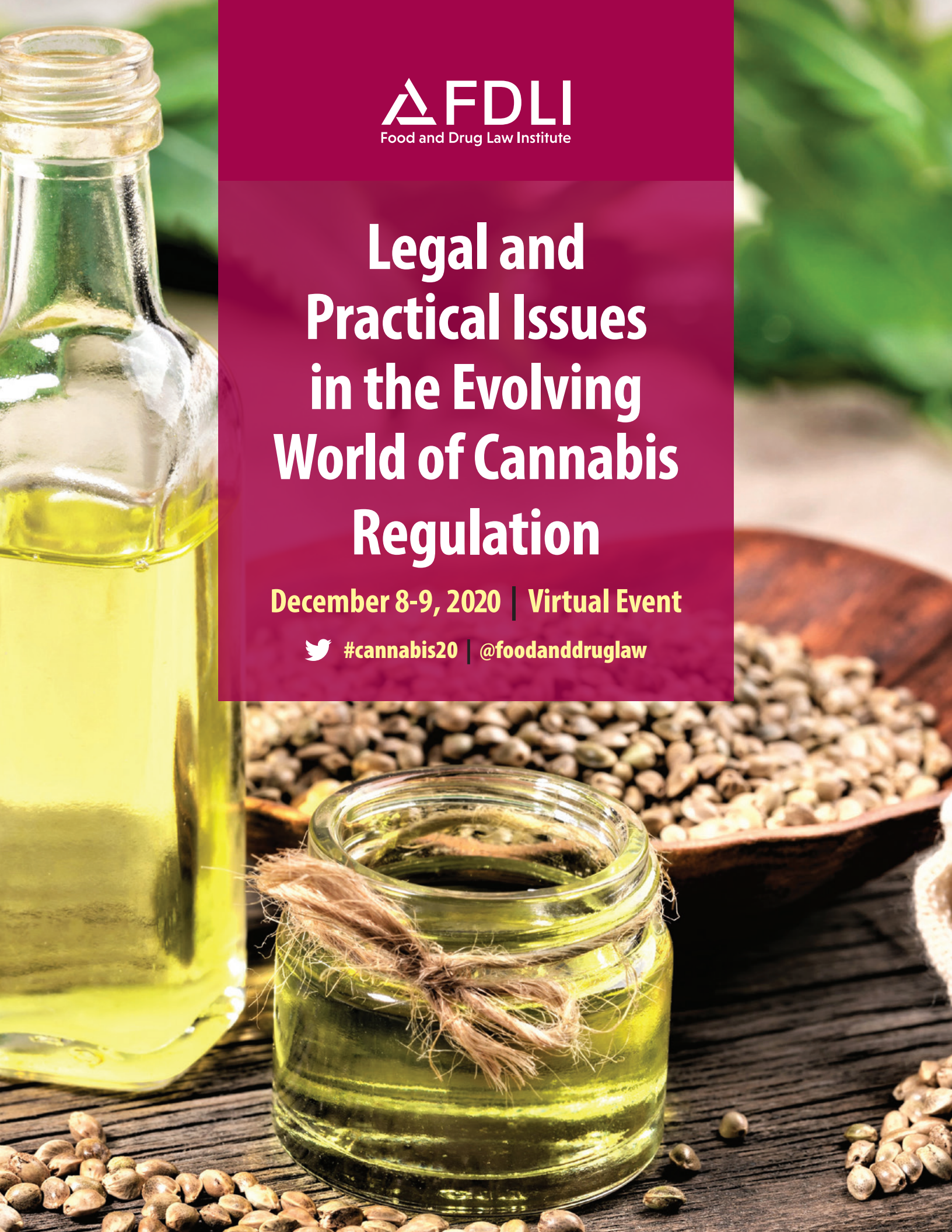

FDLI
Food and Drug Law Institute

Legal and Practical Issues in the Evolving World of Cannabis Regulation

December 8-9, 2020 | Virtual Event

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Virtual Event

We are going virtual! To promote optimal interaction between attendees, the conference will include ample audience participation and opportunities to connect with your peers between sessions.

