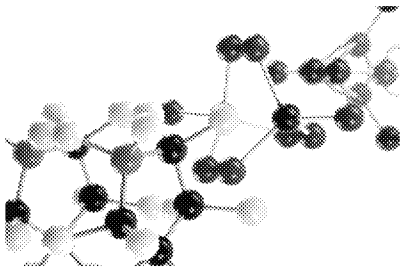
ARA
ALLIANCE FOR RISK ASSESSMENT

Beyond Science and Decisions: From Problem Formulation to Risk Assessment

February 24 & 25, 2021

A VIRTUAL EVENT



Workshop Co-Chairs:
James Bus, Exponent
Mark S. Johnson, US Army

Workshop Coordinators:
Christen Williams, TERA
Bethany Hansen, TERA

Workshop Rapporteurs:
Bernard Gadagbui, TERA
Chijioke Onyema, TERA

Workshop XII Agenda & Purpose:

To advance the recommendations in the NAS (2009) report concerning issue identification (problem formulation) and all aspects of risk assessment and management, through selection of illustrative research case studies for further development

Day 1: Wednesday, February 24th

(note: all times are UTC -5 or Washington DC time, to accommodate a diverse spread of time zones)

Chair: **James Bus,** Exponent

Welcome (9:00 to 9:05)
- **Patricia McGinnis**, TERA

The Unfinished Business of Science and Decisions (9:05 to 9:25)
- **Greg Paoli**, Member of the Science Panel

Keynote Talk: Transition to Translation: Mechanistic Modeling to Advance NAMs and Evidence Integration (9:25 to 10:10)
- **Annie Jarabek,** U.S. Environmental Protection Agency

Preliminary research case study: Review of ½ life of PFOA and related chemistries (10:10 to 10:45)
- **Bernard Gadagbui,** Toxicology Excellence for Risk Assessment (TERA)
- Discussion by the Science Panel

Morning Break (10:45 to 11:00)

Preliminary research case study continued (11:00 to noon)
- Discussion by the Science Panel
- Comments from Observers

Lunch break (noon to 12:30)

Research Case Study 1: Instantaneous Comparison Values (ICVs) and Acute Action Levels (AALs) for Use During In-Motion Monitoring and Emergency Events (12:30 to 2:30)
- **Joseph Haney** and **Darrell McCant,** Texas Commission on Environmental Quality (TCEQ)
- Discussion by the Science Panel

Afternoon Break (2:30 to 2:45)

Research Case Study 1 continued (2:45 to 4:00)
- Discussion by the Science Panel
- Comments from Observers
- Chair's Summary

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Day 2: Thursday, February 25th

Chair: **Mark S. Johnson,** US Army

Research Case Study 2: A tiered approach to the assessment of inhaled cobalt compounds (9:00 to 10:30)

- **Ruth Danzeisen,** Cobalt Institute
- Discussion by the Science Panel

Morning Break (10:30 to 10:45)

Research Case Study 2 continued (10:45 to 12:30)

- Discussion by the Science Panel
- Comments from Observers
- Chair's Summary

Lunch Break (12:30 to 1:00)

Ongoing Activities (1:00 to 2:30)

Debunking Junk Risk Assessment Science

- **Dr. Alex Berezow,** American Council on Safety and Health

Unbiased Panels to Determine Validity of Scientific Claims: Results of a Survey

- **Joseph Annotti,** Center for Truth in Science

The Metals Gateway Website

- **Chris Schlekat,** NiPERA

Afternoon Break (2:30 to 2:45)

Ongoing Activities continued (2:45 to 3:45)

The Occupational Alliance for Risk Sciences (OARS)

- **Andrew Maier,** Cardno

Ecological and Human Health: Holistic assessments and solutions

- **Charles Menzie**, Exponent

Summary of the Workshop (3:45 to 4:00)

- **Drs. Bus and Johnson**

Adjourn (4:00)

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Biographical Sketches of Workshop Co-Chairs, Speakers, Presenters, and Science Panelists [under development]

Mr. Joseph Annotti is the President and CEO of the Center for Truth in Science, a non-profit organization focused on fact-based science within issues at the intersection of science, economics, and litigation. Annotti drives the execution of the organization's vision, mission, and strategy with a key focus on the policy mission, pipeline, and final public research products while ensuring that all organizational activities are fully aligned with the vision and mission. Prior to joining the Center for Truth in Science, Annotti spent 35 years leading trade and member association management in the commercial sector. He is widely known as an industry pioneer in strategic planning, political advocacy, coalition building, public policy development, board of directors and committee relations, media relations, public affairs, personnel management, financial management, and membership services.

