Legal and Practical Issues in the Evolving World of Cannabis Regulation

FTC Enforcement: Looking Back and Going Forward

FDLI

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The views expressed today are my own and do not necessarily reflect the views of the Commission or any individual commissioner.

Jurisdiction

- The FTC has jurisdiction over the advertising of food, drugs, cosmetics, devices, and services. (This includes labeling.)
  - “Reduce your risk of COVID. Use CBD oil.”
- Advertising that contains false or unsubstantiated express or implied claims or that is misleading because of the failure to disclose material facts violates the FTC Act.
- Violations of the FTC Act can result in federal or administrative court actions resulting in injunctive relief, consumer redress, disgorgement, damages, and other bad things.

Substantiation

- The FTC targets disease and serious health-related conditions such as age-related cognitive decline.
- Health claims require competent and reliable scientific evidence.
- For disease and other casual claims, this usually requires well-controlled, randomized, human clinical trials of the product.

Human Clinical Trials: Disease Claims

- Conducted by qualified experts
- Appropriate design for the outcomes being investigated
- Control group
- Randomized
- Double-blinded
- Valid statistical analysis
- On the product or essentially equivalent product
- Representative population
- The length of the study must be sufficient to show claimed benefit
- Adequate study size
- Outcome variables match the claims
- Outcome measurements must be valid and reliable
- Compare treatment and control groups
- Results must be clinically significant
- Sufficient data is available for evaluation

Joint FTC/FDA Warning Letters

- Advanced Spine and Pain, LLC (03/28/2019)
  - Cancer, Alzheimer's, schizophrenia, substance abuse, Parkinson's, rheumatoid arthritis, & more
- Nutra Pure LLC (03/28/2019)
  - Alzheimer's, neuropsychiatric disorders, PTSD, OCD, & more
- PotNetwork Holdings, Inc. (03/28/2019)
  - Liquid Gold Gummies & "blue CBD Crystals Isolate"
  - Alzheimer's, Lou Gehrig's disease, arthritis, diabetes, & more
- Rooted Apothecary, LLC (10/10/2019)
  - Teeth/TMJ – Essential Oil + CBD Infusion
  - Ears – Essential Oil + CBD Infusion

FTC Warning Letters (2019)

- 4Bush Holdings, LLC
- NuLife LLC
- Ocanna Co.

Warning Letters (2020)

- Neuro XPF (March 31)
- Native Roots Hemp (April 6)
- Indigo Naturals (April 6)
- CBD Online Store (April 7)
- Nova Botanix Ltd dba CanaBD (April 16)
- Agro Terra, Ltd/Patriot Hemp Co. (May 7)
- Noetic Nutraceuticals (May 15)
- Apollo Holding LLC (May 21)
- CBD Gaze (May 26)
- Project 1600, Inc. (June 18)
- Living Senior, LLC (August 19)
- For Our Vets LLC dba Patriot Supreme (October 16)
- Myers Detox (SWRO) (June 3)
- CBD Center (DAP) (June 3)

Sample Claim

“The best natural defence and treatment of Coronavirus (and viruses in general) is a strong immune system. . . Bolster your defenses, so when and if Coronavirus strikes, your system is ready to fight it off. . . The Number ONE KILLER Of Your Immune System . . . that is stress. When your body is chronically stressed, your immune system suffers. With the spread of this potentially deadly Coronavirus, stress will be high . . . consider CBD Oil.” Patriot CBD

FTC v. Marc Ching d/b/a Whole Leaf Organic

- Filed 04/26/2020
- TRO & administrative complaint
- Thrive (treat, prevent, reduce the risk of COVID-19)
- Vitamin C, Echinacea, ginger, pomegranate, turmeric extract, bilberry extract, citrus bioflavonoid complex, cranberry juice extract, organic carrot root
- CBD (cancer treatment claims)
- Stipulated cease and desist order

Whole Leaf Organic: CBD Claim

The most effective innovation in cancer and immune related proactive supplement support in the past ten years. CBD-EX combines the best in cancer fighting elements, into one simple capsule. Containing clinically tested ingredients, CBD-EX is a dynamic force in anti inflammation protocols, targeting manipulated cells while working to protect healthy ones. Formulated containing Coriolus Versicolor Mushroom, CBD-EX seeks to inhibit the spread of mutated malignant cells, directly attacking the problem.

