

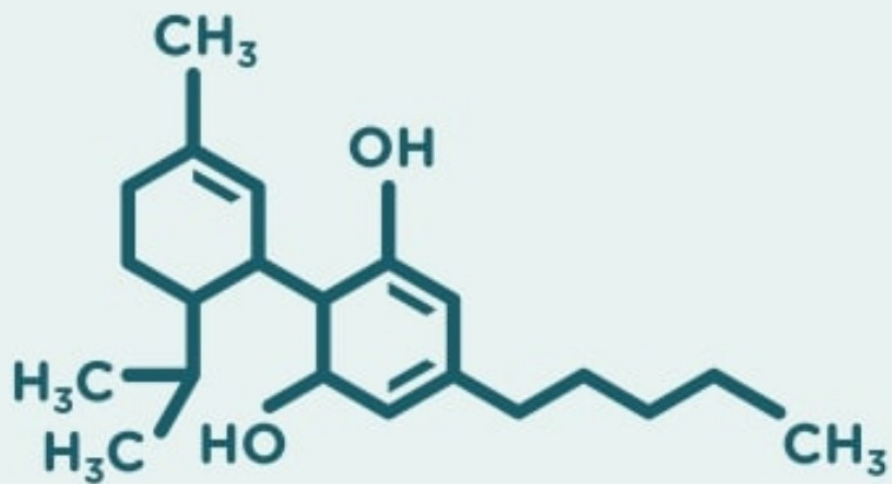
The Intersection of CBD & Therapeutic Courts

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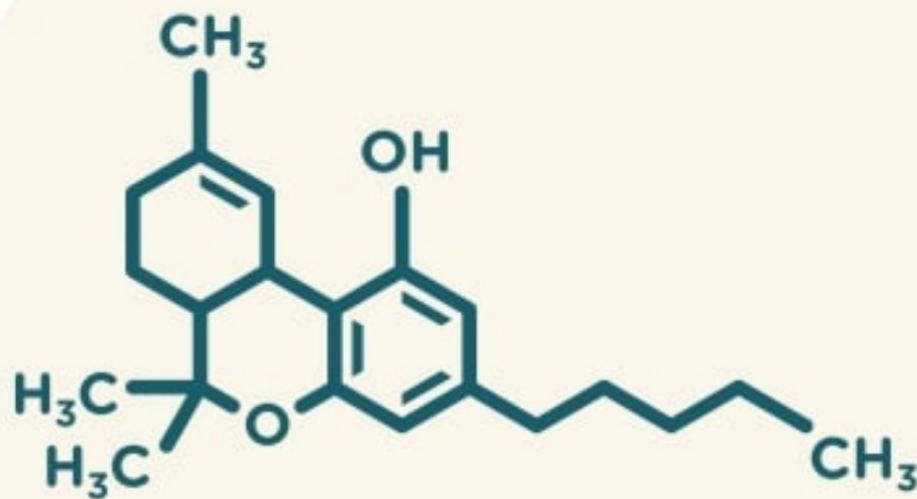


CBD

CANNABIDIOL

THC

TETRAHYDROCANNABINOL



A Cannabis History Lesson:

- Cannabis has been cultivated for its medicinal, psychoactive, and physical properties for thousands of years
- The earliest recorded medicinal uses of the plant date as far back as 1400-2000 BC.
- In the 19th century, William Osler, considered to be a “Father of Modern Medicine”, was a proponent of the medicinal use of cannabis - migraines.
- In 1937, the “Marijuana Tax Act” was passed, regulating and taxing the production of hemp and marijuana for industrial and medicinal purposes
- Act was ruled unconstitutional in 1969 and marijuana was criminalized shortly after.

