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High Times at FDA: The Federal and State Regulation of Cannabis

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West Thompson Reuters Webinar

High Times at FDA: The Federal and State Regulation of Cannabis

September 11, 2019

Rory Radding, Partner, Locke Lord
Mark Mansour, Partner, Locke Lord

Meet the Speakers

- **Rory Radding** is a partner of Locke Lord's Intellectual Property group. He is Co-Chair of the Firm's ITC Practice Group and former co-chair of the Trademark, Copyright and Advertising Practice Group. Member of Cannabis Practice group.

- **Mark Mansour** is a partner in Locke Lord's FDA practice, based in the Washington DC office. He focuses his practice on federal Food and Drug Administration (FDA) and Federal Trade Commission (FTC) regulatory matters.

Rory Radding

Rory Radding is a member of the Locke Lord's Intellectual Property group. He is Co-Chair of the Firm's ITC and former co-chair of the Trademark, Copyright and Advertising Practice Groups. He has litigated diverse patent, trademark, copyright, and trade secret cases, acting for both plaintiffs and defendants, involving LED lighting and lighting systems, plastic manufacture, electrochemical devices, ring laser gyroscopes, avionics, medical devices, communications, pharmaceuticals, computer controllers, data compression, impact sensors, bicycles, candy, wine, jewelry, personal consumer products, television commercials, and vehicle tires; to name a few. He also counsels food, cosmetics, and media companies in advertising and labeling compliance with the IP, FDA, FTC and cannabis laws.

Prior to joining the Firm, Rory was head of the Intellectual Property practice in New York for Morrison & Foerster. Prior to that he was a senior partner at Pennie & Edmonds, where he practiced for 30 years. Prior to his legal career, Rory was a pharmaceutical chemist at Wellcome Research Laboratory, and an environmental chemist at Union Carbide Corporation.

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.

Order of Presentation

I. Background
II. Current State of the Law
III. Application and Implications – FDA and CBD
IV. Other Considerations
V. Conclusion

I. Background – Cannabis Basics

- *Cannabis*
  - Hemp plant from which marijuana and CBD are derived
  - 3 species (*C. sativa, C. indica, C. ruderalis)*
- *Cannabinoids*
  - Chemicals that may interact with specific receptors located within different parts of the central nervous system

I. Background – Cannabis Basics

- 400 compounds and 80+ cannabinoids
- Main psychoactive compound is THC (tetrahydrocannabinol)
- Brain binding sites discovered in late 1980s
- Another cannabinoid CBD (cannabindiol) driving current research

I. Background – Types of Cannabinoids

- delta – 9 – tetrahydrocannabinol (THC)
  - commonly associated with marijuana
- Cannabigerols (CBG)
- Cannabichromenes (CBC)
- Cannabidiols (CBD)
- Cannbinol (CBN) and cannabinodiol (CBDL)
- Others (cannabicyclol (CBL), cannabielsoin (CBE), cannabitriol (CBT)

