



PUBLIC WORKSHOP

Evaluation of the Safety of Drugs and Biological Products used during Lactation

Wednesday & Thursday, April 27 & 28, 2016
Silver Spring, MD

PANELISTS AND PRESENTERS

Philip O. Anderson, Pharm.D., FCSHP, FASHP is a Health Sciences Clinical Professor at the University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences where he heads the course on drug information. Past work in drug information includes being Assistant Editor of the American Hospital Formulary Service and serving as co-editor of the *Handbook of Clinical Drug Data*, editions 2 to 10, 1973 to 2002. He was a founding principle in the company, Healthware, Inc. which produced the clinical pharmacokinetics software program, T.D.M.S. 2000 where he was responsible for researching and incorporating population pharmacokinetic values into the program. Dr. Anderson has lectured and published extensively on drug use during breastfeeding, including original research on drug excretion into breastmilk. Dr. Anderson founded the *LactMed*® database, which is part of the National Library of Medicine's TOXNET family of databases. He continues to write all *LactMed*® records and to expand the database. He has authored the medication appendix to the lay handbook, *The Nursing Mothers' Companion*, as well as the drugs and breastfeeding chart on BabyCenter.com. Dr. Anderson is a member of the Editorial Board of the professional journal, *Breastfeeding Medicine*, and is currently writing a monthly column on medication use during breastfeeding for the journal.

Teresa Baker, M.D., received her medical degree at UT Southwestern, followed by residency training in obstetrics and gynecology at UT Southwestern Parkland Health and Hospital System in Dallas, TX. She has a combined private and academic OB/GYN practice with the University Physicians at Texas Tech Health Sciences Center in Amarillo, where she also serves as the Residency Program Director. She is interested in teen pregnancy, postpartum depression, promoting preventive medicine. Dr. Baker was recently appointed the Rush Endowed Chair in Women's Health and Oncology for her efforts in providing cervical and breast cancer screenings for underserved women in the Texas Panhandle. Dr. Baker's passion for promoting breastfeeding has resulted in a partnership with Dr. Thomas Hale, PhD, breast milk pharmacology expert and author of the landmark text, *Medications and Mothers' Milk*. Together, they established the InfantRisk Center, which is dedicated to promoting research, education, and public service pertaining to medication safety and pregnant and breastfeeding mothers. As the only resource of its kind, the InfantRisk Center receives requests for data and counseling from mothers and providers all over the world. In addition to co-directing the center, Dr. Baker has published several book chapters and journal articles on breast milk pharmacology, and piloted grants to support breastfeeding education for new mothers.

Gilbert Burckart, Pharm.D., is Associate Director for Pediatrics in the Office of Clinical Pharmacology, CDER. Dr. Burckart came to FDA in 2008 after a 33 year academic career at four institutions and five children's hospitals. He has served as President of the American College of Clinical Pharmacology and President of the American College of Clinical Pharmacy

Christina Chambers, Ph.D., M.P.H., is a Professor in the Department of Pediatrics, School of Medicine, at the University of California San Diego, with a joint appointment in the Family Medicine and Public Health and the Skaggs School of Pharmacy and Pharmaceutical Sciences. She is a perinatal epidemiologist and teratologist whose research is focused on environmental causes of adverse pregnancy and child health outcomes. She is the Co-Director for the Center for Better Beginnings at the University of California San Diego. She is active in the MotherToBaby network of counseling services, and directs the MotherToBaby Research Center at UCSD.

Mary F. Hebert, Pharm.D., FCCP, is a Professor of Pharmacy, Adjunct Professor of OBGYN, Director of the University of Washington Obstetric-fetal Pharmacology Research Unit, Core Member of the University of Washington, Center for Ecogenetics and Environmental Health and Member of the University of Washington Institute of Translational Health Sciences. She is a Fellow of the American College of Clinical Pharmacy. Dr. Hebert received her PharmD degree (1987), completed a Clinical Pharmacy Residency (1988) and Fellowship (1990) at the University of California, San Francisco. Dr. Hebert joined the University of Washington Faculty in 1996 after serving on the Clinical Faculty at the University of California, San Francisco for 6 years. She has 29 years of experience conducting clinical pharmacology research resulting in almost 100 publications. She has been an invited speaker at many national and international conferences. Her research focuses on the clinical pharmacology of medications in pregnancy and lactation with a focus on the mechanistic basis for clinical pharmacologic changes.

