To CBD or Not to CBD?
That is the Question:
The Neuroscience of CBD oils

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Participants will:

• Evaluate medical cannabinoid products and their beneficial potential;

• Contrast the various legalization processes of medical cannabinoids in the US;

• Formulate the profile of adverse drug effects of CBD oils;

• Discuss updated prescribing models for medical cannabinoids in the US.
Medical Cannabis States 2/2020

Current marijuana laws by state

- **RECREATIONAL AND MEDICAL**
- **CBD/LOW THC**
- **MEDICAL ONLY**
- **NO CANNABIS ACCESS PROGRAM**

SOURCE: NATIONAL CONFERENCE OF STATE LEGISLATURES AS OF 8/1/2019
• What are the benefits of marijuana?
• Is marijuana a medicine (by FDA definition)?
• What are the pharmacokinetic and pharmacodynamic differences between THC and CBD?
• What are the appropriate doses for medical THC? CBD Oil? CBD edibles?
• Does marijuana have beneficial components to treat incurable chronic diseases? If so, please identify 3 evidence based articles.
• Should leaf marijuana be legalized? If so, how should marijuana be regulated?
• List 5 adverse drug effects of THC.
• List 5 adverse drug effects of CBD.
• Should marijuana be a RX or OTC?
• At what age should some be allowed to purchase marijuana?
• What penalties should be in place for illegal use of marijuana?
PURPOSE: To provide a comprehensive review of the current evidence regarding the health effects of using cannabis and cannabis-derived products

Report made 4 recommendations.
What Is the Legal Status of THC and CBD?

• This is the current question among medical practitioners (Physicians, Pharmacists, Nurses, etc.);
• 46 states have passed some form of legalization for the use of medical cannabinoids (THC and CBD);
• Some states allow THC/CBD only for specific medical conditions while other states allow only use of CBD based products to be used;
• All of these changes have occurred since 2013 and has created a medical dilemma:
• A patient population who are demanding the use of Medical cannabinoids for various chronic disease states vs. what do states do to improve healthcare in the state population.
• Thus the passage of multiple state laws to “legalize” the medical use of THC and CBD products.
DEA Schedule 1-5 Drugs

- Examples of substances listed in **Schedule 1: Marijuana (cannabis)**
  - Heroin
  - LSD
  - Peyote (mescaline)
  - Methaqualone (Quaalude)
  - 3,4-methylenedioxymethamphetamine (“ecstasy”)
  - “bath salts”

- **Schedule 2**: Vicodin, Cocaine, Meth, OxyContin, Adderall

- **Schedule 3**: Tylenol with Codeine, Steroids, Ketamine, Testosterone

- **Schedule 4**: Xanax, Valium, Ativan, Ambien, Tramadol

- **Schedule 5**: Robitussin AC, Lomotil, Lyrica

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What Does Schedule I Really Mean

- Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15.
- Schedule I Controlled Substances
  - Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.
  - Latest outcome of request for rescheduling cannabis from schedule I to schedule III, IV, or V
  - On June 21, 2011, The DEA concluded that there is NO substantial evidence that cannabis should be removed from Schedule I. This was reiterated again in June 2017.
• Effective September 28, 2018.
• With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration places certain drug products that have been approved by the Food and Drug Administration (FDA) and which contain cannabidiol (CBD) in schedule V of the Controlled Substances Act (CSA). Specifically, this order places FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V. This action is required to satisfy the responsibility of the Acting Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States obligations under the Single Convention on Narcotic Drugs, 1961. Also consistent therewith, DEA is adding such drugs to the list of substances that may only be imported or exported pursuant to a permit.
But Wait..Read the Fine Print….

• **Section 811**(d)(1) is relevant here because, on June 25, 2018, the Food and Drug Administration (FDA) announced that it approved a drug that is subject to control under the *Single Convention*. Specifically, the FDA announced that it approved the drug Epidiolex 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.

