



**Beyond Science and Decisions:  
From Problem Formulation to Dose-Response  
Workshop IV**

May 22, 23, & 24, 2012  
Texas Commission on Environmental Quality  
Austin, TX

A Project of the Alliance for Risk Assessment

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## Workshop Information

<b>Workshop Title:</b>	Beyond Science and Decisions: From Problem Formulation to Dose-Response Assessment Workshop IV
<b>Workshop Site:</b>	Texas Commission on Environmental Quality Austin, Texas
<b>Workshop Dates:</b>	May 22, 23, & 24 <sup>th</sup> , 2012

## Sponsors

- Academy of Toxicological Sciences
- Agency for Toxic Substances and Disease Registry
- American Chemistry Council Center for Advancing Risk Assessment Science and Policy
- American Petroleum Institute
- American Water Works Association
- Center for Food Safety and Applied Nutrition of the US Food and Drug Administration
- Consortium for Environmental Risk Management LLC
- CropLife America
- Dose Response Specialty Group of Society for Risk Analysis
- Electric Power Research Institute
- ENVIRON
- Ethylene Oxide Panel of the American Chemistry Council
- The Hamner Institute for Health Sciences
- Georgia Department of Natural Resources
- Georgia Pacific
- Gradient
- Hawai'i State Department of Health; Hazard Evaluation and Emergency Response
- Human Toxicology Project Consortium
- Illinois Environmental Protection Agency
- Indiana Department of Environmental Management
- Industrial Economics, Incorporated
- International Copper Association
- International Society of Regulatory Toxicology and Pharmacology
- The LifeLine Group
- Minnesota Pollution Control Agency
- The Naphthalene Council
- National Center for Toxicological Research
- New Zealand Ministry of Health
- Nickel Producers Environmental Research Association
- Noblis
- NSF International
- Ohio Environmental Protection Agency
- Pastor, Behling & Wheeler, LLC
- Regulatory and Safety Evaluation Specialty Section of Society of Toxicology
- Risk Assessment Specialty Section of Society of Toxicology
- The Sapphire Group
- SC Johnson & Son
- Society for Risk Analysis
- Society of Toxicology
- Summit Toxicology
- Ted Simon Toxicology
- Texas Association of Business
- Texas Chemical Council
- Texas Commission on Environmental Quality
- Texas Industry Project
- Toxicology Excellence for Risk Assessment
- U.S. Environmental Protection Agency

## Workshop Background & Purpose

The workshop series is continuing and expanding upon the discussion set forth by Science and Decisions: Advancement of Risk Assessment ([NAS, 2009](#)); these meetings are conducted under the aegis of the Alliance for Risk Assessment (ARA), a broad-based non-profit, government and NGO coalition. The first phase of the workshop series was three workshops over the course of about a year. The first workshop focused on brainstorming and selection of case studies illustrating various dose-response methods for different problem formulations. A broad range of case studies proposed at the first workshop was then developed by workshop participants and discussed by the Science Panel at the second workshop. In considering the case studies, the Science Panel members provided input on the utility of the case study methods to address specific problem formulations, and identified areas for additional development. The Science Panel and interested workshop participants developed an interactive [framework](#) for organizing case study methods, and the Panel used the framework to identify additional case studies that address important gaps in methodology; the third workshop focused on these case studies and associated issues. The framework references specific risk assessment methods, illustrated by case studies, and is intended for use by risk assessors and managers in a variety of settings (e.g., federal, state, and local agencies, industry). It is based on the fundamental premise that the appropriate methodology for dose-response assessment is necessarily based on objectives specific to that application, including varying levels of analysis. A manuscript describing the framework and workshop process is in preparation.

The workshop series is transitioning to an “evergreen” approach, including a standing panel that reviews methods and issues on a semi-annual basis, leading to updating of the framework.

### ***Workshop Goal***

The workshop purpose is to advance the recommendations of the NAS (2009) and subsequent framework of ARA (2012) on problem formulation and dose-response analysis, through review of illustrative case studies for further development of methods.

### ***General Workshop Series Objectives:***

- Additionally develop the content of the NAS (2009) report on improving the risk assessment process to develop a compendium of practical, problem-driven approaches for “fit for purpose” risk assessments, linking methods with specific problem formulations (e.g., prioritization, screening, and in-depth assessment) for use by risk managers at a variety of levels (e.g., states, regional managers, people in a variety of agencies, and in the private sector).
- Implement a multi-stakeholder approach to share information, ideas and techniques in support of developing practical problem-driven risk assessment methods compendium.

***Specific Workshop Objectives:***

- Identify useful dose-response techniques for specific issues, including consideration of relevant data, characterization of assumptions, strengths and limitations, and how the techniques address key considerations in the dose-response.
- These techniques should appropriately reflect the relevant biology (including the biology of thresholds), and mode of action information, at a level of detail appropriate for the identified issue.
- Provide methods to explicitly address human variability in cancer assessment, and enhance the consideration of human variability in noncancer assessment, including explicit consideration of underlying disease processes, as appropriate for the relevant risk assessment context.
- Identify methods for calculating the probability of response for noncancer endpoints, as appropriate for the relevant risk assessment context.
- Develop a risk methods compendium that will serve as a resource for regulators and scientists on key considerations for applying selected dose-response techniques for various problem formulations, with suggested techniques and resources.

## Workshop Series Overview

*Beyond Science and Decisions: From Problem Formulation to Dose-Response* Workshop I was held March 16-18 at the Texas Commission on Environmental Quality (TCEQ), Austin, Texas. Workshop participants included over 60 in-person attendees and more than 100 participants *via* webcast, including representation from federal, state, industry, NGO, academia, and research institutes, with attendees from the US and abroad.

