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Systems Biology-Informed Risk Assessment
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SPEAKERS and PANELISTS/MODERATORS BIOS

SPEAKERS

Kim Boekelheide, Ph.D., is Professor of Pathology and Laboratory Medicine at the Brown University School of Medicine. He received his B.A. from Harvard University, and M.D. and Ph.D. from Duke University. His research examines fundamental molecular mechanisms by which environmental and occupational toxicants induce testicular injury. Current projects include the study of co-exposure synergy using model testicular toxicants and the effects of in utero endocrine disruptor exposure on steroidogenesis and a predisposition to cancer. He is Director of the Brown University Superfund Research Program and the Children's Environmental Health Formative Center. His research has been continuously funded by the National Institute of Environmental Health Sciences since 1985 and he is currently a member of the National Advisory Environmental Health Sciences Council.

Ila Cote, Ph.D., DABT, is Senior Science Advisor in EPA's National Center for Environmental Assessment. This Center conducts EPA health assessments used to support Agency decision-making. She is a board certified toxicologist, and has worked in the area of risk assessment and science policy for the last twenty-five years. She is an adjunct professor at the University of Colorado Department of Molecular, Cellular and Developmental Biology.

Robert Devlin, Ph.D., received his Ph.D. degree from the University of Virginia in 1976 and served on the faculty at Emory University for several years before joining the Environmental Protection Agency in 1986. He was chief of the Cell and Molecular Biology Section of the Clinical Research Branch from 1991-94, and Chief of the Clinical Research Branch (Human Studies Division) from 1994 – 2008. He was promoted to the position of Senior Scientist in 2008. He was also acting Division Director (Human Studies Division) in 2007 and Acting National PM Program Manager in 2000. Dr. Devlin holds adjunct Professor appointments at the University of North Carolina (Department of Pediatrics and the Curriculum in Toxicology) and North Carolina State University (School of Veterinary Medicine). Dr. Devlin's research interests are focused on understanding the health effects of air pollutants in humans, using a combination of controlled human exposure studies, epidemiology panel studies, and in vitro molecular studies. His current work involves the characterization of adverse health effects in humans exposed to particulate matter (PM) as well as defining the pathophysiological mechanisms by which PM causes adverse effects. Dr. Devlin has won numerous awards for his research at the EPA, including seven Bronze medals and a Gold Medal. He has published more than 200 scientific articles has presented his research at many research institutions and international meetings. He also reviews articles for journals, is on the editorial board of several journals,

reviews research grants for several agencies, and is a member of numerous advisory panels, review groups, and professional societies in his areas of interest.

Dean P. Jones, Ph.D., is Professor of Medicine (Pulmonary Division) and Biochemistry, Director of the Clinical Biomarkers Laboratory and Co-Director of the Center for Clinical and Molecular Nutrition at Emory University. He has a B.S. in Chemistry from the University of Illinois, Urbana, and Ph.D in Biochemistry from Oregon Health Sciences Univ., Portland. He was a National Sciences Foundation Postdoctoral Fellow in Nutritional Biochemistry at Cornell University, Ithaca, and a Visiting Scientist in Molecular Toxicology at the Karolinska Institute, Stockholm He joined the Emory faculty as Assistant Professor of Biochemistry in 1979, was promoted to Associate Professor in 1985 and Professor in 1991. In 1997-98, he was a Nobel Fellow at the Karolinska Institute, Stockholm, and in 2003 he changed departments from Biochemistry to Medicine to facilitate development of a metabolomics program. Dr. Jones is recognized for his research in oxidative stress, environmental health and toxicology, mitochondrial mechanisms of cell death and the thiol antioxidants glutathione and thioredoxin.

In the past several years, Dr Jones has applied high-resolution mass spectrometry to metabolic profiling and has recently pursued development of these methods for universal environmental exposure surveillance. Dr. Jones has over 400 research publications and reviews and has edited volumes on mitochondrial toxicity and microcompartmentation of metabolism. He received the Albert E. Levy Research Award, the most prestigious research award of Emory University, the Science and Humanity Award of the Oxygen Club of California, and is a member of the Emory Millipub Club, recognizing authors of manuscripts cited more than 1000 times. He has been a visiting professor at multiple institutions, and his research has been supported by the NIEHS, NHLBI, NIA, NIDDK, NIAAA, NCI, NEI, Office of Naval Research, American Heart Association, American Institute for Cancer Research and other sources. He has served on multiple editorial boards and grant review panels, including Chair of the Alcohol and Toxicology Study Section for NIH, and is currently a member of the Basic Mechanisms of Cancer Therapeutics Study Section for NCI.

