

DON'T GET BURNED: WHAT TEXAS PROVIDERS NEED TO KNOW ABOUT MEDICAL CANNABIS & CBD OIL

Jerri Lynn Ward, J.D.

www.garloward.com

Lisa Mahfouz Morris

<http://www.lakewaybotanicals.com/>

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DISCLAIMER

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- ▶ Federal and State History of Prohibition
- ▶ Controlled Substances Act
- ▶ Farm Bill 2014 & 2018--Hemp
- ▶ DEA Marijuana Extract Definition & Policy Statements
- ▶ Texas Statutes & Regulations
- ▶ Consumer Use
- ▶ Employment issues
- ▶ Risk Management

OVERVIEW



- ▶ 1937: The Marihuana Tax Act is enacted, effectively prohibiting cannabis at the federal level. Although medical use is still permitted, new fees and regulatory requirements significantly curtail its use.
- ▶ 1969: The Marihuana Tax Act is struck down in the case *Leary v. United States*. The Supreme Court ruled that the act violated the Fifth Amendment's protection against self-incrimination.
- ▶ 1970: The Controlled Substances Act is enacted. Cannabis is classified as a Schedule I drug, determined to have a high potential for abuse and no accepted medical use, thereby prohibiting its use for any purpose.
- ▶ 1990: The Solomon–Lautenberg amendment is enacted. As a result, many states pass laws imposing mandatory driver's license suspensions for persons caught possessing cannabis, even if unrelated to driving.
- ▶ 2014: The Rohrabacher–Farr amendment passed the U.S. House and was signed into law. Requiring annual renewal, it prohibits the Justice Department from interfering with the implementation of state medical cannabis laws.
- ▶ 2018: The 2018 farm bill legalizes low-THC hemp nationwide and effectively deschedules hemp-derived cannabidiol (CBD) from the Controlled Substances Act.

FEDERAL HISTORY

- ▶ The Controlled Substances Act (CSA) is the primary federal code regulating and criminalizing drugs in the United States.
- ▶ Under the CSA, both marijuana and synthetic THC are classified as Schedule 1 drugs, which have been determined to have a high potential for abuse with no medically accepted uses
- ▶ The nationwide trend seems to be towards decriminalization of marijuana, but it is likely to remain illegal federally for the short term.
- ▶ Fortunately, industrial hemp has been excluded from the CSA's definition of marijuana.

FEDERAL CONTROLLED SUBSTANCES ACT

- ▶ The CSA defines 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.”

HOW ARE WE GETTING AROUND IT?
SAVED BY A LEGAL FICTION

To add more clarification to the text, the Farm Bill of 2018 amended the CSA to add that “the Term ‘marihuana’ does not include hemp, as defined in Section 297A of the Agricultural Marketing Act of 1946.”

THE LEGAL FICTION



- ▶ The 2014 Farm Bill made hemp legal if used for research and under State department of agriculture oversight.
- ▶ Sec. 7606: Legitimacy of Industrial Hemp Research: legalized hemp research for institutions of higher education and State departments of agriculture.
- ▶ To give “teeth” to the Farm Bill, Congress de-funded the Department of Justice with regards to hemp enforcement. Section 729 of the Act states that “none of the funds made available by this act or any other act may be used in contravention of section 7606 of the Agricultural Act of 2014; or to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with subsection 7606 of the Agricultural Act of 2014.

FARM BILL 2014

- ▶ Hemp is no longer limited to the pilot research program and was removed from the CSA list of Schedule I substances and will be treated the same as any other commodity crop.
- ▶ Any state that wishes to produce hemp commercially may do so.
- ▶ The 2018 Farm Bill includes restrictions for states that wish to regulate the production of hemp.
 - ▶ States must submit to the Secretary of Agriculture a plan to “monitor and regulate” production, including information about the land on which hemp is produced, a procedure for testing the THC levels of hemp, and a procedure for effective disposal of unlawful plants, and a procedure for conducting annual inspections of hemp

2018 FARM BILL

- ▶ Since the 2018 Farm Bill makes the entire plant legal when properly sourced, the extracts (CBD) from the plant are also legal.
- ▶ However, Industrial hemp manufacturers must be careful that the THC limit of .3% is met in order for the Farm Bill's protections to apply.
- ▶ USDA working on regulations.

