Introduction to Drug and Device Law and Regulation for Patient Organizations
November 18–19 & December 2–3, 2020
Virtual Event

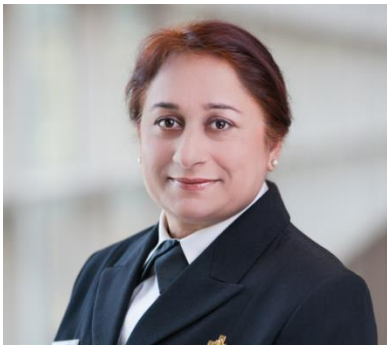
SUSAN CHITTOORAN is the Patient Engagement Project Manager on the Patient Affairs Staff at the Food and Drug Administration (FDA). In her role, Susan manages FDA's Patient Listening Session initiative, serves as the liaison between patients and subject matter experts within FDA's medical product centers, and assists in identifying and coordinating patient stakeholder participation in FDA meetings and workshops. Prior to joining Patient Affairs, Susan spent three years at FDA's Office of Health & Constituent Affairs & six years at the Women's Bureau, US Department of Labor. Susan has a MS in Social Work Policy from Columbia University, and a BA in Psychology from Auburn University.

MELISSA GOETZ is the Co-President and Co-Founder of the FCS Foundation (Familial Chylomicronemia Syndrome). Together with Lindsey Sutton, a patient living in California, Melissa and Lindsey started the FCS Foundation. Since then they have advocated for their patient population as active members of the National Lipid Association, National Pancreas Foundation, Global Genes and Rare Disease Legislative Advocates. In July 2020 they worked with congress to introduce "The Heart Act", which aims to work alongside the FDA to make the drug approval process more efficient for rare disease. You can find out more about the Heart Act at www.livingwithfcs.org/the-heart-act.

TRACY GRAY is the Patient Engagement Lead in FDA's Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST), Patient Science and Engagement Program. As the Patient Engagement lead, Tracy works in collaboration with internal and external stakeholders, to foster a culture of patient engagement in CDRH, through intentional, meaningful patient interactions that provide opportunities of mutual benefit to FDA, patient and caregiver communities. These partnerships help CDRH advance the development and evaluation of medical products in all phases of the total product life cycle. Prior to joining the FDA, Tracy held positions in the Health Resources and Services Administration (HRSA), as a Senior Nurse Consultant, Chief of the Nurse Corps Scholarship Program and Chief of the Advanced Nursing Education Branch, overseeing program operations, grant management and policy development that resulted in an increased supply of registered and advanced practice nurses, and nurse faculty working in rural and underserved areas across the nation. Tracy served as the Designated Federal Officer (DFO), for the National Advisory Council on Nurse Education and Practice (NACNEP), a council that makes recommendations to the Secretary and Congress, related to the nursing workforce, education and practice improvement. Tracy has worked for the benefit of patients throughout her healthcare career, while providing nursing care, leading grass-roots marketing and business development initiatives in a disproportionate share health system and working in the pharmaceutical industry to increase availability

of therapeutic drugs for chronic conditions. Tracy earned a BS in Biological Sciences, with a concentration in microbiology, from the University of Maryland, College Park, and earned a MBA from Marymount University, and a RN and MS degree from the University of Maryland School of Nursing, Baltimore, MD.

RYAN KAAT is a senior director at the Pharmaceutical Research and Manufacturers of America (PhRMA). At PhRMA, Ryan's portfolio includes a range of FDA- and IP-related matters. Prior to joining PhRMA, Ryan was an associate in Sidley Austin LLP's Food, Drug and Medical Device Regulatory Group.