Contact Information

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U.S. DOJ, DEA, and FTC Approaches to Marijuana and CBD Regulation and Enforcement

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Mr. Claud's views and analyses expressed here are personal, and are not intended to impart any official policy of the United States Department of Justice

Consumer Protection Branch

- Main Justice component of approximately 75 prosecutors.
- Office in Washington; travels to and works with all 93 USAOs.
- Leads DOJ efforts to enforce criminal and civil laws that protect Americans' health, safety, economic security, and identity integrity.
  - Titles 18 and 21 Offenses
  - Primary DOJ authority over FDCA and FTCA (JM 4-1.313.8-9)
- Represents the FTC, FDA and other consumer protection agencies in defensive litigation.
- https://www.justice.gov/civil/consumer-protection-branch

Consumer Protection Branch

Food, Drug, and Consumer Products

- Criminal and Civil Enforcement
  - Pharmaceuticals and Medical Devices
  - Food and Dietary Supplements
  - Compounding Pharmacies
  - Consumer Products
- Justice Manual § 4-8.000 Requirements
- Defense of FDA/CPSC

Opioids

- PIL Task Force
- Criminal and Civil Enforcement
  - Manufacturers
  - Distributors
  - Pharmacies/Prescribers
- CSA Injunctions – 21 U.S.C. § 843(f)
- National Prescription Opiate MDL
- Injection Site Litigation
- Data Analytics/Leads

Complex Consumer Fraud

- Transnational Elder Fraud Strike Force
- Criminal Enforcement
  - Telemarketing Fraud
  - Mass-Mailing Fraud
  - Tech-Support Scams
- Civil Fraud Injunctions – 18 U.S.C. § 1345
- Interagency Coordination
- Data Analytics/Leads

Deceptive Practices/ Identity Integrity

- Unfair/Deceptive Practices
- Privacy/Data Breaches
- Robocalls/Do Not Call Violations
- U.S. Servicemember Fraud

Gus Eyler, Director
www.justice.gov/civil/consumer-protection-branch

DOJ Enforcement Policy Evolution

2013 Cole Memo

Eight federal priority areas for cannabis enforcement in light of several states enacting state laws essentially legalizing the drug.

2018 Farm Bill

Exclude 0.3% hemp from Schedule I / CSA. Many regulatory restrictions remain in place.

2018 Sessions Memo

Old JM prosecutorial guidance applies to cannabis cases. Rescinds Cole Memo.

DOJ Enforcement – CBD in Consumer Products

- After the 2018 Farm Bill, 0.3% hemp is legal, but with serious restrictions.
- The regulation of hemp products is predominantly left to various states or USDA because of this amendment to the definition of marijuana specifically excluding hemp.
- Lots of enforcement road to pave here.
- FTCA, FDCA become viable tools for enforcement actions regarding non-CSA hemp, CBD in consumer products.

DOJ Enforcement – CBD in Consumer Products

- Only 0.3% hemp was exempted.
- All other cannabinoids remain in Schedule I.
- Exclusions: FDA-approved drug products (Epidiolex).

- Enforcement efforts evolving around hemp consumer products look similar to existing enforcement of other products.
- Traditional cannabis enforcement still applies, but Federal priorities and resource considerations factor in.

Key Statutes – FDCA

Follow our traditional pathway under FDCA enforcement analysis:

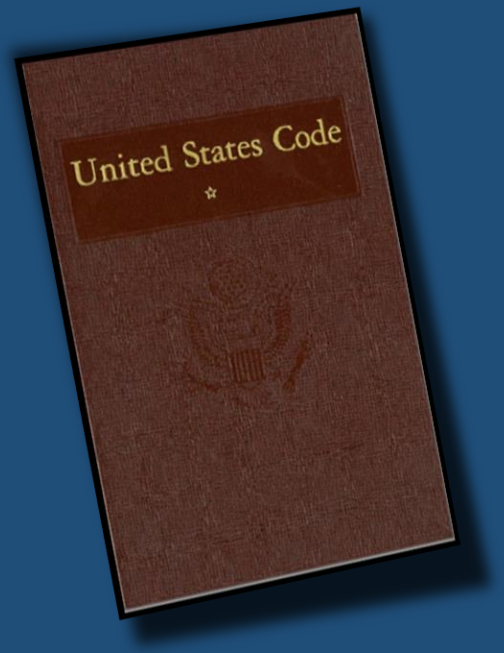
1. **What is it? What is intended use?**
2. **What is wrong with it? How is it adulterated or misbranded?**
3. **What prohibited act has occurred?**
4. **What is level of criminal intent?**

Possible Enforcement Pathways

- Akin to dietary supplements?
- Akin to adulterated food?
- Akin to compound pharmacies?
- Level of consumer harm?

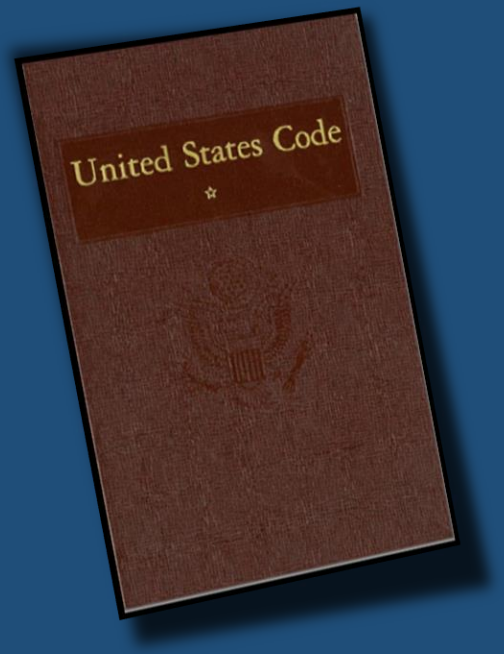
THC Vaping

- Use of CSA to combat THC in vaping products
- Not a traditional consumer-focused enforcement; many investigational complexities
- Relationship between THC and CBD vaping products



Enforcement Litigation

- DOJ will litigate based on violations of federal law.
- Focus will be on adulterated or misbranded drugs.
- Factors may include evidence of fraud based on marketing claims, healthcare fraud, smuggling, endangering patient safety.



Criminal Enforcement

- FDCA Strict-Liability Misdemeanor
  - Up to 1 year in prison
- FDCA Felony – intent to defraud or mislead
  - Up to 3 years in prison
- Title 18 – Mail Fraud, Wire Fraud, Smuggling, Conspiracy
  - Up to 5, 20 years in prison

Federal vs. State

- Interplay between state statutes and Federal statutes is a factor in assessing enforcement actions.
- Highly fact-dependent.
- State legality does not necessarily insulate from Federal enforcement.

Comments on DEA's Interim Final Rule on Implementation of the Agriculture Improvement Act of 2018

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FDLI

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- Larry Houck counsels on DEA regulatory and enforcement actions. His career encompasses over 30 years focusing 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. He advises on DEA inspections and audits. He works with clients to create the infrastructure to ensure compliant reporting, recordkeeping, and security.
- Before joining Hyman, Phelps & McNamara in 2001, Mr. Houck served as a DEA diversion investigator in the field and staff coordinator with DEA's Office of Diversion Control's Liaison and Policy Section.

Overview

- Drug Enforcement Administration (“DEA”)
- Controlled Substances Act (“CSA”)
- Cannabis Control
- Agriculture Improvement Act of 2018 (“AIA”)
- USDA’s Interim Final Rule
- DEA’s Interim Final Rule (“IFR”)
- IFR Comments
- Conclusion

DEA

- Regulates 1.8 million controlled substance manufacturers, distributors, pharmacies, practitioners, hospitals, importers and exporters.
- Is the primary federal agency responsible for enforcing the Comprehensive Drug Abuse Prevention and Control Act of 1970, the Controlled Substances Act (“CSA”).
- Enforces the CSA and regulations governing illicit street-type drugs and legal controlled pharmaceuticals and regulated chemicals.
- Mission is to eliminate illicit controlled substances and prevent, detect and eliminate diversion of controlled pharmaceuticals from legal channels while ensuring their availability for legitimate purposes.