2018 FARM BILL 2018 & UPDATES

- ▶ The FDA recognized that hemp was legalized by the Farm Bill, but they have the authority to regulate it, especially when cannabis products are involved in interstate commerce. (Under the Federal Food, Drug, and Cosmetic Act and Section 351 of the Public Health Service Act.)
- ▶ Producers CANNOT market a cannabis-derived product with claims of therapeutic benefit before the product is approved by the FDA.
- ▶ CBD products have received warning letters from the FDA after marketing their products as treatments to diseases like cancer, Alzheimer's, and diabetes.

FDA STATEMENT ON SIGNING OF THE FARM BILL (2018)

- ▶ In June 2018, the FDA approved the drug “Epidiolex,” which contains cannabis-derived CBD, for the treatment of seizures.
 - ▶ Since CBD is now an ingredient in an active and approved drug, it is unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce or to market these products as dietary supplements, regardless of whether the substances are hemp-derived or marijuana derived.
 - ▶ Three exceptions:
 - ▶ Hulled hemp seeds
 - ▶ Hemp seed protein
 - ▶ Hemp seed oil

APPROVAL OF EPIDIOLEX AND ITS EFFECT ON CBD PRODUCTS

- ▶ On May 22, 2018, the DEA published a directive regarding the presence of cannabinoids in products made from the cannabis plant.
- ▶ It stated that “products and materials that are made from the cannabis plant and which fall outside of the CSA definition of marijuana (such as sterilized seeds, oil, or cake made from the seeds, and mature stalks), are not controlled under the CSA.
- ▶ Since the passage of the 2018 Farm Bill, the DEA has not published any additional updates
- ▶ However, hemp (and hemp-derived products) are legal under the 2018 Farm Bill and the DEA is mandated to follow that law.

DEA MARIJUANA EXTRACTION DEFINITION AND POLICY STATEMENTS

- ▶ **1915 El Paso ban**—Racial implications
- ▶ **1919 Sale restricted**--In 1919, legislation was enacted to prohibit the transfer of narcotics, including cannabis, for non-medical use. Transfer of cannabis in this manner was made a misdemeanor crime; however, possession of the drug still remained legal.
- ▶ **1923 Further restrictions**--In 1923, legislation was enacted to prohibit the possession of narcotics, including cannabis, with intent to sell. As a result of this law, cannabis could no longer be purchased over-the-counter at pharmacies (only by prescription).

TEXAS HISTORY

- ▶ Possession of cannabis was banned statewide in 1931. Until 1973 it would remain classified as a narcotic with the possibility of life sentences imposed for possession of small amounts.
- ▶ 1973 Texas Controlled Substances Act.

CONTINUED

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- ▶ 1973 Significantly reduced penalties from felony resulting in 2 years to life to Class B Misdemeanor with \$1,009 fine and no more than 180 days.
- ▶ 2007—Cite and release allowed.
- ▶ 2015– Texas Compassionate Use Program
- ▶ 2019
 - ▶ Reduces Penalties—up to one oz, Class C misdemeanor.
 - ▶ Expands TCUP to additional conditions.
 - ▶ Hemp legalization

TEXAS LOOSENING OF LAWS

- ▶ Texas Compassionate Use Program
- ▶ Hemp

TEXAS STATUTES

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- ▶ Medical Cannabis program, allows prescription of Low-THC cannabis.
- ▶ Qualifying conditions:
 - ▶ epilepsy, multiple sclerosis, spasticity, autism, ALS, terminal cancer, and neurodegenerative disease.
- ▶ How qualify as patient?
 - a. A patient is a permanent resident of the state
 - b. A patient is diagnosed with one of the qualifying conditions
 - c. The qualified physician determines the risk of the medical use of low-THC cannabis by a patient is reasonable in light of the potential benefit for the patient
- ▶ 3. Will patients have to register with the state or pay a fee?
 - ▶ No requirement that patients register with or pay fee to state.

