



CANNABIS: WHERE ARE WE, AND WHERE ARE WE GOING?

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**McDermott
Will & Emery**

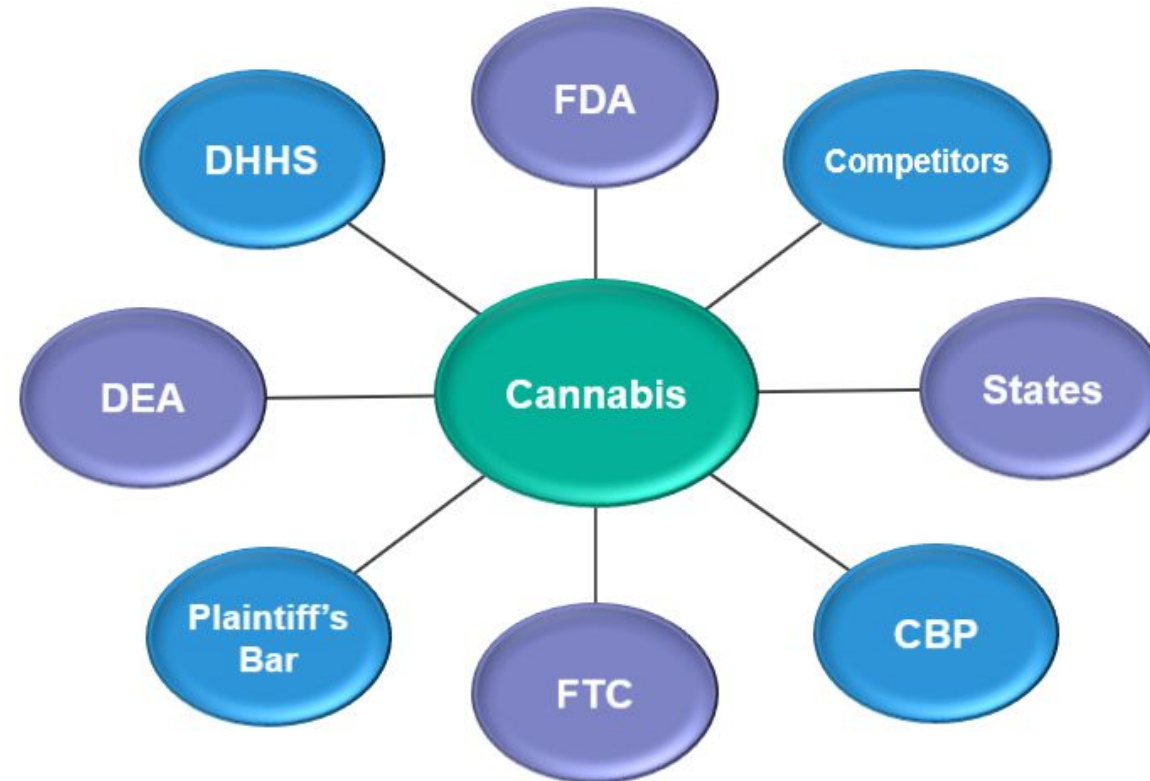
ROADMAP FOR DISCUSSION

- Status of Cannabis Under Federal Law
 - Cannabis Regulators
 - Controlled Substances Act
 - 2018 Farm Bill
 - Food & Drug Administration
 - Current Position of the Alcohol and Tobacco Tax and Trade Bureau
- Overview of State Laws
- Where Are We Headed?