Derek Knight, Ph.D., (British) is the Senior Scientific Advisor to the Executive Director of the European chemicals Agency (ECHA). For almost 18 years he headed a team of regulatory affairs professionals at a UK contract research organisation, specialising in safety assessments of chemical and biocides, but also covering a wide range projects for many regulatory schemes worldwide. Before this he registered medicinal products and worked as a technical support chemist for a UK pharmaceutical manufacturer. He has gained a broad understanding of the regulation of chemicals from the perspective of the various interested parties. He is especially interested in approaches to hazard and risk assessment using non-standard data. He is a Fellow of the Royal Society of Chemistry, a Chartered Scientist and a Fellow of The Organisation of Professionals in Regulatory Affairs. His doctoral studies at the University of Oxford in the UK were in organosulphur chemistry.

Greg Paoli, MASc., serves as Principal Risk Scientist and COO at Risk Sciences International, a consulting firm specializing in risk assessment, management and communication in the field of public health, safety and risk-based decision-support. He has experience in diverse risk domains including toxicological, microbiological, and nutritional hazards, air and water quality, climate

change impacts, and engineering devices, as well as risk assessment for natural and man-made disasters. He specializes in probabilistic risk assessment methods, the development of risk-based decision-support tools and comparative risk assessment.

Greg has served on a number of expert committees devoted to the risk sciences. He was a member of the U.S. National Research Council committee that issued the 2009 report, *Science and Decisions: Advancing Risk Assessment,* also known as the Silver Book. He serves on the Canadian Standards Association Technical Committee on Risk Management, a US NRC Standing Committee on the Use of Public Health Data at the U.S. Food Safety and Inspection Service, and has served on several expert committees convened by the World Health Organization. Greg completed a term as Councilor of the Society for Risk Analysis (SRA) and is a member of the Editorial Board of *Risk Analysis*. Recently, Greg was awarded the Sigma Xi – SRA Distinguished Lecturer Award. Greg holds a Bachelors Degree in Electrical and Computer Engineering and a Master's Degree in Systems Design Engineering from the University of Waterloo.

Justin G. Teeguarden, Ph.D., is a senior research scientist with the Pacific Northwest National Laboratory where he conducts research within a multidisciplinary team studying the relationship between cellular/tissue dosimetry and biological response. He is the principal investigator on studies of the pharmacokinetics of organic chemicals and metals and develops physiologically based pharmacokinetic models of chemical kinetics for application in study design and risk assessment for both private companies and the United States Environmental Protection agency. Through Society of Toxicology symposia, specialty sections and continuing education courses, Justin has promoted the application of the fundamental sciences in nanomaterial risk assessment. He has served on the EPA Scientific advisory board, on the National Toxicology Program Board of Scientific Councilors, and on NRC Committees. His has also served as the president of the Dose-Response Specialty Section of the Society for Risk Analysis and President of the Nanotoxicology Specialty Section of the Society of Toxicology. Justin received his PhD in toxicology from the University of Wisconsin, Madison, and is board certified in toxicology.

Maurice Whelan, Ph.D., is head of the Systems Toxicology Unit of the Institute for Health and Consumer Protection (IHCP) of the European Commission's Joint Research Centre (JRC), based in Ispra, Italy. He is also head (acting) of the Validation of Alternative Methods Unit and responsible for the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), hosted by the IHCP-JRC. The focus of his work is on the development, evaluation and promotion of new integrated methods for the safety assessment of chemicals and nanomaterials that avoid testing on animals. He is co-chair of the OECD Advisory Group on Molecular Screening and Toxicogenomics that is responsible for the OECD programme on Adverse Outcome Pathways, and is responsible for JRC collaborations with the US EPA ToxCast programme and the Tox21 consortium. He is co-chair of the scientific panel of www.axlr8.eu and is heavily involved in the coordination of www.seurat-1.eu.