In 2008, he was named President and CEO of the American Fraternal Alliance, a not-for-profit trade association representing over 60 fraternal life insurers in the United States. During his tenure, Annotti positioned the Alliance to better engage with its members, championed tax reform in Washington, D.C., and tackled insurance regulatory issues at the state level. In late 2019, Annotti announced that he would step away from the American Fraternal Alliance to pursue new opportunities, and, in 2020 he was named President and CEO of the Center for Truth in Science.

A graduate of the University of the Pacific, Annotti has also served as the Senior Vice President for the Property Casualty Insurers Association; Executive Vice President for the Independent Insurance Agents and Brokers of California; and Vice President of Public Affairs for American Business Insurance (the nation's tenth-largest insurance broker at the time).

Dr. Alex Berezow joined the American Council on Science and Health as Senior Fellow of Biomedical Science in May 2016. He is a prolific science journalist and the founding editor of RealClearScience. His work regularly appears in BBC News, The Economist, and USA Today, where he serves as a member of the Board of Contributors. He holds a Ph.D. in microbiology. In 2012, with Hank Campbell, he co-authored the book Science Left Behind, which was an environmental policy bestseller. Though he claims humble Midwestern roots and common sense values, in reality, he is often found spending an inordinate amount of money drinking fancy coffees (specifically, triple-shot, iced, vanilla lattes). He is also known to vacation frequently in Europe with his Polish-born wife. Together, they have visited 16 countries.

Dr. James S. Bus is a Senior Managing Scientist in the Health Sciences Group of Exponent, Inc. (May 2013-present). Dr. Bus retired from The Dow Chemical Company as Director of External Technology and Fellow in the Toxicology and Environmental Research and Consulting unit (1989-2013). Prior to Dow, he was Associate Director of Toxicology and Director of Drug Metabolism at The Upjohn Company (1986-1989); Senior Scientist at the Chemical Industry Institute of Toxicology (CIIT, 1977-1986); and Assistant Professor of Toxicology, University of Cincinnati (1975-1977). Dr. Bus has been an advisor to a variety of institutions including ILSI, ILSI-HESI, The Hamner Institutes (formerly CIIT), American Chemistry Council Long-Research Initiative, and on advisory boards of the EPA (BOSC and Chartered SAB), FDA (NCTR), the National Toxicology Program, the National Academy of Sciences (BEST), and BELLE. He has served as President of the Society of Toxicology, The American Board of Toxicology, and the Academy of Toxicological Sciences, and in editorial roles including *Toxicology and Applied Pharmacology*,

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Environmental Health Perspectives, *Regulatory Toxicology and Pharmacology* and *Current Opinions in Toxicology*. Dr. Bus has received the Society of Toxicology Achievement (1987) and Founders (2010) awards, the Toxicology Forum George Scott Award (2013), Rutgers University Robert A. Scala Award (1999), the Michigan State University K.E. Moore Outstanding Alumnus Award, the International Society of Regulatory Toxicology and Pharmacology International Achievement Award (2015), and the International Dose-Response Society Outstanding Leadership Award (2018). He received a B.S. in Medicinal Chemistry from the University of Michigan (1971) and PhD in pharmacology from Michigan State University (1975), and currently is an Adjunct Professor in the Dept. Pharmacology and Toxicology at that institution. He has authored/co-authored over 150 publications, books, and scientific reviews. His primary research interests include modes of toxic action of industrial chemicals and pesticides including the role of non-linear toxicokinetics as a key consideration for improving the human relevance of *in vitro* and *in vivo* toxicity test findings.

Dr. Christine Chaisson is a Director in The LifeLine Group™ and a senior member of the LifeLine Group's management team. She is one of key architects of the new generation of exposure assessment models addressing aggregate and cumulative risk concepts, called LifeLine™. Dr. Chaisson earned a doctorate in cellular biochemistry/biology from George Washington University (1982). She began her career in risk assessment in the US Environmental Protection Agency in the Office of Pesticides and Toxic Substances. At EPA, Dr. Chaisson designed and created the first probabilistic dietary exposure assessment model. She was also the liaison to international regulatory agencies such as AID and WHO. In 1985, Dr. Chaisson co-founded Technical Assessment Systems (TAS), which became the premier exposure/risk assessment consulting firm internationally. Through TAS, she introduced concepts such as population subgroup specificity, better definition of residues in forms of foods and sources of drinking water, use of human activity patterns and actual chemical usage patterns for more accuracy and relevance in risk assessment models. Through these experiences, Dr. Chaisson became well versed in the expectations of regulators in the US, UK, Canada, Germany and European Union.

