Enforcement, Litigation, and Compliance Conference

For the Drug, Device, Food, and Tobacco Industries

December 6-7, 2017

Speaker Biographies

JONATHAN H. ADLER is the inaugural Johan Verheij Memorial Professor of Law, and Director of the Center for Business Law & Regulation at the Case Western Reserve University School of Law, where he teaches courses in environmental, administrative, and constitutional law. Professor Adler is the author or editor of seven books, and over a dozen book chapters. His articles have appeared in publications ranging from the Harvard Environmental Law Review and Supreme Court Economic Review to The Wall Street Journal and USA Today. He has testified before Congress a dozen times, and his work has been cited in the U.S. Supreme Court. A 2016 study identified Professor Adler as the most-cited legal academic in administrative and environmental law under age 50. Professor Adler is a senior fellow at the Property & Environment Research Center in Bozeman, Montana and at the Center for the Study of the Administrative State at the George Mason University School of Law. He also serves on the academic advisory board of the Cato Supreme Court Review, the NFIB Small Business Legal Center Advisory Board, the Board of Directors of the Foundation for Research on Economics and the Environment, and the Environmental Law Institute's Environmental Law Reporter and ELI Press Advisory Board. Prior to joining the faculty at Case Western Reserve, Adler clerked for the Honorable David B. Sentelle on the U.S. Court of Appeals for the District of Columbia Circuit. From 1991 to 2000, Adler worked at the Competitive Enterprise Institute, a free market research and advocacy group in Washington, DC, where he directed CEI's environmental studies program. He holds a BA, magna cum laude, from Yale University, and a JD, summa cum laude, from the George Mason University School of Law.

REND AL-MONDHIRY is Associate General Counsel at the Council for Responsible Nutrition (CRN) in Washington, DC. At CRN, she provides legal counsel and advice to staff and members in the areas of legislation, regulatory compliance and advocacy, and international policy development with respect to dietary supplements and nutrition issues. She also advises the association on a variety of general business matters, including contract drafting, negotiation and review, non-profit and association governance issues, and general corporate matters affecting CRN, CRN-International, and the CRN Foundation. Previously, Ms. Al-Mondhiry worked as state legislative counsel for the Consumer Healthcare Products Association (CHPA) where she provided testimony and comments on legislative and regulatory proposals, drafted legislation and regulatory language, and served as a policy expert in food and drug law. Prior to joining CHPA, she worked at the American Speech-Language-Hearing Association, serving as the director of state legislative and regulatory advocacy. Ms. Al-Mondhiry received her BA from The George Washington University and her JD from Pennsylvania State University, Dickinson School of Law.

STEVEN ARMSTRONG is an independent advisor at EAS Consulting Group. He has over 20 years of experience advising leading consumer products companies on marketing and regulatory matters. Prior to EAS, Mr. Armstrong served as the Chief Food Law Counsel at Campbell Soup Company, where he counseled Campbell businesses on food safety, food policy, labeling and regulatory compliance, including matters involving FDA, USDA, and food agencies around the world. He has also served as the Senior Marketing Counsel at Energizer's Schick-Wilkinson Sword Division and as the Assistant General Counsel for Marketing at Unilever United States. Mr. Armstrong is on the Board of Directors of the Food and Drug Law Institute in Washington, DC, and is a frequent speaker on food law issues. Mr. Armstrong earned his bachelor's degree from Harvard College and his law degree from Columbia University.

DONALD ASHLEY is Director of CDER's Office of Compliance, where he leads efforts to protect the American public from unsafe, ineffective and low-quality drug products through measures designed to assist industry-wide compliance with federal standards for quality and safety, as well as regulatory and enforcement measures to address violations of those same standards. Mr. Ashley joined FDA after more than 18 years of criminal enforcement and investigation experience with the Department of Justice (DOJ). His many positions with DOJ included serving as a Trial Attorney in the Office of Consumer Litigation (now the Consumer Protection Branch), where he prosecuted consumer fraud offenses and violations of the Food Drug and Cosmetic Act (FD&C Act), and as Associate Director of the Office of International Affairs, where he managed international criminal law enforcement cooperation with countries throughout the world, represented DOJ's interests within the United Nations, and negotiated law enforcement cooperation treaties. In addition, Mr. Ashley served as the DOJ Attaché stationed at the U.S. Embassy in Rome, Italy, where he was responsible for facilitating closer cooperation between Italy and United States in organized crime and terrorism investigations. Mr. Ashley also served as the DOJ Attaché at the U.S. Embassy in Manila, Philippines, where he managed international law enforcement collaboration on behalf of the United States with the Philippines, Singapore, Malaysia, and Indonesia. His work focused on money laundering, public corruption, bribery, and fraud investigations. Before joining DOJ, Mr. Ashley served as senior litigation associate with the King & Spalding law firm, specializing in white-collar criminal defense work, often involving clients under investigation for FD&C Act violations. He also served on active duty as an Army captain assigned to the Office of General Counsel, Department of the Army. Mr. Ashley was an adjunct professor of law at Georgetown, George Washington, American, and Catholic Universities teaching a course on the role of federal prosecutors. He also served as vice president of the Board of Trustees at the International School Manila while in the Philippines. Mr. Ashley received a bachelor's degree in political science from John Carroll University in Ohio, and earned a law degree from Harvard Law School.

DEB AUTOR is Head of Strategic Global Quality and Regulatory Policy at Mylan, one of the largest generics and specialty pharmaceutical companies in the world. In this role, Deb represents Mylan's diverse and complex operations to government officials globally and advises Mylan's most senior leaders on how to navigate and influence the regulatory landscape. Previously, as Mylan's Global Head of Quality, Deb managed thousands of personnel around the world, driving quality improvements across scores of manufacturing sites. Prior to joining Mylan in 2013, Deb served for 12 years at FDA, most recently as Deputy Commissioner for Global Regulatory Operations and Policy, where she supervised more than 4,000 employees in FDA's Office of Regulatory Affairs and Office of International Programs in their efforts to confront the challenges of globalization and import safety. She also served for five years as Director of the Office of Compliance of FDA's Center for Drug

Evaluation and Research, where she led policymaking and enforcement for key programs for drugs, including current good manufacturing practices, human subject protection, and marketed unapproved drugs. Before joining FDA, Deb served for seven years as a Trial Attorney at the Office of Consumer Litigation of the U.S. Department of Justice, where she litigated civil and criminal cases on behalf of FDA. Deb's many recognitions for her contributions to public health include the Presidential Rank Award and FDLI's Distinguished Service and Leadership Award. She was also a finalist for the Service to America Medal.