Chihae Yang, Ph.D., is Chief Scientific Officer of Altamira LLC, a knowledge development company based in Columbus Ohio, and a lecturer and adjunct professor at the Ohio State University, teaching and leading several research collaborations at OSU. She is also a visiting scientist at US FDA CFSAN where she has been a fellow in the computational toxicology

program (Nov 2008 – Feb 2011). She previously was Chief Scientific Officer of Leadscope, Inc. She joined Leadscope in 2000 from her position as a tenured chemistry professor at Otterbein College and an adjunct professor at the Ohio State University. She worked at the Clorox Company (1984-1992) where she incorporated computational methods into product discovery and development workflows. At Leadscope she initiated a chemical genomics program, with public funding including NIH/NCI grants, and defined and developed Leadscope's predictive toxicology platform and QSAR technology. She also established the LIST focus group with grants from the US NIST Advanced Technology Program, developed and delivered ToxML, a public toxicity database standard, and developed a ToxML database entry tool in collaboration with the US FDA. Through Altamira, she plays a key role in the development of CERES (Chemical Evaluation and Risk Estimation System) at US FDA CFSAN and the cheminformatics workflow of the Chemical Inherency program at US EPA NCCT. Her research focuses on computational chemistry and structure-activity relationship methods applied to pharmaceuticals, food and cosmetic ingredients, and nano-structured materials. She continues to develop methods to advance toxicity prediction and risk assessment paradigms beyond current QSAR approaches, including QSAR21, mode-of-action chemotypes, quantitative weight of evidence assessment algorithms, and Threshold of Toxicological Concerns (TTC).

Lauren Zeise, Ph.D., is Chief, Reproductive and Cancer Hazard Assessment Branch, of the California Environmental Protection Agency's (Cal/EPA) Office of Environmental Health Hazard Assessment. In that role she oversees a variety of scientific activities concerning risk assessment, including chemical hazard and dose response assessment and development of improved methods for risk assessment. As part of Cal/EPA's environmental justice work, her group is also developing the Agency's approach to cumulative impact assessment – for characterizing the impact on communities of multiple sources of pollution and non-chemical stressors in the presence of community vulnerability. Her group works with other departments in California government in operating Biomonitoring California, the state's biomonitoring program. She co-led the team that developed California's Green Chemistry Hazard Trait regulation. Dr. Zeise has served on numerous national and international science advisory committees and boards focusing on environmental public health and improving the way chemicals are tested or evaluated for health risk. She has coauthored a number of National Academy of Science (NAS) reports, including "Science and Decisions: Advancing Risk Assessment" (2009), "Toxicity Testing in the 21st Century: A Vision and Strategy" (2007), "Sustainability and the US EPA" (2011), and "Understanding Risk: Informing Decisions in a Democratic Society" (1996). She is currently a member of the NAS committees including the Committee on Use of Emerging Science for Environmental Health Decisions. She is member, fellow, former editor and former councilor of the Society of Risk Analysis and was the 2008 recipient of the Society's Outstanding Risk Practioner Award. She is a lifetime NAS National Associate. She received her doctorate from Harvard University.

PANELISTS/MODERATORS

George Daston, Ph.D., has been employed at Procter & Gamble Company since 1985, where he is Victor Mills Society Research Fellow. Dr. Daston has spent his entire career in research to understand the effects of exogenous chemicals on biological systems, especially the developing embryo, fetus and child. His research interests include teratogenic mechanisms, in vitro

