Edward J. Pfau

Senior Scientist Hull & Associates, Inc., Dublin, Ohio

Ed Pfau has more than 20 years' experience in environmental toxicology and environmental risk assessment. He leads a group of environmental scientists who prepare and review human health and ecological risk assessments and remedial strategies for brownfields, hazardous waste management units, Superfund sites, and other sites where hazardous substances or petroleum pose a potential or known environmental or regulatory concern. He conducts environmental fate and eco-toxicological evaluations as part of chemical safety assessments prepared to meet registration requirements for chemical manufacturers in the United States and Europe. Before joining Hull, Ed was a toxicologist and lead risk assessor at the Ohio Environmental Protection Agency (Ohio EPA), where he was responsible for critical review and approval of risk assessments under the Ohio Voluntary Action Program (VAP), and for the development of technical guidance to support the VAP and other Ohio EPA programs. Ed's earliest professional experience was in the assessment of harmful algal blooms and the characterization of algal toxins.

Ed has both master's and bachelor's degrees in Biology. He has served on several committees, including the ASTM E50.04 Voluntary Cleanup Task Group and the generic standards and risk assessment committee under the Ohio EPA VAP Multi-Disciplinary Board. He is a member of the regional and national chapters of the Society of Environmental Toxicology and Chemistry and the Society for Risk Analysis.

Oliver Kroner, M.En. Toxicology Excellence for Risk Assessment

Oliver Kroner is an Environmental Scientist at the non-profit public health organization Toxicology Excellence for Risk Assessment (TERA). Mr. Kroner is the Manager of the Alliance for Risk Assessment (ARA), a partnership of non-profit organizations working to build a risk assessment community to resolve complex risk issues. In this capacity, he has built several risk tools, including the <u>Risk Information Exchange</u>, the <u>ARA Dose-Response Framework</u>, and the risk communication website <u>kidschemicalsafety.org</u>. Mr. Kroner obtained his Masters of Environmental Science from Miami University. Rod B Thompson, Alliance for Site Closure. Rod is a regulatory toxicologist and risk assessor who worked with Indiana's Risk Based Closure program for over twenty-five years. He became involved with TCE in the early 2000s, developing a Slope Factor which was used by Indiana up until IRIS issued in 2011. Rod has also been involved with Vapor Intrusion (VI) where he was a principal in the development of Indiana's initial VI program and helped develop the ITRC VI guidance. He has commented extensively and presented to USEPA on the various VI drafts, conducted a roundtable on States' VI issues and was a member of the team that developed the ARA TCE non-cancer guidance.

David R. Gillay

Partner

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David R. Gillay is a partner in Barnes & Thornburg LLP's Environmental Department. Before joining the department in 2001, he obtained an advanced environmental engineering degree and practiced as an environmental consultant on various projects across the country.

Mr. Gillay's legal practice primarily concentrates on the following subjects: underground storage tank regulation, including Indiana's Excess Liability Trust Fund; Brownfields projects; remediation projects dealing with soil, surface water and groundwater contamination under a wide variety of regulatory programs; assessing and managing the vapor intrusion pathway in real estate transactions and redevelopment activities; cost-recovery claims against owners and operators for contamination, including evaluating other mechanisms to fund investigatory and cleanup activities; environmental due diligence including Phase I Environmental Site Assessments, Phase II subsurface investigations, and evaluating remedial cost estimates; and managing environmental liability in business transactions. His work includes business and compliance counseling, voluntary clean-ups, risk-based decision making under Indiana's Risk-Integrated System of Closure and federal guidance documents, and litigation before state and federal courts and agencies.

Mr. Gillay worked as an engineer/project manager with various consulting firms from the mid-1990s to 2001. Most recently, he was project manager for IT Corporation's Engineering and Construction Group and worked in the following areas: remediation of industrial sites with chlorinated solvents and metals contamination; leaking underground storage tank clean-ups; contract and claim management on a multimillion dollar Superfund clean-up project in Monticello, Utah; environmental compliance audits; and due diligence involving phase I and II investigations in property transfers, mergers and acquisitions.

Mr. Gillay frequently writes and speaks, having participated in a variety of private associations, client and continuing legal and business education seminars. Mr. Gillay also participates in government work groups that develop policies on various technical aspects of risk-based clean-ups. Mr. Gillay is counsel of record for the Midwestern States Environmental Consultants Association (MSECA). MSECA works closely with governmental regulators on technical matters related to the characterization, clean-up, and closure of contaminated properties.

Since 2011, Mr. Gillay has been selected for inclusion in *The Best Lawyers in America*® in the area of environmental law.

He received a B.S. in civil engineering in 1995 and a M.S. in environmental engineering in 1996 from Michigan State University. He received his J.D. with

Bar Admissions Indiana, 2001

Other Court Admissions

Indiana Northern District Court

Indiana Southern District Court

Education

B.S., Michigan State University, 1995

M.S., Michigan State University, 1996

J.D., University of Tulsa, with honors, 2001

honors in 2001 from the University of Tulsa College of Law, where he was a senior staff member on the *Tulsa Law Journal* and a member of Phi Delta Phi.

