

The annual conference of *Jurimetrics: The Journal of Law, Science, and Technology* at the Sandra Day O'Connor College of Law

the biggest issues for the smallest stuff :

Regulation and Risk Management of Nanotechnology

monday, march 21, 2011

arizona biltmore / phoenix



steve owens

*Assistant Administrator
Office of Chemical Safety
and Pollution Prevention
Environmental Protection Agency*



robert falkner

*Senior Lecturer, International Relations
The London School of Economics
and Senior Research Fellow
LSE Global Governance*



Innovating law, policy and ethics for science & technology



program

8:30 a.m. Welcome remarks

Dean Paul Schiff Berman, *Sandra Day O'Connor College of Law, ASU*

8:40 a.m. Opening keynote

Steve Owens, *Assistant Administrator, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency*

9:15–10:45 a.m. Session I: The regulatory challenges of nanotechnology

Nano overview and benefits – Philip H. Lippel, *consultant on nanoscience and emerging technologies, The NanoBusiness Alliance*

Scientific challenges – Kiril Hristovski, *Assistant Professor of Environmental Technology, College of Technology and Innovation, ASU*

Regulatory challenges – Gary Marchant, *Lincoln Professor of Emerging Technologies, Law and Ethics, and Executive Director, Center for Law, Science & Innovation, Sandra Day O'Connor College of Law, Professor of Life Sciences, and Associate Director, Origins Project, ASU*

Public challenges – Elizabeth A. Corley, *Lincoln Professor of Public Policy, Ethics & Emerging Technologies, and Associate Professor, School of Public Affairs, ASU*

Moderator: Andrew (Sandy) Askland, *Instructor in Law, and Director, Center for Law, Science & Innovation, Sandra Day O'Connor College of Law, ASU*

10:45–11 a.m. Coffee break

11 a.m.–12:15 p.m. Session II: Regulatory agency perspectives

Jeff Morris, *National Program Director for Nanotechnology, Environmental Protection Agency*

Charles Geraci, *Senior Scientist and Coordinator, Nanotechnology Research Center, The National Institute of Occupational Safety and Health*

Jeffrey Wong, *Chief Scientist, California Department of Toxic Substances Control, California Environmental Protection Agency*

Moderator: Gary Marchant, *Lincoln Professor of Emerging Technologies, Law and Ethics, and Executive Director, Center for Law, Science & Innovation, Sandra Day O'Connor College of Law, Professor of Life Sciences, and Associate Director, Origins Project, ASU*

12:15–1:30 p.m. Lunch

Luncheon speaker – Robert Falkner, *Senior Lecturer, International Relations, The London School of Economics and Political Science (LSE), and Senior Research Fellow, LSE Global Governance*

1:30–3 p.m. Session III: Non-regulatory risk management approaches

Overview of non-regulatory approaches – Daniel J. Fiorino, *Executive in Residence and Director, Center for Environmental Policy, American University*

EDF-DuPont nanorisk framework – Terry Medley, *Global Director, Corporate Regulatory Affairs, DuPont*

Responsible nanocode - Steffi Friedrichs, *Director-General, Nanotechnology Industries Association*

ICON Initiatives – Kristen M. Kulinowski, *Faculty Fellow, Department of Chemistry, and Director for External Affairs, Center for Biological and Environmental Nanotechnology, Rice University*

Moderator: Greg M. Garcia, *attorney, Polsinelli Shughart PC*

3–3:15 p.m. Coffee break

3:15–4 p.m. Session IV: Stakeholder perspectives

NGO perspective – Jennifer Sass, *Senior Scientist, Health and Environmental Program, Natural Resources Defense Council*

Legal practitioner perspective – John C. Monica Jr., *attorney, Porter Wright*

Moderator: Andrew (Sandy) Askland, *Instructor in Law, and Director, Center for Law, Science & Innovation, Sandra Day O'Connor College of Law, ASU*

4–5 p.m. Closing session: Is liability in the future of nanotechnology?

