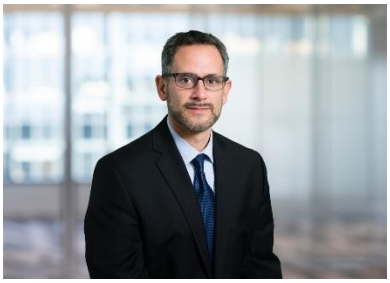
Introduction to Medical Device Law and Regulation
April 13-14, 2022
Speaker Biographies



SCOTT D. DANZIS is a partner at Covington & Burling LLP's Food & Drug and Health Care practice groups. His practice focuses on the regulation of medical devices and diagnostics. Mr. Danzis regularly works with companies in developing strategies for interacting with the US Food and Drug Administration (FDA), including strategies for clinical development and premarket review (including appeals and dispute resolution, when needed). He also advises on compliance with postmarket requirements, including advertising and promotion restrictions, quality system and manufacturing requirements, postmarket reporting, recalls, and enforcement actions.

KRISTIN M. ZIELINSKI DUGGAN is a partner at Hogan Lovells where she provides strategic advice to companies on scientific and US Food and Drug Administration (FDA) regulatory challenges, while always keeping business needs in mind. For over 20 years, she has been counseling cutting-edge companies regarding the development and regulation of medical devices, pharmaceuticals, and combination products. Kristin has a wealth of experience with the entire FDA regulatory process and agency interactions, from devising regulatory strategy for innovative products to pre-submission meetings; to assisting with preclinical and clinical programs and IDEs; to preparing regulatory submissions (510(k)s), de novo petitions and premarket approvals (PMAs); to appeals of agency decisions. Having prepared companies for dozens of advisory panel meetings over the years – including panel meetings to review 510(k) notices and PMAs, general issues panels, and classification panels – Kristin is a top thought leader in this area. She has been involved with all of the meetings of the Medical Devices Dispute Resolution Panel (MDDRP) to date. Kristin also assists companies with compliance challenges, including 483 and Warning Letter responses, adverse events reporting, recalls, Department of Justice (DOJ) investigations, and product liability litigation, as well as with due diligence for investments and acquisitions. Kristin's practice covers products in many therapeutic areas, including software products, cardiovascular products, orthopedic and gynecologic implants, plastic and reconstructive surgery devices, radiology devices, gastroenterology devices, wound care products, dental implants, endoscopes and minimally-invasive surgical solutions, and in vitro diagnostics. Kristin previously served as Vice President for Strategic Consulting at a Washington, DC-based scientific consulting firm. Throughout her career, she has published and presented on various FDA regulatory issues. She is also an adjunct professor teaching an experiential seminar on FDA Regulation of Medical Products (Medical Devices, Drugs, and Biologics), which is part of the Executive Master of Science in Health Systems Administration (EMHSA) program at Georgetown University's School of Nursing and Health Studies.

KYLE Y. FAGET is a special counsel and business lawyer with Foley & Lardner LLP. She is a member of the firm's Government & Public Policy Practice. Her practice focuses on advising clients regarding regulatory and compliance matters involving the Food, Drug & Cosmetic Act, the False Claims Act, the Anti-Kickback Statute, the AdvaMed Code, and the PhRMA Code. She has extensive experience in health law, life sciences, and a range of Food and Drug Administration (FDA) corporate and regulatory areas within the medical device and pharmaceutical industry. Additionally, she has provided clients with strategic and tactical advice regarding government and internal investigations. Her experience includes operationalizing and monitoring compliance with Corporate Integrity Agreements and Deferred Prosecution Agreements and managing Independent Review Organizations. Prior to joining the firm, Ms. Faget held several in-house positions. She has experience in all health care regulatory and compliance matters, including medical affairs, sales, marketing and promotion issues, health care provider grants and charitable donations, and health care professional research grants. She also has extensive experience drafting and negotiating agreements commonly utilized in the life science industry, including health care professional consulting agreements, informed consents, pre-clinical and investigator initiated and sponsor initiated clinical trial agreements.

DENNIS C. GUCCIARDO is a partner at Morgan, Lewis & Bockius LLP where he counsels domestic and global medical device manufacturers to help ensure they are operating in compliance with the myriad of US Food and Drug Administration (FDA) regulations, requirements, and expectations. He works with companies—from small startups to large multinational corporations—throughout the product life-cycle on how to bring novel technologies to market, maintain compliance, and avoid FDA enforcement actions. Dennis helps companies bring medical devices to market, including navigating the premarket process, establishing a quality system, and complying with postmarket requirements. Recently, in response to the coronavirus (COVID-19) global pandemic, Dennis assists companies (traditional medical device manufacturers and new market entrants) with navigating FDA enforcement policies and the Emergency Use Authorization (EUA) process for quickly bringing products to market. When FDA action does occur, Dennis works with companies to develop risk-based and right-sized action plans to address FDA concerns, including responding to FDA Form 483 inspectional observations, untitled letters, and FDA warning letters; FDA-requested certified audit programs; and preparing medical device recall plans.

