Advertising & Promotion for Medical Products Conference
October 16- 17th
Speaker Biographies

THOMAS W. ABRAMS is the Director of the Office of Prescription Drug Promotion (formerly the Division of Drug Marketing, Advertising, and Communications (DDMAC)), Food and Drug Administration. Mr. Abrams has held the positions of Acting Director, Acting Deputy Director, and Branch Chief in DDMAC. He joined FDA as a reviewer in DDMAC where he was primarily responsible for reviewing promotional material for cardiovascular products. Prior to joining FDA, Mr. Abrams worked in pharmaceutical sales and marketing for Merck and Company. Mr. Abrams received his BS degree in pharmacy from the School of Pharmacy, Rutgers University and his MBA degree from Rutgers School of Business.

KATHRYN (KIT) AIKIN is a senior social science analyst and the Research Team Lead in the Food and Drug Administration's Office of Prescription Drug Promotion (OPDP). Dr. Aikin's research has focused on topics related to promotion of prescription drugs, including consumer perceptions of direct-to-consumer (DTC) advertising, disease awareness ads, corrective advertising, marketing claims, and improvements to the consumer brief summary in DTC print ads. In addition to her research work, Dr. Aikin consults on regulatory policy and enforcement review of consumer and professional prescription drug promotional pieces. A graduate of Oberlin College and Penn State University, she is a frequent speaker at academic and professional conferences and has authored over 20 publications on topics related to prescription drug promotion. She is a member of the editorial board of the *Journal of Public Policy and Marketing.*

HEATHER BAÑUELOS is Counsel in King & Spalding's Washington, DC office and a member of the firm's FDA & Life Sciences practice group. Heather's primary practice is focused on regulatory strategies and initiatives for the labeling, promotion and advertising of FDA-regulated products. She has served on over 15 different promotional review committees and medical and scientific review committees, with a knack for practical advice and recommendations to help clients find a path forward. Heather's experience in FDA law spans 18 years and includes positions as a former Associate Chief Counsel in the FDA's Office of the Chief Counsel and senior in-house regulatory counsel for multiple clients, including two large pharmaceutical companies and a leading food company. Her experience in government and in-house give her a unique and valuable perspective as outside counsel.

KAREN BECKER is the Managing Director of Precision for Medicine's Translational and Regulatory Sciences Practice, which was established to provide value-added scientific and regulatory solutions for development, marketing authorization, regulatory compliance, and stewardship of innovative healthcare products.

Dr. Becker is an industry leader with over 25 years of experience serving hundreds of clients in a broad range of therapeutic areas, focusing on scientific and regulatory services to companies operating at the intersection of science and public policy. Successful resolution of client matters is achieved through application of sound science, reliance on leading clinical and scientific expertise, and a commitment to outstanding quality and service.

Prior to Precision for Medicine, Dr. Becker was President of IndigoBay Ventures LLC, a management consulting firm providing scientific and regulatory services to healthcare companies and investors. She was the Founder and Chief Executive Officer of Becker & Associates Consulting, Inc., a leading full-service scientific and regulatory affairs consulting firm, until its acquisition. She has published original research in pharmacology and drug development, numerous publications on FDA regulation, textbooks on the design of clinical trials for medical devices, and the *PLI Medical Device Law and Regulation Answer Book*. Dr. Becker is an Adjunct Associate Professor at Georgetown University, where she teaches public health policy and biotechnology management.

Dr. Becker received a BS in Biological Chemistry from the University of Maryland at College Park, and a PhD in Pharmacology from the University of North Carolina School of Medicine.

JOHN BENTIVOGLIO is a partner in the law office of Skadden, Arps, Slate, Meagher & Flom LLP in Washington, DC. He represents pharmaceutical, medical device and biotechnology manufacturers in FDA and health care regulatory issues, compliance programs, and civil and criminal investigations by federal and state law enforcement agencies. He advises clients on federal and state anti-kickback and false claims statutes, FDA advertising and promotional rules, and Medicare and Medicaid regulatory issues. He also has worked extensively on state laws regulating pharmaceutical and medical device companies and on physician-industry conflict-of-interest laws. Mr. Bentivoglio has extensive experience developing, implementing and assessing corporate compliance programs in line with the US Sentencing Commission and HHS OIG guidelines, and with state compliance program laws and regulations. In addition, he has assisted pharmaceutical and medical device manufacturers in investigations by various US Attorney's Offices, the Criminal and Civil Divisions of the US Department of Justice, and state attorney generals; and negotiated several Corporate Integrity Agreements. Mr. Bentivoglio received a BA from the University of California, Berkeley, and a JD from Georgetown University Law Center.

KEVIN BETTS is a Social Science Analyst at the US Food and Drug Administration's Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, where he provides research and consulting services pertaining to promotional prescription drug communications. His research has informed public thinking on a diverse array of applied issues concerning healthcare judgment and decision making and is published in leading scientific outlets such as *Journal of Communication* and *Personality and Social Psychology Review*. Dr. Betts received his Ph.D. in Health/Social Psychology from North Dakota State University.