Dr. Chaisson has been a Councilor in the International Society of Exposure Assessment, a member of Society of Risk Assessment and President of its DC chapter, the Toxicology Forum, the United Agribusiness League and the Institute of Food Technologists. She also served on the National Council for Arts and Sciences of the George Washington University and the Dean's Advisory Board for the GWU Graduate School of Political Management. Dr. Chaisson serves as a member of the External Advisory Board of the Center for Indigenous Environmental Health Research at the Zuckerman College of Public Health / University of Arizona. She is an advisor to Food Quality magazine. She has published extensively in the fields of exposure and risk assessment. In 2011 Dr. Chaisson was the invited Co-Chair of the Milan ISES/SETAC special conference on exposure science challenges presented by global legislative initiatives on consumer products and chemicals in trade. In 2014 Dr. Chaisson led a multi-presentation ISES session and panel presenting the Community Based Research in post-Sandy Brooklyn to characterize clean-up workers' exposure to industrial chemicals displaced by the storm. A follow-up symposium on that and related work was presented at the 2018 ISES-ISEE joint meetings in Ottawa, Canada.

Dr. Harvey Clewell is a Principal Consultant at Ramboll US Consulting. He has over forty-five years of experience in environmental quality and toxicology research, chemical risk assessment and hazardous materials management. He has gained an international reputation for his research on the incorporation of mechanistic data and mode of action information into chemical risk assessments, and played a key role in the

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first uses of physiologically based pharmacokinetic (PBPK) modeling in cancer and non-cancer assessments by EPA, ATSDR, OSHA, and FDA. In 2007 the Society of Toxicology recognized Clewell with the Arnold J. Lehman Award for major contributions to chemical safety and risk assessment. He has authored more than 200 peer-reviewed scientific publications and book chapters on the use of pharmacokinetics, dose-response analysis, genomics and new alternative methods (NAMs) in risk assessment. He served on the ECVAM Scientific Advisory Committee from 2012 to 2016 and is currently a member of the USEPA Scientific Advisory Board's Chemical Assessment Advisory Committee.

Dr. Ruth Danzeisen obtained her undergraduate degree in nutritional sciences and toxicology at the German University of Hohenheim (Baden-Württemberg). She has a PhD in Biomedical Sciences from the University of Aberdeen, Scotland, and has 9 years of research experience in academia in the area of metals biology and nutrition. Before joining the Cobalt Development Institute (now Cobalt Institute; CI) in 2012, Ruth has worked for 7 years with the International Copper Association (Assistant Director Human Health). Prior to that, Ruth has worked at several universities and research institutions in the UK, USA, Germany, and Italy. She obtained her Board Certification by the American Board of Toxicology in October 2007 and has several publications relating to metals in health and disease (examples are listed below).

As Principal Toxicologist of the CI, Ruth is responsible for the management of health-related scientific issues concerning cobalt, including REACH, EU CLP, GHS and other chemicals management programs around the globe. One of Ruth's main remits is the identification of information gaps and conception of new projects based on data gap analyses, regulatory requirements and industry knowledge gaps. Interpretation and dissemination of the generated data to, i.a., regulatory authorities and public domain, are further important elements of Ruth's role within the CI. Of particular interest to Ruth is the replacement of animal research with in vitro or in chemico models, and the application of predictive testing to group compounds for their hazard- and risk assessment.

Dr. Michael Dourson has a PhD in toxicology from the University of Cincinnati, College of Medicine, and is a board-certified toxicologist (i.e., DABT) serving as the Director of Science at the 501c3 nonprofit organization Toxicology Excellence for Risk Assessment (TERA). Prior to this, he was Senior Advisor in the Office of the Administrator at the US EPA. Before this, he was a Professor in the Risk Science Center at the University of Cincinnati, College of Medicine and also worked at TERA and US EPA. He has been awarded the Arnold J. Lehman award from the Society of Toxicology, the International Achievement Award by the International Society of Regulatory Toxicology and Pharmacology, and 4 bronze medals from the U.S. Environmental Protection Agency. He has been elected as a Fellow of the Academy of Toxicological Sciences (i.e., FATS) and as a Fellow for the Society for Risk Analysis (i.e., FSRA). He has co-published more than 150 papers on risk assessment methods or chemical-specific analyses, and co-authored well over 100 government risk assessment documents, many of them risk assessment guidance texts. He has made over 150 invited presentations to a variety of organizations, and has chaired over 150 sessions at scientific meetings and independent peer reviews. He has been elected to multiple officer positions in the American Board of Toxicology (including its President), the Society of Toxicology (including the presidency of 3 specialty sections), the Society for Risk Analysis (including its Secretary), and is currently the President of the Toxicology Education Foundation, a nonprofit organization with a vision to help our public understand the essentials of toxicology. In addition to numerous appointments on government panels, such as EPA's Science Advisory Board, he is a current member on the editorial board of Regulatory Toxicology and Pharmacology.