All Times Are Eastern Standard Time

Tuesday, December 8

11:15–11:30 AM **FDLI Welcome and Introduction**
Amy Comstock Rick, President & CEO, FDLI

11:30 AM–12:00 PM **Fireside Chat with FDA**
Joseph B. Franklin, Policy Director for the Principal Deputy Commissioner, FDA
Interviewed by **Suzie L. Trigg**, Partner, Haynes and Boone LLP

12:15–1:15 PM **Federal and State Election Impacts and Legislative Initiatives for Marijuana and CBD Regulation**
The 2020 election results brought several significant changes to the legal marijuana and CBD landscape, including the passage of six state-based marijuana legalization initiatives. However, relatively few changes to the House and Senate makeup may minimize the likelihood of large-scale changes to marijuana and CBD legislative efforts at the federal level. This panel will summarize federal and state election results and their impact on the marijuana and CBD industries.

William A. Garvin, Shareholder, Buchanan Ingersoll & Rooney PC
Jonathan A. Havens, Partner, Saul Ewing Arnstein & Lehr LLP
Justin Strekal, Political Director, National Organization for the Reform of Marijuana Laws – NORML
Moderated by **Paul Demko**, Cannabis Editor, Politico

1:15–1:45 PM ***Lunch Break***

1:45–2:30 PM **CBD Regulatory Updates**
Although FDA has not yet released its Cannabidiol Enforcement Policy Draft Guidance, it has undertaken several information gathering initiatives in the past year. What is the status of FDA's efforts, and what are the next steps? This panel will address the "Draft Guidance for Cannabidiol" regarding bioequivalence recommendations for generic oral cannabidiol solution; the November public meeting on "CBD and Other Cannabinoids: Sex and Gender Differences in Use

and Responses;" and reports submitted to Congress on potential regulatory pathways for CBD products and CBD sampling progress and findings.

Douglas MacKay, SVP, Scientific and Regulatory Affairs, CV Sciences
Brian J. Malkin, Partner, McDermott Will & Emery
Christopher Van Gundy, Partner, Sheppard Mullin Richter & Hampton LLP

2:45–3:45 PM **Navigating Drug Preclusion Gaps for Food and Dietary Supplements Containing CBD and Other Cannabinoids**

The push from industry and consumers for FDA to provide a legal pathway for CBD products in foods and/or dietary supplements continues with great impetus. Simultaneously, a myriad of CBD products have entered the market without FDA review, notice, or approval, resulting in products that are contaminated or contain different doses of CBD than indicated on their label. This panel will discuss FDA's position precluding CBD from regulation as a food or dietary supplement due to its drug status, the agency's current statements and other analysis on opening one or more new pathways for CBD and other cannabinoids, and regulatory and data requirements for these pathways.

Brad Douglass, Independent Consultant, EAS Consulting Group
Jensen Jose, Regulatory Counsel, Center for Science in the Public Interest
Megan L. Olsen, VP & Associate General Counsel, Council for Responsible Nutrition
Moderated by **Robert Durkin**, Of Counsel, Arnall Golden Gregory LLP

4:00–5:00 PM **DOJ, DEA, and FTC Approaches to Marijuana and CBD Regulation and Enforcement**

How are other federal agencies approaching marijuana and CBD enforcement? Speakers will discuss the Department of Justice's current marijuana enforcement practices two years after rescission of the Cole memorandum and how to minimize enforcement risks for state legal businesses, comments received in response to the Drug Enforcement Administration's (DEA's) August 2020 interim final rule, "Implementation of the Agriculture Improvement Act of 2018," and the Federal Trade Commission's recent enforcement actions regarding CBD products with COVID-19 prevention or treatment claims.

John Claud, Assistant Director, Consumer Protection Branch, US Department of Justice
Richard Cleland, Assistant Director, Bureau of Consumer Protection, Division of Advertising Practices, Federal Trade Commission
Larry K. Houck, Director, Hyman, Phelps & McNamara, PC
Moderated by **Tom Firestone**, Partner, Baker McKenzie

Wednesday, December 9

11:00–11:10 AM **Welcome**
Laura A. Brown, Director, Educational Programs, FDLI

11:10 AM–12:10 PM **Regulatory and Practical Research Limitations and Solutions for Cannabis-Derived Products**
Although FDA has requested more safety and efficacy data for cannabis-derived products to determine appropriate pathways and approvals, researchers must comply with complex regulations, imposed by a number of federal agencies, that govern this research. This panel will explore these rules and offer insights on how best to plan for and perform research while ensuring compliance. Speakers will discuss the impact of FDA's July 2020 "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research Guidance for Industry" draft guidance, and how the guidance relates to other FDA research requirements, as well as those of the United States Department of Agriculture (USDA), DEA, and states. The panel will also discuss restrictions on research and how House Bill 3797 aims to work through research hurdles.

