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Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions

Washington Marriott Metro Center • Washington, DC
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Biographies

Ernest Berndt is Professor of Applied Economics Emeritus at the Massachusetts Institute of Technology, Alfred P. Sloan School of Management. He is also a Research Associate at the National Bureau of Economic Research, where from 1998 until 2010 he was Director of its Program on Technological Change and Productivity Measurement. Between 2004 and 2013, he was Co-Director of the Biomedical Enterprise Program, a joint degree-granting program at the Harvard-MIT Division of Health Sciences and Technology and the MIT Sloan School of Management. He is an elected Fellow of the Econometric Society, and has been awarded honorary doctorate degrees from Uppsala University in Sweden in 1991 and the University of Basel in Switzerland in 2015. A major focus of his academic research over the last 25 years has been on health economics and the economics of the pharmaceutical, biotechnology, diagnostic, vaccine and medical device industries. Currently he is on the editorial board of Health Affairs, and is an uncompensated Economic Consultant to the Food and Drug Administration, Office of Strategic Programs.

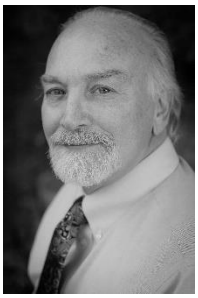
Ashley Boam currently serves as Director of the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER). OPPQ is responsible for developing and clearly communicating science- and risk-based policies and standards related to drug product quality, including application review and inspection. This Office also coordinates OPQ's work with international regulatory authorities on quality issues, leads CDER's compendial operations, coordinates CDER's involvement in quality standard-setting organizations, and addresses policy issues related to drug-device combination products. Prior to joining CDER in 2013, Ashley spent nearly 20 years in the Office of Device Evaluation (ODE) in FDA's Center for Devices and Radiological Health (CDRH), serving as a scientific reviewer, a Branch Chief in the Division of Cardiology Devices, and finally as Associate Director for Regulations and Guidance for ODE. Ashley received her MSBE from the University of Alabama at Birmingham and her BSE from Tulane University, both in Biomedical Engineering.

Marcie McClintic Coates is head of global policy at Mylan where she oversees Mylan's health and public policy efforts in the various markets Mylan serves around the world. During her 11 years at Mylan, Marcie has held several roles of increasing responsibility including head of global regulatory affairs, vice president and chief of staff in the office of the CEO and global regulatory counsel in the Legal Department, where she began her career. Marcie is also active with the generic drug industry trade association, Association for Accessible Medicine and engaged in various industry task

forces and working groups. She played a leading role in negotiating industry generic drug user fee agreements with FDA and passed by Congress in 2012 and 2017 to speed patient access to more affordable medicine as well as the passage of the Food Drug Administration Safety and Innovation Act to ensure that all prescription drugs dispensed in the US are held to the same quality standards regardless if made in the US or abroad.

Rena Conti is an Associate Professor at the Questrom School of Business, Boston University. She is also the Associate Research Director of Biopharmaceutical Markets for the Institute for Health System Innovation and Policy at Boston University. From 2006 through June 2018, Professor Conti was an Associate Professor of Health Economics and Policy at the University of Chicago Medical School and the Harris School of Public Policy. Dr. Conti is a health economist. Her research is on the organization, financing and regulation of medical care. She has written extensively on the pricing, demand and supply of prescription drugs.

Blair Childs is Senior Vice President of Public Affairs for Premier, the primary spokesperson and communications strategist for the organization on key issues impacting healthcare costs and quality. He serves as liaison to the U.S. Congress, White House, healthcare policymakers and other major bodies involved in healthcare policy and regulation. Based in Washington, D.C., Childs leads Premier's advocacy, communications, safety and thought leadership units, and is a member of Premier's Executive Team. Prior to joining Premier, Childs was Executive Vice President of Strategic Planning and Implementation for AdvaMed, the Advanced Medical Technology Association. Childs has held senior management positions in professional, trade and advocacy associations and at a Fortune 50 company. Childs has been at the center of policy issues in Washington for more than two decades, playing a leading role on issues impacting medical devices, pharmaceuticals, insurers and hospitals. He has been responsible for organizing and leading public policy advocacy programs at the state and national levels on some of the nation's most visible and complex issues over the last two decades, including tort, Medicare and healthcare reform. Childs is a respected and well-recognized expert on health policy and advocacy, and has appeared on all the major television networks, as well as been quoted in most national publications.