methodologies, and risk assessment. He has published over 100 peer-reviewed articles, reviews and book chapters, and has edited three books. Dr. Daston's professional activities include serving as Councilor of the Society of Toxicology (2001-03); President (1999-2000) of the Teratology Society; member of the National Academy of Sciences Board on Environmental Studies and Toxicology (1995-98); member of the EPA Board of Scientific Counselors (2002-08); member of the U.S. National Toxicology Program Board of Scientific Counselors (2003-06, Chair in 2006); member of the National Children's Study Advisory Committee (2003-06); and member of EPA's Endocrine Disrupter Screening and Testing Advisory Committee (EDSTAC). He has served on several NRC committees, including the Committee on Developmental Toxicology, Committee on Research Opportunities and Priorities for EPA, and the Subcommittee on Arsenic in Drinking Water. Dr. Daston has served on the organizing committees for numerous government and private sector-organized workshops on reproductive toxicity, risk assessment, and non-animal alternatives. He chaired NIEHS/ICCVAM working groups evaluating the state of validation of the Frog Embryo Teratogenesis Assay - Xenopus (FETAX) assay for teratogen screening and receptor binding and transcriptional activation assays for estrogens and androgens. Dr. Daston is Editor-in-Chief of Birth Defects Research: Developmental and Reproductive Toxicology. Dr. Daston is an Adjunct Professor in the Department of Pediatrics and Developmental Biology Program at the University of Cincinnati and Children's Hospital Research Foundation. Dr. Daston received his Ph.D. from the University of Miami and post-doctoral training at the U.S. EPA's laboratories in Research Triangle Park, North Carolina.

Richard Denison, Ph.D., is a Senior Scientist at the Environmental Defense Fund. Dr. Denison has 25 years of experience in the environmental arena, specializing in chemicals policy and hazard, exposure, and risk assessment and management for industrial chemicals and nanomaterials. He is a member of the NRC Board on Environmental Studies and Toxicology and serves on the Green Ribbon Science Panel for California’s Green Chemistry Initiative. Dr. Denison was a member of the National Pollution Prevention and Toxics Advisory Committee, which advised EPA’s toxics office. Previously, Dr. Denison was an analyst and assistant project director in the Oceans and Environment Program, Office of Technology Assessment, United States Congress. Dr. Denison received his Ph.D. in Molecular Biophysics and Biochemistry from Yale University.

Daniel Krewski, Ph.D., is Professor and Director of the R. Samuel McLaughlin Centre for Population Health Risk Assessment at the University of Ottawa, where he is involved in a number of activities in population health risk assessment within the new Institute of Population Health. Prior to joining the Faculty of Medicine at the University of Ottawa in 1998, Dr. Krewski was Director, Risk Management in the Health Protection Branch of Health Canada. While with Health Canada, he also served as Acting Director of the Bureau of Chemical Hazards and as Chief of the Biostatistics Division in the Environmental Health Directorate. Dr. Krewski obtained his Ph.D. in statistics from Carleton University and subsequently completed an M.H.A. at the University of Ottawa. His professional interests include epidemiology, biostatistics, risk assessment, and risk management.

Dr. Krewski is a Lifetime National Associate, U.S. National Academy of Sciences (2002); Chair, U.S. National Academy of Sciences Committee on Toxicity Testing and Risk Assessment (2004-

2007); Chair, U.S. National Academy of Sciences Committee on Acute Exposure Guidelines for Highly Hazardous Substances (1998-2004); Member, U.S. National Academy of Sciences Board on Radiation Effects Research (2002-present); Member, U.S. National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation (BEIR VII, 2000-present; BEIR VI, 1994-1999); Chair, Royal Society of Canada Expert Panel on the Potential Health Risks of Radiofrequency Fields from Wireless Telecommunications Devices ((1998-1999); Member, U.S. National Academy of Sciences Board on Environmental Studies and Toxicology (1996-2002); Member, Scientific Council of the International Agency for Research on Cancer (1992-1996); Fellow, Society for Risk Analysis (1993); Fellow, American Statistical Association (1990).

Donna L. Mendrick, Ph.D., is the Director of the Division of Systems Biology at the National Center for Toxicology Research (NCTR), a research Center of the FDA. Her division incorporates genomics, proteomics, metabolomics, *in silico* modeling, stem cells and other approaches to answer the needs of the FDA in terms of medical products and food safety and improving the understanding of human disease. Her FDA committee assignments include the Senior Science Council, Critical Path Steering Committee, Tox21, and the Interagency Coordination Committee on the Validation of Alternative Methods (ICCVAM). Dr. Mendrick is the Chair of the Society of Toxicology's Disease Prevention Task Force, Secretary/Treasurer of the Drug Discovery Toxicology Specialty Section and a member of the Scientific Liaison Coalition's Governance Group.

