Legal and Practical Issues in the Evolving World of Cannabis Regulation

November 18-19, 2019
Arnold & Porter
601 Massachusetts Avenue, NW | Washington, DC 20001

Conference Agenda

Monday, November 18

12:30–1:00 PM **Registration and Lunch**

1:00–1:15 PM **Welcome and Opening Remarks**
Amy Comstock Rick, President & CEO, Food and Drug Law Institute (FDLI)

1:15–2:00 PM **Level-Setting: Scope of Terms and Products Covered**
During this session, we will level-set on essential definitions, such as cannabis, hemp, marijuana, CBD, THC, extracts, broad spectrum, and botanicals, and discuss the existence of other cannabinoids. Speakers will then broadly discuss how these terms are being used both correctly and incorrectly, and how they fit into the current exploding industry.

Alva C. Mather, Partner, McDermott Will & Emery
Megan L. Olsen, Assistant General Counsel, Council for Responsible Nutrition
Moderated by **Bridget C.E. Dooling**, Research Professor, George Washington University

2:00–3:00 PM **Part I: What is the Current Federal Oversight of Cannabis-Derived Products?**
The federal regulatory climate regarding cannabis-derived products is currently in a state of flux. This session will discuss the current status of cannabis regulation among various federal agencies, including the Drug Enforcement Administration (DEA), the United States Department of Agriculture (USDA), the Environmental Protection Agency, the US Department of Justice, and the Federal Trade Commission (FTC). The panelists will also explore how the Agriculture Improvement Act of 2018 (Farm Act) changed the federal regulation of hemp-containing products such as CBD, and the interplay between the Farm Act's lack of federal preemption and state laws.

Larry K. Houck, Attorney, Hyman, Phelps & McNamara, PC
Keith Matthews, Of Counsel, Wiley Rein LLP
Kristi L. Wolff, Partner, Kelley Drye & Warren LLP
Moderated by **William A. Garvin**, Shareholder, Buchanan Ingersoll & Rooney PC

3:00–3:15 PM **Coffee and Networking Break**

3:15–4:15 PM **Part II: What is FDA's Role in the Regulation of CBD?**
Since passage of the Farm Act, what is the legal status of CBD-containing products and accessories sold as drugs, devices, foods, dietary supplements, vaping products, and/or cosmetics under the Federal Food, Drug, and Cosmetic Act? Are there solutions to the legal inconsistencies under the current statutory structure? Do recent FDA enforcement actions give us a glimpse into the future?

Brian J. Malkin, Counsel, Arent Fox LLP
Frederick A. Stearns, Partner, Keller and Heckman LLP
Christopher Van Gundy, Partner, Sheppard Mullin Richter & Hampton LLP
Moderated by **Elizabeth Oestreich**, Vice President, Regulatory Compliance, Greenleaf Health, Inc.

4:15–5:00 PM **What is the Current Status of Cannabis Regulation at the State Level?**
The US is currently a patchwork of state laws and regulations pertaining to medical and adult-use marijuana. State requirements for hemp-derived products also vary widely due to the Farm Act's lack of preemption. This panel will address the current status of state regulation, whether the Farm Act changes the state landscape, state-level social equity initiatives, and lessons learned from Colorado's experience with marijuana legalization.

Jonathan A. Havens, Partner, Saul Ewing Arnstein & Lehr LLP
Steven N. Levine, Partner, Husch Blackwell LLP

5:00–5:30 PM **Keynote Address**
Sharon Lindan Mayl, Senior Advisor for Policy, Office of Food Policy and Response, FDA
Introduced by **Melissa S. Scales**, Assistant Director, Educational Programs, FDLI

5:30–7:00 PM **Networking Reception**

Tuesday, November 19

8:30–8:55 AM **Registration and Continental Breakfast**

8:55–9:00 AM **Welcome and Announcements**
Laura Brown, Director, Educational Programs, FDLI

9:00–10:00 AM **How is the Farm Act Changing Current "Canna-Business" Practices and What Issues Does It Leave Unresolved?**
Although the Farm Act has removed some barriers for hemp-derived products, many legal and practical issues during the implementation phase remain. This panel will address how USDA's implementing regulations are likely to affect cultivation and sale of hemp-containing products such as CBD, and issues resulting from the residual state legalization patchwork of hemp products despite passage of the Federal Farm Act.

