DE-MYSTIFYING CBD AMY BACHYRYCZ, PHARMD ASSISTANT PROFESSOR, UNM COLLEGE OF PHARMACY SHARED FACULTY, WALGREENS PATIENT CARE CENTER

DISCLAIMER

• This presentation is intended to provide educational information related to CBD history, legal information, potential medical benefits and risks. It is not a recommendation to use CBD or any CBD related product.



OBJECTIVES

- List and review the process of obtaining a Medical Cannabis card in New Mexico
- List the key CBD clinical information and available CBD products
- Describe the known contraindications of CBD and Medical Cannabis
- Describe the role of CBD shops vs Medical Cannabis Dispensaries in New Mexico

MEDICAL CANNABIS CARD PROCESS REVIEW https://nmhealth.org/about/mcp/svcs/fad/

- 7.34.3.2 SCOPE: This rule governs the issuance of registry identification cards to qualified patients and primary caregivers as defined by the Lynn and Erin Compassionate Use Act.
- Cannabidiol ("CBD") is a cannabinoid and the primary non-psychoactive ingredient found in cannabis.

APPROVED DEBILITATING MEDICAL CONDITIONS

Cancer

Glaucoma

Multiple sclerosis

Damageto the nervous tissue of the spinal cord, with objective neurological indication of intractable spasticity

Epilepsy

Positive status for human immunodeficiency virus or acquired immune deficiency syndrome

Admission into hospice care in accordance with rules promulgated by the department

Amyotrophic lateral sclerosis

Chrohn's disease

Hepatitis C infection

Huntington's disease

Body myositis

Inflammatory autoimmune-mediated arthritis

Intractable nausea or vomiting

Obstructive sleep apnea

Painful peripheral neuropathy

Parkinson's disease

Posttraumatic stress disorder

Severe chronic pain

Severe anorexia or cachexia

Spasmodic torticollis

Ulcerative colitis

Any other medical condition, medical treatment, or disease as approved by the department which results in pain

APPROVED DEPARTMENT CONDITIONS

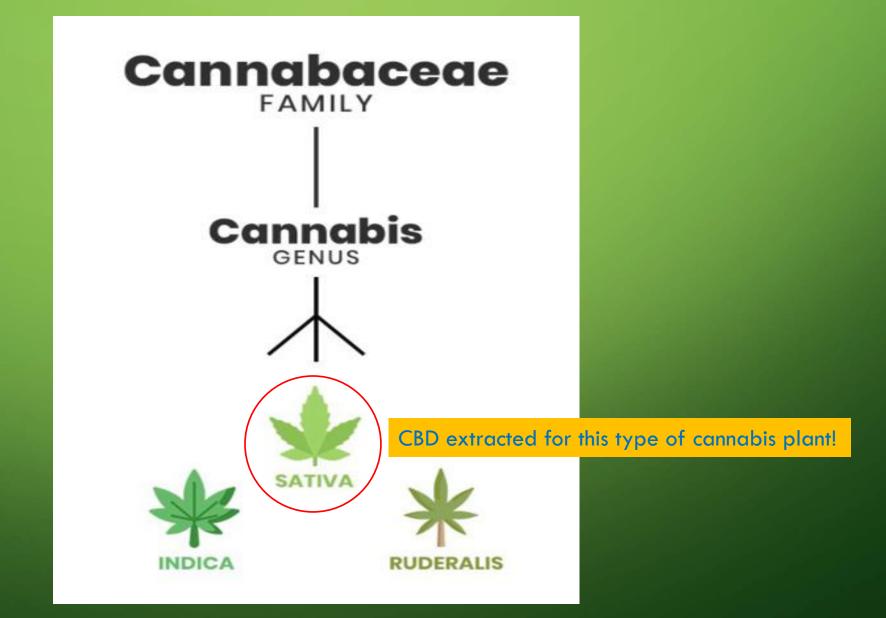
- The department finds that the following additional qualifying conditions result in pain, suffering, or debility for which there is credible evidence that the medical use of cannabis could be of benefit, through the alleviation of symptoms, and the department accordingly approves these conditions as qualifying debilitating medical conditions for the participation of a qualified patient or primary caregiver in the medical cannabis program.
 - Autism
 - Spectrum disorder
 - Friedreich's ataxia
 - Lewy body disease
 - Spinal muscular atrophy
 - Alzheimer's disease
 - Opioid use disorder
 - Such other conditions as the secretary may approve

