

PRESENTER BIOGRAPHICAL SKETCHES
HIT Standards Committee – Clinical Operations Workgroup
Medical Device Hearing
March 28, 2011

Patient/Consumer Panel

Rob Havasy, Partners Center for Connected Health

Courtney Rees Lyles, MD, Group Health Consortium

Robert Jarrin, co-chair Continua Health Alliance

Robert Havasy, Project Specialist and mHealth Strategist, Center for Connected Health, Partners Healthcare System Robert Havasy is a Project Specialist and mHealth Strategist at the Center for Connected Health (CCH), part of the Partners Healthcare System in Boston, Massachusetts. With more than a decade of experience in operations and support roles for a large communications provider, Mr. Havasy specializes in making communication technologies accessible to patients while integrating them into clinical workflows. At CCH Mr. Havasy is responsible for customer operations as well as charting the Center's mobile health (mHealth) strategy and identifying and incorporating new technologies into the Center's programs. Mr. Havasy is a frequent speaker on the topics of mHealth and connected health, having recently spoken at Stanford University, Babson College, Suffolk University, the Healthcare World Congress, and the New England chapter of HIMSS. He is frequently quoted, and has appeared in articles and publications from the California Healthcare Foundation, ComputerWorld, and the Independent (UK).

Additionally, Rob oversees customer operations for Partners DiabetesConnect and Partners BloodPressureConnect, two Partners patient monitoring programs that commenced in 2008. Prior to joining the Center in 2008, Mr. Havasy spent nine years with Enterasys Networks/Siemens Enterprise Communications, most recently as the Manager of Global Service Operations, and he began his career as an Atomic Spectroscopist with Teledyne-Leeman Labs. Rob holds a Bachelor of Science degree in Environmental Science from Keene State College. Rob speaks frequently on patient facing healthcare technology matters.

Courtney Rees Lyles, PhD, Group Health Cooperative, Department of Health Services, University of Washington, Seattle.

Robert Jarrin is a Senior Director of Government Affairs for Qualcomm Incorporated. He is based in Washington, DC and represents Qualcomm on US domestic regulatory matters relating to wireless health and life sciences.

Jarrin's areas of responsibility include wireless health policy, FDA regulatory oversight of converged medical devices, healthcare legislative affairs, CMS telehealth reimbursement and the regulation of health information technology. Externally, Jarrin serves as Co-Chair of the US Policy Working Group for the Continua Health Alliance and sits on the Scientific Advisory Board of Medical Automation.

Prior to joining Qualcomm, Jarrin worked as a Manager of Strategic Partnerships for Ericsson Wireless Communications, served as a Law Clerk in the White House Office of Counsel to President Clinton and also served as a Law Clerk and subsequent Consultant in the US Department of Justice to Attorney General Janet Reno.

Jarrin holds a Bachelor of Arts degree in Government and Politics from the University of Maryland at College Park and a Juris Doctorate from Northeastern University School of Law.

Provider Panel

Julian Goldman, MD, (anesthesiologist), Partners Healthcare

Scott Evans, Intermountain Healthcare

Jo Carol Hiatt, MD, Kaiser Permanente

Sara Toscano, RN, BSN, Clinical Informatics Coordinator & Coordinator for IntelliVue Clinical Information Portfolio, VA Maryland Healthcare System, Veterans Health Administration

Julian Goldman, MD. Julian M. Goldman, MD is Medical Director of Biomedical Engineering for Partners HealthCare System, a principal anesthesiologist in the Massachusetts General Hospital "Operating Room of the Future", and Director of the Program on Medical Device Interoperability at MGH and CIMIT (Center for Integration of Medicine and Innovative Technology).

Dr. Goldman founded the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program in 2004 to promote innovation in patient safety and clinical care by leading the adoption of patient-centric medical device integration. The MD PnP program team was the recipient of the 2007 CIMIT Edward M Kennedy award for Healthcare Innovation.

Dr. Goldman performed anesthesiology residency and fellowship training at the University of Colorado. His research fellowship was in medical device informatics,

focusing on simulation and artificial intelligence applications for monitoring and real-time decision support. He departed Colorado in 1998 as a tenured associate professor to work as an executive of a medical device company. Dr. Goldman joined Harvard Medical School and the Department of Anesthesia, Critical Care, and Pain Medicine at the Massachusetts General Hospital in 2002, where he continues to practice clinical anesthesia.

