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Richard Cleland joined the Federal Trade Commission's Division of Advertising Practices in 1991. In 1996, Mr. Cleland was appointed Assistant to the Director of the Bureau of Consumer Protection and, in 1998, he was appointed Assistant Director of the Division of Service Industry Practices. He currently serves as Assistant Director of the Division of Advertising Practices. His primary area of expertise is the advertising and marketing of health-related products and services. He also supervises many of the Commission's health fraud and weight-loss product and service law enforcement initiatives. Mr. Cleland supervised the FTC's review of the Endorsement and Testimonial Guides and the revision of the FTC's guidance on making effective disclosures on the Internet and other digital platforms (.com Disclosures). Recent projects have included social media marketing and native advertising.

Kellie Combs is a partner in the Life Sciences group at Ropes & Gray LLP, where she provides legal and strategic advice to pharmaceutical, biotechnology, and medical device manufacturers on a broad range of issues under the Food, Drug, and Cosmetic Act, and the Public Health Service Act. She serves as co-counsel to the Medical Information Working Group, represented Pacira in its litigation against FDA, and has extensive experience handling matters implicating FDA promotional rules and the First Amendment. Kellie also routinely advises clients on lifecycle management, regulation of clinical research, and post-approval compliance. In addition, she conducts regulatory due diligence in connection with transactions involving life sciences clients, and advises on government investigations of FDA-regulated companies.

Kate Cook is Executive Vice President for Drug and Biological Products at Greenleaf Health, a regulatory consulting firm. She previously worked at FDA in legal and policy positions in the Office of Chief Counsel, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health, where she served as associate director for regulations and policy. During her twenty+ years at FDA, she was involved in every aspect of policy development and provided legal review for important agency initiatives. Ms. Cook graduated from New York University School of Law, and was a New York County Assistant District Attorney and an attorney in private practice before joining FDA.

Dale Cooke is president of PhillyCooke Consulting, which helps companies use 21st century technology to communicate about FDA-regulated products while remaining compliant with regulations written in the 1960s. Dale has worked with more than 40 pharmaceutical and medical device clients around the world. He has published extensively in the industry-leading publications, including is the Food & Drug Law Institute's *Update* magazine, Regulatory Affairs Professionals Society's *Regulatory Focus*, and is the author of *Effective Review & Approval of Digital Promotional Tactics*, now in its second edition, which was published by the Food & Drug Law Institute. Dale also serves on the Google Health Advisory Board, the Digital Health Coalition, and is an active member of RAPS, FDLI, the Drug Information Association, Implementation of Regulatory Information Submission Standards, Programmatic Health Council, and the Alliance for a Stronger FDA.

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Joshua Eizen joined Actelion Pharmaceuticals US Inc. in 2014 after six years in FDA's Office of Chief Counsel, where he served as the lead FDA attorney on criminal enforcement matters throughout the Southeastern United States. In that capacity, Josh worked closely with FDA's Office of Criminal Investigations (OCI), the Department of Justice, and other federal agencies in investigating and prosecuting violations of the nation's food and drug laws. Josh has participated in major qui tam investigations involving drugs, devices, and biologic products. Josh also designed and coordinated FDA's nationwide in-service legal-training program for OCI agents and instructed all new agents (2009 to 2014) at the Federal Law Enforcement Training Center on investigative strategies, food law, felony FDCA prosecutions, and the Park Doctrine. Before joining FDA, Josh was an associate at McKee Nelson LLP (now part of Morgan Lewis), where his practice focused on pharmaceutical transfer pricing. Josh is a 2003 graduate of Georgetown University Law Center. At Actelion, Josh works primarily on healthcare compliance and FDA-regulatory matters. Since May of this year, he has also served as the company's acting Chief Compliance Officer.

