Speaker Bios

Robert Adler

Robert (Bob) S. Adler is a Commissioner at the U. S. Consumer Product Safety Commission (CPSC). He was appointed to the agency by President Barack Obama in August 2009. His term runs through October 2014. Prior to his appointment, he served on the Obama Transition Team and co-authored a report on the CPSC for the Obama administration.

Prior to assuming office, Mr. Adler served as a professor of Legal Studies at the University of North Carolina as the Luther Hodges Jr., Scholar in Ethics and Law at Chapel Hill's Kenan-Flagler Business School. At the University of North Carolina, he served as the Associate Dean of the MBA Program and as Associate Dean for the School's Bachelor of Science in Business Administration Program. As a professor, he taught courses in business law, business ethics, business-government relations and negotiation. Bob won a university-wide teaching award, the Tanner Award, in 1996 and the undergraduate program's Distinguished Teaching Award in 1990. In 2004, he received the Gerald Barrett Faculty Award for outstanding teaching and service to the MBA Program.

Bob's academic research interests included product safety, product liability, regulation, commercial law, medical malpractice, and negotiation. His article, *When David Meets Goliath:* Dealing With Power Differentials in Negotiation, in the Spring 2000 issue of the Harvard Negotiation Law Review (co-authored with Elliot Silverstein) received the annual best article award by the CPR Institute for Dispute Resolution.

Prior to his service at UNC, he spent nine years as an attorney-advisor to two commissioners at the U.S. Consumer Product Safety Commission in Washington, D.C. Subsequently, he served as counsel to the Subcommittee on Health and the Environment of the Committee on Energy and Commerce in the U.S. House of Representatives. While on the subcommittee, he worked on legislation relating to product liability, childhood vaccines, the Food and Drug Administration, medical malpractice, and the Consumer Product Safety Commission.

Before his service at the CPSC, Bob served as a deputy attorney general for the Pennsylvania Justice Department, where he headed the southwest regional office of the Pennsylvania Bureau of Consumer Protection.

Bob has been involved in numerous consumer protection and education activities for many years. He was elected six times to the board of directors of Consumers Union, publisher of Consumer Reports magazine.

Bob graduated cum laude from the University of Pennsylvania in 1966 with a major in political science. He received a JD from the University of Michigan Law School in 1969.

Anne Caldas

Anne Caldas is Senior Director, Procedures and Standards Administration at the American National Standards Institute (ANSI). Anne's primary roles relate to standards development activities. She is responsible for the implementation of the programs and committees that support the American National Standards (ANS) process and the procedures that govern US participation via ANSI at ISO. Program oversight responsibilities include the accreditation of standards developers and U.S. Technical Advisory Groups (TAGs) to ISO, the approval of standards as American National Standards (ANS), the ANSI Standards Developer Audit Program, the multi-level appeals process at ANSI, ANSI's nanotechnology standardization activities, and other special projects such as ANSI representation on the U.S. Council for Energy Efficient Manufacturing (U.S. CEEM) and issue oriented workshops.

Anne is a graduate of the University of Maryland, College Park and holds an MA in Urban Affairs and Policy Analysis from the New School for Social Research in NYC.

Scott A. Colburn

LCDR Scott A. Colburn, MS, BSN, RN is the Director of the Standards Program at the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). Since joining FDA in January of 2004, LCDR Colburn has served in numerous roles as a nurse consultant in the area of premarket review and voluntary consensus standards development within the General Hospital Devices Branch/Office of Device Evaluation. He has held the positions of lead reviewer and Acting Chief of the General Hospital Devices Branch and since August 2009 has served as Deputy Director of the CDRH Standards Program. Scott is a member to numerous national and international medical device standards working groups and is the convener to both the U.S. Technical Advisory Group (TAG) and International ISO/IEC Joint Working Group (ISO TC210 JWG4/IEC SC62D JWG10) charged with developing a manufacturing standard to address the risks associated with medical device small bore misconnections that lead to adverse and fatal events for patients. Scott has been appointed to the ANSI Executive Standards Council (ExSC), the ANSI Government Member Forum (GMF), the Interagency Committee on Standards Participation (ICSP) and the AAMI Standards Board.

Prior to coming to FDA, Scott completed his bachelor's degree in Nursing from Marquette University and was commissioned in the US Army Nurse Corps where he served four years at the Walter Reed Army Medical Center in D.C. Since coming to the FDA, he has earned a Masters of Science in Biomedical Technology Development and Management from Georgetown University and Virginia Polytechnic Institute and State University.

