Pediatric Device Consortia Grant Program

FDA OOPD Pediatric Medical Devices Workshop

THE GREAT ROOM
WHITE OAK CAMPUS

10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Speakers

Rixys Alfonso is Director of Corporate Relations for the Dan Marino Foundation, a non-profit 501c3 organization for children and young adults with autism and special needs. She currently chairs the Communications Committee and serves on the Self-Advocacy Leadership Task Force and the Public Policy & Advocacy Committee for the State of Florida, writes a charity column in AroundTown Magazine, and advocates for the Titanium Rib Program. Ms. Alfonso previously worked as a publicist and was Vice President of Development for Here's Help, a non-profit drug and alcohol rehabilitation facility for inner city youth. She volunteers with the FBI's Citizens' Academy; is a Board Member of the Titanium Rib Implant Foundation; is a Committee member for Comcast Cares; and serves on the Advisory Council for the Mailman Center for Child Development. Ms. Alfonso was named a 2012 Hispanic Woman of Distinction by Latina Style Magazine; was appointed to the Florida Developmental Disabilities Council; received community service awards from the Miami Dade County Board of Commissioners, Here's Help, and Paradise Christian School; and was twice honored as one of the 100 Outstanding Women in Broward County. She was featured in a 2007 Learning Channel documentary about efforts to enroll her son in the Titanium Rib Implant Clinical Trial.

Edward E. Berger, Ph.D., is Principal and Founder of Larchmont Strategic Advisors, where he focuses on the intersection of public policy and corporate strategy development. He also serves as a Director of Atanse, Inc., a developer of innovative neurosurgical instruments, and as a member of Mass Medical Angels. Previously, Dr. Berger served on the senior management teams of Fresenius Medical Care, Thermo Cardiosystems, and ABIOMED in the areas of reimbursement, corporate compliance, continuous quality improvement programs, and strategically sensitive corporate communications. He has worked to provide regulatory and reimbursement policy analysis, planning, and strategy for companies in mechanical circulatory support, cardiology, orthopedics, neural monitoring and neuromodulation, gastrointestinal surgery, pulmonary medicine, nuclear medicine, diagnostic imaging, clinical laboratory testing, and personalized medicine. He is past president of the Medical Development Group, individuals professionally committed to the medical device and related life sciences business sectors.

Eric Chen, M.S., is the Director of the Humanitarian Use Devices Designation Program in the Office of Orphan Products Development within FDA. Previously he held other positions at the FDA. Mr. Chen has written more than 20 publications, given numerous presentations regarding the regulatory process for mechanical circulatory support devices, is involved in several professional memberships, and has received many awards and recognitions. He received a bachelor's degree in biomedical engineering from Johns Hopkins University and a master's degree in bioengineering from the University of Pittsburgh.

Judy Cope, M.D., **M.P.H.**, is a Pediatric Medical Officer and Epidemiologist with the Office of Pediatric Therapeutics (OPT), within the FDA's Office of Commissioner. Previously she headed the OPT Safety Team, focusing on pediatric safety issues for FDA-regulated products, and also worked with the Center of Devices and Radiological Health on pediatric device issues. Dr. Cope has more than 20 years' experience in clinical pediatrics and adolescent medicine. She has worked at the Georgetown University Department of Pediatrics, George Washington University HMO Pediatrics, George Washington University Student Health Clinic, and in private practice in general pediatrics and adolescent medicine. Her research interests include pediatric safety and cancer epidemiology. Dr. Cope received her doctorate from the University of Missouri Medical School. She completed a 3-year pediatric residency at Children's National Medical Center in Washington, D.C., and an adolescent medicine fellowship at the University of Maryland-Baltimore. She received a Master of Public Health degree in epidemiology and biostatistics from George Washington University.

