FDA-University of Maryland CERSI Meeting

"Fetal Pharmacology and Therapeutics Workshop"

Speaker Bio's

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

Dionna Green, MD, FCP is the Director of the Office of Pediatric Therapeutics (OPT) in the Office of the Clinical Policy and Programs in the Office of the Commissioner at the US Food and Drug

Administration (FDA). OPT is a congressionally mandated office whose mission is to assure access for children to innovative, safe and effective medical products.

Prior to her current position, Dr. Green served as the Deputy Director of OPT for three years. She originally joined the FDA in 2009 and worked in the Office of Clinical Pharmacology, in the Center for Drug Development and Research (CDER) as a Medical Officer with the Pediatric Clinical Pharmacology Staff, and subsequently as a Medical Officer/Policy Lead with the Guidance and Policy Team.

Dr. Green received her medical degree from the Howard University College of Medicine in Washington, D.C. and her clinical training in pediatric medicine from the Herman & Walter Samuelson Children's Hospital at Sinai in Baltimore. She completed a clinical pharmacology research fellowship at the Georgetown University Drug Discovery Program, and a regulatory science fellowship with the FDA Commissioner's Fellowship Program. Dr. Green is currently President-Elect, a member of the Board of Regents, and a Fellow of the American College of Clinical Pharmacology.

Alan Jobe, MD, PhD is Professor of Pediatrics in the divisions of Neonatology and Pulmonary Biology at Cincinnati Children's Hospital, University of Cincinnati. He has worked for 29 years with NIH and Australian NHMRC funding in Perth, Western Australia, and Cincinnati on translational research to understand fetal lung maturation, fetal inflammation, and the risks of Bronchopulmonary Dysplasia. His research interests are in surfactant homeostasis, lung injury and Bronchopulmonary Dysplasia, fetal inflammation, and lung development.

He graduated Phi Beta Kappa from Stanford University with a degree in Biology in 1967, then completed MD and Ph.D. degrees in 1973 at the University of California, San Diego. He joined the Department of Pediatrics at Harbor-UCLA in 1977 where he became a Professor of Pediatrics at UCLA in 1983 and soon after was nominated to The American Society for Clinical Investigation in 1986. He became Director of the Perinatal Research Laboratories at the Walter P. Martin Research Center at Harbor-UCLA in 1995 and was named the 1st Joseph W. St. Geme, Jr. Professor of Pediatrics at UCLA in 1995.

Dr. Jobe performed many of the metabolic and physiologic studies that resulted in FDA approval of surfactant for the treatment of Respiratory Distress Syndrome. He was Chair of the Steering Committee for the NICHD Neonatal Research Network from 1996 to 2006 and participated in the NIH-Human Embryology and Development Study Section from 1983-1987. A member of the National Advisory Child

Health and Human Development Council for NIH from 2003 to 2007, he also served as the Chair of the Steering Committee for the NICHD Global Research Network, and a consultant to Fundassmin, a research foundation in Argentina. He has over 414 peer-reviewed publications and over 230 editorials, chapters, and other publications.

Kevin Prohaska, D.O., MPH is the Associate Director of the Office of Clinical Policy (OCLiP) within the FDA Office of the Commissioner. His work in OCLiP includes serving as a senior medical policy advisor with a focus on human subjects' protections including issues related to informed consent and bioethics. Dr. Prohaska is a board-certified Family Practice physician with a diverse professional background that includes academic, clinical, military, emergency, and regulatory medicine.

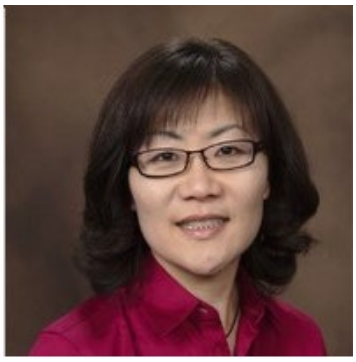
Kimberly Hatfield, PhD is a toxicologist and pharmacology/toxicology team leader in the Division of Pharmacology and Toxicology for Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (DPT-RPURM) supporting the Division of Urology, Obstetrics and Gynecology (DUOG) at the U.S. FDA, Center for Drug Evaluation and Research (CDER). She joined FDA in 2006 as a pharmacology/toxicology reviewer in DUOG, and has extensive experience reviewing applications for contraceptives, fertility products, drugs administered during pregnancy, drugs to treat menopausal symptoms, and products to treat urologic conditions. Dr. Hatfield is also a member of the CDER Pharmacology/Toxicology