If you wish to refer back to any of the presentations from the meeting or refer others to them, they will continue to be available at [www.allianceforrisk.org/workshop/materials.htm](http://www.allianceforrisk.org/workshop/materials.htm), and videos can be watched at <http://www.texasadmin.com/cgi-bin/amtnrcc.cgi>. A summary of the breakout group discussions is available online at <http://www.allianceforrisk.org/Workshop/Workshop1MeetingReport.doc>.

Workshop I focused on brainstorming and selection of case studies recommended for further development and for review at the second workshop. Lead scientists were encouraged to organize groups to develop each topic and case study, and some of the breakout groups suggested members for different groups, as described in the summary. These case studies were presented at Workshop II, held October 11-13, 2010 in Crystal City, Virginia. The emphasis of the second workshop was on discussion led by a Science Panel of the methods as illustrated through the case studies. The purpose of the case studies was to provide illustrative information on dose-response methods that can be carried forward into a methods compendium. While some case studies have focused on specific chemicals, the charge of the Panel related only to utility of the method.

Workshop III was held May 4-6<sup>th</sup>, 2011 at Noblis facilities in Falls Church, Virginia. At this workshop, the Science Panel reviewed additional case studies, and developed specific areas addressed by the NAS (2009) report through the development and application of case studies. The workshop focused on the development of a practical, solution-oriented, human health risk assessment methods compendium.

Workshop IV marks the transition to an evergreen approach, envisioned to be a continuing semi-annual workshop series to explore and review recent advances in risk assessment and dose-response assessment.

## Stakeholders

### ***Alliance for Risk Assessment (ARA)***

The Beyond Science & Decisions Workshop Series is a project of the Alliance for Risk Assessment, a collaboration of organizations teaming to take on projects that are too big or too complex for an individual company or organization to address. The work of the *ARA* focuses resources to help meet the needs of State, Local, and Tribal risk assessors. Learn more at [www.allianceforrisk.org](http://www.allianceforrisk.org).

### ***ARA Steering Committee***

The *ARA* is guided by a Steering Committee (SC) comprised of individuals of diverse affiliation and expertise. The SC will provide guidance and oversight of the workshop series and case study selection, and serve as liaison between the Expert Panel and satellite meetings. The Steering Committee will advise the Dose Response Advisory Committee (DRAC) on charge questions, and will have the final decision on members of the Expert Panel after a review of all nominations. The SC consists of 9 representatives of state, tribal, and federal government, academia, and NGOs, two of whom recused themselves on aspects of this project due to membership on the DRAC. See [www.allianceforrisk.org/ARA\\_Steering\\_Committee.htm](http://www.allianceforrisk.org/ARA_Steering_Committee.htm).

Annette Dietz, Oregon Department of Environmental Quality

William Hayes, State of Indiana

Bette Meek, University of Ottawa/Health Canada (liaison with the DRAC)

Anita Meyer, United States Army Corps of Engineers

Edward Ohanian, United States Environmental Protection Agency

Ralph Perona, Neptune & Company, Inc.

Phil Wexler, National Library of Medicine

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Michael Dourson, Toxicology Excellence for Risk Assessment (recused)

Michael Honeycutt, Texas Commission on Environmental Quality (recused for meetings I to III)

### ***Dose-Response Advisory Committee (DRAC)***

The workshop sponsors are composed of federal, state, industry, and NGO organizations. The Dose-Response Advisory Committee interacts with these various sponsors in the development of workshop structure and charge questions, and recruitment of presenters. The DRAC has the final decision on workshop structure, presenters, and content, after consultation with the *ARA* Steering Committee. Current members include:

Rick Becker, American Chemistry Council

Tiffany Bredfeldt, Texas Commission on Environmental Quality

Michael Dourson, Toxicology Excellence for Risk Assessment

Julie Fitzpatrick, U.S. Environmental Protection Agency

Roberta L. Grant, Texas Commission on Environmental Quality

## Beyond Science and Decisions: Workshop IV

Lynne Haber, Toxicology Excellence for Risk Assessment  
Lynn H. Pottenger, The Dow Chemical Company  
Jennifer Seed, U.S. Environmental Protection Agency



## Workshop IV Agenda

**Date:** May 22, 23 & 24<sup>th</sup>, 2012

**Location:** Texas Commission on Environmental Quality, Austin, Texas

**Purpose:** To advance the recommendations of NAS (2009) and subsequent framework of ARA (2012) on problem formulation and dose-response analysis, through review of illustrative case studies for further development of methods

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### Tuesday May 22nd

Welcome (1:00 to 1:15)

- **Toby Baker, Commissioner, Texas Commission on Environmental Quality**

Introductions and Updates (1:15 to 2:00)

- **Members of the Advisory Committee and Science Panel**

Keynote Talk: Incorporating New Technologies into Toxicity Testing and Risk Assessment: Moving from 21st Century Vision to a Data-Driven Framework (2:00 to 3:00)

- **Rusty Thomas, The Hamner Institutes for Health Sciences**

Afternoon Break (3:00 to 3:30)

Presentation of Beyond Science and Decisions Dose Response Assessment Framework and Discussion (3:30 to 4:15)

- **Lynne Haber, Toxicology Excellence for Risk Assessment**

EPA's Response to NRC Framework Recommendation: Framework for Human Health Risk Assessment to Inform Decision Making (4:15 to 5:00)

- **Rita Schoeny, U.S. Environmental Protection Agency**

Observer Comments (5:00 to 5:30)

Reception (dinner portion hors d'oeuvres, 6:30 to 9:00)

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### Wednesday, May 23<sup>rd</sup>

