ICCVAM-NICEATM/ECVAM/JaCVAM Workshop[1]

Acute Chemical Safety Testing: Advancing *In Vitro* Approaches and Humane Endpoints for Systemic Toxicity Evaluations

National Institutes of Health (NIH) Natcher Conference Center

February 6 – 7, 2008

Biographic Information for Invited Workshop Participants

[1] Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM); The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); European Centre for the Validation of Alternative Methods (ECVAM); Japanese Center for the Validation of Alternative Methods (JaCVAM).

Daniel Acosta, Jr., Ph.D.

Dr. Acosta is dean of the University of Cincinnati's College of Pharmacy. His accomplishments include implementing a new entry-level Pharm.D. program and several new degree programs in the professional and MS/PhD programs of the college, including one of the first national Master programs in drug development. He was a member of the University of Texas College of Pharmacy faculty for 22 years where he helped develop a nationally ranked program in toxicology. He is active in numerous scientific and professional organizations, serves on several editorial boards of toxicology and *in vitro* journals, and has been appointed to a number of government and private committees. He was the chairman of the Food and Drug Administration (FDA) Scientific Advisory Board for the National Center for Toxicology Research, Past Chairman and current member of the Texas A&M External Advisory Board of the NIEHS Center for Environmental and Rural Health, a past member of the Board of Scientific Advisors for the Office of Research and Development of the Environmental Protection Agency, a past member of the National Advisory Committee to the Director of the Center for Environmental Health of the Centers for Disease Control and Prevention, a member of the NIEHS Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) which advises both the NICEATM and the ICCVAM regarding statutorily mandated duties and activities, and a member of the Expert Committee on Toxicology and Biocompatibility of the United States Pharmacopoeia. He was appointed to the Committee on Toxicity Testing and Assessment of Environmental Agents for the National Academy of Sciences. His awards and honors include the Burroughs Wellcome Toxicology Scholar, Colgate Palmolive Visiting Professor in *In Vitro* Toxicology, and several endowed professorships at the University of Texas. He has been President of the Society of Toxicology and received the 2005 Society of Toxicology's Enhancement of Animal Welfare Award. He has recently served on the committee on Toxicity Testing and Assessment of Environmental Agents for the National Research Council (NRC). The Pharmaceutical Research and Manufacturers of America Foundation awarded him the 2006 Foundation Award in Excellence.

Melvin E. Andersen, Ph.D., D.A.B.T.,

Dr. Andersen is Director of the Computational Biology Division at the Hamner Institutes For Health Sciences in Research Triangle Park, NC. His responsibilities include imparting a computational systems biology emphasis to dose-response assessments with environmental chemicals and pharmaceuticals. The main emphasis in his 30-year career is on developing biologically realistic models of the uptake, distribution, metabolism, and biological effects chemicals and applying these models in quantitative health risk assessments. Current interests include use of genomics to better assess modes of action and to assess chemical perturbation of cell signaling pathways. Dr. Andersen was professor of environmental health at Colorado State University in Fort Collins, CO, and has served as vice president of the K.S. Crump Group of ICF Kaiser International Consulting. He has held positions in toxicology research and research management in the federal government with the U.S. Department of Defense (DoD) and the U.S. Environmental Protection Agency (EPA), as well as in private industry with the Chemical Industry Institute of Toxicology (CIIT). He is board-certified in industrial hygiene and in toxicology. He is a Diplomat of the American Board of Toxicology and maintains membership in the Society of Toxicology, the American Academy of Industrial Hygiene, the American Conference of Governmental Industrial Hygienists, and the Society of Risk Analysis. Dr.

Andersen has been associate editor of *Toxicology and Applied Pharmacology* and is author or co-author of 300 papers, 45 book chapters and numerous reports and abstracts. He has received numerous awards and was recognized in 2002 as a "highly cited" scientist by the Institute for Scientific Information. He has recently served on the committee on Toxicity Testing and Assessment of Environmental Agents for the National Research Council (NRC). Dr. Andersen received a B.S. in Chemistry from Brown University and a Ph.D. from Cornell University.

Richard A. Becker, Ph.D.

Dr. Becker is currently the Senior Director of the Public Health Team at the American Chemistry Council (ACC) in Arlington, VA. He works as a principal toxicologist within the ACC and as lead of the U.S. chemical industry's efforts to advance the development of standardized, validated, cost-effective and internationally harmonized screening and testing methods for evaluation of substances with potential endocrine activity. He is also a principal scientist with the ACC in on issues related to children's health and for emerging toxicological science issues such as development of immunotoxicity screening/testing, toxicogenomics, and reduction, refinement and replacement of laboratory animals in toxicity tests. He has previously worked with the California Environmental Protection Agency in the Department of Toxic Substances Control. He is a member of the American Association for Cancer Research, the Society of Toxicology, and the Society for Risk Analysis. Dr. Becker is a member of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), which advises both the NICEATM and the ICCVAM regarding statutorily mandated duties and activities. He has served on ICCVAM-sponsored independent scientific expert panels that reviewed the validation status of four *in vitro* assays proposed for the detection of ocular corrosives and severe irritants. Dr. Becker received his Ph.D. in Pharmacology and Toxicology from the University of California, Irvine.

June A. Bradlaw, Ph.D.

