of Pharmacy and Director of the Clinical Pharmacogenomics Laboratory at the University of Southern California. A former President of both the American College of Clinical Pharmacy and the American College of Clinical Pharmacology, Dr. Burckart received the Sumner J. Yaffe Lifetime Achievement Award in 2014. At FDA since 2008, he leads pediatric clinical pharmacology programs and mentors students, fellows, and faculty nationwide.

Dr. **Ikram Elayan** received her Ph.D. in Pharmacology and Toxicology from the University of Utah. She joined the FDA in 2001 as a pharmacology/toxicology reviewer and is currently a supervisor in DPT-N serving the Division of Psychiatry Products. In addition to her duties as a supervisor, Dr. Elayan is the cochair of the Non-Clinical Pediatric Committee and a member of a variety of committees including the Neurotoxicity Committee.

Dr. **Jeffrey Fisher** is a retired Research Toxicologist with the U.S. Food and Drug Administration's National Center for Toxicological Research, where he specialized in the development and application of physiologically based pharmacokinetic (PBPK) models for assessing health risks and guiding drug dose selection in sensitive populations, including pregnant and pediatric patients. Before joining FDA, Dr. Fisher was a Professor and Department Head of Environmental Health Sciences and Director of the Interdisciplinary Toxicology Program at the University of Georgia, following 25 years at Wright-Patterson Air Force Base, where he advanced from technician to Technical Advisor for the Operational Toxicology Branch. He has authored more than 200 publications, served on advisory panels for DoD, ATSDR, and EPA, and was a U.S. delegate to NATO. A Fellow of the Academy of Toxicological Sciences, he also served as President of the Biological Modeling Specialty Section of the Society of Toxicology and as Associate Editor of Toxicological Sciences. Since retiring in 2020, Dr. Fisher has continued consulting with ScitoVation through 2025.

Dr. **James J. Hickman** is a Professor at the University of Central Florida's NanoScience Technology Center, with joint appointments in Chemistry, the Burnett School of Biomedical Sciences, and Electrical & Computer Engineering. He is also Co-Founder of Hesperos, Inc., a pioneering human-on-a-chip company advancing preclinical drug discovery and toxicology. He has a Ph.D. from MIT in Chemistry. Dr. Hickman's research integrates biological and non-biological systems to engineer next-generation platforms for drug development, disease modeling, and artificial intelligence. He has been constructing multi-organ human-on-a-chip or body-on-a-chip systems for toxicology and efficacy with up to 6 organs and has demonstrated long-term (>28 days) evaluation of drugs and compounds. He has pioneered the development of functional platforms for CNS and PNS neurodegenerative disease. A prolific innovator with 186 publications, 20 book chapters, and 40 issued patents, Dr. Hickman is a Fellow of AIMBE, the American Vacuum Society, the International Academy of Nano-biotechnology, and the National Academy of Inventors. He received the BioFlorida Researcher of the Year Award (2022) and continues to lead NIH-funded projects focused

on Alzheimer's disease and aging-related comorbidities. He is currently the President of the International Microphysiological Systems Society (IMPSS).

Dr. **Mona Khurana** is a Pediatric Team Leader in the Division of Pediatrics and Maternal Health within the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, which is housed in the Office of New Drugs at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. In this role, Dr. Khurana's efforts primarily focus on working collaboratively with review divisions in the Office of New Drugs to assist with pediatric drug and biologic development in all therapeutic areas. Board certified in Pediatrics and Pediatric Nephrology, Dr. Khurana earned her B.S. in Chemistry from the George Washington University (GWU) and her M.D. from the GWU School of Medicine. Before joining FDA in 2009, she was an Assistant Professor of Pediatrics at Children's National Hospital in Washington D.C.

Dr. **Susan Laffan** is currently a Head of Therapeutic Area Strategy Leaders in Translational Safety & Risk Sciences at Amgen. She has over 22 years of pharmaceutical industry experience in nonclinical safety assessment. She is an expert in reproductive and developmental toxicology and has been directly involved in development teams supporting the nonclinical safety assessment of compounds from discovery through post marketing. Dr. Laffan represented PhRMA on the ICH S11 Working Group. Susan earned a PhD in toxicology from the University of North Carolina at Chapel Hill, conducting her dissertation at the USEPA, Research Triangle Park, NC. In addition to being a member of the Society of Toxicology, she is also a member of BDRP, and the HESI DART Technical Committee.