I. Background – What's the Difference?

Cannabinoids

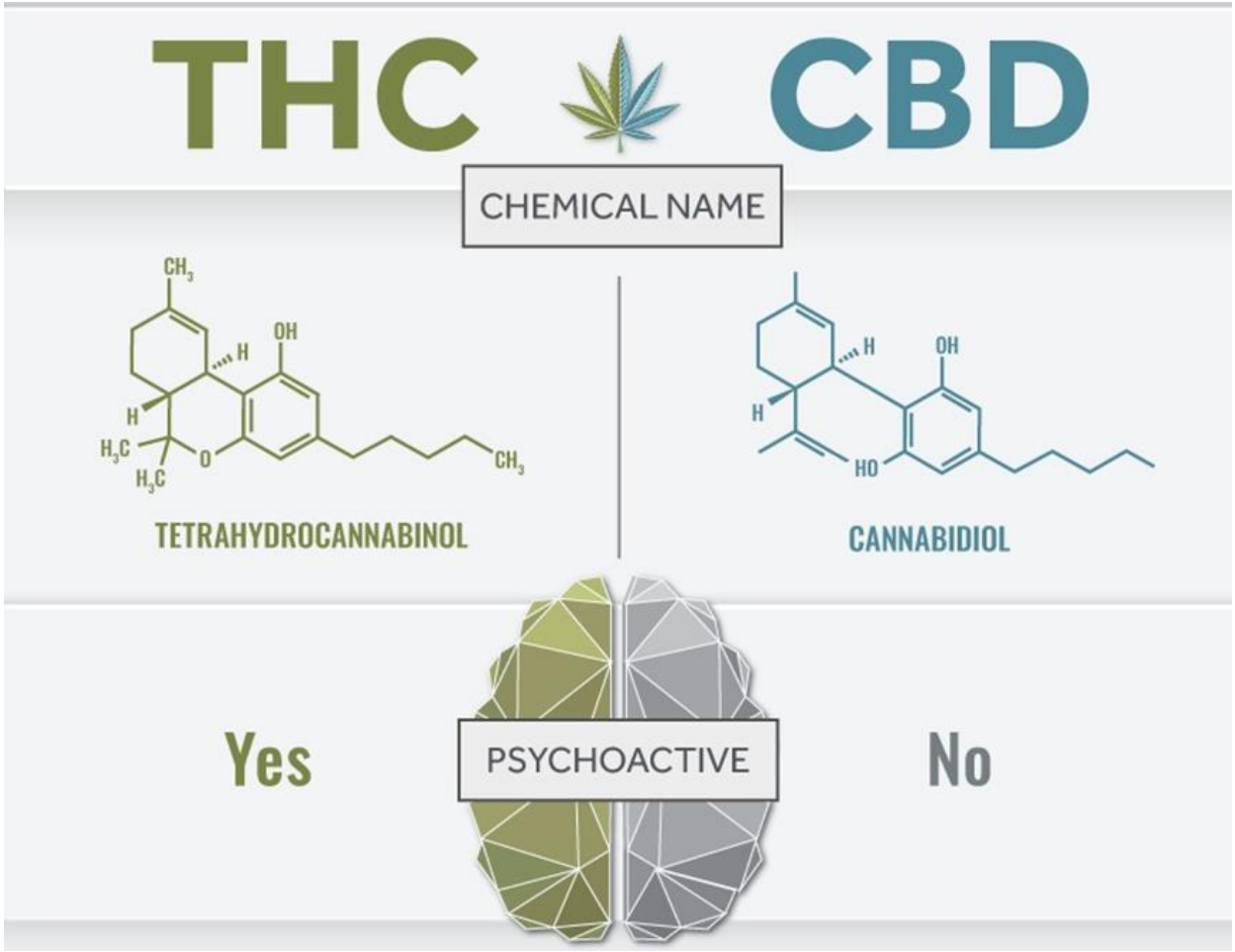
Psychoactive

- Cannabinol (CBN)
- Cannabinodiol (CBDL)
- delta – 9 – tetrahydrocannabinol (THC)

Not Psychoactive

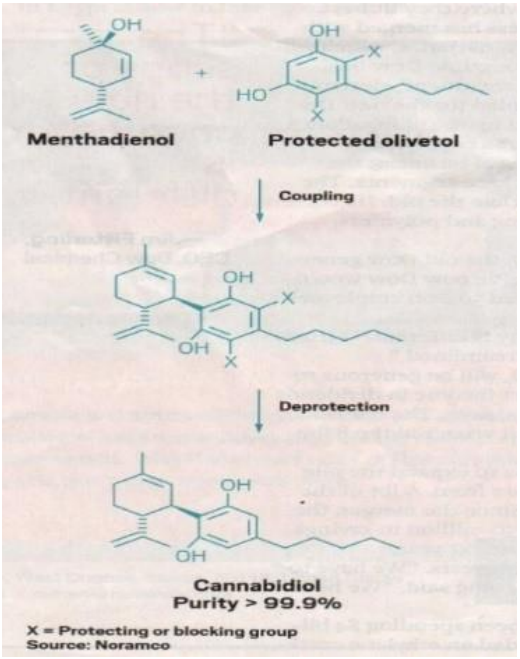
- Cannabigerols (CBG)
- Cannabichromenes (CBC)
- Cannabidiols (CBD)

