Legal and Practical Issues in the Evolving World of Cannabis Regulation

December 2-3, 2021

Virtual Event

All Times Are Eastern Standard Time

Thursday, December 2

11:30–11:50 AM **FDLI Welcome and Opening Presentation**

April Inyard Alexandrow, Science and Policy Coordinator, FDA Cannabis Product Committee, Office of the Commissioner, FDA
Amy Comstock Rick, President & CEO, FDLI

12:00–1:00 PM **Present and Future Federal Marijuana Policies and Interplay with State Regulatory Frameworks**

Federal marijuana policies are changing rapidly as states continue to overwhelmingly legalize marijuana for either medical or adult recreational use. Is federal legalization around the corner? Which federal agencies would be likely to take primary regulatory and oversight roles post-legalization? What is the likely role of FDA? How would the state regulatory patchwork interface with a federal system? This panel will discuss the present and future federal and state landscape, as well as how legalization would impact the existing cannabis industry.

Mark Bolton, Head of Global Public Policy, Jazz Pharmaceuticals, Inc.
Andrew Freedman, Senior Vice President, Forbes Tate Partners
Andrew J. Kline, Senior Counsel, Perkins Coie LLP
Moderated by **William Garvin**, Shareholder, Buchanan Ingersoll & Rooney PC

1:10–2:10 PM **How States are Responding to Marijuana's Public Health Concerns and Implications for Possible Federal Regulation**

As states continue to legalize marijuana, they are increasingly grappling with associated public health issues, such as youth access, impaired driving, effects of secondhand marijuana smoke on children, unintentional consumption, and packaging and labeling issues. This session will discuss how states are handling these issues and how these policies may inform federal regulation. The panel will also explore how manufacturers can minimize possible product liability implications.

James T. O'Reilly, Volunteer Professor, University of Cincinnati School of Medicine
Gillian L. Schauer, Executive Director, Cannabis Regulators Association
Sam Wang, Associate Professor of Pediatrics, Children's Hospital Colorado
Moderated by **Deborah Miran,** Consultant, DMiran Consulting

2:10–2:40 PM *Break*

2:40–3:40 PM **State and Federal Marijuana Policies: Addressing Racial Bias and Social Equity Reform**

The past prohibition of cannabis has disproportionately and adversely impacted people of color, particularly black and latinx populations, in several ways. This panel will first discuss how inequality in all areas of healthcare significantly impacts the ability of those in underrepresented racial groups to access relief through medical cannabis, and what sorts of regulatory reform may address this issue. Speakers will then delve into how states and cities have implemented social equity programs to ensure that people of all races, as well as those with marijuana offenses prior to legalization, be afforded an opportunity to participate meaningfully in this burgeoning industry.

John Hudak, Deputy Director, Center for Effective Public Management, The Brookings Institution
Danielle K. Perry, Cannabis Regulation Oversight Officer, State of Illinois
Shawn "Pepper" Roussel, Attorney at Law, Green Pepper Solutions
Alyssa Samuel, Attorney, Husch Blackwell LLP

3:50–4:35 PM **International Cannabis Regulation: Impact and Considerations for a U.S. Framework**

As the U.S. contemplates federal regulation of cannabis products, what can we learn from other countries that have taken steps toward legalization? How does legalization in other countries affect import and export to and from the U.S.? This panel will provide a brief overview of cannabis regulation in Canada and Israel. Speakers will then discuss the status of the recent United Nations Commission on Narcotic Drugs vote that rescheduled medical cannabis to a less restrictive category in the Single Convention on Narcotic Drugs. Finally, the panel will discuss how these developments affect U.S. markets.

Eileen McMahon, Partner, Torys LLP
Joseph Wyse, Head of Patent Department, Dr. Eyal Bressler & Co. Ltd.
Moderated by **Jessica Wasserman,** Partner, WassermanRowe LLC and Chair, Science and Regulatory Affairs Committee, Council for Federal Cannabis Regulation (CFCR)

4:45–5:45 PM **The Hazy Legal Status of Synthetic Cannabinoids**

Over the past couple years, sales of non-CBD cannabinoids, such as Delta-8 THC, have skyrocketed, partially due to claims that these substances are legal under the 2018 Farm Act. But are these chemically modified cannabinoids "hemp-derived?" This panel will explore the legal status of synthetic cannabinoids in the context of FDA's regulatory posture toward other synthetic ingredients in food and dietary supplements. Speakers will also discuss how to address safety concerns related to these substances.

