About the Authors

Afia Asamoah is product counsel at Google Inc. and is responsible for providing legal advice for all health-related products developed in Google[x], Google's innovation lab dedicated to developing unusual solutions to solve global problems. Prior to joining Google, Ms. Asamoah was a regulatory attorney at Covington & Burling LLP, advising pharmaceutical, biotechnology, and medical device clients on a range of FDA-related regulatory and compliance issues. Her work included internal investigations and audits, legislative activities, interactions with regulatory bodies, and corporate transactions. From May 2009 to January 2011, Ms. Asamoah advised senior leaders and staff as a Special Assistant in the Office of the Commissioner at FDA. She received four awards while at the agency, including the FDA Commissioner's Special Citation. Ms. Asamoah is a founding co-chair of the Medical Devices Committee of the American Bar Association's Section of Science & Technology Law and former vice chair of the Public Health and Policy interest group of the ABA Health Law Section. She also served recently on the ABA Special Committee on Bioethics and the Law. She has a law degree from Harvard Law School, a master's degree in health policy from the Harvard University Kennedy School of Government, and an undergraduate degree from Harvard College.

Erika Lietzan is Associate Professor of Law at the University of Missouri School of Law, where she teaches drug and device law as well as intellectual property. Previously, she was a partner at Covington & Burling LLP, where she specialized in the regulation of drugs, biological products, and medical devices. She had a broad-ranging practice that included regulatory and strategic counseling, advocacy in courts and before federal agencies, legislative drafting and lobbying, advice and assistance with international trade policy and non-U.S. legislation and regulation, service as an expert witness on regulatory and intellectual property issues, transactional and licensing work, and white-collar defense. While at Covington, she served as general counsel of the FDA Alumni Association, and she was a member of the board of directors of the Food and Drug Law Institute and now serves on its Drugs and Biologics Committee. In addition to her tenure at Covington, she served for several years as Assistant General Counsel of the Pharmaceutical Research and Manufacturers of America. Ms. Lietzan has been consistently voted by her peers in the bar as one of the "Best Lawyers in America" in both biotechnology law and FDA law. She is chair of the Life Sciences Division of the ABA Section of Science & Technology Law and

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Daniel Pancamo is counsel in the business group of the New Orleans office of Phelps Dunbar LLP. He has a business, regulatory, and commercial transactional practice and represents a diverse range of clients. Mr. Pancamo is a member of the Louisiana State Bar Association, the Energy Bar Association, and the American Bar Association. He has also been monitoring and writing in the field of federal regulation of preclinical research since the mid-2000s, and in recent years, he has been repeatedly ranked by his peers as a "Best Lawyer in America" for both banking and finance law and biotechnology law. Mr. Pancamo has been a member of the Biotechnology Committee of the ABA Section of Science & Technology Law. He also served as an officer and member of the board of directors of the National Tay-Sachs & Allied Diseases Association, one of the nation's oldest genetic disease support and research organizations, and was a member of its Research Initiative. He has a law degree from the Tulane University Law School and an undergraduate degree from Muhlenberg College.

Areta Kupchyk is a partner in the Washington, DC, office of Nixon Peabody, where she practices FDA law and advises biotechnology, medical device, and pharmaceutical companies as well as health care providers and institutions, researchers, and investors on FDA-related matters. Previously, she was Associate Chief Counsel for Drugs and Biologics and Assistant General Counsel for Litigation at FDA. In her practice, she focuses on pathways to market for FDA-regulated products, postapproval compliance and enforcement, and advertising and promotional activities. She publishes and speaks frequently on these topics. Ms. Kupchyk has been recognized by LMG Life Sciences since 2012 as a "Life Sciences Star" and has been listed as a leading lawyer in biotechnology law by The Best Lawyers in America since 2008. During her time at FDA, she was a three-time recipient of the FDA Commissioner's Special Citation for Outstanding Achievement, and she was recognized for her role in developing a regulatory framework for human cellular and tissue-based products and FDA guidance on pharmaceuticals produced with bioengineered plants. Ms. Kupchyk is a member of the FDA Alumni Association, the Food and Drug Law Institute, and the Maryland State Bar Association. She has a law degree from the University of Maryland School of Law and a bachelor's degree from the University of Maryland.