TIMOTHY CANDY is a Principal Consultant at Opus Regulatory, Inc., a leading regulatory affairs consulting firm serving biopharmaceutical companies throughout the US. He specializes in providing regulatory consultation services in the area of advertising & promotion compliance.

Prior to Opus, Tim served in a wide variety of roles & expanding responsibilities spanning across Medical Affairs, Clinical Affairs, and Regulatory Affairs at companies in the Northern Illinois area, including TAP Pharmaceuticals, Baxter, Hospira (acquired by Pfizer) and Baxalta (acquired by Shire).

Prior to entering a career in the Pharmaceutical Industry, Tim completed his Pharm.D. degree at the University of Nebraska –Medical Center, completed a Pharmacy Practice Residency at Nebraska Methodist Hospital, and completed a parallel program of a MS degree in Health-Systems Pharmacy Administration at The Ohio State University with a 2-year Pharmacy Administration Residency at Grant Medical Center. Tim is also a Board Certified Pharmacotherapy Specialist. He currently resides in Omaha, Nebraska, with his wife and two children.

JEFFREY CHASNOW is Senior Vice President and Associate General Counsel at Pfizer Inc, and Chief Counsel for Pfizer Innovative Health. Prior to joining Pfizer in 1999, Jeff was a trial attorney at the Department of Justice's Office of Consumer Litigation (now called the Consumer Protection Branch), where he litigated numerous cases addressing the legality of FDA regulatory actions. At FDLI, Jeff has served on the H. Thomas Austern Writing Awards Committee (including as chair) and the editorial advisory board of the FDLJ (including as chair). Jeff also has taught food and drug law as an adjunct faculty member at the Temple University School of Pharmacy and as a guest lecturer at the Fordham and Quinnipiac law schools. Jeff and his Pfizer colleague, Geoff Levitt, have published two articles on off-label product communications: "Preemption of Non-Federal Restraints on Off-Label Product Communications," 71 Food & Drug L.J. 249 (2016), which addresses preemption limitations on state-law enforcement; and "Off-Label Communications: The Prodigal Returns," 73 Food & Drug L.J. 257 (2018), which reviews First Amendment issues.

RICHARD CLELAND is Assistant Director of the Division of Advertising Practices at the Federal Trade Commission. Mr. 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 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. Kellie routinely advises clients on lifecycle management and regulatory exclusivity, regulation of clinical research, product approvals, and post-approval compliance. Kellie also has extensive experience handling matters implicating FDA promotional rules and the First Amendment, frequently performs regulatory due diligence in connection with transactions involving life sciences clients, and has advised on a number of government investigations of FDA-regulated companies.

DALE COOKE is the president of PhillyCooke Consulting, which helps companies communicate about FDA-regulated products using 21st century tools, while remaining compliant with regulations written in the 1960s. Dale has worked with more than 50 pharmaceutical and medical device clients and more than 20 advertising agencies around the world. His insights have been featured in the Wall Street Journal's Health blog, The Pink Sheet, Stat News, Law360, and other publications. Dale is an active member of the Regulatory Affairs Professionals Society (RAPS), Drug Information Association (DIA), Food and Drug Law Institute (FDLI), the Alliance for a Stronger FDA, and the Google Health Advisory Board.

Dale is the author of Effective Review and Approval of Digital Promotional Tactics, which is now in its second edition in FDLI's Topics in Food and Drug Law series. He is regularly invited to speak at industry conferences on topics including FDA enforcement trends, best practices for review processes, global review practices, and life sciences use of social media. Previously, Dale served as the head of Regulatory for Digitas Health LifeBrands, which is part of the Publicis Healthcare Communications Group.

Dale earned his BA in Philosophy from Southern Methodist University, an MA in Philosophy from the University of Arizona, and studied Epidemiology and Biostatistics at Drexel University's School of Public Health and Healthcare Compliance at Seton Hall University's School of Law. Dale is currently enrolled at Drexel University's Kline School of Law with anticipated JD completion in 2019.

CHRISTINE CORSER is a health science policy analyst in FDA's Office of Prescription Drug Promotion (OPDP). Prior to serving in this role, she was a writer/editor for US Immigration and Customs Enforcement Health Service Corps and she also served as a senior regulatory review officer in OPDP from 2010-2015. She is a pharmacy officer in the US Public Health Service Commissioned Corps and she received her Doctor of Pharmacy degree from Wilkes University.

JAMES CZABAN is a partner in the law firm DLA Piper LLP (US) in Washington, DC, where he is the Chair of the FDA and Medical Products Regulatory Practice Group and a member of the firm's Global Life Sciences Sector team. His practice focuses on serving the strategic business needs of pharmaceutical, biotechnology, food, medical device and other healthcare-related clients in all aspects of FDA regulation, including product development, FDA approvals, Hatch-Waxman and lifecycle management strategies, product advertising and promotion and the dissemination of medical information, FDA compliance and enforcement matters, and related federal and state laws impacting these clients. He also represents medical product companies in matters involving legislative strategies and advocacy, contested regulatory proceedings, administrative

litigation in federal courts, corporate disclosure issues, and regulatory due diligence and deal structuring. Mr. Czaban is a graduate of the University of California, Berkeley, and the University of Virginia School of Law.

