Legal and Practical Issues in the Evolving World of Cannabis Regulation
December 2-3, 2021 | Live Virtual Event
Speaker Biographies

APRIL INYARD ALEXANDROW works at the US Food and Drug Administration (FDA) within the Office of the Commissioner (OC) as the Science and Policy Coordinator for the FDA's cross-Agency cannabis product program, the Cannabis Product Committee (CPC). April is a Lean Six Sigma Master Black Belt (LSS MBB) and has expertise in application of organizational development, strategic operations, and process improvement tools in the regulatory science and policy space. She has been at the FDA since 2009 and served in a variety of roles including Associate Director for Quality Assurance in the Center for Drug Evaluation and Research (CDER) Office of Compliance, and the stand-up of FDA's first in-house process improvement consulting group. Prior to joining the FDA in 2009 as a consumer safety officer, April was a patent examiner for the US Patent and Trademark Office. She received her BS in Chemical Engineering (2003), MS in Biological and Physical Sciences (2006), and PhD in Pharmacology (2008) from the University of Virginia in Charlottesville, VA.

EDGAR J. ASEBEY is a founding partner of Keller Asebey Life Science Law PLLC and has been practicing regulatory and transactional law for over 20 years. Mr. Asebey advises clients in the pharmaceutical, biotechnology, biologics, medical device, food and dietary supplement industries and represents clients before the FDA, USDA, CBP, FTC, CPSC and EPA. Mr. Asebey counsels clients and preforms regulatory due diligence in support of financings, public offerings and M&A transactions. He also advises emerging life science companies on patent portfolio development, pharmacoeconomics and clinical trial development. Since 2015, he has been advising cannabis companies and today provides regulatory compliance, due diligence and transactional services to hemp/CBD, cannabis/marijuana and psychedelic drug discovery companies. In addition to his law practice, Mr. Asebey is a founding member of Iter Investments Fund I GP. Most recently, Mr. Asebey co-authored the authoritative treatise, Legal Guide to the Business of Marijuana (PLI Press, 2021) and is considered an expert in the regulation of Cannabis, hemp, and hemp-derived cannabinoids. Early in his career Mr. Asebey served as Patent and Licensing Advisor to the Natural Products Branch of the National Cancer Institute at the National Institutes of Health (NIH). He founded and served as president of Andes Pharmaceuticals, Inc., a natural products drug discovery company, from 1994 to 2000 and has served as in-house counsel to two life sciences companies. Most recently he was an equity partner in the Health Care & Life Sciences Practice Group at Jones Day and today serves as partner at Keller Asebey Life Science Law, PLLC. Mr. Asebey studied molecular biology at the University of Chicago and spent 5 works working in molecular biology research laboratories at the University of Chicago and the University of Illinois School of Medicine. He holds a law degree from Catholic University of America (Washington, DC) and is licensed to practice law in Florida and Washington, DC. He is a member of the American Bar Association, Food & Drug Law Institute (FDLI), Dade County Bar Association, and BioFlorida.

JACQUELYN L. BAINBRIDGE is a professor at the University of Colorado Anschutz Medical Campus, where she holds joint appointments in the Skaggs School of Pharmacy and Pharmaceutical Sciences, Department of Clinical Pharmacy, and the Department of Neurology in the School of Medicine. Dr Bainbridge received her doctorate in pharmacy from the University of Colorado in Denver, where she subsequently completed a specialty residency in neurology.

FREDERICK R. BALL serves as a team lead for the Duane Morris Life Sciences and Medical Technologies industry group. Mr. Ball helps pharmaceutical companies, biologics manufacturers, medical device manufacturers, contract service providers, food companies (including supplement manufacturers), pharmacies, long term care providers, and other health care 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, False Claims Act, and Anti-Kickback Statute, as well as meeting labeling and advertising requirements. Mr. Ball assists companies bring product to market through patent analysis, identifying marketing and approval pathways, and, when necessary litigation. Mr. Ball is experienced in conducting internal investigations and advising companies on actions following the investigation. Finally, Mr. Ball helps entities when they are adverse to state or federal governments, including in administrative, civil and criminal matters, with the FDA, FTC, DEA, CMS, OIG and other federal and state regulatory agencies. Mr. Ball emphasizes a team approach to client problem solving and manages matters to achieve client goals both financial and legal.