FREDERICK R. BALL is a partner at the law firm of Duane Morris LLP. He is vice-chair of Duane Morris's White-Collar Government Regulatory Division of the Trial Practice Group and heads its Pharmaceutical, Pharmacy and Food Group. He focuses his practice on assisting companies or individuals when they are adverse to state or federal governments, including administrative, civil, and criminal matters with FDA, DEA, CMS, and other federal and state regulatory agencies. Mr. Ball helps generic pharmaceutical companies, biologics manufacturers, food companies (including supplement manufacturers), pharmacies, long-term care providers, and other healthcare providers navigate the complex challenges faced by state and federal regulation of their industries, including complying with current Good Manufacturing Practices, price reporting (AMP, AWP, ASP, etc.), the Foreign Corrupt Practices Act, and fraud and abuse laws including labeling and advertising requirements. Mr. Ball also assists generic manufacturers bring products to market through patent analysis and Hatch-Waxman litigation. He serves on the FDLI Board of Directors, and is admitted to the Illinois State Bar, the Seventh Circuit, and the U.S. Supreme Court. A member of the American and Illinois State bar associations, Mr. Ball is a 1996 cum laude graduate of Cornell Law School and a graduate of the University of Colorado at Boulder.

DAVID BLOCH is Principal Legal Counsel at Medtronic, PLC. At Medtronic and in private practice before that, he has spent more than 20 years counseling clients in the healthcare industry on compliance with government regulation, including requirements of the Food and Drug Administration, anti-kickback standards, and HIPAA privacy. He has been active in industry groups on data privacy, including serving as chair of the Medical Device Privacy Consortium in 2014, leading their efforts to address privacy and cybersecurity issues for the device industry, including drafting position papers, recommending standards, and coordinating advocacy efforts. He is a graduate of Columbia College and University of Pennsylvania Law School.

CAPT SEAN M. BOYD is an active duty commissioned officer in the United States Public Health Service (USPHS). He currently serves as the Acting Director of the Office of Compliance in FDA's Center for Devices and Radiological Health (CDRH). In this capacity, he is responsible for managing the Center's quality, regulatory compliance, and enforcement programs for the medical device industry. Previously, CAPT Boyd served as the Deputy Director of the Division of Radiological Health in the Office of In Vitro Diagnostics and Radiological Health at CDRH. He began his career in 1994 as an engineering analyst in FDA's Winchester Engineering and Analytical Center, joining CDRH in 1999 as a compliance officer. CAPT Boyd progressed through several branch and division management positions within the Center, and has been responsible for a variety of premarket, compliance, surveillance and outreach programs over the course of his career. He received his undergraduate degree in Biomedical Engineering from Boston University, and his Master's Degree in Public Health and Preventive Medicine from the Uniformed Services University of the Health Sciences. CAPT Boyd is also Team Commander for one of two Washington DC-

based medical response teams (PHS-1 Rapid Deployment Force); and deployed in response to several disasters and crises, both domestically and abroad. This experience includes the USPHS Commissioned Corps Ebola Response in 2015, where he served as Deputy Officer in Charge of the Monrovia Medical Unit in Margibi County, Liberia. Past deployments also include serving as Team Commander at Brookdale Hospital (Brooklyn, NY) in 2012 following Hurricane Sandy, Lead Safety Officer at Federal Medical Center (College Station, TX) in 2008 following Hurricane Ike, and Corps Liaison to the HHS Secretary's Command Center (Washington, DC) in 2005 following Hurricane Katrina.

JENNIFER L. BRAGG is a partner at the law firm of Skadden, Arps, Slate, Meagher & Flom LLP in Washington, DC. Ms. Bragg is an experienced regulatory and litigation attorney, advising FDA-regulated companies, as well as hospitals and healthcare systems, facing government investigations and U.S. FDA enforcement challenges. Previously, Ms. Bragg served in FDA's Office of Chief Counsel as Associate Chief counsel for enforcement, where she provided advice to FDA's Office of Criminal Investigations. In addition to her thriving practice, Ms. Bragg is a member of the firm's Women's Initiatives Committee, which is designed to promote the retention and advancement of women in the firm.

BOB BUHLMANN is Director of Corporate Quality Assurance at Amgen, responsible for GxP Computerized Systems and Data Integrity Program. Bob has over 25 years of experience with specialized interest in 21 CFR Part 11 and Computer Systems Validation in a variety of settings, including national and international companies regulated by FDA and other regulatory authorizes. Bob's work has included consultant with KMI (Parexel) as well as working in the industry with several Pharmaceutical companies. He has participated in preparing responses and corrective action plans for computer-related FDA regulatory observations, developing and implementing global and site Part 11 and computer compliance programs, setting requirements on development of global Information Systems quality and compliance functions. Bob has a bachelor's degree in Information Systems from University of Massachusetts –Lowell. Bob is member of PDA and Rx360 and has spoken on the topic of Data Integrity at several industry conferences.

CATHY BURGESS is a partner in the Healthcare Group of Alston & Bird LLP in Washington, DC. Her practice focuses on regulatory compliance, product risk management, enforcement and policy matters affecting industries regulated by FDA. Prior to joining the firm, Burgess served as associate general counsel for the American Red Cross. In this role she provided legal assistance and strategic advice to Red Cross senior management and the Board of Governors on matters related to the Red Cross Amended Consent Decree. Burgess served as the defense team's first chair for expert testimony on cGMPs and analytical method validation in *United States v. Barr Laboratories*, widely recognized as the leading case on cGMPS.

DAVID BURROW currently serves as the acting Director of the Office of Scientific Investigations (OSI), within the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Compliance (OC). In this role, he provides executive leadership for all CDER's pre-, and post-market Bioresearch Monitoring (BIMO) programs. Specifically; the inspection, evaluation, compliance, and enforcement of compliance programs intended to protect the rights, safety, and welfare of human research subjects, and to verify the accuracy, reliability, and integrity of the data submitted to CDER for use in regulatory decision making. He is a recognized expert in all aspects of Good Clinical Practice, Human Subject Protection, Good Laboratory Practice, Bioequivalence, Postmarket Adverse Drug Experience, Postmarket Requirements, and Risk Evaluation and Mitigation Strategies. He also ensures that all significant actions taken by OSI comply with applicable laws and regulations, have adequate evidentiary support, and are consistent with Agency policy. Dr. Burrow has held a variety of leadership positions during his time in OSI. For example: he served as the Deputy Office Director, Policy Staff Director, Associate Director for Policy and Communication, Enforcement Policy Team Leader, and Regulatory Counsel. Before joining the CDER, Office of Compliance, Dr. Burrow served with the Center for Devices and Radiological Health (CDRH) in their Office of Compliance. Dr. Burrow holds a Doctorate of Pharmacy from Duquesne University, and a Juris Doctorate from Widener University School of Law. He is licensed to practice law in the State of Maryland.

ADRIENNE FRANCO BUSBY is a partner at Faegre Baker Daniels LLP, and an experienced litigator in product liability, commercial, employment, class action, and mass tort matters. As a member of the product liability group nationally ranked by *Chambers USA*, she represents local, national and international manufacturers of medical devices, pharmaceuticals, and consumer products across the U.S. and in Canada. Adrienne is skilled in understanding and interpreting the scientific and regulatory issues that affect product litigation. She has defended companies involved in medical device, pharmaceutical and asbestos mass torts. Adrienne has experience handling complex medical causation issues, including allegations related to systemic toxicity, cardiac injury and cancer, and litigation involving recalled medical devices. She also has represented employers in state court actions and Title VII, ADA, ADEA and FMLA actions in federal courts in several states. Adrienne has extensive mediation and negotiation experience at all stages of litigation.