Nick Deeter, M.B.A., B.S., is Chairman of the Board and Managing Director at OrthoPediatrics, where he develops and commercializes medical innovations, orthopedic devices, and implants for the global health care market, focusing solely on pediatric orthopedics. Mr. Deeter has more than 30 years of business leadership and health care industry experience. His orthopedic and medical device career began at Zimmer, Inc. and includes more than two decades of executive leadership positions for other medical organizations. Before forming OrthoPediatrics, he spent 7 years with DePuy Orthopaedics, a Johnson & Johnson company, where he was responsible for health care compliance administration, medical affairs, and Orthogenesis (custom devices), managing surgeon relationships, product engineering, production, and marketing of custom implants and limb-preservation products. Mr. Deeter also was founder, Chairman, President, and CEO of ViAtro, Corp., a medical device company specializing in infection control products; Vice President of University Technology Inc., at Case Western Reserve University, managing the technology transfer process of more than $100 million dollars per year of medical research; and President of Medical Ventures Ltd., a venture capital firm that initially funded STERIS Corp. Additionally, he managed the

orthopedic and respiratory products at Invacare Corporation. Mr. Deeter currently serves on the Executive Committee and Board of Trustees of the Corporate Partnership for Economic Growth in Indiana. He earned a Master of Business Administration from Case Western Reserve University and a Bachelor of Science from Purdue University.

Brian Duncan, M.D., is a Venture Partner at Arboretum Ventures in Cleveland and a Vice President of Business Development for BioEnterprise, a Cleveland-based biomedical technology incubator. He is responsible for monitoring FDA regulatory policy changes to ensure that Arboretum portfolio companies stay apprised of the latest guidelines. He was the Medical Director for the Cleveland Clinic's Emerging Businesses group for 2 years before joining Arboretum. Dr. Duncan has more than 13 years of clinical experience as a cardiac surgeon. After completing training at the Massachusetts General Hospital, he was a staff surgeon at Children's Hospital Boston, Seattle Children's Hospital, and the Cleveland Clinic. He is experienced in developing novel medical devices and was the principal investigator for a new pediatric ventricular assist device. Dr. Duncan also serves on the Board of Directors at BioOhio, a non-profit organization focused on accelerating bioscience industry growth in Ohio, and is a board observer for Accord Biomaterials. He earned his undergraduate and medical degrees from Indiana University and an Executive MBA from the Ross School of Business at the University of Michigan.

Jacqueline Francis, M.D., **M.P.H.**, is a pediatrician and medical officer in the FDA's Office of Device Evaluation in the Division of Surgical, Orthopedic, and Restorative Devices (DSORD) in the Plastic and Reconstructive Surgery Branch. She also provides pediatric device consultation to other surgical branches in DSORD, and is on detail in the Office of the Center Director serving as the Acting Chief Pediatric Medical Officer. Previously, Dr. Francis worked as a clinical consultant in the microbiology branch of the Office of In-Vitro Diagnostic Devices. Dr. Francis graduated from Cornell University and received her medical degree from Temple University School of Medicine. She performed her internship, residency, and fellowship in Clinical Pharmacology at Georgetown University. She completed her training at Johns Hopkins where she received her Master of Public Health for a Preventive Medicine residency.

Lynn Henley, M.S., M.B.A., is a biologist in the FDA's Investigational Device Exemption and Humanitarian Device Exemption Programs office within the Office of Device Evaluation at the Center for Devices and Radiological Health. Ms. Henley also has FDA experience in the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Office of the Commissioner. She holds a bachelor's degree in biology from the University of Maryland and master's degrees in biotechnology and business from Johns Hopkins University.

Francesca Joseph, M.D. is a medical officer in the Office of Orphan Products Development (OOPD) at the U.S. Food & Drug Administration (FDA) where she is heavily involved in the Humanitarian Use Device (HUD) program, while providing general clinical expertise to various other aspects of the OOPD mission. Previously, she was a Commissioner's Fellow in the Center for Devices and Radiological Health (CDRH) at FDA where she participated in initiatives to advance the development of pediatric cardiovascular devices. She received a B.A. in biology from Bucknell University, her M.D. from SUNY Stony Brook School of Medicine, and completed residency training in pediatrics at Children's National Medical Center where she remains clinically active.

David Ku, M.D., **Ph.D.**, is the Lawrence P. Huang Chair Professor of Engineering Entrepreneurship, Regents' Professor of Mechanical Engineering, and Director of the Center for Entrepreneurship's Program for Engineering Entrepreneurship at Georgia Institute of Technology. He teaches entrepreneurship and product development to bring technological solutions to the bedside. His areas of research include cardiovascular pathophysiology, unsteady 3-dimensional fluid mechanics, medical implants, and commercialization of university research. Dr. Ku is interested in commercialization of novel medical devices through start-up companies, and efficient methods of product development. He has been involved with four start-ups and successfully raised over $20 million in financing. His work is supported by the National Institutes of Health, the National Science Foundation, the American Heart Association, the Mason Foundation, and the Whitaker Foundation. His collaborative work is performed with Emory University, Worcester Polytechnic Institute, Texas A&M, Nagano University, and the Swiss Federal Institute of Technology in Lausanne, Switzerland. He has published more than 80 papers and given more than 200 conference presentations. Dr. Ku received his medical degree from Emory University School of Medicine, a doctoral degree in Biofluid Dynamics from Georgia Institute of Technology, a master's degree in Aerospace Engineering from Georgia Institute of Technology, and a bachelor's degree in Engineering and Applied Sciences from Harvard University.