MARK DUPLESSIS is an Associate Director in Regulatory Affairs-Advertising & Promotion at Celgene Corporation supporting the Inflammation and Immunology franchise. Mark started at Celgene in the late summer of 2017. Prior to Celgene, Mark was an Associate Director in the same role at Bristol-Myers Squibb for 3 years.

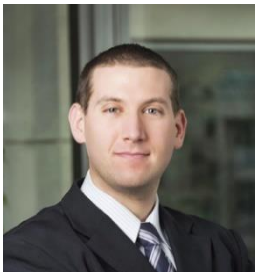
MARK GAYDOS is Vice President and Head of both Region North America General Medicines & Established Products and US Advertising & Promotion within Sanofi's Global Regulatory Affairs organization. In this role, Mark is accountable for regulatory leadership and strategy for marketed products, including lifecycle management, and development projects. He also oversees regulatory review of promotional activities across US business united to ensure compliance.

Prior to joining Sanofi, Mark has held positions of increasing responsibility with Pfizer, Amgen, Block Drug Co., Whitehall-Robins Healthcare, and Biocraft Laboratories. Mark has nearly 25 years of pharmaceutical industry experience, which includes development of regulatory strategies in the areas of advertising and promotion, labeling, product defense, clinical trials and product maintenance. His professional experience includes effective interactions with the FDA and non-US health authorities in these areas.

JEFF GIBBS is a Director in the law firm of Hyman, Phelps & McNamara, PC in Washington, DC. In this role, he advises companies on a wide range of issues, including product approvals, marketing, clinical studies, and enforcement. Prior to entering private practice, he was Associate Chief Counsel for Enforcement at the Food and Drug Administration (FDA). He has written extensively on FDA regulatory topics, and was previously Chair of the Editorial Advisory Board of the Food and Drug Law Journal. He is currently General Counsel of The Food and Drug Law Institute (FDLI) and a member of FDLI's Board of Directors. He is also on the editorial advisory board of IVD Technology, and was a member of the Human Subjects Research Board for George Mason University. Mr. Gibbs is a graduate of Princeton University and New York University School of Law.

HEIDI GERTNER is a partner at Hogan Lovells Washington, DC office where she works at the forefront of the drug regulatory industry. She provides insight to large and small pharmaceutical companies and research institutions in dealing with government regulators to maximize business potential. Heidi began her professional career with a focus on bioethics and law, completing two post-doctoral bioethics fellowships, one at the Cleveland Clinic Foundation, and another at the National Institutes of Health. At the National Institutes of Health her work focused primarily on human subject protection and research ethics issues. She hones her legal skills at FDA's Office of Chief Counsel, where she advised government regulators on almost all aspects of drug regulation for 13 years. At FDA, her portfolio focused on drug advertising and promotion, combination

products, drug safety, clinical trials and human subject protection, Rx-OTC switches, and over-the-counter drug regulation. Heidi joined Hogan Lovells in 2014 and calls the DC office her home base.



ABRAHAM GITTERMAN is a Life Sciences/Healthcare Associate at Arnold & Porter LLP in Washington, DC, where he focuses on FDA and healthcare regulatory, compliance, and fraud and abuse matters involving pharmaceutical and medical device manufacturers. He regularly counsels clients on FDA-regulated advertising and promotion, including use of social media; compliant medical affairs activities, including continuing medical education (CME); appropriate interactions with healthcare professionals; and mobile health applications. Mr. Gitterman also assists with extensive reviews of corporate compliance programs, both generally and pursuant to Corporate Integrity Agreements (CIAs) with OIG, for various life science companies and healthcare entities to ensure compliance with the Anti-Kickback Statute; the False Claims Act; and the Federal Food, Drug, and Cosmetic Act. Mr. Gitterman also has extensive experience counseling clients on the Physician Payments Sunshine Act and related state transparency and "gift ban" laws. He also advises clients on compliance with the Drug Supply Chain Security Act (DSCSA) and the Compounding Quality Act.

KELLY GOLDBERG is a vice president, law/senior counsel for biopharmaceutical regulation at PhRMA. Kelly joined PhRMA in April 2017. In her role, Kelly has responsibility for FDA and related regulatory law issues. Prior to joining PhRMA, Kelly spent over a decade at Pfizer. At Pfizer, Kelly was responsible for counseling internal clients on a wide-range of regulatory law issues, including data exclusivity, biosimilars, orphan drug provisions, drug safety and risk evaluation and mitigation strategies, drug labeling, drug approval standards and pathways, and advertising and promotion. Kelly was an associate in the Food and Drug practice group at Covington & Burling before joining Pfizer. She earned her JD, cum laude, from the University of Pennsylvania Law School and clerked for the Honorable Joseph E. Irenas on the United States District Court for the District of New Jersey.