Coordinating Committee, providing consultation for general nonclinical study review of pharmaceuticals, and the CDER Reproductive and Developmental Toxicology Subcommittee, providing consultation for reproductive toxicology study review. She has given lectures on reproductive and developmental toxicology internally at FDA and at national meetings, including the Society of Toxicology.

Dr. Hatfield completed her postdoctoral training at the University of Maryland Baltimore - School of Medicine in reproductive toxicology, investigating the mechanisms of pesticide toxicity in the ovary, and effects on fertility and function. She received her Ph.D. in Toxicology from Texas A&M University, focusing on molecular toxicology and oxidative stress mechanisms, and her B.S. in Chemistry from Ursinus College.

Anna David, PhD is Professor at University College London in London and an Honorary Consultant in Obstetrics and Maternal Fetal Medicine at UCL Hospital. In 2008 she was awarded an NIHR Senior Clinical Lectureship, and she was appointed as Director of the UCL Elizabeth Garrett Anderson Institute for Women's Health in 2018. Clinically Anna specializes in fetal medicine, congenital disease, fetal growth restriction and prevention of preterm birth. In 2019 she co-lead the implementation of fetal surgery for spina bifida in the UK. The surgery is now specialist commissioned by NHS England. Her research is developing prenatal therapies for obstetric conditions and congenital disease in the fetus, using genetic and regenerative medicine. Anna is part of the BOOSTB4 consortium performing the first clinical trial of in utero stem cell transplantation for osteogenesis imperfecta. She has lead development of the first standardized Maternal and Fetal Adverse Event Terminology: MFAET version 1.0 for use in clinical trials of pregnancy interventions. This terminology aims to transform the conduct of trials to test new maternal and fetal therapies, making them much safer for pregnant women and their babies.

Amy Inselman, PhD is a Research Biologist in the Division of Systems Biology, Biomarkers and Alternative Models Branch at the National Center for Toxicological Research, U.S. Food and Drug Administration. Dr. Inselman joined the FDA in 2010 and has investigated the developmental and reproductive toxicity of regulated products using both in vivo and in vitro test systems. Her work includes evaluation of the mouse embryonic stem cell test (mEST) and whether additional differentiation endpoints (e.g. osteoblasts) improved the predictive nature of the assay. She has served as the Principal Investigator on National Toxicology Program funded ICH guideline studies in the investigation of oxybenzone, a compound that acts as a UVA/UVB filter that is found in sunscreens. Studies focused on oxybenzone's potential impact on fertility and early embryonic development, embryo/fetal development, and pre- and postnatal development. Her current research focuses on the neurodevelopmental effects of opioid exposure during early pregnancy and investigation of SARS-CoV-2 infection during pregnancy. Dr. Inselman serves on numerous Health and Environmental Science Institute (HESI) Developmental and Reproductive Toxicity (DART) committees, an OECD expert group on developmental neurotoxicity, the Botanical Safety Consortium's DART subsection, and co-chair of the FDA DART Interest Group.



Grace Lee, PhD, is a Pharmacology and Toxicology Reviewer at CDER/FDA since 2009. Prior to joining FDA, she has worked at Schering-Plough as a reproductive toxicologist to conduct GLP reproductive and developmental toxicity studies. Sher received bother B.S. in Biochemistry and PhD in Molecular Toxicology from UCLA.

Gerri Baer, M.D. is a Medical Officer and Team Leader for Pharmacovigilance and Neonatology in the Office of Pediatric Therapeutics at FDA.

She completed pediatric residency and chief residency at Mount Sinai Medical Center and worked as a NICU hospitalist before starting her neonatology fellowship training at the Children's Hospital of Philadelphia. Prior to joining the FDA in September of 2015, she worked for 8 years as an attending neonatologist in a level III NICU in Silver Spring, Maryland. She was a partner in the practice and site lead for the Vermont-Oxford Very Low Birth Weight Neonatal Database.