I. Background – What's the Difference?



I. Background – THC vs. CBD

- I. Background – *Natural Product v. Synthetic*
  - GW Pharmaceuticals Epidiolex approved by FDA – purified CBD from cannabis
  - Naramco (J&J) – Synthetics
    - Synthetic production of CBD and other cannabinoids may be more acceptable to FDA – purity and consistency will appeal to regulators
  - Possible synthesis

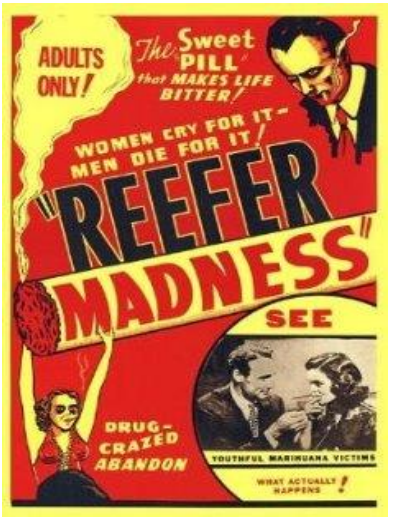


I. Background – History

- Hemp plants used as early as 4000 BC in Western and Central Asia
- Medical use dates as far back as 1400-2000 BC
- 1611: brought to Jamestown by settlers
- 1850: listed in US Pharmacopeia – classified legitimate medical compound
- Victorian era – neurologist used Indian hemp to treat epilepsy and reported success
- Recreational use began being banned in 1911
- 1913: US Dept. of Ag grows domestic cannabis
- 1915 Sir William Osler, advocated for cannabis use in migraine
- Use diminished with intro of phenobarbital (1912) and phenytoin (1937)

I. Background – History

- 1930s: William Randolph Hearst plays role in denouncing marijuana
- Crackdown begins on all uses of cannabis: term "marijuana" becomes popular
- 1936: "Reefer Madness" movie
- Marijuana Tax Act of 1937 – levy tax for medicinal and industrial uses
- 1942: Dropped from U.S. pharmacopeia
- 1960s: THC identified and synthesized
  - U of Mississippi becomes official grower under the Feds
- Recreational use surges in 1960's and 1970's



I. Background – History

- 1970: CSA classifies as Schedule I substance, “No accepted Medical Use” (classified along with heroin and LSD). Marijuana defined as “cannabis”
- 1978: New Mexico recognizes medical value
- 1978:1991 Compassionate Use Program supplies patients with THC
- 1988: First failed attempt to reschedule to Schedule II
- 1996: California becomes first state to legalize medical THC
- 2001: Dept of Health and Human Services filed patent for cannabinoids as antioxidants and neuroprotectants which issues in 2003
- 2014: Farm Bill – limited growing of industrial hemp for “research”
- 2018: State adoption status
  - 33 states (also DC, Guam, PR) full medical marijuana programs
  - 17 states allow use of “low THC, high cannabinoid (CBD)”
  - 10 states and DC allow recreational use (soon Illinois will join as the 11th state)
- 2018: Agricultural Improvements Act of 2018 (2018 Farm Bill) enacted into law – hemp legal
- 2019: FDA holds hearing on cannabis - May 2019

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 …"