John DiLoreto is the Executive Director of the Bulk Pharmaceuticals Task Force (BPTF), an industry trade organization representing manufacturers of active pharmaceutical ingredients, intermediates and excipients. Created as an affiliate organization of the Society of Chemical Manufacturers & Affiliates in response to industry demands, BPTF addresses regulatory and plant operations issues related to current Good Manufacturing Practices compliance. BPTF establishes sound working relationships with regulators, allied industries and the public and serves as a reliable source for the development and implementation of balanced regulations and industry guidance

resources. BPTF undertakes this advocacy on behalf of its member companies to achieve drug product and drug substance supply chain safety for consumers. BPTF has been a key stakeholder in negotiations with FDA on the implementation of the Generic Drug User Fee Act (GDUFA). Prior to joining BPTF, Mr. DiLoreto founded NanoReg, a professional services firm specializing in nanotechnology applications and the laws and regulations related to the development and use of nanoscale materials throughout the nanotechnology value chain. Mr. DiLoreto has been instrumental in bringing together producers and users of nanoscale materials with government policy makers and non-governmental organizations to address environmental, health and safety concerns about the products of nanotechnology. Mr. DiLoreto combines his degree in Chemical Engineering with technical professional experience in the chemical and pharmaceutical industries to work with companies and trade associations to assist in a variety of industrial sectors throughout the nanotechnology and drug supply value chains.

Todd Ebert is the Healthcare Supply Chain Association (HSCA) President and CEO. Todd Ebert is a nationally recognized supply chain leader, a group purchasing industry expert, and a registered pharmacist with more than 30 years of healthcare experience. Ebert joined HSCA in 2015 from Amerinet, Inc., a national healthcare solutions organization and HSCA member, where he had served as President and CEO since 2007. After joining Amerinet from Intermountain Healthcare in 1991, Ebert served in a series of leadership roles including Vice President of Amerinet's pharmacy program; President of Amerinet's private-label company, Amerinet Choice, LLC; Executive Vice President for Contracting Operations and Purchasing Program Development Units; President of Operations; and as President and Chief Operating Officer. Prior to Amerinet, Ebert gained extensive experience in several other sectors of the healthcare industry. He is a former vice president and general manager of a specialty healthcare product logistics company; a director of hospital and retail pharmacy; and has owned and operated a nursing home clinical pharmaceutical consulting company. Internationally, Ebert has provided pharmaceutical consulting to foreign government officials and healthcare providers. Ebert is a former Chair of HSCA and is the immediate past Chair of the Healthcare Industry Supply Chain Institute (HISCI). He is often requested as a guest speaker for industry events on subjects ranging from pharmacy to group purchasing trends. Ebert holds bachelor's degrees in pharmacy and business management from the University of Utah and a Master of Science degree in pharmacy administration. He is a registered pharmacist.

Robyn Ewing is the Manager of the Drug Shortages Unit in the Health Product Compliance Directorate of the Regulatory Operations and Regions Branch of Health Canada. Health Canada recognizes the negative impact of drug shortages on patients, health care professionals and the health care system, and is working with stakeholders throughout the supply chain to better prevent, mitigate and communicate shortages. When a critical national shortage occurs, Health Canada takes a leadership role, working with stakeholders across the drug supply chain to determine the details and status of the shortage, coordinate information sharing, and identify mitigation strategies, which may include regulatory measures and exploring access to

alternative products available in other jurisdictions. Factors such as whether the shortage is national in scope, whether alternative supplies are available, and whether the product is considered medically necessary are all considered in determining the potential impact and any necessary actions by Health Canada. Health Canada also co-chairs the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC), which brings key stakeholder groups together and plays a lead role in advancing tools to address drug shortages. Previously, Robyn was the Acting Manager of the Health Products and Food Branch's Border Integrity Unit and has held various Senior Advisor positions with Health Canada. Robyn has a master's degree in Biochemistry from the University of Ottawa.