Shinya Ito, M.D., medical training is in the field of pediatrics and is certified in both Japan and Canada. Dr Ito has training in clinical pharmacology and toxicology, which includes both adult and pediatric care relating to drug therapy. Dr Ito's research interest spans from drug transporters, pharmacogenomics, and pharmacokinetics. Presently, DR Ito is the site director (Hospital for Sick Children) of the Canadian Pharmacogenetics Network for Drug Safety, and in charge of the pharmacogenetics consultation program in the institution.

Tamara Johnson, M.D., is the Lead Medical Officer for the Maternal Health Team within the FDA/CDER Office of New Drugs (OND) Division of Pediatric and Maternal Health (DPMH). Dr. Johnson earned her Doctorate in Medicine from the Rutgers Robert Wood Johnson Medical School in New Jersey. She completed internship at the Georgetown/Providence Hospital Family Medicine program and completed residency training in General Preventive Medicine/Public Health at the University of Maryland Baltimore. Dr. Johnson has been with the FDA for eight years. Initially, as a Medical Officer in the OND Division of Gastroenterology and Inborn Errors Products, she is currently leading the DPMH Maternal Health Team. The Maternal Health Team is responsible for evaluating the safe use of drug and biologics products in pregnant and lactating women, and are the Agency experts on the Pregnancy and Lactation Labeling Rule.

Denise Johnson-Lyles, Ph.D., serves as a regulatory project manager in the Division of Pediatric and Maternal Health in FDA's Center for Drug Evaluation and Research, Office of New Drugs. She assists both the pediatric and maternal health teams of the division and helps to manage a number of maternal health related FDA guidance document working groups, as well as other projects. She has assisted with the planning and coordination of this current workshop and she has been with the FDA for 6 years.

Ruth A. Lawrence, M.D., is a magna cum laude graduate of Antioch College and earned her M.D. at the University of Rochester School of Medicine. Her residency in Pediatrics was at Yale University New Haven Hospital including a fellowship in the Rooming-In Unit with Dr. Edith Jackson. She is a Distinguished Alumna Professor in Pediatrics and Obstetrics/Gynecology at the University of Rochester School of Medicine and a member of the Division of Neonatology. She recently was installed as the Northumberland Trust Chair in Pediatrics. She has been the Medical director of the Breastfeeding and Human Lactation Study Center and the Finger Lakes Regional Poison and Drug Information Center for over 50 years. She is the author of Breastfeeding a Guide for the Medical Profession, now in its 8th edition, and many articles, chapters and reviews. Dr. Lawrence served as chairperson for the Surgeon General's Workshop on Breastfeeding & Human Lactation in Rochester in June of 1984. She also chaired the follow up meeting on the education and examination of the health care professional in Washington DC the following year. She chaired the 25th anniversary celebration of the workshop in 2009 Washington, DC. She is a founding member of the Academy of Breastfeeding Medicine and a past president. As a member of the American Academy of Pediatrics work group on breastfeeding, she participated in the preparation of the Academy's statement on breastfeeding and human lactation. She served on the Executive Committee of the Section for Breastfeeding of the American Academy of Pediatrics and was Chair of the Section for six years.

A number of awards have been given to Dr. Lawrence, some of which are Alpha Omega Alpha, Sigma Delta Epsilon, the Alumni Gold Medal, the Kaiser Medal, the Academy of Medicine Recognition, American Academy of Clinical Toxicology, American Association of Poison Control Centers, the New York State Association of Poison Control Centers and lifetime achievement award from the Academy of Breastfeeding Medicine as well as Best Doctor and Humanism in Medicine Award from the Association of American Medical Colleges. She received the Athena Award in 2007 and the Martha Mae Ellicott award from American Public Health Associate in 2009. She received an Honorary Doctor of Divinity from St. Bernard's School of Theology and Ministry in 2009.

