Speaker and Panelist Biographies

Steve Anderson	*Pediatric Working Group, AdvaMed and CEO, Preceptis Medical*	Steve Anderson is the CEO of Preceptis Medical, Inc, a device manufacturer in the ENT space. Preceptis has developed the Hummingbird TTS which enables ear tube surgery to be performed in children without the risk of general anesthesia or the costs associated with an operating room. Prior to this position, he was the President of Acorn Cardiovascular, Inc., a device manufacturer developing therapies for the treatment of systolic heart failure. Mr. Anderson has 30+ years of experience in the medical device industry, starting with Medtronic and St. Jude Medical and also including senior management positions at TÜV Product Service, St. Croix Medical. Besides his executive expertise, his specific core competencies include regulatory, clinical, reimbursement, and compliance. Mr. Anderson has a BS in Materials Engineering and an MS in Biomedical Engineering from the University of Minnesota. He was an Adjunct Professor at the University of St. Thomas Graduate School, has served on multiple boards for medical device companies (both public and private), and has authored numerous publications on medical device regulation and reimbursement (both US and worldwide).
Leonardo Angelone	*Research Biomedical Engineer, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA*	Dr. Angelone is a Research Biomedical Engineer at the Office of Science and Engineering Laboratories, Center of Devices and Radiological Health, U.S. FDA. Dr. Angelone leads a Research program that focuses on assessment of energy deposition and heating induced in the human body by medical devices using electromagnetic energy. The investigation is based on a combination of anatomically precise computational models and experimental measurements applied to several areas of clinical significance. The results of the projects have been presented in over 100 peer-reviewed journal articles and conference proceedings, and publicly available software. Dr. Angelone has been leading several projects with both internal and external support and is currently collaborating with several groups both within the FDA and worldwide at leading academic research institutes and industry organizations. He has also served as subject matter expert for the FDA CDRH in over 300 pre- and post-market scientific reviews in the area of Medical Imaging and MR Compatibility. Dr. Angelone completed a Laurea in Electronic Engineering (University “La Sapienza”, Rome, Italy), a Ph.D. in Biomedical Engineering (Tufts University, Medford, MA), and a Research Fellowship at the A. Martinos Center for Biomedical Imaging, Department of Radiology of the Massachusetts General Hospital, Harvard Medical School. Prior to joining the FDA, Dr. Angelone has been a consultant with the Research and Development Department in the Surgical Products Division of Hologic Inc.

Tim Baldwin	*Deputy Chief, Advanced Technologies and Surgery Branch, National Heart, Lung, and Blood Institute*	Dr. Baldwin is the Deputy Chief of the Advanced Technologies and Surgery Branch in the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute (NHLBI). He also serves as a Biomedical Engineer and Program Director within the branch. Dr. Baldwin is currently participating in a part-time detail as a reviewer at FDA in the Office of Device Evaluation in the Division of Cardiovascular Devices. He received his B.S. degree in Mechanical Engineering from Virginia Tech in 1985 and his M.S. and Ph.D. degrees in Bioengineering from Penn State University in 1987 and 1990, respectively. His expertise is in the fields of bioengineering, circulatory assist devices, modeling of biological systems, diagnostic instrumentation, and biomedical sensing devices. The focus of Dr. Baldwin's graduate research was the relationship between the fluid mechanics within artificial heart ventricles and thrombosis and blood damage. This developed into an interest in prosthetic heart valves and led to a position at Carbomedics, Inc., a leading prosthetic heart valve company in the 1990's and early 2000's. While working there from 1991 to 2002, he established and directed a state-of-the-art laboratory to test and evaluate an array of prosthetic heart valves developed by the company. Since joining the NHLBI in December 2002, Dr. Baldwin has managed and fostered a portfolio of grants and contracts to develop and advance the use of various types of cardiovascular devices, diagnostic and surgical tools and technologies, and related computational techniques. While at NHLBI, he served as the project officer for the NHLBI Pediatric Circulatory Support Contract Program and has been involved in development and ongoing activity of the NHLBI-funded Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). He currently serves as the project officer for the NHLBI-sponsored PumpKIN (Pumps for Kids, Infants, and Neonates) Program and the REVIVAL (Registry Evaluation of Vital Information for VADs in Ambulatory Life) Program. Dr. Baldwin was selected as the NIH Federal Engineer of the Year in 2010 and as an Outstanding Engineering Alumnus by the Penn State College of Engineering in 2013, and chosen as the ASAIO Hastings Lecturer in 2015. He is a member of the International Society of Heart and Lung Transplantation (ISHLT), the American Society for Artificial Internal Organs (ASAIO), and the American Society of Mechanical Engineers (ASME). He also served as a co-chair for the Gordon Research Conference on Assisted Circulation (2011).
James Baumberger	*Senior Director in Federal Advocacy, American Academy of Pediatrics*	James Baumberger, MPP, is a senior director in federal advocacy at the American Academy of Pediatrics (AAP) Washington, DC office. He has been at the AAP since 2007. He advocates for the needs of children and adolescents before Congress and the Executive Branch and focuses on a number of policy issues including those related to biomedical research, substance abuse, adolescence, medical workforce, and subspecialty pediatrics. He is also the primary federal affairs representative for the Society for Adolescent Health and Medicine. He has worked extensively on federal tobacco regulation and Food and Drug Administration laws related to pediatric drugs and devices for children. He holds a Master's in Public Policy from The George Washington University. He lives in Takoma Park, Maryland and is the father of two children.