Deborah Miran, Consultant, DMiran Consulting
Heike Newman, Senior Regulatory Manager, University of Colorado
Evelina Norwinski, Partner, Arnold & Porter LLP

12:10–12:40 PM ***Lunch Break***

12:40–1:40 PM **To IND or Not IND: That is the Question for CBD and Marijuana Products**
What are a company's goals in seeking drug approval for a CBD or marijuana-based product? Does lack of meaningful enforcement of drug claims on non-drug products make drug approval worthwhile? This session will first discuss the research and approval process undertaken for Epidiolex, the only FDA-approved, plant-derived prescription cannabinoid product. The session will compare and contrast the goals of pharmaceutical-based research in pursuit of drug approval with initiatives not seeking such approval. It will also explore difficulties of obtaining an IND for cannabis products due to restrictions on research. The differences between the drug pathway requirements and those for natural products will also be discussed, using the Amarin fish oil product Lovaza as case study.

Rodney William Butt, Senior Vice President - Strategic Solutions, Nutrasource Pharmaceutical & Nutraceutical Services
Kelly Fair, US General Counsel, VP US & European Affairs, Canopy Growth Corporation
Alice P. Mead, Senior Advisor, Greenwich Biosciences
Moderated by **Tish E. Pahl**, Partner, Olsson Frank Weeda Terman Matz PC

1:55–2:25 PM **Concurrent Breakout Sessions**

- **Managing Biomass and Biowaste from the Hemp and Cannabis Industries**
  As CBD and THC demand drive the production of hemp and cannabis, biomass and other waste products increase as well. Some estimates place cannabis and hemp bio "waste" at nearly 1 million tons in North America in 2019. What can producers do with that material and what regulations apply to this bio waste? Speakers will also examine other challenges for handling, transporting, and disposing of hemp and cannabis biomass and waste.

  Keith Matthews, Of Counsel, Wiley LLP
  Stephanie McGraw, Partner, Shook, Hardy & Bacon LLP

- **State Quality Issues for Marijuana and CBD**
  What marijuana and CBD quality regulations have been established at the state level that can be extrapolated to other states and even federal regulation? This panel will discuss essential quality elements, such as good manufacturing practices and finished product specifications, that certain states have established. The panel will also discuss highlights of ASTM International's Technical Committee D37 on Cannabis in the area of standards development for ensuring product quality and environmental and consumer health and safety.

  Tara Lin Couch, Senior Director for Dietary Supplement and Tobacco Services, EAS Consulting Group
  Andrew Freedman, Director of Cannabis Coordination, State of Colorado (former), Senior Vice President, Forbes Tate Partners
  Darwin Millard, Member, ASTM International Technical Committee D37 on Cannabis, and owner, TSOC LLC

2:40–3:20 PM **The Patchwork Quilt of State Hemp Regulation**

USDA announced in September that it would reopen the comment period for the interim final rule (IFR) on domestic hemp production. The IFR provides USDA with authority to approve state or tribal plans for regulating hemp production. The agency received over 1,000 comments on issues including disposal and remediation of non-compliant plants, sampling methodology, and whether testing labs needed to be registered with DEA. What comments did the agency receive and what are next steps? This panel will also discuss how some state plans may have unintended consequences, such as effectively classifying some hemp-derived products (such as CBD) as controlled substances, and how companies can reduce compliance risk.

Mai T. Dinh, Assistant General Counsel, Marketing, Regulatory, and Food Safety Programs, Division Office of the General Counsel, USDA

Daniel R. Dwyer, Partner, Kleinfeld, Kaplan & Becker, LLP
Steven N. Levine, Partner, Husch Blackwell LLP

3:35–4:20 PM **International Cannabis Regulation and Market Opportunities**

What is the status of cannabis law and regulation at the international level and what business opportunities do opening markets provide? This session will first review the historic December 2nd United Nations Commission on Narcotic Drugs vote that rescheduled medical cannabis to a less restrictive category in the Single Convention on Narcotic Drugs. Speakers will explore ramifications of the vote on national policies in the 186 countries that are signatories to the treaty. The panel will also discuss how the legal status of cannabis, hemp, and CBD in other countries, such as Canada and European Union member states, is affecting market opportunities for US-based companies.