TEXAS COMPASSIONATE USE PROGRAM

- ▶ Can you grow your own cannabis?
 - ▶ No. Only licensed dispensers will be able grow cannabis and only for use in the production of low-THC cannabis. Patients are required to purchase low-THC cannabis products from a licensed dispensing organization.
- ▶ Is CBD covered by insurance?
 - ▶ No.
- ▶ What is Low-THC cannabis?
 - ▶ "Low-THC cannabis" means the plant *Cannabis sativa* L., and any part of that plant or any compound, manufacture, salt, derivative, mixture, preparation, resin, or oil of that plant that contains not more than 0.5 percent by weight of tetrahydrocannabinols.

T-CUP CONTINUED...

- ▶ Licensed physician
- ▶ Board certified in a medical specialty relevant to the treatment of the patient's medical condition by a specialty board approved by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists; and
- ▶ Dedicating a significant portion of clinical practice to the evaluation and treatment of the patient's particular medical condition.

WHO CAN PRESCRIBE?

- ▶ Three businesses are presently licensed to cultivate, process and dispense under T.C.U.P.

DISPENSARIES

"Controlled substance" means a substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Group 1, 1-A, 2, 2-A, 3, or 4. The term includes the aggregate weight of any mixture, solution, or other substance containing a controlled substance. The term does not include hemp, as defined by Section 121.001, Agriculture Code, or the tetrahydrocannabinols in hemp.

TEXAS CONTROLLED SUBSTANCES ACT

- ▶ Federally approved therapeutic research program.
- ▶ Low-THC cannabis if:
 - ▶ Valid prescription.
 - ▶ In permitted business.

EXCEPTIONS



- ▶ "Marihuana" means the plant *Cannabis sativa* L., whether growing or not, the seeds of that plant, and every compound, manufacture, salt, derivative, mixture, or preparation of that plant or its seeds. The term does not include:
 - ▶ the resin extracted from a part of the plant or a compound, manufacture, salt, derivative, mixture, or preparation of the resin;
 - ▶ the mature stalks of the plant or fiber produced from the stalks;
 - ▶ oil or cake made from the seeds of the plant;
 - ▶ (D) a compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, fiber, oil, or cake;
 - ▶ E) the sterilized seeds of the plant that are incapable of beginning germination; or...

HEMP & CBD OIL

- ▶ Hemp, as that term is defined by Section 121.001, Agriculture Code.

Sec. 121.001. DEFINITION. In this chapter, "hemp" means the plant *Cannabis sativa* L. and any part of that plant, including the seeds of the plant 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 on a dry weight basis.

- ▶ Now legal to buy CBD oil over the counter if no more that .3% THC.

CBD OIL OUTSIDE T-CUP

- ▶ Zero-tolerance & Drug testing—will CBD oil make you fail?
 - ▶ USDA limit of THC—50mg/ml but,
 - ▶ Some tests search for all cannabinoids.
 - ▶ CBD oil contains some THC. (Except Isolates)
- ▶ Medical cannabis & Americans with Disability Act.

EMPLOYEES



- ▶ Always start with policies and procedures.
- ▶ Collaborate with health professionals and IDD authority
- ▶ Check sources of CBD oil.
- ▶ Marijuana Law Enforcement.

RISK MANAGEMENT

The End



Lakeview
BOTANICALS



Science of CBD
– Cannabidiol

PRESENTED BY LISA
MAHFOUZ MORRIS

OCT 31, 2019



CANNABIS ANATOMY 101

CBD is short for CANNABIDIOL

CANNIBIDIOL is the Dominant Cannabinoid
present in the FLOWER of Hemp PLANTS

What is a Cannabinoid? CBD?

Over 120 Cannabinoids exist in the botanical species, "Cannabis Sativa L." or HEMP plant with over 200 Terpenes & Flavonoids. This is referred to as FULL Spectrum CBD-Entourage effect

HEMP is grown to produce 99.7% Cannabidiol "CBD" with .3% of THC

CBD is non-psychoactive, non-toxic

Cannabis plants grown to produce a "high" THC-TetraHydroCannabinol also a cannabinoid is known as Marijuana-psychoactive compound

TEXAS Medical Marijuana is grown by the Department's Compassionate Care Program with .5% THC maximum content.