A CBD History Lesson:

- CBD was first discovered by Dr. Roger Adams and his team at the University of Illinois in 1940
- CBD is just 1 of hundreds of cannabinoids identified from cannabis
- In 1946, when Dr. Walter S. Loewe conducted the first CBD test on lab animals demonstrating that CBD didn't cause an altered mental state
- CBD's structure was not fully elucidated until 1963

Can CBD be legally sold in
the United States?

or

Fifty Shades of Grey

A CBD Legal Review - Federal:

- CBD extracted from marijuana remains a Schedule I Controlled Substance, and is not approved as a prescription drug, dietary supplement, or allowed for interstate commerce in the US
- CBD derived from hemp (with 0.3% THC or lower) is legal to sell as a cosmetics ingredient but cannot be sold under federal law as an ingredient in food or dietary supplements
- In 2018, the Agriculture Improvement Act of 2018 (aka the Farm Bill) legalized CBD that is derived from hemp and contains no more than 0.3% - lifted federal ban on hemp
- If a CBD product contains the legal amount of THC but wasn't grown by a licensed producer according to federal regulations, it's still illegal.

Enter the FDA:

- The day the Farm Bill was signed into law, the US Food and Drug Administration (FDA) released a statement clarifying that Congress had "explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act."
- In June 2018, the FDA approved Epidiolex (highly-purified cannabidiol) [CBD] oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older.

Confused Yet???

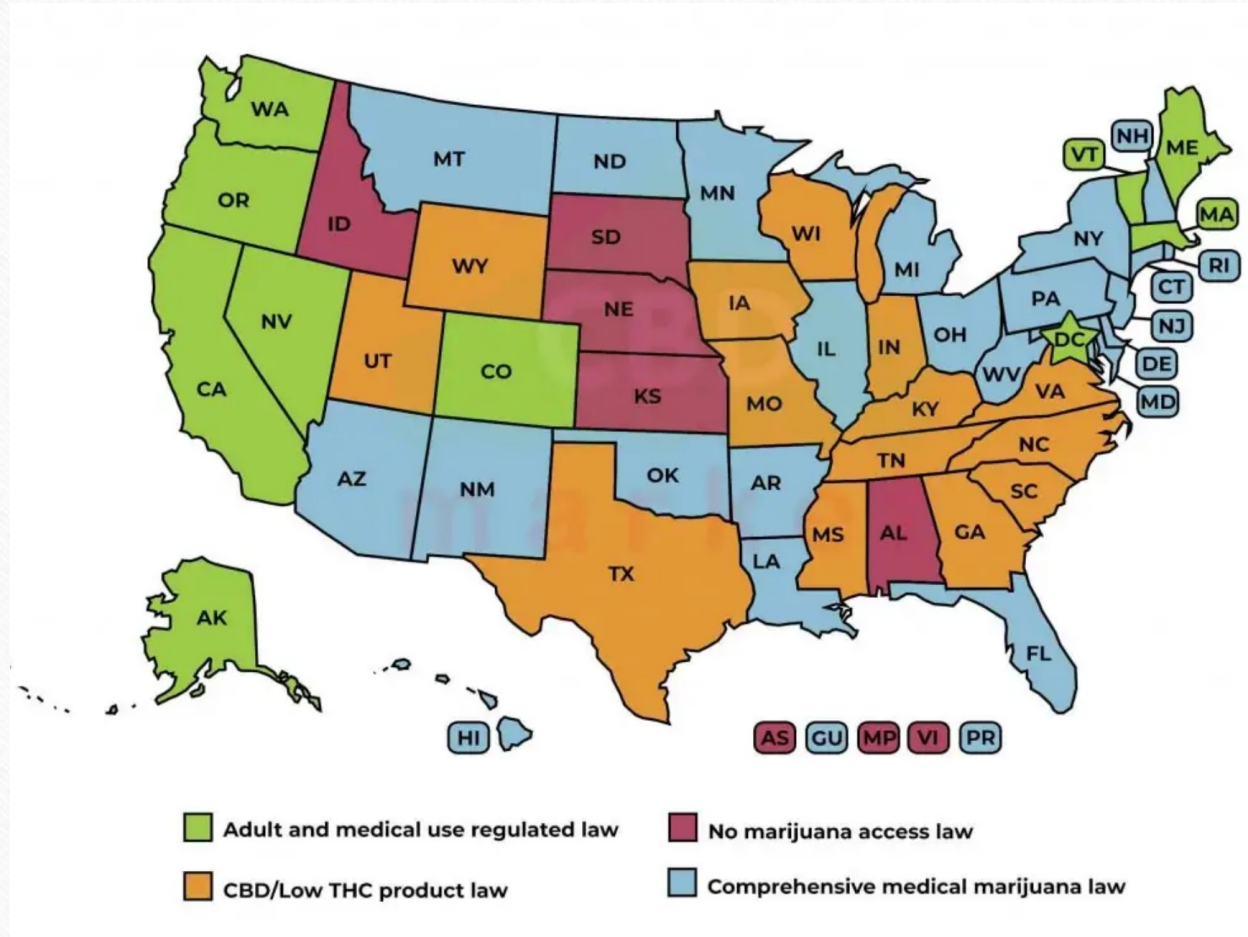
- So, what about all the CBD pills, oils and edibles currently on the market that claim to resolve, cure and eliminate all manner of illnesses and diseases?
- Well, that's what the FDA (and other federal partners) are trying to sort out.
- On May 31, 2019 – FDA held public hearings on CBD
- Public comment period that extended to June 2019
- The United States Department of Agriculture (USDA) in late October published its interim final rules for domestic hemp production in the Federal Register, including rules regarding CBD, a product of hemp.

