Michael Bartels, Ph.D.

The Dow Chemical Company

Michael Bartels, Ph.D., is an associate fellow in the Toxicology Laboratory at The Dow Chemical Company. He is Senior Group Leader for their Toxicokinetics Group, which conducts both guideline and mechanistic toxicokinetic projects, often as an integrated component of safety assessment studies. He is also co-leading a project to develop high-throughput, linked exposure-physiologically based pharmacokinetic (PBPK) models to aid in derivation of margins of exposure for Dow products, in support of Dow's 2025 Sustainability Goals.

Dr. Bartels is a member of several industry-funded groups dealing with exposure assessment or biomonitoring, including the American Chemistry Council's Antimicrobials Exposure Assessment Task Force and CropLifeAmerica's Farm Family Exposure Assessment Task Force. He has been principal investigator or co-investigator on research projects in the area of biomonitoring and metabolism funded by the American Chemistry Council ("Characterizing Risks of Chemicals Exhibiting Extensive Low Dose Clearance in the Gut, Liver, and Blood: Dietary Chlorpyrifos as a Case Example"), the European Chemical Industry Council ("Development of a Tiered Set of Modelling Tools for Derivation of Biomonitoring Guidance Values"; "In Vitro Metabolism of 4-Vinylphenol and Styrene in Mouse, Rat and/or Human Microsomes Obtained from Lung and/or Liver Tissue") and the U.S. Centers for Disease Control's National Council on Environmental Health ("Quantitative Analysis of Diethylene Glycol (DEG) and its Metabolites in Human Biological Samples"). His expert panel activities include participation in a 2007 workshop on the Derivation of Biomonitoring Equivalents, serving as a grant review panel member for the U.S. Environmental Protection Agency (EPA), the National Science Foundation, and the National Institutes of Health from 1996-2009; chair of a Continuing Education course on Toxicokinetics at the 2009 Society of Toxicology meeting; and presenter to the 2011 EPA Scientific Advisory Panel (SAP) "Chlorpyrifos Physiologically-Based Pharmacokinetic/ Pharmacodynamic (PBPK/PD) Modeling linked to the Cumulative and Aggregate Risk Evaluation System (CARES)", the 2012 EPA SAP "Scientific Issues Associated with Chlorpyrifos Health Effects", and the 2014 EPA SAP "Scientific Uncertainties Associated with New High Throughput Methods to Estimate Chemical Exposure." Recent presentations were primarily in the area of toxicokinetic modeling: China Society of Toxicology, "Toxicokinetics (TK): methodological and regulatory challenges" (May 2015), EPA HED, "Dow Predictive Safety Assessment Capabilities: Toxicokinetics" (July 2015).

Dr. Bartels has authored or coauthored over 110 publications and book chapters, primarily in the field of xenobiotic metabolism, toxicokinetic modeling and biomonitoring.

Kim Brouwer, Ph.D., Pharm.D.

Eshelman School of Pharmacy
University of North Carolina at Chapel Hill

Kim Brouwer is Associate Dean for Research and Graduate Education, Eshelman School of Pharmacy, and Kenan Distinguished Professor in the School of Pharmacy and Curriculum in Toxicology at the University of North Carolina at Chapel Hill (UNC). Prior to joining the UNC faculty, she received her B.S. in pharmacy from Oregon State University, Pharm.D. and residency training and a Ph.D. in pharmaceutical sciences/pharmacokinetics from the University of Kentucky (UK) College of Pharmacy, and postdoctoral training in pharmacology and drug metabolism in the UK College of Medicine.

Dr. Brouwer directs a National Institutes of Health (NIH)-funded research program focused on hepatobiliary drug disposition, hepatic transport proteins, and development/refinement of in vitro models to predict in vivo hepatic drug disposition, drug interactions, and hepatotoxicity. Dr. Brouwer was founding director of the UNC Pharmacokinetics/Pharmacodynamics Fellowship Program and is co-principal investigator of an NIH-funded T32 clinical pharmacology postdoctoral training program. She has mentored 39 clinical pharmacology fellows, 19 postdoctoral fellows/visiting scholars, 30 doctoral students, and 23 undergraduate/honors students, and published over 200 research papers, reviews and book chapters.