Timothy F. Malloy, *Professor, School of Public Health and School of Law, UCLA, and Faculty Director, UCLA Sustainable Technology and Policy Program*

Edward R. Glady, Jr., *attorney, Polsinelli Shughart PC*

Moderator: Gary Marchant, *Lincoln Professor of Emerging Technologies, Law and Ethics, and Executive Director, Center for Law, Science & Innovation, Sandra Day O'Connor College of Law, Professor of Life Sciences, and Associate Director, Origins Project, ASU*

speakers

Andrew (Sandy) Askland is Director of the Center for Law, Science & Innovation at the Sandra Day O'Connor College of Law at ASU, where he teaches courses in Privacy and Economics and the Law. He also has research interests in environmental ethics and bioethics and in moral and political theory generally. Askland is a member of the American Philosophical Association. Previously, he was a visiting professor at the University of Guam and at Vilnius University in Lithuania, an adjunct professor at the University of Colorado, and practiced law in Maryland and Wash., D.C.

Paul Schiff Berman is Dean and Foundation Professor of Law at the Sandra Day O'Connor College of Law at ASU. Berman's scholarship focuses on the intersection of international law, conflict of laws, cyberspace law and the cultural analysis of law. Before arriving at ASU, he was the Jesse Root Professor of Law at the University of Connecticut School of Law. He served as law clerk to then Chief Judge Harry T. Edwards, of the United States Court of Appeals for the District of Columbia Circuit, and for U.S. Supreme Court Justice Ruth Bader Ginsburg.

Elizabeth A. Corley is the Lincoln Professor of Public Policy, Ethics & Emerging Technologies, and an Associate Professor in the School of Public Affairs at ASU. Her research interests focus on technology policy, specifically the social, ethical and policy implications of emerging technologies, and environmental policy. Corley is a Co-Principal Investigator for the National Science Foundation-funded Center for Nanotechnology in Society at ASU. Her new book, *Urban Environmental Policy Analysis: Toward Sustainability*, co-authored with Heather E. Campbell, will be published by M.E. Sharpe in 2012. Corley serves on the editorial boards for *Research Evaluation* and *Evaluation and Program Planning*.

Robert Falkner is Senior Lecturer in International Relations at The London School of Economics and Political Science (LSE) and Senior Research Fellow at LSE Global Governance. He directs the Nanotechnology Policy and Regulation programme at LSE. In 2008-2009, he coordinated an international research project on European Union and United States nanomaterials regulation, which resulted in the publication of the Chatham House report, *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation* (2009). Among his most recent publications is *Business Power and Conflict in International Environmental Politics* (London: Palgrave Macmillan, 2008).

Daniel J. Fiorino is an Executive in Residence at American University in Washington, D.C., and Director of its Center for Environmental Policy. Fiorino previously held several management and advisory positions at the Environmental Protection Agency, including Associate Director of the Office of Policy Analysis, Senior Advisor to the Assistant Administrator for Policy, and Director of the National Environmental Performance Track. He is the author or co-author of four books and more than two dozen journal articles and book chapters. His writing has been recognized with nine national awards, including the 2007 Brownlow Award of the National Academy of Public Administration for *The New Environmental Regulation*.

Steffi Friedrichs is the Director-General of the Nanotechnology Industries Association, globally the only industries-focused trade association in nanotechnology, which provides a sector-independent, responsible voice for the industrial nanotechnologies supply chains. She has represented the nanotechnology industry with expert advice and evidence to numerous national and international expert committees and regulatory organizations, initiated in-depth programs in support of the ongoing advancement of nanotechnologies,

and participated in stakeholder debates and citizen's engagement panels. Friedrichs is a former Senior Nanotechnology Consultant at The Technology Partnership. She is a member of the Board of Editors for *NanoEducation*, and is a member of several expert panels/boards regarding regulatory-, safety- and innovation- aspects of nanotechnologies.