Mark Gaydos is Vice President and Head of North America General Medicines & Established Products and US Advertising & Promotion within Sanofi's Global Regulatory Affairs. In this role, Mark is accountable for regulatory leadership and strategy for investigational and marketed products, including lifecycle management, and oversees the regulatory review of promotional activities to ensure compliance and best practice sharing. Prior to joining Sanofi, Mark was Director of Worldwide Regulatory Strategy at Pfizer and has held positions of increasing responsibility with Amgen, Block Drug Co., Whitehall-Robins and Biocraft Laboratories. He has 23 years of pharmaceutical industry experience,

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Elizabeth Jungman is director of public health programs at The Pew Charitable Trusts, overseeing initiatives related to antibiotics, drug safety, and health care products. Before joining Pew, she served as a senior health policy adviser with the Senate Committee on Health, Education, Labor, and Pensions, where she played a key role in drafting and negotiating the Food and Drug Administration Safety and Innovation Act of 2012, the FDA provisions in the Pandemic All-Hazards Preparedness Reauthorization Act of 2013, and the Drug Quality and Security Act of

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Daniel A. Kracov is a partner in Arnold & Porter Kaye Scholer's Washington, DC office, where he co-chairs the firm's Life Sciences & Healthcare practice. He helps life sciences manufacturers, trade associations and early-stage ventures negotiate challenges relating to the development, manufacturing, approval and promotion of drugs, biologics, medical devices and diagnostics. In addition to day-to-day regulatory counseling, he regularly handles high stakes investigations and enforcement proceedings, the development of global compliance programs, and due diligence in financings, mergers and acquisitions. He has a widely recognized expertise in biomedical product-related public policy matters, including Congressional investigations and FDA-related legislation.

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Meredith Manning is a partner in the Washington, DC office of Hogan Lovells, and is a member of the firm's Food, Drug, Devices & Agriculture Group. She focuses her practice on regulatory and policy issues affecting clients in the pharmaceutical and biotechnology industries, with an emphasis on Food and Drug Administration (FDA) enforcement matters. Ms. Manning has substantial experience in government enforcement of a variety of statutes, particularly the Federal Food, Drug and Cosmetic Act. Previously, she served as assistant United States attorney, Civil Division for the US Attorney's Office in Washington, DC Prior to joining the US Attorney's Office, Ms. Manning was Associate Chief Counsel in the Office of the General Counsel at FDA where she handled a variety of litigation and litigation-related counseling issues. Among

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Kathleen Meriwether is the Americas Leader of the Health Sciences team of Ernst & Young's Fraud Investigation & Dispute Services practice. Kathleen specializes in assisting health sciences companies with global risk and compliance assessments and regulatory compliance analyses. Kathleen works closely with management teams, compliance officers and counsel to identify compliance and enforcement risks, determine potential vulnerabilities and recommend solutions from business and operational perspectives. Kathleen also assists counsel, both outside and in-house, with fraud investigations (health care fraud and abuse, off label marketing, FCPA and other bribery and corruption), compliance inquiries and in strategizing responses to governmental subpoenas and other inquiries. She has also worked on multiple projects assisting in-house counsel on management of significant litigation matters, from the cost management as well as investigative perspectives. Prior to her tenure with EY, Kathleen was an Assistant United States Attorney in the US Attorney's Office for the Eastern District of Pennsylvania, focusing on health care fraud in the life sciences industry.

Thomas Moskal is a veterinary medical officer with the Division of Surveillance, Center for Veterinary Medicine (CVM), FDA. He serves as a reviewer of labeling and promotional materials for approved and unapproved veterinary drugs and devices. He is Board Certified in laboratory animal medicine. Dr. Moskal received his BS from the University of Maryland, his DVM from the Virginia-Maryland Regional College of Veterinary Medicine, and a Masters in Library and Information Science from Drexel University.

John Murphy serves as the Deputy General Counsel at the Biotechnology Innovation Organization (BIO). BIO is the largest trade association in the world representing biotechnology companies. BIO members are involved in the research and development of innovative healthcare, agricultural, and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. Mr. Murphy's role encompasses all legal issues impacting healthcare biotechnology across the Country. His responsibilities include issues in Congressional legislation, FDA, CMS and various other federal agency regulatory issues, litigation, and support on state-developed biotechnology laws and regulations. Mr. Murphy is a graduate of Villanova University and the Catholic University Columbus School of Law.

