



PROGRAM MATERIALS
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Hemp-CBD: Enabling Growth by Managing Legal Risks

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A dense, vibrant green background of hemp leaves, filling the entire frame. The leaves are serrated and have a distinct palmate shape, typical of cannabis plants. The lighting is bright, highlighting the texture and veins of the leaves.

Hemp-CBD: Enabling Growth by Managing Legal Risks

September 25, 2019

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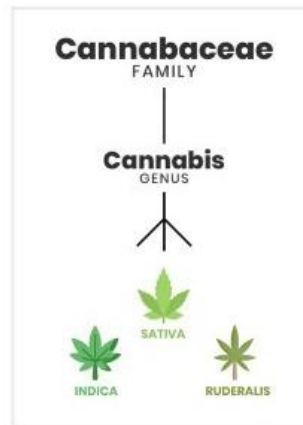
Agenda

- What are “Cannabis” and “CBD”?
- The 2018 Farm Bill, and Marketplace Growth
- Current Legal Status for Hemp/CBD Products
- FDA Developments, and the Road Ahead
- Tips for Manufacturers, Distributors, and Retailers of CBD Products



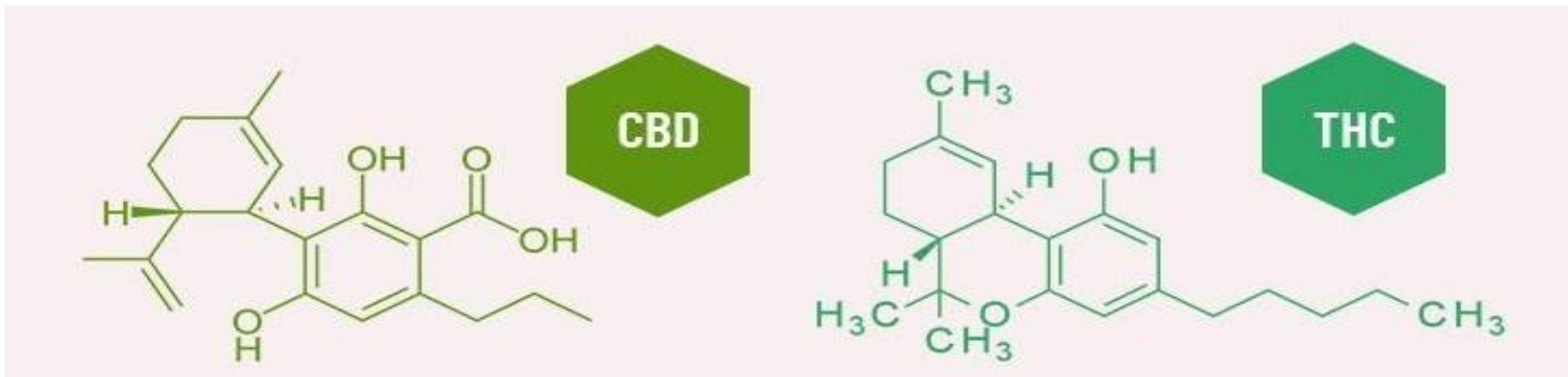
What is Cannabis?

- “Cannabis” – genus of flowering plants of the Cannabaceae family
 - Two genera: *Cannabis sativa* (hemp/“marijuana”), *Humulus lupulus* (hops) 
 - Three primary subspecies of *Cannabis sativa*, though the number is widely debated: *C. sativa sativa*, *C. sativa indica*, and *C. sativa ruderalis*
 - “Marijuana” often synonymous with the cannabis plant, typically refers to drug-use of the plant, negative history, and is a widely disfavored term
- “Hemp” is the *C. sativa* L. plant containing < 0.3% THC, historically grown for industrial use