Case Study: Hypothesis-Driven Weight of Evidence Review for Chloroform Carcinogenicity: Cytotoxic Mode of Action by Dermal and Inhalation Routes (8:00 to 10:00)

- **Chris Borgert, Applied Pharmacology Toxicology Inc.**

Morning Break (10:00 to 10:30)

## Beyond Science and Decisions: Workshop IV

“Hypothesis-Driven” continued (10:30 to 11:30)

Lunch (11:30 to 12:30)

Updates (12:30 to 2:00)

- **William Gulledge, American Chemistry Council.** Update: EO Mode of Action (MOA)
- **Jimmy Perkins, University of Texas Health Science Center.** Update: The Occupational Alliance for Risk Science (OARS)
- **Lorenz Rhomberg, Gradient.** Update: Naphthalene Mode of Action (MOA)
- **Tiffany Bredfeldt, Texas Commission on Environmental Quality.** Update: Structure Activity Relationships Applied to Short Term Exposures

Afternoon Break (2:00 to 2:30)

Case Study: A Tiered Framework for Interpreting Human Biomonitoring Results (2:30-4:00)

- **Rick Becker, American Chemistry Council**

Case Study Proposal: Value of Information (4:00 to 5:00)

- **Eric Ruder, IEC**

Observer Comments (5:00 to 5:30)

Dinner on your own

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### Thursday, May 24<sup>th</sup>

Combined Exposures Framework and Discussion (8:30 to 9:30)

- **Bette Meek, University of Ottawa**

Case Study: The Human Relevant Potency Threshold: Reducing Uncertainty by Human Calibration of Cumulative Risk Assessments (9:30 to 10:30)

- **Chris Borgert, Applied Pharmacology Toxicology Inc.**

Morning Break (10:30 to 11:00)

Case Study: Methods for Deriving Inhalation Effect Levels for Comparison to Health-Protective Values

(11:00 to noon)

- **Roberta Grant, Texas Commission on Environmental Quality**

Observer Comments and Closing remarks (noon)

Adjourn

## **Biographical Sketches**

### ***Welcome***

#### **Toby Baker, Texas Commission on Environmental Quality**

Toby Baker of Austin was appointed to the Texas Commission on Environmental Quality (TCEQ) by Gov. Rick Perry effective April 16, 2012. His term will expire on Aug. 31, 2017. Along with his two fellow full-time commissioners, Baker establishes overall agency direction and policy, and makes final determinations on contested permitting and enforcement matters.

Baker was most recently a policy and budget advisor on energy, natural resources and agriculture issues for the Governor's Office, where he was also the liaison between the office and members of the Legislature, constituents, the Railroad Commission of Texas, the TCEQ, the Texas Parks and Wildlife Department, the Texas Department of Agriculture, and the Texas Animal Health Commission. He is a past natural resource policy advisor to Sen. Craig Estes, the former director and clerk of the Texas Senate Subcommittee on Agriculture, Rural Affairs and Coastal Resources.

Baker received a bachelor's degree from Texas A&M University, where he was a member of the Corps of Cadets, and a Master of Public Service and Administration from the Texas A&M George Bush School of Government and Public Service. He is also a graduate of the National Outdoor Leadership School and the Governor's Executive Development Program at the University of Texas LBJ School of Public Affairs.

### ***Science Panel***

#### **Richard Beauchamp, Texas Department of State Health Services**

Richard A. Beauchamp is the Senior Medical Toxicologist for the Texas Department of State Health Services (DSHS) with responsibility for providing advanced toxicological and risk assessment support for the Exposure Assessment, Surveillance, and Toxicology (EAST) Group. As cooperative agreement partners with the Agency for Toxic Substances and Disease Registry (ATSDR), Dr. Beauchamp and other EAST Group members are tasked with conducting Public Health Assessments at abandoned hazardous waste sites that are proposed and added to the Environmental Protection Agency's (EPA's) National Priority List (NPL) of Superfund sites in Texas. Dr. Beauchamp is also involved with conducting other medical and toxicological Public Health Consultations involving exposures to environmental hazardous substances. After earning his medical degree at the University of Texas Health Science Center at San Antonio (1973-1977), Dr. Beauchamp completed a three year pediatric residency with the Austin Pediatric Education Program at Brackenridge Hospital in Austin, Texas (1977-1980) and began working at the Texas Department of Health as a Public Health Physician Epidemiologist (1980). Early in his career at the health department, he was tasked with developing risk assessment

expertise that would be essential for the newly-formed Environmental Epidemiology Program in the evaluation of environmental and chemical exposures. With an undergraduate degree in Electrical Engineering (U.T. Austin) and a strong background in mathematics and computer sciences, Dr. Beauchamp has applied the knowledge gained through participation at numerous risk assessment conferences, symposia, and seminars (sponsored by EPA, NGA, CDC, ASTHO, NIOSH, and others) to the development of his so-called "Risk Assessment Toolkit." Dr. Beauchamp's toolkit consists of a series of Excel® spreadsheets designed for the flexible and rapid evaluation of cancer and non-cancer risks resulting from exposures to a wide variety of environmental contaminants through all of the common exposure pathways. Risks are calculated incrementally using age-specific exposure parameters, including body weights, body surface areas, respiratory daily volumes, and EPA's early-life exposure factors. Risks are integrated over the exposure duration, using up to 46 different age intervals, to insure that childhood exposures are appropriately addressed.