OWEN CHAPUT is an associate in the Washington, DC office of Keller and Heckman, where he practices in the area of food law, as well as tobacco and e-vapor regulation. He advises domestic and foreign clients on establishing clearances for food additives and food contact materials under FDA and comparable international regulations. Mr. Chaput also counsels tobacco and e-vapor manufacturers and suppliers in matters of state and federal compliance. Prior to joining the firm, Mr. Chaput held the position of Regulatory Counsel at FDA's Center for Tobacco Products (CTP), where he analyzed industry submissions for compliance with FDA advertising laws and worked on retailer compliance and enforcement matters with respect to sales of tobacco products. While in law school, Mr. Chaput served as a law clerk in the Federal Trade Commission, Bureau of Consumer Protection. He earned his BA, cum laude, from the University of Connecticut, and his JD, with honors, from Emory University School of Law.

RICKI A. CHASE is a director in the Compliance Practice at Lachman Consultants who has 16 years of experience at the U.S. Food and Drug Administration. Ms. Chase is an expert in Food and Drug Law,

Compliance Law, and Current Good Manufacturing Practices. She has served in leadership development in all regulated program areas including pharmaceuticals, medical devices, human and animal foods, biomonitoring, veterinary medicine, biologics and imports. As Director, Investigations Branch at FDA she led the operations of the Investigations Branch including inspections, special investigations, sample collections, consumer complaints, import operations, and emergency response programs. Ms. Chase has made numerous presentations including "New Initiatives of FDA, Office of Regulatory Affairs" at ASQ, annual presentations regarding field activities, compliance activities and trends in medical devices and drug program areas at Association of Food and Drug Officials, and compliance law and field activities at John Marshall Law.

CHRISSY J. COCHRAN is the Director of the Office of Bioresearch Monitoring Operations within the Office of Regulatory Affairs (ORA) at the U.S. Food and Drug Administration (FDA). She is responsible for policy, budget, oversight, and management of all field bioresearch monitoring program activities. She is responsible for leading cross-center collaborations related to program activities, and implementation of field operational plans. Prior to ORA, Dr. Cochran held the positions of Director, Division of Enforcement and Postmarketing Safety, and Chief, Postmarketing Safety Branch within the Office of Scientific Investigations in the Center for Drug Evaluation and Research (CDER). Prior to CDER, Dr. Cochran was responsible for regulatory compliance and enforcement of the good laboratory practice regulation for the Center for Devices and Radiological Health (CDRH). At CDRH, she also provided regulatory guidance to CDRH's Office of Compliance on toxicology and biocompatibility aspects of post market safety issues including recalls, risk assessments, and enforcement actions. Prior to joining FDA Dr. Cochran worked at a large clinical research organization, and performed laboratory research at the Veteran's Administration.
She received her PhD in Toxicology from the University of Maryland Baltimore.

JAMIE COLGIN is President of Colgin Consulting, Inc., and Principal Consultant with Validant. Jamie helps Pharmaceutical, Biopharmaceutical, and Contract Research Organizations assure the integrity of their clinical data through Risk Assessments, Data Integrity Audits, Mock Inspections, Remediation Assistance, and Training. With over 25 years of hands-on experience in statistics, computer system validation, audits, and monitoring, Jamie has developed validated SAS programs to support GLP studies, managed the retrospective evaluation of hundreds of GLP and GCP systems, written policies and procedures, and set new standards for communicating audit findings by using process flow diagrams. Recipient of the prestigious Charles H. Butler Excellence in Teaching Award, 2016 Member of the Year for the Pacific Regional Chapter of SQA and 2017 SQA Distinguished Speaker, Jamie can provide training for audit staff focused on updating skill sets and understanding regulatory trends relative to data integrity. Prior to working in the pharmaceutical industry, Jamie proudly served with the U.S. Peace Corps in the Philippines. She credits this experience for her resourceful nature.

WILLIAM CORRELL is the Director of the Office of Compliance at CFSAN. In this role, he provides leadership in food compliance and enforcement operations, work planning and logistics, special field assignments, and other programmatic activities. His career in FDA's food program spans 24 years in the CFSAN and FDA's Office of Regulatory Affairs (ORA). After graduating from the University of Maryland with a Bachelor of Science degree, he began his federal career in 1990 with ORA's Philadelphia District as an investigator conducting inspections and investigations in the food, drug, and medical devices programs. In 1993, he graduated with honors from the Federal Law Enforcement Training Center, Glynco, Georgia;

and in 1994 he accepted a position at CFSAN in an entry-level compliance officer position in what was, at that time, the Office of Field Programs (now Office of Compliance). He later became a supervisor within the Division of Enforcement (DE) in 2002. Mr. Correll led a team of senior and junior compliance officers for a decade within the Division of Enforcement until his recent appointment in September 2014 to the senior executive service as the Director of the Office of Compliance. Over the years, he has served in many temporary leadership positions within the Office of Compliance including acting Director and acting Deputy Director, acting Director on multiple occasions for each of the office's two Divisions: The Division of Enforcement and the Division of Field Programs & Guidance; and acting supervisor for DE's Labeling and Dietary Supplements Compliance Team.

ALONZA CRUSE is Director, Pharmaceutical Quality Programs within FDA's Office of Regulatory Affairs (ORA). His office is responsible for all pharmaceutical quality inspections and investigations, working in conjunction with FDA's Center for Drug Evaluation & Research (CDER) and Center for Veterinary Medicine (CVM). Additionally, Mr. Cruse is leading ORA's pharmaceutical collaboration efforts under the program alignment initiative. From 2013 - 2015 Mr. Cruse served as the Director (Acting) of the Office of Medical Products & Tobacco Operations (OMPTO) within ORA, overseeing activities such as Generic Drug User Fee Amendments (GDUFA) implementation, pharmacy compounding, and the development of a New Inspection Protocols Program. From 2000 - 2015, Mr. Cruse was the Director, FDA's Los Angeles District Office, where his responsibilities included providing executive leadership to implementing, managing and evaluating FDA's regulatory operations. Mr. Cruse first joined ORA in 1983 as a microbiologist. He received his Bachelor of Science degree in Medical Technology from York College (City University of New York).

ETHAN P. DAVIS is the Deputy Assistant Attorney General for the Consumer Protection Branch at the Department of Justice. In that role, he oversees the Branch's efforts to enforce the Food, Drug, and Cosmetic Act throughout the United States. Before joining the Justice Department in June 2017, Mr. Davis was a partner at King & Spalding LLP, where his practice spanned a wide range of civil and criminal life sciences and healthcare matters. Earlier in his career, Mr. Davis was a trial attorney in the Justice Department's Civil Division and, before that, a law clerk to Judge Diarmuid F. O'Scannlain of the Ninth Circuit. He is a graduate of Yale Law School and Amherst College.

STACY L. EHRLICH is a partner at the law firm of Kleinfeld, Kaplan & Becker, LLP in Washington, DC. In her 20th year with the firm, Ms. Ehrlich's practice focuses on counseling and advocating on behalf of pharmaceutical, food, dietary supplement, tobacco, cosmetic, and medical device companies on a variety of matters involving FDA, USDA, and FTC, as well as state agencies. Ms. Ehrlich also serves as outside counsel for the Coalition of Independent Tobacco Manufacturers of America and has been involved in FDA's regulation of tobacco products since early in the legislative process of the Family Smoking Prevention and Tobacco Control Act.