Michael Krawitz, Executive Director, Veterans for Medical Cannabis Access, Serving as a Civil Society Focal Point, World Health Organization, Expert Committee on Drug Dependance, Cannabis Critical Review Process
Eileen M. McMahon, Senior Partner, Torys LLP

4:20 PM ***Closing Remarks and Adjournment***

Legal and Practical Issues in the Evolving World of Cannabis Regulation
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Speaker Biographies

RODNEY WILLIAM BUTT is Senior Vice President of Strategic Solutions at Nutrasource Pharmaceutical & Nutraceutical Services. Over the last 20 years, Mr. Butt has been involved in all aspects of clinical trials, drug development, and organizational design within the pharmaceutical and allied industries. As SVP of Strategic Solutions, Mr. Butt brings experience in clinical trials at major pharmaceutical companies and European-based international drug development. Prior to joining Nutrasource, Mr. Butt served as Head of Clinical Operations with LEO Pharma (Canada). Previously, Mr. Butt was the Director of Research for Boehringer Ingelheim where he managed a 50-member team actively engaged in all aspects of clinical research activities including international drug development planning through supporting marketing initiatives. In addition, Mr. Butt has worked as a Director of Project Management and Head of the Canadian Business Unit for a global CRO where he led bid defense meetings for key clients and oversaw global clinical trials efforts for big pharma and small biotechs.

JOHN CLAUD is Assistant Director at the Consumer Protection Branch of the US Department of Justice. John has litigated several matters involving violations of the Food, Drug and Cosmetic Act as well as Title 18 criminal offenses relating to food safety, compounding pharmacies, telemedicine fraud, and prescription drug smuggling. He has also investigated and litigated a broad range of consumer fraud for DOJ, including cases relating to telemarketing, mortgage fraud, and business opportunity fraud. Before joining DOJ, John was an associate in the Washington office of a large national law firm. He started his legal career as an Assistant District Attorney in the Manhattan DA's Office. John received his JD cum laude from the Catholic University of America Columbus School of Law, has a master's degree in Criminal Justice from the University of Colorado, and is a graduate of Trinity College in Hartford.

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

recent work has focused on supervising the Commission's efforts to stop sellers of bogus products and services promoted to treat or prevent COVID-19.

TARA LIN COUCH, Senior Director for Dietary Supplement and Tobacco Services at EAS Consulting Group, is an 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 issues pertaining to quality control (QC) in both pharmaceutical and dietary supplement manufacturing, as well as the tobacco industry. As a consultant, Dr. Couch assists with the development, improvement and implementation of quality systems that are scientifically sound, efficient, practical and compliant with FDA regulations. She also performs mock FDA inspections, gap analyses, and contractor and laboratory audits. Dr. Couch provides GMP (good manufacturing practice) and laboratory trainings via seminar, webinar and on-site presentations.

PAUL DEMKO is the cannabis editor at POLITICO Pro. Previously, he spent four years on the health care team, primarily covering the insurance industry. Prior to joining POLITICO, he was the Washington bureau chief at Modern Healthcare. Demko also spent a decade reporting in Minnesota, including stints with Politics in Minnesota and City Pages. He started his career at The Chronicle of Philanthropy.

MAI T. DINH is Assistant General Counsel for Marketing, Regulatory, and Food Safety Programs Division in the Office of the General Counsel at U.S. Department of Agriculture where she manages a staff of attorneys providing legal advice to the Agricultural Marketing Service, including the recent regulations on the Domestic Hemp Production Program and the National Bioengineered Food Disclosure Standard. Prior to USDA, she was the Assistant Chief Counsel for Regulations at the Transportation Security Administration (TSA) where she guided significant rulemaking actions and program developments on passenger information screening and general aviation security. Prior to TSA, she supervised teams of attorneys at the Federal Election Commission who developed regulations to implement sweeping campaign finance reform legislation. Ms. Dinh is a graduate of the George Washington University Law School and the University of Pennsylvania Wharton School of Business.

BRAD DOUGLASS is an independent consultant at EAS Consulting Group. Dr. 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.

DANIEL R. DWYER is a partner with Kleinfeld, Kaplan and Becker, LLP. His practice focuses primarily on representing pharmaceutical, food, dietary supplement, cosmetic, medical device, and consumer products companies on a variety of matters involving regulatory and advertising law. Mr. Dwyer has substantial expertise in Cannabis and hemp regulation, as well as pharmaceutical and controlled substance law, labeling and advertising claim substantiation, sales and marketing practices, good manufacturing practices, FDA inspections, recalls, corporate compliance programs and related matters. He regularly advises clients on developing strategies for compliance in complex legal environments.

