Fundamentals of Digital Health Regulation: Successfully Navigating Your Product Through FDA
November 9, 2021
Speaker Biographies

M. JASON BROOKE is an Attorney & Managing Member of Brooke Consulting, LLC--a boutique law and advisory firm that provides legal and consulting services to innovative medical device and digital health companies across the globe and at various stages of commercialization. Jason also serves as General Counsel and VP of Regulatory & Quality for AmalgamRx, a digital health company developing software as a medical device to improve clinical and behavioral outcomes for chronic disease management. He brings a focused expertise in the medical device industry that combines nearly 20 years of experience ranging from science and technology design, development, implementation, and testing; to business strategy and operations; to legal and regulatory compliance. Jason has conducted scientific research (pre-clinical and clinical) and technology development in academic and industry environments as a biomedical engineer, worked within the FDA's Center for Devices and Radiological Health ("CDRH") as a program analyst, counseled clients as an attorney and consultant focused on the medical device and connected health space, and served as the chief executive officer and general counsel of a small medical device company.

SHELBY BUETTNER is Principal Legal Counsel at Medtronic. She has advised pharmaceutical and medical device manufacturers, healthcare and technology companies, hospitals, and healthcare providers on a variety of regulatory and compliance matters. Shelby previously served as Associate Chief Counsel at the Food and Drug Administration and, before that, was in private practice. Shelby also has experience coordinating clinical research at an academic medical center and managing biomedical projects funded by the Department of Defense and the National Aeronautics and Space Administration.

CHRISTINE P. BUMP is Principal and founder of Penn Avenue Law & Policy. Her practice focuses on FDA issues for devices, digital health, diagnostics, genetics and genomics, wellness, and advertising and promotion. Her work in digital health includes providing legal, regulatory, strategic, and policy advice to manufacturers and developers of digital health, digital medicine, and artificial intelligence technologies in radiology, oncology, and food sensitivity. Christine counsels emerging companies, laboratories, health systems, and large corporations on the potential impact of FDA's digital health policies and advises clients with an awareness and understanding of their business and strategic goals. She has written several articles, presented and spoke and numerous industry conferences, and co-authored a book chapter regarding FDA regulation and enforcement. Christine earned a BA from Sweet Briar College, an

MPH from Emory University's Rollins School of Public Health, and a JD from Emory University School of Law.

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.

JEFFREY K. SHAPIRO is a director with the law firm of Hyman, Phelps & McNamara, P.C. in Washington, DC. He specializes in medical device law, advising and representing companies before FDA for more than 20 years. He has experience in FDA regulation of medical devices, including product clearances and approvals, MDR and Part 806 reporting requirements, labeling and advertising, recalls, and responding to Form 483s and warning letters. In recent years, he has particularly focused on digital health issues. As an advisor to start-ups, mid-sized, and large medical device manufacturers, Mr. Shapiro recognizes the operational and financial considerations involved in managing compliance and creating regulatory strategies. Mr. Shapiro actively contributes to industry conversations on medical device regulations. He is a member of the Editorial Advisory Board for both MDDI and Update magazines, co-editor of two textbooks, Promotion of Biomedical Products (Food and Drug Law Institute, 2006) and Combination Products, How to Develop the Optimal Strategic Path for Approval (FDA News 2005), has contributed chapters to many textbooks, and is a frequent speaker and contributor to the firm's FDA Law Blog, among other publications.