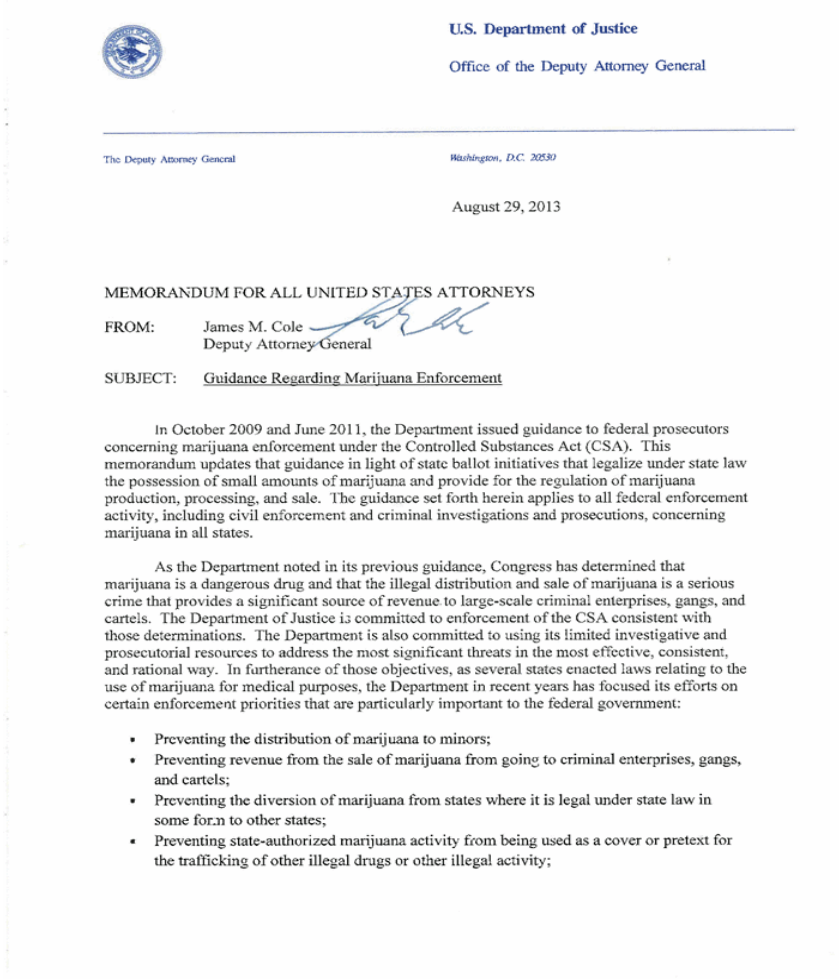
- Schedules I-V
  - Schedule I: Drug or other substance with a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety protocols for use under medical supervision.
    - Examples: Cannabis **(except hemp**), LSD, heroin
  - Schedule 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 – CBD

- CSA: law prior to December 20, 2018:
  - The term “marihuana” means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks
- CSA: post December 20, 2018: CBD from industrial hemp with less than 0.3% THC no longer a Schedule 1 controlled substance and is legal

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, but now rescinded by Attorney General Sessions
- 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.

II. Current State of U.S. Law – CBD and 2014 and 2018 Farm Bill

- 2014 Farm Bill permitted domestic growth of industrial hemp under state agricultural pilot programs which authorizes states to issue licenses to cultivate and research by state or academic institution – it did not alter the CSA
- 2014 Farm Bill defined industrial hemp as the plant Cannabis Sativa and any of its parts with a THC concentration of less than 0.3% on a dry weight basis
- 41 States have some sort of state Farm Bill
- Under 2014 Farm Bill, to legally possess CBD oil, it must be imported or extracted, sold and acquired in a state with a state Farm Bill
- 2014 Farm Bill expired September 30, 2018, but extended until at least end of 2019 (USDA) by the 2018 Farm Bill.
- 2018 Farm Bill signed into law December 20, 2019
  - Industrial hemp and "all derivatives, extracts, cannabinoids (including CBD), isomers, acids, salts and salts of isomers" legal as long as it contains less than 0.3% THC on a dry weight basis
  - Hemp exempt from definition of "marijuana"
  - Now two types (cultivars) of cannabis: hemp (agricultural commodity) and marijuana (controlled substance)

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Please notate it carefully

The presenter will only be able to read the code twice and will not be able to repeat it or email it to you.

Thank you!