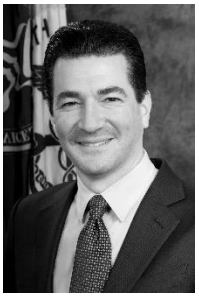
Erin Fox is a board-certified clinical pharmacist responsible for medication use policy and pharmacy purchasing at University of Utah Health, serving as senior director of Drug Information and Support Services. Erin is also Associate Professor (Adjunct), at the Department of Pharmacotherapy, University of Utah College of Pharmacy. The University of Utah Drug Information Service provides all of the content for the American Society of Health-System Pharmacists public website on drug shortages (www.ashp.org/shortages). Erin has led this project since 2001. Erin is recognized as an expert in drug shortages and frequently serves as a media resource and advocate for changes to improve the ongoing drug shortage situation. She has received the ISMP Cheers Award and ASHP Award of Excellence in recognition for her work on drug shortages.

Craig Frost is the System Vice President of Clinical Pharmacy Services for Catholic Health Initiatives in Englewood, Colorado. In his current role, Craig is responsible for pharmacy services in CHI's clinical enterprise across 18 states, including a collaborative medication use and evaluation national committee, national pharmacy supply chain, 340B and specialty pharmacy strategies and operational functions. Craig maintains membership in several professional organizations and is the Past President of the Texas Society of Health-System Pharmacists Research and Education Foundation and is a Fellow in the American College of Healthcare Executives.

Michael Ganio joined the staff at ASHP as Director of Pharmacy Practice and Quality in January of 2018. As a member of the Center on Medication Safety and Quality team, his responsibilities span the practice of pharmacy and include drug shortages, sterile and non-sterile drug compounding practices, and hazardous drug safety. Dr. Ganio earned his Pharm.D. from Rutgers University Ernest Mario School of Pharmacy, and his master's degree in Health-System Pharmacy Administration from The Ohio State University College of Pharmacy. He completed a PGY1 Pharmacy Practice residency at The Ohio State University Wexner Medical Center. Dr. Ganio has over 17 years of hospital and health-system experience. His previous job roles have included clinical pharmacy practice, pharmacy informatics and technology, and operations management of outpatient oncology infusion pharmacies. He has extensive knowledge of pharmacy informatics and automation, medication billing

and reimbursement, outpatient infusion and ambulatory care models, and sterile compounding. Dr. Ganio is a Board-Certified Pharmacotherapy Specialist and is a Certified Professional in Healthcare Information and Management Systems. He has previously served as President of the Ohio Society of Health-System Pharmacists and as a member of the ASHP Council on Pharmacy Practice.

David Gaugh is Senior Vice President for Sciences and Regulatory Affairs and has over 25 years of leadership experience in the Healthcare and Pharmaceutical business. He has been employed by the Association for Accessible Medicines (AAM, formerly GPhA) since February 2012 as the Senior Vice President for Sciences and Regulatory Affairs, where he is responsible for the professional liaison functions between member companies, agencies of the US Government and Legislative bodies for all responsible areas. Prior to joining AAM, David was Vice President and General Manager of Bedford Laboratories, a Division of Ben Venue Laboratories and a wholly owned subsidiary of Boehringer Ingelheim. Prior to Bedford Laboratories, David was Senior Director, Pharmacy Contracting and Marketing at VHA/ Novation (now Vizient). And prior to VHA/Novation, David was System Director of Pharmacy for St. Luke's Health-System, a tertiary-care hospital in Kansas City, MO. David is a registered Pharmacist and has been engaged in several board-level pharmacy-related activities.



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.

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Estay Greene is Vice President of Pharmacy Programs for Blue Cross and Blue Shield of North Carolina (Blue Cross NC). He is responsible for the management of the prescription drug program and benefits. This includes the planning, coordinating and directing the development and implementation of new and existing prescription drug benefits and pharmacy management programs, initiatives and functions for all lines of business. He provides leadership and support for all aspects of pharmacy management both strategically and on a day-to-day basis. Currently he represents Blue Cross NC at the Blue Cross Blue Shield Association Medical Policy and National Council of Physician and Pharmacist Executive Committees as well as Prime Therapeutics National P&T Committee. Prior to his current position, he was Director of Pharmacy Benefits for the Cleveland Clinic/Cleveland Health Network. There he was responsible for the operation, coordination and implementation of their prescription drug program. He was also responsible for the design of disease management strategies to improve pharmaceutical care outcomes and implement Medicare Part D strategies for the organization. He also performed as a Clinical Pharmacy Specialist for Kaiser Permanente of Ohio and Pharmacy Manager/Clinical Pharmacist for Rite Aid Pharmacies. He received his Doctor of Pharmacy degree from Duquesne University and MBA from the University of Phoenix.