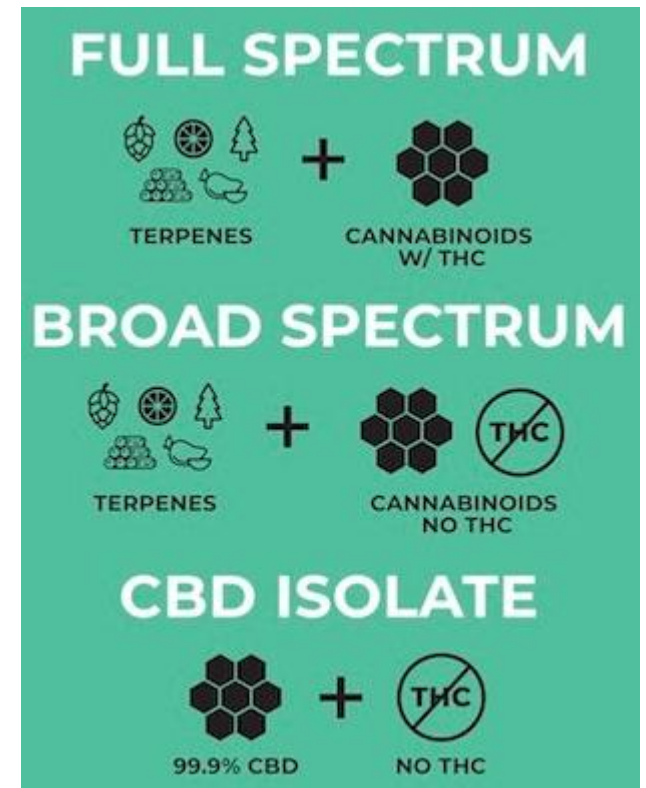
What is CBD?

- Cannabis contains naturally occurring compounds, called “cannabinoids”
 - More than 100 cannabinoids in the plant that work in harmony to create a variety of biological effects (CBC, CBG, CBN, THC, CBD...)
 - The primary psychoactive cannabinoid is Δ -9 tetrahydrocannabinol (THC)
 - Cannabidiol (CBD) is also a cannabinoid, similar in structure to THC. Clinical research is investigating impacts of CBD on anxiety, cognition, movement disorders, and pain



More CBD Terms

- “Full spectrum” CBD – full plant extract, with more compounds such as other cannabinoids (e.g. THC) and terpenes
- “Broad spectrum” CBD – CBD is isolated from the plant, typically no THC
- CBD isolate – further refined, ~ 99% pure CBD
- “Hemp oil” – Typically refers to oil derived from hemp seeds, which do not contain the same level of compounds as the leaf / flower
- “CBD oil” – Oil containing CBD that has been extracted from the plant



The 2018 Farm Bill

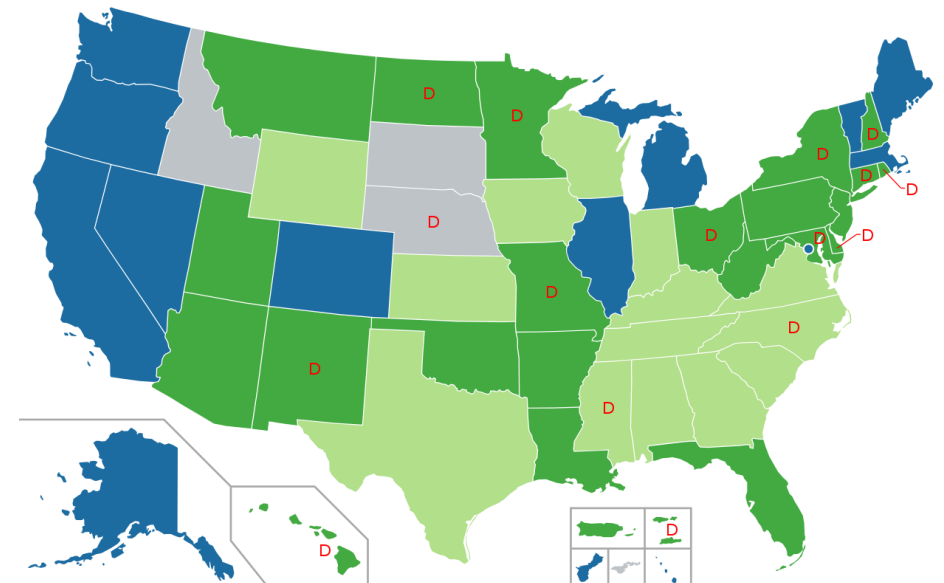
- Removes “hemp” from Schedule I of the Controlled Substances Act
 - Defines “hemp” as *Cannabis sativa L* containing < 0.3% THC (dry weight)
- Instructs USDA to implement program for commercial production of hemp
 - Regulations expected Fall 2019 (before 2020 growing season)
- After USDA program established, hemp may be grown:
 1. With valid USDA license; OR
 2. Under USDA-approved State or Tribal plan; OR
 3. Under 2014 Farm Bill pilot program (which will expire 1 year after USDA program established)
- Also after program established, states and Indian tribes may not prohibit interstate transportation or shipment of hemp lawfully produced under USDA license
 - Until then, states/Indian tribes may not prohibit if produced lawfully under 2014 Farm Bill
- But, states/Indian tribes may further restrict hemp production
- Does not affect FDA authority to regulate hemp under FDA laws



