NATIONAL ACADEMY OF SCIENCES • NATIONAL ACADEMY OF ENGINEERING • INSTITUTE OF MEDICINE • NATIONAL RESEARCH COUNCIL

The Potential of the Tissue Chip for Environmental Health Studies

July 21-22, 2014

Speakers and Panelist Biographies

Anthony Bahinski, PhD, is the Lead Senior Staff Scientist at the Wyss Institute. Dr. Bahinski's research interests are in the development of organ-on-a-chip technology for preclinical safety and efficacy evaluation of small molecules, biologics, nanoparticles, and cellular therapies. His career spans from academic research to large Pharma, with over 15 years of experience in the pharmaceutical industry. Before coming to the Wyss, Bahinski was St. Louis Site Lead for Global Safety Pharmacology at Pfizer, where he was responsible for all aspects of Safety Pharmacology for the St. Louis site (Inflammation Therapeutic Area) and a member of the leadership team responsible for global management of safety pharmacology within Pfizer. His recent research efforts were focused on development of stem cell-derived cardiomyocytes and hepatocytes for use in high throughput in vitro toxicity assays and in evaluating the efficacy and safety of cellular therapies for Regenerative Medicine. Dr. Bahinski received his PhD in Physiology at Temple University School of Medicine, followed by postdoctoral work at Rockefeller University and University of Cincinnati. He received his MBA from Xavier University.

Franziska Boess, PhD, studied Environmental Sciences at the ETH Zurich in Zurich, Switzerland followed by a PhD at the joint Zurich University/ETH Institute of Toxicology in Schwerzenbach, Switzerland. In 1998 Dr. Boess joined F. Hoffmann-La Roche as a Postdoctoral Fellow and two years later became a Principal Scientist. Currently, she leads a Mechanistic Toxicology Lab at Roche Innovation Center Basel. Together with her team she is specialized in working with primary animal and human cells and is recognized as an expert in in vitro and cellular toxicity as well as liver toxicity within Roche. Dr. Boess also holds a teaching assignment at the Pharmaceutical Division of the University of Basel and is a member of the Scientific Advisory Board of the Research 3R Foundation Switzerland.

John R. Bucher, PhD, serves as both NTP associate director, and as director of the National Toxicology Program Division. Dr. Bucher is an internationally recognized expert in the design and interpretation of cancer bioassays, and has authored a number of important publications examining critical issues in dose selection for toxicology and cancer studies. Bucher joined the NTP as a toxicologist in 1983 and since then has played a key role in shaping the program's research and policies. In 2007, he was named NTP Associate Director where he began to oversee the day to day operations of the program. Bucher has been instrumental in preparing the program to meet the needs of the 21th century. For example, in 2008 he co-authored a in the journal, Science, which describes a way to transform toxicology by taking advantage of new technologies and shifting protocols for toxicity assessments from laboratory animal studies to more cell-based tests. Bucher holds a doctorate in pharmacology from the University of Iowa, a Master of Science in biochemistry from the University of North Carolina at Chapel Hill, and a Bachelor of Arts in biology from Knox College.

Weihsueh Chiu, PhD, is an Environmental Health Scientist in the U.S. EPA Office of Research and Development, National Center for Environmental Assessment. His specialties include health risk assessment, dose-response assessment, biological and statistical modeling, pharmacokinetics, and data analysis. Since 2003, he has been the Chemical Manager for EPA's trichloroethylene health assessment. He is also currently Project Area Lead for Advancing Dose Response Analysis in the Human Health Risk Assessment Program at EPA. He worked previously in

EPA's Office of Air and Radiation on both exposure assessment and the analysis of health effects from ionizing radiation. He earned his bachelor's degree in Physics from Harvard University, a PhD in Physics from Princeton University, and holds a certificate in Science, Technology, and Public Policy from the Woodrow Wilson School for Public and International Affairs. Prior to joining EPA, he worked at the U.S. Governmental Accountability Office (GAO), where he conducted investigations for Congress on various risk assessment- related topics, including the defense against chemical and biological weapons and the health effects from Vietnam veterans' exposure to Agent Orange.