Dr. Brouwer is co-inventor of B-CLEAR®, an in vitro method to assess hepatobiliary disposition that correlates with in vivo data, and is co-founder of Qualyst Transporter Solutions, a UNC spin-off company. She is co-chair of the National Institute of Child Health and Human Development's Pediatric Transporters Working Group. She is a member of the International Transporter Consortium Steering Committee, the board of directors of the American Society for Clinical Pharmacology and Therapeutics, and the following editorial advisory boards: Clinical Pharmacology and Therapeutics (CPT), CPT Pharmacometrics and Systems Pharmacology, Clinical and Translational Science, and the American Association of Pharmaceutical Scientists (AAPS) Journal. She served as a member of the NIH Pharmacology Study Section (1998-2002) and the NIH Quantitative and Systems Pharmacology Working Group (2010-2012).

Dr. Brouwer was recognized as an AAPS Fellow in 1998 and received the 2001 PhRMA Foundation Award in Excellence in Pharmaceutics. In 2009, Dr. Brouwer was named a Kenan Distinguished Professor, one of the highest honors bestowed on UNC faculty.

Warren Casey, Ph.D.

National Institute of Environmental Health Sciences

Warren Casey is director of the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), part of the National Institute of Environmental Health Sciences (NIEHS). Prior to assuming his current position, Dr. Casey worked in the pharmaceutical industry for 15 years at GlaxoSmithKline in a variety of areas, including microbiology, toxicogenomics, investigative toxicology, discovery and molecular toxicology, and biomarker development.

Dr. Casey received his undergraduate degree in biochemistry and his Ph.D. in microbiology from North Carolina State University (NCSU) where he has been named a Distinguished Alumnus. He also holds an adjunct professorship in the NCSU Department of Microbiology. He has been a Diplomate of the American Board of Toxicology since 2007.

Stephen Ferguson, Ph.D.

National Institute of Environmental Health Sciences

Stephen Ferguson is a scientist within the Biomolecular Screening Branch of the National Toxicology Program (NTP) Division of the National Institute of Environmental Health Sciences (NIEHS). His primary role is to lead efforts within NTP to development more physiologically relevant in vitro liver models, incorporate xenobiotic metabolism into Tox21 research efforts, and integrate informative assay approaches as mechanistic windows into the dynamics cellular response to chemical exposure. Dr. Ferguson has experience with in vitro liver models and assay approaches to evaluate drug/chemical metabolism, drug-drug interactions (e.g., liver enzyme induction/ inhibition), drug transport, and in vitro toxicology. He also serves as adjunct faculty to the Curriculum in Toxicology at the University of North Carolina at Chapel Hill.

Prior to joining NIEHS, Dr. Ferguson led the ADME/Tox R&D program of Life Technologies (formerly CellzDirect) where his team focused on development of in vitro liver models (i.e. primary hepatocytes, HepaRG, Kupffer cells) and assay approaches, and served as study director on various in vitro drug metabolism-pharmacokinetics and toxicology research studies.

Dr. Ferguson completed his postdoctoral training at NIEHS, which focused on regulation of cytochrome P450 expression, drug metabolism, and pharmacogenetics. He received his B.S. and Ph.D. degrees in chemistry (graduate minor in biotechnology) from North Carolina State University. He has authored more than 40 research publications and book chapters.

Grazyna Fraczkiewicz, M.S.

Simulations Plus, Inc.

Grazyna (Grace) Fraczkiewicz is a team leader of the Simulation Studies Group at Simulations Plus, Inc. where she mentors and manages scientists performing consulting services for industrial and academic customers. She has fifteen years of experience in use of modeling and simulation approaches to integrate knowledge of pharmacokinetic, pharmacodynamic, efficacy, safety, patient demographics, and pathophysiological factors to answer product development decision-making questions. She performs and oversees over 20 projects per year that encompass all areas of pharmaceutical product development from early discovery to formulation optimization.

Ms. Fraczkiewicz holds an M.S. degree in chemistry and chemical physics from Wroclaw University in Poland. She joined Simulations Plus in 2000 as a scientist supporting development of new software tools for the pharmaceutical industry, initially working on development and validation of computer software including GastroPlus, ADMET Predictor, and DDDPlus. In 2008, she joined the newly formed Simulation Studies Team in the role of senior scientist, where she gained extensive experience in building predictive physiologically based pharmacokinetic and pharmacodynamic models. She was promoted to a team leader position in 2010. Her broad background in chemistry, physics, biochemistry, physiology, pharmacokinetics and experience in physiologically based pharmacokinetic and quantitative structure-activity relationship modeling helps her solve difficult problems provided by pharmaceutical and chemical industry clients.

Annie Jarabek, Ph.D.

Office of Research and Development
U.S. Environmental Protection Agency

Annie M. Jarabek is the deputy director of the Human Health Risk Assessment national research program in the Office of Research and Development of the U.S. Environmental Protection Agency. She is also a senior toxicologist in the immediate office of the National Center for Environmental Assessment of the Agency's Research Triangle Park Division.