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Dr. Neeraja K. Erraguntla (Neera) is a Director, at the Chemical Products and Technology division at the American Chemistry Council (ACC). Dr. Erraguntla is responsible for managing and directing ACC's 1,3-Butadiene TSCA Risk Evaluation Consortium and the Center for Advancing Risk Assessment and Science policy under ACC's Center for Chemical Safety. In addition, she also manages four other industrial chemical groups that endeavor for the development and application of up-to-date, scientifically sound methods for conducting chemical assessments. Dr. Erraguntla directs complex projects involving systematic reviews, mode-of-action, exposure characterization, and endocrine disruption.

Prior to ACC, Dr. Erraguntla was a senior regulatory toxicologist at the Texas Commission on Environmental Quality (TCEQ) from 2005 to 2015. At TCEQ, she was a team lead to review available tools for conducting systematic reviews and evidence integration and to develop a position paper on how TCEQ conducts systematic reviews and evidence integration. Neera also determined inhalation toxicity factors of arsenic compounds and hexavalent chromium compounds, and used threshold of concern to determine acute toxicity for chemicals with limited toxicity information. Neera played a major role in understanding and addressing community concerns about increased asthma rates in children and adults and prepared several science-based regulatory evaluations.

Dr. Erraguntla is a diplomate of American Board of Toxicology (DABT) and has a Ph.D. from Louisiana State University. She volunteers with SOT Risk Assessment Specialty Section and has also volunteered and served on the committee for SOT Exposure Specialty Section. Dr. Erraguntla was nominated as a Council Member for the International Society of Regulatory Toxicology & Pharmacology (ISRTP). In 2016, she served as a reviewer for the Government's Accountability Office and was a peer reviewer of the National Academies report, Acute Exposure Guideline Levels for Selected Airborne Chemicals, Volume 20, from the Board on Environmental Studies and Toxicology. Previously, Dr. Erraguntla also served as a Science Advisory Board (SAB) for US EPA's Environmental Justice Technical Guidance Panel and has been on the National Academy of Sciences Acute Exposure Guidelines Committee. Previously, she served as an Adjunct Assistant Professor at Texas A&M School of Public Health.

Dr. Bernard Gadagbui joined Toxicology Excellence for Risk Assessment (TERA) since 2004 and is currently is a Senior Toxicologist at TERA, with extensive experience in toxicology and human health risk assessment. Dr. Gadagbui received a BSc in Biochemistry with Chemistry from the University of Ghana, Legon, Ghana, and MSc in Biochemistry and PhD in Environmental Health from the University of Bergen, Norway. He has sound understanding of toxicology/risk assessment principles/practices, scientific basis for toxicity testing guidelines and application of science-based risk assessment methodologies. His extensive evaluation of clinical and non-clinical data and use of read across approaches has resulted in derivation of numerous high quality toxicologically-based risk values including reference doses/concentrations, occupational exposure limits, acceptable daily exposures, and permitted daily exposures for data-rich and data-poor chemicals, including industrial chemicals, manufacturing reagents, pesticides, cosmetic and personal care ingredients and products, botanicals and botanical preparations, petroleum hydrocarbons, and active and inactive pharmaceutical ingredients. Dr. Gadagbui is certified as a Diplomate of the American Board of Toxicology (DABT) and is also a European Registered Toxicologist (ERT). He has held leadership positions in the Toxicologists of African Origin (TAO), a Specialty Interest Group of the Society of Toxicology (SOT), African Society of Toxicological Sciences (ASTS), Ohio Valley Chapter of SOT, Ohio Chapter of Society for Risk Analysis (SRA) and currently one of the three Advisors of the recently formed African Chapter of SRA (SRA-Africa).

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Dr. Joseph "Kip" Haney has served as a regulatory toxicologist and risk assessor in the Toxicology Division of the Texas Commission on Environmental Quality for over 22 years. He has interests in multiple areas, including chemical dose-response assessment, mode of action, low-dose extrapolation issues, etc. Mr. Haney received his B.S. in Biology (summa cum laude) from the University of Houston and his M.S. in Environmental Science with Emphasis in Toxicology from the University of Texas School of Public Health. He is a member of the Society of Toxicology (SOT), SOT's Risk Assessment Specialty Section (RASS), and the Society for Risk Analysis.

Dr. Laurie Haws has substantial experience evaluating potential human health risks associated with exposures to a wide variety of chemicals and metals present as additives, ingredients, or contaminants in foods, consumer products, personal care products, pharmaceuticals, medical devices, and environmental media (air, water, soil, and sediments). She also has extensive experience assessing potential human health risks associated with personal, occupational, and community-wide exposures to air contaminants, particularly associated with chemical, petrochemical, and shale gas exploration and production activities. Dr. Haws is a recognized expert at evaluating data concerning modes and mechanisms of action and in using this type of data to assess the relevance of findings to humans. She routinely applies these skills in the development of state-of-the-science toxicity values via the application of both default and more rigorous approaches, such as benchmark dose modeling, application of weight-of-evidence techniques, and consideration of mode-of-action information. In addition, Dr. Haws also has experience designing, placing, and overseeing a broad range of toxicology laboratory studies, including ADME, developmental toxicity, and cross-fostering studies. She also has experience designing, conducting, and interpreting data from biomonitoring studies, and is adept at using such data to assess concerns regarding potential exposures.

