



2020 CLM Focus November Conference  
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Virtual

## **Cannabis: Navigating the Federal and State Regulatory Scheme**

### **I. Is Cannabis legal? . . .Well, why do they sell it at Walmart?**

Hemp and Marijuana are both products that derive from the plant Cannabis Sativa L. From a definitional standpoint, pursuant to the Farm Bill 2018 and the modification to the Controlled Substance Act, the only difference in a hemp or marijuana plant is the quantity of THC contained within it. That is, any given Cannabis Sativa L plant when tested, will produce a Delta 9 THC content on a dry weight basis. If the result is higher than 0.3% THC, it is marijuana. If it is 0.3% or less, it is hemp. A plant tested on one day could be hemp and the next day marijuana. Timing is critical.

Pursuant to the Farm Bill 2018, once a state or tribal entity submits its hemp plan to the USDA, and the same is approved, entities in the given state can grow, process and sell hemp according to the laws and regulations of that state (presuming they don't sell on an interstate basis). This includes sales at Walmart. If they sell on an interstate basis, federal laws and regulations may/will continue to impact each entity. Until the state plans are passed, any state can continue to permit hemp cultivation, processing and distribution under the 2014 Farm Bill which permits(ed) hemp research.

Cannabis cultivation, processing and/or dispensing, whether hemp or marijuana, can result in litigation beginning with real estate purchases, loan documents, sales agreements, and non-compete clauses and can extend to false claims and product liability matters. Understanding the difference between a legally operating entity and one that is not will be critical to claims management and risk assessment.

### **II. The Regulatory Framework**

Numerous federal and state agencies maintain regulatory authority over hemp and marijuana products and/or transactions related to the same. These regulatory bodies include, but are not limited to the FDA, TTB, FINCEN, NCUA, DEA, USDA, IRS, NIST and numerous state agencies across the nation. To understand this complex system of organizations, it is important to understand the purpose of each of these entities and the interplay between federal laws and regulations and their state counterparts.

These agencies will impact litigation and claims matters as a result of their decision-making authority. That is, for example, the FDA could determine that a product must be recalled due to its labeling and packaging and/or claims that the product advertising is false or misleading. As a result, civil actions may arise as a result of the recall and/or notice and counsel for plaintiff will likely attempt to utilize the FDA notices and/or warning letters as evidence of its proof of claim. Understanding the FDA process will be invaluable in evaluating the risk this might pose.

### **III. FDA REGULATORY AUTHORITY**

The Agricultural Marketing Act of 2014 (P.L. 113-79) permitted states to develop agricultural pilot programs and/or academic research for “industrial hemp”. It, however, did not address the definition of Marijuana in the Controlled Substance Act. The definition was first address in the 2018 Farm Bill, which amended the Controlled Substance Act to exclude Cannabis Sativa L with a THC concentration of not more than 0.3 percent on a dry weight basis. Further, the 2018 Farm Bill specifically addressed FDA authority and stated that the FDA will maintain authority over the types of products they already regulate. This includes CBD and other products.

The FDA is the Federal agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biologicals, and medical devices; and by ensuring the safety of the U.S. food supply and cosmetics. It is responsible for enforcing numerous laws including the FD&C Acts (as modified), Fair Packaging and Labeling Acts (as modified), and Dietary Supplement Health and Education Acts (as modified).

Failure of an insured to comply with FDA regulations and the statutes the FDA enforces, can result in increased risk to an entity and those that might insure it. Even something as simple as a testimonial from an entities client may result in the FDA considering a product to be marketed with an intended use to diagnose, cure, mitigate, treat or prevent any disease and this could result in the product being considered a drug and subject to significant regulation and oversight. However, some products which are marketed as cosmetics may have reduced regulatory scrutiny. Therefore, understanding the differences will assist in evaluating any claim for false or misleading advertising, etc. These matters often arise in class action settings.

### **IV. Banking Cannabis**

Two entities are responsible for the primary regulation/guidance of banks and credit unions in the United States. They are FINCENN and the NCUA. The mission of the Financial Crimes Enforcement Network is to safeguard the financial system from illicit use, combat money laundering, and promote national security through the strategic use of financial authorities and the collection, analysis, and dissemination of financial intelligence. On December 3, 2019- Several Agencies, including FINCEN, Clarified Requirements for Providing Financial Services to Hemp-Related Businesses. In conjunction with the state bank regulators, these agencies collectively issued a statement which clarified that they recognize the legalization of hemp, and therefore, compliance requirements for banks under the Bank Secrecy Act (BSA) for banks servicing hemp-related businesses were modified. According to NCUA, Credit unions need to be aware of the Federal, State and Indian Tribe laws and regulations that apply to any hemp-related businesses they serve. Credit unions that choose to serve hemp-related businesses in their field of membership need to understand the complexities and risks involved.