Robert "Skip" Nelson, M.D., Ph.D., is currently the Deputy Director and Senior Pediatric Ethicist in the Office of Pediatric Therapeutics, Office of the Commissioner at the U.S. Food and Drug Administration. Dr. Nelson provides consultation throughout FDA on ethical issues arising in the development of FDA-regulated products for children, and serves as a standing member of the FDA Pediatric Review Committee. Prior to joining FDA full-time in 2009, he was Professor of Anesthesiology, Critical Care and Pediatrics at The Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine. After receiving his M.D. degree from Yale University, Dr. Nelson trained in pediatrics (Massachusetts General Hospital), neonatology and pediatric critical care (University of California, San Francisco), and remains Board certified in all three areas.

He has a Master of Divinity degree from Yale Divinity School and a Ph.D. in The Study of Religion from Harvard University, specializing in ethics.

Christine Nguyen, M.D., is the deputy director for safety of the Division of Bone, Reproductive and Urologic Products (DBRUP) in the Office of Drug Evaluation III of the Office of New Drugs. DBRUP regulates a diverse group of products, including those intended for reproductive and obstetrical uses. Dr. Nguyen is board-certified in Obstetrics and Gynecology. She has had extensive clinical experience in general and high obstetrics, postpartum care, reproductive health, and other areas of women's health before starting her career at FDA in 2005.

Denise Pica-Branco, Ph.D., is a Senior Regulatory Health Project Manager with the Division of Pediatric and Maternal Health. She graduated from Walden University with a Ph.D. in Healthcare Administration. She honorably served in the United States Navy for twenty two years and retired as a Chief Petty Officer.

Andrew Plumer, MLA began his career at the Johns Hopkins Bloomberg School of Public Health, Center for Communication Programs (CCP), working on the Population Information Online (POPLINE) database. He then served as the POPLINE liaison to the NLM. Mr. Plumer returned to CCP and became manager of the Media/Materials Clearinghouse. This is a unique collection of health promotional materials from all over the world, with an emphasis on materials used in developing countries. Mr. Plumer returned to NLM in 2004 as a Reference Librarian. In 2012 he joined the Division of Scientific Information Services of the NLM where as part of the Outreach and Special Populations Branch he conducts trainings on NLM databases, manages two of the NLM SIS Twitter feeds and works on various other products including HIV/AIDS information sites and many of the K-12 resources.

Sarah Reece-Stremtan, M.D., is a pediatric anesthesiologist/pain medicine doctor/acupuncturist in practice in Washington DC. A native Oregonian, she came out to DC to attend college at the George Washington University, and ended up staying for medical school, internship, residency, fellowship, and her dream job. She became interested in breastfeeding during an international health class in medical school, where the practices of the Nestle Corporation in the late 1970s were highlighted, much to her horror. She joined the Academy of Breastfeeding Medicine while in training, as the sole anesthesiologist, and currently serves on the Board. She also works on the Protocols Committee and serves as the co-chairwoman of the Liaison Committee. Outside of work, she and her husband spend most of their time trying to keep with their 3 boys.

Zhaoxia Ren, M.D., Ph.D., is a medical officer at the Obstetrics and Pediatrics Pharmacology and Therapeutics Branch (OPPTB) in the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH). She serves as the Program Scientist for the Obstetric-fetal Pharmacology Research Centers (OPRC), formerly known as the Obstetric-fetal Pharmacology Research Centers Units (OPRU) Network, and the Program Officer for the Translational Research in Pediatric and Obstetric Pharmacology research program in the OPPTB. She is also a Project Officer for clinical trials performed within the Pediatric Trial Network (PTN) funded under the Best Pharmaceuticals for Children Act (BPCA). Dr. Ren received her M.D. in China and Ph.D. in molecular and cellular biology from the University of Alabama at Birmingham in the United States.

Hari C. Sachs, M.D., is a Medical Team Leader for Division of Pediatric and Maternal Health. She joined the pediatric group at the FDA in September 2002. She also is a member of the Pediatric Review Committee and serves as one of the FDA liaisons to the AAP Committee on Drugs. Dr. Sachs graduated from the University of Maryland at College Park with a BS in Zoology, received her MD from the University of Maryland at Baltimore and completed her residency training at Childrens' Hospital National Medical Center. Dr. Sachs has been treating patients for over 25 years and continues to see patients on a weekly basis.