ALLISON FULTON is a partner in the Washington, DC office of Sidley Austin, and advises pharmaceutical, medical device, dietary supplement, and cosmetic companies in a variety of civil and regulatory matters. Allison's areas of focus include assisting U.S. and international companies comply with current Good Manufacturing Practice (GMP) and the Quality System Regulation (QSR). She regularly advises companies on preparing for FDA inspections, responding to FDA Form 483s and Warning Letters, remediating data integrity issues and handling adverse events and medical device reports (MDR). She works with companies throughout the world on GMP and QSR compliance, including the U.S., China, Europe and South America. Allison also has led numerous internal investigations involving allegations of off-label promotion and healthcare fraud and abuse.

JILL FURMAN is the Deputy Director of the Consumer Protection Branch within the Department of Justice. The Consumer Protection Branch is responsible for the civil and criminal enforcement of a variety of federal statutes that protect public health and safety, including the Food, Drug, and Cosmetic Act. The Branch also enforces statutes that regulate unfair and deceptive trade practices, and defends government programs and policies in consumer-related areas. Ms. Furman oversees many of the Branch's affirmative pharmaceutical and medical device cases. Ms. Furman was a member of the prosecution teams for a number of major pharmaceutical cases brought by the Department of Justice. Ms. Furman is a *cum laude* graduate of the University of Pennsylvania and Boston University School of Law. Following a clerkship with Justice Roderick Ireland, then with the Massachusetts Appeals Court, Ms. Furman began her legal career as an Assistant District Attorney with the Suffolk County District Attorney's Office in Boston, Massachusetts.

JOHN FUSON is a partner at Crowell & Moring, LLP, and a member of the firm's Advertising & Product Risk Management, Healthcare, and White Collar and Regulatory Enforcement groups, specializing in U.S. Food and Drug Administration (FDA) enforcement and counseling matters. Before joining Crowell & Moring, John served as associate chief counsel at FDA, with broad law enforcement responsibilities, from 2007-2012. At FDA, John handled all types of major enforcement actions brought by the agency, including seizure actions, injunction actions, actions for civil money penalties, and contempt actions. His cases have involved drugs, devices, food, and veterinary drugs. John is a frequent speaker on FDA enforcement practices and has written extensively on food policy. He received his undergraduate degree from Grinnell College, and his law degree from the University of Pennsylvania.

JACK GARVEY has had a career-long passion for embracing innovation and leading improvement initiatives within FDA-regulated manufacturing operations. As both a chemical engineer and practicing attorney, Jack helps life sciences companies navigate issues and challenges found at the intersections of science, engineering, business and law. Known for "outside-the-box" thinking, Jack's love of tinkering, problem solving, science and computers has allowed him to bring new approaches and solutions to long-standing Quality and Compliance operational challenges, helping to create sustainable systems, effective business processes and profitable operating models. When Jack is not unraveling the mysteries of compliance systems and documentation, he spends time cycling, enjoying the Adirondack mountains of Upstate NY, and working on computers, gadgets and home improvement projects. Jack is the Founder and Chief Executive Officer of Compliance Architects LLC

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.

JEFFREY N. 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.

WILLIAM GOULD is a partner in the Washington, DC office of Holland & Knight LLP. As a co-chair of Holland & Knight's Healthcare and Life Sciences team, Mr. Gould's practice involves domestic and international enforcement defense with a focus on litigation and corporate compliance work on behalf of pharmaceutical and medical device companies. Mr. Gould's recent engagements include litigation and internal investigations involving the False Claims Act, the Foreign Corrupt Practices Act, and the federal Anti-Kickback Statute. He also provides advice regarding risk management to companies in the healthcare sector. Mr. Gould currently holds a Top Secret/SCI level security clearance. Prior to returning to private practice, Mr. Gould was a federal prosecutor with the U.S. Department of Justice for over 10 years. From 2002-08, Mr. Gould was an Assistant U.S. Attorney and then a Managing Assistant U.S. Attorney in the U.S. Attorney's Office for the Western District of Virginia. In addition, during that time Mr. Gould was appointed as a Special Assistant U.S. Attorney for two specially assigned investigations in the U.S. Attorney's Offices in the District of Columbia and the Eastern District of Virginia. From 1997-2002, Mr. Gould was an Assistant U.S. Attorney in the U.S. Attorney's Office for the District of Columbia. From 1999-2011, Mr. Gould was an adjunct professor of law at the University of Virginia School of Law. Prior to his government service, Mr. Gould was an associate with a multi-national law firm based in New York City. He also served as a law clerk for the Honorable Morton A. Brody, U.S. District Court Judge in the District of Maine.

DENNIS GUCCIARDO is a senior associate in Hogan Lovells accomplished Medical Devices practice. He understands the pressure medical device companies around the world face when working with FDA to resolve compliance concerns. From small start-up companies to large multi-national corporations, Dennis has worked with companies to avoid further enforcement from FDA. From developing corrective action plans to responding to FDA Form 483 inspectional observations, Untitled Letters, and Warning Letters; assisting companies through FDA-requested certified audit programs; and preparing medical device recall plans, Dennis can help companies navigate through the myriad of FDA regulations, requirements, and expectations. Dennis has traveled the world in preparing, assisting and defending companies before routine and directed FDA inspections. Dennis has also prepared and assisted in the execution of global remediation plans to help ensure that all company sites act in accordance with company expectations and FDA requirements.

MIRIAM GUGGENHEIM is a partner and co-chair of the Food, Drug and Device practice at Covington & Burling, LLP. Her practice focuses primarily on the food and dietary supplement industries. Ms. Guggenheim counsels clients in all aspects of food and dietary supplement development and marketing, from product formulation, manufacturing, and safety considerations to labeling and advertising. Her work for a broad range of leading global food and dietary supplement companies and major trade associations includes regulatory advice, advocacy before regulators, courts and legislative bodies, and strategic counseling in light of overarching public health and nutrition policy considerations. Ms. Guggenheim is ranked as one of America's Leading Business Lawyers, Food & Beverages: Regulatory & Litigation by Chambers USA. Ms. Guggenheim received her BA, magna cum laude, from the University of Pennsylvania and her JD, with honors, from Columbia University School of Law.

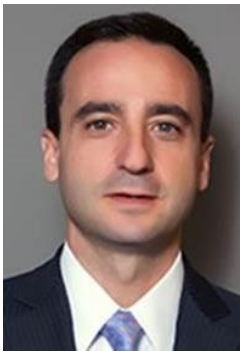
SONALI P. GUNAWARDHANA is counsel at the law firm of Wiley Rein LLP in Washington, DC. She draws on her nearly 10 years' experience as an attorney at FDA to offer clients detailed and practical guidance on how to avoid and resolve FDA regulatory challenges. Ms. Gunawardhana's practice focuses on the rapidly changing FDA regulatory requirements for bringing pharmaceuticals and medical devices to market; the complex emerging rules applicable to domestic and foreign food manufacturers, suppliers, and importers; clinical trial compliance requirements for drug and medical device studies; and the defense of FDA enforcement actions against drug, device, food and dietary supplement companies, Clinical Research Organizations (CROs), academic medical research institutions and individual researchers. Ms. Gunawardhana received a BA from Syracuse University, a MA from Webster University, a MPH from Boston University, a JD from the University of New Hampshire School of Law and a LLM from Washington College of Law, American University.

