Introduction to Medical Device Law and Regulation
November 16-18, 2021
Speaker Biographies

MICHAEL CHELLSON is Principal Consultant at NSF International. He as over 30 years of experience in the field of medical devices as a laboratory scientist, an operational quality assurance leader and a global quality and regulatory leader. He has focused on assisting organizations with Quality System integration and automation. Through practical executions of operations, regulatory affairs, and quality systems, he has developed and implemented risk-based solutions to integrate business functions and improve operational and quality performance. He's led technically-oriented projects focusing on design controls, verification and validation, process improvement, regulatory market clearance, risk management and implementation of corrective actions. In earlier roles, he served as Global Director RA with Sunrise Medical and VP RA/QA with ConMed Corporation. He also served on several U.S. FDA working groups, both as an industry partner in development of published FDA product safety guidance (SHBWG) and as a member of initial US FDA "case for quality" initiatives. Mr. Chellson began his career working with QA, microbiological and sterility testing for processed food. He then held increasingly senior positions in QA/RA leadership and consulting at small and large medical device manufacturers.

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.

RYAN M. FOURNIER is a partner at Wiley Rein where he counsels domestic and global companies regarding products that are regulated by the US Food and Drug Administration (FDA), the US Department of Agriculture (USDA), the Alcohol and Tobacco Tax and Trade Bureau (TTB), and relevant state agencies. Clients seek Ryan's counsel on a variety of regulatory and legal issues, including regulatory compliance, government inquiries, inspections, enforcement actions, food safety compliance, product life-cycle development, and transactional matters impacting the food and medical device industries. Ryan's experience extends to working with clients with new and emerging technologies, such as the at-home meal and online grocery delivery industries, companies involved in the life science industries, and those involved with various digital health platforms, such as mobile medical apps, software as a medical device (SaMD), telehealth, wearable devices, and other health technologies. During the coronavirus (COVID-19) pandemic, Ryan assists companies navigating the FDA's enforcement policies and helps companies bring products to market through designated pathways as quickly as possible, such as the Emergency Use Authorization (EUA) process. Additionally, Ryan regularly handles issues relating to medical device reporting requirements, regulatory pathway options, market entry, current good manufacturing practices (cGMPs) and quality system regulation (QSR) compliance, and postmarket compliance. He regularly assists all actors in the supply chain, including manufacturers, distributors, and retailers.

MICHAEL M. GABA is a shareholder at Polsinelli PC where he provides strategic FDA regulatory, Medicare policy, and federal relations counsel to an array of companies developing a variety of products in the life sciences space, whether traditional medical devices, digital health-based products, biotechnologies, biologic-device combinations, or pharmaceuticals. His primary goal is to bring companies to market and then help them remain there in the most efficient and effective manner possible. Working as an extension of each company's legal and business teams, Michael draws on more than 25 years of experience to navigate the FDA pre-market regulatory pathways, counsel companies on FDA post-market compliance matters, and resolve Medicare coverage, coding, and reimbursement disputes with the Centers for Medicare and Medicaid Services. By using his FDA and CMS experience during the product development phase, Michael is able to help maximize companies' opportunities to be appropriately compensated in the proper treatment venues, whether a physician's office, hospital outpatient or inpatient departments, ambulatory surgical centers or home care. During the COVID-19 pandemic, Michael continues to provide strategic FDA counsel to many medical device and diagnostic companies, including several first-time entrants to the medical device space, assisting them in obtaining

emergency use authorizations from the FDA, and advising them on how to comply with FDA's pandemic-focused enforcement discretion policies. There are times when federally-regulated life science companies and the patients they serve would benefit from changes to public policy, Michael works with members of Congress and Executive Branch officials to develop, enact and implement these policy changes.

ABEBA HABTEMARIAM is counsel in Arnold & Porter's Washington DC office and a member of the Life Sciences and Healthcare Regulatory group. Ms. Habtemariam advises life sciences companies on a range of FDA regulatory, compliance, and legislative matters, with a particular focus on counselling pharmaceutical and medical device manufacturers on compliance with the Federal Food, Drug, and Cosmetic Act. She routinely advises clients on the regulation of medical device software and healthcare IT, premarket approval and clearance strategies, exclusivity strategies, promotional review matters, and postmarket compliance. Abeba also assists clients with responding to FDA and DOJ investigations and enforcement actions. Abeba received a BA in Public Health Natural Sciences and a Masters in Biotechnology, both from Johns Hopkins University, and completed her law degree at Yale Law School.