KELLY FAIR is Canopy Growth's US General Counsel, serving as an officer of the California courts since 2006. In her role, Kelly manages all day-to-day US federal and state legal engagements for Canopy Growth. Prior to joining Canopy, Kelly was a Partner at Dentons US LLP, San Francisco office, where she led the Dentons US Cannabis Group since 2014, advising domestic and international cannabis and hemp industry clients in a broad range of state and federal regulatory risk assessments, and corporate and transactional matters, including investment transactions and financings, strategic mergers and acquisitions, joint ventures, and commercial agreements.

TOM FIRESTONE is co-chair of Baker & McKenzie's North American Government Enforcement practice and is a member of the firm's Global Compliance & Investigations Steering Committee. He represents clients in matters involving anti-corruption and the US Foreign Corrupt Practices Act (FCPA), internal investigations, anti-money laundering and transactional due diligence. Prior to joining the Firm, he spent 14 years at the US Department of Justice. He worked as an Assistant US Attorney in the Eastern District of New York where he prosecuted transnational organized crime cases. He also worked as Resident Legal Adviser and Acting Chief of the Law Enforcement Section at the US Embassy in Moscow. In the latter capacity, he facilitated US-Russian law enforcement cooperation, assisted the Russian government in drafting new criminal legislation, advised the US government on policy issues related to criminal justice in Russia and twice won the US State Department Superior Honor Award.

JOSEPH FRANKLIN is the Policy Director for the Principal Deputy Commissioner at FDA, where he focuses on scientific and policy initiatives that cut across FDA product areas, including the development of advanced technological and data capabilities to support FDA's regulatory mission. Dr. Franklin has held several previous positions at FDA, including Director of the Policy Staff in the Office of Therapeutic Biologics and Biosimilars, Associate Chief Counsel in FDA's Office of the Chief Counsel, and Deputy Chief of Staff. Dr. Franklin has a BS in Biology from Duke University, a PhD in Cell Biology from Yale University, and a JD from Washington University in St. Louis.

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 A. GARVIN is a shareholder with the firm of Buchanan Ingersoll & Rooney. William focuses his practice on issues related to the regulation and promotion of drugs, medical devices, dietary supplements, foods, and cannabis. He is a shareholder in the Food and Drug group and the co-head of the cannabis practice at Buchanan. He has extensive experience in assisting companies with complying and contesting administrative agency actions of the Food and Drug Administration, Drug Enforcement Administration, and the Federal Trade Commission. William is a member of the Cannabis Committee for the Food and Drug Law Institute, a member of the Cannabis Committee for the American Herbal Products Association, and a former member of Law360 Life Sciences Editorial Advisory Board. William has also served as part of the Compliance Program Teams for both SupplySide West and

Ingredient Marketplace. William has been recognized on the Washington, DC Super Lawyers Rising Stars list from 2013-2018. He was also recognized as a Nationwide Band 1 Cannabis Lawyer by Chambers USA in 2019 and 2020.

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 Practice and its Food, Beverage & Agribusiness Practice. Companies in the cannabis (both hemp and marijuana), life sciences, food and beverage, cosmetics, and tobacco industries turn to Jonathan for advice on how to get and keep their products on the market. Jonathan is listed in Chambers USA: America's Leading Lawyers for Business for his nationwide cannabis law practice. He is regularly interviewed by mainstream and trade press outlets, alike, and has been quoted by *The New York Times*, *The Los Angeles Times*, CNBC, WIRED, MarketWatch, Engadget, Law360, *High Times Magazine*, and *Marijuana Business Daily*. Before entering private practice, Jonathan served as regulatory counsel with FDA, and prior to law school, Jonathan served as a legislative aide in both the US Senate and US House of Representatives.

LARRY K. HOUCK is a director at Hyman, Phelps & McNamara PC where he provides counsel on regulatory and enforcement actions by the DEA. His career encompasses over 30 years of conducting investigations and negotiating on behalf of both the government and industry. Mr. Houck focuses on controlled substances, prescription drugs, and regulated chemicals, helping clients navigate federal and state licensing, registration, and compliance issues. Mr. Houck counsels clients throughout the registrant supply chain on administrative, civil, and criminal proceedings. In situations where clients face enforcement action, Mr. Houck has extensive understanding of the DEA's approach and priorities. He advises pharmaceutical and chemical companies on DEA inspections and audits. By working with clients to review business practices, he helps create the infrastructure to ensure compliant reporting, record keeping, and security. Before joining Hyman, Phelps & McNamara in 2001, Mr. Houck served as a DEA diversion investigator and policy staff coordinator. As a diversion investigator in the Washington, DC and Portland, Oregon field offices, Mr. Houck conducted a full range of regulatory and criminal investigations and inspections of controlled substance and chemical registrants. While serving as a staff coordinator for the DEA's Office of Diversion Control's Liaison and Policy, he advised government officials and pharmaceutical and health care professionals on the Controlled Substance Act and its regulations. Mr. Houck drafted and helped implement the DEA's controlled substance policies and regulations on diversion control issues that included pain management.