Dr. Goldman serves on the NSF CISE Advisory Committee, and served as a Visiting Scholar in the FDA Medical Device Fellowship Program and as a member of the CDC BSC for the NCPHI. He currently serves in leadership positions in several medical device standardization organizations including Chair of ISO Technical Committee 121, Chair of the Use Case Working Group of the Continua Health Alliance, and User Vice Chair of ASTM Committee F29. Dr. Goldman is the recipient of the International Council on Systems Engineering 2010 Pioneer Award, American College of Clinical Engineering (ACCE) 2009 award for Professional Achievement in Technology, the 2009 AAMI Foundation/Institute for Technology in Health Care Clinical Application Award, and the University of Colorado Chancellor's "Bridge to the Future" award.

R. Scott Evans, MS, PhD, FACMI. R. Scott Evans is a Senior Medical Informaticist in the department of Medical Informatics at Intermountain Healthcare, a Professor in the Department of Biomedical Informatics and an adjunct Professor in the Department of Medicine, division of Infectious Diseases at the University of Utah, Salt Lake City, Utah. Dr. Evans received his BS degree in Zoology and MS degree in Microbiology/Parasitology from Brigham Young University. He received his PhD in Medical Biophysics & Computing from the University of Utah. He is a member of the American Medical Informatics Association and is a Fellow in the American College of Medical Informatics. He is on the Editorial Boards of the Journal of American Medical Informatics Association and the Annals of Pharmacotherapy and was on the Institute of Medicine's committee for the "Identification and Prevention of Medication Errors." He is currently Treasurer on the Executive Committee of the American Medical Informatics Association Board of Directors and Chair of the Scientific Program Committee for the AMIA 2011 annual meeting. In 1992 he won the "Best Paper Award" at the annual American Medical Informatics Association meeting. In 1993 he received the "Priscilla M. Mayden Award" for outstanding contribution in the field of Medical Informatics and in 1997 received the "Osler's Cloak" award for excellence in caring and curing from Intermountain Health Care. He received the "Distinguished Poster Award" in 2005 from the American Medical Informatics Association. In 2010, his paper "Enhanced Notification of Infusion Pump Programming Errors" was nominated for the Best Paper Award at the MedInfo international meeting in South Africa.

His major experience and interests have been in the design, development, and evaluation of computerized decision support tools for the selection and management of antiinfective agents, computer methods to identify and reduce adverse drug events, adverse medical device events and venous thrombolytic events, computerized methods to identify patients needing isolation, and computerized methods to identify and reduce hospital-acquired infections and report notifiable diseases. A number of these computerized tools are clinically operational at all 22 hospitals at Intermountain Healthcare. He has published over 100 articles, most on topics involving Medical Informatics, in peer reviewed journals from the Medical Informatics literature and a number of clinical journals including the New England Journal of Medicine, JAMA and CHEST.

JO CAROL HIATT, MD, MBA, FACS. Dr. Hiatt is Chair of the National Product Council for Kaiser Permanente, and also serves as Physician Market Leader for National Accounts. She is a partner and Assistant Medical Director, Business Management, in Southern California Permanente Medical Group (SCPMG). Dr. Hiatt chairs the SCAL Technology Deployment Strategy Team and Oversight Committee for Integrated Medical Imaging.

Dr. Hiatt joined Kaiser Permanente as a general surgeon at Panorama City in 1984, later serving as Chief of Surgery at that location and member of the SCPMG Board of Directors. Dr. Hiatt received her undergraduate degree from Stanford University and her medical degree from Duke University. She trained in general surgery at UCLA. In addition to her clinical degree, Dr. Hiatt received an M.B.A from UCLA's Anderson School of Management.

Sara L. Toscano is currently the IntelliVue Clinical Information Portfolio (ICIP) Coordinator for the VA Maryland Healthcare System. She graduated from Lenoir-Rhyne College with her BSN in 1990. She began her career with the VA in Asheville, North Carolina in May 1990 and transferred to the VAMHCS in August 1992. She is currently a Secretary for the Nursing Professional Standards Board. Ms. Toscano is an active member of Nursing Practice Committee, Policy and Procedure Committee and the VAMHCS Documentation subcommittee. Sara is also on the VHA Health Systems Committee Computer Information System Taskforce Interface Subcommittee and VHA Terminology Standardization Workgroup. She is currently on a workgroup, which includes representatives from VISN 20 & 23, developing the VA National Standard version of the Philips ICU CIS.