Dr. Haws is an author on 59 peer-reviewed publications and has presented at many scientific conferences throughout her career. She is an active member of numerous professional societies, including the Society of Toxicology, Society for Risk Analysis, Toxicology Forum, American College of Toxicology, and the Regulatory Affairs Professional Society. Dr. Haws has served on numerous elected and appointed committees within the Society of Toxicology, including serving on Council, as well as serving as president of the Risk Assessment Specialty Section and the Women in Toxicology Special Interest Group. In addition, Dr. Haws has served on a number of scientific panels, technical workgroups, and advisory committees, including the World Health Organization's Toxic Equivalency Factor Review Panel. She has also served as the Chair of the International Symposium on Halogenated and Persistent Organic Pollutants, held in San Antonio, Texas, in September 2010, and served on the Exposure and Human Health Committee of the USEPA's Science Advisory Board.

Dr. Wally Hayes holds degrees from Auburn University (Ph.D. and MS) and Emory University (AB). He was an NSF predoctoral fellow at Auburn University, an NIH individual postdoctoral fellow at the Vanderbilt University School of Medicine, a NATO Senior Scientist at the Central Veterinary Laboratory in Weybridge, England, and held an NIH Research Career Development Award. Dr. Hayes is currently an Adjunct Professor, Center for Environmental Occupational Risk Analysis and Management, College of Public Health, University of South Florida and Institute for Integrative Toxicology, Michigan State University. He has been a member of numerous NIH, US EPA, US FDA, US DOD, and NAS scientific panels. Dr. Hayes has authored more than 330 peer-reviewed publications, is the editor of *Hayes' Principles*

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and Methods of Toxicology, *Human and Experimental Toxicology*, *Cutaneous and Ocular Toxicology*, *Toxicology Research and Application,* and the co-editor of the *Target Organ Toxicity* Series of books. Dr. Hayes is the Editor-in-Chief emeritus, *Food and Chemical Toxicology, and* the co-author of *Loomis' Essential of Toxicology.* Dr. Hayes is a past Secretary-General of IUTOX (two terms), past board member of the American Board of Toxicology, a past president of the American College of Toxicology, the Toxicology Education Foundation, and the Academy of Toxicological Sciences, and a past member of the council of the Society of Toxicology. He is currently the President of the Toxicology Forum. Dr. Hayes is a diplomate of the American Board of Toxicology, the Academy of Toxicological Sciences, the American Board of Forensic Medicine, and the American Board of Forensic Examiners. He is a Fellow of the Academy of Toxicological Sciences, the Royal Society of Biology (UK), the American College of Forensic Examiners, and the American College of Nutrition. Dr. Hayes is a registered toxicologist in the European Union (ERT) and a certified nutrition specialist (food safety). He was honored by the Society of Toxicology in 2006 with the Society's Merit Award, by the Mid-Atlantic Society of Toxicology with its Ambassador Award in 2012, by the American College of Toxicology in 2012 with its Distinguished Scientist Award, and by the International Dose-Response Society in 2013 with its Outstanding Leadership Award. Dr. Hayes was named a Distinguished Fellow by the American College of Toxicology in 2013 and a fellow of the American Association for the Advancement of Science in 2014.

Ms. Annie M. Jarabek currently serves as a Senior Science Advisor in the immediate office of the Center for Public Health and Environmental Assessment (CPHEA) at its Health and Environmental Effects Assessment Division (HEEAD) in the Research Triangle Park, within the U.S. Environmental Protection Agency's Office of Research and Development (ORD), following recent service as the Deputy Director of the Human Health Risk Assessment (HHRA) national research program in ORD. Ms. 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.* Ms. 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 Libby amphibole asbestos. Her current research efforts focus on multi-scale dosimetry modeling, including approaches for *in vitro* to *in vivo* extrapolation (IVIVE) of inhalation exposures to advance the application of emerging methods for translation and evidence integration across various experimental platforms. A manuscript on her collaborative IVIVE work received an honorable mention as the best 2018 paper from the Biological Modeling Specialty Section (BMSS) at the 2019 annual Society of Toxicology (SOT) meeting. Ms. Jarabek has received three awards for best manuscript in risk assessment application from the Risk Assessment Specialty Section (RASS) of the SOT, along with several best abstract presentation awards. She has also received a Lifetime Achievement Award from the University of Massachusetts, the Risk Practitioner of the Year award from the Society of Risk Analysis (SRA), the Superfund National Notable Achievement Award, and several award medals (gold, silver and bronze) and technical or special service awards from the Agency. She will be awarded the Lehman award for risk assessment at the 2020 SOT meeting in Baltimore.