Edgar J. Asebey, Partner, Keller Asebey Life Science Law PLLC

Brad Douglass, Independent Consultant, EAS Consulting Group
Howard R. Sklamberg, Partner, Arnold & Porter LLP
Moderated by **Thomas Tobin,** Associate, Perkins Coie LLP

Friday, December 3

11:00 AM–12:10 PM **Welcome and Panel Discussion: Achieving High Product Quality and Good Manufacturing Practices for Cannabis Products**

The rapidly evolving landscape for cannabis has created the need for identifying, characterizing, accurately measuring, and ensuring good manufacturing practices for a wide range of materials and chemical substances. These substances include those with limits, such as the level of THC that differentiates marijuana from hemp; substances of interest to patients and consumers, such as CBD; and contaminants of health concern, such as heavy metals and mycotoxins. The botanical nature of cannabis means levels of most of these substances vary from plant to plant, in different locations, and over time. While there are publicly available standards, the respective requirements and guidelines are not uniform. This session will discuss how companies can produce high quality products by instituting good manufacturing processes for these unique substances.

Tara Lin Couch, Senior Director of Dietary Supplement and Tobacco Services, EAS Consulting Group
Steven M. Gendel, Independent Consultant
Steven Leslie, Deputy Director, Educational Programs, FDLI
David Vaillencourt, CEO & Founder, The GMP Collective and Vice Chair, ASTM International Committee D37 on Cannabis
Moderated by **Delia A. Deschaine,** Member of the Firm, Epstein Becker & Green, PC

12:20–1:20 PM **FDA's Search for Data to Inform Cannabidiol Regulation as a Food and Dietary Ingredient**

Since the 2018 Farm Act legalized hemp, FDA has not authorized any CBD-containing substances for non-prescription drug use. The agency has repeatedly cited the need for data to better inform regulation of the CBD marketplace. The agency has also recently objected to several CBD-based new dietary ingredient notifications due to the provision in 21 U.S.C. § 321(ff) that excludes "articles" from the dietary supplement category if they were previously approved as drugs. Yet, CBD is widely available online and in brick-and-mortar stores, but the cloud of regulatory uncertainty is affecting the marketplace. Where is FDA in its search for more data? Is that data sufficient or will federal legislation be required? This panel will also discuss the potential state role in regulating hemp-derived products, and how the CBD industry can navigate the current landscape.

Robert Durkin, Of Counsel, Arnall Golden Gregory LLP
Jonathan A. Havens, Partner, Saul Ewing Arnstein & Lehr LLP
Brian J. Malkin, Partner, McDermott Will & Emery LLP
Elizabeth Oestreich, VP Regulatory Compliance, Greenleaf Health, Inc.

1:20–1:50 PM **Break**

1:50–2:50 PM **Legal, Regulatory, and Economic Challenges Facing Cannabis Growers**
What are the main market and regulatory hurdles that hinder industrial hemp from becoming a widespread commodity crop? This panel will discuss challenges posed by USDA's final hemp production rule, availability of and access to critical agricultural inputs, plant-based intellectual property issues, and post-production processing and marketing challenges. The panel will also delve into logistical and regulatory challenges in growing plants for self-use as "drugs."

Stan Benda, Barrister & Solicitor / Adjunct Professor, Osgoode Hall Law School, York University
Elizabeth Kruman, Acting Deputy Assistant General Counsel, Marketing, Regulatory, and Food Safety Programs Division, USDA
Keith Matthews, Of Counsel, Wiley LLP
Moderated by **Frederick R. Ball,** Partner, Duane Morris LLP

3:00–4:00 PM **Will Increased Supply Options Affect Marijuana Research and Drug Development?**
The Drug Enforcement Administration (DEA)'s recent approval of additional growers for marijuana research opens the door to increased supply, but also raises new logistical questions due to the wide variation in state laws and regulations. Meanwhile, small businesses looking to bring a cannabis-based prescription drug to market face a choice about whether to sell their product now in states where it would be legal or to seek full FDA approval. This session will discuss the current status of DEA's initiatives, including the projected number of additional suppliers, resources for researchers to identify supplies and products, processes to obtain marijuana flower product or final dosage forms for research, and costs and fees for products obtained for research. The panel will also discuss the pros and cons of IND drug development versus selling medical marijuana state-by-state. Other issues, such as FDA's botanical review process and intellectual property considerations, will also be discussed.

Jacci Bainbridge, Professor, Skaggs School of Pharmacy and Pharmaceutical Sciences, Department of Clinical Pharmacy, University of Colorado and Department of Neurology Anschutz Medical Campus
Rodney Butt, Senior Vice President – Strategic Solutions, Nutrasource Pharmaceutical and Nutraceutical Services
Heike Newman, Senior Regulatory Manager, University of Colorado
Moderated by **Kate W. Hardey,** Partner, McGuireWoods LLP

4:00 PM ***Closing Remarks and Adjournment***