Panelist Biographical Sketches

Mr. Harvey J. Clewell III

Dr. Clewell is Director of the Center for Human Health Assessment and a senior scientist in the Division of Computational Biology at The Hamner Institutes for Health Sciences. His duties at The Hamner include managing a research program on the use of biomonitoring results in exposure and risk assessment. Prior to joining CIIT, Dr. Clewell was a principal scientist for ENVIRON. He has over 25-years of experience in environmental quality research, toxicology research, chemical risk assessment, and hazardous materials management and is a leading expert on the use of tissue dosimetry and mode-of-action information in chemical safety and risk assessment. He is internationally known for his work in the applications of physiologically based pharmacokinetic (PBPK) modeling in cancer and non-cancer risk assessments, and was key to the first uses of PBPK modeling by EPA, ATSDR, OSHA, and FDA. In 2007 he received the Arnold J. Lehman Award from the Society of Toxicology for his contributions to risk assessment of chemicals, including pharmaceuticals.

Dr. Clewell received his B.A. in Chemistry from Bradley University, his M.A. in Physical Chemistry from Washington University, and his Ph.D. in Toxicology from the University of Utrecht. He is a Diplomate of the American Board of Toxicology. Mr. Clewell served for 20 years as an officer in the U.S. Air Force Biomedical Science Corps and was Deputy Director of the Air Force Toxic Hazards Research Unit, Director of Hazardous Materials Safety for the Air Force Aeronautical Systems Center, and consultant to the Air Force Surgeon General on Chemical Risk Assessment.

Dr. Clewell was involved with the development of a harmonized PBPK model for trichloroethylene, the development of a biologically based dose-response approach for arsenic, the estimation of methyl mercury exposures in U.S. women of child-bearing age using Markov chain Monte Carlo analysis with a PBPK model, the use of PBPK models to consider genetic polymorphisms in risk assessment, the use of PBPK models to address age-specific issues, the development of parameters for PBPK modeling of the neonatal period, PBPK modeling in cancer risk assessment, PBPK modeling of developmental toxicity, and PBPK modeling in pharmaceutical safety assessments. Dr. Clewell has authored numerous scientific publications, has provided testimony in both civil tort cases and congressional hearings, and frequently provides invited lectures and computer workshops in the areas of pharmacokinetics and risk assessment. He has also served on a number of external peer review panels for EPA, ATSDR, and Health Canada.

Dr. Clewell is Adjunct Professor at the University of Louisiana in the Department of Toxicology and is an Adjunct Professor at Colorado State in the Center for Environmental Toxicology and Technology. He is a member of the Society of Toxicology (SOT), Society for Risk Analysis (SRA), and the American Chemical Society (ACS).

Dr. Penelope A. Fenner-Crisp

Dr. Fenner-Crisp recently retired from her position as the Executive Director of the International Life Sciences Institute's (ILSI) Risk Science Institute (RSI), one she had held since December, 2000. She has expertise in risk assessment methodologies, risk assessment guidelines, and incorporation of risk assessment into regulatory decisions. She played a key role in the policy guidance for use of Monte Carlo analyses in exposure assessment, the cumulative risk conceptual framework, and implementation of the cancer guidelines as well as many other policies. Dr. Fenner-Crisp has since established a private consulting practice, and counts ILSI among her clients.

Dr. Fenner-Crisp received her B.S. in Zoology from the University of Wisconsin-Milwaukee and her M.A. and Ph.D. in Pharmacology from the University of Texas Medical Branch in Galveston. Her research interests encompassed the fields of neuro and cardiovascular pharmacology. She completed a postdoctoral fellowship in Pharmacology-Morphology from the Pharmaceutical Manufacturers' Association (now Pharma) Foundation in the Anatomy Department of the Georgetown University Schools of Medicine and Dentistry, with an emphasis on reproductive endocrinology.