At FDA, she established the Neonatal-Perinatal Medicine consultation service and is involved with neonatal product development across the Centers. She now leads the OPT Pharmacovigilance team, which works with the Centers to improve pediatric product safety. Dr. Baer serves on the coordinating committee of the International Neonatal Consortium (INC) and represents the FDA on several INC working groups. She participated in creating the "*Draft Guidance for Industry: General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products"* with CDER OND and OTS and is working on additional guidance and regulatory science research.

Simon Waddington, PhD Simon has worked in gene therapy for over two decades, contributed to translational gene therapy for hemophilia, and witnessed the emergence of clinical, market-authorised gene therapy products. Simon now develops gene therapy for a range of life-limiting, incurable and often untreatable, genetic diseases affecting children. He has spent a number of years exploring the concept of fetal gene therapy as a logical progression of treatment for some of these diseases.

Janette Strasburger, MD is a Professor of Pediatrics and Biomedical Engineering at the Medical College of Wisconsin, and an Attending Cardiologist at Children's Wisconsin Herma Heart Institute in Milwaukee. She is a fetal electrophysiologist and principle investigator on an NIH RO1 grant to determine the contribution of arrhythmias to Stillbirth. For the past 20 years, she has collaborated on Fetal Magnetocardiography research with Professor Ronald T. Wakai, at the UW-Madison Medical Physics Biomagnetism Laboratory, and with industry partners in device development through NIH-funded collaborations. This fMCG research team has evaluated almost 1000 pregnancies complicated by fetal arrhythmias from across the US, has advanced the technology for fetal cardiac recording, and has obtained an AMA CPT code for emerging devices. Dr. Strasburger has been an adhoc reviewer for NIH study sections, including large instrumentation and EMNR (Special Emphasis Panel for Translational Research in Maternal and Pediatric Pharmacology and Therapeutics). She has been on the writing committees for the AHA and the Heart Rhythm Society on major Scientific Statements on Fetal Diagnosis and Treatment where she co-wrote sections on fetal arrhythmias. She is grateful to her husband Jeff Hayes, and her grown son Tim. She enjoys gardening and travel.

Sarah Stock, MD, PhD, is Reader, Consultant and Subspecialist in Maternal and Fetal Medicine at the University of Edinburgh Usher Institute. She went to Manchester University Medical School, and has a PhD from the University of Edinburgh. Her specialist and subspecialist clinical training was undertaken in

Edinburgh, with periods in Glasgow, London and Australia. She has research interests in preterm birth and stillbirth. With a laboratory science background, she now focuses on clinical trials and international data driven studies. Her aim is to improve care options for pregnant women and develop strategies that reduce baby deaths and improve the health of children.

Tippi Mackenzie, MD is a Professor of Surgery at the University of California, San Francisco and the Director of the Eli and Edythe Broad Institute for Regeneration Medicine. She is a pediatric and fetal surgeon who is focused on developing better ways to diagnose and treat genetic diseases before birth. She runs a translational research lab examining fetal immunology and maternal-fetal tolerance, with the ultimate goal of inventing new fetal therapies for patients with genetic diseases or pregnancy complications. She has moved two fetal molecular therapies from the lab to the clinic as phase 1 clinical trials after obtaining FDA approval: in utero hematopoietic stem cell transplantation to treat fetuses with alpha thalassemia and in utero enzyme replacement therapy in fetuses with lysosomal storage disorders. Her research has been supported by the National Institutes of Health, the March of Dimes, the California Institute for Regeneration Medicine, and the Burroughs-Wellcome Fund. Tippi has been awarded the Jacobson Award by the American College of Surgeons for her innovative work and is a member of the American Society for Clinical Investigation.