We Know Three Things:

- CBD is wildly popular, even though there is no reliable research to support the medicinal claims often used to support its use.
- Disputes over the legality of CBD are a growing source of tension.
- It appears the federal government is making progress toward establishing rules for CBD

In November 2019 Forbes
estimated that the sale of
CBD would reach \$13 billion
by the end of the year.

A CBD Legal Review - States:



What Happened in Texas?

In March 2019 in Duncanville, a suburb of Dallas, the authorities broke down the door of Ms. Wazwaz's store, seized CBD products and thousands of dollars in cash, and confiscated employees' personal cellphones. "I'm not some mob boss," Ms. Wazwaz said in an interview. "I'm a soccer mom with kids."

New York Times: May 2019

What Happened in Texas?

In 2019 officials in Texas have arrested people for selling CBD products regardless of whether they contain levels of THC higher than the 0.3 percent permitted under the new federal rules.

New York Times: May 2019

What Happened in Texas?

- In 2019 officials in Texas have arrested people for selling CBD products regardless of whether they contain levels of THC higher than the 0.3 percent permitted under the new federal rules.
- CBD products are widely available in Texas, even though state law allows prosecutors to charge people with a felony for possessing a product that contains even the slightest amount of THC.

• *New York Times: May 2019*

What Happened in Texas?

- In Austin, the police say they believe CBD products containing less than 0.3 percent THC are legal.
- In Tarrant County, the district attorney has said she will prosecute all CBD cases whether or not any level of THC is present.
- San Antonio – prosecutor said, “We won’t proceed on prosecuting CBD cases until the Texas Legislature clarifies the law.” But the city’s police department says it considers any amount of THC present in CBD to be illegal, punishable as a felony.

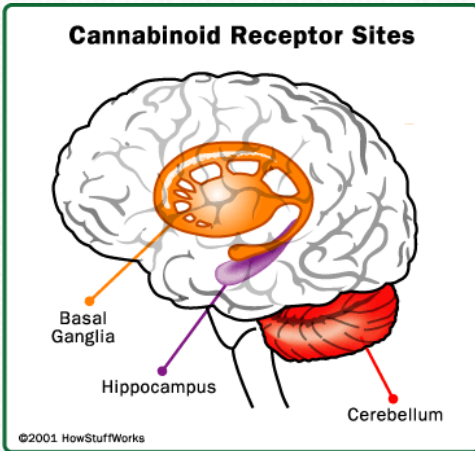
New York Times: May 2019

Current Texas Legal Status of CBD

- On June 10, 2019 Governor Abbott signed HB 1325
- Allows Texas to set up a federally approved program for farmers to grow hemp as an industrial crop
- It also expands the kind of hemp products that can be legally purchased in Texas to include any hemp or hemp-derived products containing less than 0.3 percent of THC – includes cannabidiol and CBD products
- The marijuana laws in Texas remain complex - Texas Compassionate Use Act