• Now that Epidiolex has been approved by the FDA, it has a currently accepted medical use in treatment in the United States for purposes of the CSA. Accordingly, Epidiolex no longer meets the criteria for placement in schedule I of the CSA.
• Under international treaties, **cannabis, cannabis resin, and extracts and tinctures of cannabis** are listed in Schedule I. The cannabis plant contains more than 100 cannabinoids. Among these are tetrahydrocannabinols (THC) and CBD. Material that contains THC and CBD extracted from the cannabis plant falls within the listing of extracts and tinctures of cannabis for purposes of the Single Convention. Thus, such material, which includes, among other things, a drug product containing CBD extracted from the cannabis plant, is a Schedule I drug under the Single Convention. **OTC CBD Oils have not been approved for any medical use according to FDA guidelines, thus are regarded as Schedule I drugs.**
• Approved cannabidiol drugs. (1) A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols

• **Sec. 1308.15** Schedule V. Department of Justice, Drug Enforcement Administration Rules; 21 CFR Parts 1308, 1312
The U.S. Food and Drug Administration approved Epidiolex (cannabidiol) [CBD] oral solution for the treatment of seizures associated with tuberous sclerosis complex (TSC) in patients one year of age and older. Epidiolex was previously approved for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome (LGS) and Dravet syndrome (DS). This is the only FDA-approved drug that contains a purified drug substance derived from cannabis. It is also the second FDA approval of a drug for the treatment of seizures associated with TSC.

• July 31, 2020
• In Kentucky, are physicians allowed to prescribed illegal (either by state or federal regulations) medications?

• What does the medical liability carriers required to cover malpractice?

• Under the current federal law, the only CDB product approved for use is Epidiolex per federal regulation;

• All other products are not approved and are considered Schedule I;

• More regulation will need to be needed to appropriately correct this misstep of the federal regulators.

• Please seek legal advise prior to prescribing any product other than Epidiolex.
<table>
<thead>
<tr>
<th>Checklist for Finding a High Quality CBD and Hemp Oil Product</th>
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</thead>
<tbody>
<tr>
<td>• 1.) Does it meet the following quality standards?</td>
</tr>
<tr>
<td>• Current Good Manufacturing Practices Certification(CGMP) from FDA;</td>
</tr>
<tr>
<td>• EU, AUS, or CAN organic certification;</td>
</tr>
<tr>
<td>• National Science Foundation International certification.</td>
</tr>
<tr>
<td>• 2.) Does the company have an independent review adverse event reporting program?</td>
</tr>
<tr>
<td>• 3.) Is the product certified organic or ecofarmed?</td>
</tr>
<tr>
<td>• 4.) Have the company’s products been lab tested to confirm THC levels( &lt;0.3% and no pesticides or heavy metals).</td>
</tr>
</tbody>
</table>
What Do Practitioners Need To Know About Medical Cannabinoids
Varieties of Cannabinoids

- **Endocannabinoids**
  - In your brain and body
  - Anandamide, 2-AG, Noladin ether etc.

- **Phytocannabinoids**
  - In plants
  - THC, CBD, CBG, CBDV, THCV, CBC, CBN, THCVA etc.

- **Synthetic cannabinoids**
  - From the lab
  - Nabilone, HU-210, AB-PINACA, JWH-018, etc.
Brain regions that express the CB₁ cannabinoid receptor

Red = abundant CB₁ receptor expression
Black = moderately abundant CB₁ receptor expression

Cerebral Cortex
- Higher cognitive functions

Hypothalamus
- Temperature regulation
- Salt/water balance
- Reproductive function
- Energy balance