STAN BENDA is a graduate of the Royal Military College of Canada and trained as an armoured officer in the Canadian Army. He was an exchange student at West Point. Subsequently he was a senior counsel with the Federal Department of Justice. Relevant here, his primary duties were representing two divisions of Agriculture and Agri-Food Canada (AAFC), the Intellectual Property Secretariat and the International Science Section. In the former instance he advised and trained AAFC's commercialization officers across the country regarding technology transfer / licensing / CRDAs / MTAs. In the latter instance he acted before the UN FAO (Food and Agriculture Organization) on the International Treaty on Plant Genetic Resources for Food and Agriculture, the proposed Animal genetics treaty and the Cartagena Protocol. In those instances, he acted in concert with the USDA, since the FAO operates by region not country. In 2018 he completed a 5-year appointment as a part-time vice-chair on the Ontario Agriculture, Food and Rural Affairs Appeal Tribunal. Dr. Benda has his LLM in intellectual property law and PhD on the labeling of genetically modified foods: science vs values. He writes at the intersection of food / law / science and regulation. He practices in biotechnology and licensing.

MARK BOLTON serves as Head of Global Public Policy for Jazz Pharmaceuticals. In that capacity, Mark oversees all international, federal, and state policy issues for Jazz. Before joining Jazz, Mark was a partner at Brownstein Hyatt Farber Schreck in Denver. Mark also previously served as Sr. Deputy Legal Counsel and Director of Marijuana Coordination for Governor John Hickenlooper of Colorado. During his time in Governor Hickenlooper's office, Mark administered cannabis policy issues for the state and oversaw the cannabis-related work of 12 state agencies and hundreds of agency employees, and advised numerous other jurisdictions (national, state and local) regarding legalization and regulation of cannabis.

RODNEY WILLIAM BUTT is Senior Vice President of Strategic Solutions at Nutrasource Pharmaceutical & Nutraceutical Services. Over the last 30 years Rod has been involved in all aspects of prescription drug development clinical trials, and organizational design within the pharmaceutical and allied industries. Rod's experience with pharmaceutical drug development includes a broad spectrum of related activities from participation and leading international drug development teams, acting as key consultant on product development strategies, leading medical / clinical research departments, building research physician networks and acting as key liaison between Pharma and Investigators. Rod is a frequent speaker at pharma Industry events and is a lecturer in drug development at the University of Guelph. Rod completed his MSc in Clinical Trial Methodology at McMaster University and his MBA at Queen's University.

TARA LIN COUCH is a PhD Analytical / Organic Chemist with exceptional analytical abilities and more than 30 years of diverse laboratory and regulatory experience in academic, field, contract, and manufacturing environments. She is a sought-after expert on laboratory operations, analytical test methodologies, and the performance of test method validations; and issues pertaining to quality operations and regulatory compliance with Current Good Manufacturing Practices (cGMPs) in dietary supplement, pharmaceutical, and tobacco manufacturing. As a consultant, Dr. Couch assists clients with the development, improvement and implementation of quality systems that are scientifically sound, efficient, practical, and compliant with all applicable FDA regulations. She performs mock FDA inspections, gap analyses, due diligence assessments, and audits directly for clients as well as audits of contracting partners including manufacturers, packagers, distribution warehouses, and laboratories. Dr. Couch provides training on topics of cGMP requirements, quality systems, and laboratory operations via seminar, webinar and on-site presentations.

DELIA ANN DESCHAINE is a member of the firm in the Health Care and Life Sciences practice, in the firm's Washington, DC, office. Named to the Washington DC Rising Stars list in the area of Food and Drugs (from 2018 to 2020), Ms. Deschaine focuses her practice on advising pharmaceutical and biotechnology clients on a broad range of FDA regulatory matters. In addition, Ms. Deschaine focuses her practice on the federal and state regulation of controlled substances. She defends clients, including pharmaceutical and biotechnology companies, distributors, pharmacies, hospitals, physician groups, academic medical centers, and other researchers, in government investigations and litigation. Prior to joining the firm, Ms. Deschaine served for six years as an attorney for an international law firm in the areas of pharmaceutical and biotechnology law, and two years at a boutique FDA law firm, both in Washington, DC. Before then, she was an Attorney Advisor for the DEA through the Attorney General's Honors Program, where she received a Performance Award in 2011. She was also a legal intern for Magistrate Judge Susan K. Gauvey of the US District Court for the District of Maryland.