Dr. Mark S. Johnson currently serves as the Director of Toxicology, US Army Public Health Center at Aberdeen Proving Ground, MD where he is responsible for the operational and technical arm of the Army Surgeon General and the Assistant Secretary of the Army for toxicological matters. He has worked extensively in the evaluation of the toxicity of military unique compounds and development and evaluation

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of a phased approach to the gathering toxicity data for new compounds under development. He has authored over 100 peer-reviewed publications, book chapters, and technical reports and serves on several NATO and EPA panels. He has been a member of Society of Environmental Toxicology and Chemistry (SETAC) since 1997 and is a past Steering Group Member of the Wildlife Toxicology World Interest Group, past chair of Ecological Risk Assessment World Interest Group, and a member of the World Science Committee for SETAC and SETAC North America. Dr. Johnson is also a member of the International Board of Environmental Risk Assessors (IBERA). He has been a member of the Society of Toxicology since 2009.

Dr. Johnson is a fellow of the Academy of Toxicological Sciences, Chair of the Tri-Service Toxicology Consortium (TSTC), past Steering Committee Chair of the Joint Army-Navy-NASA-Air Force (JANNAF) Propulsion Committee, Subcommittee on Safety and Environmental Protection, the past president of the American Board of Toxicology (ABT).

Dr. Sabine Lange is the section manager for the Toxicology Division at the Texas Commission on Environmental Quality (TCEQ). Dr. Lange's responsibilities include overseeing health effects risk assessments of air permit applications, ambient air monitoring projects, and hazardous waste sites; overseeing the development of chemical toxicity factors; and conducting and overseeing systematic reviews and independent analyses of risk assessments. Dr. Lange serves as a technical resource for the State and citizens of Texas for human health and environmental risk assessment, especially related to air and water quality. Dr. Lange's research interests include the toxicology of criteria air pollutants, and risk assessment methods used for derivation of toxicity factors. Dr. Lange received a bachelor's degree from the University of Western Ontario in Canada, and completed a Ph.D. and post-doctoral training in biochemistry and molecular carcinogenesis at the University of Texas at Houston and MD Anderson Cancer Center. Dr. Lange is a Diplomate of the American Board of Toxicology.

Dr. John Lipscomb began his career as a biologist at the National Center for Toxicological Research in Jefferson, Arkansas. He later served as a Captain (research toxicologist) in the U.S. Air Force, where he earned the Air Force Achievement Medal for his pioneering work on the military's first large-scale investigation of human metabolic variability. He completed his federal career as a toxicologist and risk assessor in EPA's National Center for Environmental Assessment and National Homeland Security Research Center in Ohio, where he was a chemical manager for three different risk assessment programs and led the development of EPA guidance for quantitative risk assessment and emergency exposure guidance values. He has over 100 peer-reviewed publications, book chapters and government technical reports. His interests include quantitative risk assessments of single chemicals and chemical mixtures, in vitro to in vivo extrapolation, toxicokinetics and non-default extrapolations of dosimetry among and between species. Dr Lipscomb is a Diplomate of the American Board of Toxicology and Fellow of the Academy of Toxicological Sciences. He serves on the Health Advisory Board for NSF International and American Industrial Hygiene Association's Emergency Response Planning Committee. He is past president of the American Board of Toxicology, the Society for Risk Analysis's Ohio chapter, the Society of Toxicology's Risk Assessment Specialty Section and SOT's Ohio Valley regional chapter. He serves on the Editorial Board for *Toxicological Sciences* and is an Associate Editor for *Toxicology Mechanisms and Methods*, and *Toxicology Reports*. He holds bachelor's and master's degrees in biology from the University of Central Arkansas and a Ph.D. in interdisciplinary toxicology from the University of Arkansas for Medical Sciences and is an adjunct professor of Toxicology and course director for Human Health Risk Assessment in the Department of Pharmacology and Toxicology at the University of Louisville.

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Mr. Darrell D. McCant is a Work Leader for the Toxicology, Risk Assessment, and Research Division of the Texas Commission on Environmental Quality and has served as a regulatory toxicologist and risk assessor for over 20 years. He has also made important contributions to strategic plans to assess air quality in Texas. Mr. McCant received his B.S. in Toxicology from the University of Louisiana at Monroe and his M.P.H. with Emphasis in Environmental Health from Texas A&M University School of Public Health. He is a member of the Society of Toxicology (SOT), SOT's Risk Assessment Specialty Section (RASS) and the Society for Risk Analysis.