Dr. Fenner-Crisp came to ILSI from the U.S. Environmental Protection Agency, having served in a variety of capacities over a period of more than 22 years. Through the years she was the Senior Science Advisor to the Director of the Office of Pesticide Programs (OPP), Director of the Health and Environmental Review Division (HERD) of OPPT, the Acting Deputy Director and Deputy Director for OPP, the Director of the Health Effects Division (HED) in OPP, a Special Assistant to the Assistant Administrator for OPPT, a Senior Toxicologist in the Health Effects Branch of the Office of Drinking Water (ODW), and the Manager of the Health Advisory Program for ODW.

Dr. Fenner-Crisp has been involved in many activities of several international organizations. She has participated as an Expert on WHO IPCS working groups for nine years. She served as the lead U.S. Delegate to the OECD's Endocrine Disruptor Testing and Assessment (EDTA) workgroup, the EDTA's Mammalian Validation subgroup, and the Expert Consultation on Acute Toxicity. In April, 2000, she received the Fitzhugh Green Award, for her contributions on behalf of EPA to its international activities.

Dr. Fenner-Crisp is a member of the Society of Toxicology (SOT) and the Society for Risk Analysis (SRA) and the National Capitol Area Chapter of SOT and SRA (NCACSOT and NCAC-SRA). In 1996, she was the recipient of the SRA's first Risk Practitioner award. She has been a Diplomate of the American Board of Toxicology since 1984 and was named to its Board of Directors in April, 2001. She served as a member of the Board of Directors of the Toxicology Forum from 1990-2000, also serving on its Program Planning Committee. She was honored as a Toxicology Forum Fellow at its 2003 Winter meeting.

Dr. Gary L. Ginsberg

Dr. Ginsberg is a Senior Toxicologist at the Connecticut Department of Public Health within the Division of Environmental Epidemiology and Occupational Health using toxicology and risk assessment principles to evaluate human exposures to chemicals present in air, water, soil, food, and the workplace. He has expertise with exposure and pharmacokinetic models and their use in risk assessment.

Dr. Ginsberg received his B.S. in Pharmacy from the State University of New York and his Ph.D. in Toxicology from the University of Connecticut. He was a post-doctoral fellow in carcinogenesis/mutagenesis at the Coriell Institute for Medical Research. Prior to the Connecticut Department of Public, Dr. Ginsberg was a Senior Toxicologist for TRC Environmental Corporation where he managed risk assessment and toxicology projects including developing methodologies to evaluate dose route extrapolation of carcinogens for EPA.

Dr. Ginsberg is currently the Project Manager of several EPA cooperative agreement projects. One project is researching the susceptibility differences between children and adults stemming from age-related pharmacokinetic factors and the other is the influence of genetic polymorphisms on susceptibility to toxicants and inter-individual variability.

Dr. Ginsberg is an Assistant Clinical Professor at the Connecticut School of Medicine and an Adjunct Faculty member at the Yale University's School of Medicine. He was the Chair of the Peer Review Committee for USEPA's RfD for Methylmercury. He is a member of the National Children's Health Study, Medicines/Pharmaceuticals Work Group, and the USEPA Federal Advisory Committee on Children's Health Protection.

Dr. Ginsberg is a member of the Society of Toxicology (SOT) and the Society for Risk Analysis. Dr. Ginsberg has been published in the areas of toxicology, carcinogenesis, physiologically-based pharmacokinetic modeling, inter-individual variability and children's risk assessment.

2005 Disclosure Statement: Some of Dr. Ginsberg's work is cited in the framework document that is the subject of this peer consultation

2007 Disclosure Statement: No changes to previous disclosure.

Dr. Dale Hattis

Dr. Dale Hattis is a Research Professor with the George Perkins Marsh Institute at Clark University. For the past three decades he has been engaged in the development and application of methodology to assess the health, ecological, and economic impacts of regulatory actions. His work has focused on approaches to incorporate interindividual variability data and quantitative mechanistic information into risk assessments for both cancer and non-cancer endpoints.