### **James S. Bus, The Dow Chemical Company**

James S. Bus is the Director of External Technology, Toxicology and Environmental Research and Consulting at The Dow Chemical Company (1989-present). He previously held positions as 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 currently participates in several external institutions including the Board of Directors of The Hamner Institutes (formerly CIIT) and the National Academy of Sciences/National Research Council Board on Environmental Studies and Toxicology (BEST). He has also served as Chair of the American Chemistry Council and International Council of Chemical Associations Long-Range Research Initiatives; the USEPA Chartered Science Advisory Board (2003-2009); and the FDA National Center for Toxicological Research Science Advisory Board (2004-2010). He serves as an Associate Editor of *Toxicology and Applied Pharmacology*, and on the Editorial Boards of *Environmental Health Perspectives* and *Dose Response*. Dr. Bus is a member of the Society of Toxicology (serving as President in 1996-97), the American Society for Pharmacology and Experimental Therapeutics, the American Conference of Governmental and Industrial Hygienists, and the Teratology Society. He is a Diplomate and Past-President of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences (member of Board of Directors, 2008-present; Vice-President and President-Elect, 2010). Dr. Bus received the Society of Toxicology Achievement Award (1987) for outstanding contributions to the science of toxicology; the Society of Toxicology Founders Award (2010) for leadership fostering the role of toxicology in improving safety decisions; Rutgers University Robert A. Scala Award (1999) for exceptional work as a toxicologist in an industry laboratory; and the K.E. Moore Outstanding Alumnus Award (Michigan State University, Dept. Pharmacol. And Toxicol.). He received his B.S. in Medicinal Chemistry from the University of Michigan (1971) and Ph.D in pharmacology from Michigan State University (1975) and currently is an Adjunct Professor in the Dept. Pharmacology and Toxicology at that institution. His research interests include mechanisms of oxidant toxicity, defense mechanisms to chemical toxicity, relationship of pharmacokinetics to expression of chemical toxicity, and general pesticide and industrial chemical toxicology. He has authored/co-authored over 100 publications, books, and scientific reviews.

### **Rory Conolly, U.S EPA National Health and Environmental Effects Research Laboratory**

Rory Conolly is a Senior Research Biologist in the Integrated Systems Toxicology Division of the U.S EPA's National Health and Environmental Effects Research Laboratory in Research Triangle Park, North Carolina, USA. His major research interests are (1) biological mechanisms of dose-response and time-course behaviors, (2) the use of computational modeling to study these mechanisms and, (3) the application of computational models to quantitative dose-response assessment. Dr. Conolly received the U.S. Society of Toxicology's (SOT) Lehman Award for lifetime achievement in risk assessment in 2005. He was a member of the National Academy of Sciences Board on Environmental Studies and Toxicology from 2004 until joining the EPA in 2005, President of the SOT Biological Modeling Specialty Section (2000 – 2001), President of the SOT Risk Assessment Specialty Section (1997 - 1998), a member of the SOT Risk Assessment Task Force (1998 - 2000) and is currently a Councilor with the Risk Assessment Specialty Section. He is Adjunct Professor of Biomathematics at North Carolina State University, Faculty Affiliate, Department of Environmental and Radiological Health Sciences, Colorado State University and has four times received awards from the SOT Risk Assessment Specialty Section (1991, 1999, 2003, 2004). Dr. Conolly was born in London, England and raised in Canada and the United States. He received a bachelor's degree in biology from Harvard College in 1972, a doctorate in physiology/toxicology from the Harvard School of Public Health in 1978, and spent a post-doctoral year at the Central Toxicology Laboratory of Imperial Chemical Industries, PLC, in Cheshire, England. He was a member of the Toxicology Faculty at The University of Michigan School of Public Health from 1979 through 1986, and worked with the U.S. Air Force Toxic Hazards Research Division, Wright-Patterson Air Force Base, Ohio from 1986 until 1989. In 1989 Dr. Conolly joined the Chemical Industry Institute of Toxicology (CIIT) and worked there until 2005, when he joined the U.S. EPA.

### **Mike Dourson, Toxicology Excellence for Risk Assessment**

Mike Dourson is the President of Toxicology Excellence for Risk Assessment (TERA), a nonprofit corporation dedicated to the best use of toxicity data in risk assessment. Before founding TERA in 1995, Dr. Dourson held leadership roles in the U.S. Environmental Protection Agency as chair of US EPA's Reference Dose (RfD) Work Group, charter member of the US EPA's Risk Assessment Forum and chief of the group that helped create the Integrated Risk Information System (IRIS). Dr. Dourson received his Ph.D. in Toxicology from the University of Cincinnati. He is a Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences. Dr. Dourson has served on or chaired numerous expert panels, including peer review panels for US EPA IRIS assessments, US EPA's Risk Assessment Forum, TERA's International Toxicity Estimates for Risk (*ITER*) independent peer reviews and consultations, FDA's Science Board Subcommittee on Toxicology, the NSF International's Health Advisory Board, and SOT's harmonization of cancer and non-cancer risk assessment. He served as Secretary for the Society for Risk Analysis (SRA) and has held leadership roles in specialty sections of SRA and SOT. He is currently on the editorial board of three journals. Dr. Dourson has published more than 100 papers on risk assessment methods, has co-authored over 100 government risk assessment documents, and has made over 100 invited presentations.

**R. Jeffrey Lewis, ExxonMobil Biomedical Sciences, Inc.**

R. Jeffrey Lewis is a Senior Scientific Associate with ExxonMobil Biomedical Sciences, Inc. In this position, Dr. Lewis is responsible for providing support to ExxonMobil's epidemiology and health risk assessment scientific programs. He currently manages company scientific programs related to children's health, emerging environmental health issues, legislative/regulatory affairs and regulatory impact analysis (e.g., benefit-cost analysis). He has served on a number of industry trade association scientific committees, external science advisory boards (e.g., Peer Consultation panel for EPA's Voluntary Children's Chemical Evaluation Program), and is a member of ExxonMobil's Occupational Exposure Limits committee. Dr. Lewis also has an adjunct faculty appointment at the University of Texas School of Public Health and is currently Treasurer Elect of the Society for Risk Analysis. Dr. Lewis received his Bachelors of Science degree in biology from the University of Kansas in 1985 and a M.S. and Ph.D. in Epidemiology from the University of Texas, School of Public Health in 1987 and 1990, respectively. In addition, he earned a Masters in Business Administration from Rutgers University in 1997.