Legal Status of Cannabis/CBD

- State Laws:

- 33 states and the District of Columbia currently have passed laws broadly legalizing cannabis in some form
 - Just because a state may have legalized cannabis does **not** mean hemp-CBD can be put into consumables or sold in the legal cannabis marketplace
- Other states have passed or are in the process of passing laws allowing the use of CBD extract, usually in oil form, for the treatment of epilepsy or seizures in seriously ill children



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FDA - Current Legal Hurdles

- Hemp-derived CBD is NOT permitted in foods, beverages, or dietary supplements
 - Not an approved food additive
 - Not “Generally Recognized As Safe” (GRAS)
 - Not commonly used in food before 1958
 - Substantial clinical investigations conducted, and existence of investigations made public
See FDCA §301(l) (food) & 201(ff)(3)(B)(ii) (supplement)
- Certain hemp seed products ARE permitted
 - Dehulled hemp seed, hemp seed protein powder, hemp seed oil
 - Subject to GRAS petitions



FDA - Current Legal Hurdles (cont.)

- **PERMITTED** in cosmetics, with limitations
 - No unallowed ingredients, color additives
 - Subject to adulteration and misbranding provisions of FDCA
 - Labeling regulations
- **NOT** permitted in animal feed or pet food
 - CBD not reviewed by AAFCO
 - AAFCO has asked industry to submit data
- **Vaping: gray(ish) area**
 - No clear statement from FDA
 - FDA may consider CBD-only vapes to be drugs, devices, or both



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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!

FDA Developments

- May 31, 2019 Public Hearing

- FDA needs (a lot) more scientific / medical data
 - Safe dosing
 - Effects on different patient populations
 - Consistent terminology
- FDA needs to understand the consequences of widespread use in food supply
 - Including adverse event information
- Youth access, restrictions on sales to minors
- No discretionary enforcement, yet also no real active enforcement
- Consumer groups want quality standards, label accuracy

FDA Developments (cont.)

- Pressure on FDA to act fast
 - All stakeholders expressed desire for clarity
 - Most commenters appeared to accept that some level of regulation inevitable
 - But, FDA will act only on solid scientific data
- FDA working committee is exploring regulatory options
 - Information expected starting August 2019 ... but none, yet

* For more information on the public hearing, see “What We Learned From FDA's Public Hearing On Cannabis,” (June 4, 2019)
<https://www.law360.com/articles/1165563/what-we-learned-from-fda-s-public-hearing-on-cannabis>

FDA Developments (cont.)

- Enforcement by FDA/ FTC has focused on egregious health claims

On your website www.relievuscbdoin.com: Webpage titled – “Health Benefits”

- “CBD successfully stopped cancer cells in multiple different **cervical cancer varieties.**”
- “CBD also decreased human glioma cell growth and invasion, thus suggesting a possible role of CBD as an antitumor agent.”
- “CBD may also protect brain cells from **beta amyloid toxicity**, making it a potential therapeutic agent in **Alzheimer’s and Parkinson’s disease.**”
- “CBD, due to its anti-inflammatory and antioxidant properties, may be a promising agent to treat and prolong survival in **Amyotrophic Lateral Sclerosis (ALS)** patients.”
- “CBD is a potential treatment for **psychosis.**”
- “CBD improves the symptoms of **schizophrenia.**”
- “Cannabidiol May Treat **Depression**”

On your website www.relievuscbdoin.com: Webpage titled – “Indications”

a list of indications that we can treat with our hemp oil products . . .
ic Inflammation . . . **Cancer Pain . . . Depression . . . Chronic Pain .**

. . . Alzheimer’s disease . . . **Amyotrophic Lateral Sclerosis (ALS)** . . .
immune Disorders . . . **Cancer . . . Chronic inflammation . . . Chronic**
ease . . . **Depression . . . Diabetes . . . Inflammatory Bowel Disease**
ulsive disorder (OCD) . . . **Panic disorder . . . Parkinson’s disease .**
ess disorder (PTSD) . . . **Rheumatoid arthritis . . . Schizophrenia .**
orders”

Your products “**Hemp Oil**” and “**CBD Softgels**” are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are “new drugs” under the FDCA.