Interoperability & Data Integration

Dale Wiggins, Chief Technology Officer, Philips Healthcare

Charles Jaffe, HL7

Elliot B. Sloane, PhD, Drexel University, IHE

Charles Parisot, GE Healthcare IT

John Garguilo, NIST

Dale Wiggins is Vice President and Chief Technology Officer for Philips Healthcare Patient Care and Clinical Informatics business group. In this role, he leads the team that is focused on driving strategic technology plans across the businesses and oversees activities related to several principal healthcare industry themes including systems integration within the hospital enterprise architecture, clinical decision support, interoperability standards, and outcomes improvement studies and other clinical research.

Previously, Dale was Chief Architect for the global Patient Monitoring business. He joined Philips from Hewlett-Packard/Agilent Technologies where he held various management, architecture, and engineering positions in research and development. Dale holds BS and MS degrees in Computer and Systems Engineering.

Charles Jaffe, MD, PhD, As the Chief Executive Officer of HL7, Dr. Jaffe serves as the organization's global ambassador, fostering relationships with key industry stakeholders. A 37-year veteran of the healthcare IT industry, Dr. Jaffe was previously the Senior Global Strategist for the Digital Health Group at Intel Corporation, Vice President of Life Sciences at SAIC, and the Director of Medical Informatics at AstraZeneca Pharmaceuticals. He completed his medical training at Johns Hopkins and Duke Universities, and was a post-doctoral fellow at the National Institutes of Health and at Georgetown University. Formerly, he was President of InforMed, an informatics consultancy for research informatics. Over the course of his career, he has been the principal investigator for more than 200 clinical trials, and has served in various leadership roles in the American Medical Informatics Association. He has been a board member on leading organizations for information technology standards, and served as the chair of a national institutional review board. Most recently, he held an appointment in the Department of Engineering at Penn State University. Dr. Jaffe has been the contributing editor for several journals and has published on a range of subjects, including clinical management, informatics deployment, and healthcare policy.

Elliot B. Sloane, PhD, CCE, FHIMSS, Drexel University School of Biomedical Engineering, Health Systems Engineering Program Director and Professor of Health Systems Engineering, Drexel University School of Biomedical Engineering, Science and

Health Systems. The mission of Health Systems Engineering (HSE) is to leverage the data-informed healthcare environment of the 21st Century. HSE strives to improve personalized care and the underlying metrics of quality, outcomes, efficiency, cost-effectiveness, and satisfaction. HSE benefits are achieved in many ways, including: accelerating the translation of research into products for mobile, point-of-care, and highly patient-specific clinical diagnosis and treatment; facilitating innovative public-private partnerships to achieve sustainable healthcare business applications of the technologies necessary to achieve HSE's benefits for patients and society; fostering and accelerating the interoperability of technologies and information systems to improve real-time "in the moment of care" clinical decision support and activities; empowering patients so they can direct and manage their healthcare more effectively; enhancing the underlying System of Systems Engineering research to understand and manage the complex and interdependent information systems and devices needed for modern healthcare; informing patients, society, and policy makers with timely research about these technologies' benefits, interactions and trade-offs; empowering much more timely and effective population health planning and management for healthier living and active longevity; and educating a new generation of researchers, clinicians, engineers, and scientists to properly design and implement the appropriate healthcare tools and systems effectively. Lastly, HSE helps analyze, interpret, and operationalize the newly-integrated and interoperable Electronic Health Records and Health Information Exchanges data streams as well as the myriad new sources of personal health data that goes all the way from the molecular level to people's societal and environmental interactions.

Chalres Parisot, Manager, Architecture and Standards, GE Healthcare Milwaukee, Wisconsin, USA and Buc, France. Charles Parisot is with the Information Technologies business of GE Healthcare. He is in charge of standardization and IT architecture in the Enterprise Systems group where he coordinates overall GE Healthcare products implementation of health information exchange standards. He represents GE Healthcare in the EHR Vendor Association (EHRVA) where he has been chairing the Interoperability and Standards Working Group for the past three years.

Charles was elected in September 2005 to represent the vendor community on the ANSI Health Information Technology Standards Panel (HITSP) Board. Charles has extensive experience in standards development and their successful implementation since 1976, beginning with IT networking with the Open Systems Interconnection and TCP/IP standards initiative, as the corporate networking strategies leader at the Boeing Company (Seattle, WA). He has 17 years of experience in healthcare, and is recognized as one of the primary contributors to the definition of DICOM in the early 1990's. Charles is also actively engaged in HL7, especially with the EHR Technical Committee.

