Duke | Robert J. Margolis, MD Center for Health Policy

Building a Common Risk Evaluation and Mitigation Strategies (REMS) Platform

Hotel Monaco • Washington, DC

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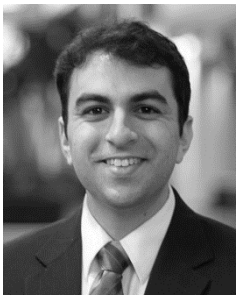
Biographies

Gregory Daniel, PhD, MPH, 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.

Michele V. Davidson, RPh is Manager, Pharmacy Technical Standards, Development and Policy within Walgreens, Government Relations and Immediate Past Chair of the Board of Trustees within National Council of Prescription Drug Programs (NCPDP). Michele graduated from the University of Florida with a B.S in Pharmacy. In her current role at Walgreens she ensures compliance with HIPAA standards throughout all business units. She engages and advises members of the government relations team and engages with stakeholders within and outside the company about pharmacy technical standards through direct participation in organization such as the National Council of Prescription Drug Programs (NCPDP). She has been very active in NCPDP over the past 15 years and is currently serving as NCPDP Immediate Past Chair of the Board of Trustees. She was co-chair of WG 11 (ePrescribing and Related Transactions) for 8 years and is the current lead of the ePrescribing REMs task group. She is the 2014 recipient of NCPDP's TIME (The Individual Member Excellence) Award. She is a member of NACDS, HIMSS, eHI and serves as the NCPDP representative on the Pharmacy HIT Collaborative Coding Work Group and is their ASC-X-12 representative.

Andrew Gettinger, MD is the Chief Medical Information Officer (CMIO) and the Executive Director of the Office of Clinical Quality and Safety. Prior to joining ONC, he was Professor of Anesthesiology and adjunct Professor of Computer Science at Dartmouth and the Geisel School of Medicine at Dartmouth and was the CMIO for Dartmouth-Hitchcock and Associate Dean for Clinical Informatics at Geisel. Gettinger has extensive experience in the field of health information technology. He led the development of an electronic health record (EHR) system at Dartmouth and subsequently was the senior physician leader during Dartmouth's transition to a vendor-based EHR. Gettinger's clinical practice and research has been focused on anesthesiology, critical care medicine, and on information technology as it applies generally to health care. He founded the clinical informatics group at Dartmouth. He has been an active participant in the policy debates regarding patient privacy at both the state and federal level testifying before the Senate HELP Committee and participating as a member of the NH Legislative Taskforce on Privacy. In 2012-13 he completed service in Senator Orrin G. Hatch's office as a Robert Wood Johnson Health Policy Fellow. Dr. Gettinger received his A.B. from Dartmouth College and his M.D. from Dartmouth Medical School. He trained at the Hartford Hospital, Boston Children's Hospital, and Dartmouth-Hitchcock Medical Center in anesthesiology, pediatric anesthesiology, and critical care medicine. He is board certified in anesthesiology, critical care medicine and was among the inaugural cohort of physicians certified in clinical informatics by the American Board of Preventive Medicine in 2013.



Adam Kroetsch advises senior staff at FDA's Center for Drug Evaluation and Research on key issues related to policy and informatics. For the past several years, he has led numerous efforts within the agency to standardize Risk Evaluation and Mitigation Strategies (REMS), integrate them into the healthcare delivery system, and better measure their effectiveness. He is currently overseeing the development of the Common REMS Platform as well as an effort to capture structured information about REMS using Structured Product Labeling (SPL).

Marie Link, RPh, PharmD is Founder and President of REMS Logic, specializes in medication risk management and FDA REMS programs. Prior to REMS Logic, Marie worked for nine years for University Hospitals of Cleveland, a large integrated delivery network with more than 25,000 employees where she served as the System Medication Safety Officer. There she was responsible for performance improvement and HIT integration of clinical decisions related to the use of medications by all clinical disciplines across 18 facilities and reported to hospital leadership on progress and outcomes. Marie brings with her 23 years' experience in healthcare and pharmacy practice and is passionate about Healthcare Information Technology, Clinical Decision Support and advanced, predictive analytics to accelerate medication safety. Marie obtained her R.Ph. from The Ohio State University and Doctorate from the University of Kansas with a 4.0 GPA. Marie maintains membership and advisory roles with IPRO, ASHP, the National Pharmacy eHIT Collaborative and Leadership Ohio.

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Mark McClellan, MD, PhD, 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 and 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.