Dr. Bradlaw is Chair of the Scientific Advisory Board, International Foundation for Ethical Research (IFER), and Science Advisor to IFER's affiliate, The National Antivivisection Society. She retired from the Center for Food Safety and Applied Nutrition, Food and Drug Administration in 1999 after 41 years of government service as a Supervisory Microbiologist. Her research interests include *in vitro* toxicology, genetic toxicology, and standardization of cell and tissue culture methodology to detect cellular toxicity at the DNA, cellular, and subcellular levels. She spent a brief time with the Office of Premarket Approval and was Adjunct Associate Professor of Microbiology, The George Washington University, between 1981 and 1985. Dr. Bradlaw was also a member of the ICCVAM Corrosivity Test Working Group (1999), the ICCVAM Peer Review Panel for *In Vitro* Ocular Toxicity Tests (2005), and the ICCVAM Peer Review Panel for *In Vitro* Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity (2006). She co-chaired the 1993 Interagency Regulatory Alternatives Group (IRAG) Workshop on Eye Irritation Testing. In 2006, Dr. Bradlaw was appointed to the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) which advises both the NICEATM and ICCVAM regarding statutorily mandated duties and activities. She has been actively involved in the Society for *In Vitro* Biology for close to 40 years and received the Lifetime Achievement Award for the Society for *In Vitro* Biology in 2001. Dr. Bradlaw received her A.B. in Botany from Connecticut College, a M.S. in Microbiology from the University of Maryland, and a Ph.D. in Microbiology from the George Washington School of Medicine.

Daniel J. Cobaugh, Pharm.D., FAACT, D.A.B.A.T.

Dr. Cobaugh is director of Research and Program Development at the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation in Bethesda, MD. He completed a residency in hospital pharmacy at Mercy Hospital of Pittsburgh and a clinical toxicology fellowship at the Pittsburgh Poison Center/Children's Hospital. He was Coordinator of the Toxicology Treatment Program at the University of Pittsburgh Medical Center and Assistant Professor of Pharmacy Practice and Emergency Medicine at the University of Pittsburgh Schools of Pharmacy and Medicine. Dr. Cobaugh was the Director of both the Finger Lakes Regional Poison and Drug Information Center and Emergency Medicine Research at the University of Rochester Medical Center in Rochester, NY and a member of the Research Subjects Review Board and the Medical Faculty Council. He was the President of the Association of Poison Control Centers of New York State and has worked with the American Association of Poison Control Centers (AAPCC) and the American Academy of Clinical Toxicology. In 2000 he became the Associate Director for Special Projects and the Toxic Exposure Surveillance System (TESS) at AAPCC where he implemented the nationwide toll-free number for poison centers and development of a standardized approach for developing patient management guidelines for poisoning. He was a Clinical Associate Professor of Emergency Medicine at The George Washington University School of Medicine and served on the Board of Directors of the American Board of Applied Toxicology. He was Director of the Section of Home, Ambulatory, and Chronic Care Practitioners at the ASHP. Dr. Cobaugh is a member of the American Academy of Clinical Toxicology Board of Trustees and the Health Services and Resources Administration-sponsored Guidelines for the Management of Poisoning Consensus Panel. He has been a toxicology consultant to the World Health Organization International Programme on Chemical Safety, the U.S. Department of Health and Human Services, and the U.S. Department of Transportation. He currently serves as a member of the Board of Visitors for the University of Pittsburgh School of Pharmacy. He has authored over 75 toxicology-related publications including peer-reviewed articles, book chapters, and abstracts. Dr. Cobaugh received his Doctor of Pharmacy degree at Duquesne University.

Helen Diggs, D.V.M., M.Ed., D.A.C.L.A.M.

Dr. Diggs is the Director of the Office of Laboratory Animal Care at the University of California, Berkeley and the University of California System-wide Veterinary Consultant. She worked for the Animal Resources Facility at the Oregon Health Sciences University and spent seven years as Chief Veterinary Medical Officer for the Veterans Affairs Medical Center in Portland, OR. She has also worked as Associate Director for Veterinary Care at the University of Texas Southwestern Medical Center in Dallas, TX before accepting her current position at UC Berkeley in 1995. Dr. Diggs is vice president of the American College of Laboratory Animal Medicine (ACLAM). She is a member of the Governing Board of Directors for the California Biomedical Research Association, the American Association for Laboratory Animal Science (AALAS), National Association for Biomedical Research (NABR), American Society of Laboratory Animal Practitioners (ASLAP), and the American Veterinary Medical Association (AVMA). Dr. Diggs serves on the Council of Accreditation for the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). She also serves on the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) which advises both the NICEATM and ICCVAM regarding statutorily mandated duties and activities.

She received her Bachelor of Arts and Masters degrees in Education from the University of Portland in Portland, OR. She received her D.V.M. from Oregon State and Washington State Universities in 1985 and is licensed to practice veterinary medicine in the states of Oregon, Washington, and California.

Eugene L. Elmore, Ph.D.

