



# Nanotechnology: The Future of EHS Regulatory Policy



## Speaker Biographies

### Sponsors

#### **Martha Marrapese, Partner, Keller and Heckman LLP**

Martha Marrapese has been a partner with Keller and Heckman LLP since 2000. Ms. Marrapese specializes in the commercialization of new technologies and serves as a U.S. delegate to the International Standards Organization TC-229 Committee on Nanotechnologies. Her expertise includes the Toxic Substances Control Act (TSCA), the Registration, Evaluation and Authorization of Chemicals (REACH) regulation in the European Union, and product defense. Ms. Marrapese is the editor of the Environmental Reporting and Recordkeeping Handbook (Rowman & Littlefield Publishing Group) and a frequent lecturer on environmental compliance.

Keller and Heckman LLP knows that ensuring global regulatory compliance is essential in today's multinational corporate environment. Our lawyers and scientists provide counseling and solutions for commercializing new technologies and for sustaining existing business throughout the world.

Whether it is the EPA, FDA, USDA, CPSC, OSHA, FHSA, DOT, FCC, or the host of other regulatory agencies in the United States or their international counterparts, the synergy between law and science is critical in maintaining and supporting regulatory compliance for global businesses. In this regard, Keller and Heckman's legal and scientific resources are unparalleled.

#### **John DiLoreto, Founder, NanoReg®**

John DiLoreto is the founder of NanoReg®, a professional services firm specializing in the application of laws and regulations related to the development and use of nanoscale materials throughout the nanotechnology value chain. He has been instrumental in bringing together producers and users of nanoscale materials with government policy makers and non-governmental organizations to address growing environmental, health and safety concerns about the products of nanotechnology.

Mr. DiLoreto is the Director of the Nanotechnology SME Coalition for the Synthetic Organic Chemical Manufacturers Association, an industry group focused on the advocacy needs of small and medium-sized producers and users of nanoscale materials.

Mr. DiLoreto also created and managed the American Chemistry Council's Nanotechnology Panel which was the chemical industry's first organized attempt to address scientific and regulatory issues related to nanoscale materials. His experience includes a working knowledge of a wide range of chemical regulatory issues including TSCA (Toxic Substances Control Act) and FIFRA (Federal Insecticide, Fungicide and Rodenticide Act).

As a national leader in the effort to engage industry in nanotechnology environmental, health and safety (EHS) issues, Mr. DiLoreto has been recognized by Lux Research as a key player in the nanotechnology EHS debate and has been identified as an industry expert in its highly influential research reports. As a principle of NanoReg® with a broad network of experienced regulatory and EHS professionals, he continues to work with nanotechnology firms and trade associations to assist companies in a variety of industrial sectors.

NanoReg® publishes the NanoReg Report, the only publication dedicated to news related to regulatory and environmental, health and safety issues throughout the nanotechnology value chain.

## **Guest Speakers**

### **Dr. E. Clayton Teague, Director, Federal National Nanotechnology Coordination Office (NNCO)**

Clayton Teague is Director of the Federal National Nanotechnology Coordination Office (NNCO), being appointed in April 2003. Established in 2001 as a component of the National Nanotechnology Initiative (NNI), the NNCO is the secretariat to the Nanoscale Science, Engineering, and Technology Subcommittee (NSET) of the National Science and Technology Council's Committee on Technology and serves as the primary point of contact for Federal nanotechnology activities. Dr. Teague is on assignment from his position as the Chief of the Manufacturing Metrology Division in the Manufacturing Engineering Laboratory of the National Institute of Standards and Technology (NIST).

For most of his professional career, Dr. Teague has worked in the scientific and technical fields now known as nanotechnology. Beginning with his metal-vacuum-metal tunneling work in 1970's, he continued to work with such precision instrumentation as scanning tunneling microscopes, atomic force microscopes, displacement and phase-measuring interferometers, stylus instruments, flexure stages, and light scattering apparatus. He designed, constructed, and used such precision instrumentation to conduct ultra-high accuracy dimensional metrology of surfaces and micrometer to nanometer-scale features.