Cannabinoids–Human, Animals & Plants

Cannabinoids are found in humans, animals & plants that interact with CB1 & CB2 receptors throughout the body.

Endocannabinoid System is part of our Immune System and is a master regulation for many systems

CBD is Safe for Topical Use, Ingestion and Sublingual delivery

- Encourages Homeostasis or Balance for all systems
- US Dept. Of Health & Human Services Patent 6,630,507 States: "Cannabinoids have been found to have antioxidant properties...Non-psychoactive cannabinoids, like Cannabidiol, are particularly advantageous to use to avoid toxicity..."
- Robust Research of 1100 clinical studies are currently underway studying CBD, THC and other components of the Cannabis plant species; HEMP & Marijuana

Endocannabinoid System and CBD

How it Works?

When the body produces its own cannabinoids it called an "endocannabinoid"

Endocannabinoids connect with receptors called cannabinoid receptors.

- Two main receptors are CB1 and CB2

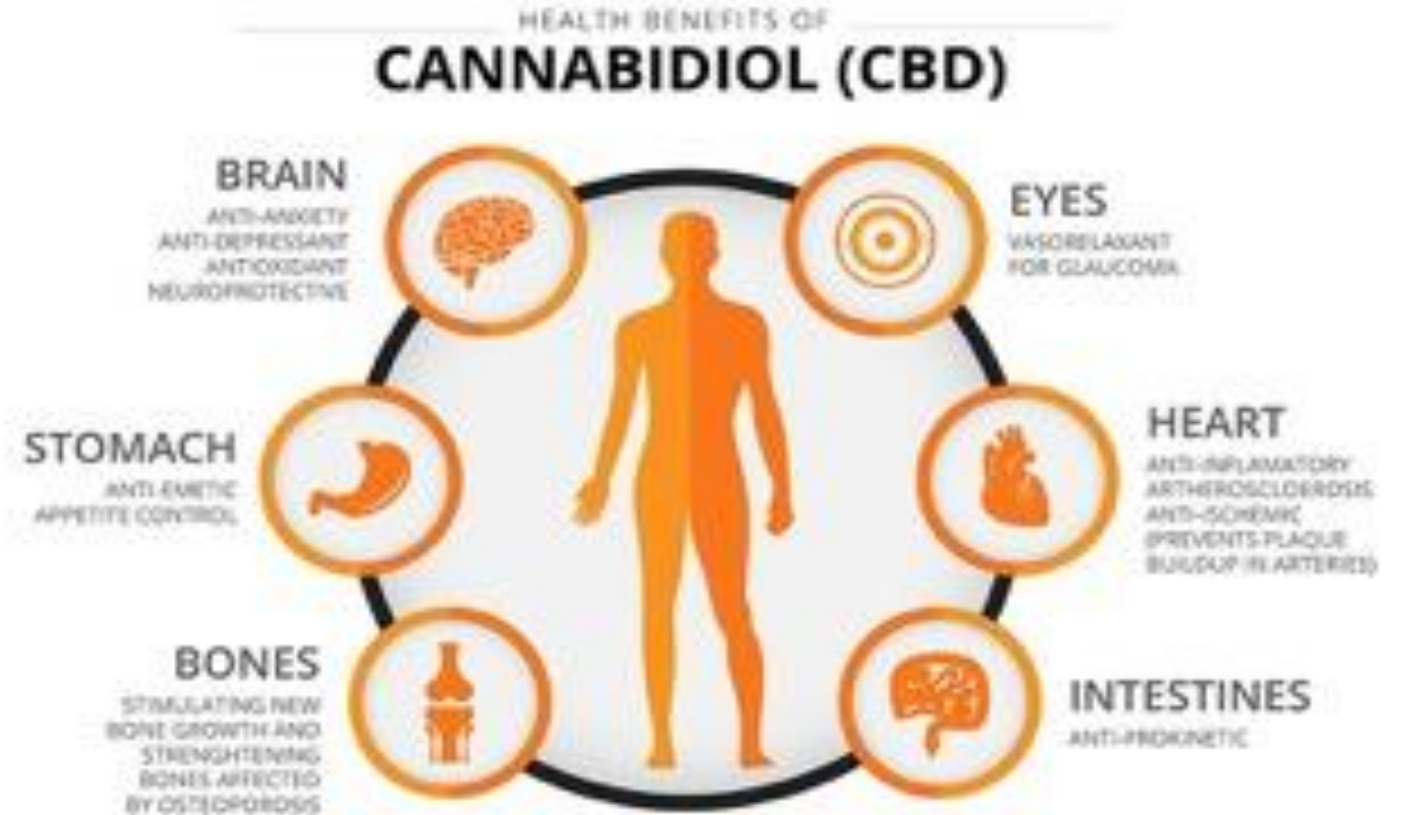
Cannabidiol – CBD – Strengthens and Improves Efficacy of Mitochondria, the Power Source for Every Cell in your Body