BRYAN HAYNES is a partner at the law firm Troutman Sanders, where he devotes his practice to representing businesses in disputes and regulatory compliance matters initiated by governmental agencies, including by state Attorneys General, and in other commercial litigation. Bryan is an accomplished trial lawyer who has served as lead counsel in state and federal courts across the country. Bryan is a member of the firm's Tobacco Law practice and is focused on representing tobacco manufacturers, distributors, retailers and suppliers in all aspects of their businesses, including regulatory compliance, Food and Drug Administration (FDA) requirements,

administrative disputes involving a federal or state governmental entity, commercial agreements, and tobacco taxation matters.

AUGUST T. HORVATH is a partner at Kelley, Drye, and Warren, where he practices false-advertising and antitrust law, spanning litigation, counseling, and responding to government enforcement actions. August currently chairs the Marketing and Advertising Subcommittee of the ABA Litigation Section's Consumer Litigation Committee and the Agriculture & Food Committee of the ABA Antitrust Section.

JOHN F. JOHNSON III is a senior associate attorney at Benjamin L. England & Associates. John Johnson III represents and advocates for clients with FDA-regulated commodities before FDA over a variety of issues, including Warning and Untitled Letters, 483 Observations, import detentions, and import alerts. He also counsels and advises clients with labeling, marketing, formulation, and manufacturing compliance, and guides clients on building in-house compliance capacity.



GEORGE KARAVETSOS is a partner at DLA Piper LLP where he focuses on FDA regulatory and healthcare matters, and white-collar crime and internal investigations. Mr. Karavetsos previously served as director of FDA's Office of Criminal Investigations where he led more than 300 personnel in the investigation of criminal violations of the Federal Food, Drug, and Cosmetic Act. Mr. Karavetsos also served for more than 12 years as an assistant US attorney in the Southern District of Florida, rising to executive assistant US attorney, the third-highest position in the office. Mr. Karavetsos also was a deputy chief in the major crimes and narcotics sections, and chief of the narcotics section. Mr. Karavetsos also was an assistant chief counsel in FDA's Office of the Chief Counsel and an assistant district attorney in Massachusetts. Mr. Karavetsos has successfully tried numerous complex white-collar crime and international narcotics and money laundering cases.

PAULA KATZ is Director of Manufacturing Quality Guidance and Policy in the Office of Manufacturing Quality at CDER's Office of Compliance. Ms. Katz has served as Branch Chief, Senior Policy Advisor, and Regulatory Counsel in OMQ since 2009. She focuses on compliance and enforcement policy regarding CGMP and drug quality issues. Ms. Katz frequently advises management and colleagues and speaks and writes on matters related to supply chain controls, contract manufacturing, data and application integrity, administrative law and procedure, and regulatory policy development and strategy. Ms. Katz has chaired intra-agency working groups and directed the drafting and publication of numerous draft and final guidances for industry and staff, proposed and final regulations, and legislation; managed and responded to Congressional and stakeholder inquiries; and served as a case officer and investigator in domestic and international enforcement actions and case reviews. Prior to joining FDA, Ms. Katz was a litigation associate at a large law firm in Washington, DC, where her practice included regulatory compliance, white-collar crime, and general commercial litigation, and where she represented food and drug manufacturers and retailers,

medical doctors, investors in the healthcare industry, and other regulated businesses and individuals. Ms. Katz is a graduate of the University of Virginia and the University of Virginia School of Law.

DAVID A. KLUFT is a partner of Foley Hoag LLP in the Boston office. His practice includes copyright, trademark, false advertising, defamation, privacy and social media. He is a litigator who has represented parties before the First Circuit, Federal Circuit, Supreme Judicial Court of Massachusetts, the Federal Trade Commission and in investigations conducted by state attorneys general. He is a co-editor of the Trademark and Copyright Law Blog at www.trademarkandcopyrightlawblog.com, which was a member of the ABA's Blawg100 from 2014-2016, and he has published articles in Law360 and the Hollywood Reporter, Esq., Massachusetts Lawyers Weekly and the Boston Bar Journal, among other publications. Previously, Mr. Kluft was a special assistant district attorney for Norfolk County, a clerk to the Hon. Judith Cowin of the Massachusetts Supreme Judicial Court, and a film and television producer. He is a graduate of Boston University School of Law, Temple University (MFA), and Brown University (BA).

PATRICIA KOVACEVIC is the General Counsel and Chief Compliance Officer of Nicopure Labs LLC, the leading e-liquid and vaping device manufacturer of U.S. made Halo and eVo e-liquids and Triton, Reactor, and G6 devices. With extensive US and international industry experience, Kovacevic held senior legal and compliance positions at, among others, Philip Morris International and Lorillard. Prior to joining Lorillard, she was a partner at Patton Boggs. Her expertise includes global e-cigarette and tobacco regulation, compliance and all regulatory aspects of marketing/media communications, corporate affairs, criminal investigations, FCPA, trade sanctions, privacy, product development, and launch. Kovacevic serves on the board of the Vapor Technology Association and on the advisory board of the Global Tobacco and Nicotine Forum. In the past she was a United Nations staff member, served on UN's Public-Private Partnership Commission, and was also an advisor to the Council for Burley Tobacco. Kovacevic is admitted to practice in New York and before the Supreme Court of the United States. She holds a JD from Columbia Law School (NY) and has graduated from the Harvard Business School "Corporate Leader" course. She is fluent in seven European languages.

LESLIE KRASNY manages the San Francisco office of Keller and Heckman. Ms. Krasny practices regulatory/administrative law, focusing primarily on food/dietary supplements, including safety (FSMA and other regulatory requirements, ingredient evaluations, GRAS/food additive/color additive submissions, recalls, inspections, defense of government investigations, import issues, agricultural practices), labeling and advertising (ingredient/allergen statements, claim eligibility and substantiation, challenges to food marketing, country of origin, Made in USA statements), organic requirements, "green" packaging claims, and California's Proposition 65. She represents food companies throughout the supply chain: growers/shippers, manufacturers, distributors, retailers, food service, and trade associations, and serves as General Counsel to the Produce Marketing Association. She is a member of the Food and Dietary Supplements Committee of FDLI, serves on the Editorial Advisory Board of Food Processing magazine, and is a frequent speaker and writer on food law topics. Ms. Krasny is ranked in Chambers USA, America's Leading Lawyers for Food & Beverages, Regulatory & Litigation, and is listed in Best Lawyers in America -- FDA Law.

