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Margolis-FDA Workshop: Challenges and Opportunities for REMS Integration, Innovation, and Modernization

Virtual Public Workshop

October 11, 2022 | 1:00-5:15 p.m. ET

Speaker Biographies

Lane Abernathy is a retired architect who was diagnosed eleven years ago with Hereditary Transthyretin Amyloidosis (hATTR) a progressive, multisymptomatic and often fatal genetic disease that usually manifests in cardiac issues and autonomic and sensory-motor neuropathy. Her father died of this disease in 1968 after a horrible end of life for which the only treatment was palliative care. He had been bed bound for several years prior to his death. At the time of Lane's diagnosis there was very little information available about the disease and no treatment other than for the specific symptoms themselves and possibly liver transplantation. Lane had both a liver and a heart transplant in 2012.

In the years since, Lane has been very involved in the National Amyloidosis Support Group and has presented her experience with the disease to physicians at Annual Heart Failure Symposiums and at many smaller educational meetings with cardiologists and neurologists in an effort to help raise awareness about this disease. She also volunteers as a mentor to newly diagnosed hATTR patients helping them access information and answering their questions about her personal experiences with the disease. A coach, speaker, and Operations Board member for the Amyloidosis Speakers Group in conjunction with the non-profit Mackenzie's Mission, Lane helps patients prepare and share their medical journeys with second-year students and residents at medical schools across the country in an effort to help these future practitioners become aware of this often misdiagnosed and certainly underdiagnosed disease.

Laurie Adami had a 25-year career in financial services and was President of Los Angeles-based fixed income software firm Capital Management Sciences. Diagnosed with incurable Stage IV follicular non-Hodgkin lymphoma at the age of 46 in 2006, Laurie spent 12 years in continuous cancer treatment. She had seven different lines of therapy including 3 clinical trials, but the first 6 therapies failed to produce complete remission. In 2018, as her seventh treatment, she received CAR-T in a clinical trial and finally achieved a complete remission where she remains today.

Laurie spends considerable time assisting cancer patients navigating the challenges a cancer diagnosis brings. She is a Leukemia & Lymphoma Society (LLS) First Connection volunteer, an LLS Public Policy Volunteer Advocate, and an active volunteer fundraiser for LLS, currently raising $250,000 for LLS funded immunotherapy research grants.

Laurie was a Russian language and International Relations major at Colgate University. She resides in the Hollywood Hills in Los Angeles with her husband, Ben, and they have a son, August who graduated from college in Washington D.C. in May 2022. August was in kindergarten when Laurie was diagnosed and spent his entire elementary, middle and high school years with a mom in cancer treatment.

Danielle Boyce is a researcher at the Johns Hopkins University School of Medicine. In her more than 25-year data analytics career, she has worked with academia, industry, government, and nonprofits. She has also served on numerous patient and caregiver advisory panels including those for industry, nonprofit patient advocacy groups, FDA, and PCORI. Danielle's work to improve the REMS program is inspired by her oldest son, Charlie, a person with a rare and severe form of epilepsy who has interacted with the vigabatrin REMS program for more than a decade.

A.J. Burnett, PharmD, is a pharmacist working for Intermountain Healthcare as part of an Internal Process Control Team focusing on compliance. His role is to ensure compliance with regulatory and accreditation bodies for hospital, community, and medical group service lines. He has worked in his current role for 7 years; prior to this role he was a hospital director and community pharmacy manager.

He is passionate about his job and enjoys learning new ways to find success in a heavily regulated profession. He values patient safety and tries to ensure a safe, caring environment in all Intermountain facilities.

He enjoys single track motorcycling with his two sons and attending recitals and plays his two daughters participate in.