Donald Lombardi, M.S., is President and CEO of the Institute for Pediatric Innovation, a non-profit organization he founded to address unmet needs for pediatric medical devices and drugs. The Institute works with a consortium of pediatric hospitals to develop medical devices aimed at measurable impact on key patient care and performance-improvement objectives, and is partnering with major pharmaceutical companies and other stakeholders to organize a global center of excellence for pediatric therapeutics. Two devices and one drug developed by the Institute have been licensed to companies for anticipated market introduction in 2013-2014. Mr. Lombardi consults for government entities, healthcare systems, universities, and research and medical institutions world-wide on strategy for translating intellectual capital into commercial opportunities. Previously, he founded both non-profit and for-profit organizations, and was Chief Intellectual Property Officer at Children's Hospital Boston for 15 years, where he founded and led a technology transfer organization. He has published several articles on opportunities and challenges in pediatric product innovation. Mr. Lombardi earned a master's degree in Life Sciences from MIT and a bachelor's degree in Biophysics from Amherst College.

Scott Merz, Ph.D., is founder of MC3, Inc., which identifies promising, early-stage device technologies and advances them through product development, pilot production, and business development. Dr. Merz has startup experience with pediatric device development, identifying the challenges of early fundraising for projects with relatively small market sizes, and determining where public funding can be used effectively to enable pediatric solutions. A number of MC3's projects have involved leveraging public funding to advance and de-risk pediatric device concepts to attract venture capital and strategic partner funding for completion of development and marketing work. Dr. Merz has been involved in many aspects of the early development in pediatric devices; he holds a number of device patents, and has raised venture funding for startups, been involved with regulatory submissions and clinical trials, and worked with major medical device companies in strategic partnerships. He earned a Ph.D. in biomedical engineering from the University of Michigan and a bachelor's degree in electrical/biomedical engineering from Duke University.

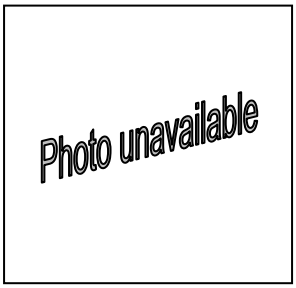
Tim Moran, M.B.A., B.S., is the founder of PediaWorks, a 501.c.3 non-profit that improves pediatric health through the commercialization of novel medical devices. He is also the founder and CEO of PediaCath, a joint venture with Medikit, Ltd. that recently launched the first FDA-cleared angiography catheters and introducers for pediatric use. Previously, Mr. Moran was the founder and president of CSF Therapeutics, a venture-backed developer of devices to treat neurodegenerative diseases; he managed the formation and initial financing of Intelect Medical (acquired by Boston Scientific) while at Innovations, Cleveland Clinic's corporate venturing arm; founded an IT services firm in Latin America; and served as a strategy consultant for IBM Global Services (PriceWaterhouseCoopers) in the United States and Europe. He began his career in sales and product development at 3M. He is a German Marshall Fellow, and an inventor or co-inventor on three patents. Mr. Moran received a master of business administration from Northwestern University (Kellogg), and a bachelor's degree in finance from Miami University.

Andre A Muelenaer, Jr., M.D., is President and Chief Medical Officer of the Pediatric Medical Device Institute, a non-profit organization that facilitates the transition from pediatric medical needs to clinically beneficial tools. He also is a section chief, pediatric pulmonology and allergy, at the Carilion Clinic Chidren's Hospital. Dr. Muelenaer's has 36 years of experience in medicine, including 27 years of active and reserve duty in the Army Medical Corps. He holds academic appointments at the Virginia Tech Carilion School of Medicine, Virginia Tech-Wake Forest University School of Biomedical Engineering and Science, and the University of Virginia. He maintains a telemedical practice in Raleigh, North Carolina, and serves as part-time medical director for several biotechnology companies in Virginia. He has served on the board of directors of several non-profit medical advocacy and service organizations. Dr. Muelenaer is board certified in pediatrics and pediatric pulmonology. His medical degree was completed at Eastern Virginia Medical School; he performed his pediatric internship and residency at William Beaumont Army Medical Center, and his pediatric pulmonary fellowship at the University of North Carolina, Chapel Hill. He earned a bachelor's degree in biology and a master's degree in zoology at Virginia Tech.