The CSA

- Congress, through the CSA, established a closed system of controlled substance distribution requiring each entity in the chain to account for the drugs they handle.
- This is achieved through a classification system based on the drugs' potential for abuse relative to their legitimate use.
- The classification, or drug scheduling, triggers specific registration, quota, recordkeeping, reporting and security requirements.

Cannabis Control

Schedule I:

- No currently accepted medical use in treatment in the U.S.;
- High potential for abuse; and
- Lack accepted safety for use under medical supervision.

- **Includes:**
  - Marijuana and any substance from parts of the *Cannabis sativa L.* plant within the CSA definition of “marihuana” (Drug Code 7360)
  - Marijuana extract (Drug Code 7350)
  - Tetrahydrocannabinols not in hemp (“THC”)(Drug Code 7370)
    - Delta-8 THC, Delta-9 THC
    - Synthetic CBD (Drug Code 7360)

  Also includes: Heroin, LSD, Peyote, Ecstasy

Cannabis Control

Schedule II

- Dronabinol (Syndros) (Synthetic THC, Drug Code 7365)
  - Oral solution in drug product approved by FDA

Schedule III:

- Dronabinol (Marinol) (Synthetic THC, Drug Code 7369)
  - Sesame oil in soft gelatin capsules approved by FDA

Not Scheduled, Not Controlled:

- Hemp and hemp-derived products (THC not more than 0.3 percent on dry weight basis)
- Tetrahydrocannabinols in hemp
- CBD and products derived from parts of the *Cannabis sativa L.* plant excluded from definition of "marihuana"
  - Excluded parts: Mature stalks, fiber from stalks, oil or cake made from seeds, any other compound, manufacture, salt, derivative, mixture, or preparation from mature stalks (except the resin therefrom), fiber, oil, or cake, or sterilized seed incapable of germination
- FDA-approved drugs in finished form containing cannabis-derived CBD with no more than 0.1% THC-Epidiolex (Cannabis-derived, Drug Code 7367)

Agriculture Improvement Act of 2018

Public Law 115-334 ("Farm Bill") (Dec. 20, 2018)

- Removed hemp from CSA definition of marihuana and excludes THC in hemp from control under CSA.
- Defined hemp as *Cannabis sativa L.* plant and any part of the plant, including seeds, and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with THC concentration of not more than 0.3% on dry weight basis.
- Established general requirements for U.S. Department of Agriculture ("USDA") and state/Indian tribal regulatory plans for oversight of hemp producers.
- Directed USDA to issue regulations and guidance "as expeditiously as practicable."
- Hemp production in a state or tribal territory that does not have a USDA-approved plan is unlawful unless producer has USDA license.

USDA's Interim Final Rule

Establishment of a Domestic Hemp Production Program, 84 Fed. Reg. 58,522 (Oct. 31, 2019)

- Established USDA hemp production requirements for itself and state/Indian Tribes.
- USDA consulted with Attorney General in establishing rule.
- CSA and DEA will continue to play a role with noncontrolled hemp under USDA, and state/Tribal plans.
- Plans must require representative hemp samples be tested by DEA-registered labs to conduct chemical analysis of schedule I substances because they could potentially be testing cannabis with THC concentration above 0.3% on a dry weight basis.
- If cannabis exceeds 0.3% THC concentration, disposal must comply with CSA and cannabis must be destroyed by DEA-registered reverse distributor or federal, state or local law enforcement officer.

DEA's Interim Final Rule

Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639, (Aug. 21, 2020).

- DEA stated it issued an IFR rather than a notice of proposed rulemaking with opportunity for prior public comment because the amendments "merely conform the implementing regulations" to amendments made to the CSA by the AIA that had already taken effect.
- DEA stated that the IFR does no more than incorporate the AIA's statutory amendments into the regulations and publishing a notice of proposed rulemaking or soliciting public comment prior to publication was unnecessary.
- DEA said it had no discretion with respect to the amendments made by the AIA.
- DEA further noted that because the statutory changes have been in effect since December 2018, "good cause exists" to make the rule effective immediately upon publication.
- The IFR requested comments be submitted within 60 days, ending October 20, 2020.