Leyla Sahin, M.D., FACOG, is an obstetrician gynecologist who is a medical officer in the Division of Pediatric and Maternal Health in FDA's Center for Drug Evaluation and Research, Office of New Drugs. The focus of her work involves providing pregnancy and lactation expertise to the review divisions at the FDA on issues such as pregnancy exposure data, drug labeling, study protocols, etc. She is involved in various FDA pregnancy and lactation policy efforts, including Guidance development. Her principal area of interest is promoting the public health of pregnant and breastfeeding women through improved data collection of medications used in pregnant and lactating women. She received her medical degree in 1992 from the University of Alberta, Edmonton, Alberta, Canada, and was in clinical practice for twelve years before joining the FDA in 2008.

Jason Sauberan, PharmD., is an experienced Neonatal-Perinatal clinical pharmacist. He currently serves as the clinical research pharmacist with the Neonatal Research Institute, at the Sharp Mary Birch Hospital for Women and Newborns in San Diego, California. Jason's main research and practice interests include drugs in breastmilk, and Pediatric: infectious disease therapy, drug formulations, medication safety, and Drug Information. He is an assistant author of the National Library of Medicine's LactMed database, co-editor of the AAP Nelson's Guide to Pediatric Antimicrobial Therapy, and author of the neonatal-pediatric dosing tables in the AAP Red Book. He has spoken to numerous groups locally and nationally on medication use during lactation, he is a member of the Scientific Advisory Boards for MotherToBaby California and the UC San Diego Breastmilk Biorepository, and is a member of the San Diego County Breastfeeding Coalition.

Mary Short, RN, MSN, is a Research Advisor for Pediatric Capabilities and co-chair of the Pediatric Steering Committee at Eli Lilly and Company. As a research scientist Mary supported multiple clinical trials including pediatric trials in sepsis and pulmonary hypertension. She is the Lilly's liaison to the International Neonatal Consortium and was a member of the PhRMA LDKIT to author a report to the Institute of Medicine: Challenges and Successes in Neonatal Drug Development (2011). She served as an editorial board member and series editor for Advances in Neonatal Care, the journal of the National Association of Neonatal Nurses. Mary is a Registered Nurse, a Perinatal Clinical Nurse Specialist, and has a Master of Science in Nursing from Indiana University. Prior to employment at Lilly, Mary was as a staff nurse and Clinical Nurse Specialist at Methodist Hospital of Indiana NICU where she was involved in research on neuromuscular development in low birth weight infants. Mary has publications on her research in neonatal neuromuscular development, neonatal sepsis, pediatric informed consent, and medication errors in children.

Mary continues her passion for serving children through her volunteer work as a Court Appointed Special Advocate in Marion County for medically fragile infants in foster care.

Jeffrey N. Simpson, Ph.D., earned his Doctor of Philosophy degree in Anatomy and Cell Biology at East Carolina University in 1995 with a research interest in the neurobiology of opioid gene expression. Following a fellowship in the Neurotoxicology Laboratory of the National Institute of Environmental Health Sciences, Jeff began his career in pharmaceutical clinical research. Jeff has served in various clinical project and program development roles over the past 20 years at companies including Schwarz BioSciences, Inc., Gilead Sciences, and UCB BioSciences, Inc., where he is currently employed. Since 2013, Jeff has served as Associate Director and Clinical Operations Lead supporting the UCB Women of Childbearing Age Program.

Melissa S. Tassinari, Ph.D., DABT is a Senior Clinical Advisor with the Division of Pediatric and Maternal Health (DPMH), in the Office of New Drugs at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). She joined the FDA after retiring from Pfizer, Inc. where she held several leadership positions in the toxicology laboratories and in regulatory affairs. Prior to joining Pfizer, she was Assistant Professor in Cell Biology at the University of Massachusetts Medical Center and taught at both Simmons and Wellesley College. She is a past-president of the Teratology Society and has broad experience in both developmental toxicology and pediatric drug development. She received her AB in Biology from Mount Holyoke College, her PhD in Anatomy from the Medical College of Wisconsin and did her post-doctoral training in the Harvard School of Dental Medicine and the Department of Orthopedics at Boston Children's Hospital.