Dr. Teague is a member of the American Society for Precision Engineering, has served twice as the Society's president, and is a fellow of the UK Institute of Physics. He served as Editor-in-Chief of the international journal Nanotechnology for ten years and is currently a member of the Editorial Board of the journal. He holds a B.S. and M.S. in physics from the Georgia Institute of Technology and a PhD in physics from the University of North Texas. He has authored or coauthored over 70 papers, has presented 50 invited talks in the technical fields described, and jointly with colleagues, has six patents. Dr. Teague has received the Gold Medal, Silver Medal, and Allen V. Austin Measurement Science Award from the Department of Commerce, the Kilby International Award from the Kilby Awards Foundation, and an IR-100 Industrial Research and Development Award for his work.

### **Mike Novak, Partner, Keller and Heckman LLP**

Mr. Novak practices environmental and business law for chemical manufacturers and other clients, including agricultural, antimicrobial, and biochemical pesticide producers. His practice focuses on the regulation of pesticides and other chemicals under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA), TSCA, EPCRA and other federal and state regulatory programs.

Mr. Novak has expertise in pesticide regulatory issues associated with product registration, including the registration of formulations and technologies containing nano-sized particles; petitions to cancel or deny registration; data compensation matters; adverse effects reporting; enforcement issues; import and export requirements; tolerance petitions, and other regulatory issues.

As lead counsel, Mr. Novak has successfully obtained settlement of pesticide or chemical enforcement actions brought by U.S. EPA Headquarters (Washington D.C.), EPA Region III (Philadelphia, PA), EPA Region IV (Atlanta, GA), EPA Region V (Chicago, IL), EPA Region IX (San Francisco, CA), the California Department of Pesticide Regulation and the New York Department of Environmental Conservation. From 2003 to 2005, Mr. Novak obtained resolution of five separate Stop Sale Use and Removal Orders issued by EPA against clients alleging the unlawful sale of a pesticide under FIFRA.

**Dr. Richard Canady, Office of the Commissioner, Food and Drug Administration (FDA)**

Dr. Richard Canady is a senior science policy analyst with the Office of the Commissioner of the Food and Drug Administration. Dr. Canady leads the "science" group within the FDA Nanotechnology Task Force that recently released a report on nanotechnology science and regulatory issues. He also represents FDA in a number of White House science and policy groups addressing nanotechnology, and serves on the Oversight Committee for the National Cancer Institute's Nanotechnology Characterization Laboratory. He also participates in two Organization of Economic Cooperation and Development working parties on nanotechnology.

Dr. Canady has over 20 years experience in human health risk assessment, including extended loan from FDA to the Executive Office of the President's Office of Science and Technology Policy (OSTP) and the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB). He is worked on a wide range of topics generally focusing on risk assessment science policy. Before joining FDA in 2000 Dr. Canady was with the Centers for Disease Control and Prevention (CDC) in Atlanta working on health risk assessment issues and taught risk assessment at the Rollins School of Public Health at Emory University. Dr. Canady received a Ph.D. from Rockefeller University in 1986.

**Dr. Kenneth A. Mundt, Principal, ENVIRON®**

Dr. Mundt brings more than 25 years of training and experience in the application of epidemiological concepts and methods to a wide range of occupational and environmental health challenges. He is a Principal of ENVIRON International Corporation and also serves as Director of Epidemiology for ENVIRON Health Sciences. Prior to joining ENVIRON, Dr. Mundt served as President and Founder of Applied Epidemiology, Inc. His interest and expertise are in the application of epidemiological concepts and methods; occupational and environmental exposure to chemicals; cancer, reproductive, cardiovascular, musculoskeletal injury and other health outcomes; quality-based critical reviews (QBCR) of epidemiological literature; expert testimony; epidemiological instruction and training.