JASON GORDON is of counsel at Reed Smith LLP in Chicago, and a member of the firm's Entertainment & Media Group. He represents Fortune 100 brands, media companies, consumer packaged goods companies, and other advertisers in all aspects of advertising, marketing, new media, branding, privacy, mobile marketing, behavioural advertising, right of publicity, and traditional trademark and copyright prosecution and counselling.

CATHERINE GRAY leads the Advertising and Promotion Policy Staff in OPDP at the FDA. Her diverse team of professionals focuses on the challenging and evolving policy issues pertaining to the promotion of prescription drugs. She oversees policy development, social science research and operational support to the full office as it realizes its mission to protect the public health. Her over twenty years of experience include roles in clinical pharmacy and the pharmaceutical industry. She completed Fellowships in the Rutgers University Pharmaceutical Industry Post-Doctoral Fellowship program and the Partnership for Public Service Excellence in Government Fellowship program.

SUE GREGORY is a Managing Counsel in the Regulatory and Commercial group within Merck's Office of General Counsel.

Sue provides legal advice to the US and Global businesses on issues such as advertising and promotion, training and compliance, with a current focus on oncology. She also provides legal advice to the research division on issues relating to clinical studies, marketing authorizations, post-market safety surveillance, compliance, and labeling.

Sue joined Merck in 1993 and has held a number of positions of increasing responsibility. Prior to joining Merck, she practiced law at Morgan, Lewis & Bockius in Washington, DC. Sue is a graduate of Georgetown University School of Law, Washington, DC, and Duke University, Durham, NC.

COLLEEN HEISEY is a partner at the law firm of Jones Day where her practice focuses on food and drug law with a particular emphasis on product promotion and advertising, compliance counseling, good manufacturing practice requirements, product recalls, FDA inspection, competitor issues, and enforcement actions. She has advised on issues surrounding the regulation of drug, biological, food, dietary supplement, medical device, and cosmetic products by the FDA, USDA, and other federal and state agencies.

JENNIFER HENDERSON is Partner at the law firm of Hogan Lovells LLP. Jennifer has extensive background in the health industry lets her strategically navigate US Food and Drug Administration (FDA) regulatory matters for medical device companies — both premarket and postmarket. She helps medical device manufacturers obtain FDA clearance for innovative device. Be it investigational device exemptions (IDEs), 510(k)s, de novo petitions, or premarket approvals (PMAs), she assists clients in all matters pertaining to premarket submissions. As the industry has evolved, so has Jennifer's practice. She is well versed in the areas of FDA regulation of mobile health, medical apps, medical software, combination product jurisdictional issues, clinical trial conduct, Bioresearch Monitoring matters, medical device appeals, and conducting regulatory due diligence. A key piece of Jennifer's practice is the advertising and promotion of medical devices, from traditional media platforms like print and TV ads to global websites and social media platforms. She helps clients in comprehensive audits of promotional materials and provides strategic advice regarding development of marketing strategies and procedures and policies. Jennifer is frequently asked to provide in-house training on advertising and promotional issues. She has also authored numerous articles on medical device regulation, advertising and promotion issues, and mobile health. Jennifer learned the ins and outs of the industry at the Center for Integration of Medicine & Innovative Technology (CIMIT), a nonprofit consortium of the Harvard Medical Institutions and the Massachusetts Institute of Technology (MIT), dedicated to medical product innovation and development. She also held several academic positions, including Research Fellow and research associate, at Massachusetts General Hospital, as well as Instructor in Dermatology at Harvard Medical School.

RYAN HOHMAN currently serves as Vice President - Public Affairs at Friends of Cancer Research (*Friends*). Previously, he was *Friends'* Managing Director of Policy & Public Affairs. *Friends* is an advocacy organization based in Washington, DC that drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients. During the past 20 years, *Friends* has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible.

At *Friends*, Ryan leads the strategic development and execution of public-policy and legislative initiatives to enhance US Food and Drug Administration regulatory policies, its institutes, and research programs. Additionally, Ryan oversees the organization's targeted outreach, comprehensive communications strategy, federal affairs, advocacy relations, and the organization's development programs. As Vice President - Public Affairs at *Friends*, Ryan has the privilege of serving on many important boards and committees of organizations who share *Friends'* mission, including: Chair, Lung-MAP Clinical Trial Public Affairs Committee; Advisory Council Member, Enroll America; Principles Working Group, National Dialogue for Healthcare Innovation (NDHI); Strategic Advisory Committee, The Ruesch Center for the Cure of Gastrointestinal Cancers at Georgetown - Lombardi CCC; and the Advisory Council, Capital Breast Care Center.