Dr. Jarabek has significant experience and training in inhalation toxicology in both laboratory and clinical environments, dosimetry modeling, risk assessment, and decision analysis. She was principal author of the Agency's "Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry." Dr. Jarabek has worked on risk assessments, dosimetry models or analysis methods across all media and routes of exposure. She was the lead for the Agency's risk assessment of ingested perchlorate and some of her other work addressed several priority, interdisciplinary Agency assessments including inhaled particulate matter, vinyl acetate, manganese, and asbestos. Her current research efforts focus on multi-scale modeling to inform mode of action and decision analysis.

Dr. Jarabek has received three awards for best manuscript in risk assessment application from the Risk Assessment Specialty Section of the Society of Toxicology, along with several best abstract presentation awards. She also received a Lifetime Achievement Award from the University of Massachusetts, the Risk Practitioner of the Year award from the Society of Risk Analysis, the Superfund National Notable Achievement Award, and several award medals (gold, silver and bronze) and technical or special service awards from the Agency.

Alice Ke, Ph.D.

Simcyp, a Certara company

Alice Ke obtained her Ph.D. in pharmaceutics from the University of Washington, Seattle, where her research was focused on the assessment of fetal and central nervous system drug distribution using clinical imaging techniques. She then accepted an Oak Ridge Institute for Science Education fellowship in the Office of Clinical Pharmacology at the U.S. Food and Drug Administration, where she developed and validated physiologically based pharmacokinetic (PBPK) models and population pharmacokinetic (PK) models to support dose adjustment for pregnant women. After completing her fellowship, Dr. Ke was a research scientist in the Department of Drug Disposition and Pharmacokinetics/Pharmacodynamics (PK/PD) at Lilly Research Laboratories, where she applied population PK and PBPK modeling and simulation techniques to provide model-based advice on the design of clinical pharmacology studies. Currently, Dr. Ke is a consultant and scientific advisor at Simcyp. Her research interests continue to center around the applications of PBPK and PK/PD modeling to predicting complex drug interactions and PK/PD in special populations.

Nicole Kleinstreuer, Ph.D.

National Institute of Environmental Health Sciences

Nicole Kleinstreuer is the deputy director of the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) within the National Institute of Environmental Health Sciences in Research Triangle Park, North Carolina. She worked previously for Integrated Laboratory Systems, Inc., as the head of the NICEATM computational toxicology group. Her research focuses on in vitro alternatives to animal testing, high throughput screening and multidimensional data analyses, and mathematical and computational modeling of biological systems and their susceptibility to environmental perturbations that may result in adverse outcomes.

Dr. Kleinstreuer received her undergraduate degrees in mathematics and biomedical engineering from the University of North Carolina at Chapel Hill and her Ph.D. in bioengineering from the University of Canterbury in Christchurch, New Zealand. She completed her postdoctoral training with the National Center for Computational Toxicology of the U.S. Environmental Protection Agency. Dr. Kleinstreuer also maintains an adjunct faculty appointment at the Eshelman School of Pharmacy at the University of North Carolina at Chapel Hill.

Annie Lumen, Ph.D.

National Center for Toxicological Research
U.S. Food and Drug Administration

Annie Lumen is a staff fellow at the National Center for Toxicological Research (NCTR) of the U.S. Food and Drug Administration. She is principal investigator in the Division of Biochemical Toxicology and the computational modeling group at NCTR. Her research interests include development of physiologically based pharmacokinetic/pharmacodynamic and dose-response models in sensitive life stages (such as pregnancy) for characterizing system-compound interactions that are of interest to the center and the agency.

Dr. Lumen received her doctorate in biological sciences from Drexel University in 2011. Her graduate research included development of mass action kinetic models for assessing the risk of transporter mediated drug-drug interactions and mechanistic strategies for in vitro to in vivo extrapolation conducted in collaboration with GlaxoSmithKline. She received her postdoctoral training at NCTR on the development of physiologically based pharmacokinetic and biologically based dose response models. She has B.S. and M.S. degrees in biological sciences and a Bachelor of Engineering degree in chemical engineering from the Birla Institute of Technology and Science, Pilani, India.

Scott G. Lynn, Ph.D.