Daniel Benjamin	*Kiser-Arena Distinguished Professor of Pediatrics, Duke Clinical Research Institute*	Dr. Benjamin obtained his medical degree and completed a pediatric residency at the University of Virginia. He then completed a fellowship in pediatric infectious diseases at Duke University and a Masters in Public Health and PhD in Epidemiology at the University of North Carolina at Chapel Hill. He is the Faculty Associate Director for the Duke Clinical Research Institute and has broad oversight for all clinical trials at DCRI. Dr. Benjamin's research group pioneered much of the methods in completing pharmacokinetic and safety trials in premature infants. His group has since expanded to the study of therapeutics in children of all ages and most therapeutic areas as evidenced by >250 publications in peer-reviewed journals. Dr. Benjamin has led and continues to lead, multi-center studies for pediatric labeling and is the PI of multiple federally-sponsored grants and contracts of $250,000,000 in current federal funding including the NICHD – sponsored Pediatric Trials Network to describe the PK and safety of off-label therapeutics in children and several device trials completed for children; the Trial Innovation Network sponsored by NCAATS, the Environmental Impact on Child Health Outcomes (ECHO) Program sponsored by the Office of the Director of NIH, and Global Pediatric Clinical Trials Network Sponsored by the FDA. Dr. Benjamin mentors high school and college students, fellows and junior faculty through his as PI of a T32, a K24, and an R25 to train the next generation of pediatric clinical trials researchers.
Elise Berliner	*Director of Technology Assessment Program, Agency for Healthcare Research and Quality*	Dr. Berliner is the Director of the Technology Assessment Program at the Agency for Healthcare Research and Quality (AHRQ). The Technology Assessment Program provides technology assessments to the Centers for Medicare & Medicaid Services (CMS) to inform Medicare coverage decisions and other policy issues. Prior to joining AHRQ, Dr. Berliner worked as a consultant to pharmaceutical and medical device companies on cost-effectiveness and outcomes research, technology assessment and reimbursement planning. Dr. Berliner also has several years of experience in research and development at a number of innovative medical technology companies. She was a Congressional Fellow at the Office of Technology Assessment. Dr. Berliner received her Ph.D. in biophysics from Brandeis University.
Mike Billig		Michael J. Billig is CEO of Experien Group, a clinical and regulatory consulting firm, which he co-founded with his wife, Darlene Crockett-Billig, in 2003. His entire 45+ year professional career has been involved with regulatory affairs, quality systems, clinical research, and general management for medical device companies. Mike has secured regulatory approval for hundreds of medical device products across the U.S., Europe, Canada, Central and South America, and Asia. He has been involved with a variety of product areas, including sterile disposable products, electronic instruments, robotics, combination products, mobile health, and devices for regenerative medicine. Mike has particular expertise in the interventional cardiology and cardiac surgery areas. Mike entered the device industry in 1973 at Medtronic, setting up the company's first microbiology laboratory in Minneapolis. He transitioned to regulatory affairs at Medtronic as a Project Regulatory Manager at the time that the U.S. Medical Device Amendments of 1976 were being finalized. Mike went on to work for a number of other large companies and public corporations, including Syntex, Oximetrix, Abbott and Guidant. Mike spent the majority of his time in the industry in senior management for start-ups, holding executive-level positions for 20 years at companies such as CardioThoracic Systems, Cardiometrics, Converge Medical, and Timi3 Systems. In these early stage companies, Mike oversaw the regulatory, clinical and quality teams and provided strategic direction for product

development and marketing. As a vice president of several companies and the former President and CEO of Timi3 Systems, Mike provided overall leadership for strategic business affairs and company growth. He was instrumental with substantial fundraising, multiple successful IPOs, and company sales/corporate acquisitions from both seller and buyer positions. Mike earned his BS degree in Microbiology from the University of Minnesota.

Randy Brockman	*Clinical Deputy Director, Office of Device Evaluation, Center for Devices and Radiological Health, FDA*	Dr. Randall Brockman joined the FDA in 2003 as a medical reviewer in the Division of Cardiovascular Devices. In 2012, he became the Chief Medical Officer for the Office of Device Evaluation, and since 2016 he has served as the Clinical Deputy Director in the Office of Device Evaluation. Prior to joining the FDA, he was in private practice for 5 years. His clinical training included fellowships in cardiac electrophysiology and cardiology at the University of Maryland, and a residency in Internal Medicine at the University of North Carolina, Chapel Hill. He received both his M.D. and undergraduate degrees from the University of Virginia.
Anthony Chang	*Chief Intelligence and Innovation Officer and Medical Director of the Sharon Disney Lund Medical Intelligence and Innovation Institute, Children's Hospital of Orange County*	Dr. Chang is the Chief Intelligence and Innovation Officer and Medical Director of the Heart Failure Program at Children's Hospital of Orange County. He is the founder and medical director of the nascent Medical Intelligence and Innovation Institute (MI3) that is supported by the Sharon Disney Lund Foundation. The institute is dedicated to implement data science and artificial intelligence in medicine and is the first institute of its kind in a hospital. He accepted a position as attending cardiologist in the cardiovascular intensive care unit of Boston Children's Hospital and as assistant professor at Harvard Medical School.. He is known for several innovations in pediatric cardiac care, including introducing the cardiac drug milrinone and co-designing (with Dr. Michael DeBakey) an axial-type ventricular assist device in children. Dr. Chang is the organizing chair for several conferences including the biennial Pediatrics2040: Emerging Trends and Future Innovations meeting, the Artificial Intelligence in Medicine (AIMed) annual meeting, the largest meeting that focuses on applications of artificial intelligence in medicine, and has started the international Society for Pediatric Innovation (iSPI). He is the co-founder and CEO of a startup company (CardioGenomic Intelligence, LLC) that focuses on artificial intelligence applications such as deep learning in clinical cardiology and genomic medicine. He is the editor of several textbooks in pediatric cardiology, including Pediatric Cardiac Intensive Care, Heart Failure in Children and Young Adults, and Pediatric Cardiology Board Review Dr. Chang attended Johns Hopkins University for his B.A. in molecular biology prior to entering Georgetown University School of Medicine for his M.D. He then completed his pediatric residency at Children's Hospital National Medical Center and his pediatric cardiology fellowship at the Children's Hospital of Philadelphia. He has completed a MBA in Health Care Administration at the University of Miami School of Business and graduated with the McCaw Award of Academic Excellence. He completed a MPH in Health Care Policy at the Jonathan Fielding School of Public Health of the University of California, Los Angeles and graduated with the Dean's Award for Academic Excellence. He completed his MS in Data Science with a sub-specialization in artificial intelligence from Stanford School of Medicine. He is also a computer scientist-in-residence at Chapman University.