PETE LEININGER is Counsel at King & Spalding LLP, and a member of the firm's FDA & Life Sciences Practice in Washington, DC. He represents medical device, pharmaceutical and biotech companies in FDA regulatory and enforcement matters, including civil and criminal government investigations. From 2012-2017, Pete served as an Associate Chief Counsel for Enforcement in FDA's Office of Chief Counsel. Pete's enforcement practice at FDA covered the range of FDA-regulated products, often focusing on product quality, GMP/QSR compliance, MDR reporting, and promotional activity. He frequently handled criminal investigations arising out of qui tam lawsuits filed against drug and medical device manufacturers under the False Claims Act. During his employment at FDA, he was admitted to serve as a Special Assistant United States Attorney (SAUSA) in several United States Attorney's Offices. As a SAUSA, Pete helped lead grand jury investigations and criminal prosecutions involving violations of the Food, Drug, and Cosmetic Act, as well as related Title 18 criminal offenses, including healthcare fraud and false statements. In 2016, Pete received an Outstanding Service award from FDA's Office of Commissioner for his representation of the agency in enforcement litigation. He also received two special recognition awards from the Los Angeles Field Office of FDA's Office of Criminal Investigations. The first was awarded for his work as a SAUSA at trial in United States v. Kaplan. The second was awarded in 2017 for his overall service to the agency.

GEOFFREY M. LEVITT is Senior Vice President and Associate General Counsel for Regulatory, Environmental, and Global Supply at Pfizer Inc, where he is responsible for managing global legal support for regulatory, medical, safety, clinical research, manufacturing and environmental operations. Mr. Levitt has published and lectured extensively on regulatory law. He is a past member of the editorial board of the *Food and Drug Law Journal* and a current member of the editorial board of the *FDA Advertising and Promotion Manual*. Mr. Levitt is past Chairman of the Board of the Food and Drug Law Institute and received the Institute's 2009 Distinguished Service and Leadership Award and the 2017 inaugural Service to FDLI Award. He has also served as Chair of the PhRMA Law Section Executive Committee and is a current member of the Board of the Friedreich's Ataxia Research Alliance. He earned his JD from Harvard Law School and his BA from Columbia University.

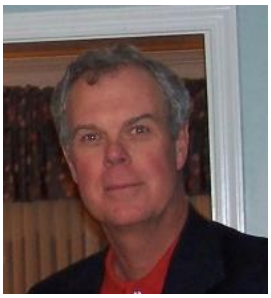
MARK LEVY is a partner with the Philadelphia Office of Eckert Seamans Cherin & Mellott, LLC. He is a member of the Litigation Department, and active in the firm's Life Sciences, Mass Tort, and White-Collar Defense Practice Groups. Mr. Levy represents prescription product companies and counsels them in managing the risks associated with products liability and regulatory compliance. He has successfully represented pharmaceutical and medical device companies in multi-jurisdictional litigation and conducted numerous internal investigations in response to drug and device enforcement issues. Mr. Levy is the author of *Compliance Training Handbook for Medical Device Sales Representatives*, published by HCPro, Inc. He has published numerous articles, papers, a Handbook for Compliance Training for Medical Device Sales Representatives (ePharmaceuticals), and chapters in several books on product liability and government enforcement including *Inside the Minds—Working with Government Agencies in Food and Drug Law* (Aspatore) and is the editor and an author of The Food & Drug Institute's "Off-Label Communications: A Guide to Sales & Marketing Compliance". He graduated from Wesleyan University and from Villanova Law School, where he was the Managing Editor of the Law Review.

DEBORAH LIVORNESE is of counsel in the Food and Drug Practice at Arnall Golden Gregory LLP. Ms. Livornese focuses her practice on a broad range of FDA matters concerning prescription and OTC drugs, medical devices, biological products, and cosmetics. She assists pharmaceutical drug and device companies on regulatory requirements and strategies related to obtaining FDA approvals and other paths to market, as well as on post-marketing regulatory requirements. Ms. Livornese spent seven years in the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research. As a Senior Regulatory Counsel at FDA, she was involved in a wide variety of policy issues affecting drug approvals and routinely met with senior leaders in the agency on controversial issues, in addition to providing guidance to the Office of New Drugs and Office of Generic Drugs on issues related to approvals and withdrawals, the regulation of unapproved drugs, and user fees. She served as one of the key members of FDA negotiating team for the OTC Monograph Reform user fee efforts. Prior to joining FDA, Ms. Livornese was Of Counsel with an FDA boutique law firm in Washington DC where she advised drug companies on promotional activities for compliance with FDA and FTC requirements, assisted clients in responding to investigational findings, warning letters, and inquiries from the agency.

SCOTT MACINTIRE is the Director of the Division of Enforcement/Office of Enforcement and Import Operations at FDA's Office of Regulatory Affairs (ORA). Scott works closely with FDA centers to include the Center for Food Safety and Nutrition and Center for Veterinary Medicine in determining regulatory strategies for follow up action. He also serves as the Agency focal point for guidance on recall plans and procedures, directs and coordinates ORA's activities related to the investigation of health fraud, and provides management and oversight of the Agency's debarment program. Scott currently is the co-lead for the FSMA Phase 2 workgroup for implementation of the Preventive Controls in Human and Animal foods regulation. Prior to his current position, Scott was Director of the Chicago District Office from 2004 to 2014 and is the former chair of the CVM Field Committee. Scott has a bachelor of science degree from East Tennessee State University and has worked in the field of public health protection for the past 34 years, 27 of those years with FDA.

MARY MALARKEY is the Director of the Office of Compliance and Biologics Quality (OCBQ), Center for Biologics Evaluation and Research (CBER), FDA. Malarkey is responsible for managing, among other things, CBER's surveillance, inspections and compliance programs, legal actions, bioresearch activities, advertising and promotional activities, and aspects of biologics license application reviews. Before her current position, she was the Director in the Division of Case Management (DCM), OCBQ, CBER. Prior to that, Malarkey was a Branch Chief in the Division of Manufacturing and Product Quality (DMPQ), CBER. Prior to joining FDA in 1989, she worked in research and development in industry. She received a BS in Microbiology from the University of Maryland.

JOHN MANTHEI, Global Co-chair of Latham's Healthcare and Life Sciences Practice, specializes in regulatory matters involving the US Food and Drug Administration (FDA) for the medical device, pharmaceutical, and biotechnology industries. He advises clients on all aspects of FDA-regulated product life cycle, post market enforcement, and administrative litigation. Mr. Manthei currently serves as outside FDA counsel to the Medical Device Manufacturers Association (MDMA), a member of the Food & Drug Law Institute (FDLI) committee for Medical Devices, and a former member of the FDLI committee for Drugs and Biologics. He previously served as Majority Counsel for the US House of Representatives' Committee on Energy and Commerce (1998-2000). Mr. Manthei is recognized as a leading FDA attorney in industry publications such as *Chambers USA* (2010-2017) and *The Legal 500 US* (2012-2017). He was recently named a "Life Sciences MVP" by *Law360* (2016), and has also been featured as a "Life Sciences Star" by *Euromoney* (2012-2017) and a "Top 40 Lawyers Under 40" by *Washingtonian* magazine (2006), and as one of Washington's top lawyers in the *Washingtonian.* In addition, Mr. Manthei has been quoted in *CBS News, Washington Post, CNN, USA Today, CNBC, Boston Globe, San Francisco Chronicle, Forbes, Business Week* and other leading national and international business journals on FDA regulatory, enforcement and policy matters.