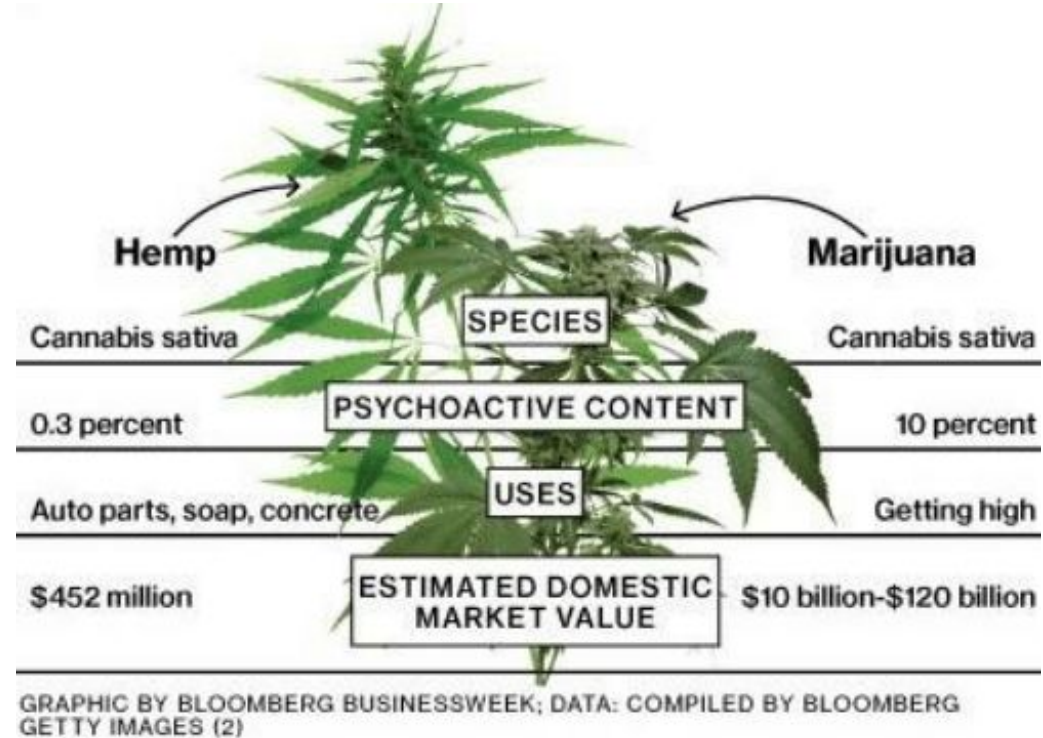
CANNABIS UNDER FEDERAL LAW

CANNABIS REGULATORS



WHAT ARE THE SUBSTANCES AT ISSUE?

- Marijuana
- Cannabidiol (“CBD”)
- Hemp
- Hemp-Based CBD



Hemp vs Marijuana

THE CONTROLLED SUBSTANCES ACT

- The **Controlled Substances Act** (“**CSA**”) regulates the manufacture, possession, use, and distribution of certain drugs, substances, and precursor chemicals
 - Until late 2018, the CSA included cannabis (the statutory term is “marijuana”) as a Schedule I drug, meaning it had a high potential for abuse and no known medicinal benefits
 - The original exemption only covered stalks and sterilized seeds
- FDA also has approved **synthetic THC as a drug** in other schedules

THE CONTROLLED SUBSTANCES ACT

- Penalties for trafficking in a Schedule I substance include up to lifetime **incarceration** and **forfeiture** of all proceeds of the criminal act
- Other laws and doctrines increase the potential legal risks
 - Aiding and abetting
 - A “criminal enterprise”
 - A “Racketeering Influence and Corrupt Organizations” (“**RICO**”) Act “predicate”
- In essence, trafficking in cannabis has been the same as trafficking in cocaine, heroine, etc.

IMPACT OF THE 2018 FARM BILL ON THE CSA

- **Before** the 2018 Farm Bill, defined **marijuana** as:

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 (except the resin extracted therefrom), fiber, oil, or cake, **or the sterilized seed** of such plant which is incapable of germination.

After the 2018 Farm Bill, the definition of marijuana now **excludes hemp**.

“Hemp” is defined as:

the plant Cannabis sativa L. and **any part of that plant**, 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 concentration of not more than 0.3 percent** on a dry weight basis.



