JP Ahluwalia, MD, MPH is a Medical Officer at the Food and Drug Administration's Center for Biologics (CBER) where he assesses the post-licensure safety of vaccines, blood products, and gene therapies. He is also an active reviewer of various new submissions, providing safety analysis and the need for post-marketing commitments, requirements, or risk evaluation and mitigation strategies. He is a Commander in the US Public Health Service. Dr. Ahluwalia spent 8 years in the Army, including a tour with the 82nd Airborne Division in Kandahar, Afghanistan. He is a Fellow of the American College of Occupational and Environmental Medicine, a Fellow of the American College of Preventative Medicine, and Board Certified in Public Health and General Preventative Medicine. He received his BA and MD from Ohio State and his MPH from Johns Hopkins.

Anne Pierson Allen

Bio: Anne Allen is an associate in the FDA and Life Sciences practice at King & Spalding LLP. Anne regularly assists pharmaceutical and medical device companies on a variety of reimbursement, pricing, and compliance matters involving the U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). Anne has particular expertise in tobacco product regulation and regulatory oversight of clinical research and human subjects protections.

Prior to joining the firm, Anne served in the Office of Chief Counsel at FDA. She worked primarily on issues related to human subject protections and advised the Center for Tobacco Products, counseling the Center on rulemakings, program development, and related issues in tobacco product user fees, investigational tobacco product exemptions, human subjects protections, premarket review of tobacco products, and advisory committee and disclosure issues.

Anne served as a research analyst at the Presidential Commission for the Study of Bioethical Issues from September 2010 through April 2013. While there, she acted as staff lead on a report examining the regulatory and ethical issues involved in high risk pediatric research and contributed to reports related to human subjects protections reform and regulation of synthetic biology.

Larissa Bergin's practice is focused on addressing the antitrust concerns of companies that arise from mergers and acquisitions, joint venture formations, federal investigations, and commercial practices. She has overseen the antitrust aspects of corporate M&A, including due diligence, Hart-Scott-Rodino (HSR) filings, Second Requests, investigational hearings, integration planning, and consent decrees with federal agencies. She works with clients in a variety of industries, including the technology, health care, retail, and pharmaceutical sectors. Many of Larissa's clients have international reach, and she has been involved in matters that require advocacy before governments in Japan, China, Germany, Korea, Singapore, Taiwan, and Canada.

Larissa also advises clients on corporate contracting and operational practices that can run afoul of the antitrust laws, including supplier agreements, information sharing, competitive benchmarking, and Robinson-Patman Act pricing matters.

Larissa has been quoted on how Obamacare has affected M&A activity and has written on abbreviated new drug applications (ANDAs) and orphan drug exclusivity.

Larissa is a member of the Antitrust Section of the American Bar Association and has contributed articles to Antitrust Law Developments. She is also Secretary of the Food, Drug and Cosmetic Law Section of the New York State Bar Association.

Karen Carr, Partner, *Arent Fox LLP*

Karen Carr is a partner at Arent Fox where she practices in the areas of biotechnology, food, and agriculture. She represents members of the regulated community in litigation and through regulatory and product counseling on issues related to food safety, advertising and labeling, testing and reporting, and data use. Karen also works closely with industry associations on coordination of industry regulatory strategy and on federal and state legislative issues.

Michael A. Carrier

Michael A. Carrier is Distinguished Professor at Rutgers Law School. He is the co-author of the leading IP/antitrust treatise, *IP and Antitrust Law: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, the author of *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law*, and the editor of *Critical Concepts in Intellectual Property Law: Competition*. He has written more than 100 book chapters and articles in leading law reviews, has been quoted more than 1000 times in the media, and has been cited in courts including the U.S. Supreme Court. Professor Carrier has testified before the Senate Judiciary Committee, FDA, FTC, and National Academies; is a member of the Board of Advisors of the American Antitrust Institute; is a past chair of the Executive Committee of the Antitrust and Economic Regulation section of the Association of American Law Schools (AALS); and served on the 2016 ABA Antitrust Section's Presidential Transition Task Force.