DEA's Interim Final Rule

1. Clarified, consistent with AIA, material previously controlled as marijuana or marijuana extract containing 0.3% Delta-9-or less THC on a dry weight basis unless specifically controlled under the CSA (defined as "hemp") is not controlled.
   - Any material that exceeds 0.3% THC limit is a schedule I substance even if the plant from which it was derived contained 0.3% or less THC.
   - To be a derivative of hemp, and be exempt from schedule I control, derivative cannot exceed 0.3% THC limit.
2. Clarified, consistent with AIA, that tetrahydrocannabinols in hemp is not a schedule I substance, but THC not in hemp is a schedule I substance.
   - DEA interpreted AIA as excluding only naturally-derived THC from control under the CSA; synthetically-derived THC is a CI regardless of concentration.
   - This is why DEA views synthetic CBD as a schedule I substance.

DEA's Interim Final Rule

3. Removed FDA-approved products containing CBD derived from cannabis with no more than 0.1% THC concentration from schedule V and control under the CSA.
   - FDA approved Epidiolex, an oral CBD solution derived from cannabis, for treatment of seizures associated with Lennox-Gastaut and Dravet syndromes on June 25, 2018.
   - DEA rescheduled FDA-approved drugs that contain CBD derived from cannabis with no more than 0.1% residual THC in schedule V (September 28, 2018).
   - So, DEA descheduled Epidiolex.

4. Removed import and export restrictions for drug products in finished dosage forms that have been approved by FDA that contain CBD derived from cannabis with 0.1% residual THC content.

5. Limited definition of "Marihuana Extract" to extracts containing greater than 0.3% Delta-9-THC on a dry weight basis.

IFR Comments

- DEA received 3,340 comments from a wide range of commenters including CBD/hemp manufacturers/processors, researchers, testing labs, national advocacy organizations, law firms, patients and interested citizens.
- Comments available at regulations.gov (DEA-2020-0023).
- I reviewed representative sampling of the comments received.
- Comments range from the trivial to the more substantive.
- Most oppose or have concerns about some aspects of the IFR; a few support it and DEA.
- Many industry comments focused on several specific DEA interpretations of the AIA.

IFR Comments-THC Exceeding 0.3%

- Hundreds of comments express concern that DEA considers in-process hemp materials temporarily exceeding 0.3% THC concentration to be a schedule I substance.
- They assert:
  - In the course of processing hemp into CBD products, there are intermediary compounds that temporarily contain more than 0.3% THC;
  - Current technology makes this unavoidable;
  - The IFR does not allow these middle steps even if product at increased THC level does not leave the processing facility;
  - Processors engaged in hemp extraction would have to obtain a DEA registration though the beginning material and end product does not exceed 0.3% THC;
  - Congress understood when enacting the AIA that extraction and processing hemp would result in temporarily exceeding the 0.3% THC content;
  - DEA should allow hemp beginning and ending at 0.3% THC concentration be considered non-controlled throughout the production process; and
  - THC increases during processing and manufacturing must be permissible without in-process materials becoming temporary schedule I substances.

IFR Comments-THC Exceeding 0.3%

- I disagree with those who argue that any material derived from hemp should be non-controlled regardless of future THC concentration.
- DEA must clarify exactly what the IFR means with respect to hemp that temporarily exceeds 0.3% THC concentration.
- DEA should not impose additional registration and recordkeeping requirements on processors who begin with hemp, and end with a product that does not exceed 0.3% THC.
- Additional requirements should not be more than possibly requiring additional security to protect in-process material.