Dr. Andrew Maier has over 25 years of professional work experience in the areas of environmental health, occupational hygiene, and toxicology. He currently serves as a Principal Science Advisor with Cardno ChemRisk. Prior to joining Cardno he served as an Associate Professor of Environmental and Industrial Hygiene at the University of Cincinnati (UC) College of Medicine leading a research program in occupational exposure assessment, toxicology and risk assessment. Prior to joining UC he served as the Director for the non-profit organization Toxicology Excellence for Risk Assessment (TERA). In his capacity as an industrial hygienist, toxicologist and risk assessor, he has led numerous projects and has co-authored toxicological reviews, EPA and NIOSH technical reports and human health risk assessment documents for several hundred individual substances. Dr. Maier has an established history in occupational toxicology and industrial hygiene. He completed his B.S. in natural resources from Ball State University and M.S. in industrial health from the University of Michigan. He is certified in comprehensive industrial hygiene practice by the American Board of Industrial Hygiene (CIH). Dr. Maier completed his Ph.D. in toxicology from the University of Cincinnati and is board certified in toxicology (DABT). He continues to be actively engaged in teaching and developing research to improve risk assessment approaches through the integration of basic biology and risk assessment science. He is a lead instructor for risk assessment professional development courses offered through various non-profit organizations. He has served as a Toxicology Fellow at NIOSH in support of exposure limit methods development and is the Publications Coordinator and past-Chair of the Workplace Environmental Exposure Levels (WEEL) Committee.

Dr. Patricia McGinnis is an experienced toxicologist and human health risk assessor. She currently serves as TERA's President and a Senior Toxicologist. Since joining TERA in 2014, Dr. McGinnis has contributed to projects for government, legal research, and commercial entities. Formerly an executive at SRC, Inc., a not-for-profit organization, Dr. McGinnis led the Chemical, Biological, and Environmental Center, one of four business units within the company. Her business skills include strategic and operational thinking, organizational vision and planning, management of profit/loss centers, organizational policies and procedures, and staff development programs. Among Dr. McGinnis' unique leadership skills is her ability to build and manage teams and to develop sound and sustainable scientific business partnerships to achieve technical excellence and innovations for customers.

Dr. McGinnis is a board-certified toxicologist. She has served on the NAS AEGL Subcommittee, on the Expert Consultation Panel for EPA's National Homeland Security Research Center (NHSRC), and as an external peer reviewer for regulatory risk assessment methods and documents, including EPA's IRIS, Drinking Water toxicological reviews, and U.S. Department of Agriculture (USDA) human health assessments. She has authored more than 200 government reports, publications, and presentations.

Dr. Bette Meek is the Associate Director of Chemical Risk Assessment at the McLaughlin Centre for Risk Science, Faculty of Medicine, University of Ottawa. Previously, she contributed to and managed several chemical risk assessment programs within Health Canada. With colleagues internationally, she has

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contributed to or led initiatives in developing methodology in chemical risk assessment, including mode of action, chemical specific adjustment factors, physiologically-based pharmacokinetic modeling, combined exposures and predictive modeling. These initiatives have involved collaborations with a range of international organizations and national Agencies, including the World Health Organization International Programme on Chemical Safety, the Organization for Economic Cooperation and Development, the U.S. Environmental Protection Agency, the European Joint Research Centre and the Agency for Food, Environmental and Occupational Health and Safety of France (ANSES). She has authored approximately 200 publications in this area and received several awards for contribution in this domain.

Dr. Charles Menzie is principal and former practice director at Exponent, Inc. He was global executive director for the Society of Environmental Toxicology and Chemistry (SETAC) from 2014 to 2020. He specializes in the application of ecological and human health risk assessment and causal analysis methods for evaluating the potential for effects and for diagnosing the causes of environmental harms and damages. His technical expertise includes the evaluation of the environmental fate and effects of physical, biological, and chemical stressors on terrestrial and aquatic systems. He has applied his expertise to situations involving nutrient enrichment, chemical contamination, use of pesticides and other chemical products, oil and gas operations, fossil fuel and nuclear power plants, alternative energy projects, mining, invasive species, water management, and vulnerability assessments for climate change. As part of his risk assessment practice, he has developed exposure and food web models to evaluate how people and ecological receptors may be exposed to a variety of chemicals. These include several spatially-explicit models used to refine exposure estimates. He previously served on the National Academies Committee on the Bioavailability of Contaminants in Soils and Sediments. Dr. Menzie has a B.S. in Biology from Manhattan College and an M.A. and Ph.D. in Biology from City University of New York.