LCDR Colburn transferred to the U.S. Public Health Service Commissioned Corps in January 2004. Prior to his commission into the USPHS, Scott was enlisted in the Army as a combat medic prior to his Commission in the U.S. Army Nurse Corps in 1999.

Julia Doherty

Ms. Julia Doherty is Senior Director in the Office of WTO and Multilateral Affairs of the United States Trade Representative (USTR). Ms. Doherty is responsible for developing, coordinating and implementing U.S. trade policy on technical barriers to trade, including standards, conformity assessment procedures and technical regulations. She leads the United States delegation on matters related to technical barriers to trade in the World Trade Organization (WTO), the Asia-Pacific Economic Cooperation (APEC) and other international organizations. In 2011, Ms. Doherty served as the Chairman of the APEC Subcommittee on Standards and Conformance. In 2010, Ms. Doherty received the ANSI Chairman's Award for her work leading the APEC Toy Safety Initiative. Prior to working on technical barriers to trade, Ms. Doherty coordinated U.S. trade policy on the negotiations on the Doha Development Agenda of the World Trade Organization, including the WTO Ministerial meetings at Cancun and Hong Kong. She also worked on international economic issues at the U.S. Office of Management and Budget, and was responsible for spearheading the creation of an interagency system to assess sovereign credit risk.

Prior to OMB, she worked for the Joint Economic Committee of the U.S. Congress and the investment bank of Kidder, Peabody & Co.

Ms. Doherty holds a Masters of Arts in Economics from the University of Maryland.

Mary Donaldson

Ms. Donaldson serves as the National Institute of Standards and Technology (NIST) contact for standards-related issues arising out of the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A-119. She is responsible for preparing the annual report to OMB on use of voluntary consensus standards in government procurement and regulation, and serves as Executive Secretary for the Interagency Committee on Standards Policy (ICSP). Ms. Donaldson is responsible for the content of a government web portable that supports the use of standards in government (www.standards.gov). She serves on the ANSI Executive Standards Council, the ANSI Government Member Forum and represents NIST to the ANSI ISO Council.

Prior to joining NIST, Ms. Donaldson was a Senior Economist at the U.S. Consumer Product Safety Commission (CPSC) where she conducted regulatory analyses of proposed Commission actions. Ms. Donaldson began her career with the U.S. Army Laboratory Command where she served as the agency project manager for a program which evaluated foreign developments in science and technology.

Ms. Donaldson received her BS in Agronomy and MS in Agriculture and Resource Economics from the University of Maryland.

Gordon Gillerman

Gordon Gillerman, Chief of Standards Services at the National Institute of Standards and Technology (NIST), coordinates and advises federal agencies, US industry and other stakeholders on standards and conformity assessment policy. Standards Services operates the U.S. Inquiry Point for the World Trade Organization's Technical Barriers to Trade Agreement and is a key information source for US industry on standards related market access issues.

Gordon has extensive experience coordinating standards policy and development across a wide range of critical issues in the U.S. including cloud computing, health IT, homeland security, safety, and health and protection of the environment. Gordon is the Public Sector Co-Chair of the American National Standards Institute's (ANSI) Homeland Security Standards Panel, an expert on conformity assessment systems and their nexus with regulatory and trade issues and a sought-after lecturer on standards, conformity assessment and regulation.

Prior experience includes leading government affairs for the largest U.S. product safety certification and standard development organization, Underwriters Laboratories (UL) in Washington, DC, and Staff Engineer for the medical device and information technology sectors at UL's Northbrook, IL headquarters.

Gordon has worked collaboratively within the standards community to enhance health, safety, the environment and security throughout his career. In 2008 he received an Environmental Protection Agency Gold Medal, a Department of Commerce Bronze Medal and the ANSI Meritorious Service Award. In 2010 Gordon received a Department of Commerce Gold Medal for leadership in enhancing the performance standards and certification program for law enforcement body armor and EPA's Award for Outstanding Leadership in Collaborative Problem-Solving for his work in guiding the development of a Green Clean-Up standard. In 2012 Gordon received the ANSI Gerald H. Ritterbusch Conformity Assessment Medal.

Gordon received a Bachelor's Degree in Electrical Engineering Technology from Bradley University in Peoria, IL.

David Karmol

David Karmol is Vice President for Federal and External Relations at the International Code Council. He has responsibility for managing the Council's relationships with Congress, Federal agencies, and outside organizations.