Gerald McEvoy, PharmD is Assistant Vice President of Drug Information at ASHP. In addition, Dr. McEvoy has served as Editor in Chief of AHFS Drug Information (AHFS DI), ASHP's federally recognized drug compendium, for over 30 years. Dr. McEvoy is responsible for a variety of publishing and database management projects within ASHP focusing on dissemination of drug information in both electronic and print formats to various audiences, including healthcare professionals and patients. Dr. McEvoy also participates in the development of medication data transfer standards through work with the National Council for Prescription Drug Programs (NCPDP). He currently serves as Co-lead of NCPDP's SPL Activities Task Group, its SPL REMS Requirements Task Group, and its Naming Standards for Drugs, Biologics, and Biosimilars Task Group. Dr. McEvoy was the originator of the proposal to standardize and codify REMS through SPL in November 2010, and subsequently recommended at FDA's public meeting in July 2013 that the agency designate as one of the 4 priority projects outlined by PDUFA V the implementation of a standardized, highly structured and codified electronic submission requirement for REMS using the SPL model and public access via DailyMed.

J. Marc Overhage, MD, PhD is Chief Medical Informatics Officer for Cerner Corporation, is a distinguished medical informatician-internist who has conducted groundbreaking research in clinical decision support, interoperability of electronic healthcare data and large scale analysis of healthcare data. Perhaps more importantly he has championed implementation of these technological approaches at the academic medical center level, regional level and eventually national level. For example, he built pioneering work done by his colleagues at the Regenstrief Institute to establish the Indiana Network for Patient Care which he then evolved into the self-sustaining, non-profit Indiana Health Information Exchange which is by any measure the largest health information exchange in the US which support care for millions of patients across the State of Indiana and surrounding geographies. He also initiated [with others] the Observational Medical Outcomes Project, the results of which, are fundamentally transforming the approach to analyzing and interpreting observational data – a core capability of a learning health system. And as an international thought leader, his scholarly and applied contributions have dramatically impacted national policy and practice in informatics.

Roger Pinsonneault, R.Ph. is the Vice President, Product Innovation for Gemini Health. Roger is an energetic, results-driven product innovation development professional. He has a demonstrated ability of conceptualizing and delivering new products and services that improve the delivery of pharmaceutical care. Roger joined Gemini Health in October, 2015. In his Product Innovation role, Roger leads a highly collaborative, cross-functional team to deliver best-in class user experience products for prescribers. He applies user-centered design methodologies to conceptualize new, and enhance existing, Gemini Health's cost transparency solutions. Prior to joining Gemini Health, Roger was the Vice President, Business Development at RelayHealth-Pharmacy, a business unit of McKesson Corporation, where he was responsible for pharmacy network innovation. At McKesson Corporation he was awarded the 2009 McKesson Chairman's Award for Innovation & Collaboration, recognized as a 2010 Distinguished Technologist, and recognized in 2013 as a McKesson Fellow. Previous to RelayHealth he was with Total Pharmacy Solutions as an Industry Consultant; Label Systems International – Vice President Business Development; NDCHealth – Vice President, Product Management and Director, Pharmacy Operations; and Eckerd Corporation - Director, Pharmacy Systems & Administration. He received his B.S. in Pharmacy from the University of Connecticut. He is a patent or co-patent inventor for 16 awarded patents from the U.S. Patent & Trade Office. He has been a member of the National Council for Prescription Drug Programs (NCPDP) since 1994 and is a current Co-Chair of Work Group 1 (Telecommunication) and co-leads the Real-Time Prescription Benefit Inquiry Task Group. He is the recipient of the 2002 NCPDP Time Award and 2007 NCPDP Benjamin D Ward Distinguished Member award.

Scott M. Robertson, PharmD, RPh, FHL7 is Principal Technology Consultant for Kaiser Permanente Health IT Strategy and Policy. He has held this role for more than 15 years, and managed Kaiser Permanente's Southern California Outpatient Pharmacy Systems for 10 years prior to that. Robertson is a current member of the National Council for Prescription Drug Programs Board of Trustees and serves as co-chair of Work Group 10 Professional Pharmacy Services. In Health Level 7 International (HL7), Scott was a founding co-chair and current co-chair of the Pharmacy Work Group, serves as an editor for HL7 v2.x and publishing facilitator for HL7 v3 Pharmacy. He has been recognized as a Fellow of HL7. Additional experience includes participation in ISO TC215 Healthcare WG6 Medications, the Technology Advisory Council of the Academy of Managed Care Pharmacy (AMCP), clinical faculty at the University of Southern California School of Pharmacy, and a variety of inpatient and outpatient pharmacy positions. Robertson received his Doctor of Pharmacy from the University of the Pacific in Stockton, California.

Paul Sheehan joined Celgene Corporation in 2005, and is currently the Head of the U.S. REMS department where he is responsible for the operations, modifications, and assessments of Celgene's REMS programs for REVLIMID®, POMALYST® and THALOMID®. Paul has 17 years' experience working in the pharmaceutical risk management industry, and previously was the head of global risk management operations at Pharmion, and a consultant at SI International who designed, developed and managed risk management programs for a number of pharmaceutical companies. Paul holds a BSc (Hons) Information Systems Management from Bournemouth University, England, is completing his Master's Degree in Healthcare Law from Seton Hall University School of Law, and is a Certified Professional in Health Information and Management Systems. Paul has co-authored a number of articles about pharmaceutical risk management, and presented at international conferences about the subject.