CBD BASIC TERMS & DEFINITIONS

<u>Cannabinoid</u> — a class of chemical compounds that acts on cannabinoid receptors; the active constituents of cannabis

- There are 100+ cannabinoids that have been isolated from the cannabis plant
 - Tetrahydrocannabinol (THC) The psychoactive cannabinoid; responsible for the "high"
 - Cannabidiol (CBD) a non-psychoactive cannabinoid

SCIENTIFIC CLASSIFICATION



HEMP



THC < 0.3%

MARIJUANA



THC > 0.3%

100S OF CANNABINOIDS





CBD

THC



CANNABIS SATIVA USES:



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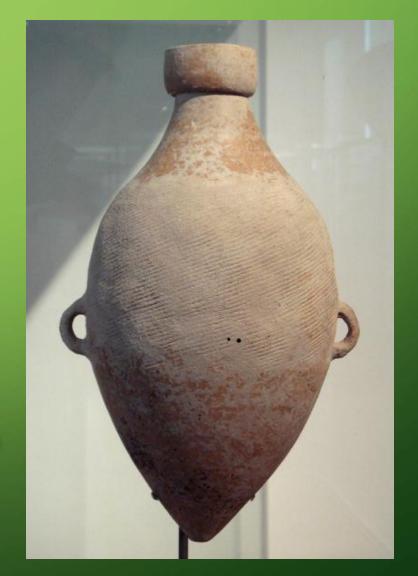


An article featuring hemp in Popular Mechanics Magazine in Feb 1938

- Lotions
- Rope
- Plastic composites
- Paper
 - Declaration of Independence
 - Bible
- Clothes
- Carpet
- Livestock food
- Bank notes
- Plasterboard
- Insulation

CANNABIS <u>REMOTE</u> HISTORY

- 8000 BC Asian archaeology finds
- Middle Ages Hemp sails & rope for navy
- 1553 King Henry VIII passes an act that requires landowners to dedicate ¼ acre to cannabis plants
- 1619 1st New World (Jamestown)
 Marijuana legislation settlers required to grow cannabis
- 1700s A main crop at George Washington's
 Mount Vernon estate



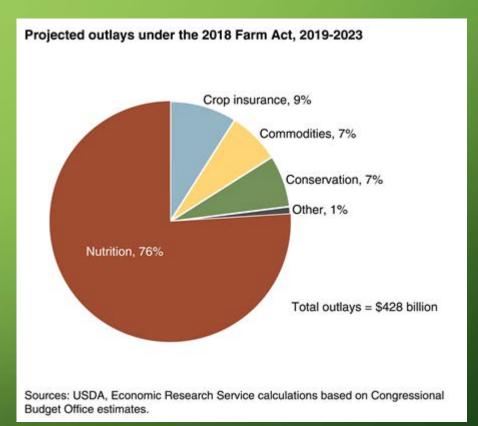
CANNIBIS <u>RECENT</u> HISTORY

- 1839 Irish physician and medical researcher, William O'Shaughnessy, publishes a study on the cannabis' therapeutic effects
- 1937 Marijuana Tax Act levies tax on many aspects of the plant product
- 1940 American Harvard trained chemist Roger Adams isolates the CBD compound
- 1970 United States passes the Controlled Substance Act
 - Marijuana classified as schedule I drug (abuse potential with no medical benefits)
- 2006 Charlotte Figi born with intractable life-threatening seizures related to a rare genetic disorder "medical marijuana" or "Charlotte's web" with low THC/high CBD suppresses her seizures
- 2018 Epidiolex (purified CBD) receives FDA approval for rare genetic seizure disorders