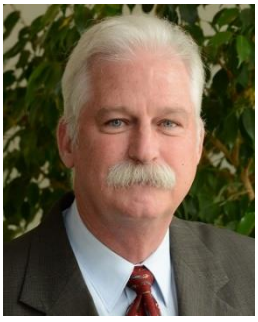
During his diverse career, Ryan has experienced first-hand the vital need and incredible impact that sustained federal funding of the biomedical field has on physicians, researchers, and scientists and the difficulties many of these communities face when engaging in and navigating the regulatory process. Before joining *Friends*, Ryan was Director of Corporate and Institutional Partnerships at Georgetown University Medical Center-Lombardi Comprehensive Cancer Center. While at Georgetown, Ryan focused on the development and execution of strategic corporate and philanthropic engagement to support the center's biomedical research and cancer treatment and education programs. During this time, Ryan was appointed to the Board of Directors of the Cancer Research Alliance and worked to support and expand the programs of the Capital Breast Care Center, which provides comprehensive, culturally appropriate breast cancer screening services and health education to women in the Washington, DC metropolitan area.

Prior to his time at Georgetown, Ryan was an associate with a DC & Boston-based public relations firm, specializing in health and trade association media and governmental strategy. Ryan has also served in numerous political campaigns and offices, including: former Senate Majority Leader Tom Daschle's 2004 Senate race, Senator John Edwards' Presidential Campaign, and at the Democratic National Committee under then Chairman Terry McAuliffe.

SCOTT LASSMAN is Chair of the FDA Practice Group at Goodwin Procter LLP, a leading international law firm focused on life sciences companies. With more than twenty-five years of experience in food and drug law, Mr. Lassman provides strategic advice and advocacy on complex legal, regulatory and legislative matters affecting companies regulated by the Food and Drug Administration (FDA), including pharmaceutical, biotech, medical device, food and cosmetic companies. Mr. Lassman combines a strong public policy background with a deep understanding of the real-world challenges faced by regulated industry, with

particular expertise on pharmaceutical lifecycle management and competition issues, advertising and promotion, drug and device labeling, drug and device product approval, biosimilars, and FDA regulatory policy. He strives to achieve his clients' business objectives through both counseling and advocacy and has a successful track record using FDA's Citizen Petition process and, when necessary, in litigation with FDA in federal court. Prior to joining Goodwin in 2016, Mr. Lassman served as Chair of the FDA Practice Group of a large, international law firm, as a partner in a well-regarded FDA boutique, and as Senior Assistant General Counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA), where he was responsible for FDA regulatory and policy matters.

ANNE MAHER is a partner in the law firm of Kleinfeld, Kaplan & Becker, LLP in Washington, DC. She specializes in the needs of Food and Drug Administration (FDA)-regulated companies and related entities. She counsels clients on food, drug, dietary supplement and cosmetic advertising issues and requirements and represents clients in investigations and advertising challenges. She also frequently speaks at industry and association meetings involving advertising law and policy. Before joining KKB, Ms. Maher was the Assistant Director for Advertising Practices Division in the Federal Trade Commission's (FTC) Bureau of Consumer Protection, where she supervised law enforcement investigations and industry outreach. Prior to her appointment as Assistant Director, she served in the Office of the Director, Bureau of Consumer Protection and as Attorney Advisor to an FTC Commissioner as well as a staff attorney. Ms. Maher was the FTC's designated liaison with FDA and USDA, and worked closely with the staff of both agencies on a wide range of projects and regulatory actions. She directed the development of FTC's 1994 Food Advertising Enforcement Policy Statement, and was integral in the creation of FTC's 1998 Dietary Supplement Advertising Guide, as well as the 1999 Report to Congress on Self-Regulation in the Alcohol Industry. She is a recipient of the Federal Trade Commission's Award for Distinguished Service. Ms. Maher received her BA from Boston University and her JD from Northeastern University School of Law.



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.

AMIE O'DONOGHUE is a Social Science Analyst in the Office of Prescription Drug Promotion (OPDP), Center for Drug Evaluation and Research (CDER), Food and Drug Administration. She has published over 25 articles on professional and direct-to-consumer (DTC) advertising and the communication of information to physicians and consumers. She also provides technical assistance on research and communication issues to FDA staff and external organizations. Before joining OPDP in 2003, Dr. O'Donoghue taught psychology at St. Mary's College of Maryland. She received her doctorate in psychology from Washington University in St. Louis.

ELIZABETH PEPINSKY is a Health Science Policy Analyst in FDA's Office of Prescription Drug Promotion, where she focuses on guidance and policy development. Prior to joining OPDP, she served as a Regulatory

Counsel in FDA's Center for Tobacco Products. Ms. Pepinsky received her BS from Wake Forest University and her J.D. from the University of Baltimore School of Law.

KAI PETERS is a partner at the law firm of Gordon Rees Scully Mansukhani, LLP where he specializes in acting as outside general counsel for businesses on a broad range of corporate, commercial and litigation matters, and in representing businesses in simple and complex litigation.

Mr. Peters has significant experience in litigation, including product liability, mass torts, class actions, breach of contract, and business disputes. He has a particular emphasis in complex commercial litigation representing pharmaceutical, medical device, and other FDA-regulated companies, solar companies, and hi-tech and new media companies. Mr. Peters acts as national and local litigation counsel for companies of all sizes in state and federal courts, including in MDL's and in coordinated proceedings. He has recovered significant sums in breach of contract matters as well. He also advises corporate clients in the area of avoidance of potential liability and litigation, from training and organization of sales representatives to the form and content of internal and external documents.