In order for a hemp business to “bank” in a conventional sense, it must sell products that are in compliance with Federal and State laws. The failure of a company to bank conventionally could result in additional risks to employees who must handle significant cash flow and products that may evidence products/a company that does not comply with regulations.

#### **VI. WHY DOES THE DOJ FAIL TO PROSECUTE ENTITIES THAT SELL MARIJUANA? . . . IT IS STILL FEDERALLY ILLEGAL.**

There are two reasons that DOJ does not prosecute state legal marijuana entities. First, amendments to the Omnibus Spending Bills passed by Congress as far back as the Obama administration, precluded the DOJ from using federal funds provided under the bill to prosecute state legal marijuana companies. Second, the Cole Memo (which may or may not be followed under Attorney General Barr’s tenure) still seems to guide any prosecutions. That memo set for priorities for prosecution of marijuana crimes. The priorities are:

1. Preventing the distribution of marijuana to minors;
2. Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs and cartels;
3. Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
4. Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
5. Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
6. Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
7. Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
8. Preventing marijuana possession or use on federal property.

#### **VII. Interaction Between Federal and State Marijuana Laws**

Hemp is now a legal product to cultivate, process and dispense in the United States, assuming it is cultivated, processed and dispensed in conformance with the law of the state or tribe where it is cultivated, processed and/or sold. Marijuana is not legal federally, but has been legalized in at least 33 states, D.C., Guam, Puerto Rico and the Virgin Islands.

Each state has its own body of laws and regulations that govern each part of the process. Each law/regulation is different and compliance with the same will impact the entities ability to engage in a common marketplace. Further, interstate sales can impact the regulatory

framework and laws with which an entity must follow. These laws include labeling and packaging laws, advertising laws, permissible products, product registration, etc.

Federal Preemption will also be a consideration in evaluating the applicable laws/rules related to any given entity. Federal Preemption has recently arisen in numerous cases as it relates to Medical Marijuana laws and whether federal agencies can test for and/or must pay for a person in a state where marijuana is legal to take marijuana. In a case in Massachusetts, *Wright v Department of Industrial Accidents*, an employee who wanted to be reimbursed for his payments for medical marijuana by his workers compensation carrier. The carrier denied the claim because it believed payment for medical marijuana would violate the CSA, even though state law permitted it, subjecting it to criminal prosecution. The employee acknowledged the Supremacy Clause of Article VI of the US Constitution. However, the employee argued that this would not answer the question. The question was whether the CSA precluded the insurer from reimbursing the cost of medical marijuana. Ultimately, the Court decided that the state law permitting medical marijuana would create an obstacle to the execution of the CSA which prohibits the unlawful manufacture, distribution, dispensing or possession of a controlled substance. Recently, the Veterans Administration and the Armed forces have grappled with whether their agencies can test for Marijuana and/or whether CBD usage is permissible and compensable. Carriers will have to deal with these issues on an ongoing basis.

#### **VIII. What is CBD and is it “legal” under Federal or State Marijuana Laws?**

Cannabidiol (CBD) is a naturally occurring compound found in the resinous flower of cannabis, which has little or no psychoactive effects. It, along with hundreds of other phytocannabinoids appear to have some therapeutic effects, but have not been well studied. FDA has approved a very concentrated form of CBD for the intended use of treating seizures associated with Lennox-Gastaut Syndrome or Dracet Syndrome in patients 2 years of age and older <https://www.epidiolex.com/about-epidiolex> Occasionally, FDA has taken action against CBD manufacturers in the form of warning letters <https://www.adlawaccess.com/2019/08/articles/cbd-and-false-advertising-lessons-learned-from-the-food-court/> . These letters often result in actions against the manufacturers. In this instance, the letters resulted in a case filed against KOI alleging KOI knowingly sold products that were illegal. Other actions have resulted in class actions alleging misbranding, etc. For the most part the FDA has taken a back seat, allowing states to regulate CBD if they wish, for now. However, FDA has issued guidance <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd> in relation to their priorities.

Many states have taken a “don’t ask don’t tell” approach to CBD, allowing any business that wishes to manufacture and sell CBD containing products to do so. Other states have banned or in some way restricted CBD containing products.

#### **IX. Investing in Marijuana Businesses?**

Many many people, from all walks of life have been eagerly investigating the possibility of owning a piece of the marijuana industry. The presenters will briefly discuss some of the difficulties faced by potential investors/owners, as time allows.