Tippi trained in classical piano at Juilliard before obtaining her undergraduate degree from Harvard College and her medical degree from Stanford University. She completed her surgical residency at Brigham and Women's Hospital in Boston and obtained additional fellowships in Fetal Surgery and Pediatric Surgery at the Children's Hospital of Philadelphia. She joined the faculty at the University of California, San Francisco in 2007 and is now a Professor of Surgery. She recently co-founded the Center for Maternal-Fetal Precision Medicine, with the aim of accelerating the processes that link basic research to clinical trials to improve maternal, fetal, and neonatal health. This Center is testing methods to improve prenatal diagnosis of birth defects and developing new cellular and molecular therapies for definitive fetal treatment.

Jill A. Morgan PharmD, is a Professor and Chair in Pharmacy Practice and Science at the University of Maryland School of Pharmacy. She received her Doctor of Pharmacy degree from the University of Illinois Chicago and completed pharmacy practice and pediatric pharmacy specialty residencies at the University of Maryland Medical Center in Baltimore, Maryland. She is a Pediatric Clinical Pharmacy Specialist with practice sites at the President's Interdisciplinary GI clinic and the Children's Hospital Intestinal Rehabilitation Program (CHIRP) at the University of Maryland Medical Center. For several years, Dr. Morgan has been teaching pediatric and neonatal pharmacotherapy to nursing and pharmacy students as well as medical residents. She has performed research in a variety of areas related to pediatrics. Dr. Morgan is the Director for the Pediatric Pharmacy Fellowship program. She is also a board-certified pharmacotherapy specialist.

John N. van den Anker, MD, PhD, FAAP, FCP is a Professor of Pediatrics, Pharmacology, Physiology, Genomics and Precision Medicine at the George Washington University School of Medicine and Health Sciences, Washington, DC and holds the Evan and Cindy Jones Endowed Chair in Pediatric Clinical Pharmacology. He also is the Eckenstein-Geigy Distinguished Professor of Pediatric Pharmacology at the University Children's Hospital of Basel, University of Basel, Switzerland.

Dr. van den Anker has been the President of the American College of Clinical Pharmacology (2016-2018) and twice the President of the European Society of Developmental, Perinatal and Paediatric Pharmacology (2006-2008 and 2017-2019). His awards include the Distinguished Investigator Award from the American College of Clinical Pharmacology (2008), the Distinguished Researcher award of the George Washington University (2012), and the Sumner J. Yaffe Lifetime Achievement Award in Pediatric Pharmacology and Therapeutics (2019) from the Pediatric Pharmacy Association.

Over the past 30 years, Dr. van den Anker' research has focused on developmental, neonatal and pediatric pharmacology. He has authored over 500 peer reviewed publications and has received NIH funding as well as funding from the European Union to support his research and the development of training programs in Pediatric Clinical Pharmacology.

William Slikker, Jr., PhD is the director of FDA's National Center for Toxicological Research. He received his Ph.D. in pharmacology and toxicology from the University of California at Davis. Dr. Slikker holds adjunct professorships in the Department of Pediatrics, and in the Department of Pharmacology and Toxicology at the University of Arkansas for Medical Sciences. He is the past president of the Academy of Toxicological Sciences, the Teratology Society, and the Society of Toxicology. Dr. Slikker has authored or co-authored over 380 publications in the areas of transplancental pharmacokinetics, developmental neurotoxicology, neuroprotection, systems biology, and risk assessment.

Alison Harrill, PhD, is a toxicologist and Program Director in Obstetric and Pediatric Pharmacology and Therapeutics at the NIH National Institute of Child Health and Human Development. Dr. Harrill recently joined the NICHD after serving as a researcher at the National Toxicology Program, where she led efforts to develop population-based in vivo and in vitro models of genetic susceptibility, pharmacogenetics, and developmental neurotoxicity. Dr. Harrill served as team lead for efforts on biomarker development,

particularly for miRNA and protein biomarkers of kidney injury. She has served as Deputy Editor of the journal *Toxicological Sciences* and has held society leadership positions, including as Counselor of the Society of Toxicology Executive Board and as co-chair of the genomics committee within the Health and Environmental Sciences Institute. More recently, she completed a six-month detail as the Data & Analytics Team lead on the Healthcare Resilience arm of the White House Coronavirus Task Force. She has received numerous awards, including the Burroughs Wellcome Innovation in Regulatory Science Award and the COVID-19 Pandemic Civilian Service Medal.