Recent research has explored age-related differences in sensitivity to carcinogenesis and other effects, a taxonomy of different non-mutagenic modes of action for carcinogenesis with likely differential implications for age-related sensitivity, PBPK modeling of acrylamide dose in rats and humans, and mechanism-based dose response modeling of carcinogenic effects from ionizing radiation. Dr. Hattis is a leader in efforts to replace the current system of uncertainty factors with distributions based on empirical observations.

Dr. Hattis is a member of the Environmental Health Committee of the EPA Science Advisory Board, and for several years he has served as a member of the Food Quality Protection Act Science Review Board. He has recently been chosen to be the Chair of the Dose Response Specialty Group of the Society for Risk Analysis. He has also served as a member of the National Research Council Committee on Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations.

Dr. Hattis has been a councilor and is a Fellow of the Society for Risk Analysis, and serves on the editorial board of its journal, Risk Analysis. He holds a Ph.D. in Genetics from Stanford University and a B.A. in biochemistry from the University of California at Berkeley.

Ms. Ann Marie Jarabek

Ms. Jarabek works in the Office of Research and Developmet of the U.S. Environmental Protection Agency. As a special assistant to the Associate Director for Health in the National Center for Environmental Assessment (NCEA), she is currently on detail to the Environmental Toxicology Division of the National Health and Environmental Effects Research Laboratory (NHEERL). Via this assignment, she is working on a modeling effort to develop a Bayesian hierarchical model to define different tissue states of oxidative stress in the respiratory tract due to inhaled chlorine. The goal of the modeling is to statistically formalize the confidence in mechanistically based model descriptions of dosimetry and tissue reactions for inhaled reactive gases using a value-of-information approach.

Ms. Jarabek received a B.S. in biology from the University of Notre Dame and trained in inhalation toxicology at the University of Cincinnati Medical Center. She is currently pursuing a Ph.D. at the Department of Environmental Sciences and Engineering at the University of North Carolina at Chapel Hill. Ms. Jarabek is the principal author of the EPA's methods to derive inhalation reference concentrations (RfCs) that incorporate dosimetry modeling of inhaled particles and gases to improve characterization of dose, and was the team leader for the Agency's risk characterization of ingested perchlorate.

Most of her EPA research involved developing mode-of-action dosimetry models for the inhalation, oral, and dermal routes. Ms. Jarabek has represented the Agency on a number of public-private partnership steering committees that developed case studies for the application of mode of action information per the 1996 proposed cancer assessment guidelines, she also consulted on committees evaluating how to harmonize approaches of noncancer and cancer and on the use of biomarkers in risk assessment. She also contributed to the practice of using dosimetry modeling for route-to-route extrapolation, and technical reviews and negotiations to use pharmacokinetic data to inform alternative testing strategies. Annie was involved with implementation of the benchmark dose approach for dose-response modeling and developed a Bayesian application that provides for statistical combination of dose-response estimates and allows for calculation of risk above reference levels, which was recently extended to combine health and ecotoxicological risks.

Ms. Jarabek is active in the National Occupational Research Agenda, the Society of Toxicology (SOT) and the Society for Risk Analysis (SRA). She has been an elected councilor to the SRA and continues to serve SRA on the annual meeting program , continuing education and workshop committee, and the nominating committee. She has received four awards for outstanding presentation from the Risk Assessment Specialty Section (RASS) of the SOT, as well as an award for best manuscript demonstrating a risk assessment application in 2001. She was elected as a four-year officer to the SOT RASS and served as its president in 2004-2005.

Ms. Jarabek has received numerous medals, including one gold, one silver, and four bronze, for her significant contributions to the Agency. She has provided invited presentations on dosimetry methods, mode of action, and statistical considerations for dose-response assessment to the National Academy of Sciences (NAS), the Science Advisory Board (SAB) of EPA, the Toxicology Forum, and the EPA's Risk Assessment Forum. Annie was recognized with the Practitioner of the Year award in 2006 by the Society for Risk Analysis.

