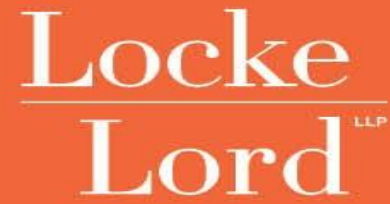




Ethically Speaking: Issues and Uncertainties in Practicing Cannabis Law

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September 27, 2019

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Mark Mansour



Mark Mansour has more than two decades of experience handling federal Food and Drug Administration (FDA) regulatory matters. He has significant experience working with clients in the food, pharmaceutical, medical device, dietary supplements and cosmetic industries to develop and implement strategies for regulatory approvals, compliance and enforcement actions, crisis management, rulemaking and public policy issues. He counsels corporations and organizations on how to negotiate effectively with government agencies in the United States and key global markets.

I. Background – Market Data

Marijuana Business Daily predicts the industry (including CBD) could have a maximum economic impact of some \$68 billion by 2021

II. Current State of Law – Where Legal in the U.S.?

- ✓ Alaska
- ✓ Arizona
- ✓ California
- ✓ Colorado
- ✓ Connecticut
- ✓ Delaware
- ✓ District of Columbia
- ✓ Florida
- ✓ Guam
- ✓ Hawaii
- ✓ Illinois
- ✓ Louisiana
- ✓ Maine
- ✓ Maryland
- ✓ Massachusetts
- ✓ Michigan
- ✓ Minnesota
- ✓ Missouri
- ✓ Montana
- ✓ Nevada
- ✓ New Hampshire
- ✓ New Jersey
- ✓ New Mexico
- ✓ New York
- ✓ North Dakota
- ✓ Ohio
- ✓ Oregon
- ✓ Pennsylvania
- ✓ Rhode Island
- ✓ Utah
- ✓ Vermont
- ✓ Washington
- ✓ West Virginia

II. Current State of Law – Where Legal Globally?

- ✓ Argentina
- ✓ Australia
- ✓ Austria
- ✓ Canada
- ✓ Chile
- ✓ Czech Republic
- ✓ Columbia
- ✓ France
- ✓ Germany
- ✓ Israel
- ✓ Italy
- ✓ Jamaica
- ✓ Mexico
- ✓ Netherlands
- ✓ Romania
- Full Legalization**
- ✓ Uruguay
- ✓ Canada

II. Current State of Law – Federal Controlled Substance Act (CSA) 1970

Five Schedules – Marijuana is under Schedule 1, alongside heroin and LSD since “no currently accepted medical use ...”

- Schedules I-V
 - Schedule I: Drug or other substance with a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety protocols for use under medical supervision.
 - Examples: Cannabis (**except hemp**), LSD, heroin
 - Schedule II: High potential for abuse; a currently accepted use in treatment in the United States, or currently accepted medical use with severe restrictions, abuse may lead to severe psychological or physical dependence.
 - Examples: Cocaine, morphine, pentobarbital
 - Schedule III: Potential for abuse less than Schedule I or II substances; currently accepted medical use in treatment in the United States; abuse may lead to moderate or low physical dependence or high psychological dependence
 - Schedule IV: Low potential for abuse relative to Schedule III; currently accepted medical use in treatment in the United States; abuse may lead to limited physical or psychological dependence relative to Schedule III
 - Schedule V: Low potential for abuse relative to Schedule IV; currently accepted medical use in treatment in the United States; abuse may lead to limited physical or psychological dependence relative to Schedule IV
 - Example: Epidiolex (2018 FDA-approved **CBD for child epilepsy**)

II. Current State of Law – Federal CSA

- Controlled Substance Act of 1970:
 - Marijuana regulated under Schedule I - high potential for abuse
 - Use, possession, advertising and sale of marijuana – medical and recreational is illegal and a federal crime
 - No currently accepted medical use (except one CBD epilepsy drug)
 - Lack of accepted safety for use under medical supervision except one CBD product
 - Industrial hemp (including extracts, derivatives, etc.) no longer listed as Schedule 1 Controlled Substance since now excluded from definition of marijuana by 2018 Farm Bill.