Shelly Spiro, RPh, FASCP is Executive Director of the Pharmacy HIT Collaborative (Collaborative). The Collaborative is an organization of the major national pharmacy associations and associate members focused on advocating and educating key stakeholders regarding the meaningful use of health IT and the inclusion of pharmacists within a technology-enabled integrated health care system. The goals of the Collaborative are to assure pharmacists' services through health IT are accessible, can connect, and support national quality initiatives. Spiro is active in national pharmacy associations, standards development organizations (NCPDP, HL7 and X12) and is a leader in Pharmacy HIT including 2014 appointment to Federal Advisory Committees Health IT Policy Committee's Interoperability and Health Information Exchange Workgroup. She is an American Society of Consultant Pharmacists (ASCP) Past President, ASCP representative member of the LTPAC HIT Collaborative, and 2014 Archambault Award recipient. She has authored several articles and is a national speaker on topics relating to various professional pharmacy, HIT systems and electronic prescribing.

Katie Stabi, PharmD, BCPS is the Clinical Coordinator for Drug Use Policy and Compliance at the University of Chicago Medicine. Her primary job responsibilities include formulary management, drug shortages, policies and procedures, and REMS implementation. Katie previously was the REMS Pharmacist at Cleveland Clinic, where she coordinated REMS programs for the health system.

Annette Stemhagen, DrPH, FISPE is an epidemiologist with more than 30 years of public health research experience, including 20 years in safety surveillance of pharmaceutical, biotechnology and vaccine products. She is the Senior Vice President of Safety, Epidemiology, Registries and Risk Management within United BioSource, where she provides strategic consultative services to pharmaceutical, biotech and medical device clients. Dr. Stemhagen has specific expertise in safety surveillance and design, implementation, and analysis of epidemiologic studies, registries, large streamlined safety studies and actual use and observational studies for products in Phase IIIb and post approval. She has designed and evaluated risk assessment studies, including more than 50 regulatory-mandated long term global safety studies. She has designed risk intervention programs, risk management evaluation studies, Risk Minimization Action Plans (RiskMAPs), Risk Evaluation and Mitigation Strategies (REMS), and risk minimization programs for EU Risk Management Plans for more than 100 products. Dr. Stemhagen is active in the International Society for Pharmacoepidemilology and the Drug Information Association. She served on the Board of Directors for each of these organizations. Dr. Stemhagen has held adjunct faculty appointments at the University of Pennsylvania Center for Epidemiology and Biostatistics in the School of Medicine, the Temple University School of Pharmacy and the Drexel University School of Public Health. In 2004, Dr. Stemhagen was appointed as the first Industry Representative to the FDA Drug Safety and Risk Management Advisory Committee.

Theresa (Terry) Toigo, RPh, MBA Associate Director for Drug Safety Operations, Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA) is the lead for CDER's Safety First Initiative. She is responsible for the creation and oversight of CDER processes for management of cross-Office and cross-Center safety projects, including REMS. Immediately prior to returning to CDER in October 2010, Ms. Toigo served as Director, Office of Special Health Issues for 15 years, working with patients, their advocates, and health professionals to encourage and support their active participation in FDA regulatory decision-making. Ms. Toigo joined FDA in 1984, working as a Consumer Safety Officer in CDER. She held various FDA positions in CDER, the Center for Biologics Evaluation and Research, and the Commissioner's office. Ms. Toigo received her pharmacy (BS) and business (MBA) degrees from Rutgers University. She completed a pharmacy residency at the USPHS Hospital in Staten Island, NY.

Kelly Wygal is Vice President, REMS Business Development, McKesson Specialty Health. For the past seven years, Kelly as served as the national leader for REMS business development at McKesson focused on both individual products and class-wide single shared system REMS programs. In this strategic role, she is the primary point of contact for advancing the portfolio of REMS services for manufacturer sponsors across the entire McKesson organization. Kelly brings expansive business development experience, both as an individual performer and sales leader. She has an extensive sales and marketing background with more than 20 years' experience in the healthcare industry, and has worked on both the pharmaceutical manufacturer and supplier sides of industry. Having joined McKesson in 2001, Kelly represented the manufacturer-focused business development team for specialty products. Kelly also served as an executive director of client relationships and filled a role serving as the primary point of contact across McKesson's portfolio of services for strategic accounts, including reimbursement, co-pay assistance, distribution and specialty pharmacy services. Additionally, Kelly lead the business development teams for health informatics, research and marketing services for manufacturers as an extension of McKesson's US Oncology business.