Mr. Chijioke Onyema has a background in Microbiology from the University of Lagos, Nigeria, and a master's degree in Medical Microbiology from the same University. He also holds an MPH degree from the University of Cincinnati and currently works as a Junior Toxicologist with TERA (Toxicology Excellence for Risk Assessment). As part of his penchant for applied research, he has been involved as a co-author in quite a few noteworthy publications and reports, including an exposure assessment report centered on the potential for the presence of phthalates and other specified elements in undyed manufactured fibers and their colorants, and a preliminary research case study with PFOA. In his leisure time, you can find him listening to self-improvement and inspirational audiotapes or playing capoeira.

Dr. Greg Paoli's career has spanned a wide spectrum of public risk management domains. This has included the safety of food, drinking water, air quality, consumer products, drugs, medical devices and the blood supply, engineered devices, transportation of dangerous goods, museum collections, emergency management for natural and man-made disasters, and climate change impacts on infrastructure. Due to the diversity of this experience, Greg was commissioned by the University of Pennsylvania Law School to prepare a discussion paper on "The Analytical Capabilities of a Best-in-Class Regulator" as part of its international Best-in-Class Regulator Project.

Dr. Paoli has served on a number of expert committees devoted to the risk sciences. He was a member of the U.S. National Academy of Sciences committee that issued the 2014 report, *A Framework to Guide the Selection of Chemical Alternatives*, and the 2009 report, *Science and Decisions: Advancing Risk Assessment*. He was invited to serve as a member of an expert peer review panel for the US EPA's Framework for Human Health Risk Assessment to Inform Decision Making. He has served on numerous expert committees

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convened by the World Health Organization and the Food and Agriculture Organization of the United Nations. He recently served a three-year term on the Scientific Advisory Committee for Health Canada's Chemical Management Plan.

Dr. Paoli completed a term as Councilor of the Society for Risk Analysis (SRA) and served two terms as a member of the Editorial Board of the journal Risk Analysis. In 2011, he was awarded the Distinguished Lectureship Award by the Society for Risk Analysis and the scientific society, *Sigma Xi*.

Dr. Chris Schlekat is the Executive Director of NiPERA Inc., which is located in Durham, North Carolina. NiPERA is a not-for-profit organization supported by the major producers and downstream users of nickel that identifies key issues regarding the environmental fate, effects, and risks of nickel, and develops and manages research programs that produce science-based results to address these issues. Chris is responsible for the strategic research direction of NiPERA, which is the science arm of a larger organization called the Nickel Institute. Prior to being appointed Executive Director, Chris was Senior Environmental Toxicologist and Deputy Executive Director, responsible for ensuring that regulations pertaining to nickel and nickel substances are based on current scientific knowledge. Chris also represents NiPERA in global regulatory processes, with specific emphasis on bioavailability-based risk-assessment approaches for nickel in water, sediment, and soil.

Before joining NiPERA in 2003, Chris was manager of Environmental and Health Sciences for Rio Tinto Borax in California. He serves on the editorial board of *Environmental Toxicology and Chemistry*.

Chris holds a Bachelor's degree in Biology, a Masters in Marine Biology and a Doctorate in Environmental Health Sciences. He is a Diplomate of the American Board of Toxicology since 2009.

Dr. Pamela Williams is a Principal at E Risk Sciences, LLP, an independent scientific consulting firm that provides sound analyses and tools to support risk-based decision-making related to human health and the environment. She is also a Clinical Assistant Professor in the Department of Environmental and Occupational Health at the Colorado School of Public Health as well as a Fellow with the non-profit organization Toxicology Excellence for Risk Assessment (TERA). Dr. Williams specializes in assessing human exposures and health risks in environmental, community, and occupational settings. Her particular areas of expertise include human health risk assessment, exposure science, exposure modeling, and uncertainty analysis. She has published over 100 papers, book chapters, and presentation abstracts on various risk-related topics. She has also taught graduate-level and continuing education courses related to exposure and risk assessment at the Colorado School of Public Health, Harvard School of Public Health, Society of Toxicology, and the American Industrial Hygiene Association (AIHA). She routinely serves as a technical peer-reviewer for a number of scientific journals, peer review panels, and government agencies. Dr. Williams is past President of the Society for Risk Analysis (SRA) and past Chair of AIHA's Risk Committee. She has received several awards for her contributions to the fields of risk analysis, exposure science, and industrial hygiene. These include the Chauncey Starr Distinguished Award granted by the Society for Risk Analysis for excellent contributions to the field of Risk Analysis, the Joan M. Daisey Outstanding Young Scientist Award granted by the International Society of Exposure Science for outstanding contribution to the science of human exposure analysis, and both a Leadership Award and Outstanding Individual Contributor Award granted by AIHA in recognition of leadership and outstanding contributions to AIHA. Dr. Williams has a B.A. in Sociology and Applied Social Research from San Diego State University, M.S. in Health and Social Behavior from Harvard University, and ScD in Environmental

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Health and Health Policy and Management from Harvard University. She is also a certified industrial hygienist (CIH).

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