Lenny Siegel Center for Public Environmental Oversight c/o PSC, 278-A Hope Street Mountain View, CA 94041-1308 650/961-8918 or 650/969-1545 fax: 650/961-8918 <lsiegel@cpeo.org> http://www.cpeo.org

Lenny Siegel has been Executive Director of the Center for Public Environmental Oversight since 1994. He is one of the environmental movement's leading experts on both military facility contamination and the vapor intrusion pathway, and for his organization he runs two Internet newsgroups: the Military Environmental Forum and the Brownfields Internet Forum. In July 2011 Siegel was awarded U.S. EPA's Superfund Citizen of the Year award.

Siegel serves on numerous advisory and technical committees including the ITRC Munitions Response Classification Work Team, the Moffett Field Restoration Advisory Board, the National Research Council's Committee to Review the IRIS Process, and the California Brownfield Reuse Advisory Group. Siegel is founder of the Save Hangar One Committee, working to restore and reuse Moffett Field's landmark dirigible hangar.

Michael L. Dourson, Ph.D., DABT, ATS President Toxicology Excellence for Risk Assessment (TERA)

Michael Dourson is the Director of Toxicology Excellence for Risk Assessment (TERA), a nonprofit corporation dedicated to the best use of toxicity data in risk assessment. TERA develops partnerships among government, industry and other interested groups to address risk assessments of high visibility, such as formaldehyde, perchlorate, chloroform, and soluble nickel, and cooperative ventures such as the Voluntary Children's Chemical Exposure Program (VCCEP), the International Toxicity Estimates for Risk (ITER) database (available at the National Library of Medicine's ToxNet), and the Alliance for Risk Assessment (ARA). 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).

He 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 two journals. He has also 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.

Calvin C. Willhite, B.S., M.S., Ph.D.

Calvin Willhite is a Senior Contract Toxicologist with Risk Sciences International, Washington, D.C. where he develops health risk assessments for man-made and naturally-occurring chemicals. Dr. Willhite has published primarily in developmental toxicology, and quantitative structure-activity relationships. He serves on the editorial boards of Toxicology & Applied Pharmacology, the Journal of Toxicology and Environmental Health and Toxicology. Dr. Willhite has been a member of the National Academy's Committee on Toxicology, the U.S. EPA's National Advisory Committee, the NTP's SACATM, ILSI's Structure-Activity Database Project, the National Research Council's Submarine Air Quality and Acute Exposure Guidelines Subcommittees, the NSF Health Advisory Board, the ACGIH Committee on Threshold Limit Values, the IARC Cancer Chemoprevention Panel and Cal/OSHA's Lead in Construction PEL Committee. He is a member of the Society of Toxicology and his biography appears in Who's Who in America, Who's Who in Science and Engineering and Who's Who in Medicine and Healthcare.

Edward Carney Director, Predictive Toxicology Organization The Dow Chemical Company



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Edward Carney is Director of Predictive Toxicology at The Dow Chemical Company, where he has worked since 1992. Ed also leads Dow's Chemicals & Health Science Policy team and serves on the Toxicology Department leadership team. He holds an appointment on the NTP Board of Scientific Counselors, is VP-Elect of the Teratology Society, VP of the Society of Toxicology Reproductive & Developmental Toxicology Specialty Section, and serves on the Board of Toxicology Forum, various ILSI-HESI project teams, and the Humane Society's Human Toxicology Project Consortium. Ed also is an adjunct professor at The University of Michigan School of Public Health and a lecturer in the University of Surrey (UK) Master's Programme in Toxicology. He has published over 70 peer-reviewed papers to date, including work on in vitro teratogenicity methods, developmental toxicokinetics and assessment of chemical mixtures. He holds a B.S. from Cornell University (1981) and graduate degrees in reproductive physiology from the University of Wisconsin-Madison (M.S., 1986) and Cornell University (Ph.D., 1990). He conducted postdoctoral research in molecular developmental biology at Mount Sinai Hospital Research Institute in Toronto.

Biographical Sketch

Linval R. DePass, Ph.D., DABT

Dr. DePass received his B.S. (Biology major) from Georgetown University, his M.S. (Biology) from the University of Miami and his Ph.D. (Interdisciplinary Toxicology) from the University of Arkansas for Medical Sciences in a program that was managed jointly with the National Center for Toxicological Research. He is currently the Executive Director of Nonclinical Safety and Principal Scientist at Durect Corporation in Cupertino, CA. Prior to joining Durect, he was the Department Head, Toxicology for Roche Palo Alto (formerly Syntex and Roche Bioscience). Before the acquisition of Syntex by Roche in 1994, he was a Department Head in the Department of Toxicology at Syntex where he started working in June 1984. From February 1978 until joining Syntex, Dr. DePass worked at Union Carbide Bushy Run Research Center (BRRC) where he was Manager of Oral and Dermal Toxicology. Dr. DePass has been a member of the Society of Toxicology (SOT) since 1983 and served on the Animals in Research Committee from 1997 to 2000. He was a Councilor and Secretary/Treasurer in the Regulatory and Safety Evaluation Specialty Section of SOT from 2001-2004. He is a past President of the Northern California Chapter of SOT and he was a founding member of the Chapter. He is also a member of the American College of Toxicology and AAAS. Dr. DePass was a member of the editorial board of Fundamental and Applied Toxicology from 1989 to 1995 and is a Diplomate of the American Board of Toxicology (DABT), recertified in 2011.