JOHN F. JOHNSON III is counsel at Shook, Hardy & Bacon LLP where he works with companies to develop and implement solutions for complying with the laws administered by Food and Drug Administration (FDA), US Department of Agriculture (USDA), Customs and Border Protection (CBP) and other federal and state agencies. He works with manufacturers, distributors, brand owners, importers and retailers of food, drugs, medical devices, cosmetics and animal products to satisfy their regulatory obligations. John represents companies before FDA and other government agencies subject to inspections or compliance activities, including a judicial action, Warning Letter, Untitled Letter, regulatory meeting, administrative detention, import detention and import alert, and FDA Form 483. Additionally, he helps companies evaluate complaints to determine if a recall is necessary, and if so, he works with clients to manage the product recall to remove the product from market. John counsels clients throughout the product life cycle, including product development and specifications, marketing and labeling, and manufacturing, importation, distribution and sales. This includes determining the possible registrations, permits, licenses and pre-market submissions. Also, he works with clients to create, implement, and maintain internal programs to help foster smooth compliance.

JUSTINE E. LENEHAN is an associate at Kleinfeld, Kaplan & Becker, LLP in Washington, DC where she advises pharmaceutical, device, tobacco, dietary supplement, food, and cosmetic clients on a variety of regulatory matters before FDA and other regulatory agencies. Ms. Lenehan also counsels clients regarding regulatory strategies for product development and postmarketing compliance, as well as advertising and labeling issues.

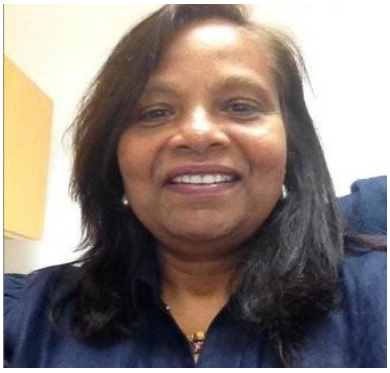
GREGORY LEVINE is chair of the FDA Regulatory practice group at Ropes & Gray LLP. He focuses his practice on FDA regulation of pharmaceuticals, biotechnology and medical devices, regularly representing such clients before state and federal regulators on all phases of the product lifecycle, and assisting with both internal and government compliance investigations and enforcement actions. Greg also advises manufacturers of other FDA-regulated products, including cosmetics and dietary supplements, on a broad range of issues under the Food, Drug, and Cosmetic Act and related laws. Prior to joining Ropes & Gray, Greg was a partner at an international law firm in Washington, DC. He is also a former legislative staff member in the US House of Representatives, where he worked on FDA-related legislation, policy, and appropriations.

REBECCA (BECCA) JONES McKNIGHT is an FDA regulatory and compliance partner at DLA Piper LLP (US). Becca advises clients who develop, make and distribute FDA-regulated products and who play a part in the investigation and delivery of healthcare products and services. She provides strategic regulatory counseling to help clients commercialize products and services and establish and maintain compliant operations. She has extensive experience in developing policies and procedures for FDA and healthcare compliance; conducting proactive reviews, risk assessments and internal compliance investigations; and correcting and remediating non-compliance. Her FDA experience spans a range of products, with an emphasis on medical device, pharmaceutical and biological drug regulation and compliance. Her work has also focused on potential compliance matters, under the Anti-Kickback Statute, Sunshine Act and other laws, raised by relationships between physicians and industry, including those arising in the context of clinical research; product development; and product sales, purchasing and promotion. She provides advice on the intersection of clinical trial and healthcare

law with "big data" business models, addressing regulatory and compliance considerations for the collection, sharing and use of patient and product information. Becca earned her JD at the University of Texas School of Law in 2003, with honors, and her BA in Politics from Wake Forest University in 2000, Phi Beta Kappa. In 2017 and 2018, Becca was named a Super Lawyers Rising Star in the area of Food and Drug law, in a joint project of Super Lawyers and Texas Monthly magazine. In 2021 Becca was named to The American Lawyer's inaugural list of South Trailblazers. The list recognizes professionals in the South "who have moved the needle in the legal industry."

GEORGIA C. RAVITZ is a partner in the life sciences practice of Wilson Sonsini Goodrich & Rosati, where she specializes in FDA regulatory, healthcare, and consumer products innovation and compliance. In particular, she focuses on food and drug law and regulatory policy governing the regulation and promotion of medical devices, pharmaceuticals (including OTCs), health and beauty aids (cosmetics), dietary supplements, vitamins, food and agribusiness, tobacco and e-cigarettes, cannabis, and a wide variety of consumer goods and emerging consumer technologies. She counsels US and foreign manufacturers, distributors, retailers, and importers of regulated products in all phases of their product lifecycle, from innovation through product commercialization and ongoing post-market compliance. Prior to joining the firm, Georgia was a senior partner in the FDA and advertising practices of Arent Fox in Washington, DC, where she led the firm's consumer product safety practice. She is a frequent speaker at conferences and events, and a regular contributor to leading trade and consumer media outlets.