Dr. Elmore is a Project Scientist in the Department of Radiation Oncology, Chao Family Comprehensive Cancer Center, University of California, Irvine. Previously, he was the Scientific Director of the National Institute for the Advancement of *In Vitro* Sciences, Irvine, California. Prior to that he was Supervisor of Cellular and Molecular Toxicology, ManTech Environmental, Research Triangle Park, NC. His research interests include human cellular systems for predicting cancer prevention efficacy, normal human epithelial cellular models for acute and chronic toxicity, drug-induced changes in gene expression and pathway analysis, and the biological effects of low dose radiation. Dr. Elmore has over twenty five years of experience in developing and validating human cellular systems for predicting toxicity and efficacy for various governmental organizations, including: the National Institute of Environmental Health Sciences (NIEHS), the National Toxicology Program (NTP), the National Cancer Institute (NCI), the National Institute for Occupational Safety and Health (NIOSH), and the U.S. Environmental Protection Agency (EPA). He serves on the Scientific Advisory Board for the International Foundation for Ethical Research. In 2006, he served on the ICCVAM Peer Review Panel for "Use of *In Vitro* Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Systemic Toxicity Testing." In 2000, he participated in the ICCVAM International workshop on *In Vitro* Methods for Assessing Acute Systemic Toxicity. Dr. Elmore has served as Treasurer of the Environmental Mutagen Society and Treasurer of the International Association of Environmental Mutagen Societies. In 1996, he was Vice Chair of the World Congress on *In Vitro* Biology and in 1997 he chaired the Congress on *In Vitro* Biology. He served on the council and executive board for the Society for *In Vitro* Biology and received the society's Fellow Award in 2004. Dr. Elmore received his M.A. and Ph.D. in Genetics from the University of North Carolina, Chapel Hill.

Robert Guest, B.Sc. (Honours.) *C. Biol., MI Biol.*

Mr. Guest is the Head of the Alternative and Acute Toxicology Department at Safepharm Laboratories Limited and has served as Deputy Chairperson of the Company's Ethical Review Committee. He has been the Head of Project Management and managed multi-disciplinary testing programs in support of worldwide registration of new chemicals and preparations. He has performed contract research at Safepharm for 28 years in technical, Study Director, and managerial positions and manages a GLP-accredited laboratory that conducts regulatory short-term toxicology studies for the chemical, agrochemical and pharmaceutical industries. He has expertise in acute toxicity, local tolerance, contact sensitization, and photosafety. He implements the 3Rs in regulatory toxicology using tiered testing strategies incorporating *in vitro* and *ex vivo* screening tests. Mr. Guest develops, validates, and uses alternative test methods for the prediction of the hazardous properties of chemicals and the safety evaluation of consumer products. He has been a member of the British Toxicology Society and UK Institute of Biology for 18 years. He is a member of the UK *In Vitro* Toxicology Society, the UK Chemical Hazards Communication Society, the Institute of Biology, the British Toxicology Society, the Chemical

Hazards Communication Society, and the *In Vitro* Toxicology Society. He has contributed to previous activities of ICCVAM/NICEATM (ICCVAM Expert Panel Meeting to Assess the Current Validation Status of *In Vitro* Test Methods for Identifying Ocular Corrosives and Severe Irritants, 2005), ECVAM, the International Life Sciences Institute (ILSI), the UK National Centre for the 3Rs, the UK Chemical Industry Association Toxicology Reference Group, the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) Implementation Working Group on Acute Toxicity, and the European Partnership for Alternative Approaches to Animal Testing. Mr. Guest gained his B.Sc. (Honours) degree in Biological Sciences at Nottingham Trent University in 1990.

Steven R. Hansen, D.V.M., M.S., M.B.A., D.A.B.T., D.A.B.V.T.

Dr. Hansen manages the American Society for the Prevention of Cruelty to Animals (ASPCA) Midwest Office, which includes the ASPCA Animal Poison Control Center, the Animal Behavior Center, Counseling Services, the Knowledge Management Center, the Animal Product Safety Service, the Pet Nutrition and Science Advisory Service, and related expert consulting services. Prior to joining the ASPCA in 1997, Dr. Hansen was the Director of Veterinary Research and Support for Wellmark International (formally Sandoz Agro Animal Health Division, now Central Life Sciences) now located in Schaumburg, IL. He also practiced clinical medicine in suburban Houston and Chicago. Dr. Hansen is board certified by the American Board of Toxicology and the American Board of Veterinary Toxicology and holds an adjunct appointment at the University of Illinois College of Veterinary Medicine. Dr. Hansen currently chairs the American Association of Poison Control Centers' Veterinary Committee, serves as treasurer for the American College of Animal Welfare specialty organizing committee, represents the Illinois State Veterinary Medical Association on Veterinary Technology accreditation audits for the AVMA Committee on Veterinary Technician Education and Activities and serves on the P & G Petcare International Animal Welfare Advisory Board. Dr. Hansen has appeared on "Today," Anderson Cooper 360, CNN American Morning and Fox Pet News, and is regularly interviewed by radio and print reporters. He is a member of the Iams Science Advisory Board and the American Veterinary Medical Association (AVMA) Animal Welfare Advisory Committee. Dr. Hansen received his B.S. and D.V.M degrees from Iowa State University. He completed a residency program in Veterinary Toxicology and received an M.S. in Veterinary Medical Science (toxicology) from the University of Illinois. Dr. Hansen earned an M.B.A. with honors also from the University of Illinois.

Thomas Hartung, M.D., Ph.D.