Eric Chen	*Director, Humanitarian Use Device and Pediatric Device Consortium Programs, Office of Orphan Product Development, FDA*	Mr. Chen serves as the Director of the Humanitarian Use Device (HUD) Program and Pediatric Device Consortia (PDC) Grants Program in the Office of Orphan Products Development at FDA. As Director of the HUD Program, he serves as the program's lead to promote the development of devices for the diagnosis or treatment of rare diseases or conditions. As Director of the PDC Grants Program, he is responsible for overseeing a grants program that provides funding to non-profit consortia to promote the development of pediatric medical devices. Prior to these positions, he served as the expert Biomedical Engineer in the Circulatory Support Branch where he was responsible for the review of mechanical circulatory support devices. Mr. Chen received a Master's of Science Degree in Bioengineering from the University of Pittsburgh and a Bachelor of Science Degree in Biomedical Engineering from Johns Hopkins University.
Barbara Christensen	*Senior Director of National Cardiovascular Data Registry and Accreditation Services, American College of Cardiology*	Barbara Christensen oversees all operational and strategic activities of the NCDR registry programs which include registry support, training and orientation, clinical quality teams, business development, and international expansion initiatives. Recently, Ms. Christensen expanded her role to include operational and strategic oversight of ACC Accreditation Services Field Operations and Customer Service. Ms. Christensen is a registered nurse with extensive experience in cardiovascular leadership and administration. Prior to joining the ACC in 2008, she was the Executive Director for Cardiovascular Services at Washington Adventist Hospital in Takoma Park, Maryland. In this role, she oversaw all aspects of acute care cardiovascular programs, including the development and implementation of quality improvement processes for clinical outcomes. Ms. Christensen received her Bachelor of Science in Nursing from Loma Linda University, Loma Linda, CA and her Master of Science in Healthcare Administration from the University of Maryland. She received her designation as an Associate of the American College of Cardiology in 2012.
Edward Connor	*Chairman and Chief Scientific Adviser, Institute for Advanced Clinical Trial for Children*	Dr. Connor is Chairman and Chief Scientific Adviser of the Institute for Advanced Clinical Trials for Children, Executive Director and Scientific Lead for the Pediatric Trials Consortium at Critical Path Institute, President of Clinical Research Alliance LLC, and Emeritus Professor of Pediatrics, Microbiology, Immunology and Tropical Medicine at George Washington University School of Medicine and Health Sciences and Children's National Health System in Washington DC. Dr. Connor has more than 35 years of experience in pediatric clinical trials and product development in academia and the biotechnology industry. He was Chair of the Pediatric AIDS Clinical Trials Group and Principal Investigator of ACTG 076 that led to FDA approval of zidovudine for prevention of mother-to-infant transmission of HIV. Dr. Connor served as Executive Vice President, Clinical Development and Chief Medical Officer at MedImmune and Director of the Office of Innovation Development at Children's National Health System and member of the executive team at the Clinical and Translational Science Institute at Children's National where he is currently a member of the Board of Directors at the Children's Research Institute. Dr. Connor served in advisory roles in pediatrics and pediatric product development with many public and private organizations including the NIH, the US FDA, the CDC and Prevention, the World Health Organization, and the American Academy of Pediatrics. Dr. Connor received an MD and Masters in Bioethics from the Perelman School of Medicine at the University of Pennsylvania, and was a resident and chief resident in Pediatrics at Northwestern School of Medicine, and fellow in Pediatric Infectious Diseases at the University of Rochester School of Medicine and Dentistry.

Mark Del Monte	*Interim CEO/Executive VP, American Academy of Pediatrics*	Mark Del Monte, JD serves as interim CEO/Executive Vice President of the American Academy of Pediatrics (AAP). In this capacity, Mark leads a strong chief executive team for the organization which serves 67,000 pediatrician, pediatric medical subspecialist, and pediatric surgical specialist members. Prior to this role, Mark served as the AAP's Chief Deputy and Senior Vice President for Advocacy and External Affairs where he directed the organization's communications, public relations and advocacy activities. Prior to joining AAP in 2005, Mark served as Director of Policy and Government Affairs for the AIDS Alliance for Children, Youth & Families, a national organization advocating for children and families with HIV/AIDS. Before moving to Washington, DC, Mark worked as a lawyer in his home state of California, providing direct legal services to HIV-positive, low-income children and families. Mark holds a law degree from the University of California (Berkeley) and a bachelor's degree from Gonzaga University.
Pedro del Nido	*William E. Ladd Professor of Child Surgery, Harvard Medical School and Chairman, Department of Cardiovascular Surgery, Boston Children's Hospital*	Dr. Pedro J. del Nido, is Chief of the Department of Cardiovascular Surgery at Boston Children's Hospital, and the William E. Ladd Professor of Child Surgery at Harvard Medical School. His laboratory research work aims to design and develop novel medical devices and procedures that address the specific needs of pediatric patients. He has over 460 peer reviewed publications, and 19 issued and pending patents, including for "del Nido Cardioplegia" one of the most widely used cardioplegia formulations in adults and children in the world. He has served as P.I. for the Boston Pediatric Device Consortium for nine years, and has supervised over 30 pre- and post-doctoral research fellows. He is Founder of Nido Surgical, Inc., a medical device start-up developing technology for beating heart video-endoscopic surgery.
Declan Dineen	*Senior Regulatory Affairs Director, Structural Heart, Medtronic*	Declan Dineen is a Senior Director of Regulatory Affairs for Medtronic Structural Heart. Following almost two decades of experience in coronary and structural heart medical device development and commercialization, expertise includes global regulatory strategy development, clinical research, commercialization and post market management of global Class III portfolios. Product expertise includes coronary stents, heart valves and combination products. Declan currently holds global regulatory responsibility for all Medtronic transcatheter and surgical valve products. Declan is a graduate of Trinity College Dublin, the University of Dublin, with a Bachelor's degree in Natural Sciences and also holds an M.S.C in Toxicology. Declan is based in Santa Rosa, CA.
Jacqueline Francis	*Medical Officer, Office of Device Evaluation, Center for Devices and Radiological Health, FDA*	Dr. Francis is a pediatrician and medical officer at FDA. She began her career at FDA in the office of In-Vitro diagnostic devices where she worked in the microbiology branch as a clinical consultant. In her current home office, the Office of Device Evaluation in the Division of Surgical Devices, she specializes in policy, regulation and clinical protocol design of plastic and reconstructive surgery devices as well as pediatric surgical devices. She also serves as an Attending Physician with the KIDS mobile clinic (Georgetown/ Medstar Hospital) and the Hoya clinic that serves the shelter patients at DC General campus. A graduate of Cornell University in 1993, Dr. Francis continued on to Temple University School of Medicine where she earned a Medical Degree, Georgetown University for internship, residency (Pediatrics) and, fellowship (Clinical Pharmacology) then, completed her training at Johns Hopkins (Preventive Medicine Residency) where she also received a MPH.