“PAINBOMB HAS RELIEVED PAIN AND TREATED THE FOLLOWING CONDITIONS: Arthritis pain, back pain, bone metastases/cancer pain, diabetic neuropathy, . . . fibrocystic breasts, fibromyalgia, glaucoma pain, gout, . . . lupus, . . . MS, osteoarthritis, **restless leg syndrome, rosacea, sciatica, shingles.**”

“PainBomb is also **Antiseptic, Antibacterial, Anti-Viral & Anti-Tumoral.**”

Claims on the label of CBD Muscle Gel that demonstrate its intended use as a drug:

- “Hand crafted with the most effective herbal ingredients for rapid **relief of aching, painful joints, muscles and tissues.**”
- “Uses: For the temporary relief of **minor aches and pains** at muscles and joints associated with sore muscles, strains, **joint discomfort & arthritis.**”

FDA Developments (cont.)

- Total of 23 Warning Letters sent to manufacturers to date
 - Majority cited hemp or CBD-derived oils, tinctures, and other ingestibles (e.g., gummies, lollipops, and capsules)
 - One-third of the letters mentioned topical products, such as salves and lotions
 - One quarter of the letters discussed vape products (e.g., e-liquid, vape pens)
- Most recent letter issued in July, 2019
- All letters cite to claims made on web sites and/or social media (e.g., Facebook, Twitter)
 - Testimonials are promotional in nature
- 4 letters issued to companies selling pet products
 - Pet anxiety, including separation anxiety, are not permitted

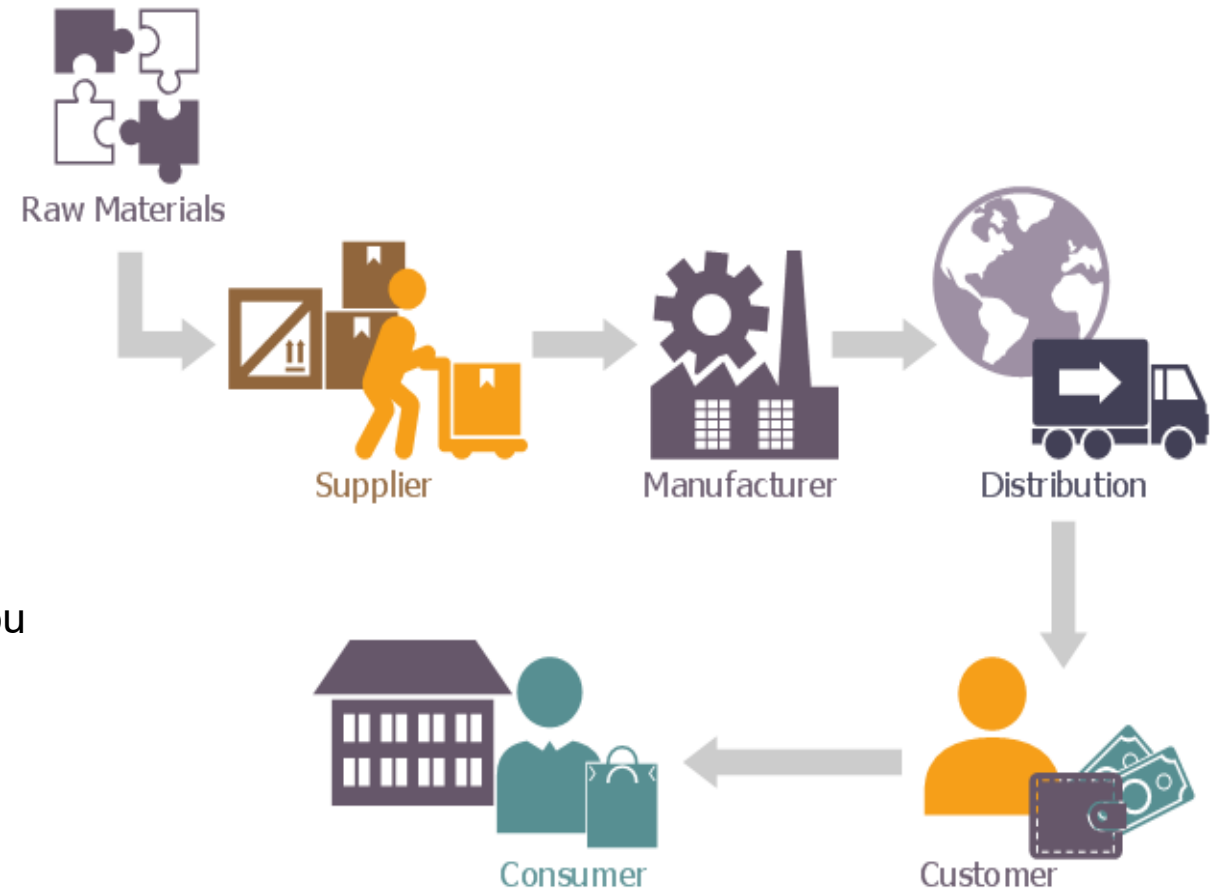
FDA Developments (cont.)