Robert O. Cotes, MD, is an Associate Professor at Emory University School of Medicine in the Department of Psychiatry and Behavioral Sciences. He is a practicing psychiatrist, educator, and researcher. He is Director of the Clinical & Research Program for Psychosis at Grady Health System, which comprises of two clinical programs: 1) PSTAR Clinic (Persistent Symptoms: Treatment, Assessment and Recovery) and 2) Project ARROW (Achieving Recovery through Resilience, Optimism, and Wellness). The PSTAR Clinic provides evidence-based, recovery-oriented care for individuals with persistent symptoms of psychosis, specializing in the use of clozapine. He is a member of the Clinical Expert Team for SMI Adviser (www.smiadviser.org), which is funded by the Substance Abuse and Mental Health Services Administration and administered by the American Psychiatric Association. SMI Adviser provides evidence-based resources to clinicians, individuals with serious mental illness, and their families. For SMI Adviser, he co-chairs the SMI Adviser Clozapine Center of Excellence. He has been actively involved in discussions with the FDA and the Clozapine Product Manufacturer's Group regarding changes to the clozapine REMS system.

Lauren DiCristofaro is a Lead Software Systems Engineer at The MITRE Corporation. She has 10+ years of experience applying systems thinking to critical problems across various government organizations. Lauren specializes in healthcare data standards and interoperability, and her technical experience has spanned telehealth technical research, clinical quality measurement, and certified HealthIT tracking. She has worked with several HHS agencies, including CMS and ONC, and her most recent work with FDA focuses on finding opportunities for a more efficient and effective FDA REMS (Risk Evaluation and Mitigation Strategies) program.

Lauren holds a B.S. in Computer Science and Engineering Physics from Cornell University and an M.S. in Computer Systems Engineering with a concentration in Engineering Software Design from Northeastern

University. She has several years of experience with HL7 FHIR including participation in multiple HL7 FHIR Connectathons, and she is also a recent member of NCPDP.

Ilona Frieden, MD, is Professor of Pediatrics and Dermatology at the University of California San Francisco School of Medicine. She currently serves as Chair of the American Academy of Dermatology Association iPLEDGE workgroup, which has been advocating for reforms in iPLEDGE, the isotretinoin REMS program for several years. She has served in many professional leadership roles including President of the Society for Pediatric Dermatology, the American Board of Dermatology and the Pediatric Dermatology Research Alliance. For 12 years she served as co-editor-in-chief of the journal, Pediatric Dermatology. She has authored more than 300 articles and numerous book chapters.

Cathy Graeff, RPh., MBA, is CEO of Sonora Advisory Group, a consulting firm offering prescription drug program advisory services including litigation support and expert testimony related to NCPDP standards.

In her role as a panelist for this Margolis-FDA Workshop, Cathy represents her long-time client, the National Association of Chain Drug Stores.

Cathy has over thirty years' experience in senior and executive management roles in healthcare organizations including pharmacy management organizations, pharmacy benefit managers, HIT system developers, and Medicaid managed care organizations.

Cathy is currently Co-chair of the National Council for Prescription Drug Programs (NCPDP) Work Group 10 Professional Pharmacy Services and has a deep understanding of NCPDP and its many industry standards. She has held a number of lead roles at NCPDP including the current Digital Therapeutics Task Group and the Pharmacy Service Billing Task Group.

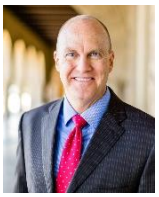
Cathy also serves on the USP Health Information and Technology Expert Committee where she recently served as Vice-Chair. She also participates on the USP Compounded Preparation Exchange Expert Panel.

Michelle Kershaw, PharmD, MS is a Senior Manager at CVS Health with 20 years of pharmacy experience. After graduating from the University of Southern California, School of Pharmacy in 2009, Michelle served in the Medical Unit at the US Embassy in Moscow. After leaving the Embassy, Michelle was a Pharmacy Manager and District Pharmacy Supervisor in southeastern Virginia before shifting to CVS Health's corporate office. She led the retail customer experience and end-to-end pharmacy workflow team until moving to her current role in Industry Relations and Strategic Product Management. Under her current role, Michelle's focus is with healthcare industry standards development, government program compliance and product innovation. Michelle lives in New England with her husband, John, two daughters, Madison and Regan, and adopted Russian cat, Sergei.

Michele Kidd, Pharm.D., is a residency-trained pharmacist with specialty and hospital experience. She joined Accredo, a specialty pharmacy, in 2005 and is the Senior Manager Clinical Technology over the development, implementation, and monitoring of system generated DUR and regulatory rules. In addition, she has extensive experience in REMS implementation, management, and monitoring. Michele is currently a Co-Chair of NCPDP's

Specialty Workgroup and is a co-lead of the Specialty Requirements for ePrescribing Task Group housed within the Specialty Workgroup.