INDUSTRIAL HEMP

Agricultural Act of 2014 (2014 Farm Bill)

- Created a definition of “industrial hemp”
- Authorized limited academic research activities by state departments of agriculture or state institutions of higher education
- DEA, FDA, and the US Department of Agriculture (USDA) interpreted the bill to prohibit the sale of industrial hemp across state lines

Agriculture Improvement Act of 2018 (2018 Farm Bill)

- Created a new definition of “hemp” and carved out “hemp” from the CSA’s definition of marijuana
- Excludes the THC in hemp from CSA Schedule I
- Did not change FDA’s authorities or the Federal Food, Drug, and Cosmetic Act
- Did not create restrictions on interstate commerce of hemp or hemp products, but did not change existing restrictions in other laws

FDA AND TTB

FEDERAL FOOD & DRUG ADMINISTRATION

- FDA considers the addition to food (a term that would encompass alcohol beverages) of the active ingredient in an approved drug, or one undergoing clinical trials, as a prohibited Act
- Nor is marijuana **Generally Recognized as Safe** (“GRAS”) under FDA food ingredient standards
- FDA continues to monitor the marketplace and recent warning letters indicate the FDA intends to focus on the inclusion of CBD as an “inactive ingredient” and creative labeling attempts to avoid federal regulations.
- Following the passage of the 2018 Farm Bill, FDA announced that it has not seen sufficient evidence to permit the addition of hemp-derived CBD to food (as a GRAS ingredient) or as a dietary supplement
- FDA has, however, recognized a variety of other hemp-derived ingredients as GRAS

FEDERAL FOOD & DRUG ADMINISTRATION:

SIX BASIC PRINCIPLES

1. FDA regulates Rx and OTC Drugs, Medical Devices, Food, Dietary Supplements, Cosmetics, Tobacco and Radiation-emitting devices (*e.g.*, cell phones, microwaves)
2. All FDA-regulated products must undergo premarket review by FDA unless they are exempt from this requirement
3. All products must conform to applicable regulations and controls to ensure that the product has the quality, purity and/or safety or effectiveness it purports to have
4. Claims about product benefits, risks, and health outcomes must be truthful, not misleading and substantiated by the appropriate level of scientific evidence required by law
5. FDA's jurisdiction is based on interstate commerce. Therefore, the agency's jurisdiction attaches to "products" and product-related "activities" in interstate commerce (defined as commerce between the states and/or instruments of interstate commerce (*e.g.*, mail, internet, transportation, etc.))
6. Any person or entity in the product supply or distribution chain may be liable for violations of the Federal Food, Drug and Cosmetic Act

FEDERAL FOOD & DRUG ADMINISTRATION: *ENFORCEMENT PRIORITIES*

1. FDA is currently concentrating its resources on products making “over the line” curative and related health claims.
2. Most enforcement involves public “Warning Letters.” FDA issued 5 warning letters in 2021, compared to the 22 it issued before the pandemic.
3. Not to say the FDA will not turn its attention to products with less egregious claims.
4. Variety of enforcement actions available including seizure, injunction, and prosecution.

COMMON CBD CLAIMS MENTIONED IN WARNING LETTERS

Both explicit and implicit claims suggesting CBD effectiveness in treating/preventing a disease or condition, including the following and many more

- Pain and inflammation
- Cancers
- Fibromyalgia
- Diabetes
- Arthritis
- Allergies
- Crohn's Disease
- Schizophrenia
- PTSD
- Opioid Addiction
- Psychosis
- Depression
- Anxiety
- Irritable Bowel Syndrome
- Glaucoma
- Cholesterol
- Alzheimer's Disease
- Autism
- Parkinson's Disease
- Stroke/TBI
- Asthma
- Cold and Flu Symptoms
- Insomnia
- Headache and Migraine Relief
- Coronavirus (COVID-19) and other viral infections (11 of 14 Warning Letters in 2020)

