Introduction to Biological Products, Including Vaccines, Biosimilars, Cell and Gene Therapies, and Other Advanced Therapies
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Speaker Biographies

SARAH BLANKSTEIN is an associate at the law firm of Ropes & Gray LLP in Boston, Massachusetts and is a member of the firm's Life Sciences Regulatory & Compliance practice group. In this role, she provides legal and strategic advice to pharmaceutical, biotech and medical device companies on a wide array of FDA regulatory matters, with a focus on regulatory risk management, promotional compliance matters, good manufacturing practices and product development. Ms. Blankstein also advises on FDA regulatory aspects of transactions as well as complex internal investigations and government enforcement matters involving promotional, product quality, and safety reporting issues. Ms. Blankstein received an AB from Harvard College and a JD, magna cum laude, from Harvard Law School.

CATHERINE (KATE) M. COOK is a principal at Greenleaf Health, which she joined following a distinguished career of more than 20 years with the US Food and Drug Administration (FDA). During her FDA tenure, Kate provided crucial direction on strategic initiatives related to the regulation of drugs, biological products, and medical devices. Kate continues her commitment to public health at Greenleaf as Principal, Regulatory Policy. She leads the firm's services focused on supporting clients with expertise and guidance on FDA regulatory policies and programs, working with clients to bring innovative medical products to patients. Kate's FDA career began in the Office of the Chief Counsel, where she served for more than 15 years as a legal counsel on medical product issues including issues related to biosimilars, gene therapy, vaccines, allergenics, human tissue and cellular products, blood products, medical devices, and combination products. She also provided guidance on human subject protection and advertising and promotion. Kate went on to serve as Associate Director for Regulations and Policy within the FDA's Center for Devices and Radiological Health (CDRH), where she led strategic development and implementation of policies and regulations applicable to medical devices and radiation-emitting products. Later, as senior advisor in the FDA's Center for Biologics Evaluation and Research (CBER), she played a pivotal role in the development and implementation of regulations and regulatory policy related to biological products, combination products, and medical devices regulated by CBER. Kate is the recipient of numerous FDA awards, including the FDA Award of Merit, the Secretary's Award for Distinguished Service, the Commissioner's Special Citation, and the CDRH Director's Special Citation. A graduate of Swarthmore College, Kate received her law degree from the New York University School of Law.

NEIL DiSPIRITO is an FDA law partner in Brown Rudnick's Corporate and Global Life Sciences Practice Groups where his practice focuses on a wide array of regulatory and compliance issues in the pharmaceutical, biologic, supplement, and medical device industries (and related data privacy and security regulatory issues). Neil also advises on many business transactions and filings for FDA regulated products and companies. Prior to joining Brown Rudnick, Neil was a partner at Epstein Becker Green and at Ballard Spahr, where he was a member of the Life Sciences and Technology and Health Care Groups, and established Ballard's FDA practice. Prior to becoming an attorney, Neil worked as an executive for major pharmaceutical manufacturers in the US, EU, Asia Pacific and Latin America in marketing, manufacturing, advertising, FDA regulatory and compliance, new drug approval, and worldwide business development. He also negotiated with regulatory authorities to launch products and manage them throughout the product life cycle. Neil teaches pharmaceutical, biologic, and medical device law at the Food and Drug Law Institute (FDLI) and to FDA's newly hired attorneys, reviewers, and compliance officers. He serves on FDLI's Audit Committee and was co-chair of its 2018 Annual Conference Planning Committee. Neil has also served as chair of the Regulatory Committee of the Florida Medical Device Manufacturers Consortium.

MICHELLE DIVELBISS is an associate in Covington & Burling LLP's Washington, DC office, where she is a member of the Food, Drug, and Device Practice Group. She advises pharmaceutical and biotechnology companies on a variety of regulatory and compliance issues.

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.

GAIL JAVITT is a director at Hyman, Phelps & McNamara, P.C. where she provides strategic FDA regulatory advice for leading medical device, diagnostics, pharmaceutical, biological products, and human cellular, and tissue-based products (HCT/Ps) throughout the product life cycle and has successfully resolved disputes at both the pre- and post-market stage. She also has significant experience advising clinical laboratories on FDA and CLIA requirements for laboratory developed tests. Ms. Javitt's experience prior to joining Hyman, Phelps & McNamara includes serving as a partner in a leading Washington, DC health law practice and as a law and policy director at the Genetics and Public Policy Center, part of Johns Hopkins University. At the Center, she was responsible for developing policy options to guide the development and use of reproductive and other genetic technologies. Earlier in her legal career, Ms. Javitt clerked for the Honorable Gary Taylor of the US District Court for the Central District of California. In addition, Ms. Javitt has published and spoken widely on issues at the intersection of law, science, ethics and policy, including FDA regulation of genetic testing, precision medicine, and next-generation sequencing. Her academic experience has included serving as a faculty member at the Berman Institute of Bioethics at Johns Hopkins University and as an adjunct professor at the Georgetown University Law Center, American University's Washington College of Law, and the University of Maryland School of Law. She was previously a Greenwall Fellow in Bioethics and Health Policy, a collaborative effort between Johns Hopkins University and Georgetown University.