II. Current State of Law – DOJ Memos

U.S. Attorneys not to prosecute users of marijuana for medical purposes [rescinded January 2018 by AG Sessions]



U.S. Department of Justice
Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

August 29, 2013

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: James M. Cole 
Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Enforcement

In October 2009 and June 2011, the Department issued guidance to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). This memorandum updates that guidance in light of state ballot initiatives that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing, and sale. The guidance set forth herein applies to all federal enforcement activity, including civil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

As the Department noted in its previous guidance, Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. The Department of Justice is committed to enforcement of the CSA consistent with those determinations. The Department is also committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, as several states enacted laws relating to the use of marijuana for medical purposes, the Department in recent years has focused its efforts on certain enforcement priorities that are particularly important to the federal government:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;

II. Current State of U.S. Law – Rorhabacher-Farr Amendment

- Introduced in 2003; passed May 2014
- Prohibits the Justice Department from spending funds “to prevent [the listed] States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana.”
- Not permanent
- Currently applies to 44 states, Washington D.C., Guam and Puerto Rico, but curiously does not include North Dakota or Indiana

II. Current State of U.S. Law – DOJ

- Under the Obama Administration, the United States Attorney General (Cole Memo) relaxed federal enforcement of criminal marijuana laws, rescinded by Attorney General Sessions and renewed hands off approach under Barr
- President Donald Trump has sent mixed messages on his views regarding marijuana but has indicated some support to amend the CSA to exempt state legal marijuana
- Currently about 30 bills introduced in Congress on CBDs including STATES Act to exempt cannabis from Federal law in states where legal.

II. Current State of U.S. Law – CBD

- 2003 DEA Final Rule – exempt paper, cloth from stalks, animal feed, sterilized seeds, **personal care products with an ingredient of oil from sterilized seed**
- 2004 Hemp Industry Association v. DEA
 - Non-psychoactive hemp products from “mature stalk” or constituting “oil as cake made from the seeds” not within the CSA
- 2007 Monson v. DEA: CSA covers all varieties of Cannabis Sativa - industrial hemp cannot be grown domestically
- 2016 DEA Rule – marijuana extract, such as CBD, de facto illegal
- January 2018 Sessions Memo – U.S. Attorney prosecutorial discretion
- May 22, 2018 DEA internal directive tried to clarify

Products and materials that are made from the cannabis plant and which fall outside the CSA definition of marijuana (such as sterilized seeds, oil or cake from the seeds, and mature stalks) are not controlled under the CSA. Such products may accordingly be sold and otherwise distributed throughout the United States without restriction under the CSA or its implementing regulations. The mere presence of cannabinoids is not itself dispositive as to whether a substance is within the scope of the CSA; the dispositive question is whether the substance falls within the CSA definition of marijuana.

- 2018 Farm Bill – industrial hemp and its extracts and derivatives are legal.

III. Applications and Implications – FDA and CBD

■ Summary

- CSA - CBD federally (except FDA) legal if derived from industrial hemp
- Many states legal with some restrictions
- Farm Bill 2014 until at least December 2019 but probably longer because of USDA
- Farm Bill 2018 –industrial hemp and its derivatives (CBD) legal as long as less than 0.3% TCH
 - States delegated authority to regulate production of hemp but need to submit regulatory plan to USDA for approval after USDA issues rules

III. Applications and Implications – FDA and CBD

■ State Legislation on Cannabis

- Several states have either passed laws that remove state restrictions on the medical use of marijuana and its derivatives or are considering doing so.
- The FDA supports researchers who conduct adequate and well-controlled clinical trials which may lead to the development of safe and effective marijuana products to treat medical conditions.
- University of Pennsylvania School of Medicine Study found 70% of cannabinoid extracts are mislabeled
 - 43% too little CBD
 - 26% too much
 - 20% contained THC