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Dr. **Lang Li** is Professor and Chair of the Department of Biomedical Informatics in the College of Medicine at The Ohio State University. He received his Ph.D. and completed postdoctoral training at the University of Michigan, where he developed a foundation in pharmacology, systems biology, and informatics. Dr. Li's research integrates translational pharmacology, AI/ML, and systems biology to understand drug interactions, pharmacogenetics, and cancer systems biology. His lab translates molecular mechanisms into clinical insights using advanced modeling and data-mining approaches. Notably, he identified the loratadine/simvastatin drug interaction causing myopathy through combined literature and electronic health record analyses. He leads the development of informatics platforms such as DrugCombo, MPRINT-KP, and SLKB to support clinical trial design, maternal and pediatric pharmacotherapy, and synthetic lethal gene discovery. Dr. Li's research has been continuously funded by NIH (NLM, NIGMS, NCI, NICHD, NCATS) for 20 years.

Dr. **Rajanikanth (Raj) Madabushi** is Associate Director for Guidance and Scientific Policy and Director of the CDER Quantitative Medicine Center of Excellence (QMCoE) in the Office of Clinical Pharmacology (OCP) at the U.S. Food and Drug Administration (FDA). With more than 15 years of regulatory experience, he has served as a Pharmacometrics Reviewer and Clinical Pharmacology Team Lead within FDA's Office of Translational Sciences. Dr. Madabushi plays a leading role in advancing Model-Informed Drug Development (MIDD) at FDA and serves as CDER's Point-of-Contact for the MIDD Paired Meeting Program, a key initiative under PDUFA. He also contributes to international harmonization efforts as Rapporteur for the ICH M12 Expert Working Group on Drug Interaction Studies. Dr. Madabushi earned his Ph.D. in Pharmaceutical Sciences from the Birla Institute of Technology and Science (BITS), Pilani, India, and continues to shape regulatory science policy through quantitative and translational approaches to drug development.

Dr. **Marjory Moreau** is Principal Scientist and Lead for Next Generation Risk Assessment (NGRA) at ESQlabs, a digital life-sciences company specializing in PBPK, PBTK, and QSP/T modeling and simulation to advance R&D across the pharmaceutical, crop, and chemical industries. Her research focuses on developing human systems biology–based approaches for chemical safety assessment, integrating in vitro biokinetic modeling, physiologically based pharmacokinetic (PBPK) modeling, and quantitative in vitro–to–in vivo extrapolation (QIVIVE). Dr. Moreau's work bridges non-animal and human cell–based toxicity data with human exposure modeling to improve health risk assessment. She earned her Ph.D. in Public Health (Toxicology) from the University of Montreal, where she investigated biomarker evolution and early biological effects of BaP exposure. She completed a postdoctoral fellowship at Health Canada's Computational Toxicology Laboratory, supported by NSERC, applying pharmacokinetic and high-throughput screening data to evaluate chemical hazards in a public health context.

Dr. **Aaron C. Pawlyk** is Chief of the Office of Pharmacology and Physiological Therapeutics Branch (OPPTB) at the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), where he has served since 2019. His research and leadership span drug discovery, preclinical development, pharmacogenomics, and mathematical modeling, with applications across multiple therapeutic areas. Prior to NICHD, Dr. Pawlyk was a Program Director and Senior Advisor in the Division of Diabetes, Endocrinology, and Metabolic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), where he led initiatives in drug response, pharmacogenomics, and therapeutics translation. He directed the Type 1 Diabetes–Rapid Access to Interventional Development Program and managed NIH partnerships including the Accelerating Medicines Partnership for Type 2 Diabetes. Dr. Pawlyk earned his Ph.D. in Biochemistry from Texas A&M University, conducted postdoctoral research at the University of Pennsylvania, and previously worked in the pharmaceutical industry.

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Dr. **Bhagwat Prasad** is a pharmacologist, researcher, and Director of the Division of Translational and Clinical Pharmacology at Cincinnati Children's. Trained in pharmacy, translational pharmacology, and analytical chemistry, his research focuses on drug metabolism, disposition, and safety, especially in pediatric populations underrepresented in clinical trials. His lab integrates physiologically based pharmacokinetic modeling, metabolomics and quantitative proteomics to develop noninvasive tools for predicting drug safety and variability. Before joining Cincinnati Children's in 2025, Dr. Prasad was Professor of Pharmaceutical Sciences at Washington State University. He has authored over 150 publications, delivered 125 invited talks, and trained more than 45 scientists and clinicians. An elected member of the Washington State Academy of Sciences, he has received awards from ISSX, ASPET, and WSU, and currently serves as Chair-Elect of the ASPET Drug Metabolism Division, Chair of the ISSX Transporter Focus Group, Vice-Chair of the 2025 Gordon Research Conference, and was a 2024 FDA Visiting Faculty Fellow.