Larissa Lapteva, MD is the Associate Director in the Division of Clinical Evaluation, Pharmacology, and Toxicology, in the Office of Tissues and Advanced Therapies in the Center for Biologics Evaluation and Research at FDA. Dr. Lapteva is a physician with long-standing experience in clinical research with novel drugs and biological products. Prior to her work at FDA, Dr. Lapteva conducted clinical studies in rheumatic conditions at the National Institutes of Health (NIH). Since joining FDA in 2006, Dr. Lapteva has held review and leadership positions in the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research where she provided scientific and regulatory advice for clinical development programs with investigational products across different therapeutic areas, in the last five years in the fields of cell and gene therapies. Dr. Lapteva received her degrees of Master of Health Sciences from Duke University and Master of Business Administration from R.H. Smith School of Business.

Robert M. Ward, MD, FAAP, FCP completed medical school at Johns Hopkins University and trained in Pediatrics, Neonatology and Clinical Pharmacology at the University of Minnesota. After serving as assistant professor in Pediatrics and Pharmacology at Pennsylvania State Univ, he moved to the University of Utah in 1985 as associate professor of Pediatrics. He served as Medical Director of the Primary Children's Medical Center NICU from 1989-1997 and was promoted to professor of Pediatrics in 1995.

In 1997, he began the Pediatric Pharmacology Division at Utah, to study medications in children. He was PI of the Utah site in the NICHD Pediatric Pharmacology Research Unit Network from 2004-2010. In 1997, Dr. Ward became Chair of the AAP Committee on Drugs and consulted in the development of FDAMA, BPCA and PREA. He has consulted with the FDA, NIH, Institute of Medicine, and USP and testified before Congress regarding the need for study and approval of drugs for pediatric patients. His research interests focused on neonatal and fetal pharmacology through studies of narcotic analgesics, inhaled corticosteroids, neonatal abstinence syndrome, gastrointestinal reflux, and inositol for prevention of ROP. He retired to emeritus status in 2015, but returned to direct the clinical pharmacology division in 2017.

Endress Darsey, PharmD, graduated with her Doctorate of Pharmacy Degree from Mercer University. She completed a Clinical Pharmacy Practice Residency at the University of Alabama in Birmingham followed by a Specialty Residency in Clinical Pharmacokinetics at Mercer University. Following her training, Edress spent eight years developing and leading clinical pharmacy services and a pediatric pharmacy residency program at Children's Healthcare of Atlanta. During this time, she researched and published studies around pediatric pharmacokinetics, pain management and other areas of need. In 2000, Edress joined Pfizer Pharmaceuticals where she worked on a variety of medical teams until January 2014 when she was offered an opportunity to help build Pfizer's Pediatric Center of Excellence

in the office of the Chief Medical Officer. Edress has served as a Global Pediatric Medical Director/Pediatric Clinical Director at Pfizer for the last 8 years. In this position, Edress works internally across many Pfizer medicine teams to provide end to end support of pediatric studies, including study protocol development, regulation, pediatric pharmacology and formulations. In addition, Edress works externally with Children's Hospitals to build and maintain relationships with a network of major children's hospitals and pediatric research centers in order to facilitate pediatric clinical trial site identification and to optimize clinical trial process execution for investigators and patients.

Edress has served on the Board of Directors for the Pediatric Pharmacy Association (PPAG) and is current chair of the Drug Development Committee. She is a member of the American College of Clinical Pharmacologists (ACCP) and the American Academy of Pediatrics Section on Advances in Therapeutics and Technology.

Homa K. Ahmadzia, MD, MPH is a Maternal-Fetal Medicine specialist and Assistant Professor in the Department of Obstetrics and Gynecology. Dr. Ahmadzia completed her undergraduate, medical school education, and Masters of Public Health at The George Washington University. She then completed her residency at Yale University where she was awarded the Outstanding Resident Teaching Award in both her second and third year of residency and also served as Administrative Chief resident. She completed her fellowship in Maternal-Fetal Medicine at Duke University.