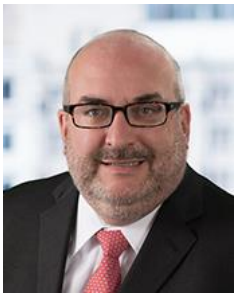
DANIEL MCCHESNEY is the Director of the Office of Surveillance and Compliance in FDA's Center for Veterinary Medicine. He has served in this position since October 2003. Prior to becoming the Director, he served as the Deputy Director for the Office of Surveillance and Compliance (1999-2003) and as the Acting Director of the Division of Compliance. His Office is responsible for developing and implementing surveillance and compliance policy concerning FDA regulatory responsibility with respect to animal drugs, feeds, food additives, veterinary medical devices, and other veterinary medical products. He joined FDA's Center for Veterinary Medicine (CVM) as a microbiologist in 1990 and served as the Center's expert on microbial contaminants of animal feed, and application of HACCP programs to the feed industry. He received a BS in Biology from Mercer University in Macon, Georgia and his MS and PhD in Cell and Molecular Biology from the Medical College of Georgia, Augusta, Georgia. Upon completing his degree, he entered the U.S. Army and was stationed at the Walter Reed Army Institute of Research (1978-1987) where he served as a research microbiologist. After completing his active military service, he was a senior investigator at the Armed Forces Radiobiology Research Institute responsible for determining the mechanism involved in increasing survival after radiation injury.

YVONNE M. MCKENZIE is a partner in the Health Sciences Department of Pepper Hamilton LLP, resident in the Philadelphia office. Ms. McKenzie focuses her practice on counseling and defending companies with FDA-regulated products. Ms. McKenzie routinely advises food and cosmetic clients on compliance with state and federal laws and regulations, including counseling on product recalls, advertising and other promotional activities, as well as statements made in labeling, scientific disclosures, press releases and regulatory submissions to U.S. and foreign regulatory agencies. She also has extensive experience litigating class action suits brought by consumers alleging false advertising and fraud in violation of state consumer fraud and unfair trade practice laws.

GINETTE MICHAUD is a hematologist with twenty years of regulatory experience in biological products and medical devices. In March 2016, she was named Director of ORA's Biologics Program and today she serves as the Director, Office of Biological Products Operations in ORA. Prior to joining ORA, Dr. Michaud was the Deputy Director, Office of Blood Research and Review in the Center for Biologics Evaluation and

Research. She is currently active in the PIC/S Expert Circle on Human Blood, Tissues, Cells and ATMPs. This follows many years of engagement in international regulatory capacity building, global regulatory harmonization, and in the development of international reference standards.

ANNE MILLER is Principal Legal Counsel at Medtronic. Anne joined Medtronic in 2007 and advises Medtronic clients on FDA-related matters. Anne focuses her practice on medical device quality system issues, including regulatory inspections and responses to FDA-483s and Warning Letters. Anne also advises in the medical device post-market area, including issue escalation/investigation, CAPA, Medical Device Reporting (MDR), and field corrective action decisions. She also supports Medtronic clients on combination product matters, including GMP and post-market safety reporting requirements. Outside of the FDA area, Anne also supports Medtronic clients on implementation of the EU Medical Device Regulation requirements. Prior to joining Medtronic, Anne spent four years in FDA's Office of the Chief Counsel (1996-2000), where she counseled FDA clients on international issues and handled enforcement matters and defensive litigation. She graduated from Hamline University School of Law in 1996, and from Gustavus Adolphus College in 1990 with a BA in English.



NEIL F. O'FLAHERTY is a partner in Baker & McKenzie's Intellectual Property Practice Group in Washington, DC. He has over 25 years of experience involving FDA regulation of medical devices. Neil has spoken and written extensively on medical device and other FDA-related topics, including: the regulation of mobile medical apps and other medical software products, in vitro diagnostics, inspectional and enforcement authority, clinical trial requirements, device regulatory obligations of hospitals, and the impact of FDA law on business transactions and agreements. His practice also focuses on FDA regulation of human cellular and tissue-based products. Over the years, Neil has provided assistance to and collaborated with various medical device industry and health care groups, including providing guidance on device tracking, medical software, and device reclassification matters. Neil received his BA from the University of Notre Dame in 1987 and his JD from Loyola University of Chicago School of Law in 1990.

AMY COMSTOCK RICK is the President and Chief Executive Officer of the Food and Drug Law Institute, having joined in August, 2014. Prior to joining FDLI, Ms. Rick was the Chief Executive Officer of the Parkinson's Action Network (PAN) from 2003-2014. PAN is a Washington DC-based national nonprofit focused on educating the public and government leaders on better policies for research and therapy development and an improved quality of life for people living with Parkinson's disease. Ms. Rick has also served as the President of the Coalition for the Advancement of Medical Research, on the Boards of Directors of Research!America, the National Health Council, and the American Brain Coalition. Before joining PAN, she was the Senate-confirmed Director of the U.S. Office of Government Ethics from 2000-2003 and the Associate Counsel to the President in the White House Counsel's Office from 1998-2000. Ms. Rick began her federal service as a career attorney at the U.S. Department of Education in 1989 and became the Assistant General Counsel for Ethics in 1993. Prior to her government service, Ms. Rick was an associate attorney at the law firm of Beveridge & Diamond. She received a Bachelor of Arts degree from Bard College and a Juris Doctor degree from the University of Michigan.

ANN SIMONEAU is the Director of the Office of Compliance and Enforcement in the Center for Tobacco Products at the U.S. Food and Drug Administration (FDA). Ms. Simoneau joined the agency in 2001 and has worked in FDA's New England District Office; the Center for Drug Evaluation and Research's (CDER) Division of Drug Marketing, Advertising, and Communications; and the Center for Devices and Radiological Health's (CDRH) Office of Compliance. Prior to working for FDA, she was a practicing litigation attorney in Boston for several years. Ms. Simoneau has received a BS degree in pharmacy from Massachusetts College of Pharmacy; a JD degree from Boston University School of Law; and an MBA from Suffolk University, Sawyer Business School.

HOWARD SKLAMBERG is a partner in the health care and life sciences practice at Akin Gump Strauss Hauer & Feld LLP, who focuses on regulatory compliance and strategy involving food and drug law. From January 2014 to April 2017, Mr. Sklamberg was the Deputy Commissioner for Global Regulatory Operations and Policy at the U.S. Food and Drug Administration (FDA), which is the directorate comprising the Office of Regulatory Affairs (ORA) and the Office of International Programs (OIP). Mr. Sklamberg provided executive oversight, strategic leadership, and policy direction to many of FDA's domestic and international product quality and safety efforts, including global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities. Prior to being named Deputy Commissioner in January 2014, Mr. Sklamberg served for one year as Director of the Office of Compliance at FDA's Center for Drug Evaluation and Research (CDER). He led the office in its efforts to protect the American public from unsafe and ineffective drug products. Mr. Sklamberg played key leadership roles in global drug supply chain security, pharmacy compounding oversight, pharmaceutical quality, and expanded cooperation with international regulatory partners. Mr. Sklamberg also served as FDA's Deputy Associate Commissioner for Regulatory Affairs in the ORA from July 2011 until he joined the CDER in January 2013. Prior to that, he was Director of the ORA's Office of Enforcement. Mr. Sklamberg's work at the ORA led to the development and use of the FSMA's new enforcement tools. Mr. Sklamberg earned a JD from Harvard Law School, a master's degree from the Fletcher School of Law and Diplomacy, and a bachelor's degree in economics and political science from Yale University.