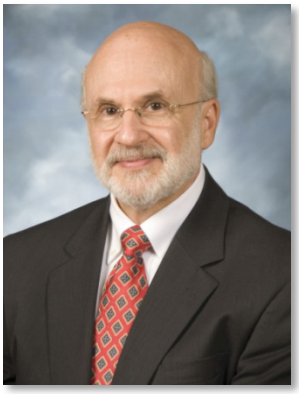
Gayatri R. Rao, M.D., J.D., Director for the Office of Orphan Products Development (OOPD) received her M.D. from the University of Medicine & Dentistry of New Jersey - New Jersey Medical School. Upon graduation from medical school, she went on to earn a joint J.D. from the University of Pennsylvania Law School, where she concentrated on healthcare and FDA related issues, and a masters in bioethics from the University of Pennsylvania School of Medicine. Following law school, she worked for an international law firm, in Washington, D.C., focusing primarily on food and drug law and other healthcare related matters, including matters related to orphan products. She then joined the FDA's Office of the Chief Counsel where she provided advice on a wide range of issues related to medical devices, combination products, clinical trials, and human subject protection. She has brought her unique medical, legal/regulatory, and bioethical background to help move the OOPD rare disease mission forward.

Richard E. Ringel, M.D., is Associate Professor of Pediatrics, Director of Pediatric and Congenital Heart Disease Catheterization, and a practicing interventional pediatric cardiologist at Johns Hopkins Heart and Vascular Institute. He has served for many years on congenital heart disease advisory committees for the American Heart Association and the American College of Cardiology. Since 1997, he has been a consultant to the FDA's Center for Devices and Radiological Health, performing expert reviews of Premarket Approval applications for congenital heart disease-related devices. Dr. Ringel also has served on multiple FDA expert panels. He is a Sponsor and Principal Investigator for the multicenter Coarctation of the Aorta Stent Trial (COAST), which was designed to study the bare metal stent. In 2007 he received an Investigational Device Exemption (IDE) for the NuMED bare and covered Cheatham Platinum Stent (G060057); in 2010 work began on the COAST II multicenter trial of the Covered CP stent for prevention and treatment of aortic wall injury associated with coarctation of the aorta. Dr. Ringel has submitted a request for an IDE to study the NuMED Covered CP stent to repair tears occurring during balloon dilation of the right ventricular outflow tract in preparation for implantation of transcatheter pulmonary valves; the target start of the Pulmonary Artery Repair with Covered Stents trial is the fourth quarter of 2012. Dr. Ringel is certified in Pediatrics and Pediatric Cardiology. He received his training at Albert Einstein College of Medicine of Yeshiva University and performed his residency and fellowship at the University of Maryland Medical System.

Schuyler Ritter, M.B.A., is Senior Vice President of Business Development at Beaufort, LLC, a company he co-founded and helps direct. He has worked in the healthcare industry for 35 years. Previously, Mr. Ritter was Vice President of Marketing and Sales at Bio-Reg, a medical device and in-vitro diagnostic regulatory consulting and contract research organization; President of Vangard Laboratories, a generic, unit-dose packaging pharmaceutical company servicing the hospital and long-term care market; Cardiovascular Vice President and Account Supervisor for Klemtner Advertising, the health care division of SAATCHI & SAATCHI; In-Line Product Manager, New Product Development Manager, and Cardiovascular Group Product Manager at Boehringer Ingelheim Pharmaceuticals Inc., and held a succession of positions at Merck, Sharp & Dohme Pharmaceutical, Inc. Mr. Ritter earned his master of business administration degree from the University of Georgia and his bachelor of science degree in marketing management from Virginia Tech.



