

# COMMERCIALIZING CANNABIS

Bringing **cannabis** products into the light.



# Hemp v Marijuana

**Hemp is used as a description of high CBD Content Plant**

**'Marijuana' is generally used to refer to high THC plant.**

Play it safe: Congressional Research Service: Defining Hemp: A Fact Sheet. [Fas.org/sgp/crs/misc/r44742.pdf](https://fas.org/sgp/crs/misc/r44742.pdf)

# Terminology

Isolate – Highly purified Cannibidiol often above 99%

Broad Spectrum – Extraction of all Plant Matter with THC content below the federally mandated limit of 0.3%

Full Spectrum – Extraction of all plant matter including THC.

# Hybrids/Clones

**According to the EU there are 63 registered strains approved for use. The EU appears unique with their registration system at this time.**

**In the US, via the Farm Bill, still defines hemp as Cannabis Sativa with less than 0.3% THC**

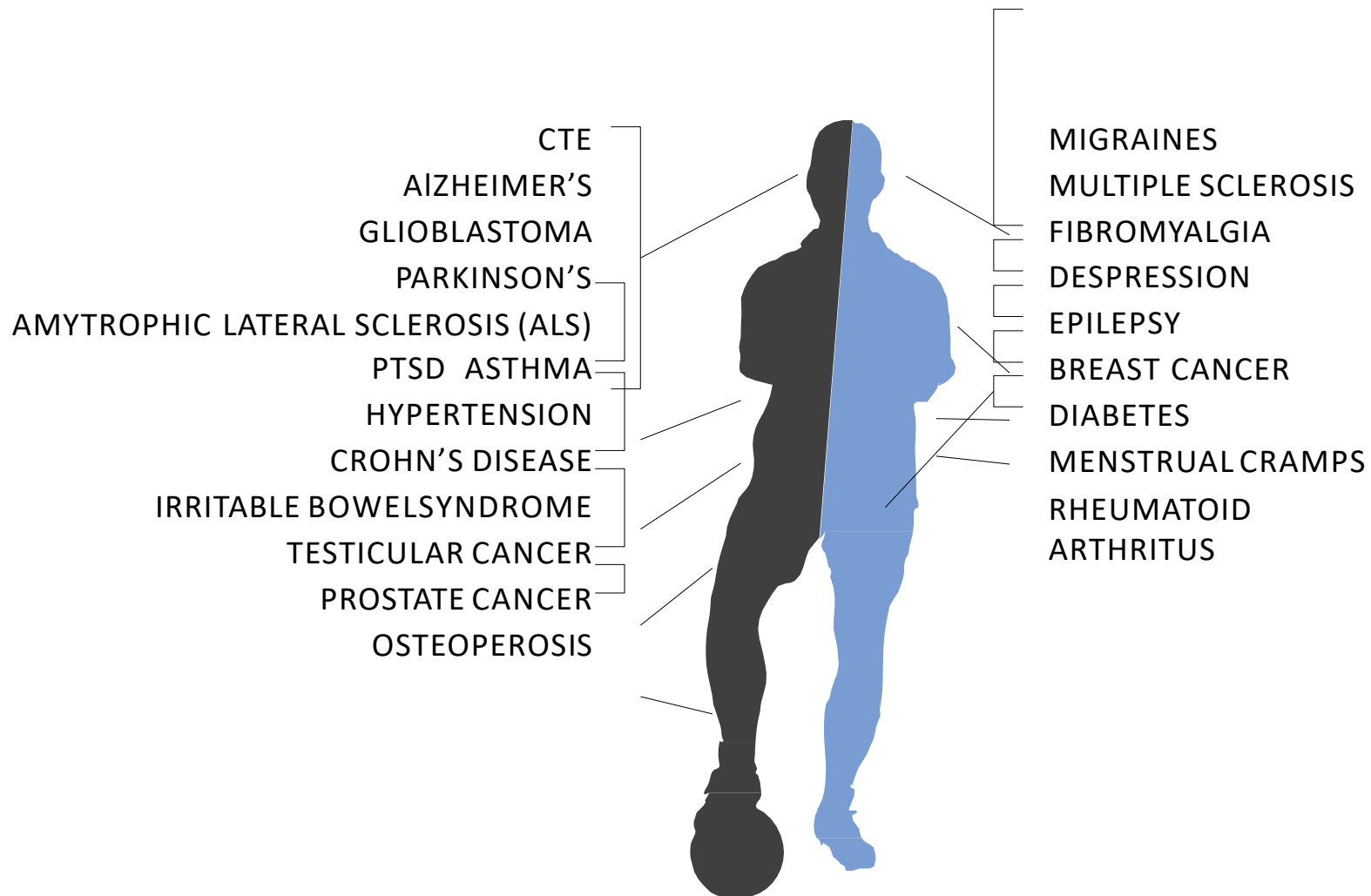


## Opinion:

Given the degree to which marijuana and cannabinoid derivative use has been stigmatized in the past, their Schedule I classification as illegal substances, and lack of FDA approval, valid medical research on the effects of CBD isn't plentiful, yet. Much of the anecdotal evidence suggests that CBD's neuro-protective and anti-inflammatory effects with regard to topical applications are promising.