BRAD DOUGLASS holds a doctorate in Organic and Medicinal Chemistry, an MS in Regulatory Science, and BS degrees in Computer Science and Neuroscience from the University of Southern California. Dr. Douglass possesses over a decade of professional experience in the pharmaceutical, dietary supplement, and cannabis industries. Prior to devoting his attention to the cannabis industry in 2013, he developed fine-chemical and active pharmaceutical ingredient applications using continuous flow reaction design before acting as an FDA Affairs consultant focused on the regulation of food, drugs, and dietary supplements. Over the past six years, Dr. Douglass has served in a variety of roles related to cannabis and hemp including; Scientific Director of a state-certified cannabis laboratory, Manufacturing Controls and Formulation Consultant, Director of Advanced Botanical Strategy, and VP of Regulatory Affairs. Dr. Douglass is a tireless advocate for a utilitarian approach to cannabis regulation that borrows principles from existing regulatory frameworks, believing that this will help side-step pitfalls. Dr. Douglass is currently an independent consultant with the EAS Consulting Group.

ROBERT DURKIN is of counsel at Arnall Golden Gregory LLP. As a former acting Director and Deputy Director of the Office of Dietary Supplement Programs (ODSP) in the FDA's Center for Food Safety and Applied Nutrition (CFSAN), he brings a wealth of knowledge and insight to his legal practice. In working with AGG clients, Bob will draw from the extensive experience he gained at the FDA where he was responsible for performing policy analysis and evaluations related to all aspects of the agency's dietary supplement programs while also providing skillful advice on compliance and enforcement issues (such as Warning Letters, seizures, injunctions, import detention/refusal, etc.). During this time, he was active in a variety of agency working groups, including: Agency-wide Marijuana Working Group, Agency-wide CBD Policy Working Group, and the Agency-wide

Investigational New Drug (IND) Policy Working Group. While helping to lead ODSP, Bob also successfully led the Office through multiple GAO investigations. Just prior to joining ODSP, Bob was the acting Director of CFSAN's Food Defense Staff. In this role, Bob led a dedicated group of professionals whose duty it was to determine the best regulatory strategies to help protect our nation's food supply from intentional contamination. The Food Defense staff's work includes the implantation of the Food Safety and Modernization Act's Rule for Mitigation Strategies to Protect Food against Intentional Adulteration and determining the best ways to educate, and then regulate, industry relative to the Rule. Bob has also served in both the Commissioner's Office and the Center for Drug Evaluation and Research (CDER). While in the Commissioner's Office, Bob managed a staff of Emergency Response Coordinators whose focus was on coordinating an over-all Agency approach to mitigate and respond to urgent health concerns related to FDA regulated commodities. While at CDER, Bob worked in the areas of health fraud, over the counter drugs, and pharmacy compounding.

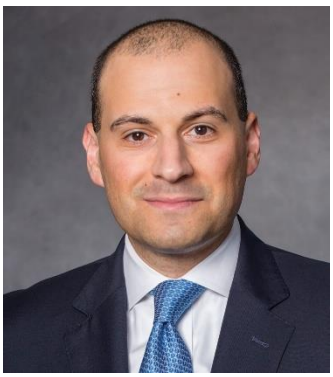
ANDREW FREEDMAN is a senior vice president at Forbes Tate, having come from Freedman & Koski, a consulting firm dedicated to making cannabis legalization successful. Andrew was Colorado's first cannabis czar under Governor Hickenlooper from 2013 to 2017. His firm has since worked directly for dozens of governments including California, Canada, Florida, Massachusetts, Maine, Rhode Island, and Illinois; and testified to all governments considering legalization. He has been a featured speaker at dozens of conferences including Code Conference, Summit, and Aspen Ideas Fest. Andrew is also a General Partner at Caldwell Capital, a San Francisco-based seed and series A VC firm that funds and advises the entrepreneurs that will define the new era of cannabis legalization. Andrew's role in developing a successful operating model for cannabis regulation and stakeholder collaboration was identified as one of the reasons for the State of Colorado's success in implementing adult-use cannabis legalization by the Brookings Institution. Andrew has received national recognition for his leadership. He was recognized as one of Fast Company's "100 Most Creative People in Business" in 2016. Men's Health Magazine named him one of the 30 top health influencers of the last 30 years, labeling him "legal weed's best friend". He has been featured on 60 Minutes, NBC Nightly News, The Today Show, The New York Times, The Washington Post, The Wall Street Journal, Politico, The Boston Globe, Governing Magazine, and dozens of local stories throughout the nation and internationally. Andrew holds a JD from Harvard Law School and a BA in philosophy and political science from Tufts University.

