CBD?

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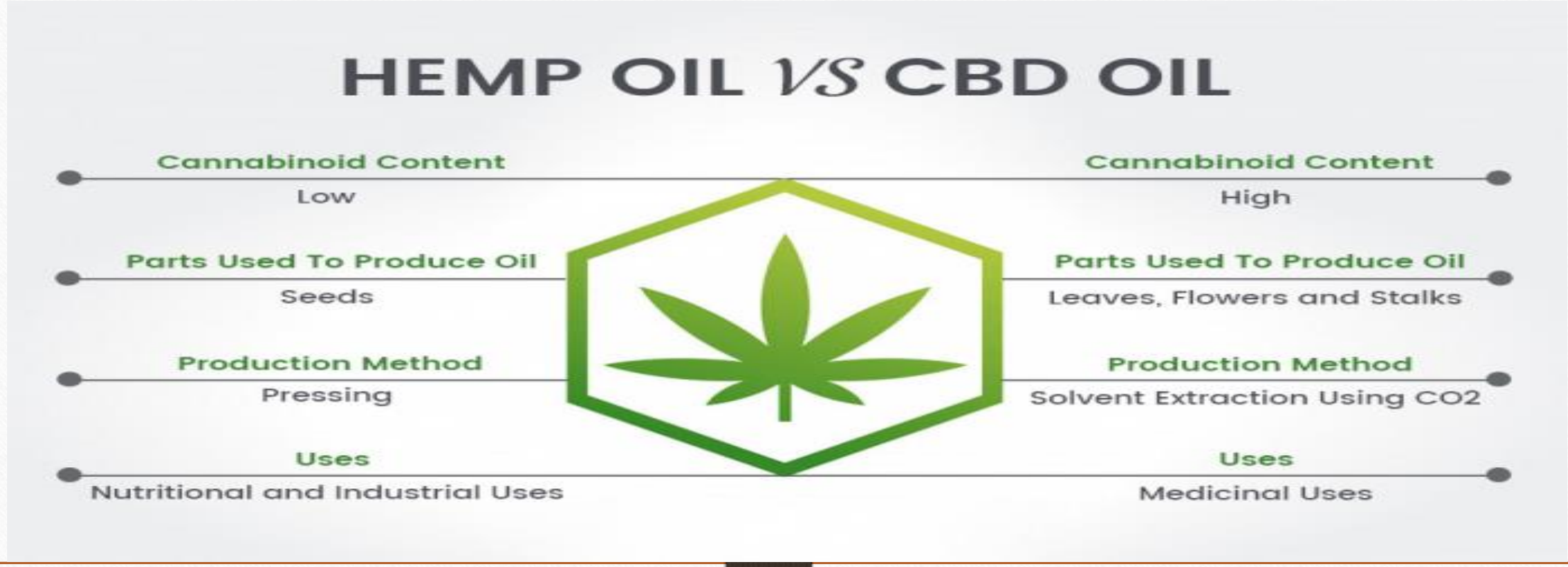
Disclosure Statement

I have no financial relationship in regard to the content of this presentation - JDW

What are cannabis, CBD, HEMP and marijuana?

- Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the Cannabis sativa plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21 U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

What are CBD and HEMP?



How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?

At the federal level, the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, 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."** These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that **contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.**

The 2018 Farm Bill, however, **explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act** (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?

To date, the agency has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

FDA has approved Epidiolex, which contains a purified form of the drug substance CBD for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means FDA has concluded that this particular drug product is safe and effective for its intended use.

The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients.

Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?

- No. There are no other FDA-approved drug products that contain CBD. We are aware that some firms are marketing CBD products to treat diseases or for other therapeutic uses , and we have issued several warning letters to such firms. Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. CBD was not an ingredient considered under the OTC drug review. An unapproved new drug cannot be distributed or sold in interstate commerce.

Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?

Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns.

The agency has and will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved.

Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?

FDA is aware that unapproved cannabis or cannabis-derived products are being used for the treatment of a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition and thus has not determined that cannabis is safe and effective for any particular disease or condition. The agency has, however, approved one cannabis-derived and three cannabis-related drug products

Is it legal for me to sell CBD products?

It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.

We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.

Will FDA take action against cannabis or cannabis-related products that violate the FD&C Act?

The FDA has sent warning letters in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

What is the Federal Food, Drug, and Cosmetic Act (FD&C Act)?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) is a federal law enacted by Congress. It and other federal laws establish the legal framework within which FDA operates. The FD&C Act can be found in the United States Code, which contains all general and permanent U.S. laws, beginning at 21 U.S.C. 301.

FDA develops regulations based on the laws set forth in the FD&C Act or other laws under which FDA operates. FDA follows the procedures required by the Administrative Procedure Act, another federal law, to issue FDA regulations. This typically involves a process known as "notice and comment rulemaking" that allows for public input on a proposed regulation before FDA issues a final regulation. FDA regulations are also federal laws, but they are not part of the FD&C Act. FDA regulations can be found in Title 21 of the Code of Federal Regulations (CFR).

State Regulations

With the adoption of SB 1020 the Florida Legislature established the necessary framework for a wholistic hemp and hemp product marketplace. The bill provides critical definitions and regulatory authority to the Florida Department of Agriculture and Consumer Services (FDACS) to seek approval for Florida's hemp plan from the federal government. The bill further provides legislative findings that hemp is an agricultural commodity and hemp-derived cannabinoids, including but not limited to hemp-derived cannabidiol, are not controlled substances or adulterants. The legislative findings, along with the removal of "hemp" and "industrial hemp" from the Florida Controlled Substance Act, s. 893.02, F.S., ends decades of hemp prohibition in Florida.

The bill defines "Hemp" 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 thereof, whether growing or not, that has a total delta-9 tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry-weight basis."

State Regulations

A license from FDACS will be required to cultivate hemp. There is no cap or limit on the number of hemp cultivation licenses available. License applications will have to be submitted on a form developed by FDACS, along with a full set of fingerprints. FDACS will adopt rules for the issuance and renewal of hemp licenses. A licensee will be required to provide FDACS with the legal land description and global positioning system coordinates of the location where hemp will be cultivated. A registry of land where hemp has been grown within the past three calendar years will be maintained, and that information will be reported to the U.S. Secretary of Agriculture each month. FDACS and law enforcement may enter private premises where hemp is being cultivated during regular business hours to perform random inspections.

State Regulations

FDACS must deny licenses to applicants if it is determined that an applicant has falsified any information in an application for a hemp license or hemp license renewal, or if the applicant has been convicted of a felony related to controlled substances within the past ten years. Licensees may only cultivate hemp seeds or cultivars that have been "certified" by a seed certifying agency or a university conducting a hemp pilot project pursuant to s. 1004.4473.

State Regulations

The bill provides that hemp extracts **may only be distributed and sold** in Florida if the extract has been batch **tested** by an independent testing laboratory. The independent **lab test must show** the total delta-9 THC in the extract does not exceed 0.3 percent on a dry-weight basis, and it does not contain contaminants unsafe for human consumption. Hemp extracts **must** be **distributed and sold** in packaging that includes a scannable barcode or quick response code (QR code) linked to the certificate of analysis produced by the independent laboratory. The packaging must also include the **batch number**; **web address where batch information is available; the expiration date; milligrams of hemp extract; and a statement that the extract contains a total delta-9 tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry-weight basis.**

WHAT ANOTHER LAWYER SAYS…

From David Evans, a lawyer for Cannabis Industry Victims Educating Litigators, who noted he has 1,000 cases pending against the opioid industry: "If our dreams come true, we'll have the same thing going against the marijuana industry in a year or two."