Mahnu Davar

Mahnu Davar is a Partner at Arnold & Porter Kaye Scholer LLP where his practice focuses on assisting FDA-regulated entities with complex regulatory and compliance matters. He has represented early stage medical technology companies, clinical labs, major academic research institutions, and some of the largest multinational drug and device companies in the oncology, ophthalmology, pain, and diabetes care spaces.

Mr. Davar routinely counsels clients on the regulatory and compliance aspects of promotional launch campaigns, clinical research, educational grants and charitable giving, manufacturing and supply chain, deal diligence, and other mission-critical activities. He has conducted significant compliance investigations and audits for business operations in the US, Europe, and Asia, and has assisted clients to prepare for and navigate state and federal regulatory inspections. Mr. Davar's practical approach to counseling in these areas is informed by his experience working first-hand with business leaders as a "secondee" in the legal departments of several leading multinational drug and device companies. Mr. Davar received his J.D. and M.A. in Bioethics from Penn Law School where he is also a Lecturer.

Manya Deehr

Manya is a Partner at Cooley. She has spent over 24 years strategizing with public and private life sciences companies on ways to maximize the value of company assets. She has experience with companies in all stages of development and with a broad spectrum of product offerings, including animal health, over the counter, diagnostics, pharmaceuticals, biologics, specialty pharma, branded generics, medical devices, as well as a spectrum of drug delivery platforms.

SUCHIRA GHOSH

SUCHIRA GHOSH is Counsel at Axinn, Veltrop & Harkrider LLP and practices primarily in the areas of drug law and intellectual property litigation. Ms. Ghosh's practice focuses on issues unique to the pharmaceutical and biologics industries, including exclusivity strategies, due diligence and various aspects of drug and biologic approvals by the FDA. She is licensed to practice before the U.S. Patent and Trademark Office. Prior to law school, Ms. Ghosh worked in the pharmaceutical industry for four years as a process engineer with Schering-Plough Research Institute's Sterile Pharmaceutical Product Development group, where she worked on developing injectables, proteins and lyophilized drug products. While in law school, Ms. Ghosh also interned with the Office of Policy within the Office of the Commissioner at the Food and Drug Administration. She received her BS in chemical engineering from Columbia University and her JD from University of Michigan Law School.

Nancy E. Halpern, DVM, Esquire, a licensed veterinarian and attorney, represents animal owners and animal-related businesses from pharmaceutical companies to farmers, trade associations, universities, pet stores, veterinarians, and other individuals involved in all areas of animal law in support of their interests in the humane use of animals, health care, USDA, EPA and FDA regulatory issues at Fox Rothschild LLP, a national law firm. Also a patent attorney, Dr. Halpern represents clients in the prosecution of patents in animal and agricultural biotechnology and pharmaceuticals, and in defense of their intellectual property interests and rights. Dr. Halpern previously served as Director of the Division of Animal Health for the New Jersey Department of Agriculture and New Jersey's State Veterinarian where she was responsible for: the state's emergency response regarding animal care concerns to natural or man-made disasters; supervision of the only animal health diagnostic laboratory in New Jersey; and implementation of regulatory and statutory provisions governing animal care, well-being and safety, as well as animal disease surveillance and control.

James Klaiber

James R. Klaiber is Counsel in the Intellectual Property Group of Hughes Hubbard & Reed. His practice is focused on patent litigation, prosecution, and transactions, including medical devices, automotive, telecommunication, semiconductors, display devices, and packaging. Jim has litigated in U.S. District Courts, the Federal Circuit, and the Supreme Court, as well as the PTAB and the ITC. He is a former AT&T Bell Laboratories Member of Technical Staff, where his work included research and development of high speed undersea cable deployment equipment, low-power optical amplifiers, and high-energy-density batteries.

He has mechanical engineering degrees from MIT, the University of California at Berkeley, and the University of Michigan, and his law degree is from Fordham University Law School. Jim is the immediate past Chair of the ABCNY Committee on Patents, and is a board member and former Chair of the MIT Enterprise Forum of New York City.

Michael Knight

With more than 25 years of experience as an antitrust lawyer in both government and private practice, Mike Knight advises clients on a full range of competition law matters including mergers, joint ventures, competitor collaborations, distribution issues, price discrimination, monopolization, and intellectual property restraints. He routinely represents clients before federal and state antitrust agencies and federal courts. Mike also co-heads Jones Day's Hart-Scott-Rodino Act premerger notification team.