III. Applications and Implications – FDA and CBD

■ State of Activity of Interest – California

- In July 2018 California announced that it would follow the U.S. FDA on the marketing of dietary supplements or food additives containing marijuana or its constituents including CBDs and THC
- Cannabis was legalized in California many years ago so this is a total reversal and affects the California CBD industry
- However, California Bill AB-228 introduced and states:
 - “A cosmetic is not adulterated because it includes industrial hemp . . . or cannabinoids, extracts or derivatives from industrial hemp. The sale of cosmetics that include industrial cannabinoids, extracts or derivatives shall not be restricted or prohibited based solely on inclusion of industrial hemp or cannabinoids, extracts or derivatives from industrial hemp.”

III. Applications and Implications – FDA and CBD

- Industrial Hemp and DEA's announcement of exercise of prosecutorial discretion
- March 21, 2003 DEA announced it would exercise prosecutorial discretion in connection with enforcement of the CSA for personal care products containing industrial hemp oils. This may have been superseded by the 2018 Farm Bill.
- Recognized that without conducting a chemical analysis on personal care products it could not determine whether the products were in fact THC free.
- DEA focused on the fact that THC in shampoos, lotions and moisturizers would not enter the human body from personal care use and could not readily be extracted from these personal care products.

III. Applications and Implications – FDA and CBD

- The claims you make for the product will probably determine how the product will be considered by government agencies.

IV. Trademarks, Advertising and Banking

- Trademark office as of May 2019 will now register trademarks on hemp-related products and related services with less than 3% THC. Previously, it would not since not “legal use in commerce” before the 2018 Farm Bill.
- SAFE Banking Act of 2019 currently pending in Congress hopes to protect banks and insurance companies.

IV. Trademarks, Advertising and Banking

- Cannabis related advertising still may not be accepted by the media
 - Facebook
 - Google
 - TV networks – CBS rejected Acreage Holdings’ Super Bowl commercial promoting medical marijuana – “under CBS broadcast standards it does not currently accept cannabis related advertising.”

V. Conclusions

- The laws and Rules are confusing and contradictory and in a state of flux
- CBD from industrial hemp is now legal under the CSA but FDA has the last word
- What is clear - FDA will not permit CBD for human consumption, but beyond that has issued little guidance
- What is not clear is whether DOJ or Congress will take action
- DOJ does not want to enforce until Congress acts
- The solution will have to come from Congress
- The conundrum is that despite all of the activity surrounding marijuana, it is still illegal under federal law

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Associate, Cannabis Law | Food & Beverage | Life Sciences

SAUL EWING ARNSTEIN & LEHR LLP

FDLI, Food Advertising, Labeling, and Litigation Conference

September 27, 2019

**SAUL EWING
ARNSTEIN
& LEHR^{LLP}**

Lauren A. Farruggia

Lauren Farruggia is a regulatory attorney who focuses on evaluating products for conformance with U.S. Food and Drug Administration (FDA) regulations and guidance. Clients in industries ranging from medical devices to food products and dietary supplements rely on Lauren to provide regulatory due diligence as part of their process for bringing products to market. Her experience includes matters involving medical device classification, marketing, and clearance, as well as claim substantiation, labeling, and distribution in the food industry. She also provides regulatory advice to the cannabis industry.

In addition to her FDA regulatory practice, Lauren assists health care providers and health-care related companies with compliance and transactional issues. Her experience includes helping clients respond to inquiries, audits and investigations by government parties, as well as assisting with provider scope of practice and facility licensure issues in the post-transaction context. She also assists with preparation of state certificate of need applications for facility and treatment expansion.



State v. Federal Approaches to Hemp and Hemp-Derived Products

- The CSA does not preempt state law. Many states automatically follow the Federal CSA, but some do not.
- A number of states are moving to align their CSA analogs with federal law (*i.e.*, descheduling hemp, and, perhaps, hemp-derived CBD).
- Yet, other states and even some municipalities have taken note of FDA's position (*i.e.*, that CBD is not a lawful food/supplement ingredient), and in reaction to the same, have banned CBD, even if it is not a controlled substance (*e.g.*, New York).
- Other states ignore FDA's position entirely, permitting the addition of hemp-derived compounds (including hemp-derived CBD) in dietary supplements and food (*e.g.*, New Jersey).