Rodger D. Curren, PhD, President of the Institute for In Vitro Sciences, Inc., received his BS in Biology from Purdue University, followed by an MS from Ohio University and a PhD in microbial genetics from the Institute of Microbiology at Rutgers University. His post-doctoral work (human cell mutagenesis and DNA repair) was conducted at the Michigan Cancer Foundation and Michigan State University. After more than 10 years of specializing in genetic toxicology and chemical carcinogenesis, he created an In Vitro Toxicology Division as part of the contract research organization Microbiological Associates, now BioReliance, in 1988. This activity was subsequently incorporated as its own non-profit Institute, the Institute for In Vitro Sciences, Inc. (IIVS). Since 1997 IIVS has provided educational and laboratory-based resources for non-animal safety testing to industry, government, and animal welfare organizations, as well as the general public. In addition to assisting in the IIVS educational programs, Dr. Curren serves on many national and international committees and science advisory boards of organizations focused on the development, validation, and practical use of alternative methods to whole animal testing. Among other activities, he is currently president of the American Society for Cellular and Computational Toxicology, and is a member of the Scientific Advisory Committee for the European Union's validation authority, ECVAM. Dr. Curren's efforts in optimizing and promoting new alternative methods have earned him several honors in the in vitro field, including the Russell and Burch Award, the Bjorn Ekwall Memorial award, and the William and Eleanor Cave award for outstanding achievements in the development, validation and advancement of humane alternatives for product testing.

***William H. Farland** *(Chair of the ESEH Standing Committee)* is the Senior Vice President for Research and Engagement at Colorado State University in Fort Collins, CO. He is also a Professor in the Department of Environmental and Radiological Health Sciences, School of Veterinary Medicine and Biomedical Sciences at that institution. In 2006, Dr Farland was appointed Deputy Assistant Administrator for Science in the US Environmental Protection Agency's (EPA) Office of Research and Development (ORD). He had served as the Acting Deputy Assistant Administrator since 2001. In 2003, Dr. Farland was also appointed Chief Scientist in the Office of the Agency Science Advisor. He served as EPA's Acting Science Advisor throughout 2005. Formerly, he was the Director of the ORD's National Center for Environmental Assessment (NCEA) which had major responsibility for the conduct of chemical-specific risk assessments in support of EPA regulatory programs, the development of Agency- wide guidance on risk assessment, and the conduct of research to improve risk assessment. Dr. Farland's 27 year federal career was characterized by a commitment to the development of national and international approaches to the testing and assessment of the fate and effects of environmental agents. Dr. Farland holds a Ph.D. (1976) from UCLA in Cell Biology and Biochemistry. Dr. Farland served on a number of executive- level committees and advisory boards within the Federal government. In 2005-2006, he chaired the Executive Committee of the National Toxicology Program (NTP). He is also a member of the Scientific Advisory Council of the Risk Sciences and Public Policy Institute, Johns Hopkins University School of Hygiene and Public Health, a public member of the American Chemistry Council's Strategic Science Team for its Long Term Research Initiative (ACC/LRI) and a member of the Programme Advisory Committee for the WHO's International Programme on Chemical Safety. In 2002, Dr. Farland was recognized by the Society for Risk Analysis with the "Outstanding Risk Practitioner Award," and in 2005 was appointed as a Fellow of the Society. In 2006, he received a Presidential Rank Award for his service as a federal senior executive. In 2007, he was elected as a Fellow, Academy of Toxicological Sciences. He continues to teach and publish and has been a member of the Editorial Board for *Risk Analysis*, *Environmental Health Perspectives* and *Chemosphere*.

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Jonathan Himmelfarb, MD, is Professor of Medicine and the Director of the Kidney Research Institute at the University of Washington. He is currently the Joseph W. Eschbach Endowed Chair in Kidney Research. Dr. Himmelfarb attended the George Washington University School of Medicine. Following internship and residency in Internal Medicine at Maine Medical Center, he pursued research training in nephrology at the Brigham and Women's Hospital at Harvard, and further clinical training at Maine Medical Center in Portland. Since then, while establishing a research career of international stature, he has served as Director of the Maine Medical Center transplant program and as its interim Chief of Medicine and Associate Chair for Research. Recognized nationally and internationally for his expertise in the area of dialysis, Dr. Himmelfarb has made significant contributions to leading renal societies and foundations, served as chair of the American Society of Nephrology Dialysis Advisory Group and served on the board of advisors to the American Society of Nephrology. He has served on numerous editorial boards, including *Kidney International* and the *Journal of the American Society of Nephrology*, and is currently chair of the Public Policy Board for the American Society of Nephrology.