Greg M. Garcia, an attorney at Polsinelli Shughart PC, has substantial litigation experience in commercial, insurance and personal injury matters, and he has obtained favorable jury verdicts and represented clients at the appellate level. Garcia is trained in the legal and business aspects of the biosciences, and he also focuses on the environmental, regulatory and liability issues associated with the biosciences and the use of nanotechnology in manufacturing. He is a Commissioner on the Arizona Biomedical Research Commission, which supports translational medical research and the State of Arizona's investment in the biosciences, and he is a member of the Arizona BioIndustry Association, where he chairs the Government Affairs Committee. Garcia also participates in the Biotechnology Committee of the Section of Science and Technology Law of the American Bar Association.

Charles Geraci is a Senior Scientist and Coordinator of the Nanotechnology Research Center at the National Institute of Occupational Safety and Health (NIOSH). Geraci provides overall coordination and strategic guidance to the nanotechnology research program, and collaborates internationally with other country programs on various aspects of nanotechnology workplace safety and health. He has authored or co-authored many of the papers that have helped set the direction for proactive thinking in nanotechnology safety and health, and manages several nanotechnology projects that focus on the development and dissemination of workplace risk management guidelines. Geraci also sponsors the NIOSH nanotechnology field team that is conducting visits to nonmaterial producers and users to characterize exposures, evaluate controls and develop best practices.

Edward R. Glady, Jr. is an attorney at Polsinelli Shughart PC, where much of his practice involves scientific and technological issues in diverse areas, including environmental, toxic tort, mass tort, product liability, manufacturing, construction and aerospace. Glady also has extensive experience in insurance law and has represented clients in most states and in several foreign countries. While attending Georgetown University Law School, from which he graduated with honors, he worked for a prominent Washington, D.C., intellectual property firm. Glady has practiced law for nearly 30 years, focusing much of his time on representing clients in risk management, dispute resolution and litigation.

Kiril Hristovski is an Assistant Professor of Environmental Technology at the College of Technology and Innovation at ASU, and a member of the civil, environmental and sustainable engineering graduate faculty at the School of Sustainable Engineering and the Built Environment, also at ASU. Hristovski teaches and researches in the areas of environmental implications and applications of nanomaterials, water and wastewater treatment technologies, emerging contaminants, solid and hazardous waste management, environmental chemistry and emergency management.

Kristen M. Kulinowski is a Faculty Fellow in the Department of Chemistry, and Director for External Affairs for the Center for Biological and Environmental Nanotechnology at Rice University. She is Director of the International Council on Nanotechnology, an international, multi-stakeholder organization that develops and communicates information regarding potential environmental and health risks of nanotechnology in order to foster risk reduction while maximizing societal benefit. Kulinowski is the principal investigator on an OSHA grant to develop and disseminate training materials for safe handling of nanomaterials in the workplace, and she co-authored a guidance document on the subject for the National Institute for Environmental Health Sciences.

Philip H. Lippel is a consultant on nanoscience and emerging technologies for The NanoBusiness Alliance. Lippel has worked on a variety of technical, policy and science communication issues at the national and international level in fields including nanotechnology, science education and workforce, informatics, telecommunications and commercialization of emerging technologies. He has provided top level scientific support to the leadership of the U.S. National Nanotechnology Initiative, helped to keep current Congress, the public and other interested parties on federally funded nanotechnology research and development, and liaised with companies, NGOs and state agencies interested in nanotechnology commercialization.

Timothy F. Malloy is a Professor in the School of Public Health and the School of Law at UCLA, and Faculty Director of the interdisciplinary UCLA Sustainable Technology and Policy Program. Malloy joined the faculty after working in private practice and at the Environmental Protection Agency. His research interests focus on environmental, chemical and nanotechnology policy, regulatory policy and organizational theory, with particular emphasis on the relationship between regulatory design and implementation and the structure of business organizations. Malloy has worked and written extensively in the area of risk governance and pollution prevention, melding together his academic interests with his work in the Sustainable Technology and Policy Program.