Office of Science Coordination and Policy
U.S. Environmental Protection Agency

Scott Lynn is a biologist in the Office of Science Coordination and Policy at the U.S. Environmental Protection Agency (EPA). Dr. Lynn had a broad range of research experience in toxicology, biology, and environmental science prior to coming to EPA. He developed and presented a physiologically based toxicokinetic model (PBTK) on organic xenobiotic accumulation in bullfrogs and has published numerous GenBank sequences of cloned endocrine genes in lower vertebrates. He has experience with both mammalian and fish cell culture and hepatocyte isolation. Dr. Lynn came to EPA in 2011 to work on the Endocrine Disruptor Screening Program (EDSP). His work in the EDSP has involved leading fish and amphibian toxicity testing guideline validations and contributing to the effort to integrate computational tools into prioritization and screening. He has taken a lead in implementing reverse toxicokinetics (rTK) into the EDSP by developing contract vehicles and chairing a recent Society of Environmental Toxicology and Chemistry session on rTK in aquatic organisms.

Dr. Lynn received his Ph.D. degree in biology from the University of Kentucky, where his research focused on molecular endocrinology in lower vertebrates. He completed a postdoctoral fellowship in molecular toxicology at Michigan State University with the Center for Integrative Toxicology and was a Fulbright Research Scholar postdoctoral fellow. Dr. Lynn also received a M.S. (environmental toxicology) from Drexel University and a B.S. (environmental science) from The Pennsylvania State University. He is an author on 17 peer-reviewed publications.

Alicia Paini, Ph.D.

European Union Reference Laboratory for Alternatives to Animal Testing
European Union Joint Research Centre

Alicia Paini holds a M.Sc. in food science and technology from the University of Parma, Italy, as well as a M.Sc. in food safety from Wageningen University (WUR), Netherlands, where she gained know-how in generation of data to develop physiologically based pharmacokinetic (PBPK) models, PBPK model development, and cell in vitro testing. In 2012 she defended her Ph.D. at WUR, the research for which was carried out mainly at the Nestlé Research Center in Switzerland. She started as a postdoc at the European Union Joint Research Centre in early 2012, within the System Toxicology Unit of the Institute of Health and Consumer Protection, mainly working on the COSMOS/Seurat-1 project. Since October 2015, she has been working on the implementation phase of the Toxicokinetic Strategy for the European Union Reference Laboratory for Alternatives to Animal Testing. Alicia is registered as a Toxicologist within the Netherlands Society of Toxicology and as European Registered Toxicologist. She has (co)-authored multiple peer-reviewed articles in the field of toxicology.

Paul Price, Ph.D.

National Exposure Research Laboratory
U.S. Environmental Protection Agency

Paul Price is an exposure scientist with National Exposure Research Laboratory of the U.S. Environmental Protection Agency (EPA), where he is providing support to EPA's Chemical Safety for Sustainability Research Program. Dr. Price has over 36 years of experience in assessing exposures to chemical stressors.

Prior to joining EPA, Dr. Price was a risk assessment leader at The Dow Chemical Company. Earlier in his career, he was president of The Lifeline Group, Inc. where he was a lead designer of the LifeLine™ dietary and residential exposure models. He also co-developed COMET, a high-throughput exposure-ranking tool, for Health Canada. Current areas of research include use of simulation modeling to assess chemical exposures.

Dr. Price is a charter member of the Society for Risk Analysis and the International Society of Exposure Science and the author of more than 50 papers and book chapters in the fields of exposure and risk assessment.

Caroline Ring, Ph.D.

National Center for Computational Toxicology
U.S. Environmental Protection Agency

Caroline Ring is an Oak Ridge Institute for Science and Education postdoctoral fellow in the National Center for Computational Toxicology (NCCT) at the U.S. Environmental Protection Agency. During her doctoral work, Dr. Ring became interested in the problem of including interindividual variability in computational models of biological systems used in clinical or regulatory decision-making and risk assessment. At NCCT, she has developed a module to include interindividual variability in a high throughput physiologically based pharmacokinetic modeling framework used for in vitro to in vivo extrapolation in the context of chemical risk prioritization.

Dr. Ring received her B.S. in physics from the University of North Carolina at Greensboro and her M.S. and Ph.D. in biomedical engineering from Duke University.

Nisha Sipes, Ph.D.

National Institute of Environmental Health Sciences

Nisha S. Sipes is a health science evaluator in the Biomolecular Screening Branch in the Division of the National Toxicology Program at the National Institute of Environmental Health Sciences (NIEHS). Her projects are focused on analyzing and developing computational approaches for the Tox21 and ToxCast high throughput screening datasets as well as genomics datasets, developing better estimates of in vivo likelihood of exposure, and facilitating better public understanding and use of the data. Prior to joining NIEHS, Dr. Sipes spent five years in the National Center for Computational Toxicology at the U.S. Environmental Protection Agency, where she analyzed ToxCast high throughput screening data and built computational models of developmental toxicity.