Jason Leedy is an entrepreneur, technologist, and business executive with over 15 years' experience in REMS. He is currently Corporate Vice President, Technology Strategic Design and Innovation at United BioSource, LLC (UBC). He is the founder and former president of both Gigamoto, LLC, and Examoto, LLC. which was recently acquired by UBC. Examoto, a UBC Company, focuses on innovation with the goal of maximizing the benefits and safe use of prescription drugs, while reducing the burden to patients, healthcare providers, and the healthcare delivery system.



Sean Mackey, MD, PhD, is Chief of the Division of Pain Medicine and Redlich Professor of Anesthesiology, Perioperative and Pain Medicine, Neurosciences and Neurology at Stanford University. Dr. Mackey received his BSE and MSE in Bioengineering from University of Pennsylvania, and his PhD in Electrical and Computer Engineering, as well as his MD from University of Arizona.

Under Dr. Mackey's leadership, Stanford Pain Management Center has twice been designated a Center of Excellence by the American Pain Society (APS). As Director of Stanford Systems Neuroscience and Pain Lab (http://snapl.stanford.edu/), his primary research interest involves the use of advanced psychophysical, neurobehavioral and neuroimaging tools to investigate chronic pain.

Currently, he is developer of a free, open-source learning health system—CHOIR (http://choir.stanford.edu). He has served as principal investigator for multiple NIH (P01, R01's, R61, U01, K24, T32, R21) and foundation sponsored grants to investigate mechanisms of chronic pain.

Dr. Mackey is author of over 200 journal articles and book chapters in addition to numerous national and international lectures. He co-authored the Institute of Medicine's report, *Relieving Pain in America*. He was co-chair of the Oversight Committee for the NIH/Health and Human Services *National Pain Strategy (NPS*), an effort to establish a national health strategy for pain care, education, and research. In the last few years, he has received APS's Wilbert E. Fordyce Clinical Investigator Award, AAPM's Pain Medicine Fellowship Award, Distinguished Service Award, and Robert G. Addison, MD Award, and NIH Directors' Award for his efforts on the NPS.

Sahil Malhotra is a Software Systems Engineer at The MITRE Corporation with a few years of software engineering experience across various domains such as Healthcare, GPS/Navigation, Networking, Commercial Payment Processing, Artificial Intelligence/Machine Learning, and Cyber Security. Sahil also has technical leadership experience, operating as the Technical Lead and Scrum Master on different professional projects.

Sahil graduated with a B.S. in Computer Science form the University of Massachusetts Amherst back in May of 2021 and has been working with government agencies at MITRE since. His most recent work involves HL7 FHIR healthcare data standards development. On one project, he supports the Reference Implementations for the DaVinci Burden-Reduction/Prior-Authorization use case for CMS. On the other project, he works on prototype development for the FDA's Risk Evaluation and Mitigation Strategies (REMS) use case, which is run under HL7 CodeX.

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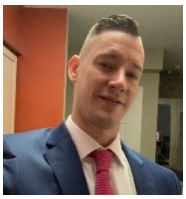
Jennifer Martin received her Doctorate of Pharmacy from the University of Illinois at Chicago College of Pharmacy in 2004 and subsequently completed a Psychiatric Pharmacy Practice Residency at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center in 2005. She became a Board Certified Psychiatric Pharmacist in 2006. Since that time, Jennifer has functioned in a variety of different roles during her employment with the VA including Clinical Pharmacy Specialist – Mental Health, PGY-2 Residency Director, and Associate Chief of Pharmacy at the Captain James A Lovell Federal Health Care Center. Jennifer is currently the Deputy Chief Consultant, VA Pharmacy Benefits Management Service. In her current role, Jennifer oversees activities related to formulary management, data management, and pharmaceutical contracting.

Dr. Ann McGee has spent her career practicing pharmacy at an academic medical center. She has served for the past 10+ years as the Director of the Center for Medication Policy at Duke University Health System. Dr. McGee is fortunate to work with a team of pharmacists, who collaborate with healthcare professionals across the health system to promote safe, effective and fiscally responsible use of medications. Engaging with healthcare professionals across the health system is key to establishing medication formulary policies, including REMS. In addition, she participates in drug shortage management and medication stewardship activities. The Center for Medication Policy also investigates and responds to medication related queries from health care professionals. She serves as the Director of the Drug Information Residency Program and finds particular enjoyment in the teaching and research roles that come with working in an academic medical center.