**Bette Meek, McLaughlin Centre for Population Health Risk Assessment, University of Ottawa**

Bette Meek has a background in toxicology receiving her M.Sc. in Toxicology (with distinction) from the University of Surrey, U.K. and her Ph.D. in risk assessment from the University of Utrecht, the Netherlands. She is currently the Associate Director of Chemical Risk Assessment at the McLaughlin Centre for Population Health Risk Assessment, University of Ottawa, completing an interchange assignment from Health Canada. She has extensive experience in the management of chemical assessment programs within the Government of Canada, most recently involving development and implementation of process and methodology for the health assessment of Existing Substances under the Canadian Environmental Protection Act (CEPA) and previously, programs for contaminants in drinking water and air.

With colleagues within Canada and internationally, she has contributed to or led initiatives to increase transparency, defensibility and efficiency in health risk assessment, having convened and participated in initiatives in this area for numerous organizations including the International Programme on Chemical Safety, the World Health Organization, the International Life Sciences Institute, the U.S. Environmental Protection Agency, the U.S. National Academy of Sciences and the U.S. National Institute for Environmental Health Sciences. Relevant areas have included frameworks for weight of evidence analysis including mode of action, chemical specific adjustment factors, physiologically-based pharmacokinetic modeling, combined exposures and predictive modeling. She has also authored over 175 publications in the area of chemical risk assessment and received several awards for contribution in this domain.

**Greg Paoli, Risk Sciences International**

Greg Paoli 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. Mr. Paoli has experience in diverse risk domains including toxicological, microbiological, and nutritional hazards, air and water quality, climate change impacts, medical and engineering devices, as well as emergency planning and response 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. Mr. Paoli 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*. He serves on the Canadian Standards Association Technical Committee on Risk Management, advisory committees of the National Roundtable on the Environment and the Economy, 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. Mr. Paoli completed a term as Councilor of the Society for Risk Analysis (SRA) and is a member of the Editorial Board of *Risk Analysis*. Recently, Mr. Paoli was awarded the Sigma Xi – SRA Distinguished Lecturer Award. He has provided training in risk assessment methods around the world, including the continuing education programs of the Harvard School of Public Health and the University of Maryland. Greg holds a Bachelors Degree in Electrical and Computer Engineering and a Master's Degree in Systems Design Engineering from the University of Waterloo.

### **Lorenz Rhomberg, Gradient**

Lorenz R. Rhomberg Ph.D. FATS is a Principal at Gradient, a Cambridge, Massachusetts (USA), environmental consulting firm, where he specializes in critical review of toxicological information, human health risk assessment, and science policy issues for environmental and consumer chemical exposures. Before joining Gradient, Dr. Rhomberg was on the faculty of the Harvard School of Public Health. From 1984-1994, he was a risk assessor at the U.S. Environmental Protection Agency in Washington. Dr. Rhomberg earned his Ph.D. in population biology from the State University of New York at Stony Brook and an Honours B.Sc. in biology from Queen's University in Ontario. His interests lie in methodology and science policy for quantitative risk analysis, including dose-response modeling, pharmacokinetic modeling and probabilistic methods, with special emphasis on cross-species extrapolation, chlorinated solvents and endocrine active agents. Dr. Rhomberg has served on several US National Academy of Sciences committees, and numerous review and advisory panels sponsored by government, trade associations, and professional societies. He is the author/editor of several books and more than 60 articles on risk analysis topics. He is a member of several scientific societies, including the Society of Toxicology and the Society for Risk Analysis, for which he is a past Councilor and a Past-President of the New England Chapter. He is a Fellow of the Academy of Toxicological Sciences and was awarded the Outstanding Practitioner of the year award in 2009 by the Society for Risk Analysis.

### **Rita Schoeny, U.S. EPA Office of Water**

Rita Schoeny is Senior Science Advisor for the U.S. Environmental Protection Agency's Office of Water. She received her B.S. in biology at the University of Dayton and a Ph.D. in microbiology from the School of Medicine of the University of Cincinnati. After completing a postdoctoral fellowship at the Kettering Laboratory, Department of Environmental Health, she was appointed Assistant Professor in that department of the U.C. Medical School. Dr. Schoeny has held several

adjunct appointments and regularly lectures at colleges and universities on risk assessment. She has given lectures and courses on risk assessment in many areas of the world. Dr. Schoeny joined the U.S. EPA in 1986. Prior to her current position she was Associate Director of the Health and Ecological Criteria Division of the Office of Science and Technology, Office of Water. She has been responsible for major assessments and programs in support of the Safe Drinking Water Act, including scientific support for rules on disinfectant by-products, arsenic, microbial contaminants and the first set of regulatory determinations from the Contaminant Candidate List. She has held various positions in the Office of Research and Development including Chief of the Methods Evaluation and Development Staff, Environmental Criteria and Assessment Office, Cincinnati; Associate Director NCEA-Cin; and chair of the Agency-wide workgroup to review cancer risk assessments. Dr. Schoeny has published in the areas of metabolism and mutagenicity of PCBs and polycyclic aromatic hydrocarbons; assessment of complex environmental mixtures; health and ecological effects of mercury; drinking water contaminants; and principles and practice of human health risk assessment. She was a lead and coauthor of the *Mercury Study Report to Congress* and was a principal scientist and manager for Ambient Water Quality Criterion for Methylmercury. She has been the chair of an EPA working group on use of genetic toxicity data in determining mode of action for carcinogens. She participates in many EPA scientific councils as well as national and international scientific advisory and review groups. Current involvement includes panels on interpretation of DNA adduct data for risk assessment and evaluation of episodic and less-than-lifetime exposure to carcinogens. Dr. Schoeny is the recipient of several awards including several U.S. EPA Gold, Silver and Bronze Medals; EPA Science Achievement Award for Health Sciences; the Greater Cincinnati Area Federal Employee of the Year Award; the University of Cincinnati Distinguished Alumnae Award; Staff Choice Award for Management Excellence; and the FDA Teamwork Award for publication of national advice on mercury-contaminated fish.