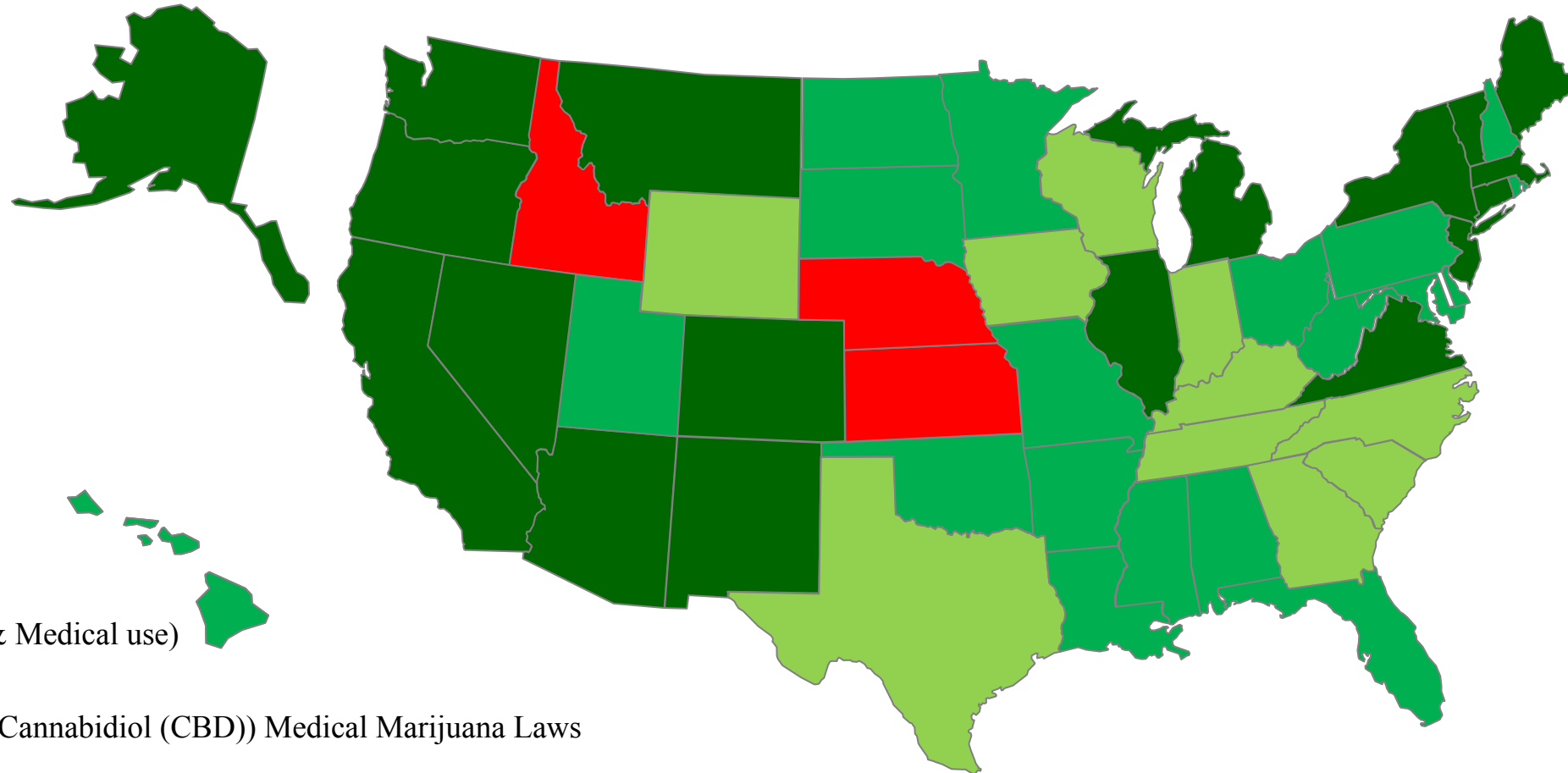


FEDERAL ALCOHOL AND TOBACCO TAX AND TRADE BUREAU (TTB)