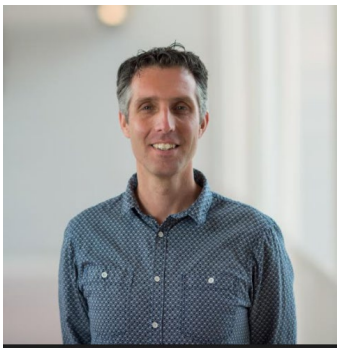
Dr. Ahmadzia has presented her research at numerous national and regional conferences including the American Institute of Ultrasound in Medicine, The Society for Maternal Fetal Medicine and The American Congress for Obstetricians and Gynecologists. She received the Charles B. Hammond Fund research award to fund her fellowship thesis project. She also attended the Excellence in Clinical Research course and NICHD Young Investigators Conference. During fellowship, she served on the Society of Maternal Fetal Medicine Global Health Committee. She has previously received the Clinical and Translational Science Institute KL2 Mentored Career Development Award through the GW-CNMC partnership with NIH and currently on a K23 Career Mentored Development Award from NHLBI. She has a specific clinic for Pregnancy and Hematology issues and is the Director of Maternal-Fetal Medicine Research at GW. She also has other grant funded research from the FDA and Gates foundation as well as serves as the Medical Monitor for the Maternal-Fetal Medicine Unit Network.

Dr. Ahmadzia's clinical areas of interest include prenatal diagnosis, ultrasonography, management of high risk pregnancies, bleeding disorders and thrombophilias, preconception counseling and infectious diseases. She enjoys taking care of women during pregnancy and hopes to improve perinatal outcomes for women in the US and abroad through her clinical and research interests.

André Dallmann, PhD works as Scientist for Systems Pharmacology at Bayer, Germany. He completed his PhD in Clinical Pharmacy at the University of Münster, Germany, in 2017. Thereafter, he worked as a postdoctoral researcher at the Pediatric Pharmacology & Pharmacometrics Research Center at the University Children's Hospital Basel in Switzerland and joined the department of Clinical Pharmacometrics at Bayer in 2018. His research interests focus on in vitro to in vivo extrapolation for oral drug formulations, DDI modeling and the exploration of obstetric and neonatal pharmacology through PBPK modeling.

Anne Zajicek, M.D., Pharm.D., FAAP, is a board-certified pediatrician and pediatric clinical pharmacologist who currently serves as Deputy Director of the Office of Clinical Research at the National Institutes of Health, Office of the Director. Dr. Zajicek received a Bachelor's degree in Pharmacy from Duquesne University, PharmD from the State University of New York at Buffalo, post-PharmD fellowship at St. Jude Children's Research Hospital; MD degree from the University of Pittsburgh, pediatrics residency at Children's Hospital of Pittsburgh, and T32 clinical pharmacology fellowship at Stanford

University. Following this fellowship, she joined the US FDA in the Division of Oncology Drug Products as a clinical pharmacology reviewer, and then in 2003 joined the NIH at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, where she was appointed Chief of the Obstetric and Pediatric Pharmacology and Therapeutics Branch in 2010. Recruited to the newly created Office of Clinical Research in 2017, Dr. Zajicek serves as Deputy Director of the Office of Clinical Research in developing strategic partnerships with the extramural community and developing and overseeing clinical research training courses.

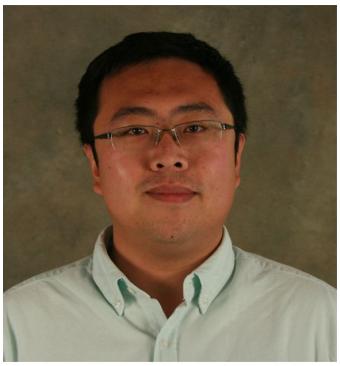


Rick Greupink, PharmD, PhD, is faculty at the Department of Pharmacology and Toxicology, Radboud university medical center, Nijmegen, The Netherlands. His research focuses on translational and predictive pharmacology, in particular the in vitro-to-in vivo extrapolation (IVIVE) of drug disposition and drug-induced toxicity. He aims to develop a better understanding of how drugs behave in the body, predict clinical pharmacokinetics and anticipate therapeutic and off-target effects. In his work, Rick combines laboratory studies in human cells and tissues with physiology-based pharmacokinetic (PBPK) modeling to predict systemic and tissue exposure of drugs. In addition, he employs pharmacophore modeling approaches to study and predict target binding of compounds. Within the field, Rick has a special interest in the pharmacological roles of drug-transporting membrane proteins. Current projects center around the placental disposition and effects of small and large molecule pharmaceuticals during pregnancy, in relation to maternal, fetal and perinatal pharmacokinetics and drug safety.