### **Alan Stern, New Jersey Department of Environmental Protection**

Dr. Alan H. Stern is the Section Chief for Risk Assessment in the Office of Science of the New Jersey Department of Environmental Protection; Adjunct Associate Professor in the Department of Environmental and Occupational Health of the University of Medicine and Dentistry of New Jersey-School of Public Health. He received a bachelor's degree in biology from the State University of New York at Stony Brook (1975), a master's degree in cellular and molecular biology from Brandeis University (1978), a master of public health degree (1981) and a doctorate in public health from the Columbia University School of Public Health (1987). Dr. Stern is board-certified in toxicology by the American Board of Toxicology (Diplomate of the American Board of Toxicology). Dr. Stern's areas of expertise include risk assessment and exposure assessment including the application of probabilistic techniques to quantitative estimation of exposure and risk. His research interests have focused on heavy metals including lead, mercury, chromium and cadmium. Dr. Stern was a member of the National Research Council/National Academy of Sciences Committee on the Toxicology of Methylmercury (1999-2000) and a member of the recent USEPA Science Advisory Board panel for the National-Scale Mercury Risk Assessment for Coal- and Oil-Fired Electrical Generating Units (June-July 2011) as well as the USEPA Science Advisory Board Panel for Peer Review of the All-Ages Lead Model (Oct. 27-28, 2005). He has also served on numerous USEPA-IRIS review panels including Toxicological Review of Urea (Dec. 13, 2010, Panel Chair), Toxicological Review of Trichloroacetic Acid (Dec. 10, 2009, Panel Chair), Toxicological Review of 2-Hexanone (May 22, 2008, Panel Chair), Toxicological



Review of Toluene (Feb. 5, 2004, Panel Chair). Other panels, committees and workshops include, ATSDR Toxicological Profile Review of Revised Minimal Risk Levels (MRLs) for 1,4-Dioxane (March-April, 2010), ATSDR Toxicological Profile Review of Revised Inhalation MRL for 1,4-dioxane (Sept. 2011), USEPA Panel for the Review of Draft Exposure Factors Handbook (March 3-4, 2010), USEPA Workshop on Cardiovascular Toxicity of Methylmercury (Jan. 12-13, 2010), USEPA Panel for Review of —Draft Child-Specific Exposure Factors Handbook (Sept. 19-20, 2007). Dr. Stern has authored numerous articles in peer-reviewed journals, and contributed a book chapter on Exposure Assessment for Neurotoxic Metals in —Human Developmental Neurotoxicology - D. Bellinger, ed. (Taylor & Francis, New York, 2006.), and the article on *Environmental Health Risk Assessment* in the *Encyclopedia of Quantitative Risk Assessment and Analysis*. John Wiley and Sons Ltd., 2008.

## **Speakers**

### **Richard Becker, American Chemistry Council**

Richard A. Becker earned a B.A. in Chemistry from Swarthmore College and a Ph.D. in Pharmacology and Toxicology from the University of California, received post-doctoral training at the University of Toronto and the International Agency for Research on Cancer, and is a Diplomate of the American Board of Toxicology. He was a toxicology study director for NTP and NCI sponsored toxicity studies at SRI International (1985-1987), and then served as a senior scientist with the State of California from 1987 to 1999. His experience in California government included appointments to increasingly important technical and scientific management positions, beginning in Department of Toxic Substances Control, rising first to Deputy Director of Scientific Affairs in the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA), and subsequently to Director of OEHHA by appointment of Governor Wilson. In these positions, he initially conducted and then managed hazard evaluations, exposure assessments and risk characterizations to determine health and environmental threats posed by the exposures to hazardous substances in the environment. Dr. Becker joined the American Chemistry Council in 1999, where he continues to serve as the organization's senior toxicologist in addressing emerging health risk science issues, including advanced risk assessment techniques, biomonitoring, sensitive subpopulations, endocrine screening and testing and alternative test methods.

### **Tiffany Bredfeldt, Texas Commission on Environmental Quality**

Tiffany Bredfeldt is a Senior Toxicologist at the TCEQ. She received a B.S. in microbiology from the University of Arkansas in 2001 and a Ph.D. in pharmacology and toxicology from the University of Arizona in 2006. Her research focus during her graduate studies was the carcinogenicity of arsenic metabolites and their underlying mechanisms of action. This research into the mechanisms of arsenic-induced carcinogenesis was published in various peer-reviewed journals and was acknowledged through awards from the Society of Toxicology and the National Institute of Environmental Health Sciences (NIEHS). Upon completion of doctoral studies, she conducted postdoctoral research with Dr. Cheryl Walker at the University of Texas M.D. Anderson Cancer Center, where she was the recipient of a NIEHS Ruth L. Kirschstein National Research Service Award. Dr. Bredfeldt's postdoctoral research investigated the mechanisms by which early life exposure to endocrine disrupting chemicals called xenoestrogens increased

cancer risk in adulthood by modulation of epigenetic structures. She is a Society of Toxicology member. Her current professional activities focus upon human health risk assessment, generation of toxicity factors, and NexGen risk assessment approaches. She is also actively involved in public policy and outreach.