Marie Teil, M.D., holds a medical degree from University Claude Bernard in Lyon, a Masters in Statistics from University Pierre & Marie Curie in Paris, and the Regulatory Affairs Certification US. After 3 years in clinical research with Sanofi, she joined academia at Mount Sinai School of Medicine in New York in 2001 as Conflict of Interest Officer and Director of Education for the Ethics Committee. In 2004, she was appointed associate professor in the Department of Medicine where she created and led the Clinical Trials Office, supporting the department to enable collaborative research between the pharmaceutical industry, NIH, and the Mount Sinai researchers. In 2007, she took the leadership of the Institute for Personalized Medicine as director of operations heading the IPM Biobank. Marie left Mount Sinai in 2011 to join The Medicines Company as head of Clinical Operations Europe, and then joined UCB in 2013 to build and lead the Women of Childbearing Age program in the Immunology Unit. Marie is the mother of 3 and currently lives with her husband in London, UK.

Marsha Walker, R.N., IBCLC, is a registered nurse and international board certified lactation consultant. She has been assisting breastfeeding families in hospital, clinic, and home settings since 1976. Marsha is the executive director of the National Alliance for Breastfeeding Advocacy: Research, Education, and Legal Branch (NABA REAL). As such, she advocates for breastfeeding at the state and federal levels. She served as a vice president of the International Lactation Consultant Association (ILCA) from 1990-1994 and in 1999 as president of ILCA. She is a board member of the US Lactation Consultant Association, USLCA's representative to the USDA's Breastfeeding Promotion

Consortium, and NABA REAL's representative to the US Breastfeeding Committee. Marsha is an international speaker, and an author of numerous publications including ones on the hazards of infant formula use, Code issues in the US, and *Breastfeeding Management for the Clinician: Using the Evidence*.

Jian Wang, Ph.D., is Acting Associate Director for Regulatory Science at Office Drug Evaluation 4, CDER. Before joining FDA in 2008, Dr. Wang received his Ph.D. in pharmacology and pharmaceuticals and his M.S. in Regulatory Sciences from University of Southern California in Los Angeles. He subsequently completed an Amgen postdoctoral fellowship at USC in pharmacokinetic/pharmacodynamics modeling and simulation. Dr. Wang's activities at the FDA include participation in pharmacometric and pediatric Guidance working groups.

Tacey White, Ph.D., received her Ph.D. from the University of Rochester in Toxicology with a concentration in Reproductive Toxicology. She obtained additional training in endocrine disruption, molecular biology and the role of tumor suppressor genes in ovarian cancer through postdoctoral fellowships at the University of Rochester and Fox Chase Cancer Center. Dr. White's professional career has focused on general, developmental and reproductive toxicology in the pharmaceutical industry (Sanofi and GSK) where she has had more than 12 years of experience as a DART study director, the supervisor of an investigative teratology laboratory and a safety assessment project team representative. She was also global director of small animal DART at Covance Laboratories, providing scientific oversight into the design, conduct and interpretation of DART studies. Since 2012, Dr. White has worked as a regulatory toxicology consultant, advising pharmaceutical clients on DART and nonclinical safety assessment strategy during the drug development process. In 2014, Dr. White was co-organizer of a HESI-sponsored workshop on implementation of the PLLR.

Janet Woodcock, M.D., is Director of the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). In 2015, Dr. Woodcock also operated in the role of Acting Director of CDER's newly formed Office of Pharmaceutical Quality, (OPQ). Dr. Woodcock first joined CDER in 1994. From 2005 until 2008, she served in the FDA's Commissioner's office, holding several positions, as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. Her responsibilities encompassed oversight of various aspects of scientific and medical regulatory operations. Before joining CDER, Dr. Woodcock served as Director, Office of Therapeutics Research and Review, and Acting Deputy Director in FDA's Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School. Prior to that, she completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

Lynne Yao, M.D., is the Director of the Division of Pediatric and Maternal Health in the Office of New Drugs, a position she has held since 2012. 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 pregnancy and lactation-related information in product labeling. Dr. Yao started at FDA as a Medical Officer and primary reviewer on the Inborn Errors of Metabolism team in the Division of Gastroenterology and Inborn Errors Products (DGIEP) in 2008, and was a team leader in DGIEP from 2009-2012. Dr. Yao graduated from the George Washington University

School of Medicine, completed residency in Pediatrics at Walter Reed Army Medical Center, and fellowship in Pediatric Nephrology at the Georgetown University Children's Medical Center. Dr. Yao is board certified in both Pediatrics and Pediatric Nephrology.