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

- FDA has enforcement role to target nationally marketed products making egregious health claims
  - Includes products that contain CBD
- FDA need for tracking and testing – drug interaction also a concern.
- Drug Exclusion Rule vs. Prior Marketing Clause

III. Applications and Implications – FDA and CBD

- FDA Regulates Products
  - **What is the definition of a "drug"?**
    "drug" means
    - (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
    - (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
    - (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
    - (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

III. Applications and Implications – FDA and CBD

- FDA Regulates Products
  - **What is not a "drug"?**
    - A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim.
    - A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement

III. Applications and Implications – FDA and CBD

- FDA Regulates Products
  - **What is the definition of "food"?**
    - (1) articles used for food or drink for man or other animals,
    - (2) chewing gum, and
    - (3) articles used for components of any such article
    - raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

III. Applications and Implications – FDA and CBD

- FDA Regulates Products
  - **What is a "food additive"?**
    - "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include - (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; (2) a pesticide chemical; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4

III. Applications and Implications – FDA and CBD

- FDA Regulates Products
  - **What is the definition of "dietary supplement"?**
    - (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral;(C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
    - (2) means a product that- (A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or (ii) complies with section 350(c)(1)(B)(ii) of this title; (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labeled as a dietary supplement; and

III. Applications and Implications – FDA and CBD

- FDA Regulates Products
  - (3) does- (A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and (B) not include: (i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

III. Applications and Implications – FDA and CBD

- FDA Role in the drug approval process
  - The FDA has not approved cannabis and its derivatives as a safe and effective drug for any indication except in three (3) instances:
    - Approved one specific drug product that contains the purified substance **cannabidiol (CBD)**, one of more than 80 active chemicals in cannabis, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.
    - Approved two drugs containing a synthetic version of a substance that is present in the marijuana plant and one other drug containing a synthetic substance that acts similarly to compounds from marijuana but is not present in marijuana.
    - The FDA is aware that there is considerable interest in the use of cannabis to attempt to treat a number of medical conditions, including, for example, glaucoma, AIDS wasting syndrome, neuropathic pain, cancer, multiple sclerosis, chemotherapy-induced nausea, and certain seizure disorders.

III. Applications and Implications – FDA and CBD

- FDA Role in the drug approval process
  - Before conducting testing in humans of a drug that has not been approved by the FDA, an investigator submits an investigational new drug (IND) application, which is reviewed by the FDA.
  - An IND includes protocols describing proposed studies, the qualifications of the investigators who will conduct the clinical studies, and assurances of informed consent and protection of the rights, safety, and welfare of the human subjects.
  - The FDA reviews the IND to ensure that the proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm.
  - The FDA also verifies that there are adequate assurances of informed consent and human subject protection.

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.

III. Applications and Implications – FDA and CBD

- FDA action on CBD products
  - Over the past several years, FDA has issued several warning letters to firms that market unapproved new drugs that allegedly contain cannabidiol (CBD).
  - CBD Warning Letters - FDA has issued four sets (Feb 2015, Feb 2016, March 2019 and July 2019) of warning letters (about 20) to entities marketing unapproved drugs for the diagnosis, cure, mitigation, treatment, or prevention of diseases.

III. Applications and Implications – FDA and CBD

- FDA action on CBD products
  - As part of these actions, FDA has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed to contain.
  - It is important to note that these products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease.
  - Also a 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

- FDA Action on CBD products – enforcement discretion
  - For example, see Warning letter 10/31/17:

"This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at www.cbdoil.life in August 2017 and has determined that you take orders there for the products "CBD All-Natural Hemp Oil," "Bosom Lotion Potion," and "CBD-Rich Healing Crème," all of which you claim to contain cannabidiol (CBD). FDA also reviewed your social media websites at www.facebook.com/ThatsNaturalCBDoil and at www.twitter.com/PureCBDHempOil; these websites direct consumers to your website, www.cbdoil.life, to purchase your products. The claims on your websites establish that your products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease."

III. Applications and Implications – FDA and CBD

- FDA Action on CBD products – enforcement discretion
  - Example continued

Although you market "CBD All-Natural Hemp Oil" as a dietary supplement, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. Under that provision, if an article (such as CBD) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. **There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD**

III. Applications and Implications – FDA and CBD

- **Drug Exclusion Rule**: FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, respectively.
- Under those provisions, i**f a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved** under 21 U.S.C. § 355 (section 505 of the FD&C Act), or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement.