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Marc J. Scheineson is a partner in the Washington, DC office of Alston & Bird. He heads the firm's food and drug law practice. He has practiced food and drug law, health care law, and administrative law for over 30 years in national law firms and at the Food and Drug Administration (FDA). His practice focuses on determining the "regulatory course of least resistance" to market medical products, and assisting clients with legal and regulatory issues, drug and medical device applications, marketing, compliance, and enforcement matters. He also represents small businesses engaged in tobacco and e-product manufacture and sale. Mr. Scheineson provides legal, regulatory, and legislative counsel to a variety of marketers, research institutions, professional associations, and manufacturers of pharmaceutical and biological drug products, medical devices, cosmetics, dietary supplements, tobacco and traditional foods. He is a frequent speaker in industry forums. He is also experienced with the application of the Office of Inspector General (OIG) anti-kickback statute, HIPAA privacy rules, clinical trial regulation, human research protection, scientific misconduct, technology transfer and licensing, advertising and promotion law, and advises on the FDA regulatory aspects of health care transactions. He previously served as Associate Commissioner for Legislative Affairs at FDA. He received his BA and JD from the University of Cincinnati and its College of Law, and his LLM from the Georgetown University Law Center.

Michele Sharp is Senior Director, Global Regulatory Affairs, at Eli Lilly and Company. Ms. Sharp joined Lilly in 1995 where her career has included assignments in Medical and Regulatory Affairs. Her experience in Regulatory includes labeling development, working with a product team and the FDA to obtain regulatory approvals, and for the last 10 years leading a team who advise the US business on advertising and promotion for marketed products.

Lance L. Shea is a partner at BakerHostetler LLP with focus on legal science advocacy, Mr. Shea represents clients in medical products industries such as drugs, medical devices and biotechnology products. Matters span regulatory (e.g., FDA and EPA) and litigation forums (e.g., federal and state courts) and often involve complex scientific evidence and cutting-edge arguments based on interpretation of scientific studies. In recent regulatory matters, Lance advised clients on assessment of safety signals for prescription drug products, drug postmarketing studies required under Risk Evaluation and Mitigation Strategy (REMS), preparation for cGMP food inspection and efficacy, and safety positions based on epidemiology studies of competing medical device products. In litigation matters, he recently represented drug companies in nationwide dockets of products liability cases and a drug/device company on breach of contract litigation.

Norma Skolnik has over 35 years of regulatory experience working with the pharmaceutical, OTC drug and dietary supplement industries. She served as Director of Regulatory Affairs for the Americas for Cadbury Adams until her retirement. Prior to that she was Director of Regulatory Affairs for the Adams Division of Pfizer and Associate Director of Regulatory Affairs for the Warner-Lambert company. She also served as Director of Regulatory Affairs for Lederle Consumer Healthcare and as Associate Director of Marketed Product Support for Lederle Laboratories and Associate Director of Regulatory Affairs for Wyeth. She is currently a consultant with EAS Consulting Group in Alexandria, VA. where she advises Pharmaceutical and Consumer Healthcare companies on FDA regulatory issues.

Michael K. Stern is a special counsel at Covington & Burling LLP. He specializes in FDA's regulation of pharmaceuticals and biotechnology products, and has particular expertise with Hatch-Waxman and biosimilars issues. Mr. Stern joined Covington from FDA, where he served as an Associate Chief Counsel from 2010 to 2016. While at FDA, Mr. Stern provided legal advice to FDA officials on Hatch-Waxman and biosimilars matters that raised complex legal and scientific issues. In addition, Mr. Stern worked with the US Department of Justice in defending FDA against legal challenges to agency decisions, as well as in prosecuting enforcement actions.

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Kristi Wolff is a partner at Kelley Drye, & Warren LLP. Ms. Wolff's practice focuses on food, drugs, dietary supplements, medical devices, personal care and consumer health products, as well as wearable technology and health privacy issues. She has extensive experience advising clients whose products are within the overlapping jurisdictions of the Food and Drug Administration and the Federal Trade Commission. Ms. Wolff handles matters across the full product lifecycle, including concept analysis, claim substantiation, label review, quality and recall scenarios, and contested matters involving the FTC, FDA, National Advertising Division, state attorneys general, and class action litigation. Having served as in-house counsel in the healthcare and food products industries, Ms. Wolff is particularly attuned to balancing business objectives with legal considerations.