Ping Zhao, PhD obtained his BS in Pharmacy from Beijing Medical University in China in 1994, and his PhD in Pharmaceutics from University of Washington in Seattle, WA, USA in 2002. Since then, Ping worked as a DMPK scientist at Pfizer in La Jolla CA (2002-2005), a pharmacokineticist at Sonus Pharmaceuticals in Seattle (2005-2007), a clinical pharmacologist at Amgen in Seattle (2008), and the

Scientific Lead of PBPK (physiologically-based pharmacokinetic modeling) Program and Expert Pharmacologist at the Office of Clinical Pharmacology, US FDA in Silver Spring, MD (2008-2017). At FDA, Ping led review of PBPK submissions in IND/NDA/BLAs. He was responsible for the review of more than 200 PBPK analyses in IND, NDA, and BLA submissions. More than 40 of these submissions had simulation results being used in product labels to support optimal use of the drugs. He championed PBPK regulatory research and engineered policies around PBPK, including authoring the agency's first PBPK guidance (2016) and implementing evidence-based PBPK approaches in FDA's drug-drug interaction guidances (2017). In June 2017, Ping joined the Bill and Melinda Gates Foundation in Seattle, WA as a Senior Program Officer of Quantitative Sciences, where he applies pharmacology concepts and manages Model-informed Drug development (MiDD) efforts in programs funded by the foundation to academic centers, product development partners, and regulatory agencies around the world.

Jashvant Unadkat, PhD is the Milo Gibaldi Endowed Professor at the School of Pharmacy, University of Washington, Seattle. He received his Bachelor's degree in Pharmacy (B.Pharm.) from the University of London (1977), his Ph.D. from the University of Manchester (1982; advisor Prof. Malcolm Rowland) and his postdoctoral training at the University of California at San Francisco (1982-85; advisor Dr. Lewis Sheiner). Dr. Unadkat's research interests are focused on elucidating the mechanisms of transport and metabolism of HIV and related drugs. In particular his laboratory has been interested in metabolism and transport of drugs during pregnancy, and transport of drugs across the placental, hepatic, intestinal and blood-brain barrier. Dr. Unadkat has published more than 200 peer-reviewed research papers. He is a fellow of AAAS, AAPS, JSSX, and the founding co-chair (1999-2001) of the focus group of AAPS on Drug Transport and Uptake. Dr. Unadkat received the AAPS Research Achievement Award in 2012. Dr. Unadkat created and leads the UW Research Affiliates Program on Transporters (UWRAPT), a cooperative effort between the UW School of Pharmacy and pharmaceutical companies. He also leads UWPKDAP, a NIDA funded Program Project grant (P01) on drug disposition during pregnancy. Dr. Unadkat has been an Associate Editor for the Journal of Pharmaceutical Sciences, an Editor of AAPS Journal, and a member of the NIH Pharmacology study section (2000-3). Dr. Unadkat has organized or co-organized numerous national and international conferences on the role of transporters and pregnancy in disposition of drugs.



Miao Li, PhD works in the Division of Biochemical Toxicology of FDA NCTR since September 2019. He got his PhD in Toxicology from the University of Iowa. Following that, he had his postdoctoral training from the Institute of Computational Comparative Medicine in Kansas State University to apply physiologically based pharmacokinetic (PBPK) modeling for food safety assessment. His main research interests are PBPK modeling for perinatal life stages and in vitro to in vivo extrapolation to support parameter estimation for biological modeling.