Mr. Peters has extensive experience in all phases of litigation, including the initial phases of litigation; development and preparation of witnesses for testimony; depositions of experts and company witnesses of all backgrounds (including special emphasis on working with sales representatives, regulatory employees, and company executives); analysis and development of defenses, including those based on medical and scientific causation issues, labeling, and preemption; motion practice; written discovery; major document organization and review (including e-discovery); summary judgment motions; alternative dispute resolution including mediation; evaluation of cases with experts; and the trial phase.

WAYNE PINES is President of Healthcare and Regulatory Services at APCO Worldwide. He also is an independent consultant and serves on the promotional review committees of companies as the regulatory reviewer. Mr. Pines is chair of the advisory board for the Center for Communication Compliance and developed a certification test and program for advertising/promotion professionals (www.communicationcompliance.com). Mr. Pines served for ten years at the FDA, including four as Associate Commissioner for Public Affairs. In 2004 was named FDA's Alumnus of the Year. Mr. Pines is a director and was founding President of the Alliance for a Stronger FDA, an organization that is seeking to increase FDA's budget. For 12 years he has been as a director (Chairman of the Board for three years) of the MedStar Health Research Institute, which oversees research at a dozen hospitals in the Washington DC and Baltimore area. Mr. Pines also was a founding director of the FDA Alumni Association, and serves on the board of The Wellness Channel, which provides TV programming to hospitals; and Excel Life Sciences.

PETER PITTS is President of the Center for Medicine in the Public Interest. A former member of the United States Senior Executive Service, Peter was FDA's Associate Commissioner for External Relations, serving as senior communications and policy adviser to the Commissioner. He supervised FDA's Office of Public Affairs, Office of the Ombudsman, Office of Special Health Issues, Office of Executive Secretariat, and Advisory Committee Oversight and Management. He served on the agency's

obesity working group and counterfeit drug taskforce and as a Special Government Employee (SGE) consultant to the FDA's Risk Communications Advisory Committee.

Specific areas of global policy expertise include FDA policy and process, healthcare technology assessment and reimbursement issues, real world evidence, social media, off label-communications, pharmacovigilance, patient-focused drug development, abuse-deterrent opioids, biosimilar development, Rx-to-OTC switching, risk management plans, GMP policies, pharmacy education programs, drug safety, Critical Path, personalized medicine, clinical trial transparency, IP protection, FDA reform, drug importation, counterfeiting, genetically modified food issues, food safety and security, recalls, nutritional labeling.

In 2010, he was named by *Modern Healthcare* magazine as one of the 300 "most powerful people in American healthcare."

His comments and commentaries on health care policy issues regularly appear in *The New York Times, The Los Angeles Times, The Washington Post, The Wall Street Journal*, *The Financial Times*, *Health Affairs*, Time, Newsweek, *The Boston Globe*, *The Washington Times*, *The Chicago Tribune, The San Francisco Examiner*, *Investor's Business Daily*, *The Baltimore Sun*, *The Economist, The Lancet, Nature Biotechnology, The Journal of Life Sciences the BBC World Service, Fox News, CNBC, Bloomberg, The PBS NewsHour*, NBC Dateline, *The Daily Show with John Stewart*, among others.

He has given healthcare policy presentations throughout Europe, Canada, and the United States, as well as in Russia, China, Hong Kong, Taiwan, India, the Philippines, Malaysia, Saudi Arabia, Lebanon, Oman, Israel, Turkey, The United Arab Emirates, Kuwait, Qatar, Jordan, Kenya, South Africa, Egypt, Algeria, Ukraine, Thailand, Japan, Brazil, Mexico, Vietnam, Indonesia, Singapore, Panama, Costa Rica, Argentina, and Columbia.

His book, *Become Strategic or Die*, is widely recognized as a cutting edge study of how leadership, in order to be successful over the long term, must be combined with strategic vision and ethical practice. He is the editor of *Coincidence or Crisis*, a discussion of global prescription medicine counterfeiting and *Physician Disempowerment: A Transatlantic Malaise.*

He is a Visiting Lecturer at the École Supérieure des Sciences Économiques et Commerciales (Paris and Singapore), and has served as an adjunct professor at Indiana University's School of Public and Environmental Affairs and Butler University. A graduate of McGill University, he is married to Jane Mogel, and has two sons.

VERNESSA POLLARD is a partner at the law firm of McDermott Will & Emory where she advises companies on regulatory, compliance, enforcement and policy matters involving pharmaceuticals, medical devices, health information technology (HIT) and digital health solutions, services and software. She advises companies and investors on regulatory and compliance issues arising from mergers, acquisitions and other transactions involving Food and Drug Administration (FDA)-regulated products. She also counsels manufacturers, distributors and retailers on regulatory and compliance issues related to food and cosmetic marketing and safety.