Prior to joining the Code Council, Mr. Karmol was the Standards Advisor to Iraq, stationed at U.S. Embassy Baghdad for one year, where he was detailed by the National Institute of Standards and Technology (NIST), U.S. Department of Commerce. He was considered to be a "standards expert" by NIST, and was relied upon by U.S. Embassy and U.S. military personnel for advice relating to standards and codes involved in the reconstruction and re-development of Iraq, and assisted various ministries of the Government of Iraq in developing standards systems and capabilities. Immediately following his assignment to Iraq, Mr. Karmol was hired as a

consultant to NIST to research and submit a report outlining options to improve relations between NIST and Arab nations in the area of standards and conformity assessment.

He previously served five years as Vice President, Public Policy and Government Affairs at the American National Standards Institute (ANSI). In that position, he was responsible for representing the Institute before committees and members of the U.S. Senate and House of Representatives, and all federal agencies. He made numerous presentations regarding the ANSI process, and the system of standardization in the United States.

Prior to joining ANSI, Mr. Karmol held the position of General Counsel at the National Spa and Pool Institute (NSPI) for ten years. In that position, he was responsible for managing the legal aspects of the Institute, which was an accredited ANS developer. In addition, he managed the defense of several lawsuits which involved issues related to the development of NSPI standards, both standards developed through NSPI's own internal process, and its later ANSI-approved process. He became a recognized expert on questions related to liability of standards developers to individuals injured by products allegedly manufactured or built in compliance with standards, and was a frequent speaker to legal, insurance and standards organizations on this subject.

He has held several positions in the federal government, including Press Secretary at the United States Mint, and Associate Counsel to the U.S. House Judiciary Committee, specializing in issues relating to the administrative process by which federal agencies adopt rules and regulations. Before moving to the Washington area, he was an elected member of the Ohio House of Representatives, serving two terms representing a district in Toledo, Ohio.

Mr. Karmol is an attorney, licensed to practice law in Ohio, Virginia and the District of Columbia.

Timothy A. Klein

Timothy A. Klein is the Senior Policy Advisor for the U.S. Department of Transportation's (DOT) Research and Innovative Technology Administration (RITA). He supports the RITA Administrator on multiple policy and program issues affecting RITA's missions:

- Advancing intermodal transportation research, development and deployment of innovative technologies;
- Leading university education and research in transportation and transportation-related fields: and
- Coordinating, facilitating, and reviewing the Department's research, development and technology programs and activities.

He serves as DOT's Program Manager for the Nationwide Differential GPS (NDGPS), a national positioning, navigation and timing (PNT) utility for multiple terrestrial applications; and is responsible for RITA's international, technical standards, and Ombudsman programs. He is active as RITA's representative to the AASHTO Standing Committee on Research (SCOR) and Research Advisory Committee (RAC). Mr. Klein has received numerous honors, including the

Secretary's Transportation Safety Award, and was featured as the Washington Post's "Fed Face" in June 2011.

Prior to joining DOT, Mr. Klein worked for 15 years in a progressively responsible series of program and project management positions at NASA's Goddard Space Flight Center.

Mr. Klein received his undergraduate and graduate training at The George Washington University, Washington, DC.

Steve Lowell

Steve Lowell is the Deputy Director of the Defense Standardization Program Office and has been with this office since 1985 in different capacities. From 1983-1985, he was the Head of the Electrical, Materials, and Machinery Branch in the Naval Sea Systems Command's Standardization Program and Documents Division. Some of his most notable past positions include:

- President of the Standards Engineering Society (2003-2005)
- Chairman of the Aerospace Materials Division of the Society of Automotive Engineers (1996-2004)
- Chairman of ANSI's United States Standards Strategy Sub-Group on National Priorities and Processes (2004-2005)
- Chairman of the Government/Industry Equal Partner Implementation Committee (1987-1995)

Mr. Lowell has been awarded the Robert H. Stearns Award from the National Defense Industries Association, an SES Fellowship and Distinguished Service Award, the SAE Technical Standards Board Outstanding Contribution Award, and Vice President Gore's National Performance Review Award in recognition of his contributions to standards and standardization. He was also awarded first place for writing the winning paper in the 1997 and 1999 World Standards Day Paper Competition, and is certified in Standards Management.

Ileana Martinez

Ileana Martinez is International Affairs Advisor, Standards Coordination Office at the National Institute of Standards and Technology (NIST). She also serves as International Affairs Advisor to the National Voluntary Laboratory Accreditation Program (NVLAP) at NIST and is President of the Inter American Accreditation Cooperation (IAAC).

Ms. Martinez has expertise in the U.S. approach to standards, regulations, conformity assessment, laboratory accreditation, as well as in the National Technology Transfer and Advancement Act (Public Law 104-96), U.S. trade obligations under the World Trade

Organization (WTO) Technical Barriers to Trade Agreement (TBT), the U.S. Inquiry Point, and related topics.