Dr. Hartung is Head of the European Centre for the Validation of Alternative Methods (ECVAM), Joint Research Centre in Ispra, Italy since joining in 2002. ECVAM was established in 1992 and coordinates the validation of alternative test methods at the European Union level; acts as a focal point for the exchange of information on the development of alternative test methods; sets up, maintains and manages a data base on alternative procedures; and promotes dialogue between legislators, industries, biomedical scientists, consumer organizations and animal welfare groups, with a view to the development, validation and international recognition of alternative test methods. Dr. Hartung has participated in ICCVAM-sponsored activities and supports activities that are jointly sponsored by ECVAM and ICCVAM. His main research interests are inflammation, infectious disease, immune recognition of bacteria, pyrogen testing,

and alternatives to animal testing especially for chemical and cosmetics safety testing. He was awarded the Enhancement of Animal Welfare Award from the Society of Toxicology in 2007. Dr. Hartung became an honorary full professor of the University of Konstanz, Germany in 2002. From 1999-2002, he was an associate professor, non-tenure-track lecturer (habilitation) for pharmacology and toxicology and a member of the university senate. He was a Senior Lecturer for Biochemical Pharmacology (C2) from 2001-2002 and an assistant professor in Konstanz (1994-1999). Dr. Hartung also specialized in surgery at the hospital of Singen, Germany. From 1996-2002 he was the CEO of the Steinbeis Technology Transfer Center for *In Vitro* Pharmacology and Toxicology (InPuT). He completed a medical internship at the University of Freiburg (1991-1992). In 1991 Dr. Hartung became Dr.rer.nat. (Ph.D.) in Konstanz (Biochemical Pharmacology) and in 1992 a Dr.med. (M.D.) in Tübingen (Toxicology). He received a Diploma in Biochemistry from the University of Tuebingen in 1989.

Gabrielle M. Hawksworth, Ph.D.

Dr. Hawksworth is Professor of Molecular Toxicology at the University of Aberdeen, UK. Her research interests are in the molecular mechanisms of drug-induced hepatotoxicity and nephrotoxicity and the role of nuclear receptors in the induction and regulation of cytochrome P450 and uptake and efflux transporters. She is author of over 150 peer-reviewed papers in these areas. She has organized and chaired a number of ECVAM Workshops and is currently involved in the EU FP6 A-Cute-Tox project on the optimization and pre-validation of an *in vitro* test strategy for predicting human acute toxicity. She is a member of the UK Advisory Committee on Pesticides (ACP) and chairs the Medical and Toxicology Panel of the ACP. Dr. Hawksworth is Vice Chairman of the UK Herbal Medicines Advisory Committee and a member of the Executive Committee of the International Union of Pharmacology (IUPHAR). In 2000, she participated in the ICCVAM International workshop on *In Vitro* Methods for Assessing Acute Systemic Toxicity. She has served on the committee for The International Union of Pure and Applied Chemistry (IUPAC) and is currently President of the British Toxicology Society. She has served as President of the Pharmaceutical Society of Great Britain (2003-2004) and has served on the UK Medicines Commission, which advises Ministers on matters relating to the Medicines Act 1968. Dr. Hawksworth received her Ph.D. from the Wright Fleming Institute, St. Mary's Hospital Medical School, UK.

A. Wallace Hayes, Ph.D., D.A.B.T., F.A.T.S., Flbiol

Dr. Hayes is currently a Visiting Scientist at Harvard School of Public Health. Prior to his work at Harvard School of Public Health, he was a Corporate Vice President for The Gillette Company, a Professor at the Wake Forrest University School of Medicine, Vice President for RJR Nabisco, the Director of Toxicology at Rohm Haas, and a Professor at the University of Mississippi Medical School. Dr. Hayes has served as President of the American College of Toxicology, a Council member for the American College of Toxicology, a Council member for the Society of Toxicology, President of the Toxicology Education Foundation, and President of the Academy of Toxicology Sciences. Dr. Hayes currently is the Secretary-General of the International Union of Toxicology (IUTOX). He also is a member of the American Society for Pharmacology and Experimental Therapeutics (ASPET) and the American Chemical Society. Dr. Hayes was a National Science Foundation (NSF) pre-doctoral fellow at Auburn University, a National Institutes of Health (NIH) postdoctoral fellow at the Vanderbilt University School of

Medicine, a NIH Research Development Award recipient, and a NATO Senior Scientist at the Central Veterinary Laboratory, Weybridge, England. He received the 2006 Society of Toxicology Merit Award. Dr. Hayes is a diplomat 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, and a member of the Institute of Biology (UK) and the American College of Forensic Examiners. He has served on committees and expert panels for the National Academy of Sciences, the NIH, the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Defense as well as on several international expert panels. He has served as an independent peer review panelist and expert scientist for ICCVAM for: *in vitro* ocular toxicity test methods; acute oral toxicity test methods (the revised Up-and-Down Procedure [UDP]); *in vitro* test method for assessing dermal corrosivity potential of chemicals (Corrositex®), and *in vitro* alternatives to acute systemic toxicity. He is a former member of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) which advises both the NICEATM and the ICCVAM regarding statutorily mandated duties and activities. He has published more than 200 peer-reviewed papers and is the editor of the textbook, Principles and Methods of Toxicology, 5th Edition. Dr. Hayes received his A.B. from Emory University and his M.S. and Ph.D. from Auburn University.