Lee Grant	*Distinguished Regulatory Affairs Advisor, Spine, Medtronic*	Distinguished Regulatory Affairs Medtronic Spine, Memphis, TN (1998 to Present) • Author of more than 150 cleared 510(k) applications for spinal devices including: • First 510(k) clearance for posterior cervical pedicle screw usage – 2008 (K062254) • First 510(k) clearance for pediatric pedicle screws for AIS – 2010 (K091445) • First 510(k) clearance for interbody devices to treat scoliosis – 2013 (K123027) • First 510(k) clearance for traditional growth rods – 2014 (K133904) • First 510(k) clearance for cement-augmented screws – 2016 (K152604) Regulatory Affairs Consultant (2005 to Present) Author: Our Vanishing Americana: A North Carolina Portrait (2007, Lorimer Press); Everybody on the Truck – The Story of the Dillards (1995, Eggman Publishing) Radio Host: The Modern World on WEVL (FM 89.9 Memphis and WEVL.ORG – 2014 to Present)
Scott Gottlieb	*Commissioner of the U.S. Food and Drug Administration, FDA*	Dr. Scott Gottlieb was sworn in as the 23rd Commissioner of Food and Drugs on May 11, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and before that, as a senior advisor to the FDA Commissioner. He also worked on implementation of the Medicare drug benefit as a senior advisor to the Administrator of the Centers for Medicare and Medicaid Services, where he supported policy work on quality improvement and the agency's coverage process, particularly as it related to new medical technologies. In 2013 Dr. Gottlieb was appointed by the Senate to serve on the Federal Health Information Technology Policy Committee, which advises the Department of Health and Human Services on healthcare information technology. Dr. Gottlieb was previously a Resident Fellow at the American Enterprise Institute, and a Clinical Assistant Professor at the New York University School of Medicine in Manhattan, where he also practiced medicine as a hospitalist physician. He completed a residency in internal medicine at the Mount Sinai Medical Center in New York, New York and is a graduate of the Mount Sinai School of Medicine and of Wesleyan University, in Middletown, Connecticut, where he studied Economics.
Pamela Haworth	*Clinical Research Director, Program Management, Diabetes, Medtronic*	Pamela Haworth is the Global Clinical Research Director for Program Management at Medtronic Diabetes. She has been in clinical research for 26 years, overseeing clinical trials both in Pharma and Medical Devices. Pamela joined Medtronic in 2015 and has been intimately involved in the oversight of the execution of the studies included for MiniMed™ 670G PMA approval for both adults and pediatrics.
Martin Ho	*Director of Quantitative Innovation Program, Office of Surveillance and Biometrics, Center for Devices*	Mr. Martin Ho created and lead the CDRH Quantitative Innovation Program, which provides innovative and pragmatic solutions to novel challenges of regulatory decision making as technology rapidly evolves. He co-leads the Real-World Performance Work Stream of the CDRH Digital Health Pre-Certification Program. Mr. Ho provided methodological leadership for the FDA Patient Preferences Information Guidance released in 2016. Mr. Ho is the past president of the FDA Statistical