### **Roberta Grant, Texas Commission on Environmental Quality**

Dr. Roberta Grant is a Manager of the Toxicology Division at the Texas Commission on Environmental Quality (TCEQ). She manages staff conducting the toxicological evaluation of air permit applications, monitoring projects, risk assessments, and for conducting toxicity assessments to develop acute and chronic inhalation toxicity factors. She also provides technical recommendations to management and technical staff; prepares briefing materials and technical reports; and acts as liaison to upper management on critical toxicological issues. Roberta has a Ph.D. in toxicology from the College of Pharmacy, University of Texas at Austin (UT Austin) and completed a postdoctoral fellowship in the Integrated Toxicology Program at Duke University before joining the TCEQ in January 1997. Roberta participated with other staff toxicologists in writing *TCEQ Guidelines for Developing Toxicity Factors* (RG-422, revised draft 2012) which has been peer-reviewed and is now undergoing an additional public comment period. She has served on USEPA's National Advisory Committee for Developing Acute Exposure Guideline Levels (AEGs), as a member on FIFRA Scientific Advisory Panels, and is a member of the Science and Decisions Dose-Response Advisory Committee (DRAC). She is on the editorial board of *Toxicology in Vitro* and is an adjunct professor in the College of Pharmacy, UT Austin.

### **William P. Gullledge, American Chemistry Council**

Bill Gullledge is the Senior Director of the American Chemistry Council's (ACC) Chemical Products and Technology Division. On behalf of its chemical industry members, the Division conducts a wide variety of advocacy programs, manages research and testing projects, and supports voluntary product stewardship programs. He currently manages industry groups focused on innovative technologies, chemical information technology, ethylene oxide, ethylene glycols, hydrogen peroxide, hydrogen fluoride, pesticide inerts, endocrine screening, and quality management issues.

Prior to re-joining ACC in 2000, Mr. Gullledge worked as an environmental risk management consultant and was a major player in founding and operating two environmental and innovative technology insurance companies. Prior to this, Mr. Gullledge worked in the Environmental Division of the American Chemistry Council where he primarily managed hazardous waste, superfund and air toxics issues. He received a BA in Public Affairs from the American University (AU) in Washington, D.C. and an MS in Environmental Sciences and Engineering from AU/George Washington University.

### **Lynne Haber, Toxicology Excellence for Risk Assessment**

Dr. Haber is the Associate Director of *TERA*, responsible for strategic direction, training and overall quality initiatives at *TERA*. She has 18 years of experience in development of assessment documents and in risk assessment methods development, including consideration of mechanism/mode of action. She was the lead author of more than 30 major documents for

multiple EPA offices, other government agencies, and private sponsors, and has been a coauthor or reviewer of 100's more. She has served as a panel chairperson or panel member for scientific peer reviews organized by *TERA*, EPA, and other U.S. and foreign government agencies. She has also served on two panels for the NAS/NRC. Dr. Haber is active in communicating her findings to the broader scientific community through participation in professional societies, routine publication of her work, authoring book chapters, service as an editorial reviewer for scientific journals, and through presentation of invited lectures. She has experience in benchmark concentration/ benchmark dose (BMC/BMD) modeling and categorical regression modeling, and served as a peer reviewer for EPA's BMD modeling guidelines. Other methods development work includes the combination of PBPK and BMD/BMC modeling in the development of RfDs and RfCs; research into methods for improving the scientific basis for uncertainty factors by addressing genetic polymorphisms; consideration of mode of action in cancer risk assessment; toxicology issues related to children's risk; and use of biomarker data in risk assessment. She served as chair-elect, vice president and councilor of the SRA Dose-Response specialty group and as an officer of the SOT Risk Assessment Specialty Section (RASS), and is a Diplomate of the American Board of Toxicology. She is one of the lead teachers for *TERA's* Dose-Response Assessment Boot Camp, developed a course on issues related to children's risk assessment, and presents specialized risk assessment courses to diverse groups of risk assessors and at professional society meetings.

### **Jimmy Perkins, University of Texas**

Jimmy L. Perkins, PhD is currently Professor of Environmental Health Sciences at the University of Texas School of Public Health. He is a Certified Industrial Hygienist and has worked in the petroleum industry, the US National Institute for Occupational Safety and Health, and with a wide range of industries including foundries, specialty metals products, poultry production, printing, telecommunications, educational facilities, and petrochemicals. He has presented short courses in Kenya, Australia, Columbia, South Africa, and Mexico. He has served as Chairman of the American Board of Industrial Hygiene and ACGIH and was Board liaison to the TLV Chemical Substances Committee. Publications span a wide range of topics including environmental exposure assessment, dermal exposure risk management, air and water quality, and hazardous waste. His most recent research used modeled air pollution levels, including speciated particulate matter, and effect estimates from dozens of epidemiological studies to examine health risks associated with coal fired power plants.

### **Henry A. Roman, Industrial Economics, Incorporated**

Mr. Roman has more than 17 years of experience analyzing environmental policy and a strong background in environmental sciences and chemistry. His expertise includes analytical support for human health risk analysis and natural resource damage assessment; development of guidance for risk assessment methods; regulatory benefits analysis of existing or proposed rules; and uncertainty/decision analysis, including the use of expert elicitation methods to improve the characterization of uncertainty in key elements of regulatory analysis. Mr. Roman holds an A.B. cum laude in Chemistry from Harvard University, and an M.S. in Environmental Health Management from the Harvard University School of Public Health.