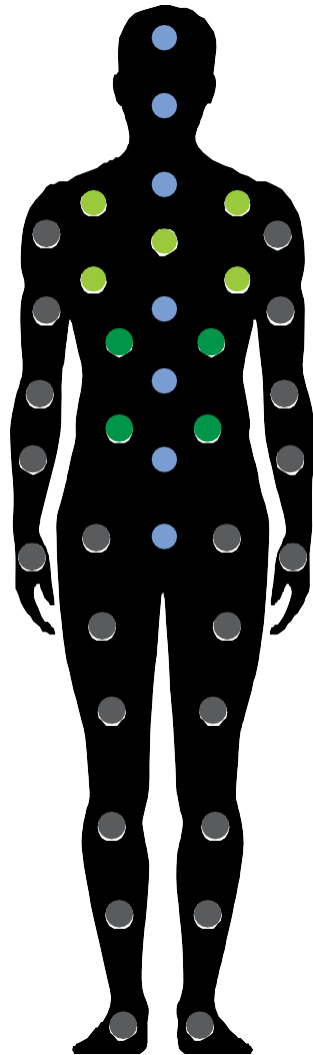
# What is CBD? Why is it used?

CBD IS ANTI-INFLAMMATORY, ANALGESIC, ANTI-SPASMODIC, ENHANCES CIRCULATION AND CELLULAR REGENERATION.



# CB Receptor

## ENDOCANNABINOID SYSTEM



**CB1 RECEPTORS** are concentrated in the brain and central nervous system, but are also present in nerves and in some organs.



**CB2 RECEPTORS** are mostly in peripheral organs, especially cells associated with the immune system.



**TRPV1 RECEPTORS** are concentrated in the blood, bone marrow, tongue, kidney, liver, stomach & ovaries.



**TRPV2 RECEPTORS** are concentrated in the skin, muscle, kidney, stomach & lungs.

# NAVIGATING THE COURSE



## *Federal Regulation*

Jonathan Miller, general counsel for the U.S. Hemp Roundtable, an industry group, says the Farm Bill includes the Hemp Farming Act, sponsored by Senate Majority Leader Mitch McConnell (R-KY) and endorsed by 25 other senators, including Minority Leader Chuck Schumer (D-NY).

*“It would permanently remove hemp from the Controlled Substances Act, making it an agricultural commodity”*

rather than a Schedule 1 substance, Miller says. The bill defines hemp as all parts of the plant containing less than 0.3% THC, including extracts, derivatives and cannabinoids (such as CBD) from the cannabis plant.

<https://www.webmd.com/pain-management/news/20180618/congress-may-soon-make-cbd-from-hemp-legal>





## *State Regulation*

### **Texas Consumable Hemp Product Regulation Overview**

HB 1325; Signed by Greg Abbott 10 June 2019

HB 1325 requires *in-state* processors and manufacturers to obtain a license from the Department of State Health Services (DSHS or department) to manufacture hemp-derived consumable products in Texas, but does not require out-of-state manufacturers to register or be licensed with the state.

HB 1325 generally requires that consumable hemp products be tested at three stages: (1) the hemp plant must be tested to determine the concentration of cannabinoids and various heavy metals and pesticides; (2) the input material (i.e. extract or crude oil) must be tested before being incorporated into a consumable hemp product for the presence of harmful microorganisms and the presence or quantity of residual solvents and other materials that maybe prescribed by the department during rulemaking; and (3) before the finished product may be sold it must be tested by a laboratory that is accredited by ISO/IEC 17025 to determine the final THC content and confirm that the product does not contain any prohibited substances. Alternatively, the finished product does not have to be tested if each hemp ingredient has been tested in accordance with (1) and (2) and does not contain more than 0.3% THC.

# Texas, cont.

**Note:** HB 1325 contains limitations regarding retail sales of out-of-state consumable hemp products. The products must be processed or manufactured in another state in compliance with:

1. that state or jurisdiction's plan approved by the USDA;
  2. in the absence of a state submitted plan, a plan established by the USDA;
- or,
3. the laws of that state or jurisdiction if the products are tested in compliance with, or similar to those set out in Section 443.151 of HB 1325.