Mai T. Dinh, Assistant General Counsel, Marketing, Regulatory, and Food Safety Programs Division, Office of the General Counsel, US Department of Agriculture
Patrick Moen, Managing Director and General Counsel, Privateer Holdings
Evelina Norwinski, Partner, Arnold & Porter LLP
Moderated by **Frederick (Rick) R. Ball**, Partner, Duane Morris LLP and Treasurer, FDLI Board of Directors

10:00–10:15 AM **Coffee and Networking Break**

10:15–11:15 AM **What is the Current Status of Cannabis Research?**
The DEA has traditionally restricted US research on cannabis-derived products to plants grown at the University of Mississippi. How did the Farm Act change the scope of this research? In the midst of increased demand for research on potential therapeutic outcomes, what is the current status of DEA's review of other potential research facilities? This panel will also provide an overview of the current state of cannabis research regarding both therapeutic benefits and acute and long-term toxicity. Speakers will explore current restrictions on research, including access issues, and how GW Labs was able to conduct the research necessary to obtain FDA approval of Epidiolex.

Aidan Hampson, Special Content Expert: Cannabis, National Institute on Drug Abuse, National Institutes of Health
Angelique Lee-Rowley, Global Chief Compliance Officer, Greenwich Biosciences
Heike Newman, Senior Regulatory Manager, University of Colorado
Moderated by **Christina M. Markus**, Partner, King & Spalding LLP

11:15–12:15 PM **What Safety and Product Quality Issues are CBD Producers Facing?**
This session will address safety and quality of CBD and other cannabis-derived products in this era of scant federal regulation. Speakers will discuss practical issues involving toxicology and cGMPS, analytical testing, pesticide use, and verifying consistent and stable dosages amid varying mixtures of ingredients. Speakers will discuss whether FDA's existing authority regarding safety and quality covers these products and where gaps exist. The panel will also discuss potential impacts to the cannabis industry from recent vaping lung illnesses.

Deborah Miran, Former Commissioner, Maryland Medical Cannabis Commission
Jessica Parsons O'Connell, Partner, Covington & Burling LLP
Lee Rosebush, Partner, BakerHostetler
Moderated by **Libby Baney**, Partner, Faegre Baker Daniels LLP

12:15–1:15 PM **Networking Luncheon**

1:15–2:15 PM **How Are Manufacturers Handling CBD Labeling and Marketing Issues?**
What do manufacturers need to know about federal regulation of CBD labeling and marketing? We will cover issues such as directions for use, warnings, certificates of analysis, and finding industry-wide consistency in product labeling terms. We will also discuss the fine line between structure-function and disease

claims, advertising and promotion issues, and areas where FDA and FTC have stepped in to enforce. Finally, we will discuss ways to minimize risk when labeling and advertising cannabis-derived products.

Richard Cleland, Assistant Director, Bureau of Consumer Protection, Division of Advertising Practices, Federal Trade Commission
Areta L. Kupchyk, Partner, Foley Hoag LLP
Douglas MacKay, Senior Vice President, Scientific and Regulatory Affairs, CV Sciences
Moderated by **Stuart M. Pape**, Shareholder, Polsinelli PC

2:15–3:15 PM **What Is the Future of Federal Regulation of Cannabis?**

Regulatory updates regarding cannabis-derived products are happening quickly, making it difficult for businesses to predict what's ahead. Is the CBD market likely to continue its explosive growth? Will increased research lead to more FDA-approved THC- and CBD-containing drugs? Will legalization of state medical/adult-use marijuana continue to spread? With more than half of Americans supporting marijuana legalization in some form, how probable is federal legalization? What would marijuana legalization at the federal level look like? Is Congress likely to enact banking protections for cannabis businesses? This session will discuss the future of federal and state regulation. We will also cover whether legalization in other countries, such as Canada, is likely to impact US policies.

Linda D. Bentley, Member, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Kelly Fair, Director of Legal, USA, Canopy Growth Corporation
Andrew Kline, Director of Public Policy, National Cannabis Industry Association
Moderated by **Michael Werner**, Partner, Holland & Knight LLP

3:15 PM **Closing Remarks and Adjournment**