WILLIAM GARVIN is a Shareholder in the FDA Practice Group and co-head of the Cannabis Practice Group at Buchanan Ingersoll & Rooney where he focuses his practice on issues related to the approval, regulation, promotion, sale, and reimbursement of drugs, medical devices, biologics, dietary supplements, foods, and cannabis-related products. William assists companies in navigating federal and state law issues related to the promotion and sale of cannabis-related products. William is a Member of the Cannabis Committee for the American Herbal Products Association, the Cannabis Law and Policy group for the American Bar Association, the Law 360 Cannabis Editorial Advisory Board, and the Cannabis-Derived Products

Committee for the Food and Drug Law Institute. Since 2013, William has been named to the Washington, DC Super Lawyers Rising Stars list from 2013–18. He has also been recognized as a Nationwide Cannabis Lawyer by Chambers USA in 2019, 2020, 2021.

STEVEN M. GENDEL has been working to protect food safety and the integrity for over 35 years. This includes academic positions at Harvard University, the University of Toronto, and Iowa State University. He served as a policy expert in the FDA Center for Food Safety and Applied Nutrition where he was the first FDA Food Allergen Coordinator, as the lead for the program that publishes the Food Chemicals Codex, and is currently an independent consultant supporting industry and governments. He is a creative, analytical, and independent thinker committed to providing technically sound and practical ways to recognize and respond to existing and emerging opportunities and problems. He has over 90 publications and numerous presentations.

KATE W. HARDEY is a partner at McGuireWoods LLP where she advises healthcare provider, pharmaceutical, medical device, dietary supplement and life sciences clients on regulatory and compliance matters and in all types of transactions including sales and acquisitions, as well as advising lenders and investors evaluating regulatory risks in cash flow and asset based debt financing transactions. She has a combined 25 years of law firm, in-house and healthcare industry experience. She represents various healthcare providers including physician practices, hospitals, academic medical centers, pharmaceutical and medical device manufacturers among others. Kate also advises businesses and lenders involved in the cannabis supply chain. At the forefront of the industry, Kate currently serves on the Law360 editorial advisory board for life sciences where she advises the legal newswire on industry trends and issues facing companies, organizations, and law firms. Prior to joining McGuireWoods, Kate was Senior Regulatory Counsel at a leading middle market healthcare lender where she oversaw the healthcare regulatory diligence for all transactions. In this position, she partnered with the risk underwriting teams to create an effective, coordinated and streamlined diligence process to identify and mitigate complex compliance and regulatory risks. Kate worked as in-house legal counsel in a large ten-hospital health system where she served on hospital boards and leadership teams. She also counseled hospital clients on a wide range of legal issues such as physician contracting and employment, transactional matters, pharmacy compliance, real estate transactions, accreditation and licensure issues, medical staff matters, patient privacy and patient care issues. Kate was the emergency department administrator at a major academic medical center where she directed physician contracting, compliance, finance, strategic planning and hospital emergency preparedness. She received an award for turning a department deficit into a significant profit in twelve months by developing comprehensive financial analysis and payer reimbursement monitoring program. Kate is a business-focused attorney with demonstrated leadership and strategic planning skills. Her diverse legal and healthcare practice has kept her at the forefront of critical issues affecting the healthcare industry.



JONATHAN A. HAVENS is a partner at Saul Ewing Arnstein & Lehr LLP, where he serves as co-chair of both the firm's Cannabis Law and Food, Beverage & Agribusiness Practices. Companies in the cannabis (both hemp and marijuana), life sciences, food and beverage, and cosmetics industries turn to Jonathan for advice on how to get and keep their products on the market. Since 2019, Chambers USA has recognized Jonathan as one of America's leading lawyers in cannabis law. In 2021, Law360 selected Jonathan as a cannabis law rising star, making him one of only five attorneys nationwide to receive that honor. He is regularly interviewed by mainstream and trade press outlets, alike, and has been quoted by or authored pieces for The New York Times, The Los Angeles Times, Reuters, CNBC, WIRED, MarketWatch, Engadget, Law360, High Times Magazine, and Marijuana Business Daily, among others. Jonathan began his legal career as a regulatory counsel with the US Food and Drug Administration, and prior to law school, Jonathan served as a legislative aide in both the US Senate and US House of Representatives.

JOHN HUDAK is the deputy director of the Center for Effective Public Management and a senior fellow in Governance Studies at the Brookings Institution. His research examines issues including presidential power, bureaucratic organization, legislative-executive relations, and state and federal cannabis policy. He is the author of two books, Presidential Pork: White House Influence over the Distribution of Federal Grants and Marijuana: A Short History. He has testified before dozens of government bodies at the local, state, federal, and international levels. He holds bachelor's degrees in political science and economics from the University of Connecticut and a master's degree and PhD in political science from Vanderbilt University.