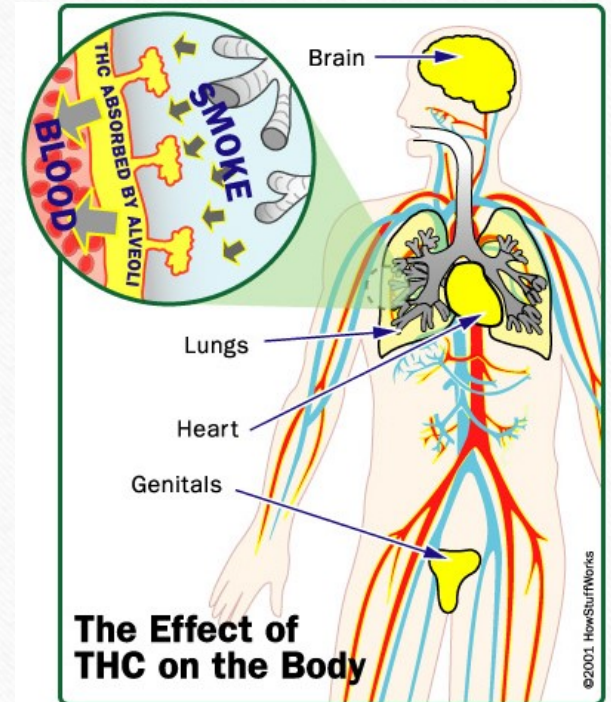
Pharmacology of Cannabidiol (CBD)

Cannabinoid Receptor System



Delta-9 THC binds to the CB1
What does CB1 receptor control?

- n BG: motor control, learning
- n Hippo: memory, spatial navigation
- n CB: cognitive functions - attention, language, emotions
- n THC acts on the brain



Cannabinoid Receptor System

CBD does not bind to the CB1 receptor

CBD does not act directly on the brain

CBD also has low affinity for the CB2 receptor

CBD has an esoteric pharmacology and MAY effect:

- circulatory system

- nervous system

- skeletal system

- muscular system

How does the use of CBD-
containing products affect
treatment court programs and
their participants?

A Review of Drug Court Goals

- Drug courts aim to reduce recidivism and substance abuse among eligible, nonviolent drug offenders.
- Drug courts require participants to abstain from drug and alcohol use, be accountable for their behavior, and fulfill the legal responsibilities of the offenses they committed.
- Key Component #5: *Abstinence is monitored by frequent alcohol and other drug testing*
- Does CBD interfere with the achievement of those goals?

Reduce recidivism & substance abuse:

There is no research on the effect of CBD use and its effect on recidivism or whether CBD is detrimental to substance abuse recovery.

Abstain from drug and alcohol use:

- Abstinence is a major tenet and goal of treatment courts
- Court supervision requires the limitation or prohibition of non-essential medicines
- BUT, we also know that “pain” can be a relapse trigger

Key Component #5: Abstinence is monitored by frequent alcohol and other drug testing

Does the use of CBD complicate the court's ability to successfully perform routine drug testing?

Abstinance Monitoring in
a CBD Use Environment

Two-Step Testing Approach

- screening test – designed to separate negative samples from samples that are “presumptively” positive
- confirmation test – follow-up procedure designed to validate positive test results
 - distinctly different analytical technique
 - more specific and more sensitive

Step One – Screening

- often based on immunoassay technology
- more drug – more binding - more “color” produced – more instrument detector response
- numerous commercial manufacturers
- designed for high throughput instrumentation or on-site devices

On-site Drugs of Abuse Screening

- often based on immunoassay technology
- concept of color “switch”
- “dynamic” versus “static” calibration
- hand-held cassettes or test-cup devices
- one test at a time - no batching
- available in DOA panels or single drugs
- numerous commercial manufacturers
 - differential sensitivity & selectivity