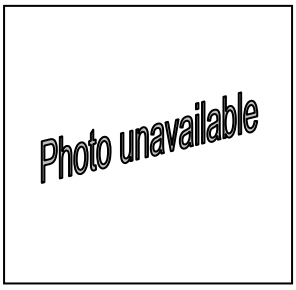
Marjorie Shulman, M.B.A., is the Director of the FDA's Premarket Notification (510(k)) Program in the Office of Device Evaluation, Center for Devices and Radiological Heath (CDRH). She is also the Reclassification/Classification Coordinator for CDRH. Ms. Shulman has been with CDRH for 28 years and previously was on the Premarket Approval staff, drafted guidance documents and regulations regarding the 510(k) program, trained staff, and assisted in the implementation of the Medical Device User Fee Modernization Act (MDUFMA), FDA Modernization Act (FDAMA), and the Food and Drug Administration Safety and Innovation Act (FDASIA). Ms. Shulman has been on numerous policy-setting groups within the FDA, including the 510(k) Working Group to evaluate the 510(k) program and explore actions CDRH could take to enhance 510(k) decision making. Ms. Shulman received her undergraduate degree from the University of Maryland, University College, and her master of business administration from Hood College.



Stephen P. Spielberg, **M.D.**, **Ph.D.**, is Deputy Commissioner for Medical Products and Tobacco of the FDA. Previously, Dr. Spielberg was the Marion Merrell Dow Chair in Pediatric Pharmacogenomics, and Director of the Center for Personalized Medicine and Therapeutic Innovation at Children's Mercy Hospital, Kansas City, MO.; Principal Investigator for the Institute for Pediatric Innovation; Dean of Dartmouth Medical School and Vice President for Health Affairs at Dartmouth College; chair of the PhRMA Pediatric Task Force; Rapporteur for the Pediatric International Conference on Harmonisation Initiative (ICH E-11); Vice President for Pediatric Drug Development at Johnson & Johnson; Executive Director, Exploratory Biochemical Toxicology and Clinical and Regulatory Development at Merck Research Laboratories; Professor of Pediatrics and Pharmacology, Director of the Division of Clinical Pharmacology and Toxicology, and Director of the Centre for Drug Safety Research at the University of Toronto, Hospital for Sick Children; and Assistant

Professor of Pediatrics and Pharmacology at Johns Hopkins University School of Medicine. He has served as Associate Editor of *Drug Metabolism and Disposition*; on editorial boards of multiple pediatric and pharmacology journals; on the Board of Directors of the Foundation for the National Institutes of Health, the Science Board Advisory Committee for the FDA, and the Executive Board of the Observational Medical Outcomes Partnership; and was President of the American Society for Clinical Pharmacology and Therapeutics. His research interests include mechanisms of idiosyncratic adverse drug reactions, human pharmacogenetics and personalized medicine, and pediatric clinical pharmacology. He has received multiple awards and published over 130 papers. Dr. Spielberg received a medical degree and doctorate in pharmacology from the University of Chicago; completed a pediatric internship and residency at Children's Hospital, Boston; and a post-doctoral fellowship in human biochemical genetics at the National Institute of Child Health and Human Development. He earned a bachelor of arts degree in biology from Princeton University.

Linda Ulrich, M.D., is a pediatrician working in the FDA's Office of Orphan Products Development (OOPD). She has been the director of the FDA's Pediatric Device Consortia Grant Program since its inception in 2009. She holds the rank of Captain in the United States Public Health Service. Before coming to OOPD, Dr. Ulrich served as a medical officer in FDA's Office of Generic Drugs, and served 7 years as a full-time general pediatrician in the U.S. Navy. She completed her internship and residency at Portsmouth Naval Medical Center, and received her medical degree from the Uniformed Services University in Bethesda, Maryland.



CDR Nicole L. Wolanski, B.S., is the Director of the Premarket Approval (PMA) staff in the FDA's Office of Device Evaluation (ODE), Center for Devices and Radiological Health. The PMA staff oversees incoming and outgoing PMA documents; ensures that PMA decisions are complete, scientifically sound, and regulatorily correct; and updates PMA policies, letters, and guidance documents. Previously, CDR Wolanski spent a year as the Acting Deputy Director of the Division of Reproductive, Gastroenterology, Renal and Urology Devices in ODE and 2 years as Chief of the Cardiovascular and Neurological Devices Branch in the Office of Compliance. She was also a PMA staff member and reviewer in ODE. CDR Wolanski received her bachelor's degree in biomedical engineering from Catholic University of America in Washington, DC.