SOT FDA Colloquium: Dermal Absorption and Toxicity: Concepts for Application to Safety Assessment
December 12, 2019

Speaker Biographies

Nancy Monteiro-Riviere, PhD, Colloquium Chair

Dr. Monteiro-Riviere is University Distinguished Professor Emeritus and former Director of the Nanotechnology Innovation Center of Kansas State. She is Emeritus Professor of Investigative Dermatology and Toxicology at NCSU and Professor in the Joint Department of Biomedical Engineering at UNC-Chapel Hill/NCSU and Research Adjunct Professor of Dermatology, at UNC School of Medicine. She did a postdoctoral fellowship in toxicology at the Chemical Industry Institute of Toxicology in RTP, NC. She was past-President of the Dermal and *In Vitro* Specialty Sections of SOT and elected to several SOT committees and selected to present at the SOT Eminent Toxicologist lecture series in March 2016. Dr. Monteiro-Riviere was elected to the ATS Board of Directors and serves on the SOT Endowment Fund Board. She was recipient of the Purdue University Inaugural Distinguished Women Scholars Award, KSU Woman of Distinction, and elected to attend the National Academy of Sciences Keck Futures Initiative. She is Associate Editor for two and serves on the editorial board of six other toxicology journals, as well as serving on several national (NRC) and international (EU) expert review panels. She was on Thomson Reuters's 2014 list of the top 1% most highly cited researchers in pharmacology and toxicology. She published 312 manuscripts in skin toxicology and nanotoxicology and is editor of three books: "Nanotoxicology Characterization and Dosing and Health Effects," "Toxicology of the Skin-Target Organ Series," and "Nanotoxicology: Progress toward Nanomedicine." Current research interests *involve in vivo* and *in vitro* studies of skin absorption and chemical and nanomaterial penetration and toxicity.

Jeffrey J. Yourick, PhD, DABT, ATS, Colloquium Co-chair

Dr. Yourick is the Chief of the Developmental Reproductive Toxicology and Immunotoxicology Branch in FDA's Center for Food Safety and Applied Nutrition (CFSAN). Dr. Yourick completed his PhD in Pharmacology and Toxicology at the University of Kansas. His current focus is on toxicology research and safety assessment of chemical contaminants in foods, dietary supplements, and cosmetics. Previously, he was the Senior Science and Technology Manager at the Defense Threat Reduction Agency (DTRA) for the Department of Defense in the Joint Science and Technology Office (JSTO), Chemical and Biological Technologies Directorate (DTRA CB). He managed an extensive scientific research portfolio related to the development of chemical and radiological medical countermeasures. Prior to DTRA, Dr. Yourick was a Research Toxicologist for 15 years at the FDA where his research interests pertained to skin absorption and metabolism of cosmetic ingredients and color additives. Dr. Yourick was a Research Pharmacologist at the US Army Medical Research Institute of Chemical Defense (USAMRICD) before joining the FDA. He was involved in investigating the biochemical mechanisms of sulfur mustard injury to the skin and lung. Dr. Yourick is a Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences. Dr. Yourick has served as both a Councilor and President of the Dermal Toxicology Specialty Section of SOT and the Association of Government Toxicologists. He is on the editorial board

for the journal *Regulatory Toxicology and Pharmacology*. He has published extensively in the areas of dermal toxicology and chemical warfare agents.

Gerald B. Kasting, PhD, Speaker

Dr. Kasting, Professor of Pharmaceutics and Cosmetic Science at the University of Cincinnati's (UC) James L. Winkle College of Pharmacy, teaches in their graduate and professional programs and has been Director of Graduate Studies and Chair of the Division of Pharmaceutical Sciences. He is currently the skin health advisor for the UC Research Institute Skin Science and Technology Collaborative (S2TC). Dr. Kasting's research is in percutaneous absorption. Before 1999, he was senior scientist with the Skin Beauty Care Technology Division of Procter & Gamble's Miami Valley Laboratories, developing improved skin care products. His BA is in chemistry from Vanderbilt University in 1975 and PhD in Physical Chemistry from MIT in 1980. In 2013 Dr. Kasting received the Excellence in Doctoral Mentoring Award from the UC. He has published over 100 papers and holds eight patents. A two-time recipient of the Shaw Mudge Award from the Society of Cosmetic Chemists, he was chair of the 2005 Gordon Research Conference on Barrier Function of Mammalian Skin. He serves on the Editorial Board of the *Journal of Pharmaceutical Sciences* and *Pharmaceutical Research and Development* and as a referee for several other major pharmaceutical journals. His research improves computational models for topical delivery and dermal risk assessment based on a mechanistic understanding of the percutaneous absorption process. Recent projects have included development of a dynamic computational model for skin hydration, transport kinetics of glycerin/water mixtures in skin, predictive approaches to surfactant-induced skin irritation, and release of suspended agents from polymer/surfactant coacervate deposits on skin and hair. Additional projects include heat effects on transdermal products with Dr. Kevin Li and computational models for biomarkers in sweat with Dr. Jason Heikenfeld.