Vernessa regularly counsels companies on product development and premarket strategy, Good Manufacturing Practice (GMP) and Quality System (QS) requirements, advertising and promotion, adverse

event report FDA warning letters, FDA inspections, recalls, import detentions and corporate compliance programs. She has represented companies and executives in FDA and Department of Justice (DOJ) investigations and enforcement matters. She also conducts due diligence evaluations and analyses of FDA regulatory issues relating to mergers and acquisitions.

Previously, Vernessa spent six years as an associate chief counsel for enforcement in the Office of Chief Counsel at the FDA, where she represented the FDA in a variety of litigation, compliance and regulatory matters. In conjunction with the DOJ, she handled civil injunction and consent decree actions involving pharmaceutical, medical device, food and cosmetic manufacturers. She obtained the FDA's first administrative civil money penalty (CMP) judgment for violations of the Medical Device Report (MDR) requirements. She also handled defensive matters involving FDA regulations and policies for product labeling, advertising and product approval issues arising under the Administrative Procedure Act (APA), the First Amendment, and the Federal Food Drug and Cosmetic Act (FDCA).

While in law school, Vernessa was the managing editor for the Temple Political and Civil Rights Law Review.

JENNIFER ROMANSKI is Vice President and Chief Privacy Officer of Porzio Life Sciences, LLC. In collaboration with the other Directors of Regulatory and Compliance Services, Ms. Romanski is responsible for ensuring that all products are relevant to the needs of the industry and working with other personnel to create new products. Ms. Romanski is also a principal of Porzio, Bromberg & Newman PC, and a member of the firm's Life Sciences Compliance and Commercialization team. Ms. Romanski counsels pharmaceutical and device manufacturers on federal and state fraud and abuse laws, sampling compliance, and state disclosure and prohibition laws. She develops policies and procedures and conducts training programs for clients, in connection with their comprehensive compliance programs. She evaluates grants and contributions, drug and device advertising and promotion, and marketing activities directed to healthcare professionals. Additionally, Ms. Romanski provides general business counseling on contractual issues. Ms. Romanski received a JD from University of Pennsylvania Law School, in 1997. She earned her BA in Biological Basis of Behavior, cum laude, from University of Pennsylvania in 1994.

JASON ROSE is a co-chair of Venable's Product Liability and Mass Torts practice group where he focuses on pharmaceutical and medical device litigation, particularly mass torts. In this area, he has significant experience with expert witness development, briefing substantive and Daubert issues, company story development, fact and expert depositions, and trial proceedings. Mr. Rose is currently serving as deputy co-national counsel to a major pharmaceutical company in MDL and consolidated state court litigation involving proton pump inhibitor drugs. Mr. Rose is a member of the International Association of Defense Counsel (IADC) and serves as Chair of the Drug, Device & Biotechnology Committee.

PAUL SAVIDGE is Senior Regulatory Counsel at Spark Therapeutics, a leading gene therapy company, where he provides counsel on a broad range of issues, including those related to drug development and commercialization. Prior to joining Spark, Paul was senior vice president and deputy general counsel at Bristol-Myers Squibb and led the legal groups assigned to the company's global commercial and research organizations. Prior to BMS, Paul held positions in the US and European legal departments at Merck. Paul received his JD from Washington & Lee University, an MBA from the Kellogg School of Management at Northwestern University and a BSFS from Georgetown University's School of Foreign Service.

CASSIE SCHERER is Principal Legal Counsel at Medtronic. Cassie is part of the Corporate Legal Regulatory team at Medtronic, and advises on a wide variety of FDA legal and regulatory matters relating to medical devices. Cassie joined Medtronic from Covington and Burling, where she was Special Counsel in the firm's food and drug practice group. At Covington, Cassie advised companies on compliance with FDA's premarket and postmarket requirements relating to medical devices. Prior to that, Cassie was with FDA where she served as an Associate Chief Counsel in FDA's Office of Chief Counsel and as Director of Strategy and Regulatory Operations in CDRH's Office of Center Director. Cassie received her BA from University of Pennsylvania summa cum laude and her J.D. from the University of Virginia School of Law.

ELLEN SCHUMACHER is Executive Director of US Commercial Regulatory Affairs, joined Bristol-Myers Squibb in 1998 as a Medical Information Specialist. In 2007, Ellen moved to the regulatory side of the company where she utilized her pharmaceutical and medical expertise, as well as her knowledge of FDA regulations and guidance documents, to provide strategic regulatory advice across multiple therapeutic areas and multiple alliances. In demonstrating her leadership, Ellen facilitated the Companies' efforts in comprehending the utilization of social media in promotion, as well as, her participation in the many forums in the advancement of patient understanding of promotional materials. Ellen excels at managing and coaching teams, and currently leads a large team of regulatory professionals and operations specialists. Prior to her time at Bristol-Myers Squibb, Ellen worked as a hospital pharmacist and then moved on to Director of Operations at a private home care company pharmacy. Ellen is an active member of the FDLI Planning Committee. She is a graduate of the Brooklyn College of Pharmacy and holds a Bachelor of Science degree in Pharmacy.