Upon approval of the Texas state hemp plan by USDA, DSHS will establish a process to register retailers selling consumable hemp products containing CBD. At that time, existing retailers selling consumable hemp products containing CBD and new retailers wishing to sell these products will be required to register with DSHS.

<https://www.dshs.texas.gov/consumerprotection/hemp-program/default.aspx>

# Important Considerations

When selecting a supplier of CBD it is important to build a material portfolio consisting of:

- Chain of custody paperwork

- Where grown

  - Grow license

- Where extracted

  - Extraction License

- Certificate of Analysis including;

  - Purity

  - THC Content (less than 0.3%)

  - Cannabinoids

  - Terpenes

  - Residual Solvents

  - Pesticides

  - Microbiological Challenge Testing

  - Heavy Metals

There are a number of registered laboratories available to perform this testing. Suppliers are expected to have their material tested through 3<sup>rd</sup> party laboratories. A list of approved labs can be found at [confidentcannabis.com](http://confidentcannabis.com)

# Sticky Wicket

Over the Line

. FDA.



## Claims:

Best to make none. Contains CBD is as detailed a claim a product should make.

Testing is now underway and the future is wide open. Or, better put, anyone's guess.

The plant has remarkable physiological properties, many of them. Topical claims will most likely be the first to emerge, drug statements are a different story.

# Does CBD convert to THC?

A laboratory setting with a gloved hand holding test tubes containing green and yellow liquids, a graduated cylinder, and petri dishes with plant material.

**4 years of study and more than 30 independent laboratory tests have not revealed this conclusion. Heat has been used for extended periods of time and subsequent third party laboratory results have consistently reported no THC following this processing.**



# Path Forward

## Education:

- Physician's and clinicians • University Studies
  - In Vivo clinical analysis
- Institutional Studies (VA and other Medical Centers) Teaching program

## Basic Research

Marijuana Terpenes  
Additional Cannabinoids  
Clone Research

# Conclusion

- Aim to provide appropriate treatment alternatives to Prescription Drugs that:
  - Are kinder to the body
- Effective prophylaxis for conditions related family histories and environmental conditions
  - Effective early stage treatments
    - Patient accessible, Kinder on the wallet
- No contribution to the insurance lobby and the high costs of medical care

Disclaimer: Statements made in this presentation have not been evaluated by the FDA. The sources for the information are listed in the bibliography and are taken from government websites, and direct third party laboratory analysis.





CBD  
FOR LIFE

PURE CBD  
FACE & BODY  
CLEANSER

6.7 fl. oz / 198 ml

CBD  
FOR LIFE

PURE CBD  
FOOT CREAM

5 fl. oz / 147 ml

CBD  
FOR LIFE

THE FUTURE OF HEALING  
PURE CBD FACE CREAM 1.34 fl. oz

CBD  
FOR LIFE

PURE CBD  
EYE BALM

0.17 fl. oz

CBD  
FOR LIFE

99% PURE CBD EXTRACT  
HEALTHY SKIN  
PURE CBD EXTRACT

4 fl. oz / 120 ml

CBD  
FOR LIFE

99% CBD  
PURE EXTRACT

0.34 fl. oz

CBD  
FOR LIFE

CBD  
EYE SERUM

0.5 fl. oz / 15 ml

CBD  
FOR LIFE

PURE CBD  
BODY MASSAGE  
LOTION

6.7 fl. oz / 198 ml







# CBD Skin Care Studies

source: Project CBD

## SKIN CONDITIONS

Cannabinoids inhibit human keratinocyte proliferation through a non-CB1/CB2 mechanism and have a potential therapeutic value in the treatment of psoriasis

CBD exerts sebostatic and antiinflammatory effects on human sebocytes

The endocannabinoid system of the skin in health and disease

Epigenetic control of skin differentiation genes by phytocannabinoids

A novel control of human keratin expression: cannabinoid receptor 1-mediated signaling down-regulates the expression of keratins K6 and K16 in human keratinocytes in vitro and in situ

Endocannabinoids modulate human epidermal keratinocyte proliferation and survival via the sequential engagement of cannabinoid receptor-1 and transient receptor potential vanilloid-1

Cannabinoid 1 receptors in keratinocytes modulate proinflammatory chemokine secretion and attenuate contact allergic inflammation

Attenuation of allergic contact dermatitis through the endocannabinoid system

Topical cannabinoid agonists. An effective new possibility for treating chronic pruritus

The role of cannabinoids in dermatology

Cannabidiol upregulates melanogenesis through CB1 dependent pathway by activating p38 MAPK and p42/44 MAPK

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Maybe She's Born With It...



Maybe It's CBD