ANDREW KLINE advises companies involved in all aspects of cannabis law and public policy, regulatory compliance, due diligence, civil litigation, and investigations. He brings a rare combination of public policy, cannabis, and prosecutorial experience to the firm, following decades of service in the highest levels of government and in the private and nonprofit sectors. Andrew also has a deep and celebrated background in coalition creation and management. Drawing on his nearly 15 years of experience as a federal prosecutor, and public service working as policy advisor to then-Vice President Biden and counsel to then-Senator Biden, Andrew represents clients in some of most sensitive areas of law and policy. Most recently, Andrew served as public policy director for the National Cannabis Industry Association, the leading trade organization for the state-legal cannabis industry. Andrew held several critical roles in the Obama-Biden administration including as crime and drug policy advisor to the vice president, chief of staff, and senior advisor to the intellectual property enforcement coordinator, and enforcement counsel at the Federal Communications Commission (FCC). As policy advisor to then-Vice President Biden, Andrew was responsible for strategic

oversight of the Office of National Drug Control Policy, including a $15 billion interagency budget process, President Obama's drug control strategy, and the anti-drug youth media campaign. He also led White House/Executive Branch interagency working groups on complex policy issues, including prisoner reentry and drug demand policies. Andrew also co-led the strategic development, interagency coordination, and successful implementation of the president's intellectual property enforcement strategy including establishing the first Office of the Intellectual Property Enforcement Coordinator. Andrew's experience as a federal prosecutor includes six years as an assistant US attorney in the District of Columbia. He also served as a federal prosecutor for six years in the Civil Rights Division's Criminal Section. Andrew has first-chaired over 40 criminal jury trials, 12 bench trials, and argued numerous criminal appeals. He also conducted hundreds of multi-agency investigations during the course of his 14-year tenure at the department.

ELIZABETH KRUMAN is currently the Acting Deputy Assistant General Counsel in the Marketing, Regulatory, and Food Safety Programs Division of the Office of the General Counsel at USDA. She has been an attorney with the USDA Office of the General Counsel since 2014, working primarily with the Agricultural Marketing Service, the Food Safety Inspection Service, and the Animal Plant Health Inspection Service. Her practice focuses on regulatory and administrative law, including administrative and Federal litigation. Since the passage of the 2018 Farm Bill, Ms. Kruman has served as the lead attorney working with the Agricultural Marketing Service on hemp matters. Ms. Kruman is a graduate of Wayne State University Law School and the University of Michigan.

BRIAN MALKIN is a partner in McDermott Will & Emery LLP's Washington, DC Office and counsels pharmaceutical and biologic clients on Food and Drug Administration (FDA) regulatory matters and intellectual property (IP) law, with an emphasis on patent litigation. His practice at the intersection of FDA- regulated products and patent law makes him a valuable partner to drug manufacturers, biotechnology clients, medical device companies and cannabis companies as they develop new products and protect their innovations though life cycle management, bring their products to market and pursue transactional opportunities. Brian's regulatory experience includes all types of FDA-regulated products: drugs and biologics (including animal drugs and biologics), medical devices, cannabis, foods and dietary supplements, cosmetics and tobacco products. He is a key advisor to pharmaceutical and biologic clients in the premarket, regulatory review, and marketing, enforcement and lifecycle management phases of product development. Brian works alongside his clients on drug development strategies and patent strategies across a variety of areas, including orphan drugs. With more than 20 years of FDA and intellectual property law experience, including time spent in the Office of the Commissioner and the Center for Drug Evaluation at the FDA, and a degree in biochemistry, Brian's background is uniquely tailored to the needs of life sciences innovators. He is also active in the

promoting the biotechnology community and life sciences entrepreneurs in Maryland, Virginia, the District of Columbia and beyond. Brian is active in a number of leading bar associations including the Co-Chair of the Intellectual Property Community (Section) for the DC Bar and founding and current member of the New York Bar Association's Committee on Cannabis Law and current member of the Executive Committee for the Food, Drug and Cosmetics Section.

KEITH MATTHEWS has over 25 years of private sector and government experience in environmental law related to chemical substances regulation. He is a former Director of the Biopesticides and Pollution Prevention Division (BPPD) in the US Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP). Prior to becoming Director of BPPD, Keith served in EPA's Office of General Counsel (OGC), first as a staff attorney, then as an Assistant General Counsel where he supervised attorneys providing legal counsel to programs in EPA's Office of Air and Radiation, Office of Pesticide Programs, and the Office of Research and Development. Keith's practice focuses on the regulation of chemical substances, including agricultural chemical and biochemical products, microbial products of biotechnology; and genetically engineered agricultural products that are regulated by EPA, FDA, and the US Department of Agriculture. Keith counsels and advises his clients using his breadth of knowledge on a variety of statutes, including the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Plant Protection Act, and the National Bioengineered Food Disclosure Standard.