Charles has applied his extensive experience at ensuring successful standards implementation in large and complex multi-stakeholder industries through the launching of the Integrating the Healthcare Enterprise (IHE) initiative in the USA and later in Europe in 1997. IHE has overcome the barriers to effective implementation and use of interoperability standards in a number of healthcare domains, a result of his tireless contributions. Charles has been co-chair of the IHE IT Infrastructure Technical Committee for three years, where his major focus has been the development of cross-enterprise interoperability for EHRs in regional and national health information networks. He is presently co-chair of the IHE IT Infrastructure Planning Committee. He is also an active member of the HIMSS Interoperability Showcase Planning Committee and has been active in the national healthcare field for the past 17 years, gaining respect from several physician societies, industry associations and leading government health officials around the world.

The EHR Vendor Association, with its current membership of 43 EHR vendors active in the US market selected Charles to be its representative on the Healthcare IT Standards Panel (HITSP) in 2005. Through his many years of experience in contributing to a user driven harmonization and implementation of standards, Charles has earned the trust of many healthcare user communities in the USA and abroad to effectively achieve the rapid adoption of interoperability standards using a collaborative approach. As a HITSP Board member since the end of 2005, he has contributed in stressing the role of the vendor community in supporting HITSP success, the need for engaging all stakeholders, the imperative for HITSP review processes to offer reasonable public comment periods, as well as valuing the contributions of the volunteer subject matter experts. As Consumer Empowerment Technical Committee co-chair, Charles has demonstrated a commitment to the challenges of interoperability in a practical manner. If chosen to continue to serve on the HITSP Board, Charles is committed to serve in a respectful manner and use his global interoperability knowledge, collaboration and consensus building skills to advance the standards development and practical implementation of standards that are delivering better care today.

John J. Garguilo, Computer Scientist, Software and Systems Division, Information Technology Laboratory, National Institute of Standards and Technology, Department of Commerce.

Data Accuracy & Integrity

Tim Escher, Epic

John Zaleski, Nuvon

Marlene Haddad, Office of Health Informatics Management, Veterans Health Administration

Tim Escher, Epic. Tim Escher is currently Division Manager for Epic's Database and Reporting/Analytics group. He has been with Epic for 21 years and has had several roles in R&D and software development and management, including system architecture, scalability, data interfaces, and application development.

He holds a BS degree in Electrical and Computer Engineering from University of Wisconsin - Madison.

John Zaleski, PhD, CPHIMS is Vice President of Clinical Applications and CTO at Nuvon. A renowned leader in the biomedical informatics and health care technology industries, Dr. Zaleski brings more than 23 years of experience in researching and bringing to market devices and products to improve health care. Dr. Zaleski has a particular expertise in designing, developing, and implementing clinical and non-clinical point of care applications for hospital enterprises.

Dr. Zaleski holds four issued patents related to medical device interoperability, as well as more than 50 patent disclosures applied for and/or pending. He is the author of numerous articles on information technology and medical devices, and authored two books on biomedical device interoperability, including the first book published on integrating medical device data into electronic health records. The most recent book is on the use of biomedical device data to assist in clinical decision making at the point of care.

Dr. Zaleski holds a PhD in Biomedical Systems Engineering from the University of Pennsylvania. He earned his Master of Science and Bachelor of Science degrees in Aerospace Engineering from Boston University. He is certified through the Health Information Management Systems Society (CPHIMS). He has a Quality and Regulatory Training Certificate and a Clinical Workflow Training Certification from Siemens Medical Solutions USA. He also holds Data Warehousing and Design Certification from the Data Warehousing Institute. Additionally, Dr. Zaleski is a senior member of the Institute of Electrical and Electronics Engineers (IEEE) and International Council on Systems Engineering (INCOSE).

Prior to joining Nuvon, Dr. Zaleski most recently served as senior director and research department head of Biomedical Informatics for Philips Research North America. In this role, he oversaw more than 20 researchers and clinicians to manage the company's global research portfolio in biomedical informatics. He also had responsibility for a \$6+ million project portfolio and departmental budget focused primarily upon acute care patient monitoring informatics, oncology informatics, imaging informatics and women's health, and genomics and biomarkers.