How do we advise clients in light of conflicting state and federal treatment of cannabis and hemp products?

Varied Approaches

- Some firms elect to have limited involvement in the cannabis and hemp spaces because of uncertainty and enforcement risks.
- Others take a cautious, well-informed approach to advising clients in the cannabis and hemp spaces.

ABA Guidance on Representing Cannabis Clients

- On July 2, 2019, the American Bar Association (ABA) published a feature addressing ethical issues in representing clients in the cannabis business where state and federal law conflict.
 - *See:*
https://www.americanbar.org/groups/professional_responsibility/publications/professional_lawyer/26/1/ethical-issues-representing-clients-the-cannabis-business-one-toke-over-line/
- The ABA highlights two key Model Rules for Professional Conduct (Model Rule) that are applicable to attorneys advising clients in the cannabis industry: Model Rules 1.2(d) and 8.4(b).

ABA Model Rule 1.2(d)

“A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is criminal or fraudulent, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of the law.”

- Comment 9 explains that “This prohibition . . . does not preclude the lawyer from giving an honest opinion about the actual consequences that appear likely to result from a client’s conduct.”

ABA Model Rule 8.4(b)

“It is professional misconduct for a lawyer to commit a criminal act that reflects adversely on the lawyer’s honesty, trustworthiness or fitness as a lawyer in other respects.”

Application of the Model Rules When State and Federal Law Conflict

- The feature takes the position that “a lawyer does not violate the Model Rules of Professional Conduct, specifically Rule 1.2(d) or Rule 8.4(b), when a lawyer advises and/or assists a client under state law in operating or withdrawing from a business of medical or recreational marijuana to the extent that it is authorized by that jurisdiction.”
- Although the feature does not specifically address hemp or hemp-derived products such as CBD, it is nevertheless illustrative for attorneys advising clients in that space.
- The feature recommends that, in order for attorneys advising cannabis clients to remain compliant with Rule 1.1 (Competence) and 1.3(a)(2) and (b) (Communication), attorneys must “be extremely careful and fully advise the client of the conflicting laws and the risks and challenges resulting.”

Best Practices for the Cannabis Industry

- Firms electing to advise clients in the **cannabis** space may want to consider:
 - Including disclaimers on the firm's website and in marketing materials explaining that marijuana remains a Schedule I controlled substance
 - Developing expanded policies for client vetting
 - Drafting special engagement letter language which emphasizes the legal and regulatory uncertainty in the cannabis industry
 - Staying apprised of related changes in state and federal law, as well as changes in ethical guidance for practitioners
 - Withdrawing from representation if a client uses legal advice for anything other than state-authorized activity

Best Practices for the Hemp Industry

- Firms electing to advise clients in the **hemp** space may want to consider:
 - Encouraging the client to take a close look at its product sourcing to ensure that its hemp products consistently meet the definition of “hemp” (*i.e.*, have a THC concentration of not more than 0.3 percent on a dry weight basis)
 - Staying apprised of FDA’s rules and guidance as the Agency develops a concrete policy with respect to CBD in dietary supplements and foods
 - Developing a firm understanding of how state hemp law differs from FDA’s rules and guidance

Additional Best Practices

- Over the course of representation, attorneys should remind both cannabis and hemp clients that:
 - Compliance with state law does not equal compliance with federal law
 - Federal cannabis and/or hemp policy may change at any time
 - No legal advice provided regarding cannabis and/or hemp law or policy is ever intended to guide or assist clients in violating federal law

Hypothetical Scenarios and Open Discussion



Hypothetical #1

- A client asks you to review its CBD product line. Each product label states, “Completely eliminates arthritis pain, the natural way.” The client is based in Manhattan and intends to sell its products (which include topical balms, beverages, and gummies) in upscale boutiques throughout New York and New Jersey.
- What advice would you give the client?





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