JAMES R. RAVITZ is a partner in the Washington, DC, office of Wilson Sonsini Goodrich & Rosati, where he is a member of the firm's US Food and Drug Administration (FDA), healthcare, and consumer products compliance practice. Jamie regularly works with manufacturers and distributors of products that are extensively regulated by the FDA, such as medical devices (including digital applications), drugs, biologics, food, cannabis, dietary supplements, and cosmetic products. He has worked with clients at all points in the product life cycle, from providing strategic regulatory approval direction at the product concept stage through post-marketing issues including product marketing, labeling, advertising, and recalls and crisis matters. A substantial part of Jamie's practice includes counseling manufacturers and providers on healthcare compliance matters, including broad-based fraud and abuse laws, the Anti-Kickback Statute, the False Claims Act, the Sunshine Act, patient privacy statutes, and product reimbursement. He has worked with clients on numerous internal investigations and responses to Office of Inspector General (OIG) and US Department of Justice (DOJ) subpoenas, and has assisted in the defense of qui tam whistleblower suits alleging violations of the False Claims Act.



DHANMATI RUPNARINE is Principal Consultant at NSF International where she brings more than 30 years of Quality, Compliance and Regulatory experience to this forum, having served in regulated industries covering medical products, drug-device combination products, pharmaceuticals and in vitro diagnostic (IVD) products in markets world wide. In addition to her work in quality and regulatory affairs, Ms. Rupnarine has experience in company acquisitions, integrations and divestitures. In her career of increasing technical responsibilities, Ms. Rupnarine has served key industrial leaders such as Baxter, Boston Scientific, J&J and Cardinal Health. Capitalizing on her personal industry experiences, Dhanmati has served as a principal consultant to a wide array of industry leaders, providing pragmatic leadership and cultural sensitivity to global teams. Ms. Rupnarine earned her Bachelor of Science in Food Science at the University of Manitoba, her Master of Science in Quality Management with Honors from the University of Miami, and her Doctorate in Business Administration in Quality Systems Management from the National Graduate School of Quality Management in Boston, MA.

ELAINE H. TSENG is a partner in King & Spalding's FDA & Life Sciences practice. Elaine has over 20 years of experience working with life sciences companies on FDA pre- and post-market regulatory matters, including strategies to optimize pathways to market, compliance with clinical study and marketing requirements, and addressing FDA compliance challenges. A substantial part of Elaine's practice involves advising medical device companies on quality system matters, including handling and responding to FDA inspections, resolving FDA Warning Letters and import detentions, and evaluating and managing legal risk associated with quality system issues, including in internal investigations and corporate transactions.

BETH P. WEINMAN is a member of Ropes & Gray's life sciences regulatory and compliance practice group, and focuses her practice on FDA regulation and enforcement of laws governing pharmaceuticals, biologics, medical devices and foods, including dietary supplements. Beth represents clients in False Claims Act (FCA) and Federal Food, Drug, and Cosmetic Act (FDCA) investigations, and other enforcement actions before state and federal regulators, and also represents clients in administrative litigation matters. Beth also provides counseling on issues related to marketing practices, current good manufacturing practices, good clinical practices, compounding, medical product development and approval, and product recalls and withdrawals. Prior to joining Ropes & Gray, Beth spent nearly eight years as Associate Chief Counsel for Enforcement within FDA's Office of Chief Counsel. In that role, she worked closely with FDA's Office of Criminal Investigations, the Department of Justice and other government agencies to investigate and, when appropriate, prosecute alleged violations of the FDCA and related crimes under Title 18 (including, e.g., mail fraud, wire fraud, healthcare fraud, and conspiracies to defraud). She also worked on

numerous parallel and independent FCA investigations involving FDA regulated drugs and devices, including biologics. Before starting at FDA, Beth spent more than seven years as an associate in the litigation department of a large New York law firm, where, among other matters, she represented a number of pharmaceutical companies in government investigations and securities class action lawsuits.

BLAKE E. WILSON is a senior associate at Hogan Lovells US LLP in the Medical Device group. He has advised on 510(k) premarket notifications, de novo submissions, premarket approval applications (PMAs), and investigational device exemption applications, among other regulatory filings. He also has experience in drafting clinical trial agreements and contracts for device development, manufacturing, and associated Quality System Regulation (QSR) responsibilities. Prior to joining Hogan Lovells, Mr. Wilson worked as an associate at another international law firm and was a lead research assistant at Brown University, where he managed phase 1 and 2 pharmaceutical clinical trials. Mr. Wilson takes advantage of his clinical research background to help companies navigate the FDA's clinical data requirements. While attending law school, he was executive editor for the University of Pennsylvania Journal of International Law and published a student comment regarding the use and regulation of foreign clinical trials in the FDA's drug marketing approval process. Mr. Wilson also served as a judicial intern to the Honorable Leonard P. Stark of the US District Court for the District of Delaware.