BRIAN J. MALKIN is a partner in McDermott Will & Emery LLP's Washington, DC Office where he counsels pharmaceutical and biologic clients on Food and Drug Administration (FDA) regulatory matters and intellectual property (IP) law, with an emphasis on patent litigation. His practice at the intersection of FDA- regulated products and patent law makes him a valuable partner to drug manufacturers, biotechnology clients, medical device companies and cannabis companies as they develop new products and protect their innovations though life cycle management, bring their products to market and pursue transactional opportunities. Brian's regulatory experience includes all types of FDA-regulated products: drugs and biologics (including animal drugs and biologics), medical devices, cannabis, foods and dietary supplements, cosmetics and tobacco products. He is a key advisor to pharmaceutical and biologic clients in the premarket, regulatory review, and marketing, enforcement and lifecycle management phases of product development. Brian works alongside his clients on drug development strategies and patent strategies across a variety of areas, including orphan drugs. He is also an experienced litigator, representing clients in FDA and patent cases, including Hatch-Waxman Act cases and Biologics Price Competition and Innovation Act (BPCIA) cases. In particular, his patent law knowledge makes him an asset to drug and biotech companies, working alongside them to develop proactive strategies that protect their pioneering life sciences products from the earliest stages of development through approval, marketing and next-generation products, and wielding litigation when required. Brian is also a strong partner in the boardroom, providing FDA and IP due diligence for deals and

transactions in the life sciences space, supporting mergers and acquisitions and licensing for investors, private equity clients, and pharmaceutical and biotechnology companies. His combined experience across regulatory, IP, litigation and transactions in pharmaceuticals and biotechnology enables him to spot and mitigate issues that may negatively impact his clients' investments and partnerships. With more than 21 years of FDA and intellectual property law experience, including time spent in the Office of the Commissioner and the Center for Drug Evaluation at the FDA, and a degree in biochemistry, Brian's background is uniquely tailored to the needs of life sciences innovators. He is also active in the promoting the biotechnology community and life sciences entrepreneurs in Maryland, Virginia, the District of Columbia and beyond.

CHRISTINA M. MARKUS is a partner and Deputy Team Leader in the Washington, DC office of King & Spalding for the FDA & Life Sciences Group. Her practice focuses on the regulation of drugs, biologics, and other products by FDA, DEA, and related state agencies (e.g., boards of pharmacy). Ms. Markus represents companies in a range of regulatory compliance, enforcement, and business transactions (e.g., due diligence assessments) involving product development and approval, safety, labeling, marketing and advertising, and supply chain. Ms. Markus was selected as a "Life Sciences Star" in the 2012, 2013, and 2014 LMG Life Sciences publications, and as one of the Best Lawyers in America (2015 edition) for FDA Law. She recently completed an appointment by the Institute of Medicine (IOM)/National Academy of Sciences as the legal member of the IOM Committee on Pediatric Studies Conducted Under the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). In response to a Congressional request, and with funding from FDA, IOM evaluated studies of drugs and biologics that have been performed under two statutory regimes that incentivize and, in some instances, mandate pediatric research through the drug approval process. The Committee assessed historical execution under these laws and offered recommendations and briefings to FDA and the US Congress, which were considered during the reauthorization of BPCA and PREA (signed into law in July 2012).

CHRISTOPHER M. MIKSON is a partner at DLA Piper in Washington, DC and Philadelphia, PA where he is a member of the Litigation and Regulatory practice group. With his unique combination of training and experience as a medical doctor, registered patent attorney, and seasoned litigator, Chris focuses his practice on advising and representing clients in FDA regulatory matters and complex litigation and transactional matters involving healthcare and the life sciences. He has extensive experience in the regulation of drugs, biologics, human cell and tissue products (HCT/Ps), and medical devices by FDA and other federal and state agencies. Chris has counseled and represented clients in regulatory matters across all stages of the product life cycle from research and development to nonclinical testing, clinical trials, premarket clearance and approval, manufacturing and distribution compliance, and post market surveillance and reporting. He has handled a broad range of agency proceedings such as Orange Book listing disputes, comments during rulemaking,

citizen petitions, establishment inspections, responses to agency letters, and enforcement actions, as well as litigation against FDA under the Administrative Procedure Act. Chris has taught patent and FDA law at the University of Pennsylvania, and has spoken and written extensively on regulatory and intellectual property issues. LMG Life Sciences has recognized him as a "Life Sciences Star" since 2018.

EVA TEMKIN is a partner in King & Spalding's FDA and Life Sciences practice where she counsels clients regarding complex issues associated with FDA-regulated biomedical products. Eva draws upon her deep experience with these products at FDA to help clients navigate development, approval, post-market regulation and life-cycle management of drugs and biologics, biosimilars and combination products. Prior to joining K&S, Eva acted as Director for Policy at FDA's Office of Therapeutic Biologics and Biosimilars. In that position, Eva was the Agency lead for the Biosimilars Action Plan and oversaw policy development related to biosimilars and other therapeutic biologics.

STEVEN S. TJOE is a senior associate in Goodwin Proctor's Technology and Life Sciences groups and a member of the firm's FDA practice. He focuses his practice on product development strategies and regulatory compliance counseling, in particular as related to medical devices, digital health products, in vitro diagnostics, laboratory developed tests, compounded drugs, cell and gene therapies, and other drugs and biologics. Mr. Tjoe advises clients in analyzing premarket pathways, product adverse event risk profiles, product communications and marketing, and GMP compliance. Mr. Tjoe also advises on Hatch-Waxman patent listing and exclusivity issues, is a contributor to Goodwin's Guide to Biosimilars Litigation and Regulation in the U.S, and regularly conducts risk analyses for offerings and transactions involving FDA-regulated entities across the medical device, drug, and biologic industries.