Gary Marchant is the Lincoln Professor of Emerging Technologies, Law and Ethics, and Executive Director, Center for Law, Science & Innovation at the Sandra Day O'Connor College of Law, Professor of Life Sciences, and Associate Director, Origins Project, all at ASU. Marchant teaches and researches in the areas of environmental law, risk assessment and risk management, genetics and the law, biotechnology law, food and drug law, legal aspects of nanotechnology and law, science and technology. Prior to joining the ASU faculty in 1999, he was a partner in the Washington, D.C., office of the law firm Kirkland & Ellis LLP, where his practice focused on regulatory issues.

Terry Medley is Global Director of Corporate Regulatory Affairs at DuPont, and has more than 30 years of experience in science, environmental and regulatory matters with a particular focus in biotechnology, nanotechnology and environmental protection laws. Medley is a member of The National Academies, the National Research Council's Board on Environmental Studies and Toxicology and the University of Pennsylvania's Center for Bioethics' External Advisory Board. He is the Chair of the Business Industry Advisory Committee (BIAC) Nanotechnology Committee, and the BIAC delegation lead to the Organization for Economic Cooperation and Development's Working Party on Manufactured Nanomaterials.

John C. Monica Jr., an attorney at Porter Wright, has considerable litigation experience in defending national and international products liability claims for Fortune 500 companies. Monica is a nationally recognized authority on nanotechnology environmental, health and safety, insurance, consumer product and product liability issues. He wrote the full-length legal treatise, *Nanotechnology Law*, first published by West/Thomson/Reuters. As a member of the American National Standards Institute and American Society for Testing and Materials, Monica participated in the development of voluntary international nomenclature and EHS standard for the nanotechnology industry. He was named in 2009 as one of the top ten experts in environmental, health and safety issues related to engineered nanoscale materials.

Jeff Morris is the Environmental Protection Agency's National Program Director for Nanotechnology, where he manages the agency's Nanomaterials Research Program. Morris led the development of EPA's 2007 Nanotechnology White Paper and the 2009 EPA Nanomaterials Research Strategy. He also co-leads the U.S. delegation to the Organization of Economic Cooperation and Development's Working Party on Manufactured Nanomaterials, and co-chairs the Working Party's test guideline's steering group.

Steve Owens is Assistant Administrator for the Office of Chemical Safety and Pollution Prevention at the Environmental Protection Agency. Owens manages the nation's regulatory and scientific programs on pesticides and industrial chemicals, and oversees many collaborative pollution prevention programs. He was the longest-serving (2003-2009) Director of the Arizona Department of Environmental Quality in the agency's history, where he provided executive leadership and set overall agency policy and priorities. He made protecting children from toxic exposures a top priority, and among many other initiatives, he helped launch Arizona's Children's Environmental Health Project and established an Office of Children's Environmental Health. An attorney, Owens also practiced environmental law in Phoenix for 14 years, and is a former President of the Environmental Council of the States.

Jennifer Sass is a Senior Scientist in the Health and Environment program of the National Resources Defense Council, and a Professorial Lecturer at George Washington University in the Department of Environmental and Occupational Health. Sass is an expert in U.S. chemical policy and regulations, and has published more than three dozen articles in peer-reviewed journals, presented testimony in the U.S. Congress, and participated in U.S. government scientific advisory committees.

Jeffrey Wong is the Chief Scientist at the California Department of Toxic Substances Control, California Environmental Protection Agency. Wong manages efforts in environmental measurements, biological and exposure monitoring, toxicology and risk assessment, pollution prevention and technologies. Wong previously was involved in forensic investigations for law enforcement. He has served on study committees for the National Academy of Sciences, the EPA and the Department of Energy, and has worked in areas related to the management and disposal of nuclear materials. Wong is leading efforts focused on nanotechnologies, emerging contaminants and green chemistry.