Mike's recent representations include securing antitrust clearance for Cintas Corporation's acquisition of G&K Services and the long-fought acquisition by Hertz of Dollar Thrifty Automotive Group. He also has represented Aetna, Axiall, Conagra, and Indivior, among other clients, on antitrust matters. Mike served as an assistant director of the Federal Trade Commission's Bureau of Competition from 2003 to 2007, heading the Bureau's Mergers II Division, where he oversaw hundreds of investigations across an array of industries including technology, chemical manufacturing, mining, and agriculture. He was a trial attorney at the U.S. Department of Justice Antitrust Division from 1997 to 2000. In private practice before joining Jones Day, Mike represented technology firms Adobe, NVIDIA, and Synopsys, among other clients.

Mike has held various leadership positions in the American Bar Association's Section of Antitrust Law over the past 17 years and currently serves as a vice chair of t he Mergers & Acquisitions Committee. He writes and speaks frequently on antitrust enforcement topics.

Lisa Landau

Lisa Landau has spent her career championing the rights of New Yorkers, and particularly the rights of women and children, through her work on civil rights, health and anti-poverty issues in a wide range of settings. Lisa currently serves as Chief of the Health Care Bureau at the New York State Attorney General's Office, where her bureau enforces health care law, including consumer protection law, to protect New Yorkers as they confront the challenges of the health care system. Prior to rejoining the AG's office in 2011, Lisa was Executive Director of New York City's Nurse-Family Partnership (NFP), a nationally recognized, early intervention anti-poverty program run out of the NYC Department of Health and Mental Hygiene (DOHMH), through which registered nurses work intensively with first-time, low-income mothers over a two-year period. During her five-year tenure at NFP, she oversaw a more-than-sevenfold expansion of the program to the point where it was serving approximately 2500 New York City families citywide. Lisa previously served in the New York AG's office from 1999 to 2006, serving as Director of the Reproductive Rights Unit (2003- 2006), and prior to that as an Assistant Attorney General in the AG's Civil Rights Bureau (1999- 2003) working on an array of civil rights cases, including sex discrimination, police misconduct and mortgage lending fraud. Earlier in her career, she advocated for women and children as a staff attorney at the American Civil Liberties Union's Reproductive Freedom Project and The Legal Aid Society's Harlem Neighborhood Office, and worked in refugee camps in Thailand with the U.S. resettlement operation for Indochinese refugees. She is a graduate of the University of Pennsylvania and New York University School of Law.

Kristin Landis

Kristin Landis is currently the Deputy General Counsel for Agriculture and Environment at the Biotechnology Innovation Organization (BIO), the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. Ms. Landis advises the association and its members on legal, regulatory, policy, and legislative issues relating to agricultural and industrial biotechnology. Before joining BIO in 2017, Ms. Landis served as Deputy General Counsel for CropLife America, the primary trade association representing the manufacturers and distributors of crop protection products. Ms. Landis began her legal career as a litigator in the Honors Program at the U.S. Department of Justice and then spent almost a decade in private practice with the international law firm of McKenna, Long & Aldridge LLP. She obtained her law degree from the George Washington University Law School, where she was a member of the GW Law Review. She also holds a Bachelor of Science in neurobiology and physiology from the University of Maryland.

Janet Linn is an intellectual property litigator with more than 25 years' experience trying and litigating patent, trademark, unfair competition, and trade secret cases in a broad range of technologies, including pharmaceuticals, medical devices, consumer products, and mechanical devices.

Janet has extensive experience in pharmaceutical (Hatch-Waxman) patent litigation, and has acted as trial counsel in patent, trade secret and antitrust actions involving pharmaceuticals with annual billion dollar sales. She was the past Chair of the Patents Committee of the Association of the Bar of the City of New York and is currently the Vice Chair of the Food, Drug and Cosmetic Section of the New York State Bar Association, and is a past Chair of the Patents Committee of the Association of the Bar of the City of New York.

James Major

James Major is an associate at the intellectual property boutique firm of Lucas & Mercanti, LLP in Manhattan. James's practice focuses on U.S. and foreign patent prosecution in the fields of biologicals, small molecules, industrial processes, and treatment methods. He also renders patentability, freedom-to-operate, white-space, and invalidity opinions in these fields, as well as litigating patent and trademark disputes.