EILEEN McMAHON is the Chair of Torys' Food/Drug Regulatory and IP Practices at Torys. Eileen is ranked in by Chambers for her expertise in Life Sciences Law, Cannabis and Agribusiness. She is on recognized by Managing Intellectual Property as one of the Top 250 Women IP Lawyers Worldwide. She is also a recognized expert in regulatory and IP law affecting cannabis products and accessories. Eileen has over 30 years of experience advising clients in the various regulated sectors. For about 20 years, Eileen has been actively advising clients in the cannabis sector and has spoken frequently and published articles in relation to Canada's cannabis laws. She is also a trustee of the Board of Governors of the Centre for Addiction and Mental Health (CAMH), which has played a leading role with the Canadian government in developing cannabis-related laws.

DEBORAH MIRAN, former commissioner, was a member of the Natalie M. LaPrade Maryland Medical Cannabis Commission from 2013- 2016. While serving on the commission, she was also a member of the executive committee, policy, and research subcommittees, and was chair of the education subcommittee. She was responsible for developing education programs for doctors and patients and was also an integral part of crafting the current regulations. Prior to the commission she was president and founder of Miran Consulting, Inc. There she advised both brand and generic drug makers on the FDA approval process. Ms. Miran was senior director of regulatory affairs for Alpharma, a generic drug manufacturer, where she directed the submission activities for new and abbreviated new drug applications to the FDA. She has spent over 30 years in the US pharmaceutical industry. Ms. Miran received her Bachelor of Science in chemistry from Iowa State University.

HEIKE NEWMAN works as Senior Regulatory Manager in the Office of Regulatory Compliance at the University of Colorado Denver | Anschutz Medical Campus. She provides assistance and guidance for FDA and DEA submissions to basic and clinical researchers involved in cannabis research since 2014.

ELIZABETH (LIZ) OESTREICH is Vice President, Regulatory Compliance at Greenleaf Health Inc., where she brings a diverse background of legal, public policy, and non-profit sector knowledge to her position. In her consultation of drug and medical device clients, she works to remediate compliance issues by reviewing Form 483 and warning letter responses, offering guidance on how to build a culture of quality within a company, and providing tips for communicating global quality improvements to FDA. In addition, she advises clients navigating the regulatory landscape for tobacco products and offers guidance on content and format of applications, interpretation of FDA regulation, communication with the FDA, and analysis of proposed rules. Ms. Oestreich also works with clients in the Cannabidiol space, offering strategic guidance and risk-based strategies as the FDA contemplates how to regulate the product category. Prior to joining Greenleaf Health, she served as Director of Educational Programming for the Food and Drug Law Institute (FDLI) in Washington, DC. While at FDLI, she gained extensive experience in all FDA-regulated product areas

through regularly corresponding with FDA officials, as well as creating and supervising the development of curricula for an array of educational programs. She earned a BS in Political Science from the University of Arizona and a JD from the University of the District of Columbia's David A. Clarke School of Law.

JIM O'REILLY The US Supreme Court quoted Prof. Jim O'Reilly's FDA treatise as 'The Experts Have Written" in March 2000. His 57 textbooks and 203 articles have grown out of 41 years classroom teaching for medical and law students and MPHs. He has been active with FDLI since 1974 and had served as chair of the programs committee and he has been a longtime member of the FDLJ editorial board. His textbook 'The Business of Marijuana, CBD and Hemp (3d ed. PLI.edu) has expanded in recent editions. He chairs the ABA's FDA Committee and serves as a city councilmember in Ohio.

DANIELLE PERRY is honored to serve as the Cannabis Regulation Oversight Officer (CROO) for Illinois. Appointed by Governor JB Pritzker after legalizing Adult Use of Cannabis, she works with 13 state agencies to direct the regulation and taxation of Illinois' cannabis industry. Danielle's top priority for the office is ensuring Illinois reaches its social equity goals through community reinvestment, diversifying the industry, and expungements. Within her first year, Danielle led the expungements of nearly half a million cannabis-related arrest records three years ahead of schedule. A combination of experience makes Danielle Perry the right leader to be Illinois's first CROO – notably being the youngest and first Black woman to lead a state's cannabis regulatory. She's been an urban agriculture non-profit executive director who trained individuals with employment barriers and created Chicago's first and only USDA organic farm. As Director of Communications and Outreach for the City of Chicago, she engaged citizens about police accountability and government efficiency. Danielle has also worked on Capitol Hill as a Congressional Aide in charge of social security, health care, and civil rights issues. Lastly, Danielle Perry had the pleasure of serving as Special Advisor to the Assistant Secretary for Civil Rights for the United States Department of Agriculture (USDA) in the Obama Administration, leading a National Community and School Garden Initiative in food-insecure communities. Danielle earned her BA and JD from Howard University in Washington DC.