FARM BILL (AGRICULTURAL IMPROVEMENT ACT) 12/20/2018

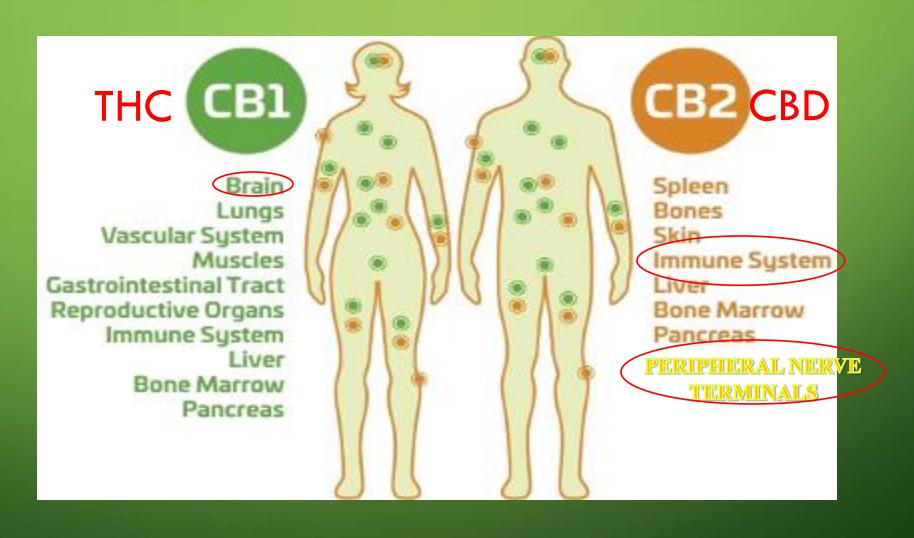


- Hemp derived CBD legalized under federal law
- Makes few major changes in agricultural and food policy



• Allowed farmers to receive payment for not growing food on a percentage of their land

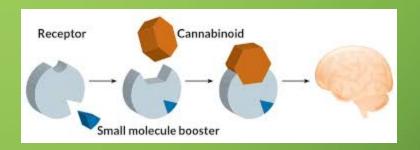
ENDOCANNABINOID RECEPTORS



CBD CLINICAL INFORMATION

CBD ALSO HAS AN AFFINITY FOR OTHER RECEPTORS:

- Dopamine
 - **Emotion**
 - Movement
 - Sensations of pleasure and pain
- Serotonin
 - Mood & happiness
- Opioid
- Pain



CBD ADMINISTRATION

- Inhalation (vape)
 - quickest onset
 - may have a greater bioavailability
- Topical application
 - lotions/creams
- Oral CBD
 - oil based capsules
 - oils/tincutures (sublingual or added to food/beverages)
- Edibles
 - gummy bears
- Transdermal skin patch

BUYER BEWARE! (POOR REGULATION)

- Is THC in the product?
 - This could potentially result in a failed drug test



- 1) may have more CBD
- 2) may have less CBD
- 3) may have no CBD





(US DEPT OF HHS & CDC)



- Most common cause of accidental death
- #1 killer 24 44 y.o.
- 130+ daily
- ~ 50,000 yearly
- 2,000,000+ estimated opioid use disorder

Nearly 90% 3 year relapse rate after detox

CBD OVERDOSE STATS

None reported

- i. No apparent tolerance issues
- ii. Not addicting
- iii. No (or minimal) CB2 receptors on the brainstem so no respiratory depression





- Not established for OTC products
 - Bioavailability dependent on mode of administration
- Epidiolex (100 mg purified CBD/ml)
 - FDA approved in June 2018
 - Only approved for rare genetic seizure disorder
 - Maximum recommended dose 20 mg/kg/day
 - Recommended starting dose is much lower
 - Adjusted rates for hepatic impairment
 - Recommended monitoring of liver enzymes & bilirubin





The American College of Obstetricians and Gynecologists





- THC crosses the placenta and passes into milk
- THC may cause low birth weight, pre-term delivery, still birth and affect fetal brain development
- Scant studies on CBD

CBD CONTRAINDICATIONS

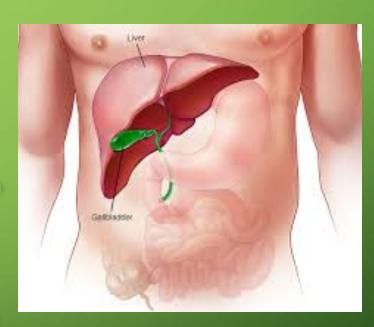


- Sedation/lethargy
- Decreased appetite
- Diarrhea
- Rash
- Sleep disorder
- Psychiatric (suicidal ideation, depression, anxiety)
- Liver toxicity
 - Long-term consequences??