JENSEN JOSE works as Regulatory Counsel for The Center for Science in the Public Interest where he focuses on food additive and dietary supplement safety issues. Previously, Jensen served as regulatory policy specialist for the American Optometric Association. He also worked as an associate counsel for the US Department of Veterans Affairs and a research associate for the National Academies of Sciences, Engineering, and Medicine. Jensen earned his JD from the University of Maryland law school, and a BS in Biology and BA in Political Science from the University of Washington.

MICHAEL KRAWITZ is a disabled United States Air Force Veteran [Sergeant, 1981 -1986]. He serves as Executive Director of Veterans for Medical Cannabis Access [VMCA] as well as other board and advisory roles. After California's 1996 Proposition 215 Michael observed that cannabis used as a palliative adjunct pain treatment to opiates not only produced better pain relief but also significantly lowered the number of pain pills used. Michael identified the emerging use of so-called "pain contracts" as a policy that would eventually make it impossible for patients to use cannabis as an adjunct medication and therefore lose any associated opiate overdose and suicide reduction. Leading VMCA Michael successfully negotiated the first ever VA medical cannabis policy in 2010 and has since overseen the nationwide effort to add post-traumatic stress as a qualifying condition under state medical cannabis access laws. Recently, Michael led an international team that ensured the Critical- Review process of the World Health Organization Expert Committee on Drug Dependence was in possession of all available evidence and in turn produced groundbreaking and historic recommendations for change in the treaty status of Cannabis. Currently, Michael is overseeing the final stages of the United Nations voting process on those WHO recommendations.

STEVEN N. LEVINE is a partner at Husch Blackwell LLP where he leads the firm's national cannabis practice. Since 2010, Steve's major focus has been on the burgeoning cannabis industry, where he guides clients through the tangle of shifting regulations governing the sale and use of cannabis in both the marijuana and industrial hemp sectors. Prior to cannabis, Steve honed his skills representing midcap public oil and gas companies and acting as a general corporate transactional attorney for numerous industries, guiding clients through mergers and acquisitions, securities laws, the capital markets, regulatory issues and intellectual property issues. He understands that a cannabis business's success hinges not only on high-quality products and service, but also on smart business and legal decisions regarding corporate structure and financing, lease or real property purchase negotiations, permits and licenses, and employment procedures. Cannabis clients also rely on Steve for help as their businesses scale quickly. He helps negotiate remediation plans and stipulated settlement agreements with state and local agencies, and he

represents landlords and tenants in warehouse leases and development of commercial greenhouses used by cannabis tenants. Steve serves on the firm's Executive Board.

DOUGLAS MACKAY is Senior Vice President, Scientific and Regulatory Affairs for CV Sciences, makers of PlusCBD™ Oil. Dr. MacKay is responsible for CV Sciences scientific and regulatory affairs functions that drive product quality, safety, and innovation. Dr. MacKay also serves, as an associate editor for the Journal of Dietary Supplements, the advisory board of the American Botanical Council (ABC), and the editorial boards of Integrative Medicine a Clinician's Journal, and Natural Medicine Journal. Dr. MacKay comes to CV Science after a ten-year career with the Council for Responsible Nutrition (CRN) where he served as the senior vice president, scientific and regulatory affairs. Dr. MacKay oversaw the scientific and regulatory affairs department, ensuring that the association's scientific, policy and legislative positions were based on credible scientific rationale. While at CRN, Dr. MacKay completed the four-year Institute of Organizational Management (IOM), a course designed for executives working in non-profit organizations, followed by serving two years on the IOM Board of Regents.

BRIAN J. MALKIN is a partner at McDermott Will & Emery where he 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. He is also an experienced litigator, representing clients in FDA and patent cases, including Hatch-Waxman Act cases and Biologics Price Competition and Innovation Act (BPCIA) cases. In particular, his patent law knowledge makes him an asset to drug and biotech companies, working alongside them to develop proactive strategies that protect their pioneering life sciences products from the earliest stages of development through approval, marketing and next-generation products, and wielding litigation when required. Brian is also a strong partner in the boardroom, providing FDA and IP due diligence for deals and transactions in the life sciences space, supporting mergers and acquisitions and licensing for investors, private equity clients, and pharmaceutical and biotechnology companies. His combined experience across regulatory, IP, litigation and transactions in pharmaceuticals and biotechnology enables him to spot and mitigate issues that may negatively impact his clients' investments and partnerships. With more than 18 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.