Ronald Baynes, PhD, Speaker (approval pending)

Dr. Baynes obtained his BSc (Biology) from the University of the West Indies, veterinary degree from Tuskegee University, MS in pharmacology from the University of Georgia, and PhD in pharmacology from North Carolina State University. He is currently a Professor of Pharmacology at NCSU College of Veterinary Medicine and prior to his current appointment, he was a Toxicologist at Syracuse Research Corporation in Atlanta, GA. Dr. Baynes' primary responsibilities at NCSU College of Veterinary Medicine for the last 21 years include teaching and research in two areas of quantitative pharmacology and toxicology, 1) Formulation and mixture effects on drug and chemical disposition of topical formulations leading to the development of Quantitative Structure Activity Relationship (QSAR) models to inform risk assessment of skin exposures to chemical mixtures, and 2) Contaminant and veterinary drug residue pharmacology and development of novel pharmacokinetics modeling approaches to inform risk management of veterinary drug residues via the national Food Animal Residue Avoidance Databank (FARAD) program. His research at NCSU has been supported by several NIH, USDA, US DOD, and industrial grants. He has generated more than 130 peer-reviewed publications and book chapters pertaining to his teaching, extension, and research activities. In addition to training of veterinary graduate students in his laboratory, he is actively involved in preparing undergraduate and DVM students for careers in veterinary research through several honors and summer programs.

Simon Charles Wilkinson, PhD, Speaker

Simon Wilkinson has been a Senior Lecturer in Pharmacology in the School of Biomedical, Nutritional, and Sports Sciences at Newcastle University since November 2018, where he is Chair of the Pharmacology Curriculum at Newcastle as well as module leader on the Pharmacology degree program. Prior to this he was a Staff Scientist at the Medical Toxicology Centre (MTC) at Newcastle University from 2006 to 2018. He worked as a toxicologist for the UK Health Protection Agency from 2004 to 2006, and was a researcher on the EU Edetox project, which evaluated *in vitro* methods for dermal absorption, from 2001 to 2004. Dr Wilkinson has held joint responsibility for collaborative research (with staff at Public Health England and at the Institute of Cellular Medicine in Newcastle) in dermal absorption and metabolism in projects funded by the UK National Institute of Health Research, including the efficacy of novel methods for skin decontamination used in mass casualty incidents. He was a consultant in skin absorption and metabolism for a major European Cosmetics Firm (slogan: because he's worth it) from 2011 to 2015. He has been a member of the UK Expert Committee on Pesticides since 2015 and was Co- Editor for the *British Toxicology Society Newsletter* from 2010 to 2013.

Timothy J. McCarthy, PhD, DABT, Speaker

Tim McCarthy is a Director of Toxicology and Fellow at Johnson & Johnson Consumer Products in Skillman, NJ. Previously he was a Senior Principal Scientist at the former Schering-Plough HealthCare Products in Memphis, TN. He has over 20 years of experience in the consumer products sector supporting dermal OTC drugs, cosmetics, ingestible OTC drugs, Rx-to-OTC switches, NDA line extensions, and 510(k) medical devices. He supports product development and commercial launch through ingredient hazard and risk assessments and formulation tolerance testing. In addition, he provides technical support for regulatory toxicology, product stewardship, and professional communication activities within Johnson & Johnson Consumer and externally through the Personal Care Products Council. In his 13-plus years at Johnson & Johnson, Dr McCarthy has provided toxicology support for the Johnson's baby franchise. Dr. McCarthy received a PhD in toxicology from Rutgers University/UMDNJ Joint Graduate Program in Toxicology, Piscataway, NJ. He conducted postdoctoral research at the Johns Hopkins School of Public Health, Baltimore, MD. He is a Diplomat in the American Board of Toxicology and has a BS in chemistry from Juniata College.

Nakissa Sadrieh, PhD, Roundtable Discussant

Dr. Sadrieh obtained her doctorate in Toxicology in 1993 from Rutgers University in New Jersey. Following a postdoctoral fellowship in the Laboratory of Chemical Carcinogenesis at the National Cancer Institute, Dr. Sadrieh joined the Food and Drug Administration in 1996 as a pharmacology and toxicology reviewer. In 1998, Dr. Sadrieh became the supervisory pharmacologist in the Division of Medical Imaging and Radiopharmaceutical Drug Products, Center for Drug Evaluation and Research (CDER). In 2002, Dr. Sadrieh joined CDER's Office of Pharmaceutical Science, as the Associate Director for Research Policy and Implementation, where her work focused on scientific research that directly impacted regulatory decision making. In October 2013, Dr. Sadrieh Joined the Center for Food Safety and Nutrition (CFSAN) as the Director of the Cosmetics Division in the Office of Cosmetics and Colors (OCAC). Dr. Sadrieh is responsible for the oversight of FDA's cosmetics program, both from a scientific and regulatory perspective.