	and Radiological Health, FDA	Association and Chair-elect of the American Statistical Association (ASA) Medical Device and Diagnostic Section, the largest organization of medical device statisticians. Mr. Ho is the sole CDRH voting member in the FDA's IRB.
Pieter Kappetein	*Chief Medical Officer and Vice-President, Medtronic*	Pieter Kappetein, MD, PhD, is a Consultant Cardiothoracic Surgeon, is Professor at the Thorax Center at the Erasmus Medical Center in Rotterdam, The Netherlands. Before he joined Medtronic as Chief Medical Officer and Vice-President, he was Secretary General of the European Association for Cardiothoracic Surgery for 9 years, President of CTSnet and member of the Board of the Society of Thoracic Surgeons and chairman of the International Cooperation committee of the STS in the USA. Besides this he was member of the Editorial Board of the Annals of Thoracic Surgery and Eurointerventions. His clinical interests include aortic valve surgery, indications, outcome and innovations in transcatheter aortic and mitral valve replacement and repair, and coronary surgery. He is also interested in education, and epidemiology. He was co-principal investigator of the SYNTAX and EXCEL trial (comparing coronary surgery with drug eluting stents) and member of the steering committee of SURTAVI trial on percutaneous valves and the RESHAPE trial: the evaluation of the Mitraclip in patients with heart failure. He was also member of the steering committee of the Re-align trial on Dabigatran in patients with mechanical heart valves. His current research efforts are focused on the evaluation of new surgical techniques and the comparison of new techniques in cardiothoracic surgery with new techniques in interventional cardiology. He is project leader of the "One valve for life" research program, a study together with the Technical University in Eindhoven and the University Hospital in Utrecht, developing a tissue engineered heart valve.
Chester Koh	*Co-Founder and Co-PI of the Southern California Consortium for Technology and Innovation in Pediatrics(CTIP)*	Dr. Chester Koh is a pediatric urologist at Texas Children's Hospital (TCH) and a Professor of Urology, Pediatrics, and OB/GYN at Baylor College of Medicine (BCM). He also serves as the director of the Pediatric Robotic Surgery Program. Dr. Koh received his B.S. degree in Mechanical Engineering from UC Berkeley and his medical degree from Tufts University School of Medicine. He completed his urology residency at USC and his pediatric urology fellowship at Children's Hospital Boston / Harvard Medical School. He is the founder and executive director of the Southwest National Pediatric Device Consortium based at TCH / BCM, as well as co-founder and co-PI of the Southern California Consortium for Technology and Innovation in Pediatrics (CTIP), one of the current FDA-funded pediatric medical device consortia that are dedicated to improving children's health through innovative pediatric medical devices.
Bob Kroslowitz	*CEO, Berlin Heart and Chairman, Pediatric Medical Device Working Group, AdvaMed*	Bob Kroslowitz serves as President and CEO of Berlin Heart Inc. and is responsible for the company's business interests in North America. Bob also serves as the Chair of the Advamed Pediatric Medical Device Working Group, on the National Advisory Board for Mended Little Hearts, on the Oversight Committee of the Philadelphia Pediatric Device Consortia, and on the Board of Trustees for the American Society of Artificial Internal Organs. Bob has participated on panels related to pediatric device development and commercialization with representatives from industry, the medical community and governmental regulatory bodies, speaks frequently on topics related to pediatric device development, approval and commercialization, and serves as an advisor to other early stage medical device companies.

Andrew Lo	*Charles E. and Susan T. Harris Professor and Director of the Laboratory for Financial Engineering, Sloan School of Management, Massachusetts Institute of Technology*	Andrew W. Lo is the Charles E. and Susan T. Harris Professor at the MIT Sloan School of Management, the director of MIT's Laboratory for Financial Engineering, a principal investigator at MIT's Computer Science and Artificial Intelligence Lab, and an external faculty of the Santa Fe Institute. He received a B.A. in economics from Yale University in 1980, and an A.M. and Ph.D. in economics from Harvard University in 1984. His most recent research focuses on systemic risk in the financial system; evolutionary approaches to investor behavior, bounded rationality, and financial regulation; and applying financial engineering to develop new funding models for biomedical innovation. He has published extensively in academic journals (see http://alo.mit.edu) and his most recent book is *Adaptive Markets: Financial Evolution at the Speed of Thought*. His awards include Sloan and Guggenheim Fellowships, the Paul A. Samuelson Award, the Harry M. Markowitz Award, the Eugene F. Fama Prize, and election to Academia Sinica, the American Academy of Arts and Sciences, the Econometric Society, and Time Magazine's 2012 list of the "100 most influential people in the world." He has also received teaching awards from the University of Pennsylvania and MIT.
Dennis Lund	*Interim President and CEO, Lucile Packard Children's Hospital - Stanford*	Pediatric surgeon Dennis Lund, MD, is the chief medical officer and interim President and CEO of Lucile Packard Children's Hospital Stanford. He also serves as associate dean for maternal and child health at the Stanford University School of Medicine. Dr. Lund has spent three decades as a leader in pediatric medicine. Prior to coming to Stanford in 2015, he served as Executive Vice President and surgeon-in-chief at Phoenix Children's Hospital. He served as a professor of surgery and surgeon-in-chief at the University of Wisconsin Children's Hospital, where he was appointed chair of the university's Division of General Surgery in 2001 and was the driving force behind the creation of the American Family Children's Hospital, which opened in 2007 and is affiliated with the University of Wisconsin. Dr. Lund graduated from Harvard College and Harvard Medical School. He trained at the Massachusetts General Hospital and Boston Children's Hospital, and began his career as a pediatric trauma and transplant surgeon at Boston Children's, where he developed the level-1 trauma program and built a large pediatric surgical practice. Dr. Lund grew up in Minnesota, is married and has 3 children.
Kevin Maher	*Professor of Pediatrics Emory University School of Medicine Director, Cardiac Intensive Care Children's Healthcare of Atlanta Medical Director, Pediatric Technology Center Georgia Institute of Technology*	Dr Kevin Maher is a professor of Pediatrics at the Emory University School of Medicine and the director of the pediatric cardiac intensive care unit at Children's Healthcare of Atlanta. He attended medical school at University of Maryland, followed by a residency and chief residency in pediatrics, at the University of Maryland. He attended the University of Michigan for a fellowship in pediatric cardiology, followed by additional training in critical care. In 2004, Dr Maher joined the Pediatric Cardiology group at Children's Healthcare of Atlanta and Emory University. Dr Maher's research activities include heart failure in children, cardiac biomarkers, pediatric medical device development, Big Data and Analytics, and application of nanotechnologies to pediatric diseases. Dr Maher works on a number of research collaborations between Children's of Atlanta and Georgia Tech, and serves as the medical director of the Pediatric Technology Center at Georgia Tech and Children's of Atlanta. He is an adjunct professor of Biomedical Engineering at Georgia Tech. Dr Maher is an active member the American Heart Association, serving as the president of the AHA Board for the SE United States. Dr Maher resides with his wife and three children in Atlanta.