Step Two - Confirmation



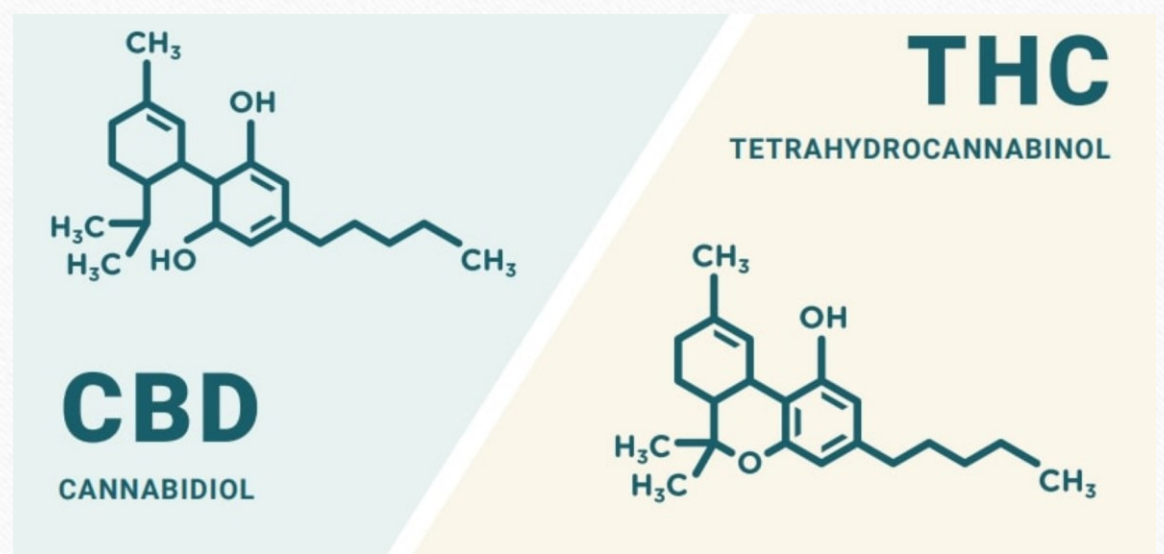
- gas chromatography-mass spectrometry (GC/MS) or LC/MS
 - drug molecules separated by physical characteristics
 - identified based on chemical “finger-print”
 - considered “gold standard”
- other chromatographic techniques

Why confirm ?

- Is it really necessary to confirm drugs that tested positive by initial screening tests?
- Why can't the court adjudicate cases based on the screening test results?
- FALSE POSITIVES

Drug tests & cross reactivity:

- screening tests can and do react to “non-target” compounds
- these “non-target” compounds generally share chemical/structural similarities



False Positive Screening Tests ?

- Many of the common automated immunoassay tests for cannabinoids have not defined their cross-reactivity toward CBD
- Most of the common on-site devices for cannabinoids have not studied their cross-reactivity CBD
- How does cutoff play a role – 20ng/mL vs. 50 ng/mL

Cannabis (marijuana) contains more than 400 different chemical compounds, of which 61 are considered cannabinoids

Other cannabinoids in CBD

- cannabinol (CBN),
- cannabigerol (CBG),
- [DB14050] (CBDV)
- [DB11755] (THCV)

The cross-reactivity of CBD (and its breakdown products) toward most initial screens (instrumented and on-site) is significantly under studied. Therefore, the potential for “false-positive” cannabinoid results may be problematic.

Potential Drug Testing Scenario

- Court participant is taking CBD
- Tests positive for cannabinoids on initial screen
- Denies use of cannabis
- Sample sent for confirmation

Confirmation GC/MS or LC/MS/MS

- These technologies detect the marijuana metabolite
- THC-COOH
- Carboxy-THC is produced following the use of cannabis
- Carboxy-THC is NOT a metabolite of CBD
- Confirmation results indicate NEGATIVE result
- Court is faced with “discrepant” testing results.

Key Component #5: Abstinence is monitored by frequent alcohol and other drug testing

The court's primary role is participant supervision in an effort to promote low-term recovery from substance abuse.

Court is obligated to monitor client abstinence.

If the court is unable to monitor client abstinence for marijuana if CBD is being used – what options does the court have?

Items Often Banned by Treatment Courts

- poppy seeds
- creatine
- alcohol-containing OTC medicines
- dietary supplements
- energy drinks
- homeopathic substances
- herbal products
- sports nutrition powders
- anything not regulated by FDA

The Bottom Line!

Treatment courts should prohibit the use of ingestible materials (i.e. chemicals, drugs, non-medicinal products, non-FDA approved supplements, etc.) that have the potential to interfere with the court's ability to accurately and reliably evaluate or interpret the results of abstinent monitoring testing – unless, that ingestible material has been legally prescribed by a licensed physician.

QUESTIONS?