A British subject, James has a Bachelors from the University of Cambridge where he studied the role of controlled cell death in arterial disease. He has a doctorate from the University of Oxford where he studied the interactions of the immune system with the virus used to eradicate smallpox. He graduated magna cum laude from New York Law School and is a member of the New York City Bar Association Patents Committee.

Victoria (Vicki) Malia-Piekarz is Senior Counsel for the New York Genome Center (NYGC), a non-profit research center that integrates sequencing, bioinformatics, and data management. Vicki manages an intellectual property portfolio comprising patents, trademarks, and copyrights, as well as educates NYGC personnel regarding intellectual property matters. Vicki also drafts, reviews, and negotiates a wide variety of research-related agreements to facilitate collaborations with other institutions and companies.

Earlier in her career, Vicki practiced in the intellectual property law departments of several large law firms and Fortune 500 companies. A former university researcher, Vicki became interested in patents and intellectual property after inventing improvements to various assays and devices.

Brian J. Malkin

Brian is Chair of NYSBA's Food, Drug and Cosmetic Section and Co-Chair and founder of NYSBA's new Committee on Cannabis Law. Brian is an attorney in Arent Fox's FDA, Intellectual Property, and Health Care Groups. He has more than 23 years of food and drug law practice and over 12 years of intellectual property law practice. In particular, his practice includes the interrelation between patent law and food and drug law. Brian's regulatory experience includes all types of FDA-regulated products: drugs (including animal drugs), biologics, medical devices, foods and dietary supplements, tobacco products, and cosmetics. Brian's intellectual property experience includes FDA and patent litigation for both innovator and generic companies. Brian began his legal career as a regulatory counsel at the U.S. Food and Drug Administration, where he worked for more than nine years in both the Office of the Commissioner and the Center for Drug Evaluation and Research. At FDA he focused on new product evaluations, compliance issues related to clinical investigations and intellectual property (e.g., patent term restoration). Brian's work resulted in new product approvals as well as new industry guidance documents and policies, such as the animal efficacy rule for counter-terrorism products. Following several years of practice in an FDA law firm, Brian recognized an unmet need to understand both food and drug and intellectual property law for life cycle management and diligence, particularly concerning products affected by the Hatch-Waxman Act such as generic and 505(b)(2) new drug applications. As a result, Brian returned to university to obtain a Bachelor of Science degree in biochemistry. Prior to joining Arent Fox, Brian practiced for more than nine years at an intellectual property law firm, where he worked on a variety of new product evaluations, FDA and patent litigations, due diligence projects, patent prosecutions, and licensing and commercial transactions and has also led an FDA Group at an international law firm for nearly three years.

Christopher C. Palermo

Chris Palermo is a Partner at Bleakley Platt & Schmidt, LLP in the Firm's Litigation practice group. His practice focuses on helping pharmaceutical companies and other clients resolve commercial and regulatory disputes across a wide range of legal areas. Mr. Palermo has represented pharmaceutical companies in government investigations, class action litigation, antitrust matters, False Claims Act litigation and claims brought by the U.S. Department of Justice and state Attorneys General relating to the marketing and sale of pharmaceuticals. Mr. Palermo has also advised pharmaceutical company clients on compliance issues.
Mr. Palermo serves on the Executive Committee of the Food, Drug and Cosmetic Law Section of the New York State Bar Association and is a frequent speaker at CLE programs on commiercial litigation and on antitrust issues impacting the pharmaceutical industry. Mr. Palermo is cum laude graduate of Princeton university and Georgetown University Law Center.