JIM SOLYST is the Vice President, Federal Regulatory Affairs with Swedish Match North America, where he coordinates the Company's Modified Risk Tobacco Product (MRTP) process and related regulatory science engagements. He has held senior positions in Washington, DC-based companies and associations, including the National Governors' Association, American Chemistry Council, and the consulting firm Ramboll-Environ. During his over 35 years in Washington, he has worked closely with federal agencies, including the U.S. Environmental Protection Agency (EPA), U.S. Food and Drug Administration (FDA), and the Office of Management and Budget (OMB). He has also worked with international organizations, including the United Nations (UN), World Health Organization (WHO), and Organisation for Economic Co-operation and Development (OECD). Mr. Solyst is a member of the Food and Drug Law Institute (FDLI) Tobacco Committee and has served on the American Chemical Society (ACS) Committee on Environmental Improvement, the National Academy of Sciences (NAS) Chemical Sciences Roundtable, and the NAS Committee on Promoting Safe and Secure Chemical Management in Developing Countries. He also served as an External Affiliate to the Johns Hopkins Risk Sciences and Public Policy Institute. Mr. Solyst has written several articles for FDLI and other journals and has given numerous presentations on a range of regulatory science and public policy issues.

THOMAS SOUTH is the Special Agent in-Charge (SAC), of the U.S. Food and Drug Administration (FDA), Office of Criminal Investigations (OCI), with oversight of all OCI investigative and administrative operations. Prior to joining OCI, Tom worked for the United States Postal Service-Office of the Inspector General, the Department of Labor, and the Drug Enforcement Administration. He also served for six years with the United States Army and is a graduate of Florida State University. Tom started his OCI career assigned to the OCI Northern Virginia Domicile Office, Metro Washington Field Office and the Special Prosecution Staff.

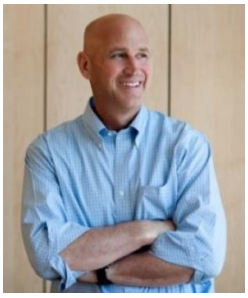
MICHAEL SWIT has been addressing critical U.S. Food and Drug Administration (FDA) legal and regulatory issues since 1984. Before returning to private law practice in late 2017, he served for three years at Illumina, Inc., the world's leading developer of gene sequencing technology, as its chief regulatory 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.

JENNIFER THOMAS is currently the Acting Director, Office of Enforcement and Import Operations (OEIO) at FDA. Her regular position is as the Interim Director for FSMA Operations in the Food and Drug Administration, Center for Food Safety and Applied Nutrition. Before that, she worked in CFSAN, Office of Compliance, as the Director, Division of Enforcement, then as the Director of the Compliance Policy Staff. Before joining CFSAN, Ms. Thomas worked in FDA in different capacities related to compliance and enforcement, including Center for Biologics Evaluation and Research/Office of Compliance and Biologics Quality and the Office of Regulatory Affairs/Baltimore District Office.

MARTA L. VILLARRAGA is a principal in biomedical engineering at Exponent, and is based in Philadelphia, PA. She has expertise in biomechanics and biomaterial-tissue interactions in medical devices and evaluation of medical device performance during the premarketing and postmarketing stages. Dr. Villarraga has experience with orthopedic, spinal, plastic, and reconstructive surgery; urology; urogynecology; general surgery; women's health; and diagnostic medical devices. She has provided technical support for due diligence, regulatory submissions, regulatory compliance, risk management, postmarketing surveillance, product development, product liability, and intellectual property matters. As a Regulatory Affairs Certified (RAC) professional, Dr. Villarraga uses her knowledge of FDA regulations to support identifying and justifying technical

evaluations for premarket assessments or postmarket compliance matters. Dr. Villarraga has a PhD in Biomedical Engineering from Tulane University.

ANNE WALSH is a director at Hyman, Phelps & McNamara, PC, and served as an Associate Chief Counsel with the U.S. Food and Drug Administration's (FDA's) Office of Chief Counsel from 2004 to 2010. While in the government, Ms. Walsh focused on bringing enforcement actions, both civil and criminal, against FDA-regulated industry. Now Ms. Walsh uses that experience in the private sector to benefit clients faced with such enforcement actions. She has been successful in helping companies avoid criminal charges, negotiating favorable resolutions, or litigating against FDA. She also advises clients in conducting internal investigations and risk assessment audits so that they can resolve regulatory issues and minimize litigation risks. She has won numerous awards for her work in groundbreaking prosecutions and settlements, including cases involving pharmaceutical, medical device, and in vitro diagnostics companies. Ms. Walsh graduated from the College of William and Mary in 1994 with a BA in economics, and a JD in 1997. She is admitted to practice law in New York and the District of Columbia.



JEFF WEISS serves as General Counsel and EVP of Government Affairs for NJOY, LLC. In 2017, NJOY, LLC acquired the assets of NJOY, Inc., a pioneer in the electronic nicotine delivery system (ENDS) market. NJOY's products are distributed in brick and mortar stores in all 50 U.S. states. Jeff has oversight responsibility for NJOY's legal and regulatory affairs, both in the U.S. and abroad. From 2012 to 2017, Jeff served as General Counsel for NJOY, Inc. and from July 2016 to February 2017 as its Interim President. Jeff's involvement with ENDS dates back to NJOY, Inc.'s history-making litigation with FDA (*Sottera v. FDA*), which established the legal foundation for the entire U.S. ENDS industry. In addition to his law degree, Jeff holds a Masters Degree in Biotechnology from Johns Hopkins and a Master of Laws in International Law from the Georgetown University Law Center.

ANN H. WION was in the Office of the General Counsel, Department of Health and Human Services (DHHS), Food and Drug Division, from 1979 to 2017. She received a PhD from Cornell University and a JD from Stanford Law School. After joining the DHHS Office of General Counsel in 1979, she specialized primarily in drug and biologics law. From 1993 to 2013 she was Deputy Chief Counsel for Program Review and oversaw the attorneys providing legal counsel in DHHS on U.S. Food and Drug Administration (FDA)-related matters. From 2014 to 2017 she was Senior Advisor to the Chief Counsel.

REBECCA K. WOOD is Chief Counsel to the U.S. Food and Drug Administration (FDA) and Associate General Counsel in the Office of the General Counsel, U.S. Department of Health and Human Services (DHHS). Becky is an experienced and accomplished litigator who has managed complex litigation and appeals in federal and state courts, including matters arising under the Federal Food, Drug, and Cosmetic Act and U.S. Constitution. Becky received her BA from Yale University and her JD from New York University School of Law. She previously served as a law clerk to the Honorable Pasco M. Bowman II of the United States Court of Appeals for the Eighth Circuit.