Dr. DePass has given lectures to advanced undergraduates and graduate students at UC Berkeley, UC Davis, University of Pittsburgh and Carnegie-Mellon University. He has also lectured at workshops sponsored by other professional organizations, most recently the California Analytical Chemists Organization in Foster City and San Diego, CA. In 2011, Dr. DePass gave three lectures in various aspects of toxicology at the University of the West Indies, Mona Campus, Kingston, Jamaica. This visit was sponsored by the SOT as part of their Global Toxicology Scholar program.

Dr. DePass worked for 61/2 years in a laboratory (BRRC) that did research and testing on industrial chemicals and pesticides regulated by the EPA. Based on his work at the BRRC, Dr. DePass was invited to participate in six EPA-sponsored workshops between 1981 and 1988. He was also an invited reviewer of EPA's draft guidelines for dermal carcinogenicity testing. Thus, he is aware of the issues related to the safe use of industrial chemicals in the workplace and the consequences of environmental exposures to these compounds.

Stephen B. Harris, PhD, FATS, FSB

Dr. Harris is President of Stephen B. Harris Group in San Diego, CA, since September 1982. He has over 40 years of professional experience in developmental and reproductive toxicology and has been an independent consultant for over 30 years. Since 1985, he has held several teaching appointments at San Diego State University, Stanford University, and National University in the areas of developmental and reproductive toxicology. He continues to mentor graduate students, and supervises thesis research, as an Adjunct Associate Professor in the Graduate School of Public Health at San Diego State University. Dr. Harris's area of expertise includes: (1) scientific interpretation of data from developmental and reproductive safety evaluation testing programs for the pharmaceutical and chemical industries globally, (2) management and training of Contract Research Organization (CRO) personnel especially in developmental and reproductive toxicity testing including fetal morphological assessments in multiple species, (3) CRO testing facility design, operations, and study monitoring, (4) CRO client pre-qualification site assessments, (5) due diligence, and (6) product liability issues. He has successfully authored many opinion papers and critiqued numerous technical reports for the pharmaceutical and chemical industries to assure compliance with worldwide regulatory requirements for product approval. Dr. Harris has been invited to deliver several national and international scientific presentations and workshops. He interfaces with both national and international regulatory agencies. Dr. Harris is a Managing Editor for Food And Chemical Toxicology, on the Editorial Board of the International Journal of Toxicology and the Journal of Environmental Science and Health, Part C, Environmental Carcinogenesis and Ecotoxicology Reviews (ECER). Dr. Harris was President of the American College of Toxicology (2006-2007). Currently is a Councilor of the Teratology Society (2012-2015) and Fellow of the Academy of Toxicological Sciences and Society of Biology.

Melissa C. Marr, Research Toxicologist

Ms. Marr received her B.A. degree in Biology (1976) at the University of North Carolina at Greensboro, with course concentrations in embryology, vertebrate morphology, and physiology.

In 1979, Ms. Marr joined RTI International as a Biologist in the Developmental Toxicology Laboratory. In 1981, she was promoted to Supervisor. In 2003 she became a Study Coordinator in the RTI Reproductive and Developmental Toxicology Laboratory. During this time she participated in the C-section, external examination, visceral examination and fetal head and double-stained fetal skeleton examination for over 100 developmental toxicity studies in rats, mice and rabbits. She is responsible for protocol development, study scheduling, maintaining Standard Operating Procedures for prenatal and reproductive toxicology procedures, oversight of in-life and necropsy phases, quality control of study data, and coordination with support laboratories for dose formulation, analytical chemistry, clinical chemistry, and histopathology, as well as authorship of final study reports. In 1991, she attended the American Association of Laboratory Animal Science Technologists course and was certified in 1992. She is currently certified as a Registered Laboratory Animal Science Technologist (RLATG) and is a member of the Teratology Society and the Society of Toxicology.

She is responsible for overseeing Good Laboratory Practice Regulation compliance for developmental reproductive toxicity, pre- and postnatal studies conducted under EPA and FDA Guidelines, as well as OECD guideline studies. She has supervised over 175 studies in mice, rats, and rabbits, including FDA Segment I, II, and III studies, EPA OPPTS reproductive and developmental toxicity studies, as well as OECD 407, 414, 146, 421,422 and 440 studies. Her double staining procedure is referenced in the US EPA and OECD Guidelines for Prental Developmental Toxicity Studies.

Sine 2009 she has been Study Coordinator for 5 NTP Reproductive Assessment by Continuous Breeding Studies (RACB) as well as 3 studies for the NTP Modified One-Generations (MOG) study design. She is familiar with protocol input and data collection for in-life and necropsy for RACB and MOG study designs.