Sam Maldonado	*Vice President of Child Health Innovation and Leadership Department, Johnson & Johnson*	Dr. Maldonado is Vice President of Child Health Innovation and Leadership Department, at Johnson & Johnson. He joined J&J in February 2000. Dr. Maldonado graduated with an MD degree from the National University of Honduras and completed his pediatric residency at Henry Ford Hospital in Detroit, MI and a 3-year fellowship in Pediatric Infectious Diseases at Children's National Medical Center in Washington, D.C. and a Regulatory Medicine Fellowship at the Food and Drug Administration. Dr. Maldonado was a Medical Officer in the Divisions of Anti-Infective Drug Products and Antiviral Drug Products of the FDA from 1990 to 1998. In 2007, Dr. Maldonado represented J&J and the pharmaceutical industry in the negotiations for the renewal of the pediatric laws in the US. As part of those activities, he testified before the Health, Education, Labor and Pensions committee of the US Senate. Dr. Maldonado remained involved in the policy work that culminated with the signing into law of BPCA and the Pediatric Research Equity Act (PREA) as permanent laws in July 2012. Since leaving the FDA, he has worked in three pharmaceutical companies and has focused efforts in furthering pediatric drug development. Dr. Maldonado has participated in the clinical and regulatory planning and execution of multiple global pediatric programs across therapeutic areas. Dr. Maldonado's experience in public policy, operational and scientific issues related to drug development expands over 27 years, of which 8 he served as Medical Officer at the FDA and the last 19 in Industry.
Peter Margolis	*Learning Networks Program and PEDSnet, Co-Director of James M. Anderson Center for Health Systems Excellence, Cincinnati Children's Hospital Medical Center*	Peter Margolis, MD, PhD, is Cincinnati Children's Professor of Pediatrics and Co-Director of the James M. Anderson Center for Health System Excellence at Cincinnati Children's Hospital Medical Center. His work encompasses the application and study of systems improvement methods across a broad range of areas including primary and sub-specialty care, communities and public health settings to improve the health outcomes of children, families and communities. Over the last 20 years, he and his research team have developed innovative approaches that engage patients, their families, clinicians, scientists and communities in developing network-based learning health systems that simultaneously improve care, spawn innovation and accelerate research. This work has repeatedly demonstrated significant impact on the process and outcomes of care. Dr. Margolis was co-PI of an NIH Transformative Research Grant focused on developing learning health systems for children with chronic illness by harnessing the inherent motivation and expertise of all stakeholders involved. Dr. Margolis has extensive experience in large scale comparative effectiveness research, the creation of large scale interoperable data systems, managing large project teams and engaging individuals from diverse backgrounds to co-produce improved care and research. He served as Chair of the PCORnet Council guiding the Patient Centered Outcomes Research Institute's $300 million investment in transforming research infrastructure in the US. Recently, the ImproveCareNow Network which he leads was awarded the Drucker Prize, the largest non-profit management and innovation award in the US.

Mary Clare McCorry	*AIMBE Scholar, American Institute for Medical and Biological Engineering*	Dr. Mary Clare McCorry is an American Institute for Medical and Biological Engineering (AIMBE) Scholar at the U.S. Food and Drug Administration in the Center for Devices and Radiological Health (CDRH). The AIMBE Scholars Program is a post-doctoral fellowship in science policy intended to train rising leaders in the field to learn firsthand about the regulatory process. Mary Clare has spent fiscal year 2018 positioned with the Program for Pediatrics and Special Populations at CDRH. She obtained her Ph.D. in Biomedical Engineering from Cornell University. During her time as a PhD candidate, Mary Clare served as a Howard Hughes Med into Grad fellow and a NIH TL1 Clinical and Translational Sciences Fellow. Additionally, Mary Clare worked on a collaborative project with GE Global Research through Empire State Development's Division of Science, Technology and Innovation (NYSTAR) program.
Bob McDonough	*Head of Clinical Policy Research & Development, Aetna*	Robert S. McDonough, M.D., is Senior Director for Clinical Policy Research and Development for Aetna, where he is responsible for developing Aetna's clinical policies. He is cochairman of Aetna's Pharmacy and Therapeutics Committee. He is a member of the governing board of the Systemic Review Data Repository, and the EXCITE International payers advisory committee. He has special interests in preventive health services, technology assessment, and outcomes research. He is former senior analyst and project director with the Health Program of the Congressional Office of Technology Assessment. He is a graduate of Duke University School of Medicine and School of Law (J.D.), and has a master's degree in policy analysis from Duke's Sanford Institute of Public Policy. He completed an internship in internal medicine at Stanford University School of Medicine, and is a Fellow of the American College of Legal Medicine.
Gabriel Movsesyan	*Staff Fellow Economist, Office of Planning, FDA*	Gabriel Movsesyan is a Staff Fellow Economist with the FDA's Office of Planning, within the Office of the Commissioner. He conducts benefit-cost analysis of agency regulations and research on programs and policies affecting public health. Gabriel is a graduate of Queens College (City University of New York) and a PhD candidate in Economics at the CUNY Graduate Center. During his time as a PhD candidate, he also served as a Fellow with the CUNY Institute for Demographic Research.
Kurt Newman	*President and CEO, Children's National Health System*	Kurt Newman, MD, is President and CEO of Children's National Health System. Children's National is ranked as one of the top five best pediatric hospitals in the nation and is a leader in NIH pediatric medical research funding. Dr. Newman has been a surgeon at Children's National for over 30 years. His book, "Healing Children" debuted as an Amazon bestseller in Pediatrics in 2017. Dr. Newman is a graduate of the University of North Carolina at Chapel Hill, and Duke Medical School. He completed his surgical residency at Brigham and Women's Hospital and Harvard Medical School before joining Children's National.
John Parker	*Founder and Managing Director, - Springhood Ventures*	Mr. Parker founded Springhood Ventures to provide critical early support to companies developing important healthcare solutions for children. In this role, he established and manages the program-related investment (PRI) initiative of the Charles H. Hood Foundation, a Boston-based private foundation that supports pediatric research and where he also serves as a trustee. He is an observer on the boards of Prapela, Aldatu Biosciences, Breegi Scientific, and Noninvasix. Previously, Mr. Parker spent 25 years in the alternative investment industry, including senior roles in venture capital, private equity, and hedge funds. He earned his BA from Dartmouth College and MBA from the Tuck School of Business.