Beverly Holcombe is a Clinical Practice Specialist with the American Society for Parenteral and Enteral Nutrition (ASPEN). Dr. Holcombe received her BS Pharmacy from University of North Carolina and a Doctor of Pharmacy from the University of Tennessee at Memphis Health Sciences Center. She completed an ASHP Research and Education Foundation Pharmacy Nutrition Support Services Fellowship at the University of Tennessee at Memphis. Prior to joining ASPEN, she was a Senior Clinical Specialist in the Pharmacy Department at the University of North Carolina Health Care and Clinical Professor at the UNC Eshelman School of Pharmacy for more than 25 years. While at UNC Dr. Holcombe's specialty practice was adult nutrition support. Dr. Holcombe has been involved with managing shortages of parenteral nutrition products and components for over 20 years and served as chairman of the ASPEN Nutrition Product Shortage Subcommittee. Dr. Holcombe has presented and published extensively on various aspects of parenteral and enteral nutrition therapies, parenteral nutrition safety and strategies for managing shortages of parenteral nutrition components.

Erez Israeli Chief Operating Officer and Global Head Generics & PSAI Business at Dr. Reddy's. He joined Dr. Reddy's in April 2018 from Enzymotec where he was President and CEO. With over 25 years of experience, Erez is an accomplished leader with a proven track record of achievement. He has held several leadership positions that have contributed significantly to the performance of companies he worked for. Prior to Enzymotec, he completed 23 years with Teva Pharmaceuticals Limited, where he held positions of responsibility including Vice President Marketing & Sales for North America, Vice President Asia Operations, President Teva API, Group Executive Vice

President, Head of Global Quality, and President & CEO Growth Markets. Erez holds a Master of Business Administration degree from Bar Ilan University, Israel.

Navin Katyal is General Manager of Pfizer Injectables, the company's market-leading U.S. sterile injectables business – which represents the industry's broadest portfolio of sterile injectable medications in the United States and a diverse selection of surgical products. Navin joined Pfizer almost 12 years ago, and prior to his current role, he served as Vice President, U.S. Account Management Lead for the U.S. Pfizer Essential Health business unit. Previous to that role, he served as Vice President, Chief of Staff to Pfizer's Chairman and CEO, Ian Read. Before managing operations in the Office of the Chairman and CEO, Navin served as Chief of Staff for the U.S. Primary Care Leadership team and was previously a Managing Director in Pfizer's Marketing Incubator, where he was responsible for advancing innovation priorities for the marketing organization. Navin led several incubator initiatives aimed at developing new channels to improve patient care in a variety of therapeutic areas. Prior to joining the Incubator, Navin led Consumer Marketing for Chantix™, a prescription medicine to help adults with **smoking cessation,** and oversaw the development of the brand's strategic planning and execution. Navin began his career as a management consultant in Accenture's Health and Life Sciences practice, spending seven years serving a variety of pharmaceutical clients, including Pfizer, AstraZeneca, Johnson & Johnson, and Takeda. In addition to his daily responsibilities, Navin serves on the Board of the Columbia University Business School's Healthcare Management Program. Navin holds a Master of Business Administration from Columbia University in New York City, and a Bachelor of Science in Chemical Engineering from the University of Illinois at Chicago.

Adam Kroetsch serves as the Deputy Director for the Office of Program and Strategic Analysis in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). The office supports several important strategic initiatives in CDER, including economic analysis of FDA policies and decision support for CDER's benefit-risk assessments of drugs. In his time at FDA, Adam has managed and carried out research and analysis projects in a range of topics, including drug shortages, drug labels and boxed warnings, drug safety, and the safe use of opioid analgesics. Adam began his career with FDA in 2008 as an analyst in OPSA's Economics Staff. He received his undergraduate degree from Cornell University and his Master of Science in Public Policy and Management from Carnegie Mellon University.