Adeniyi Olagunju, BPharm, MRes, PhD is a Tenure Track Fellow in Pharmacology and Therapeutics at the University of Liverpool. His focus within Centre of Excellence for Long-acting Therapeutics is at the translational research interphase, including the safety and efficacy of infectious diseases therapeutics in pregnancy and lactation. His contributions to the field include papers on the impact of maternal adaptations, host genetics and/or drug-drug interactions on drug exposure during pregnancy. In addition to developing innovative bioanalytical methods to support clinical pharmacology studies in special populations, he uses physiologically based pharmacokinetic (PBPK) models to characterise differential drug distribution into maternal tissues during pregnancy and prenatal drug exposure. He has led a number of multi-centre clinical research projects, including a phase II drug repurposing clinical trial for mild to moderate COVID-19. He is part of the Pharmacometrics Africa team that run online and face-to-face training courses to expand pharmacometrics capacity on the Africa continent. He studied pharmacy at the Obafemi Awolowo University in Nigeria, Master of Research in Biomedical Science & Translational Medicine (2012), and PhD in Pharmacology (2015) from the University of Liverpool, United Kingdom.

Paola Coppola, MSc is a Pharmacokinetics Assessor at the Medicines and Healthcare products Regulatory Agency (MHRA), UK. She obtained her MSc in Biological Sciences from the University Federico II of Naples, Italy. Since 2010 she gained professional experience in pharmacokinetics, having worked in pharmaceutical industry in the position of Pharmacokinetics Scientist before joining the MHRA in 2017. In Industry she actively collaborated in clinical drug development programs for small molecules in a number of therapeutic areas. She has advanced PK expertise in early phase clinical trials and extensive experience in Clinical Pharmacology. She has a strong interest in the PK modelling and gained experience on pregnancy PBPK modelling approach.

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.

Khaled Abduljalil PhD, is a Senior Principal Scientist at Certara UK Limited's Simcyp Division. He received his PhD in Population PK/PD Analysis. Since joining the Simcyp team in 2008, he has worked on various projects in PBPK/PD with a major interest in systems pharmacology including PK/PD in children and during pregnancy and lactation. Khaled is a line manager and project lead for multiple Simcyp projects.

Jeremiah Momper, Pharm.D., PhD, is an Associate Professor at the University of California, San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences. Dr. Momper's research focuses on the application of quantitative pharmacology approaches to optimize the development and clinical use of drugs. Current research directions include evaluation of potential therapies for HIV infection in infants and pregnant women and the use of model-based methods to support scientific decision making in drug development. Dr. Momper directs the Translational Pharmacology and Bioanalysis Laboratory at UC San Diego concentrated on novel quantitative bioanalytical methods, in vitro ADME assays, and pre-clinical and clinical pharmacokinetic studies.

Zhaoxia Ren, MD, PhD, is a program officer at the Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB), NICHD. She joined the OPPTB as a medical officer in May 2008 and served as the program scientist for the Obstetric Pharmacology Research Centers (OPRC), formerly known as the Obstetric Pharmacology Research Units (OPRU) Network from 2009 to 2020. Dr. Ren is also in charge of the branch's pharmacogenomics, maternal-fetal pharmacology and therapeutics, and translational research programs. She is the program director for the Centers of Excellence in Therapeutics (CETs) of the Maternal and Pediatric Precision in Therapeutics Hub (MPRINT).

Stephan Schaller, PhD is the founder and managing director of esqLABS GmbH (www.esqlabs.com), a biosimulation and MIDD CRO. He is a systems scientist with over ten years of industry experience applying modeling & simulation to support decision-making processes in life sciences. Stephan is also the chair of the Board of www.Open-Systems-Pharmacology.com, an initiative to foster open collaboration in systems pharmacology and develop open-source (PBPK and QSP) modeling tools PK-Sim® and MoBi®, used for model-based decision-making, including, amongst many application areas, maternal-fetal PBPK modeling and simulation.
His experience ranges from target validation in the early phases of drug discovery, to drug development, to the development of automated decision support systems for drug dosing at the point of care, as well as applications in Toxicological Risk Assessment. Stephan Schaller studied Control Systems Engineering and Systems Biology at the University of Stuttgart, Germany. He received his Ph.D. from the RWTH Aachen University, Germany, in collaboration with Bayer in Computational Engineering for the development of an automated decision support system for precision dosing in Diabetes.

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