Bakul Patel	*Associate Director of Digital Health, Office of the Center Director, Center for Devices and Radiological Health, FDA*	Bakul Patel is Associate Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless and information technology. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software. Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Bakul chairs the International Medical Device Regulators Forum (IMDRF) "software as a medical device" working group, a global harmonization effort. Before joining FDA, Mr. Patel held key leadership positions working in the telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations. Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.
Vasum Peiris	*Chief Medical Officer, Pediatrics and Special Populations, Office of the Center Director, Center for Devices and Radiological Health, FDA*	As Chief Medical Officer for Pediatrics and Special Populations at the U.S. Food and Drug Administration Center for Devices and Radiological Health, Vasum provides executive and clinical leadership on Center policies and initiatives associated with medical devices intended for use in pediatric and special populations. He is the Center's senior clinical expert on pediatrics and pediatric medical device issues. He leads initiatives that facilitate internal and external innovation and synergy, enhancing the ability of the Agency to optimally fulfil its public health mission. Prior to joining the FDA, Vasum was the Joon Park MD Endowed Chair in Medical Excellence and Chief of Pediatric and Adult Congenital Cardiology at Texas Tech University Health Sciences Center. Vasum is triple board-certified by both the American Board of Pediatrics and the American Board of Internal Medicine. He is a Fellow of the American Academy of Pediatrics, the American College of Cardiology, and the American Society of Echocardiography. Vasum completed fellowship at Harvard Medical School/Children's Hospital Boston, residency at the Yale School of Medicine/Yale-New Haven Hospital, medical degree with an AOA Honor Medical Society Scholarship at The University of Vermont College of Medicine, graduate degree 'with distinction' at the Yale School of Medicine Department of Epidemiology and Public Health, and undergraduate degree in the honors major of Ethics, Politics and Economics at Yale University.
Rachel Rath	*Deputy Director of National Evaluation System for Health Technology (NEST) Coordinating Center*	Rachel R. Rath, MPH is the Deputy Director for the NEST Coordinating Center. She joins MDIC from the Patient-Centered Outcomes Research Institute (PCORI). Since joining PCORI in 2014, she helped build and manage the development of the PCORnet, the National Patient-Centered Clinical Research Network, a transformational effort to engage patients and leverage electronic health data to improve the speed and efficiency of clinical research in the United States. Most recently she focused her on governance, sustainability, and communications efforts to advance the mission of PCORnet. PCORI's investment in PCORnet has exceeded $400 million from a combination of infrastructure and research investments. In March 2017, the PCORnet partners successfully launched an independent non-profit entity to advance the

		long-term sustainability of PCORnet. Prior to joining PCORI, she worked with disease-specific organizations including the National Multiple Sclerosis Society and the COPD Foundation and served as an Applied Behavioral Analysis (ABA) Therapist for children with Autism Spectrum Disorders. Rachel received her MPH in global health policy from The George Washington University and is currently pursuing an MBA from Georgetown University.
Mark Schlesinger	*Department Chair and Professor of Public Health (Health Policy), Yale School of Public Health*	*Mark Schlesinger, Ph.D.* is Chair of the Department of Health Policy and Management, Professor of Health Policy, a fellow of the Institution for Social and Policy Studies at Yale University and past editor of the Journal of Health Policy, Politics and Law. He studies patient experience and patients' responses to problematic medical encounters, including ways of enhancing the scope, clarity, and influence of patient voice. Dr. Schlesinger's other research addresses the determinants of public opinion about health and social policy, the influence of bounded rationality on medical consumers, and the impact of economic insecurity on public well-being and political attitudes. His favored sports include uncompetitive volleyball and unlighted table tennis.
Eliane Schutte	*Chief Development Officer, Xeltis*	Eliane Schutte holds the position of Chief Development Officer at Xeltis and has extensive expertise in regulatory affairs and global product development in medical devices. With over 20 years of experience in the biotech/ medtech industry, she joins from The Medicines Company where she was vice president for global product development in the peri-operative care space. Eliane Schutte was previously Chief Development Officer at Profibrix, a Dutch-US biotech start-up, acquired by The Medicines Company and vice president for regulatory affairs and EU operations at IsoTis Orthobiologics. She is the owner of regulatory/ QA consulting firm Signifx BV. She holds a Regulatory Affairs Certification.
Doug Silverstein	*Medical Officer, Office of Device Evaluation, Center for Devices and Radiological Health, FDA*	Dr. Douglas Silverstein is a pediatric nephrologist and medical officer in the Center for Devices and Radiological Health, Renal Devices Branch. Dr. Silverstein completed his fellowship at the Albert Einstein College of Medicine/Montefiore Medical Center in New York. He practiced for 17 years, with a focus on bench and clinical research, and, was the medical director of the dialysis program at Children's National Medical Center. At the FDA, Dr. Silverstein reviews applications for all devices related to nephrology, including dialysis systems and other extracorporeal therapies, hemodialyzers and other filters, vascular access devices, and devices for the management of hypertension.
Michelle Tarver	*Director of Patient Science & Engagement Program, Office of the Center Director, Center for Devices and Radiological Health, FDA*	Michelle Tarver is the Director of Patient Science and Engagement at the Center for Devices and Radiological Health (CDRH). She attended Spelman College in Atlanta, GA where she received a B.S. in biochemistry. She completed the MD/PhD program at The Johns Hopkins University Bloomberg School of Public Health in 2002 earning her doctorate in clinical epidemiology and her MD at the Johns Hopkins School of Medicine in 2003. Following her internal medicine internship, she completed a residency in ophthalmology with fellowship training in ocular inflammation at the Wilmer Eye Institute (Johns Hopkins). As a board-certified ophthalmologist and epidemiologist, she has worked on developing patient-reported outcome measures and surveys to capture patient preferences with medical devices. She currently directs the patient science development and policy work and leads the patient engagement efforts including the Patient Engagement Advisory Committee. In addition to facilitating patient engagement opportunities across CDRH, she helps foster research in patient-reported outcomes