SHAWN "PEPPER" ROUSSEL is an attorney, ecoculinarean, and food activist. Pepper is Managing Attorney of Green Pepper Legal, consultant with Green Pepper Consulting, C0-founder of Dandelion & Moss, member Attorney with Green Justice New Orleans, and the Founding Director of Culinaria Center for Food Law, Policy, and Culture. She is also Chairperson of the Board for New Orleans Food Policy Advisory Committee, Secretary of the Living School Board of Directors, member of the LA Clinical and Translational Center LA Community Advisory Board, and an Advisor to Imagine Water Works. Pepper holds a BS in Computer Information Systems from Tulane University; an MS in

Computer Information Technology with a concentration in eCommerce from Regis University; and a JD with certificates in both Environmental and International Laws from Loyola University New Orleans School of Law. She is barred and admitted in all Louisiana courts and Chitimacha Tribal Court. Her writings focus on food and environmental injustice, remediation of invasive species, food systems and Black farmers, and the environmental impacts on food.

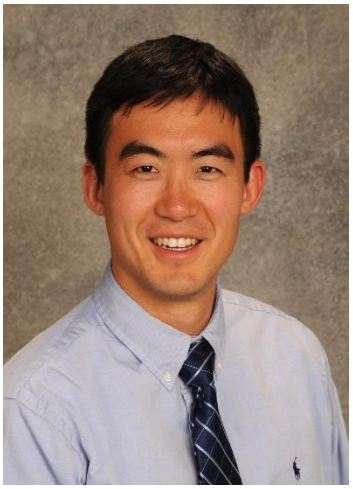
ALYSSA SAMUEL is a Corporate Regulatory MA and Securities attorney at Husch Blackwell LLP and is a part of the cannabis practice group. With over ten years of experience, her practice focuses on the regulatory aspects of corporate transactions, and she has extensive industry experience advising cannabis companies from small startups to publicly traded companies. In her experience with the industry, she has seen firsthand how the opportunities available benefit many while disenfranchising others, particularly those of color. In 2021 she has devoted a portion of her practice to helping social equity applicants launch businesses in Colorado and she has worked with the Husch Blackwell Communities for Change program to launch an initiative to provide pro bono resources to diverse social equity applicants.

GILLIAN L. SCHAUER is the Executive Director of the Cannabis Regulators Association (CANNRA), a non-profit, non-partisan, member funded organization that convenes cannabis regulators from more than 37 states and territories to identify and share best practices to protect consumer safety and public health, promote equity, and create regulatory certainty. Dr. Schauer has worked in public health and drug policy for nearly two decades and has a decade of experience working with federal and state agencies on cannabis policy, data monitoring, and research translation, including work with the National Institute on Drug Abuse and the Centers for Disease Control and Prevention. Prior to her work on cannabis issues, Dr. Schauer worked on tobacco prevention and control, with a focus on tobacco cessation and treatment. Dr. Schauer is also an Affiliate Research Scientist with the Addictions, Drug & Alcohol Institute at the University of Washington and has more than 65 peer-reviewed research publications on cannabis, tobacco, and other substances. She has a PhD in Behavioral Science from Emory University, a Master of Public Health from University of Washington, and a BS from Northwestern University.

HOWARD R. SKLAMBERG is a partner at Arnold & Porter where he counsels clients on a wide range of compliance and enforcement issues related to US Food and Drug Administration (FDA) regulation and policy. His experience is rooted in a deep understanding of US and foreign food, drug and medical devices law and policy, and is able to guide domestic and international clients through the regulatory challenges they face. Areas of expertise include inspections and warning letters, investigations, civil and criminal enforcement, medical product applications and clinical research, food and hemp regulation, imports, the development of FDA policy and FDA-related legislation, and business transactions involving FDA-regulated companies. Prior to entering private practice, Mr. Sklamberg held a variety of roles at the FDA from2010 to 2017, including Deputy Commissioner for Global Regulatory Operations and Policy; Director of the Office of Compliance, Center for Drug Evaluation and Research; Deputy Associate Commissioner for Regulatory Affairs; and Director in the Office of Enforcement. While at the agency, he directed an office of over 5,000 employees in more than 200 offices, laboratories and import facilities across the United States, Asia, Europe, and Latin America. As Deputy Commissioner, Mr. Sklamberg was FDA's top enforcement official. He oversaw the agency's inspections, enforcement, recalls, and import operations programs. Mr. Sklamberg also led FDA's international program, including its agreements and cooperation with foreign regulators, harmonization initiatives, and oversight over the global supply chain. He also interacted with and testified before Congress on behalf of the agency, co-led FDA's implementation of the FDA Food Safety Modernization Act and was the lead official at FDA on a variety of issues including cannabis and hemp, counterfeit drugs, and FDA's Mutual Recognition Agreement with the European Union. Earlier in his career, Mr. Sklamberg served as a prosecutor in the US Attorney's Office in Washington, DC, and in the Public Integrity Section of the Criminal Division at the Department of Justice.