Hajime Kojima, Ph.D.

Dr. Kojima is the Director of the Japanese Center for Validation of Alternative Methods (JaCVAM) at the National Institutes of Health Sciences (NIH) in Tokyo, Japan. JaCVAM has been supported by the Health and Labour Sciences Research Grants and performs collaborations with the Japanese Society of Alternatives to Animal Experiments (JSAAE), the Japanese Environmental Society, Mammalian Mutagen Study (JEMS-MMS), ICCVAM, ECVAM, the Japanese Cosmetic Industry Association (JCIA) and various companies. Validation assays and peer review currently underway include: non-radioisotopic LLNA validation study; *in vitro* sensitization test pre-validation study; *in vitro* corrosive and skin irritation studies using 3-dimensional skin models peer review; i*n vitro* photoirritation test validation study; endocrine disrupter screening validation studies; and, the Comet assay (development of protocol). Dr. Kojima is a Visiting Lecturer at the Fujita Health University School of Medicine. He has been a researcher at the National Institute of Genetics and the Nippon Menard Cosmetic Co, Ltd. Dr. Kojima's interests include mutagenicity and toxicology. He is a member of the Japanese Society for Contact Dermatitis (trustee), the Japanese Society of Toxicology (Editor), the Japanese Environmental Mutagen Society, the Japanese Society of Alternative to Animal Experiments, and the Japan Society of Endocrine Disrupter Research. Dr. Kojima has received several awards for presentations from the JSAAE. Dr. Kojima graduated from Gifu University, Department of Agriculture, Faculty of Agricultural Chemistry (1983) and received his Ph.D. in Information Science from the University of Nagasaki.

Albert P. Li, Ph.D., M.B.A.

Dr. Li is currently Co-Founder, President, and Chief Executive Officer of *In Vitro* ADMET Laboratories LLC (IVAL, Columbia, MD), Advanced Pharmaceutical Sciences Inc. (APSciences, Columbia, MD), and BRiVAL Inc. (Vancouver, British Columbia). Dr. Li's companies provide *in vitro* toxicity testing service (IVAL), *in vitro* drug metabolism service

(BRiVAL), and *in vitro* cell-based products (APSciences). Dr. Li was previously President and CEO of Phase I Molecular Toxicology Inc. (Santa Fe, NM); Chief Scientific Officer of *In Vitro* Technologies Inc. (Baltimore, MD); Director and Research Professor, Surgical Research Laboratories, St. Louis University Medical School; Senior Research Fellow, Monsanto Company (St. Louis, MO); Cellular and Genetic Toxicology Group Leader, Lovelace Inhalation Research Institute (Albuquerque, NM); and Research Scientist and Assistant Professor, Cancer Research and Treatment Center, University of New Mexico. Dr. Li is instrumental in the development and applications of human-based *in vitro* experimental systems in the evaluation of human drug properties. He was influential in the approach of using *in vitro* human liver models in the evaluation of drug metabolism and drug-drug interactions. His latest contributions include the optimization of cryopreservation procedures for human hepatocytes and the invention of the patented Integrated Discrete Multiple Organ Co-culture (IdMOC) system which models the whole animal/human, allowing the evaluation of multiple organ toxicity while allowing multiple organ interactions as occur *in vivo*. Dr. Li has published over 150 peer-reviewed papers, edited five books and five special journal issues, and co-authored three U. S. patents. He serves as editor and editorial board member on various journals in toxicology and drug metabolism. He has served as an independent peer review panelist and expert scientist for ICCVAM for evaluating *in vitro* methods for pyrogenicity testing. Dr. Li obtained his Ph. D. degree in Biomedical Sciences from the University of Tennessee, Oak Ridge Graduate School of Biomedical Sciences. He also holds an Executive M.B.A. degree from the University of Maryland.

Daniel S. Marsman, D.V.M., Ph.D., D.A.B.T.

Dr. Marsman is the Section Head of Animal Welfare and Alternatives at The Procter and Gamble Company (P & G) of Cincinnati, OH. He has worked at P & G as an anatomic and toxicologic pathologist and as a senior scientist/toxicologist. He served as the expert pathologist for the Environmental Toxicology Program located at the National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS). Dr. Marsman has contributed to NTP technical reports as a study scientist, writer, and pathologist. He completed a postdoctoral fellowship studying the pathobiology of neoplasia at the Chemical Industry Institute of Toxicology (CIIT), Research Triangle Park, NC. He also served as Head of Study Design for the NTP's chronic toxicity/carcinogenicity testing program. He has published extensively on the pathobiology of hepatic neoplasia, cell kinetics/apoptosis, peroxisome proliferator carcinogenesis, renal and reproductive toxicity, and most recently the use of non-animal data in quantitative risk assessments for consumer products. His collaborative contributions have included service on NIH, FDA and the International Life Sciences Institute (ILSI)/Health and Environmental Sciences Institute (HESI) technical committees, and as a past and/or present scientific advisory member for Johns Hopkins University Center for Alternatives to Animal Testing (CAAT), the Institute for *In Vitro* Science, the Animal Welfare Committee of the AVMA, and the Scientific Advisory Committee for Alternative Toxicological Methods (SACATM) which advises both the NICEATM and the ICCVAM regarding statutorily mandated duties and activities. He served on the ICCVAM Peer Review Panel for *In Vitro* Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity (2006). Dr. Marsman received his doctor of veterinary medicine from Michigan State University and his Ph.D. in pathology from the University of North Carolina – Chapel Hill.