**Terry L. Medley, J. D., Director of Global Regulatory Affairs, DuPont**

Mr. Medley is Global Director of Corporate Regulatory Affairs, DuPont Environmental and Sustainable Growth Center.

He is recognized internationally as an expert on biotechnology, nanotechnology and environmental regulatory matters. He has served on numerous international steering committees, advisory committees and expert working groups, reviewing the biosafety of biotechnology products. He served two three-year terms as a member of the U.S. National Academies, National Research Council's Board on Agriculture and Natural Resources. He is an Executive Committee member and chair of the Advisory Board for the International Society for Biosafety Research.

His current responsibilities include leading the DuPont Nanotechnologies Safety Health and Environment Advisory Team. He served as the DuPont project lead for development of the June 21, 2007 Environmental Defense-DuPont Nano Risk Framework document for the responsible development of nanomaterials. He is the Chair of the American Chemistry Council's Nanotechnology Panel; Chair of the Business Industry Advisory Committee (BIAC) delegation to the Organization for Economic Co-operation and Development (OECD)'s Expert Group on Nanotechnology; a member of the International Council on Nanotechnology (ICON)'s Steering Committee; a member of the Meridian Institute's Global Dialogue on Nanotechnology and the Poor Critical Connection Group; and he participated in the U.S. Environmental Protection Agency (EPA)'s National Pollution Prevention and Toxics Advisory Committee (NPPTAC) Interim Ad Hoc Work Group on Nanoscale Materials.

He graduated cum laude from Amherst College and received a Doctor of Jurisprudence degree from the University of Virginia.

**Dr. Martin Fritts, Senior Principal Scientist, Nanotechnology Characterization Laboratory and SAIC-Frederick**

Dr. Fritts is a Senior Principal Scientist supporting the Nanotechnology Characterization Laboratory and SAIC-Frederick in accelerating the transition of nanotechnology to cancer and biomedical applications. He is also a computational and experimental physicist assisting in the implementation of advanced imaging and measurement instrumentation, modeling and simulation to elucidate the structure-activity relationships of nanomaterial, and informatics systems to advance knowledge sharing. Dr. Fritts also assists in developing standards as the co-chair of ASTM's E56.02 Subcommittee on Nanotechnology Characterization. Prior to joining SAIC-Frederick, he developed and prototyped nanotechnology applications for industry and government through SAIC's Nanotechnology Initiatives Division. Dr. Fritts' previous work also focused on joint experiment and computation in advanced product and process design and the use of information technology and modeling for collaboration in large research and development projects such as laser fusion with LLNL and LANL; counterterrorism with DTRA; ship design with DARPA, NAVSEA, and industry; and the design of Stars and Stripes, the winner of the 1987 America's Cup. He earned a bachelor's degree in physics at Holy Cross College and a doctorate in nuclear physics at Yale University.

**Jim Willis, Division Director, Environmental Protection Agency (EPA)**

Since October 2004, Jim Willis has been Director the Chemical Control Division (CCD) in EPA's Office of Pollution Prevention and Toxics (OPPT). CCD is responsible for the implementation of EPA's new and existing chemicals programs, the chemical testing program, and special projects such as the Nanoscale Materials Stewardship Program, the HPV Challenge and the PFOA Stewardship program. Jim co-chaired EPA's nanotechnology white paper development and, since 2006, has chaired the OECD Working Party on Manufactured Nanomaterials. Prior to his return to EPA, he was Director of Chemicals for the United Nations Environment Programme, a position he held since November, 1995, where he also facilitated the negotiations of, and served as Executive Secretary of the Rotterdam Convention on Prior Informed Consent and the Stockholm Convention on Persistent Organic Pollutants. He also directed UNEP's mercury program, its chemical safety capacity building program, and its efforts to develop a "Strategic Approach to International Chemicals Management". Jim joined EPA in 1984 and served in a variety of staff and management roles in OPPT before transferring to UNEP.