IFR Comments-Synthetic THC

- DEA's statement that non-plant, synthetically-derived THC is a schedule I substance regardless of THC concentration also elicited many comments.
- Commenters contend that the AIA does not exclude synthetic cannabinoids including CBD from the definition of "hemp."
- They believe the AIA exempts THC in synthetic cannabinoids with less than 0.3% THC from control under the CSA, because its definition of hemp, which included all parts of the *Cannabis sativa L.* plant, *whether growing or not*, with THC concentration of not more than 0.3% on a dry weight basis.
- They contend that synthetic CBD with less than 0.3% THC is a non-growing cannabinoid falling within the AIA's definition of hemp.
- They state that DEA should clarify and schedule cannabinoids including CBD based on THC concentration, not whether its origin is natural or synthetic.
- In many cases, THC concentration in synthetic CBD is less than the acceptable 0.3% of plant-derived CBD.

IFR Comments-Synthetic THC

- Commenters characterize DEA's distinction as artificial for there are no differences in chemical structure, abuse potential or diversion risk for synthetic cannabinoids vs. naturally-produced cannabinoids.
- They observe that there is no scientific justification for DEA to treat synthetic material that otherwise meets the definition of "hemp" differently than material derived from the *Cannabis sativa L.* plant.
- The commenters believe DEA's interpretation creates an unlevel playing field for manufacturers and handlers of synthetic cannabinoids, requiring them to obtain DEA registrations and comply with restrictive CSA controls that those handling natural cannabinoids are not subject to.
- They conclude that DEA's interpretation is arbitrary and capricious because of disparate treatment for similarly situated manufacturers, distributors and others.
- They note that CBD is non-addictive, non-psychoactive and does not require protection of the public.

IFR Comments-Synthetic THC

- I agree there is no justification for treating synthetic THC products with the same THC content of 0.3% or less differently than naturally-derived products with the same or less THC concentration.
- DEA's interpretation deems naturally-occurring THC (and CBD) as non-controlled while synthetic THC (and CBD) are schedule I substances, the most stringently regulated controlled substances.
- There may be policy reasons for treating the substances differently but there no scientific justification; synthetic THC does not have an increased abuse potential.

IFR Comments-Rulemaking

- A number of commenters also contend that DEA changing its interpretation of the AIA by limiting "hemp" to material derived from the *Cannabis sativa L.* plant should have been conducted through notice and prior comment rulemaking, not an IFR.
- They assert that the IFR does not merely conform DEA's regulations to the AIA but significantly revises the agency's interpretation of "hemp."
- They say that the IFR adds additional requirements.
- They point out that DEA through the IFR reversed its interpretation of the definition of "hemp" that the agency had communicated to some in the industry in 2019.
- Some had asked about synthetic CBD with THC concentration of 0.3% or less, and DEA advised that synthetic CBD would be considered hemp, therefore not controlled.

IFR Comments-Rulemaking

- The commenters are correct that DEA's decision about the regulatory status of synthetic cannabinoids was final agency action that they reasonably relied upon and from which legal consequences might flow.
- DEA reversed its interpretation to exclude synthetic cannabinoids without notice or explanation, resulting in a crucial and substantive change without opportunity for comment and acknowledging the policy change.
- DEA should have conducted notice and comment rulemaking, not an IFR.

IFR Comments-Miscellaneous

- A number of patients are concerned that the AIA exemption of hemp applies only to Delta-9-THC and not Delta-8-THC submitted comments.
  - Delta-8-THC appears to remain a schedule I substance, and a number of commenters fear they will lose access to effective medication that has helped alleviate many ailments.
- Many commenters express concerns about “Big Pharma,” opining it was pulling DEA’s strings and is behind DEA’s IFR for financial gain.
- Several commenters state that DEA should focus not on cannabis but on opioids and the pharmaceutical companies.
- A few commenters support DEA’s IFR, stating they are pleased with DEA’s approach, oppose the strong hemp lobby and have concerns about bad actors manipulating THC content of their products.

Conclusion

- DEA has the opportunity to assess and address legitimate concerns expressed by the public, including patients who rely on natural hemp and synthetic products to alleviate a multitude of medical ailments.
- The products have useful and legitimate medical purposes.
- Heeding many of the comments would allow for the availability of non-abused substances with necessary safeguards that would not increase potential for abuse and misuse.
- DEA can accomplish this within the spirit of the AIA and would hardly be reckless or audacious given what many states have done with respect to cannabis.

Questions?

Thank You.

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