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James Marttila is the head of the Formulary and Pharmaceutical contracting area for Mayo Clinic. Originally employed to start up Outpatient Pharmacy services at Mayo Clinic 26 years ago, he created the contracting area for outpatient and managed care pharmaceuticals which was eventually evolved to include the 22 hospitals that Mayo Clinic acquired or constructed over the past three decades. He helped develop a system wide formulary for pharmaceuticals 18 years ago to assist in the coordination of a more efficient clinical approach to cost effective pharmaceutical use across the Mayo Clinic hospitals, clinics and managed lives, and more recently to determine alternate therapy during drug shortages. Prior to this, he taught at the University of Minnesota in the areas of Clinical Pharmacy and Pharmacy Administration. He also was a consultant in the managed care and nursing home industries from the mid-seventies to 1987. He has won awards for innovative practice from APhA, VHA and Mayo Clinic. He has authored published papers and book chapters on a number of topics over the past 40 years, in addition to numerous presentations. He has served on the boards of national and state professional organizations plus community groups.

Daniel Motto is an Executive Vice President at Hikma Pharmaceuticals, with responsibility for leading the company's US Injectables business. He and his team focus on providing a broad portfolio of quality medicines to doctors, pharmacists, hospitals and the patients they serve. Today Hikma is a top supplier of generic medicines and it is estimated that one out of every six generic injectable medicines used by US hospitals is a Hikma product. Dan has spent almost 20 years in the pharmaceuticals industry, gaining extensive experience and insight from his leadership roles across multiple functions. He began his pharmaceutical career at Johnson & Johnson, and then moved into the generic industry, holding senior roles at Novartis/Sandoz, Actavis and Teva. Dan joined the Hikma team in early 2018. Dan earned a bachelor's degree Environmental Science from Rutgers University, a master's degree in Civil and Environmental Engineering from Cornell University's College of Engineering and a Master of Business Administration from Cornell University's Johnson Graduate School of Management.

Lee Rosebush currently serves as a Partner at Baker Hostetler, where he is the Chair of the Pharmacy and Reimbursement team and co-Leader of the FDA practice, and as the Chairman of the OFA (Outsourcing Facility Association). With a background as a defense and regulatory attorney who has also worked as a registered pharmacist (and still holds these licenses today), Lee Rosebush provides his clients with legal counsel that is grounded in first-hand experience. In addition, Lee has a background that also includes post-graduate degrees in both finance and business, which means that Lee has the ability to smoothly shift between the legal, governmental, and pharmaceutical environments to help understand the more complete picture in the complex worlds of pharmacy and pharma. Active with the Drug Quality and Security Act (DQSA), as well as the Federal Food and Drug Administration's (FDA) regulation of pharmacy compounding, Lee speaks and writes on both issues, and is passionate about orchestrating and advocating for pharmacists and pharmacies.

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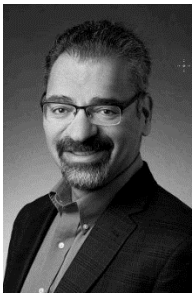
Matthew Rosenberg is an Operations Research Analyst on the Economics Staff within the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). In this role, he serves as an economic consultant and policy analyst for CDER and FDA Senior Leadership, helping to evaluate the impacts of FDA regulation on market structure and public health. Matthew's previous work at FDA has touched on areas such as drug shortages, drug pricing, safety labeling, and opioids. He holds a master's degree in Public Policy and Management from Carnegie Mellon University, and a bachelor's degree in Mathematics and Economics from Rensselaer Polytechnic Institute.

Jessica Settimi is Director of Strategy and Innovation at Patheon, part of Thermo Fisher Scientific. She joined Patheon in 2013 and prior to this role she served as Director of Strategic Marketing supporting Patheon Pharmaceutical Development Services and Biologics. Prior to her roles at Patheon, Ms. Settimi worked as a consultant through the Center for Innovation Management Studies focusing on the application of big data analytics in the biopharmaceutical industry. She earned a Master of Business Administration and Master of Microbial Biotechnology from North Carolina State University and holds a Bachelor of Science in Biotechnology from Rochester Institute of Technology.

Harsher Singh is the Chief Commercial Officer of American Regent, a subsidiary of Daiichi Sankyo. He is responsible for leading sales, marketing, business development, portfolio operations and commercial operations for American Regent's human Injectable businesses. Mr. Singh joined the company in January 2016. Prior to American Regent Harsher was an Associate Partner at McKinsey & Company in New York, where he worked with generic pharmaceutical, medical device, specialty pharmaceutical and private equity-owned healthcare companies on issues related to strategy, M&A, portfolio and commercial model innovations. Harsher holds a Bachelor of Science degree in economics from the London School of Economics and a master's degree in business administration from the Kellogg School of Management at Northwestern University.