J. Julie Kim, PhD, is Associate Professor of Obstetrics and Gynecology-Reproductive Biology Research at North Western University's Feinberg School of Medicine. Dr. Kim earned a BSc degree in Microbiology at the University of Toronto, Toronto, Canada. She earned her PhD degree in Cellular and Molecular Biology at Laval University in Quebec, Canada. Dr. Kim completed postdoctoral training at the Department of Obstetrics and Gynecology at the University of Illinois at Chicago. She joined Northwestern University as Assistant Professor in October 2003. She is currently the Susy Y. Hung Associate Professor in the Division of Reproductive Biology Research in the Department of Obstetrics and Gynecology at Northwestern University. Her lab is interested in delineating the molecular mechanisms of progesterone action through its receptor, PR in the uterus. This is done in the context of normal endometrial differentiation, specifically, decidualization, as well as in uterine pathologies, such as endometriosis, endometrial cancer and uterine fibroids. Specifically, the Kim Laboratory is interested in studying PR function in relation to other signaling pathways and transcription factors.

Kyle Kolaja, PhD, is currently the Vice President of Business Development at Cellular Dynamics International (CDI), a leading developer of stem cell technologies for *in vitro* drug development, *in vivo* cellular therapeutics, and stem cell banking. Prior to joining CDI, Dr. Kolaja was Leader/Global Head of Predictive Toxicology Screens and Investigative Toxicology-US at Roche, where he oversaw laboratories that conduct all safety screening assays, provided toxicology support to projects, and applied stem cell-derived tissues to safety. Prior to joining Roche, Dr. Kolaja was Vice President of Chemogenomics and Toxicology at Iconix Pharmaceuticals, and prior to that, he was a project toxicologist and site head of investigative toxicology at Searle/Pharmacia. Dr. Kolaja has served as President of the Society of Toxicology's Drug Discovery Toxicology Specialty Section, is currently President-elect of the Stem Cells and Toxicology Specialty Sections, and is on the board of directors for the American Board of Toxicology. Dr. Kolaja has nearly 60 peer-reviewed publications and reviews (including seven to eight in the last year on applications of stem cell-derived tissues in early safety). He received his B.S. degree from Michigan State University and his PhD degree in toxicology from Indiana University and conducted his postdoctoral research at the University of Kansas.

Edward LeCluyse, PhD, is an Associate Investigator in the Institute for Chemical Safety Sciences at The Hamner Institutes for Health Sciences, and is a participating faculty member of the Curriculum in Toxicology at The University of North Carolina at Chapel Hill (UNC-CH). Dr. LeCluyse has over 25 years of experience in the fields of pharmacology and toxicology, has held industry positions at Merck, CellzDirect, and Invitrogen, and academic positions at UNC's Eshelman School of Pharmacy (1996-2004). More recently, his research has focused on the development and validation of novel in vitro hepatic model systems with which to identify and explore mechanisms of drug- and chemical-induced hepatotoxicity. Dr. LeCluyse is the author of over 100 publications, book chapters, and review articles, and has presented numerous lectures and workshops in topics such as enzyme-induced drug interactions, liver toxicity, and in vitro hepatic culture model systems.

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Lois Lehman-McKeeman, PhD, is currently a Distinguished Research Fellow in Discovery Toxicology at the Bristol-Myers Squibb Company in Princeton, New Jersey. She was employed in the Human and Environmental Safety Division of the Procter & Gamble Company for 15 years prior to joining Bristol-Myers Squibb in 2001. Dr. Lehman-McKeeman has active research interests and programs broadly in biochemical mechanisms of toxicity, with emphasis on secondary mechanisms of carcinogenesis. She is also working to develop and apply metabonomic and transcriptomic technologies to mechanistic toxicology. Dr. Lehman-McKeeman has published extensively in these fields. She has been active professionally in the Society of Toxicology (SOT) serving as the current Past President and on numerous SOT committees, and she held elective office in the SOT as President 2013–2014 and Councilor from 2000–2002, and the SOT Awards Committee from 2008–2010. In 2003, Dr. Lehman-McKeeman was appointed Editor of *Toxicological Sciences*, a position she held through 2011, and she serves on a number of other editorial boards.