Ed Millikan, PharmD, is the Senior Informatics Pharmacist in the Division of Mitigation Assessment and Medication Error Surveillance in the Office of Surveillance and Epidemiology (OSE), within FDA's Center for Drug Evaluation and Research. With over 20 years of experience as an informatics pharmacist, his background includes: REMS integration, drug information database development, healthcare terminologies (e.g., NLM RxNorm, SNOMED CT) and data standards (e.g., NCPDP SCRIPT, HL7® FHIR®), interoperability, and coding. Dr. Millikan currently serves as a champion for the HL7® CodeX® REMS Integration Use Case and is a co-lead for the HL7® Vulcan® Adverse Event project.

Dr. Millikan graduated magna cum laude from the Campbell University School of Pharmacy and completed a residency in Drug Information and Pharmaceutical Informatics at the University of California, San Francisco, and First Databank.

George Neyarapally, Pharm.D., J.D., M.P.H., R.Ph., works as a subject matter expert in the Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), FDA on regulatory science and policy initiatives and research. George also previously worked at MITRE/the Health Federally Funded Research and Development Center for the U.S. Department of Health and Human Services (HHS), as a Medicaid Pharmacy Director, in HHS as a Fellow at the Agency for Healthcare Research and Quality and the Assistant Secretary for Preparedness and Response, as a Congressional Health Fellow in the United States Senate, and as a drug information and safety pharmacist.

George received his B.S. in Finance from the University of Connecticut, Pharm.D. from the University of North Carolina, M.P.H. from the Johns Hopkins Bloomberg School of Public Health, and J.D. from the University of Maryland.

Nicole Ng is a Principal Software Systems Engineer at The MITRE Corporation with 10+ years of software engineering experience across a variety of domains including cyber security, defense, and healthcare. She holds a B.S. and an M.S. in Electrical Engineering from Tufts University, and specializes in leadership of health data interoperability projects.

In recent years, Nicole has supported the mCODE (minimal Common Oncology Data Elements) initiative, which aims to improve the quality and consistency of cancer data to improve patient care and clinical research. Nicole also has experience working with various HHS agencies, including ONC, and is currently working with FDA to explore opportunities for enhancing the FDA REMS (Risk Evaluation and Mitigation Strategies) program leveraging current technology around electronic health data exchange and data standards for REMS integration.

Dr. Diana Schreier is an informatics pharmacist at Mayo Clinic. She completed her PharmD and MBA degrees at Drake University and went on to complete her PGY1 pharmacy practice and PGY2 pharmacy informatics residencies at Mayo Clinic, Rochester. She specializes in clinical decision support, artificial intelligence, and healthcare quality.

John Simon is a patient advocate and was diagnosed with incurable, stage 4 follicular lymphoma in February, 2015. Although considered incurable, follicular lymphoma has an average survival of 18 years with a subset of patients resulting in early treatment failure (<2 years following Chemo/Immunotherapy). This subgroup of patients was originally titled the High Risk for Death Subgroup and later renamed the Progression of Disease within 24 months (POD24). John's disease pathway resulted in his becoming a member of this subgroup. In total, John failed 6 lines of treatment within the first 4 years after diagnosis.

In October, 2018, John and his healthcare team agreed to try a non-FDA approved protocol in the hopes of "bridging" a couple of months to hopefully allow John to participate in yet to open follicular lymphoma Chimeric Antigen Receptor T-Cell (CAR-t) clinical trial. The "bridging" treatment involved two drugs, Obinutuzumab and Lenalidomide, with Lenalidomide being managed using REMS. The plan was to continue with the protocol until it failed. To everyone's dismay, the protocol has yet to fail. John continued the protocol until March, 2022 when Obinutuzumab was discontinued due to cumulative toxicity and pathogen risk concerns. John continued use of Lenalidomide. In July, 2022, John achieved a complete remission for the first time since first being diagnosed in February, 2015.