### **Eric Ruder, Industrial Economics, Incorporated**

Eric Ruder is a Principal at Industrial Economics, Incorporated (IEc) with over 20 years of consulting experience, specializing in environmental policy and risk assessment. A primary focus of his project work involves developing improved risk assessment techniques for policy applications. Mr. Ruder's risk assessment experience ranges from developing improved techniques to address emerging issues in the use of risk assessment in policy settings, such as evaluating cumulative risk at the community level, to conducting numerous human health and environmental risk assessments. His work in this area has been conducted in support of a variety of activities, including EPA policy-making efforts, priority-setting efforts in Eastern Europe, site-specific remediation decisions, and natural resource damage assessments. Mr. Ruder holds a B.A. in Environmental Science from Wesleyan University and an M.S. in Environmental Health Management from the Harvard University School of Public Health.

### **Russell Thomas, The Hamner Institutes**

Russell Thomas is the director of the Institute for Chemical Safety Sciences at The Hamner Institutes for Health Sciences. Dr. Thomas maintains an adjunct faculty appointment in the Division of Pharmacogenomics and Individualized Therapy at the University of North Carolina at Chapel Hill. His laboratory has diverse interests that range from basic research in cancer biology to applied research in chemical risk assessment. Dr. Thomas completed his M.S. in radiation ecology and Ph.D. in Toxicology at Colorado State University. Following his doctoral studies, Dr. Thomas performed postdoctoral research in molecular biology and genomics at the McArdle Cancer Research Laboratory at the University of Wisconsin. Prior to coming to The Hamner, Dr. Thomas worked in the biotech and biopharmaceutical industry.

Academic and professional honors of Dr. Thomas include the Agilent Thought Leader Award (2011), Society of Toxicology Achievement Award (2009), Honorable Mention for Society of Toxicology Board of Publications Best Paper Award (2009), Best Papers Advancing the Science of Risk Assessment by the Risk Assessment Specialty Section (2007, 2008, and 2011).

## **Rapporteurs**

### **Tiffany Bredfeldt**

See speaker bio above.

### **Shannon Ethridge, Texas Commission on Environmental Quality**

Shannon Ethridge has been a Toxicologist in the Toxicology Division of the Texas Commission on Environmental Quality (TCEQ) for 9 years. Shannon graduated from the University of Texas, School of Pharmacy with an M.S. in Pharmacy in 2001, and graduated summa cum laude with a B.S. in Biology from Texas State University in 1996. Shannon was certified as a Diplomat of the American Board of Toxicology in 2011. Prior to joining the TCEQ, she worked as a Research Associate for an identity genomics company.

### **Neera Erraguntla, Texas Commission on Environmental Quality**

Neera joined the Texas Commission of Environmental Quality (TCEQ) as a Senior Toxicologist in 2005. Her main role as a toxicologist at the TCEQ is to help the agency make scientifically sound decisions when developing environmental regulations and policy. Neera had been appointed as a National Advisory Committee Member for the U.S. EPA's National Advisory Committee for the Development of Acute Exposure Guideline Levels for Hazardous Substances and has an Adjunct Faculty appointment with the Texas A&M University Health Science Center. She has also presented guest lectures at the University of Texas at Austin and at Hutson Tillotson University in Austin. She also volunteers to teach and review Toxicology and Risk Assessment to the employees of the TCEQ who are preparing for the Professional Engineer Certification Exam.

### **Lynne Haber**

See speaker bio above.

### **Carla Kinslow, Texas Commission on Environmental Quality**

Carla is a Toxicologist in the Toxicology Division of the Texas Commission on Environmental Quality (TCEQ). She attended Indiana University Southeast in New Albany, where she started her scientific career as a research assistant in 1989. After receiving her Bachelors of Arts in biology from IU, she continued her research in plant molecular biology and ecology before starting her Master's studies at Michigan Technological University in Houghton, Michigan. While in Michigan, Carla was funded by the Office of Naval Research to develop the techniques to study the genetics of the marine diatom, *Achnanthese longipes* and successfully established a transfection technique for gene expression in this organism. Upon receiving her Master's in Science degree, she traveled to The Woodlands, Texas to work in the biotechnology industry, developing cancer gene therapies. She then moved to viral gene therapies in the Viral Vector Core facility at MD Anderson Cancer Center in Houston, Texas. While working in science, Carla began her environmental consulting company, which soon became a full time job to evaluate human health hazards and develop remediation schemes for indoor air quality projects. She then recognized that this was the type of work she wanted to continue in an academic arena, so she enrolled as a graduate student at the University of Texas Medical Branch (UTMB) in Galveston, Texas and focused on developing her molecular toxicology skills. While at UTMB, she was granted a National Institute of Environmental Health and Safety (NIEHS) pre-doctoral fellowship, completed an industrial internship with Proctor and Gamble and completed four peer-reviewed publications. She finished her Doctorate of Philosophy with a concentration in molecular toxicology and began work as a regulatory toxicologist for the TCEQ that same year.

### **Stephanie Shirley, Texas Commission on Environmental Quality**

Stephanie Shirley is a Toxicologist in the Toxicology Division of the Texas Commission on Environmental Quality (TCEQ). Her responsibilities include conducting and reviewing health effects reviews of ambient air monitoring data and projects. She also conducts and reviews the development of Effects Screening Levels and Air Monitoring Comparison Values. Stephanie serves as a technical resource for TCEQ management and staff on issues concerning air and water quality, soil contamination, as well as participating in public meetings.

## Evaluation Form

We want to make these series of workshops as excellent as possible. Please help by giving us your honest feedback of the Workshop. Our goal is to provide high quality workshops in an efficient process. Your suggestions for improvement are welcome.

What went well?

What could have been better?

Any other comments/suggestions?

Thanks for your help!

Name (Optional): \_\_\_\_\_