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.

STEPHANIE McGRAW is a partner at Shook, Hardy & Bacon LLP where she focuses on the defense of companies in product liability litigation before state and federal courts. She has represented major US and international corporations and individual clients in all phases of the litigation process, including discovery and depositions, motion practice, mediation, trial preparation, trial and settlement. Stephanie routinely represents corporations in the defense of class actions, multidistrict litigation and other high-stakes litigation. She has represented clients in litigation involving birth control medications, orthopedic implants, personal protective equipment, durable infant products and various consumer products. Prior to joining Shook, Stephanie was with an international firm in New York City, where she was the senior associate on a litigation team that represented the only product manufacturer named in In re World Trade Center Litigation, a consolidated action arising out of the September 11, 2001, terrorist attacks. Stephanie has also advised consumer product manufacturers and distributors on pre- and post-market safety issues, including compliance with state and federal regulations, warnings and instructions laws, and product recall and corrective action best practices. Stephanie is an active member of the Houston community. She is the vice president of the Young Professional's Leadership Council for the Houston Women's Home and 2017 incumbent President, and she is also involved in the Houston Bar Association as a member of the Campaign for the Homeless and Golf Tournament Committees. Stephanie has also been a Cornell Alumni Admissions Ambassador Network member since graduating from Cornell University in 2004.

EILEEN M. McMAHON is the Chair of Torys' Food/Drug Regulatory and IP Practices at Torys. Eileen is ranked in Band 1 for Life Sciences Law nationwide by Chambers. 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, including agribusiness/food, drug, device and other regulated sectors. She has been recognized as a leading lawyer in regulatory law, intellectual property, biotechnology, and life sciences. For about 15 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.

Alice P. Mead is Senior Advisor at Greenwich Biosciences. Ms. Mead received her Juris Doctor degree from University of Santa Clara School of Law and her Master of Law degree from Yale. She served for twelve years as an in-house counsel to the California Medical Association (CMA), one of the largest state medical associations in the country. Prior to that time, Ms. Mead was a litigation associate at a global law firm and an Assistant Professor of Law at Arizona State University College of Law, where she taught courses in constitutional law. From 1999 through 2019, she served as Vice President, US Public Policy and Public Affairs, for GW Pharmaceuticals (and its US subsidiary, Greenwich Biosciences), one of the first companies in the world to develop cannabis-derived medications as prescription products in adherence to modern scientific and regulatory standards for pharmaceutical products. She focuses on domestic and international drug control laws and policy issues.

DARWIN MILLARD is an active member of ASTM International's Technical Committee D37 on Cannabis which is an international group dedicated to the development of voluntary consensus standards for the global cannabis/hemp industry. Darwin is the Subcommittee Vicechair of D37.04 on Processing and Handling of Cannabis and Cannabis-derived Products, and the Co-chair of Subcommittee D37.07 on Industrial Hemp. He has been active in cannabis policy change and an advocate of the cannabis plant for over a decade. Darwin Millard specializes in mechanical and solvent based extraction methodologies for isolating highly volatile terpenophenolic secondary metabolites from botanicals. For the past 14-years, Darwin has been focusing on the extraction and manufacture of nutraceutical products comprising of phytocannabinoids and other bioactive constituents from the cannabis plant. He works with clients to design and implement cost-effective built-for-purpose phytocannabinoid processing and herbal product manufacturing solutions.

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 Anschutz Medical Campus. Since 2014, she provides assistance with FDA and DEA submissions and provides regulatory guidance to clinical researchers conducting cannabis research at the University.

EVELINA NORWINSKI is a partner at Arnold & Porter LLP where her practice focuses on white collar defense and compliance issues. She has conducted internal investigations for a variety of domestic and multinational companies in industries such as consumer products, pharmaceutical, government contractors, financial services, and agricultural products. She also regularly counsels clients on corporate compliance programs, regulatory compliance, legislation, and ethics. She has particular experience assisting clients in developing and implementing strategies to address product distribution issues, including federal and state compliance, strategies to address counterfeit or contraband versions of a client's products in the distribution chain, collaborative engagement with law enforcement agencies, litigation strategies, and longer-term legislative strategies. Ms. Norwinski also maintains an active pro bono practice, representing individuals in criminal matters in federal courts. Before joining the firm, Ms. Norwinski served as an Assistant Federal Public Defender in Washington, DC, where she briefed and argued more than 20 federal criminal appeals in the US Courts of Appeal and lectured on criminal law issues. Ms. Norwinski clerked for the Honorable Donald S. Russell of the US Court of Appeals for the Fourth Circuit.