Previously, at Siemens Health Services USA, where he held several titles over an eight year period, Dr. Zaleski brought medical device information technology products from concept to general commercial availability in the medical/surgical space. He also developed and managed new product lines from concept through FDA approval and market realization, including Siemens Health Services' first Class II medical device for bedside vitals collection in medical surgical wards. Additionally, he managed the critical care product line with budgets and product sales of more than \$10 million. While with Siemens, he was one of two employees named "Principal Expert" out of an organization of more than 3,000 employees, and was awarded "Innovator of the Year" three times in the seven years the program existed.

Marlene Haddad joined VHA DQ as a Clinical Quality Specialist. She has been with the VA for over 20 years where she worked as a Staff Nurse, Quality Manager, Utilization Review Manager, and most recently in a clinical informatics role within Health Information Management. She has worked with partners such as HL7, HITSP, DoD and others on the use of current standards in EHR-S models. Marlene graduated from St. Louis University where she obtained a nursing degree, as well as masters' degrees in epidemiology and biostatistics.

KAREN R. THOMAS, President of Advanced TeleHealth Solutions, a telehealth company, and Oxford HealthCare, a home care agency, providing services to over 5,000 patients daily. Ms. Thomas holds a Bachelors degree in Accounting; a Masters degree in Business Administration; and is a Certified Management Accountant. She is a Board member of the National Association for Home Care, an Ex Officio member of the advisory board of Home Care Technology Association of America (HCTAA), a member of the Private Duty Home Care Association, and a former board member of the American Diabetes Association and Alzheimer's Association. Ms. Thomas is a speaker for Missouri State University's Health Care Administration Masters program and a contributing author to "Home Telehealth: Connecting Care Within the Community" published by Royal Society of Medicine Press Ltd. Ms. Thomas began a successful telehealth program in 2002 generating documented savings in the 50% range for hospital/emergency room visits and 80% cost savings for hospitalization days on a

pre/post comparison. She has been a speaker for numerous webinars and conferences providing education as to the benefits of home telemonitoring: generating enhanced clinical outcomes, patient engagement and coordination of care. Ms. Thomas has been a patient advocate co-hosting a radio show for three years to educate the public on the availability, accessibility and desirability of home health and telemonitoring.

Device Security & Data Security Panel

Patrick Heim, Kaiser Permanente, Healthcare Security Alliance

Todd Cooper, ISO Technical Committee 215

Richard Eaton, MITA

Rik Primo, Siemens

Patrick Heim, CISO, Kaiser Permanente, Patrick Heim is responsible for the shared security services, policies, strategy and leadership that protect the confidentiality of Kaiser Permanente's members, patients, and workforce. His mission is to develop innovative and effective capabilities that balance risk with the need to provide care.

Prior to joining Kaiser Permanente, Heim served as CISO officer at McKesson. Prior to McKesson, he led the technical security consulting practice at Ernst & Young for the Pacific Northwest region and has also held leadership roles at two information security technology startup companies.

Heim has a diverse background and views the problems of information security from the angles of a system administrator, auditor, security consultant, security product vendor, and chief information security officer. Each of these experiences has provided him with valuable insight and a different perspective into the unique challenges that come with information security.

Heim earned a bachelor of science degree in business marketing from Indiana University. His postgraduate education includes an international MBA in finance from the University of South Carolina and the Vienna University of Economics and Business Administration (Wirtschaftsuniversität Wien).

Todd Cooper is co-convenor of the joint ISO and IEC working group that is developing IEC 80001. He currently serves as president of Breakthrough Solutions Foundry. He is also cochair of the Integrating the Healthcare Enterprise (IHE) board, and cochair of the technical committee for the Patient Care Devices domain of IHE. He holds leadership roles in numerous other informatics standards groups including ISO, HL7, IEEE, and HITSP.

Richard M. Eaton is the Industry Manager at the Medical Imaging & Technology Alliance (MITA) with responsibility for the Medical Imaging Informatics Section. MITA is the medical division of the National Electrical Manufacturers Association (NEMA) with headquarters in Arlington, VA. MITA is the collective voice of medical imaging manufacturers, innovators and product developers, and represents manufacturers of medical imaging and radiation therapy equipment, and radiopharmaceuticals.

In addition to his responsibilities in the Medical Imaging Informatics Section, Mr. Eaton is also the Industry Manager for the MITA Molecular Imaging Section and MITA Ultrasound Section. These Sections address technical and regulatory issues which pertain to nuclear medicine imaging products such as SPECT and PET, and diagnostic ultrasound equipment, respectively. He also serves as the Technical Advisory Group (TAG) Administrator for two International Electrotechnical Commission (IEC) technical committees, IEC SC62C and IEC TC87, which develop international standards for electromedical equipment.