THOMAS TOBIN is an Associate in Perkins Coie's Seattle office, where his practice focuses on complex commercial litigation and class action matters involving statutory, constitutional, and regulatory issues in a range of industries, including food and beverage, consumer packaged goods, and cannabis. Tommy recently edited the American Bar Association's Food Law: A Practical Guide, a resource book for practitioners to assist them in meeting the unique needs of food and beverage clients across various domains of legal practice. Tommy is a Lecturer at UCLA Law, where he teaches a seminar on food litigation. Tommy has written extensively about cannabis and CBD, including a recent book chapter on cannabis litigation.

DAVID VAILLENCOURT is dedicated to empowering individuals and teams to perform at their best through education and effective communication. As the founder and President of The GMP Collective, he brings nearly 15 years of academic and industry experience to build strategic relationships with experts across the world and is a respected speaker on business strategy and compliance in the evolving cannabis industry. David serves on, advises, and leads many governments and non-profit industry organizations including Chair of the National Cannabis Industry Association's Facility Design Committee, the Sustainable Cannabis Coalition, and is the incoming Vice-Chair of ASTM International's D37 Cannabis Standards Committee which he has been a member of since inception in 2017 where he developed and passed the first consensus laboratory standard. Prior to founding the Collective, David's experience included the Director of Quality for a large multi-state cannabis operator and supervisory roles in Quality Control and project management for multi-million-dollar life science projects for the federal government. He holds a MS and has also developed curriculum and taught courses at the college and secondary levels. When he is not busy with the Collective you can find him off the grid in remote mountainous areas hiking, camping, and skiing with his dog Humphrey.



G. SAM WANG is an associate professor of pediatrics at the University of Colorado Anschutz Medical Campus and Children's Hospital Colorado. He has been involved in regulatory discussions in the state of Colorado since legalization of recreational cannabis in 2012. Dr. Wang has published studies on the unintended impacts of cannabis legalization on the pediatric population.

JESSICA WASSERMAN is the founder of Washington-DC based law and regulatory policy firm WassermanRowe. She brings to decades of experience as a practitioner representing highly regulated industries before federal agencies, including at the Food and Drug Administration on behalf of food, beverage, wellness and medical device companies. Jessica gets into the nitty gritty of premarket approvals, withdrawals, recalls, labeling and claims for FDA-regulated food, drugs, dietary supplements, medical devices, cosmetics, petfood and tobacco/vape products. Most recently, Jessica is proud of her role in assisting Covid 19 test developers to receive FDA Emergency Use Authorizations, necessary to get these important tests on the market. Jessica has worked since 2018, when hemp was de-scheduled, assisting hemp and CBD companies to

commercialize their products. She has also donated many hours working on behalf of the industry as a whole in advocacy efforts toward a regulatory pathway at FDA for the marketing of CBD products. With experience working on Capitol Hill and as a political appointee at the Departments of Agriculture and Commerce, Jessica has a 360-degree view of the legislative, regulatory, and political path toward cannabis legalization. Jessica is a graduate of St. John's College and the University of Michigan Law School.

JOSEPH WYSE is Patent Attorney and head of the Patent and Analysis Dept. at the Bressler IP Group (Israel). He has a PhD in Genetics (University of London). Dr. Wyse is an Israeli patent attorney with many years of patent and IP expertise in the medical cannabis industry, throughout the cannabis supply chain. He has developed and prosecuted patent portfolios in cannabis strain development, agri-technical and cultivation technology, security systems, cannabinoid extraction technologies, software in the cannabis industry, cannabis formulations, analysis of cannabinoids, cannabinoids for medical conditions, and cannabis devices. Dr. Wyse is a contributor to many cannabis meetings. He is the lead author of the most comprehensive peer reviewed article yet published on Intellectual Property in Medical Cannabis: *Trends in intellectual property rights protection for medical cannabis and related products* Journal of Cannabis Res 2021 Jan 6;3(1)