Kathleen A. Murray, D.V.M., M.S., D.A.C.L.A.M.

Dr. Murray is the Senior Director, Animal Program Management at Charles River Laboratories in Wilmington, MA. In her current role, Dr. Murray provides oversight to the animal care and use programs including the Institutional Animal Care and Use Committees at all North American sites in order to ensure animal welfare regulatory compliance. She has also been the director of transgenesis services at Charles River Laboratories. Prior to joining Charles River Laboratories in 1988, she worked as Staff Veterinarian at Merck, Sharpe and Dohme Research Laboratories and previously was an Assistant Professor in the Department of Veterinary Clinical Sciences at Louisiana State University School of Veterinary Medicine. She is a Diplomate of the American College of Laboratory Animal Medicine. Dr. Murray is a member of the American Veterinary Medical Association (AVMA), American Association for Laboratory Animal Science (AALAS), and the American Society of Laboratory Animal Practitioners (ASLAP). Dr. Murray earned her D.V.M. at Purdue University and her M.S. in laboratory animal medicine at the Hershey Medical Center, the Pennsylvania State University.

Steven M. Niemi, D.V.M., D.A.C.L.A.M.

Dr. Niemi is Director of the Center for Comparative Medicine at Massachusetts General Hospital and Instructor in Pathology at Harvard Medical School. With over 30 years experience in biomedical research and commercial biotechnology as both a scientist and executive, he has held senior management positions in companies engaged in contract research and testing, gene therapy, and genomics. Dr. Niemi is a Diplomate and past Director of the American College of Laboratory Animal Medicine. He also has served on the boards of the Biotechnology Industry Organization Food and Agriculture Governing Body, Illinois Bio-technology Industry Organization, National Association for Biomedical Research, Massachusetts Biotechnology Council, Massachusetts Society for Medical Research, and Scientists Center for Animal Welfare (SCAW). Dr. Niemi has written or co-authored over 30 scientific publications. In 1995, he served as an Invited Chair, Regulatory Acceptance Criteria and Processes Breakout Group, U.S. National Toxicology Program (NTP)/ICCVAM Workshop on Validation and Regulatory Acceptance of Alternative Toxicological Testing Methods. Dr. Niemi earned an A.B. in biology from Harvard College, a D.V.M. from Washington State University, and was a Postdoctoral Fellow in the Division of Comparative Medicine at the Massachusetts Institute of Technology where he received a Public Health Service National Research Service Award. He later completed the Program for Management Development at the Harvard Business School.

Frank P. Paloucek, Pharm.D., D.A.B.A.T., FASHP

Dr. Paloucek is currently the director of Residency Programs at the University of Illinois at Chicago (UIC) College of Pharmacy. Dr. Paloucek is also associated with the professional staff of the Great Lakes Center for Occupational and Environmental Safety and Health at UIC School of Public Health. He has been a UIC professor in the departments of emergency medicine, clinical toxicology, and internal medicine/nephrology. Dr. Paloucek's areas of interest include emergency medicine, pharmacokinetics and clinical toxicology. He has authored/co-authored more than 50 scientific exhibits and abstracts, 15 books chapters, and more than 30 publications. He is the co-author of the Handbook of Poisoning/Toxicology, 4th edition (2008), published by CRC Press. He has also provided more than 70 scientific presentations. Dr. Paloucek has been

the editor-in-chief for the PEPID™ Portable Drug Companion (PDC) and editor of the *Poison Review* and *Annals of Pharmacotherapy, Forensic Medicine*. He maintains professional memberships in the American Society of Hospital Pharmacists, the American College of Clinical Pharmacy, the American Academy of Clinical Toxicology, and the American Board of Applied Toxicology and is a Fellow of the American Society of Health System Pharmacists (FASHP). Dr. Paloucek received his Doctor of Pharmacy degree from the Philadelphia College of Pharmacy and Sciences in 1984.

Amy S. Rispin, Ph.D.

Dr. Rispin is a Senior Scientist with the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP), Field and External Affairs Division. She is active in the following ICCVAM working groups: biologics, corrosivity, ocular, acute toxicity, dermal corrosivity and irritation, and immunotoxicity. She is an EPA representative to the ICCVAM and served on the NICEATM-ICCVAM Five-Year Plan (2008-2012) subcommittee. Dr. Rispin has participated in numerous national and international activities concerning regulatory affairs and alternative toxicological test methods and is deeply involved with ICCVAM and NICEATM projects. She is knowledgeable in the development of the Organization for Economic Co-operation and Development (OECD) test guidelines and guidance documents and is influential in the United Nations (UN)-sponsored updating of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Dr. Rispin contributed to the ICCVAM-NICEATM independent peer review evaluation entitled The Revised Up-and-Down Procedure (UDP): A Test Method for Determining the Acute Oral Toxicity of Chemicals (2001). She served as the leader of the UDP Technical Task Force that developed the revised UDP test method protocol and the supporting documentation.