- What can we expect in the near term?
 - FDA will be in data collection mode
 - FDA will not pass a regulation to permit CBD
 - Congressional action not likely
 - FDA could act on a new dietary ingredient or GRAS notification for low-risk/ low-dose products (and with certain limitations)
 - FDA could use enforcement discretion for very low-dose CBD supplements



Supply Chain & Potential Liability Exposure

- FDCA prohibits introduction or delivery of adulterated or misbranded products. Also covers receipt in interstate commerce, proffered delivery for pay
 - States have similar regulations
 - Product liability lawsuits implicate the entire chain
- **Tips to reduce risks:**
 1. Vet your manufacturers and the products you sell
 2. Have contracts with your manufacturers that specify:
 - Manufacturer's product safety requirements
 - Liability for defects or other problems
 - Manufacturer's agreement to fund defense costs if you are sued over a problem arising from the manufacturer's product
 - Requirement to maintain adequate insurance
 3. Get good insurance
 4. Have a recall plan



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Tips for Enabling Growth



1. Transportation across state lines
 - USDA non-binding opinion letter
 - Seizures still happen
2. Online sales
 - Legal risks of selling hemp-derived CBD products via e-commerce are low but still exist...
3. Shipping via USPS
 - USPS authorizes the mailing of Hemp-CBD products so long as it complies with certain requirements.
 - **Caveat:** Mailing Hemp-CBD food and dietary supplements would not be lawfullyailable given that these products violate the Food, Drug, and Cosmetic Act (i.e., the laws enforced by the FDA); however, this issue has yet to be administratively litigated.

Tips for Enabling Growth (cont.)

4. Consider state laws – constantly evolving!
 - Example: California AB-228
 - Local enforcement agencies
5. Product labels – accuracy is key
 - Accurate disclosure contents
 - No undeclared ingredients
6. Product quality, consistency – a differentiator in an emerging market
 - Raw material quality – know your supply chain
 - Manufacturing consistency
7. Review claims in labeling, advertising and marketing
 - Stay away from “drug” claims, including pain relief and anxiety
 - Cosmetic claims are OK



Best Practices in Action



- A Chicago-based maker of hemp-derived CBD products ships products to just 40 states, where those products are not explicitly prohibited and where there has been no enforcement action against product manufacturers to date
- A Colorado hemp-CBD company pays state sales taxes to every state where it ships products
- A national distributor of CBD products requires its brand partners to have certificates of analysis that show products have been tested for potency and contaminants, and it does not feature products that make medical claims
- Many reputable manufacturers of cannabis-infused and hemp-derived CBD products avoid making medical claims on their products' labels, packaging and websites. As one CEO said, "We have an obligation to be responsible actors. I see products that overreach in some claims, and that paints the entire category in not a great light."

Questions?

Thank you for joining us!



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