***Ivan Rusyn** is Professor with tenure in the Department of Environmental Sciences and Engineering in the School of Public Health at the University of North Carolina at Chapel Hill. He directs the Laboratory of Environmental Genomics and the Carolina Center for Computational Toxicology in the Gillings School of Global Public Health at UNC. He is a member of the Lineberger Comprehensive Cancer Center, Center for Environmental Health and Susceptibility, Bowles Center for Alcohol Studies, and the Carolina Center for Genome Sciences. Dr. Rusyn served on several committees convened by the National Research Council and the WHO/IARC. Dr. Rusyn's laboratory has an active research portfolio funded by the National Institutes of Health and the US EPA with a focus on the mechanisms of action of environmental toxicants, the genetic determinants of the susceptibility to toxicant-induced injury, and computational toxicology. His laboratory applies molecular, biochemical, genetic and genomics approaches to understanding the mechanisms of environmental agent-related disease. His studies on health effects of environmental agents resulted in more than 105 peer-reviewed publications. Dr. Rusyn received his M.D. (with honors) from Ukrainian State Medical University in Kiev and his Ph.D. in Toxicology from UNC-Chapel Hill. He also trained at the University of Dusseldorf in Germany and at the Massachusetts Institute of Technology.

Christie M. Sayes, PhD, is the program manager for nanotoxicology and nanopharmacology in the Center for Aerosols and Nanomaterials Engineering at RTI. Dr. Sayes has more than a decade of experience in the fields of nanotechnology and nanotoxicology. She has authored numerous publications, including original research, invited reviews, and book chapters. Dr. Sayes has conducted basic and applied research in complex-particle toxicology and biocompatibility using cell culture-based and animal-based models as well as nanomaterial and nanotoxicology research techniques and instruments. Dr. Sayes was formerly a professor of toxicology at Texas A&M University, where she maintains her adjunct faculty appointment. She serves on the scientific advisory board for the EPA's FIFRA program and on the editorial board of the journals *Nanotoxicology* and *Toxicology Letters*. Recently, she was elected to the executive committee of the North Carolina Chapter Society of Toxicology. Dr. Sayes' research addresses several fundamental issues relevant to the development of safe and effective nanomaterials in biological and environmental applications. These issues include: the importance of material characterization, dose-response and time-course, correlation of in vitro findings to in vivo results, mechanistic and synergistic analyses, developing mathematical and computational models for predicting nanoparticle toxicities, and defining appropriate endpoints in hazard identification and exposure conditions for risk evaluation.

***Martin L. Stephens** is Senior Research Associate at the Johns Hopkins Center for Alternatives to Animal Testing. He coordinates the Center's activities on evidence-based toxicology. Prior to joining Hopkins in October, 2011, Dr. Stephens was vice president of the Animal Research Issues Section at The Humane Society of the United States. He served on the National Academy of Science' committee that produced *Toxicity Testing in the 21st Century*, as well as on the Scientific Advisory Panel of the Institute for In Vitro Sciences, the scientific program committees for the World Congresses on the Use of Animals and Alternatives in the Life Sciences, the Scientific Advisory Committee on Alternative Toxicological Methods for the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods, and committees at the Organization for Economic Cooperation and Development and the U.S. Environmental Protection Agency. He currently serves on the management teams of

AltTox and Altweb, websites devoted to alternative methods (replacements, reductions, refinements). Dr. Stephens has extensive experience in animal protection and in vitro testing sciences. He earned a Ph.D. in Biology from the University of Chicago.

Danilo Tagle, PhD, is Program Director for Neurogenetics at the National Institute of Neurological Disorders and Stroke (NINDS), where he is involved in developing programs in genomics and proteomics for basic and translational research in inherited brain disorders. Dr. Tagle obtained his PhD in molecular biology and genetics from Wayne State University in 1990. He was a National Institutes of Health (NIH) National Research Service Award (NRSA) postdoctoral fellow in human genetics in the laboratory of Dr. Francis S. Collins at the University of Michigan. Prior to joining NINDS in 2001, Dr. Tagle was an investigator and Section Head of Molecular Neurogenetics at the National Human Genome Research Institute (NHGRI) since 1993 and was involved in the positional cloning of genes for Huntington disease, ataxia-telangiectasia, and Niemann-Pick type C disease