Robert A. Scala, Ph.D., D.A.B.T., D.A.T.S.

Dr. Scala is the former Senior Scientific Advisor at Exxon Biomedical Sciences, Inc. His thesis research involved anti-metabolites of riboflavin and stimulated a career-long interest in chemical structure-biological activity relationships. On completion of his graduate studies, Dr. Scala joined the Advisory Center on Toxicology, National Academy of Sciences-National Research Council. The Center evaluated the toxicity of chemical agents of interest to the military. He later joined Hazleton Laboratories, a contract research organization, and served in various line management positions including Director of Laboratory Operations. He has worked with a variety of chemicals used in food, pharmaceuticals, agriculture, cosmetics and industry and the associated regulatory aspects of toxicology. Dr. Scala joined Exxon and remained there for the duration of his active career. During that time he developed and supervised testing programs, established a state-of-the-art toxicology laboratory, provided advice to management and operating organizations on a worldwide basis and recruited and trained a staff of qualified professionals. In retirement, Dr. Scala's scientific interests continue to be the effects of chemicals on skin and eye, experimental carcinogenesis, pharmacokinetics and alternatives to animal testing. Dr. Scala is a past Secretary and President of the Society of Toxicology, a former President of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences. He continues to serve on numerous boards and panels for government and universities and reviews books and manuscripts for several journals. He has recently served on the committee on Toxicity Testing and Assessment of Environmental Agents for the National Research Council (NRC). He has served as an independent peer review panelist for

ICCVAM for: *in vitro* ocular toxicity test methods; acute oral toxicity test methods (the revised Up-and-Down Procedure [UDP]); *in vitro* test method for assessing dermal corrosivity potential of chemicals (Corrositex®). Dr. Scala was educated at Hamilton College, Clinton New York and the University of Rochester (New York) School of Medicine and Dentistry. His undergraduate major was chemistry and he holds an M.S and Ph.D. in Physiology.

Karen L. Steinmetz, Ph.D., D.A.B.T.

Dr. Steinmetz, Ph.D., D.A.B.T. is the Director of the Mammalian Toxicology Program at SRI International (Menlo Park, CA). She has over 25 years experience in the fields of toxicology, safety and preclinical development applicable to a wide variety of pharmaceutical products. She has served as Study Director on numerous GLP studies in support of IND applications, as Principal Investigator on NIH preclinical testing contracts including those with the National Institute on Aging and National Institute of Diabetes & Digestive & Kidney Diseases, and as the preclinical representative on industrial project teams. Her industrial background includes overseeing preclinical development activities and IND preparation for several San Francisco Bay Area biotechnology pharmaceutical companies. Dr. Steinmetz received her B.S. from the University of California-Davis, Masters Degree from California State University-San Jose, and Ph.D. from Indiana University-Indianapolis.

William Stokes, D.V.M., D.A.C.L.A.M.

Dr. Stokes is currently Director of the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), where he directs the review of new test methods that support improved human health and improved animal welfare. He also serves as the Executive Director for the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). Dr. Stokes worked as a veterinarian with the U.S. Army Veterinary Corps at the U.S. Army Medical Research Institute of Infectious Diseases where he completed a residency in laboratory animal medicine and attained board certification in the American College of Laboratory Animal Medicine (ACLAM). In 1983 he became Chief of Veterinary Services for the Tripler Army Medical Center in Honolulu, Hawaii. Dr. Stokes transferred to the Commissioned Corps of the U.S. Public Health Service in 1986 with assignment at the National Institutes of Health as the Animal Program Director for the National Institute of Child Health and Human Development. He later became the Animal Program Director and Chief of the Comparative Medicine Branch at the National Institute of Environmental Health Sciences. In 1992 he was appointed Associate Director for Animal and Alternative Resources. As Co-chair of ICCVAM from 1994-2001, he led the interagency development of criteria and procedures to validate and gain regulatory acceptance of new and alternative safety testing methods, and led the interagency review and adoption of several new methods that significantly reduce the numbers of animals and the pain and distress involved in testing. Dr. Stokes is an internationally recognized authority on the humane care and use of laboratory animals for biomedical research and testing, and has authored or co-authored more than 60 publications and reports. He served as a Council member for the Institute for Laboratory Animal Research (ILAR) at the National Research Council (NRC) from 1998-2004. He is a recipient of the Society of Toxicology's Enhancement of Animal Welfare Award and the AVMA's Charles River Prize for outstanding contributions to laboratory animal science. The U.S. Surgeon General appointed Dr. Stokes as the Chief Veterinary Officer for the U.S. Public

Health Service in 2003, and in 2006 he was promoted to Rear Admiral and Assistant Surgeon General. Dr. Stokes earned his Doctor of Veterinary Medicine degree from the Ohio State University in 1979.

William T. Stott, Ph.D., D.A.B.T.