QUYNH HOANG is a senior regulatory consultant in the FDA and Life Sciences practice of King & Spalding's Washington, DC office. She specializes in the FDA's premarket process for medical devices and combination products with a device constituent part (e.g., 513(g), 510(k), De Novo, IDE, HDE, PMA, RFD, and Reclassification Petition), as well as, in the FDA's postmarket process for adverse signals. She joined King & Spalding in 2014 after 24 years at the FDA's Center for Devices and Radiological Health.

SAMANTHA HONG is an associate at Kleinfeld, Kaplan & Becker where she advises clients in the food, drug, cosmetic, dietary supplement, and tobacco industries on wide-ranging legal and regulatory matters related to the Food and Drug Administration (FDA) and other federal and state agencies. As a former attorney at FDA, Samantha brings valuable insight regarding regulatory compliance matters and FDA enforcement actions. Prior to joining Kleinfeld, Kaplan & Becker, Samantha served as an Associate Chief Counsel in the Office of the Chief Counsel at FDA where she handled enforcement matters across all product areas and litigated challenges to agency actions on issues ranging from drug exclusivity and tobacco product policies to emergency use authorizations. In this role, Samantha worked closely with the US Department of Justice and was responsible for advising senior agency officials on case strategy, implications for agency policy development, and settlement negotiations. Samantha also previously served in the Office of the General Counsel at the US Department of Health & Human Services (HHS) where she advised various HHS components including the Office of Research Integrity and the National Vaccine Program Office. Prior to her government tenure, Samantha worked as a patent litigator at two international law firms.

ALAN G. MINSK is a partner and leader of the Food and Drug Practice Team at Arnall Golden Gregory LLP. Alan is licensed to practice in Georgia and Washington, DC. He works out of AGG's Atlanta and Washington offices. Alan is recognized by Chambers USA America's Leading Lawyers for Life Sciences, Regulatory/Compliance and has been selected for inclusion in the International Who's Who of Life Sciences Lawyers from 2013 – 2020. Nominees are selected based upon comprehensive, independent survey work with both General Counsel and private practice lawyers worldwide. He serves as general counsel of The Sharing Alliance Inc., a pharmaceutical trade organization focused on compliance with the Prescription Drug Marketing Act and sample accountability. Alan focuses his practice on advising pharmaceutical, biologic, medical device, cosmetic, food (including dietary supplements and medical foods) companies, on all legal and regulatory matters relating to the US Food and Drug Administration. For companies in the pre-approval phase, he counsels on the following areas: clinical trial issues,

communications with the FDA during the review process, imports and exports, regulatory strategy including 505(b)(2) new drug applications, orphan drug designation, Fast Track and Breakthrough Therapy designations, combination product determinations, market exclusivity, premarket notification (510(k)) submissions, premarket approval applications, and pre-approval discussions. In addition, Alan works with life science companies and venture capital firms on regulatory diligence matters involving acquisitions, divestitures, regulatory opinion letters, co-promotions and licensing agreements. He also drafts and reviews agreements relating to clinical trials, quality, and contract manufacturing. He conducts in-house training on FDA and fraud and abuse topics. Alan's client base is primarily focused on early-stage to mid-sized life science companies, where he must clearly articulate the legal and regulatory issues for consideration while also recognizing the client's business realities and needs. He currently serves on a number of editorial boards for professional publications, including the RAPS Focus magazine and the Food and Law Drug Institute's Food and Drug Law Journal.

BRANDON J. MOSS is a partner at Wiley LLP where she defends companies and their executives in complex civil and criminal cases involving alleged health care fraud, the False Claims Act (FCA), whistleblower allegations, the Foreign Corrupt Practices Act (FCPA), antitrust, regulatory violations, and contract and procurement fraud. She has extensive experience shepherding life sciences companies, government contractors, not-for-profits, and technology companies through internal investigations and responding to subpoenas and civil investigative demands (CIDs). She also advises a broad range of companies on privacy, telecommunications, compliance, Team Telecom, and new media issues.