D. Lansing Taylor, PhD, is the Director of the University of Pittsburgh's Drug Discovery Institute and the Allegheny Foundation Professor of Computational & Systems Biology. In his role as the Director of the University of Pittsburgh's Drug Discovery Institute, Dr. Taylor has the goal of assisting academic and commercial collaborators to discover and develop efficacious and safe therapeutics based on the integration of outstanding science, technology and drug discovery/development methods. Dr. Taylor received his BS from the University of Maryland and completed his PhD in cell biology at the State University of New York at Albany. He then went on to complete a postdoctoral fellowship at Woods Hole Marine Biological Laboratory. Dr. Taylor's research interests have been rooted in understanding the temporal-spatial dynamics of signaling molecules and proteins in living cells, coupled to defining the mechanisms of fundamental cell functions such as cell division and cell migration. He has always integrated the development of new technologies in fluorescence-based reagents and light microscope imaging in order to improve the ability to define molecular events in cells and tissue models. His interests have evolved from single cell activities to understanding cellular population dynamics, including the biological basis for heterogeneity in response to perturbations such as drug treatments. Research at the Drug Discovery Institute also involves the investigation of populations of cancer cell models labeled with a panel of fluorescent probes of pathway nodes, organelle functions and cell health to measure, model and predict outcomes using computational and systems biology methods.

Russell Thomas is the director of the National Center for Computational Toxicology at the U.S. Environmental Protection Agency. Dr. Thomas' academic training includes a BA in chemistry from Tabor College, an MS in radiation ecology and health physics from Colorado State University, and a PhD in toxicology also at Colorado State. 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 U.S. EPA, Dr. Thomas was the director of the Institute for Chemical Safety Sciences at The Hamner Institutes for Health Sciences. Dr. Thomas also maintains an adjunct faculty appointment in the Division of Pharmacogenomics and Individualized Therapy at the University of North Carolina at Chapel Hill. 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).

***Joyce S. Tsuji** is a Principal Scientist within the Center for Toxicology and Mechanistic Biology of Exponent's Health Sciences practice. She is a board-certified toxicologist and a Fellow of the Academy of Toxicological Sciences. Dr. Tsuji specializes in assessing exposure and risks associated with chemicals, and in communication of scientific issues. She has worked on projects in the United States and internationally for industry, trade associations, U.S. EPA and state agencies, the U.S. Department of Justice, the Australian EPA, municipalities, and private citizens. Dr. Tsuji's experience includes human health and environmental toxicology related to a wide variety of chemicals in the environment as well as in products. She has designed and directed dietary and environmental exposure studies and community programs involving heatlh eeducation and biomonitoring for populations potentially exposed to chemicals in the environment, including soil, water, and food-chain exposures.

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She has also assessed exposure and health risks associated with chemical exposures from air, foods, medical devices, and a variety of consumer products (e.g., cleaners, air fresheners, cosmetics, paints and coatings, carpets, glues, wood preservatives, building materials, and children's toys and play equipment), including those containing nonotechnology or nanomaterials. Dr. Tsuji has served on expert panels on toxicology and health risks issues for the National Academy of Sciences/National Research Council (including their Board on Environmental Studies and Toxicology and Committee on Toxicology), Institute of Medicine, and federal and state agencies.

Frank F. Weichold is director for the Office of Regulatory Science and Innovation (ORSI) as well as the Office of Critical Path and Regulatory Science Initiatives at the FDA in the office of the Chief Scientist and the Office of the Commissioner for the Food and Drug Administration. The expertise he brings to the FDA builds on his ability to advance, coordinate, and integrate the scientific resources of the Agency addressing mission critical regulatory responsibilities in a global environment. Dr. Weichold's experience includes execution of strategic and operational initiatives across the sciences' value chain. Dr. Weichold has led the development of international collaborations and public private partnerships for discovery and early development, implemented global operating and development models, and executed large-scale business model transformations. He has accumulated more than a decade of industrial research and medical product development experience while leading teams in Clinical Pharmacology, DMPK, as a Director at MedImmune LLC, Gaithersburg, Maryland. Prior, he directed research and clinical development of vaccines at the Aeras Foundation (founded by The Bill and Melinda Gates Foundation). As a tenured Professor in the University of Maryland system, he developed and managed independent research programs and trained graduate students. He also held faculty positions at the University of Maryland Biotechnology Institute to study signal transduction pathways that affect immune responses, as well as the Humboldt University, Berlin (Germany) to teach and study microbial immune modulation. During the five years of postdoctoral education, Dr. Weichold worked at the National Institutes of Health in Bethesda, Maryland, first at the LTCB (NCI) where he researched immune pathologies in HIV infection, then at the Hematology Branch of the NHLBI where bone marrow pathologies, transplantation immunology and gene therapy were the focus of his studies.

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