CBD DRUG INTERACTIONS

- CBD is metabolized by the liver by the Cytochrome (CYP) enzyme system
- Many drugs either "ramp up" or "ramp down" the CYP metabolic pathway which can affect CBD concentration in the blood

 CBD competes as a substrate for some of the same CYP enzymes that metabolize coumadin; coumadin blood levels elevate resulting in an increased risk of bleeding



MEDICAL CANNABIS DRUG INTERACTIONS

MEDICAL CANNABIS CONTRAINDICATIONS

ANTECDOTAL OBSERVATIONS (NOT SCIENTIFIC STUDIES)

- Many patients have anecdotally provided unsolicited feedback that CBD helps control their pain including neuropathic pain
- CBD does not help all patients NOT A MIRACLE DRUG
- Coumadin levels are harder to regulate while taking CBD
- No side effects reported
- Failed drug test



TRUE OR FALSE: CBD INFUSED FOOD OR BEVERAGES ARE AGAINST THE LAW?

- The FDA defines a dietary supplement as a product taken by mouth that contains a dietary ingredient (i.e. amino acids, herbs, botanical, minerals or vitamins).
- Dietary supplements can be added to food or beverage if they comply with certain marketing rules
- CBD is not considered to be a dietary supplement but rather an active ingredient drug
- Hemp seed, hemp seed oil, and hemp seed protein were granted exceptions by the FDA in December 2018

AAOS NOW MAGAZINE

(AMERICAN ASSOCIATION OF ORTHOPEDIC SURGEONS)

"Cannabinoids Can Serve as Alternatives to Narcotic Pain Medication for Fracture Healing" – April 2019

- 1. Animal studies suggest a possible potential benefit of faster bone fracture healing
 - CB receptors have been identified on both osteoclasts & osteoblasts and hence may enhance bone metabolism
- II. Evidence is mixed for post-operative pain management
- III. Evidence is better that CBD provides analgesia for cancer, chronic, and neuropathic pain

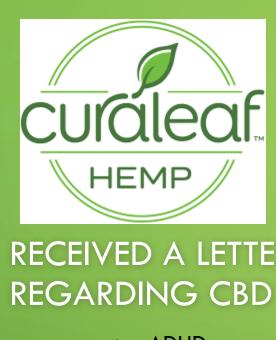


- In humans, CBD exhibits no effects indicative of any abuse or dependence potential
- There is preliminary evidence that CBD may be a useful treatment for a number of other (i.e. non-seizure) medical conditions
- CBD is generally well tolerated with a good safety profile. Reported adverse effects may be the result of drug-drug interactions between CBD and patients' existing medications
- To date, there is no evidence of recreational use of CBD or any other health-related problems associated with the use of pure CBD



Primary role is to protect the public health by ensuring the safety, efficacy, security of, and labeling/marketing of human drugs and biological products effectively ensuring the safety of our nation's food supply.

- Seem to be loosely enforcing some CBD guidelines right now
- Will target grossly embellished health claims



Publicly traded company that supplies CBD products to CVS pharmacy

RECEIVED A LETTER FROM THE FDA IN JULY 2019 REGARDING CBD TREATMENT CLAIMS RELATED TO:

- ADHD
- Cancer
- Alzheimer's
- Parkison's disease
- PTSD
- Depression
- Eating disorders
- Opioid withdrawal
- Claiming to be a dietary supplement

AVAILABLE CBD PRODUCTS

































CBD CULTURE















CBD SHOPS VS DISPENSARIES