Mr. Eaton holds a bachelors degree in political science from The Johns Hopkins University, and a J.D. degree from Rutgers University.

Henri “Rik” Primo is Director of Strategic Relationships for the Image and Knowledge Management Division, Siemens Medical Solutions USA, Inc. Primo’s career with Siemens began in 1998 as a Marketing Manager in the Health Services Division. His general expertise with digital imaging, PACS and healthcare information systems proved invaluable in this position, which included the marketing of enterprise-wide IT applications to healthcare.

Prior to his career in the RIS/PACS industry, Mr. Primo managed the Biomedical Engineering and Electronic Data Processing Departments at the 500-bed Holy Family Hospital in Ghent, Belgium. Mr. Primo assumed the function of Secretary and Director at the board of The Society for Imaging Informatics in Medicine (SIIM) for six years. He is currently the Chairman of the Medical Imaging Informatics section of the Medical Imaging & Technology Alliance (MITA), the medical division of the National Electrical Manufacturers Association (NEMA). He serves also on the MITA Board of Directors.

A native of Ghent, Belgium, Mr. Primo holds a degree in electrical engineering from the city’s Institute of Technology.

Unique Device Identification

Jay Crowley, Food and Drug Administration, HHS

Terrie Reed, Food and Drug Administration, HHS

Betsy Humphreys, National Library of Medicine

Janet Trunzo, GMDN Agency

Jim Keller, ECRI

Jay Crowley, Senior Advisor for Patient Safety, Food and Drug Administration, HHS.

Terrie Reed, MS Industrial Engineering is Associate Director of Informatics, at the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Office of Surveillance and Biometrics (OSB). Ms. Reed leads an Informatics staff on projects related to the incorporation of data exchange and vocabulary standards into FDA data submissions and leads the internal FDA implementation efforts for integration of UDI into FDA regulatory processes. She has led several information management initiatives including a joint project between the National Cancer Institute (NCI) and FDA CDRH focused on improving and simplifying the device and patient problem codes used to code medical device adverse event reports. In addition she is the CDRH representative to FDA enterprise-wide initiatives including the FDA Data Standards Council and the FDA Vocabulary Work Group. Prior to working in government, she worked for 13 years at a healthcare facility in Indianapolis in various positions as a process engineer, quality analyst, and medical information specialist.

Betsy L. Humphreys, Deputy Director, National Library of Medicine.

Janet Trunzo, Executive Vice President for Technology and Regulatory Affairs, Nexon and AdvaMed; representing the Global Harmonization Task Force.

James Keller, Jr., is Vice President, Health Technology Evaluation and Safety. He directs ECRI Institute's internationally recognized medical device evaluation program, which has been referred to by the New York Times as the "country's most respected laboratory for testing of medical products." He is responsible for numerous ECRI Institute print and Web-based publications and databases, consultation services, educational programs, software tools, and instrument design services. He is a recognized expert and frequently invited speaker on a wide range of medical-technology-related topics including patient safety, strategic planning, and forecasting.

Mr. Keller is responsible for all operations, sales and marketing support, and product and business development for the Health Devices program. His staff consists of approximately 30 scientists, engineers, writers, editors, and product managers. The

products and services of the Health Devices program are relied on by thousands of healthcare organizations throughout the world for objective advice on the safe and cost-effective selection, use, and management of medical devices. Mr. Keller is also responsible for several other ECRI Institute products and services, including the Health Devices Inspection and Preventive Maintenance System; Health Devices Alerts; ECRI Institute Alerts Tracker; the ISO 9000 Quality System for Medical Equipment Service; a quarterly series of interactive telephone seminars; and the International Medical Device Problem Reporting System.

Mr. Keller also directs various medical-technology-related product development and consultation services. These include on-site technology planning studies, development of technical specifications for medical device contracts, analyses of manufacturer proposals for medical device contract bids, and accident investigations in support of ECRI Institute's Health Systems Group and Accident and Forensic Investigation Group; third-party review of U.S. Food and Drug Administration 510(k) medical device clearances; customized device testing and technology assessment analyses; software development; and instrument design.

Mr. Keller has been with ECRI Institute since 1984. He has a bachelor of science degree in zoology from the University of Massachusetts and a master of science degree in biological engineering from the University of Connecticut. In 1993, he received AAMI's Biomedical Engineering Achievement Award, which recognizes individual excellence and achievement in the field of biomedical engineering.