- TTB has made it clear that it will not approve any formula for a product containing a Schedule I controlled substance
- TTB has also made it clear that it has conferred with FDA and will not approve a formula for a product containing ingredients not recognized as GRAS
- Even if a producer or importer could find a way around the formula requirement, TTB almost certainly would **not issue a COLA** (*i.e.*, approve a label) for an alcohol beverage whose label discloses the use of cannabis, CBD, THC, or another cannabis-derivative
- Like FDA, TTB takes a more **liberal stance towards hemp**, and there are a variety of hemp beers and spirits on the market

STATE REGULATION

THE STATE OF LEGALIZATION



KEY:

- Legal (Adult & Medical use)
- Medical Only
- Limited (e.g., Cannabidiol (CBD)) Medical Marijuana Laws
- Illegal

KEY MARKETS



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State	Legal Status	Medicinal	CBD Beverages?	Hemp Beverages?
California	Fully Legal	Yes	Yes	Yes
Florida	Mixed	Yes	No	Yes
Illinois	Fully Legal	Yes	Yes	Yes
New York	Fully Legal	Yes	Yes	Yes
Texas	Mixed	CBD Oil Only	No	Yes

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CRITICAL STATE LAW CONSIDERATIONS

- Just because state law authorizes the recreational production and sale of cannabis products does not mean that state law authorizes cannabis-infused beverages
- Indeed, to date **most states prohibit the production of alcohol beverages infused with cannabis**
- Many state marijuana codes even prohibit the storage of alcohol beverages on a “premises” licensed to produce, store, or sell cannabis
- Such rules could impact the ability to use a licensed premises to produce any cannabis-infused products, even those that do not fall within TTB’s regulatory authority

ALCOHOL BEVERAGE COMPANIES HAVE JUMPED IN

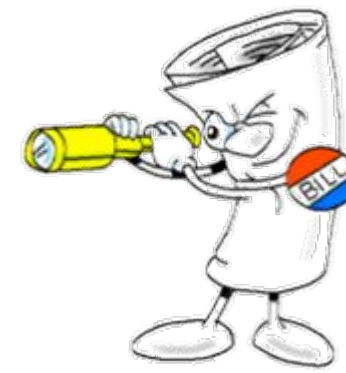
- **Constellation Brands** made a \$4 billion investment in Canada's Canopy Growth
- **Southern Glazer's** Canadian operation, Great North, has become the Canadian distributor for cannabis supplier Aphria
- **Lagunitas Brewing**, owned by **Heineken**, has licensed its name to a line of CBD- and THC-infused sparkling waters
- **Molson Coors** and **HEXO** formed Truss CBD which offers sparkling nonalcoholic CBD drinks
- Numerous small brewers and small-brewer start ups (*e.g.*, **Ceria Brewing**, founded by the original brew master of Blue Moon) have attempted to introduce infused beers or non-alcohol beers, sometimes attracting enforcement attention from TTB
- **Tilray's** acquisitions of **SweetWater Brewing Company**, **Breckenridge Distillery** and two California craft beer brands, **Alpine** and **Green Flash**

WHERE ARE WE HEADED?

BIG PICTURE

- Cannabis beverages are still a young market. Convergence is coming.
- States continue to lead the way on legalization and reform
- Federal Efforts
 - Biden administration lukewarm on legalization
 - Momentum led by Senators in legalized states to relax key federal limitations
 - Senator Schumer's Cannabis Administration and Opportunity Act
 - SAFE Banking Act
 - MORE Act
 - States Reform Act

BIG PICTURE



- Pending legislation suggests if Cannabis is de-scheduled that it would fall under TTB's jurisdiction for alcohol beverages
 - State control deference
 - Cannabis would be de-scheduled under the CSA
 - Permissible to transport cannabis in interstate commerce
 - **FDA to regulate cannabis products with same authority that it has with respect to alcohol**
 - Marijuana or Industrial Hemp would be deemed GRAS
 - **Cannabis-infused food and beverages to be regulated under FAA**

States Reform Act H.R. 5977 (introduced 11/15/2021)

THANK YOU / QUESTIONS?

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