Research indicates that when you supplement your body's Endocannabinoid System with CBD, it is possible to develop and maintain a healthier endocannabinoid system

Health Benefits CBD may Influence

DISCLAIMER:

These statements have not been evaluated by the FDA, and are not intended to diagnose, treat, cure or prevent any diseases. Consult with your licensed healthcare provider before using any natural products.



ENTOURAGE EFFECT of CBD

Cannabinoids, Terpenes and Flavonoids comprised in the HEMP plant work together to produce "Entourage Effect"

FULL SPECTRUM-When the full spectrum of compounds is extracted from the HEMP plant, it creates a synergy or "ENTOURAGE EFFECT" to UNLOCK CBD's full potential and efficacy -- homeostasis.

- HEMP Legal Limit in TEXAS is .3%
- CBD oils may contain full spectrum compositions in a wide range from .01% up to .3%

CBD, THC FREE-Cannabinoids, Terpenes extracted from HEMP plants with untraceable amounts of the cannabinoid THC known as broad spectrum. THC and CBD exist in a natural equilibrium; the more CBD a cannabis plant has, the less THC it has and vice-versa.

CBD ISOLATE – Purest form of CBD in scientific terms "isolate" removes (Co2 extraction) other cannabinoids, terpenes and flavonoids to produce only CBD.

FORBES Magazine

"Cannabis for the Non-Stoner"

Article by K. Alindahao

"CBD is extremely anti-inflammatory and neuroprotective." says [Dr. Shivani Amin](#), a physician and cannabis expert who is a member of the [AMMPA \(American Medical Marijuana Physicians Association\)](#).

Dr. Amin says, " I have treated many patients with chronic conditions with full spectrum CBD and attained great results... CBD works in conjunction with THC. Usually this requires at least 3–5% THC to work for serious forms of pain and more chronic medical conditions. I have patients come in with chronic and severe pain expecting to have their pain alleviated with just CBD. Although CBD works well for pain, in many situations patients with severe pain need to have some THC. [The cannabinoids] work synergistically to help ease severe pain."

CBD .3% vs Texas Medical Marijuana .5%

Texas Medical Marijuana Compassionate Care Program Includes:

Seizure Disorders

ALS

Autism

Terminal Cancer

Parkinson's Disease

Multiple Sclerosis – MS

*EPIDIOLEX is the only FDA Approved CBD indicated for a very rare, uncontrollable form of Epilepsy in Children ages 2 and older.

*MARINOL is the only FDA Approved Synthetic THC indicated for terminal cancer pain, and for wasting syndrome in AIDS patients.

CBD Quality, Purity and SAFETY

QR Codes Product
Traceability - Certificates of
Analysis

Cannabidiol MG – Label
Content

MG Servings per Day

(Approx. Half-Life 24-72 Hours)



Rigorous, Strictest Testing &
Verification Process Beyond 3rd Party
Testing – Industry Gold Standard

Different KINDS OF CBD

Water
Soluble

Liposomal

Oils &
tinctures

Topicals

Capsules

Airless, Lock
Delivery

THANK YOU !

QUESTION & ANSWERS