Doug Throckmorton is Deputy Director for Regulatory Programs and shares responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks. Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the

FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital.



Yoram Unguru is a pediatric hematologist/oncologist at the Herman and Walter Samuelson Children's Hospital at Sinai and Core Faculty member, John Hopkins Berman Institute of Bioethics. He is also Assistant Professor in the School of Medicine, Johns Hopkins University. He completed his pediatric residency at the Children's Hospital at Sinai, his pediatric hematology/oncology fellowship at Children's National Medical Center, and was a postdoctoral Greenwall Fellow in Bioethics and Public Policy at Johns Hopkins University. Dr. Unguru is board certified both in pediatrics and in pediatric hematology/oncology. Dr. Unguru's research interests include clinical and research ethics. His scholarship and publications have focused on the role of children and providers in facilitating shared decision-making, end-of-life decision-making, allocation of scarce lifesaving medications, and ethics education. Dr. Unguru has served as an ethics consultant to national organizations, including the American Academy of Pediatrics and American Medical Association. He is on the Editorial Board of *Pediatric Ethicscope* and serves as a peer reviewer for leading academic medical journals. Dr. Unguru is a member of the Children's Oncology Group, Bioethics Steering Committee. Dr. Unguru is the Chairman of the Ethics Committee at Sinai Hospital of Baltimore where he implemented and directs a clinical ethics curriculum for the pediatric house staff at The Herman and Walter Samuelson Children's Hospital at Sinai. He is a recipient of "Teacher of the Year" as chosen by the pediatric house staff at The Herman and Walter Samuelson Children's Hospital. Dr. Unguru leads a multidisciplinary, transnational working group examining the ethical and policy implications of chemotherapy shortages in childhood cancer.

Martin VanTrieste brings over 35 years in the pharmaceutical industry—focusing on manufacturing and quality. He was ranked #2 on the 2018 Medicine Maker Power List of Industry Influencers. Martin VanTrieste was the Chairman of the Parenteral Drug Association (PDA) Board of Directors. The PDA represents over 10,000 members, and is the leading global facilitator of scientifically sound, practical technical information, quality systems and expertise to advance pharmaceutical/biopharmaceutical manufacturing science and regulation so members can better serve patients. He recently retired as the senior vice president of quality at Amgen. He was responsible for quality assurance, quality control, compliance, operational excellence, environment, health and safety along with training at Amgen. Prior to joining Amgen, VanTrieste was with Bayer Healthcare's Biological Products Division as vice president of worldwide quality and Abbott Laboratories as the vice president of quality assurance for the Hospital Products Division. While at Abbott, VanTrieste held various positions in Quality, Operations, and Research and Development. He started his career at Abbott in 1983 after obtaining his Pharmacy degree from Temple University School of Pharmacy.

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Heather Zenk is Senior Vice President, Replenishment and Manufacturing Operations at AmerisourceBergen Corporation. In this role, she has responsibilities for developing and implementing traceability business processes and technology that will enhance patient safety, further secure the pharmaceutical supply chain and create broader service offerings to manufacturer partners and AmerisourceBergen customers. In addition, Heather also manages replenishment operations for the enterprise as well as manufacturer programs and data. Heather has over 15 years of pharmacy, procurement and supply chain experience, which she has utilized in her career at AmerisourceBergen including that of Vice President, Distribution Center Manager at the Chicago Distribution Center, SAP business liaison; and running operations at the Canadian Distribution network. Heather received a Bachelor of Arts degree from the College of St. Benedict, St. Joseph, MN, and a Doctor of Pharmacy degree from the University of Minnesota.

Duke-Margolis Moderators:

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and in Washington DC. The new Center will support and conduct research, evaluation, implementation, and educational activities to improve health policy and health, through collaboration across Duke University and Health System, and through partnerships between the public and private sectors. It integrates the social, clinical, and analytical sciences to integrate technical expertise and practical capabilities to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a doctor and an economist, and his work has addressed a wide range of strategies and policy reforms to improve health care, including such areas as payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and more effective drug and device innovation. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. He also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food & Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA, is a member of the National Academy of Medicine and chairs the Academy's Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He has also previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury.

He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

Gregory Daniel is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel's research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoeconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes form the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.