She was an Assistant Professor of Pathology at Harvard Medical School and Brigham and Women's Hospital. She joined Human Genome Sciences and, as a Group Leader in Pharmacology, oversaw multiple project teams, toxicity studies, pharmacology studies, etc. Prior to joining the FDA, she was a Scientific Fellow and Vice President of Pharmacogenomics at Gene Logic where she oversaw pharmacogenomics and spearheaded its toxicogenomics effort. For the latter, she formed a pharmaceutical consortium to help guide the development of the program. Dr. Mendrick has many years of experience in the fields (in alphabetical order) of immunology, pathology, pharmacogenomics, pharmacology, toxicology and toxicogenomics employing small molecule drugs, recombinant therapeutic proteins and monoclonal antibodies. Dr. Mendrick has published on the use of pharmacogenomics, metabolomics and proteomics to identify biomarkers. She is past President of the National Capital Area Chapter of the Society of Toxicology. Dr. Mendrick was on the Editorial Board of the Journal of Histochemistry and Cytochemistry for 8 years, a member of the NIH SBIR Immunology Study Section for 8 years and a member of the Board of Directors of the National Kidney Foundation of Massachusetts for 4 years.

John Quackenbush, Ph.D. received his PhD in 1990 in theoretical physics from UCLA working on string theory models. Following two years as a postdoctoral fellow in physics, Dr. Quackenbush applied for and received a Special Emphasis Research Career Award from the National Center for Human Genome Research to work on the Human Genome Project. He spent two years at the Salk Institute working on developing physical maps of human chromosome 11 and two years at Stanford University working on new laboratory and computational strategies for sequencing the Human Genome. In 1997 he joined the faculty of The Institute for Genomic Research (TIGR) where his focus began to shift to post-genomic applications with an emphasis on microarray analysis. Using a combination of laboratory and computational approaches, Dr.

Quackenbush and his group developed analytical methods based on integration of data across domains to learn biological meaning from high-dimensional data. In 2005, he was appointed Professor of Biostatistics and Computational Biology and Professor of Cancer Biology at the Dana-Farber Cancer Institute (DFCI) and Professor of Computational Biology and Bioinformatics at the Harvard School of Public Health. Since that time, his work has increasingly focused on the analysis of human cancer using systems-based approaches to understanding and modeling biological problems. In 2010 he launched the Center for Cancer Computational Biology (CCCB) at the DFCI which provides broad-based bioinformatics support to the local research community using a collaborative consulting model as well as performing and analyzing data generated through ultrahigh-throughput DNA sequencing.His expertise is in genomics technologies, including sequencing and array-based approaches, integrative genomics, personalized genomics, and the integration of clinical and research data to drive discovery.

Joyce Tsuji, Ph.D., is a Principal Scientist within the Center for Toxicology and Mechanistic Biology of Exponent's Health Sciences practice. She is a board-certified toxicologist and a Fellow of the Academy of Toxicological Sciences. Dr. Tsuji specializes in assessing exposure and risks associated with chemicals, and in communication of scientific issues. She has worked on projects in the United States and internationally for industry, trade associations, U.S. EPA and state agencies, the U.S. Department of Justice, the Australian EPA, municipalities, and private citizens. Dr. Tsuji's experience includes human health and environmental toxicology related to a wide variety of chemicals in the environment as well as in products. She has designed and directed dietary and environmental exposure studies and community programs involving heatlh eeducation and biomonitoring for populations potentially exposed to chemicals in the environment, including soil, water, and food-chain exposures. She has also assessed exposure and health risks associated with chemical exposures from air, foods, medical devices, and a variety of consumer products (e.g., cleaners, air fresheners, cosmetics, paints and coatings, carpets, glues, wood preservatives, building materials, and children's toys and play equipment), including those containing nonotechnology or nanomaterials. Dr. Tsuji has served on expert panels on toxicology and health risks issues for the National Academy of Sciences/National Research Council (including their Board on Environmental Studies and Toxicology and Committee on Toxicology), Institute of Medicine, and federal and state agencies.