Dr. John Lipscomb

Dr. Lipscomb is a toxicologist with the U.S. EPA, Office of Research and Development, National Center for Environmental Assessment. His responsibilities at the agency involve the development and assessment of refined risk assessment methods, including evaluation of toxic mechanisms of action, dose-response assessments, exposure quantifications, and definitions of intrinsic modifiers of toxicity. He also reviews methods and guidelines related to the toxicological effects of environmental pollutants.

Dr. Lipscomb received his B.S. and M.S. degrees in Biology from the University of Central Arkansas and his Ph.D. degree in Interdisciplinary Toxicology from the University of Arkansas for Medical Sciences. Prior to joining EPA, he served as Captain in the U.S. Air Force and Chief of the Metabolism Section in the Toxicology Division of the Armstrong Laboratory at Wright-Patterson Air Force Base. While in that assignment, he designed and conducted research in xenobiotic metabolism in response to Air Force environmental and occupational health needs, determined the enzymological basis for human inter-individual and species-dependent differences in bioactivation, and identified potential modifiers of toxicity.

Dr. Lipscomb currently is Adjunct Assistant Professor in the Department of Therapeutics, College of Pharmacy, University of Cincinnati, and also in the School of Public Health and Tropical Medicine, Department of Biological Sciences, Tulane University. He has been a Diplomate of the American Board of Toxicology since 1995.

Dr. Lipscomb is a member of the Society of Toxicology, the Society for Risk Analysis, and the International Society for the Study of Xenobiotics. He also is past and present office-holder in the regional chapters and specialty sections of these organizations. He has received numerous achievement awards and medals from the U.S. Air Force, Army, EPA and the National Institute for Occupational Safety and Health. In 2000, 2002 and 2003 he received awards from the SOT Risk Assessment Specialty Section for Outstanding Poster and Platform Presentations, Best Abstract, and Top Ten Best Papers.

Dr. Lisa M. Sweeney

Dr. Sweeney is a Program Manager at The Sapphire Group, where her responsibilities include the development and refinement of physiologically-based pharmacokinetic (PBPK) models and their application to risk assessment. She has a broad range of experience in the application of toxicology, chemistry, and engineering to problems in the health and environmental sciences. Dr. Sweeney has over 10 years experience in risk assessment, pharmacokinetics, and biochemical engineering from a variety of private sector and non-profit backgrounds.

Dr. Sweeney received her B.S.E. in Chemical Engineering from Case Western Reserve University and her Ph.D. in Chemical Engineering with a minor in toxicology from Cornell University. She worked as a research engineer for Amoco Corporation, where she established a research program on the biological effects of contaminated soil and water and designed experiments to enable ecological and human health risk assessments. She also was a team member of the Industrial Health Risk Assessment program at Concurrent Technologies Corporation where she led efforts to support three Department of Defense manufacturing or maintenance facilities.

Dr. Sweeney is currently managing a High Production Volume (HPV) toxicology data review for glycol chemicals. This work involves development of robust summaries, the test plan, and the SIDS Initial Assessment Report. Dr. Sweeney has been involved in the development of workplace exposure limits for glycol ethers. It has included identifying critical NOELs from animal studies, developing PBPK models of the chemicals' disposition in animals, men, and pregnant women, and using equivalent internal dosimetry and uncertainty factors derived from Monte Carlo simulation as the basis for scientifically-defensible workplace exposure limits.

Dr. Sweeney is a member of the Society of Toxicology, the Society for Risk Analysis, and several other professional organizations. In 2003, she was the recipient of the SOT's Risk Assessment Specialty Section award for Outstanding Paper Demonstrating an Application of Risk Assessment. She has been a Diplomate of the American Board of Toxicology since 1998 and is a Certified Hazardous Materials Manager.