Dr. **Rebecca Racz** is a Senior Scientific Advisor in the FDA's Office of Clinical Pharmacology. She currently leads multiple projects in the office, including knowledge management and process improvement initiatives. Dr. Racz is a pharmacist by training and received her BS in Biomolecular Science (2013) and PharmD (2016) from the University of Michigan. She joined FDA's Division of Applied Regulatory Science in 2016 and was the primary investigator on multiple research projects focusing on secondary and safety pharmacology, natural language processing, and database development. She has published over 30 papers, serves as the lead for numerous international collaborations, and won the 2021 FDA Outstanding Junior Investigator Award.

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Will Redfern is Vice President of Quantitative Systems Toxicology & Safety (QSTS) in Certara. He is an experienced safety pharmacologist, having previously worked at Syntex, Quintiles and AstraZeneca, contributing to over 10 drugs that successfully reached the stage of product registration. Will has co-authored over 50 papers, review articles and book chapters, and is a Fellow of the Royal Society of Biology and of the British Pharmacological Society, a Diplomate in Safety Pharmacology, and an Honorary Senior Lecturer at the University of Manchester. Will is a former President of the Safety Pharmacology Society (SPS) and has received several of its awards, namely the Distinguished Service Award (2014), the Technological Innovation Award (2018) and the Translational Research Publication Award (2023). He is co-chair of the newly formed SPS Biological Modelling Group. Will has lectured on courses run by the universities of Manchester, Birmingham, Cardiff, Surrey, Cambridge, Liverpool and King's College London.

Dr. **Nicholas Tatonetti** is Vice Chair of Operations in the Department of Computational Biomedicine and Associate Director of Computational Oncology in the Cancer Center at Cedars-Sinai Medical Center, where he also serves as Professor of Computational Biomedicine. He earned his Ph.D. from Stanford University, developing novel statistical and computational methods for mining large-scale observational data. For more than a decade, Dr. Tatonetti has pioneered the use of machine learning and data science to improve drug safety surveillance and uncover previously unknown adverse drug interactions. His research integrates real-world clinical data with high-dimensional molecular and omics data to drive discovery in systems biology, pharmacology, and bioinformatics. Dr. Tatonetti has authored over 180 peer-reviewed publications and leads a lab at Cedars-Sinai dedicated to leveraging massive-scale clinical and molecular datasets to detect, explain, and validate drug effects—reshaping how data-driven science informs patient safety and precision medicine.

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Jean-Pierre Valentin PhD, HDR, ERT, FRCPath, DSP is a scientist with over 30 years of pharmaceutical industry experience in both scientific and leadership roles. After completing his PhD in Physiology & Pharmacology at the University of Montpellier and a postdoctoral fellowship at UCSF, he began his career at Pierre Fabre Research Centre, contributing to the discovery of three drug candidates. He then joined AstraZeneca, where he established and led the Department of Safety Pharmacology, overseeing the safety evaluation of around 200 candidate drugs across multiple therapeutic areas. In 2014, he moved to UCB-Biopharma as Senior Director of Investigative Toxicology and now serves as Fellow, Strategic Advisor. Jean-Pierre is a former President of the Safety Pharmacology Society and holds leadership roles within HESI, IQ-DruSafe, and ICH. He has been extensively involved in training and mentoring through scientific societies, universities, and trade associations, and has authored several patents and over 250 publications.

Dr. **Paul B. Watkins** is a clinically trained hepatologist and leading investigator in drug metabolism and hepatotoxicity, recognized for his research on why safe and effective drugs can sometimes cause liver injury. His work spans basic laboratory science and patient-based clinical studies, advancing understanding of drug-induced liver injury (DILI) mechanisms and genetic susceptibility. Dr. Watkins currently co-chairs the Steering Committee and chairs the Genetics Committee of the U.S. Drug-Induced Liver Injury Network (DILIN), funded by the National Institutes of Health, and serves as Principal Investigator of the **Triangle Center of Excellence in Regulatory Science and Innovation (CERSI)**, funded by the U.S. Food and Drug Administration. A graduate of Cornell University (B.A. in Physical Chemistry) and Cornell Medical College (M.D.), Dr. Watkins has received numerous honors, including the Agilent Therapeutic Frontiers Award (2013), Rawls-Palmer Award (2015), and the Distinguished Scientist Award (2023) from the American College of Toxicology.

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Dr. **Lynne Yao** is Director of the Division of Pediatric and Maternal Health (DPMH) within the Office of New Drugs at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). She also serves within the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM). Dr. Yao leads initiatives that promote the study of drugs and biologics in pediatric populations and enhance data collection to ensure safe use during pregnancy and lactation. She collaborates across FDA and with external stakeholders to advance development of safe and effective therapies for children and maternal populations. Board certified in Pediatrics and Pediatric Nephrology, Dr. Yao earned her B.S. in Biology from Yale University and her M.D. from the George Washington University School of Medicine. Before joining FDA in 2008, she was Director of Dialysis and Associate Pediatric Residency Program Director at Inova Fairfax Hospital for Children in Virginia.