III. Applications and Implications – FDA and CBD

- Hemp/CBD companies now use total cannabinoid content ("full spectrum"), rather than isolated CBD, like Epidiolex, the product approved as a drug, in an attempt to make the concentrations more like the naturally occurring levels in the plant or traditional hemp extract preparations (the rice case).
- The Rice Case
  - Red yeast rice used for thousands of years for healing.
  - The FDA had approved an isolated compound, lovastatin, as a drug in the treatment of cholesterol.
  - Companies continued to sell and market lovastatin as a dietary supplement.
- FDA Challenged Pharmanex's sale and marketing of its product, Cholestin.
- Pharmanex sued the FDA in Federal Court challenging the FDA position.

III. Applications and Implications – FDA and CBD

- The Court held in 2001 that the lovastatin found in “Cholestin” was not in its natural form in red yeast rice because Pharmanex selected and used a method to produce specific levels of Lovastatin greater than the levels in naturally occurring red yeast rice.
- The Court found Cholestin was a drug.
- Likewise it is argued that if one used unadulterated naturally occurring full spectrum hemp marketed as full spectrum hemp, not CBD, then FDA enforcement could be mitigated.
- Thus “full spectrum” hemp means that all the natural constituents of the hemp plant are in the product in the same percentages as found in nature.

III. Applications and Implications – FDA and CBD

- **Prior Marketing Clause**: there is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable.
- However, based on available evidence, FDA has concluded that this is not the case for THC or CBD. And the FDA has concluded that THC and CBD cannot be added to foods as the required testing and approvals have not been obtained.

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 THCs
  - 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

- FDA position on CBD products
  - Enforcement Discretion especially if drug, medical or health claims
  - As far as FDA's perspective on products containing industrial hemp with low levels of THC, the FDA has not instituted enforcement actions and Customs and Border patrol follow the DEA position on admission of these hemp personal care products into the U.S.
  - FDA looking at CBD issue for foods and topicals and may make recommendations by December 2019 which may set concentration levels.

III. Applications and Implications – FDA and CBD

- FDA position on CBD products
  - Former Commissioner Gottlieb has said: "CBD in high concentrations isn't risk-free. In low concentrations, it is probably safe."
  - Gottlieb also tweeted on April 12, 2019:

    "I was also concerned to hear recently that several national pharmacy chains and other major retailers have begun to sell or will soon begin to sell cannabidiol (CBD) products in several states.
    We'll be contacting them to remind them of FDA obligations and our commitment to protect consumers against products that can put them at risk."

III. Applications and Implications – FDA and CBD

- FDA position on CBD products
  - Cosmetics defined: "articles intended to be rubbed, poured, sprinkled or sprayed on . . . or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness or altering appearance" (except soap).
  - Cosmetics not tightly regulated however if harmful ingredients, then adulterated.
  - CBD does not fall into that category (see FDA FAQs):
  - "Certain cosmetic ingredients are prohibited or restricted by regulation but currently that is not the case for any cannabis or cannabis derived ingredients."
  - CBD also must be safe.