JEFFREY SHAPIRO specializes in medical device law, advising and representing companies before FDA for 25 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. Mr. Shapiro also counsels clients on FDA requirements governing IVDs and HCT/Ps. Mr. Shapiro is an expert in FDA's regulation of combination products, including preparation of RFDs. 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.

LAUREN SILVIS serves as the Chief of Staff to FDA Commissioner Scott Gottlieb, M.D. In this capacity, she provides advice and counsel to the Commissioner and acts as the Commissioner's direct liaison to other agencies and organizations on key initiatives. She also works closely with the agency's individual product centers to support their implementation of agency policy and commitments. She provides strategic direction to senior leadership to advance agency priorities.

Ms. Silvis has deep expertise in all aspects of the Federal Food, Drug and Cosmetic Act and the oversight of FDA-regulated products. She has significant experience in regulatory and compliance issues, including clinical trials, premarket review and approval, product safety and promotion, import and export, and current good manufacturing practice.

Before being appointed Chief of Staff, Ms. Silvis served as Deputy Center Director for Policy in FDA's Center for Devices and Radiological Health. In this role, she led the development and implementation of all medical device policies, regulations, and guidance, and oversaw the Center's communication and education functions. She regularly advised on regulatory, programmatic and legislative issues affecting medical devices and represented the Center on cross-cutting Agency policy issues.

Prior to joining FDA in 2015, Ms. Silvis was a partner practicing food and drug regulatory law at a large international law firm. She graduated cum laude from Duke University and earned her law degree cum laude from Georgetown University Law Center, after which she served as a law clerk to the Honorable James L. Ryan, US Court of Appeals for the Sixth Circuit.

SARAH STEC is an associate in the Healthcare Practice at Squire Patton Boggs (US) LLP in Washington, DC. She has experience in assisting healthcare and life sciences companies understand new and evolving regulatory duties, including how those international regulations can work together as well as providing guidance on international corporate accreditation and regulatory issues. Her background in quality systems and experience with international regulators gives her a unique view on the legal and regulatory requirements for medical device, pharmaceutical, and food manufacturers.

LISA STOCKBRIDGE is Chief of the Advertising and Promotional Labeling Branch (APLB) in CBER's Office of Compliance and Biologics Quality. APLB is responsible for reviewing promotional materials, product labeling, proposed proprietary names, and proper name suffixes. Dr. Stockbridge is a recognized subject matter expert, serving on many workgroups, taskforces, and special projects. She holds a BA in Biology and Psychology from Manhattanville College, an MS and PhD in Medical Physiology from New York Medical College, and postdoctoral experience in Physiology/Biophysics from University of Alberta-Edmonton and the NIH.

HELEN SULLIVAN is a Social Science Analyst in the Office of Prescription Drug Promotion at the US Food and Drug Administration (FDA). Prior to joining FDA, she was a Cancer Prevention Fellow at the National Cancer Institute. She received her BA from Yale University; her PhD in psychology from the University of Minnesota, Twin Cities; and her MPH from Johns Hopkins Bloomberg School of Public Health.

MICHAEL SWIT is Managing Principal at the Law Offices of Michael Swit where he has been addressing critical US Food and Drug Administration (FDA) legal and regulatory issues since 1984. Before returning to private law practice in late 2017, he served for three years at Illumina, Inc., the world's leading developer of gene sequencing technology, as its chief regulatory counsel. Prior to that, Swit was a special counsel in FDA Practice at the global law firm of Duane Morris LLP in its San Diego office. Before joining Duane Morris in March 2012, Swit served for seven years as a vice president at The Weinberg Group Inc., a preeminent scientific and regulatory consulting firm in the Life Sciences. His expertise includes product development, compliance and enforcement, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts for all types of life sciences companies, with a particular emphasis on drugs, biologics, and therapeutic biotech products. His FDA legal and regulatory work also has included tenures in the food and drug law practices McKenna & Cuneo (now Denton's) and Heller Ehrman, and as vice president, general counsel, and secretary of Par Pharmaceutical, a top public generic and specialty drug firm, where he helped spearhead the company's recovery from prior management's involvement in the Generic Drug Scandal of the late 1980's. He also was, from 1994 to 1998, CEO of *FDANews.com,* a premier publisher of regulatory newsletters and other specialty information products for FDA-regulated firms. He has taught and written on many topics relating to FDA regulation and associated commercial activities and is a past member of the *Food & Drug Law Journal* Editorial Board. He earned his AB, *magna cum laude*, with high honors in history, at Bowdoin College, and his law degree at Emory University.

DEBORAH WOLF is an attorney and regulatory counsel in the Office of Compliance in FDA's Center for Devices and Radiological Health. She has worked for many years on issues related to the labeling and promotion of medical devices. She has worked in this general subject matter area since 1995 except for a three year period during which she supervised CDRH's Regulations Staff.