ALLYSON B. MULLEN is a director in the Washington, DC office of Hyman, Phelps & McNamara, P.C. where she provides counsel to medical device and in vitro diagnostic (IVD) manufacturers. Ms. Mullen assists clients with a wide range of pre and postmarket regulatory topics including developing regulatory strategy, preparing regulatory submissions, drafting regulatory policies and procedures, reviewing advertising and promotional materials, and addressing enforcement matters. In the premarket area, Ms. Mullen prepares IDEs, 510(k)s, de novos, and PMAs. She also prepares pre-submissions, breakthrough device designation requests, and assists clients in preparing for and represents clients at pre-submission meetings with FDA. In the postmarket area, she advises clients on complaint handling, MDRs, field actions, advertising and promotion, and QSR compliance. Ms. Mullen also helps clients with contract matters and regulatory due diligence. Prior to joining the firm in 2013, Ms. Mullen worked as in-house counsel at Waters Corporation, an IVD company. In this role, Ms. Mullen conducted a range of legal and regulatory functions.

MAURA MARTIN NORDEN joined Greenleaf from the law firm Sidley Austin LLP in January 2015, following nearly a decade advising leading medical device and drug companies and investors on a broad range of FDA regulatory matters. Maura uses her comprehensive and in-depth understanding of the FDA's statutory jurisdiction, regulatory requirements, and regulatory processes to provide strategic advice to FDA regulated companies throughout the product lifecycle, from development to FDA premarket review and postmarket regulation. Maura advises a broad range of clients, including early-stage companies, large, multinational industry leaders, trade associations, and public health organizations. Maura received her JD, with honors, from the George Washington University Law School where she was an associate of The George Washington International Law Review. She received her BA from the University of Virginia where she was a Jefferson Scholar.

PREEYA NORONHA PINTO is a partner at King & Spalding LLP where she assists life science manufacturers with strategic reimbursement planning during all stages of the product life cycle. She also engages in healthcare regulatory and policy advocacy before government agencies and the US Congress. A former Health and Human Services Acting General Counsel and Department of Justice litigator, she helps healthcare clients seek regulatory and policy change and combat adverse government action arising from the Medicare and Medicaid programs, Food and Drug Administration regulation, fraud and abuse matters, and ongoing healthcare reform.

HEATHER ROSECRANS brings more than 40 years of public health and medical device experience to Greenleaf. She continues her commitment to public health by providing strategic consulting services and working with Greenleaf clients to deliver innovative devices to patients. Before joining Greenleaf, Heather served as Director of the 510(k) Premarket Notification Staff at the FDA's CDRH. In this role, she was responsible for implementing administrative and regulatory policy for the 510(k) Program, the 513(g) Program, Classification and Reclassification, de novo petitions, and other premarket regulatory requirements. Heather started her FDA career as a biologist in the Bureau of Medical Devices. In 1980, she joined the newly organized CDRH Premarket Application (PMA) Staff. For the next 7 years, she coordinated the administrative, scientific, and regulatory review of PMAs, as well as product development protocols, master files and associated submissions. In 1987, Heather joined the 510(k) Section of CDRH's

Program Operations Staff. In this role, she served as a Consumer Safety Officer and was a key contact for CDRH and within FDA on 510(k) matters. Heather held this position until 1992, when she became Director of the 510(k) Staff. Heather's accomplishments include drafting guidance documents and regulations on the 510(k) Program, training FDA staff and other stakeholders as well as assisting in the implementation of the Medical Device User Fee Modernization Act, the Food and Drug Administration Modernization Act and the Safe Medical Devices Act. Heather's extensive experience at CDRH—specifically her pivotal role in developing the 510(k) Program—enabled her to become one of the nation's leading 510(k) experts. Since its inception in 1976, more than 150,000 510(k)s for devices have been reviewed for a determination regarding substantial equivalence via the program. Heather has represented and spoken on behalf of CDRH in multiple forums, including national conferences, FDA advisory committee meetings, and international symposiums. Her published work includes numerous guidance and regulatory documents. She has also worked collaboratively with the Center for Medicare and Medicaid Services and other regulatory agencies. Heather holds a BS in Biology from Pfeiffer College in Misenheimer, NC.

SARAH H. STEC is Senior Counsel, Medical Device Regulatory Law at Johnson & Johnson. She has experience in assisting healthcare and life sciences companies understand new and evolving regulatory duties, including how those international regulations can work together as well as providing guidance on international corporate accreditation and regulatory issues. Her background in quality systems and experience with international regulators gives her a unique view on the legal and regulatory requirements for medical device, pharmaceutical, and food manufacturers.