		and patient preference information to inform medical device evaluation. She is a co-leader of the FDA Innovation Challenge on devices to prevent and treat opioid use disorder. She continues to see uveitis patients through her privileges at The Johns Hopkins Wilmer Eye Clinic and Solomon Eye Associates.
Cara Tenenbaum	*Senior Policy Advisor, Office of the Center Director, Center for Devices and Radiological Health, FDA*	Cara is a Senior Advisor in the Office of the Center Director, Center for Devices and Radiological Health. She provides policy analysis and serves as a liaison to external stakeholders regarding policy issues. She was previously a Senior Advisor in the Office of External Affairs in the Office of the Commissioner where she handled stakeholder strategy and outreach for policy issues at the Agency. Before joining the FDA, Cara served as Vice President for Policy and External Affairs at the Ovarian Cancer National Alliance (Alliance). At the Alliance for seven years, she was responsible for the public policy and educational efforts for the organization, including federal appropriations, legislation and regulations affecting women with ovarian cancer. She worked on laws and regulations related to health reform, safe and effective drug approvals and reimbursement practices. Additionally, Ms. Tenenbaum often served as the spokesperson for the Alliance, providing insight on important ovarian cancer issues to media outlets like the Wall Street Journal, New York Times and Fox Business News. Ms. Tenenbaum holds a Bachelor's Degree in Economics from the University of Maryland, College Park, a Juris Doctor from Case Western Reserve University and a Masters in Business Administration from Case Western Reserve University.
Mark Throdahl	*President & CEO, OrthoPediatrics*	Mark Throdahl has 40 years of experience in the medical device industry. Since 2011 he has been President & CEO of OrthoPediatrics, the only diversified company focused exclusively on orthopedic surgical systems for children. Formerly, he was Group President of Zimmer Holdings. From 2001 to 2007 he was Chief Executive of Consort Medical plc in London. During a 13-year career at Becton Dickinson, he served as Senior Vice President, President of the Drug Delivery Sector, and President of Nippon Becton Dickinson in Tokyo. He is a graduate of Princeton University and has an MBA from Harvard University.
James Wall	*Assistant Director at Biodesign Innovation Fellowship Program and Assistant Professor of Pediatric Surgery, Stanford University*	Dr. James Wall is Pediatric Surgeon who focuses on minimally invasive approaches to children's surgery. He is an alumnus of the Stanford Biodesign program and holds a Masters degree in Bioengineering. His research focuses on how we educate others to design and develop health technology as well as flexible endoscopic surgery in children. He has developed multiple health technologies including a novel epidural needle, a protection device for umbilical catheters and a wearable leg compression system. James currently leads the Stanford Children's Health perioperative Value Analysis Committee and is the Assistant Director of the Byers Center for Biodesign Innovation Fellowship.
Tiffany Wilson	*CEO, Global Center for Medical Innovation/T3 Labs Philanthropic Model*	*Tiffany has spent over 15 years working with early stage companies to bring innovative medical technology from benchtop to bedside. She leads the Global Center for Medical Innovation, a non-profit organization tha*t represents the Southeast's first *medical device innovation center. GCMI has supported over 150 innovative medical technologies making their way through design, prototype, preclinical testing, and clinical trials to commercialization. The organization is catalyzing a highly capital*

		efficient method approach to move innovation to products that impact patient outcomes and healthcare efficiently. Tiffany began her career in management consulting and investment banking and brings considerable U.S. and international experience in building partnerships, strategic planning, business development, financial analysis, and market evaluation in technology related industries. She earned a BBA in International Business from Loyola University and an MBA from Georgetown University McDonough School of Business.
Lynne Yao	*Director, Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, FDA*	Lynne Yao, M.D., is the Director, Division of Pediatric and Maternal Health in the Office of New Drugs, Center for Drug Evaluation and Research. She has held this position since 2012 and has been with the FDA since 2008. The Division of Pediatric and Maternal Health oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve pregnancy and lactation-related information in product labeling. She collaborates with numerous stakeholders both in and out of FDA to advance development of safe and effective therapies for children, as well as pregnant and lactating women. Dr. Yao graduated from the George Washington University School of Medicine, completed residency in Pediatrics at Walter Reed Army Medical Center, and fellowship in Pediatric Nephrology at the Georgetown University Children's Medical Center. Dr. Yao is board certified in both Pediatrics and Pediatric Nephrology.
Lijie Grace Zhang	*Associate Professor, George Washington University, March of Dimes funding recipient*	Dr. Lijie Grace Zhang is an associate professor in the Department of Mechanical and Aerospace Engineering at the George Washington University. She obtained her Ph.D. in Biomedical Engineering at Brown University. Dr. Zhang joined GW after finishing her postdoctoral training at Rice University and Harvard Medical School. She is the director of the Bioengineering Laboratory for Nanomedicine and Tissue Engineering at GW. She has received the ASME Sia Nemat-Nasser Early Career Award, NIH Director's New Innovator Award, Young Innovator in Cellular and Molecular Bioengineering, John Haddad Young Investigator Award by American Society for Bone and Mineral Research, and Early Career Award from the International Journal of Nanomedicine, etc. Her research interests include 3D/4D bioprinting, nanobiomaterials, complex tissue engineering and breast cancer bone metastasis. Dr. Zhang has authored 3 books, over 118 journal papers, book chapters and conference proceedings, 6 patents and has presented her work on over 290 conferences, university and institutes. She also serves as the Editor of Materials Science and Engineering C: Materials for Biological Applications; Associate Editor-in-Chief of International Journal of Nanomedicine; and Associate Editor of ASME Journal of Engineering and Science in Medical Diagnostics and Therapy.