III. Applications and Implications – FDA and CBD

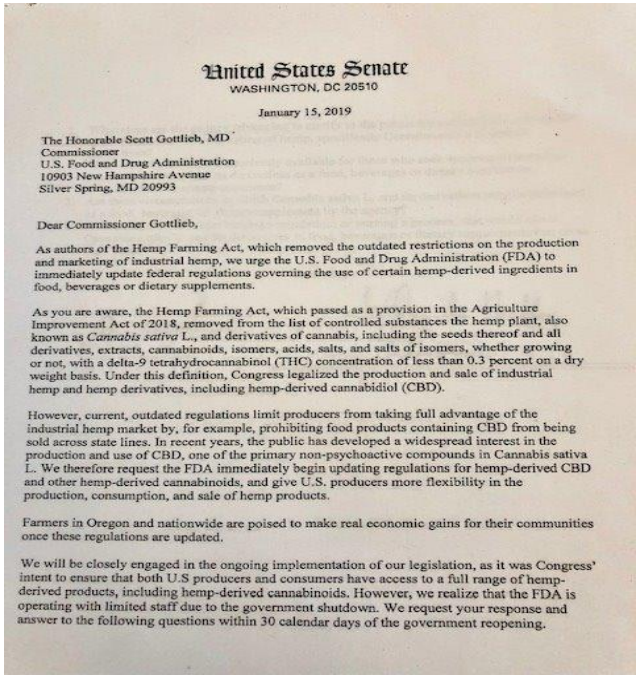
- On December 20, 2018 FDA issued statement on an application by Fresh Hemp Food:
  - The FDA "has no questions about the Fresh Hemp Food's conclusion that the following ingredients are GRAS under their intended conditions of use: hulled hemp seed (GRH 765), hemp seed protein powder (GRN 771) and **hemp seed oil** GRH 778)."

III. Applications and Implications – FDA and CBD

- So the question is what we recognize – the claims you make for the product may control how the product will be considered by government agencies.

III. Applications and Implications – FDA and CBD

- Request to FDA by Oregon Senators who authored 2018 Farm Bill – January 15, 2019 to "immediately update federal regulations governing the use of certain hemp-derived ingredients in food, beverages or dietary supplements"



United States Senate
WASHINGTON, DC 20510

January 15, 2019

The Honorable Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

As authors of the Hemp Farming Act, which removed the outdated restrictions on the production and marketing of industrial hemp, we urge the U.S. Food and Drug Administration (FDA) to immediately update federal regulations governing the use of certain hemp-derived ingredients in food, beverages or dietary supplements.

As you are aware, the Hemp Farming Act, which passed as a provision in the Agriculture Improvement Act of 2018, removed from the list of controlled substances the hemp plant, also known as *Cannabis sativa* L., and derivatives of cannabis, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of less than 0.3 percent on a dry weight basis. Under this definition, Congress legalized the production and sale of industrial hemp and hemp derivatives, including hemp-derived cannabidiol (CBD).

However, current, outdated regulations limit producers from taking full advantage of the industrial hemp market by, for example, prohibiting food products containing CBD from being sold across state lines. In recent years, the public has developed a widespread interest in the production and use of CBD, one of the primary non-psychoactive compounds in Cannabis sativa L. We therefore request the FDA immediately begin updating regulations for hemp-derived CBD and other hemp-derived cannabinoids, and give U.S. producers more flexibility in the production, consumption, and sale of hemp products.

Farmers in Oregon and nationwide are poised to make real economic gains for their communities once these regulations are updated.

We will be closely engaged in the ongoing implementation of our legislation, as it was Congress' intent to ensure that both U.S producers and consumers have access to a full range of hemp-derived products, including hemp-derived cannabinoids. However, we realize that the FDA is operating with limited staff due to the government shutdown. We request your response and answer to the following questions within 30 calendar days of the government reopening.

IV. Other Considerations – Patents, Trademarks, Advertising and Banking

- Thousands of patents (utility and plant) relate to cannabis and CBDs
  - Patent for Epidiolex limited by Patent Office (IPR) as obvious based on prior work
  - Toothpaste and mouthwash patent (No. 10,172,786) wherein at least one cannabinoid is present in a certain concentration
- Patent litigation has begun
  - *United Cannabis Corporation v. Pure Hemp Collective Inc.* in Colorado Federal Court filed July 2018
  - United – biotech company
  - Pure – retailer of wellness products
  - U.S. Patent No. 9,730,911 – "Cannabis extracts and methods of preparing and using same"
    - Claim 10: "A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is cannabidiol (CBD)
  - Motion to dismiss denied since highly concentrated liquid formulation is not naturally occurring and thus patentable.

IV. Other Considerations – Patents, 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. Other Considerations – Patents, 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

QUESTIONS?

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