From 1996 through 2000, Ms. Martinez served as the NIST Regional Standards Attaché at the U.S. Embassies in Buenos Aires, Argentina and in Brasilia, Brazil, with standards-related responsibilities for South America, seeking to reduce technical barriers to trade in the region. Ms Martinez earlier worked as a Standards Engineer in a variety of industrial sectors for both U.S. and overseas organizations gaining hands-on experience in national, regional and international standardization and conformity assessment activities.

Ms. Martinez earned a bachelor degree in Mechanical Engineering from the Catholic University of America in Washington, D.C. and did graduate work at American University in Washington, D.C. in Science/Technology Policy.

Steven Posnack

Steven Posnack is the Director of the Federal Policy Division within the Office of the National Coordinator for Health Information Technology (ONC), Office of Policy and Planning. Steve joined ONC in July 2005 and has been involved in a number of ONC programs. His past assignments include servings as the Project Officer of the Health Information Security and Privacy Collaboration (HISPC) and lead staff to the American Health Information Community Confidentiality, Privacy, and Security Workgroup.

Steve is now responsible for ONC's legislative analysis, regulatory affairs, and Federal policy development efforts. In response to the HITECH Act, his responsibilities were expanded to include regulation development. Since then, he has led all of ONC's regulatory actions including the regulations for its certification programs and standards and certification criteria for EHR technology.

Mr. Posnack earned a B.S. in Computer Science from Worcester Polytechnic Institute, a M.S. in Security Informatics from Johns Hopkins University Information Security Institute, and a M.H.S in Health Policy from Johns Hopkins University Bloomberg School of Public Health.

Mary Saunders

Mary Saunders currently serves as Director, Standards Coordination Office, NIST. In this capacity, she represents NIST and its significant interests in the standards and conformity assessment community and advises NIST leadership on policy and strategy as they relate to NIST's role in standardization. Her responsibilities include serving as a central point of focus for standards and conformity assessment policy for NIST, coordinating with the private sector and other federal agencies on standardization activities, leading interagency standards coordination, and leading NIST's standards interactions with foreign governments.

Prior to her return to NIST, Ms. Saunders served as Deputy Assistant Secretary for Manufacturing and Services, where she managed the day-to-day operations of the International Trade Administration's (ITA) Manufacturing and Services division.

At NIST, she previously served in a variety of positions during a 15 year career, including Chief, Standards Services Division. In that capacity, she administered a range of standards-related programs to provide solutions to regulatory and industry needs and increase trade opportunities. Over the course of her Commerce career, Ms. Saunders has managed programs to advance U.S. business and technology interests in the European Union, Russia and the Newly Independent States, China and Japan. She has worked with a broad range of sectors on competitiveness and market access issues, including information and communications technologies, telecommunications, medical devices, oil and gas equipment, construction equipment, energy technologies and consumer goods.

She has received the Department's Silver and Bronze Medals for outstanding achievements on several occasions during her Commerce career. Ms. Saunders received her B.A. from Vanderbilt University and an M.P.A. from the Woodrow Wilson School of Public and International Affairs, Princeton University

Katharine (Joni) Teter

Katharine (Joni) Teter is a long time sustainability entrepreneur in one of the largest bureaucracies in the world: the U.S. government. Her passion is helping people see the interconnections among activities and systems that impact the human and natural worlds, and finding opportunities for positive social change at those intersections. Joni is currently based in the Office of Federal High Performance Green Buildings at the General Services Administration (GSA) in Washington, DC. Joni's work centers around "levers for change" that will facilitate significant, enduring, and transformative change towards sustainability in the government sector. She currently works on a variety of matters, including certification systems, performance metrics & tracking systems to enable high performance building operations; submetering and occupant behaviors to facilitate reduction in energy use; greenhouse gas emissions accounting in buildings and the supply chain; the use of labeling & certification systems to facilitate sustainable acquisition of goods and services; and identifying means to increase adoption of high performance building technologies and strategies by facility managers.

Before joining GSA, Joni worked for the U.S. Environmental Protection Agency as a green building and environmental management system expert, and as negotiation lead on complex multi-million dollar remediation projects. She has worked extensively with government agencies and businesses to better integrate technical, environmental, scientific and legal considerations in business planning and implementation, including providing environmental auditing support to the Malaysia Department of Environment.

As a Fulbright Scholar and Specialist, she has worked extensively on developing green building programs in Egypt. Joni has served as adjunct faculty at Colorado universities for more than 20 years.