The treatment plan going forward for John is to use Lenalidomide as a maintenance protocol similar to what has become a standard of practice for myeloma, but having not yet been evaluated as a maintenance protocol for lymphoma. The maintenance treatment plan is to continue Lenalidomide until either Lenalidomide is no longer tolerated by John's body or until return/progression of disease.

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Marta Sokolowska, Ph.D., is the Deputy Center Director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research (CDER). She serves as the center's executive-level leader responsible for advancing FDA's public health response to the non-medical use of substances with abuse potential. With expertise in science-based assessment and management of drug abuse risks, Dr. Sokolowska advises senior FDA officials on shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and behavioral health programs.

Dr. Sokolowska joined CDER in 2018 as Associate Director for Controlled Substances in the Office of the Center Director. In 2020, she began leading the Controlled Substances Program (CSP), which comprises the Controlled Substance Staff (CSS) and the Controlled Substances Initiatives (CSI) group. CSS provides consultation throughout FDA on evaluation of abuse potential of drugs and advises on all matters related to domestic and international drug scheduling. The strategy group pursues activities and policies to identify, mitigate, and manage emerging issues with controlled substances to minimize risks associated with problematic use while enabling appropriate access to these products for medical use.

Dr. Sokolowska is a recognized expert in drug abuse liability and scheduling strategies. She has facilitated numerous initiatives to improve public health by advancing the science of assessing drug abuse liability. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in psychology from McMaster University in Canada.

Duke-Margolis Moderators

Dr. Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Center for Health Policy in Washington, DC, strategically leading and managing the Center's RWE Collaborative. As an engagement expert, researcher, bioethicist, and policy practitioner, her work centers on addressing implementation and ethical, legal, and social implications issues at the intersection of health policy and innovation. She also partners with Duke University faculty, scholars, students, and external health experts to advance the Center's biomedical innovation work. She is presently adjunct faculty at rural Ohio University, teaching graduate courses in the Department of Interdisciplinary Health Science's Health Policy Certificate program, and has taught graduate courses within the Masters of Health Care Innovation program at the University of Pennsylvania's Perelman School of Medicine.

Prior to joining Duke-Margolis, Dr. Hendricks-Sturrup was Health Policy Counsel and Lead at the Future of Privacy Forum (FPF), leading the organization's health and genetic data initiatives and workgroup. Prior to FPF, she served in several administrative and scientific roles at various industry, health care, and academic institutions. To date, she has published several commentaries and original research papers in high-quality, peer-reviewed journals. Dr. Hendricks-Sturrup is also an accomplished health and science journalist, having completed a comparative effectiveness research fellowship with the Association of Health Care Journalists in 2017.

Dr. Hendricks-Sturrup received her Bachelor of Science in Biology from Chicago State University, her Master's in Pharmacology and Toxicology from Michigan State University, her Master's in Legal Studies from the University of Illinois, and her Doctor of Health Science from Nova Southeastern University. She

completed a predoctoral internship with the National Health Service in London, UK, and postdoctoral research training within the Department of Population Medicine at Harvard Pilgrim Health Care Institute and Harvard Medical School.

Dure Kim, PharmD, is an Assistant Research Director for the Biomedical Innovation portfolio, focusing on the Center's Cooperative Agreement with the FDA in the advancement of regulatory science and health policy research. Prior to joining Duke-Margolis, he was a Research Scientist at the National Evaluation System for health Technology Coordinating Center, where he helped manage and develop Real-World Evidence studies with medical device stakeholders and researchers. Dure received his Doctor of Pharmacy from Mercer University in 2016 and completed a fellowship in Comparative Effectiveness Research and Patient-Centered Outcomes Research at the University of Maryland, Baltimore in 2018.

Mark McClellan is the Robert J. Margolis, M.D., Professor of Business, Medicine and Policy and Director of the Duke-Margolis Center for Health Policy. A physician-economist focused on advancing quality and value in health care, his COVID-19 response work spans virus containment and testing strategies, resilient care delivery, and accelerating therapeutics and vaccine development. Dr. McClellan is a former leader of the Centers for Medicare & Medicaid Services and the U.S. Food and Drug Administration. An independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ, Dr. McClellan co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network and serves as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.