MEGAN L. OLSEN is Vice President and Assistant General Counsel for the Council for Responsible Nutrition (CRN) in Washington, DC. At CRN, she provides legal counsel and advice to CRN's staff and members in the areas of legislation, regulatory compliance and advocacy, and international policy development with respect to dietary supplements and nutrition issues. Prior to joining CRN, Ms. Olsen was in-house counsel for Walgreen Co., where she provided legal advice about Food and Drug Administration, Federal Trade Commission, and other consumer protection regulatory requirements for a wide variety of consumer products, including conventional food, dietary supplements, OTCs, and cosmetics. Ms. Olsen began her career at Kelley Drye and Warren LLP working on a variety of consumer protection, regulatory, and advertising law issues.

TISH E. PAHL is a principal at Olsson Frank Weeda Terman Matz PC. She is regulatory counsel to drug, cosmetic, dietary supplement, and food clients with concerns before the Food and Drug Administration, the Federal Trade Commission, and other federal agencies. Her work has encompassed representation of companies making and marketing human and animal prescription and over-the-counter drugs, dietary supplements, and cosmetics. Further, she advises trade association clients on a range of antitrust and trade regulation issues. Since November 2013, Tish has been heavily involved with implementation of the Drug Quality and Security Act (DQSA). She has advised pharmacy compounders and outsourcing facilities on their new FDA responsibilities under Title I of the DQSA. She has worked closely with pharmaceutical supply chain stakeholders, including manufacturers, repackagers, and wholesale distributors, on implementation of Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA). She is a frequent speaker on DSCSA requirements and implementation. Tish graduated from Northwestern University and earned her Juris Doctor from Northwestern University (cum laude).

JUSTIN STREKAL is the Political Director for NORML, where he serves as an advocate to end the federal prohibition of marijuana and to reform our nation's laws to no longer treat marijuana consumers as second-class citizens. Before working on drug policy, he focused on tax, wage, and campaign finance reform as well as managed electoral campaigns throughout the country for positions in every level of government.

SUZIE LOONAM TRIGG is a partner at the law firm of Haynes Boone where she focuses on guiding companies through FDA regulatory issues, supply chain management and strategic growth, Suzie Trigg represents restaurant chains, retailers, franchisors, and consumer products companies in negotiating and documenting transactions and understanding regulatory requirements so that they can make informed choices.

CHRISTOPHER VAN GUNDY is a partner at Sheppard Mullin Richter & Hampton LLP. His practice involves counseling and representing food and consumer product manufacturers, distributors, and retailers both in litigation and as to regulatory matters. He defends companies in consumer false advertising purported class actions, and advises on FDA, USDA, California Proposition 65, and CBD matters.

Legal and Practical Issues in the Evolving World of Cannabis Regulation

December 8-9, 2020

Virtual Event

Attendee List (current as of 12/7/20)

First Name	Last Name	Job Title	Company Name	City and State
Rebecca	Anderson	Principal Engineer		Eau Claire, WI
Steven	Armstrong	Senior Regulatory Advisor	Haynes and Boone LLP	Naples, FL
Andy	Arnold	Freelance Reporter	CBD-Intel	London,
Jane	Axelrad	Principal, Axelrad Solutions LLC	Axelrad Solutions LLC	Chevy Chase, MD
Eric	Barker	Director, Regulatory Strategy	Altria Client Services LLC	Richmond, VA
Minnie	Baylor-Henry	President	B-Henry & Associates	Boston, MA
Donald	Becker	Assistant General Counsel	Turning Point Brands, Inc.	Louisville, KY
Michael	Benson	Compliance Attorney	Turning Point Brands, Inc.	Louisville, KY
Luisa	Bigornia	Vice President, Intellectual Property	BioMarin Pharmaceutical Inc.	Novato, CA
Laura	Brown	Director, Educational Programs	Food and Drug Law Institute (FDLI)	Washington, DC
Matt	Browning	Regulatory Scientist	Swedish Match North America	Owensboro, KY
Kristiana	Brugger	Regulatory Counsel	FDA - CDER	Silver Spring, MD
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Katherine	Ciambrone	EVP, Compliance	Cresco Labs	Wayne, PA
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Dean	Cirotta**	President	EAS Consulting Group	Alexandria, VA
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