SADHNA KHATRI is a regulatory officer in Professional Affairs and Stakeholder Engagement (PASE) in the Office of the Center Director in the Center for Drug Evaluation and Research at the US Food and Drug Administration (FDA). She is the Supervisor of the PASE Engagement team. She develops strategic contacts and outreach to other federal agencies, members of professional organizations, and health-related societies. She also organizes public workshops for patient advocacy groups, helping increase engagement with the FDA and helping the patient voice be heard in the regulatory process of drug development. Before joining PASE, Dr. Khatri was a senior pharmacist with CDER's Office of Communications' Division of Drug Information, responding to public inquiries concerning all aspects of drug review, regulation, and FDA's MedWatch program. She was also director of the FDA's Pharmacy Student Experiential Program (PSEP). As such, Dr. Khatri developed and implemented new measures to significantly improve the visibility of PSEP across the FDA, making it a highly-acclaimed and nationally-recognized program for fostering the development of the next generation of pharmacists. Modelling the success of PSEP, Dr. Khatri has also launched a new experiential program for medical students and residents to experience and understand the FDA's broad regulatory authority and responsibility in protecting the public health. Dr. Khatri joined the FDA from Kaiser Permanente, where she worked as the Director of the Mid-Atlantic Anticoagulation Services. She collaborated with clinical teams to launch a new electronic documentation system and created an automated workflow for clinical pharmacists to route correspondence to the pharmacy and providers. Dr. Khatri earned a Doctor of Pharmacy degree from the University of Maryland School of Pharmacy in 2000. She also holds a Master of Public Health degree from Morgan State University

PAMELA TENAERTS is the Executive Director at the Clinical Trials Transformation Initiative (CTTI) where she works closely with the Executive Committee to develop and implement strategies to accomplish CTTI's mission. She orchestrates efforts to effectively engage all interested stakeholders to improve the conduct of clinical trials. She is on the Board of Directors for the Society of Clinical Trials and a member of DIA's Advisory Council North America and DiMe Society's Scientific Advisory Board. She is an independent director on the board of TRxADE group, Inc. Dr. Tenaerts practiced medicine in both the emergency department and private practice setting before embarking on a career in research. Dr. Tenaerts received her MD from Catholic University of Leuven, Belgium, and an MBA from the University of South Florida. She speaks five languages and has obtained Six Sigma Green Belt certification.

JAMES VALENTINE is an attorney at Hyman, Phelps & McNamara, P.C. where he assists medical product industry and patient advocacy organization clients in a wide range of regulatory matters, including new drug and biologic development and approval issues. He has helped several sponsors secure FDA approval of new molecular entities, often for serious and rare diseases. James has also been central to the transition of the FDA Patient-Focused Drug Development (PFDD) program to externally-led meetings, having helped plan and moderated nearly 75% of the 30+ such meetings to date, and is also working on novel methodologies for capturing patient experience data. James has also authored an analysis cataloguing FDA's flexibility in assessing efficacy in the approval of drugs for rare, or orphan, conditions. Before joining the firm in 2014, James worked in FDA's Office of Health and Constituent Affairs (previously Office of Special Health Issues) where he facilitated patient input in benefit-risk decision-making and served as a liaison to stakeholders on a wide range of regulatory policy issues. James administered the FDA Patient Representative Program, facilitated stakeholder consultations during the reauthorization of PDUFA and MDUFA, helped launch the PFDD program, and developed the FDA Patient Network. In recognition of his work in advocating for rare disease patients, in 2019, Global Genes named him a RARE Champion of Hope. James is also an adjunct professor of food and drug law at the University of Maryland Carey School of Law. Mr. Valentine earned his law degree from the University of Maryland Carey School of Law and his Master of Health Science in health policy from the Johns Hopkins Bloomberg School of Public Health.

DAVID ZOOK is a strategy consultant and advocate on federal policy and regulatory matters. His practice focuses on complex challenges across the health and life sciences sector. Dave also leads the Faegre Drinker government and regulatory affairs group. Dave has a three-decade record of achieving concrete results with Congress, the Executive Branch, and government markets. Recent accomplishments include an array of health and science policy legislative provisions, several rulemaking projects, and various competitive funding outcomes. A number of these initiatives involved building nationwide coalitions such as the Collaborative for Effective Prescription Opioid Policies and PFDDworks. In the patient advocacy arena, Dave and his

firm colleagues have served over two dozen organizations on research, public health, regulatory and access topics. The group is a leader in developing precompetitive platforms for disease-specific purposes such as in patient-focused drug development and value-based reimbursement models.