William Stott is a Scientist level staff member of the Toxicology & Environmental Research and Consulting group of The Dow Chemical Company located in Midland, Michigan. Over the past 30 years he has been involved in a wide spectrum of toxicology studies, but maintains a focus upon mode-of-action, primarily related to chemical carcinogenesis and has published on most aspects of toxicology. He serves as a toxicology consultant for several businesses within Dow, is a company technical representative on several trade associations, represents Dow on the Johns Hopkins Center for Alternatives to Animal Testing (CAAT) Advisory Board, and is responsible for promotion and incorporation of alternative methods to animal testing and the 3 "Rs" within Dow Chemical laboratories. He is a long-term member of the Society of Toxicology (SOT) and has been involved in the Mechanism and Food Safety Specialty Sections of SOT. He participated in the 2005 International Society of Regulatory Toxicology and Pharmacology (ISRTP) Workshop for Progress and Barriers to Incorporating Alternative Toxicological Methods in the U.S. Dr. Stott received his degrees from the University of Wisconsin – Madison, University of Nebraska – Lincoln, and Oregon State University.

Raymond Tice, Ph.D.

Dr. Tice is the Deputy Director of the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) at the National Institute of Environmental Health Sciences (NIEHS) and the Acting Branch Chief of the National Toxicology Program (NTP) Biomolecular Screening Branch. NICEATM administers the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM); provides operational/technical support to ICCVAM; supports/organizes workshops, expert panels, and peer reviews; disseminates information; and conducts independent validation studies. One of ICCVAM's responsibilities is to review and evaluate new, revised, and alternative test methods that would reduce, refine, or replace the use of animals in regulatory testing. The NTP Biomolecular Screening Branch is responsible for coordinating the NTP High Throughput Screening (HTS) Initiative, the purpose of which is to identify and evaluate HTS assays that could be used to assess the ability of chemicals to perturb critical cellular pathways. This information could then be used to prioritize chemicals for further in-depth toxicological evaluation, identify mechanisms of action, and develop predictive models for *in vivo* biological response. Dr. Tice was employed by Brookhaven National Laboratory from 1976-1988, and by Integrated Laboratory Sciences, Inc. from 1988 to 2005, where his last position was Senior VP for Research & Development. He joined NIEHS in 2005. Dr. Tice has served as President of the Environmental Mutagen Society and as Vice-President of the International Association of Environmental Mutagen Societies, has served on a number of international expert panels and committees related primarily to genetic toxicology, and has edited four symposia proceedings and published 130 peer-reviewed articles and book chapters. Dr. Tice has served on the editorial boards of Mutation Research and Environmental and Molecular Mutagenesis. Dr. Tice earned his Ph.D. in Biology (Human Genetics) from Johns Hopkins University.

Marilyn L. Wind, Ph.D.

Dr. Wind is the Deputy Associate Executive Director in the Directorate for Health Sciences at the Consumer Product Safety Commission (CPSC). She has been at the Commission for 28 years. She has been the principal representative from the CPSC to ICCVAM since its inception in 1997 and is currently is the Chairman of ICCVAM. Dr. Wind has served as Chair of the ICCVAM Acute Toxicity Working Group (ATWG), Co-Chairman of the Endocrine Disruptors Working Group (EDWG), and Vice Chairman of the ICCVAM. In addition, she has served on the ICCVAM Ocular Toxicity Working Group (OTWG), the 5-Year Strategic Plan Working Group, the Immunotoxicity Working Group (IWG), and the Reproductive and Developmental Toxicity Working Group. Dr. Wind is the CPSC representative to the National Toxicology Program (NTP) Executive Committee, is the CPSC representative to the NTP Center for the Evaluation of Risk to Human Reproduction Core Committee, and also serves as Chairman of the NTP Interagency Committee for Chemical Evaluation and Coordination. She is also a member of the Johns Hopkins Center for Alternatives to Animal Testing (CAAT) Advisory Board. Dr. Wind received a Ph.D. in Pharmacology from New York University School of Medicine and did her postdoctoral work in Teratology at the National Institute of Dental Research.

Gary Wnorowski, B.A., M.B.A.

Mr. Wnorowski is President of Eurofins Product Safety Laboratories (EPSL). He has been employed by EPSL since 1988, having served as a toxicology technician, Study Director and Laboratory Director until appointment to his present position in 2003. EPSL provides research and testing services to the agrichemical, chemical, pharmaceutical, dietary supplement/functional foods, personal care, animal health, biotechnology and household product industries. EPSL offers a broad range of services including toxicology, analytical and bioanalytical chemistry and pharmacology. Mr. Wnorowski has extensive hands-on experience in study and facilities management. He is knowledgeable in areas of toxicology and pharmacology as well as marketing, finance, accounting and personnel management. Mr. Wnorowski has attended numerous continuing education courses in the areas of GLP compliance, animal science, general toxicology, inhalation toxicology, neurotoxicology and aerosol research. He has made major contributions to the design and operation of EPSL's inhalation facility and is considered a specialist in this field. Mr. Wnorowski is recognized as an authority on the conduct and interpretation of short-term regulatory toxicology studies. He was an independent peer review panelist for ICCVAM to assess the proposed “Acute Oral Toxicity: Modified Up-and-Down Procedure (Revised UDP)” in July 2000. He is the chairman of the Chemical Specialties Manufacturing Association (CSMA), Pesticide Division Critical Issues Committee and a member of the American Chemical Society – Chemical Toxicology. Mr. Wnorowski received his BA in Biological Sciences and Psychology from Rutgers University in New Jersey and his MBA from Monmouth University in New Jersey.