Dr. Sipes earned a B.S. degree in mechanical engineering, an M.S. in biomedical engineering, and a Ph.D. in cell and molecular biology from the University of Cincinnati, Cincinnati, Ohio. She is a member of the Society of Toxicology and an active member of the Teratology Society, and serves on the editorial boards of Reproductive Toxicology and Frontiers in Predictive Toxicology.

Ted Simon, PhD, DABT

Ted Simon, LLC

Ted Simon is the principal and owner of Ted Simon, LLC, a solo consulting practice that provides scientific support to a select group of clients. Dr. Simon has provided consulting services to clients that include large and small private sector companies, industry trade groups, attorneys, state, federal and international regulatory agencies, university faculty and others. He has provided scientific and policy support in the areas of toxicology, environmental risk assessment, mathematical modeling, product liability, statistics, drug and alcohol abuse, and other issues. He has also taught graduate-level university courses and private/public sector short courses in risk assessment, statistics and simulation modeling. Recently, he published a textbook *Environmental Risk Assessment: A Toxicological Approach* through CRC Press.

Before establishing his consulting practice, Dr. Simon worked for 12 years in the U.S. Environmental Protection Agency (EPA) Region 4 office in Atlanta. At EPA he served as the senior toxicologist in the Waste Management Division, for which he developed national and regional guidance in the areas of toxicology, exposure assessment, probabilistic methods, soil cleanup, and statistics. He received a Ph.D. in neuroscience from Georgia State University in Atlanta, and a B.A. in biology from Middlebury College in Vermont.

John Wambaugh, Ph.D.

National Center for Computational Toxicology
U.S. Environmental Protection Agency

John Wambaugh is a physical scientist with the U.S. Environmental Protection Agency (EPA), working within the National Center for Computational Toxicology (NCCT). His areas of active research include high throughput methods for exposure, toxicokinetics, and toxicology, often involving Bayesian statistics, machine learning, and methods development for biostatistics. Dr. Wambaugh co-leads the EPA Rapid Exposure and Dosimetry project (home of ExpoCast research), and is also a member of the ToxCast research team. His research on ExpoCast and ToxCast focuses on using in vitro laboratory measurements and computer simulations applicable to thousands of chemicals that may be in our environment. The aim is to predict the level of chemical exposure and any biological changes caused by that exposure, and to evaluate these predictions using both statistical analysis and the collection of new data.

Dr. Wambaugh received his Ph.D. in physics in 2006 from Duke University for work in experimental non-equilibrium statistical mechanics. He started work with NCCT in 2006 as a postdoctoral researcher with Woodrow Setzer (EPA/NCCT) and Hugh Barton (Pfizer, formerly EPA/NCCT). As a postdoc, he studied statistical analysis of biological models with an emphasis on Bayesian methods and integrating multiple data types. He transitioned to a principal investigator role at NCCT in 2008. Dr. Wambaugh received a B.S. (physics) from the University of Michigan, Ann Arbor; an M.S. (physics) from Georgia Institute of Technology; and a second M.S. (computer science) from Duke University.

Barbara Wetmore, Ph.D.

ScitoVation, LLC

Barbara Wetmore is a senior investigator at ScitoVation in Research Triangle Park, North Carolina. Her research interests focus on the development and assessment of in vitro experimental and modeling tools that can be utilized to inform toxicity testing and risk assessment. Specifically, she has extensive expertise in vitro-in vivo extrapolation (IVIVE) modeling, pharmacokinetics, in vitro and high throughput screening (HTS) approaches, chemical mode of action assessments, and life-stage based modeling to assess population variability. Her recent publications in IVIVE and life-stage based modeling received international awards (Simcyp Academic Awards: 2012, 2015; Outstanding Paper Advancing the Science of Risk Assessment, Risk Assessment Specialty Section of the Society of Toxicology: 2014). Other research interests have focused on the application of genomic and proteomic tools to inform chemical mode of action assessments and biomarker discovery.

Dr. Wetmore has served in various capacities as an expert or peer reviewer for organizations including the National Academy of Sciences, European Union Reference Laboratory for Alternatives to Animal Testing, the U.S. Environmental Protection Agency, and Health Canada. She is an active member of the Society of Toxicology, currently serving as vice president-elect for the In Vitro and Alternative Methods Specialty Section. She received her doctorate in toxicology from North Carolina State University.