Nancy L. Perkins

Nancy L. Perkins, Counsel at Arnold & Porter LLP in Washington, D.C., advises clients, including pharmaceutical and medical device companies, on a wide range of data protection issues at the federal and state levels, as well as on cross-border data privacy and security matters. She counsels clients on HIPAA privacy, security, and data breach notification matters and advises on privacy compliance in online communications and innovative health care delivery mechanisms, including mobile apps. Ms. Perkins also assists clients on financial data protection and works with them in responding to data security breaches generally, including through notifications to individuals and government authorities, as well as in defending against related litigation. A graduate of Harvard Law School, Harvard's Kennedy School of Government, and Harvard College, Ms. Perkins is the author of numerous articles on data privacy and security regulation, and is an Adviser on the American Law Institute's Adviser for the American Law Institute Project, Principles of the Law, Data Privacy. She has been ranked among America's Leading Lawyers for Privacy & Data Security by Chambers USA every year since 2009, and ranked among the World's Leading Lawyers for Privacy & Data Security (USA) by Chambers Global since 2010.

April Polikoff has worked in-house for Akorn Pharmaceuticals since April, 2014. Prior to that, she worked in the legal and regulatory affairs departments at Hi-Tech Pharmacal Co. Inc. With nearly 10 years of experience in the industry, April handles an array of legal matters including commercial transactions, pharmaceutical compliance, and litigation.

(Panel Chair)

Nancy K. Stade

NANCY STADE is a partner in Sidley Austin's Food, Drug and Medical Device Regulatory practice within the global Life Sciences team. Her practice focuses on advising clients in the medical device, combination product, digital health and life sciences arenas on all aspects of FDA oversight. She has twenty years' experience in Food and Drug law, specializing in medical device and combination product regulation and has deep knowledge of the Food and Drug Administration's regulatory processes, such as requests for designation of combination products, appeals of significant decisions within the Center for Devices and Radiological Health, and requests for information concerning devices.

Before joining Sidley, Nancy worked for 17 years at the U.S. Food and Drug Administration (FDA) in a variety of senior positions, including Deputy Director for Policy at the Center for Devices and Radiological Health, where she led the development and implementation of FDA's device regulatory policy.

David S. Weinstock

David S. Weinstock has served as in-house and outside counsel advising prescription and OTC drug, biotech, medical device and cosmetic companies. His areas of specialization include: research and development/GLP, clinical trials/GCP, manufacturing/GMP, labeling, advertising and promotion, controlled substances, anti-kickback, fraud and abuse and the Animal Welfare Act. Mr. Weinstock also served as the Deputy Director (and Interim Director) of the National Advertising Division of the Council of Better Business Bureaus. He has also advised on compliance, trademark, contract and general corporate matters.

Mr. Weinstock earned an LL.M. in Trade Regulation (with concentrations in food and drug law and antitrust law) from New York University School of Law and holds a J.D. from Albany Law School of Union University. He received a B.A. with High Honors in Economics from Hobart College prior to which he attended the Bronx High School of Science.

Ilene Wilets, PhD (Updated Short Bio) 12/18/2017

Ilene Wilets, PhD, is a research ethicist with nearly 20 years' experience within academic medicine. Her interests include, but are not limited to, human subjects protection regulation, informed consent and decision-making for research participation, expanded access to experimental therapeutics, public health research, disaster medicine, emergency medicine, and global health.

Dr. Wilets serves as an IRB Chair for the Program for the Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai, and is on faculty with the Department of Environmental Medicine and Public Health. She is also an adjunct faculty member with the Masters of Science in Bioethics Program at Columbia University, and a Board member for the Global Bioethics Initiative, an international non-profit organization dedicated towards fostering public awareness of bioethical issues and exploring solutions to bioethical challenges.

Christina R. Young

Dr. Christina R. Young is a Regulatory Consultant in the FDA & Life Sciences practice group of King & Spalding's Washington, D.C. office. One of the first employees hired to FDA's Center for Tobacco Products (CTP) in 2010, she served as Chemistry Reviewer for six years. Throughout her tenure at CTP, Dr. Young was recognized as a key contributor to the development of some of CTP's first Rulemakings and Guidances for Industry along with internal policies supporting application review processes. From 2011-2016, she served as one of FDA's first federal government representatives on ISO/TC 126. Prior to FDA, Dr. Young held a post-doctorate fellowship in the Centers for Disease Control and Prevention's Tobacco Analysis Branch where she led international method validation efforts for the World Health Organization in fulfillment of the United Nation's first public health treaty, the Framework Convention on Tobacco Control. Dr. Young holds a Ph.D. in Chemistry from the Georgia Institute of Technology and a Bachelor of Science in Chemistry from the University of South Carolina.