James Turner

James Turner is Senior Counsel and Director of Energy Policy, Association of Public and Land Grant Universities (APLU). Mr. Turner joined the staff of APLU after his retirement from the House of Representatives' Committee on Science and Technology in January 2009 where he had served as the Committee's chief counsel, technology staff director, and energy counsel. In these capacities, he worked on much of the important technology and energy legislation over a 30 year period. Prior to his work with the Committee on Science, he worked for Wheelabrator-Frye, Congressman Gary Myers, NASA, and the FAA. His work for APLU parallels the work he did on Capitol Hill but in the university context.

Turner has received numerous awards and honors including the Association of University Technology Managers 2009 Bayh-Dole Award, a 2009 Award of Appreciation from the American Society for Engineering Education, the 2008 Ronald L. Brown Standards Leadership Award on World Standards Day, the 2006 NIBS Honor Award from the National Institute of Building Sciences, the American Society of Mechanical Engineers. 2005 Melvin R. Green Codes and Standards Medal. the Virginia Engineering Foundation (UVA) 2002 Service Award; the Federal Patent Lawyer Association, 2001 Distinguished Service Award; the Howard Coonley Medal of the American National Standards Institute; and the Thomas Jefferson Award of the Technology Transfer Society. In 2008, Turner became an Honorary Fellow of the American Society of Civil Engineers. He served on the Obama Presidential Transition Team in 2008 and the Clinton Presidential Transition Team in 1992. Turner currently serves a trustee of the University of Virginia School of Engineering; on the boards of directors of the American National Standards Institute, Oak Ridge Associated Universities; on the Board of Advisors of Innovations: Technology, Governance, Globalization, a Journal published by MIT Press, and on two committees of the American Society of Mechanical Engineers. At University of Virginia he is also Chair of Advisory Board for the Department of Science, Technology and Society. He has been the Academic Cochair of the President's Advisory Council for the Heinz College at Carnegie Mellon; and a board member at ASTM, Scientists and Engineers for America, and a number of other organizations.

Turner received a B.S. degree in mathematics from Westminster College, a M.Div. degree from Yale University, and a J.D. degree from Georgetown University, where he did graduate study in tax law. He also completed the Senior Managers in Government Program at Harvard's Kennedy School of Government.

Andrew Updegrove

Andrew Updegrove is a co-founder and partner of the Boston law firm of Gesmer Updegrove LLP. Since 1988 he has worked with over 115 consortia, accredited standards development organizations and open source foundations. He is a frequent international speaker on standards and open source topics, and has testified before the United States Department of Justice, Federal Trade Commission, and Congressional subcommittees regarding consortia, standard setting and intellectual property matters. He has also filed pro bono "friend of the court" briefs with the Federal Circuit Court, Supreme Court, and Federal Trade Commission in support of the standards setting process in leading standards related litigation.

In 2002, he launched <u>ConsortiumInfo.org</u>, the most extensive resource on the Internet dedicated to consortia and standard setting, and <u>Standards Today</u>, an e-Journal with thousands of government, industry and academic subscribers around the world. In 2005, he launched the <u>Standards Blog</u>, which reports and provides analysis on issues of importance to the open standards and open source communities. In 2004 he was asked to join the United States Standards Strategy revision committee, and in 2005 received the President's Award for Journalism from the American National Standards Institute (ANSI). He has served as a member of the Boards of Directors of ANSI, the Free Standards Group, and the Linux Foundation, on the Advisory Boards of HL7 and Open Source for America, and as a Fellow of the OpenForum Academy.

Mr. Updegrove is a graduate of Yale University and the Cornell University Law School.

David Wollman

Dr. David Wollman is one of NIST's smart grid team leads, managing NIST's smart grid standards and research efforts and overseeing Smart Grid Interoperability Panel activities. Before joining the Smart Grid and Cyber-physical Systems Program in the NIST Engineering Laboratory, he managed efforts within the Physical Measurement Laboratory to maintain and advance the Nation's electrical standards and metrology supporting the electric power industry. He has worked closely with a variety of standards development organizations, and he is the NIST official representative on the Board of Directors at the North American Energy Standards Board (NAESB), an ANSI-accredited SDO whose standards are often referenced by the Federal Energy Regulatory Commission (FERC). In addition, he has served in several other positions at NIST, including Scientific Advisor in the Electronics and Electrical Engineering Laboratory, Program Analyst in the NIST Director's Program Office, and bench-level scientist in Boulder, Colorado developing advanced high-resolution x-ray detectors.

Before joining NIST, Dr. Wollman received his Ph.D. from the University of Illinois at Urbana-Champaign in the areas of superconducting electronics and device micro/nanofabrication. He has given numerous invited talks at international conferences, and holds three U.S. patents. He has received many awards, including the U.S. Department of Commerce Gold Medal and the NIST Applied Research Award.