Prefrontal Cortex
- Executive function

Basal ganglia
- Cognition
- Learning
- Emotional response
- Motor control

Amygdala
- Emotional response
- Fear

Hippocampus
- Learning
- Memory
- Stress

Periaqueductal Gray
- Analgesia

Nucleus of the Solitary Tract
- Visceral sensation
- Nausea/vomiting

Cerebellum
- Posture

Brain Stem
- Sleep arousal
- Temperature regulation
- Motor control

Spinal cord
- Peripheral sensation
  - Including pain

CB₂ Receptors: immune system modulators

- CB₂ receptors found in spleen, tonsils, thymus gland, bones, skin
  - Localized in monocytes, macrophages, B-cells and T-cells
  - Limited CB₂ in brain, except in inflammatory states (microglia)
- Stimulation of CB₂ can reduce inflammation and neuropathic pain
The Human Endocannabinoid System

THC and CBN are known to “fit” like a lock and key into the network of existing receptors. The Endocannabinoid System exists to receive cannabinoids produced inside the body called “Anandamide” and “2-Arachidonyl-glycerol”. Stimulating the ECS with plant-based cannabinoids restores balance and helps maintain symptoms.

CB1 receptors are concentrated in the brain and central nervous system but also sparsely populate other parts of the human body. Receptors are found on cell surfaces.

CB2 receptors are mostly in the peripheral organs especially cells associated with the immune system.

www.the-human-solution.org
CBD and Endocannabinoids

- Universal body mechanism for homeostatic regulation
- Largest neurotransmitter system in the body
- Regulates/Balances:
  - Nerve Function (pain levels, anxiety levels, sleep, seizure activity, nerve growth/repair, attention)
  - Movement coordination
  - Immune system activity
  - Inflammation (injury repair, swelling, pain)
  - Energy Intake and Storage (appetite/metabolism)
  - Cell life-cycles/apoptosis
  - Reproduction (hormone levels, implantation)
  - Circulatory System (Blood pressure, pulse rate)
  - Bone Metabolism (osteoclast activity)
  - Mood/Reward signaling (Addiction Implications)
Varieties of Cannabinoids

Endocannabinoids
In your brain and body
Anandamide, 2-AG, Noladin ether etc.

Phytocannabinoids
In plants
THC, CBD, CBG, CBDV, THCV, CBC, CBN, THCVA etc.

Synthetic cannabinoids
From the lab
Nabilone, HU-210, AB-PINACA, JWH-018, etc.
>100 cannabinoids in the plant. Most are non-psychoactive.

Each has its own pharmacological actions and therapeutic potential.

“Entourage” effects
Hemp vs Marijuana

• Both are considered *Cannabis sativa* but there is a distinction between hemp and marijuana.

• Marijuana contains significant amounts of the psychoactive phytocannabinoid known as THC.

• Industrial Hemp is cultivated very differently and has very little if any THC after extraction.

• Cannabidiol (CBD) - the non-psychoactive component of marijuana.

• Hemp CBD products can technically come from either cannabis plant – it just really boils down to being below that magic number of 0.3% of THC in the product.
Phytocannabinoids
Marijuana vs Hemp

- Tetrahydrocannabinol (THC)
  - Psychoactive
  - Has medicinal value

- Cannabidiol (CBD)
  - Not Psychoactive
  - Has anxiety relieving properties
  - Antagonizes effects of THC
  - Has medicinal value

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Cannabidiol (CBD) modulates many of the effects of THC in cannabis

THC and CBD =

THC only =
AVERAGE THC CONCENTRATIONS IN CANNABIS
SEIZED BY DEA
1980 TO 2014

Preclinical research identifies a range of possible therapeutic effects from phytocannabinoids

<table>
<thead>
<tr>
<th>Cannabinoid</th>
<th>Intoxicates?</th>
<th>Possible Medicinal Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>THC</td>
<td>√</td>
<td>Nausea and Vomiting, Muscular Spasms, PTSD, Pain, Cancer, Inflammation,</td>
</tr>
<tr>
<td>CBD</td>
<td>x</td>
<td>Epilepsy, Psychosis, Anxiety, PTSD, Addiction, Dementia, Cancer, Insomnia</td>
</tr>
<tr>
<td>CBDA</td>
<td>x</td>
<td>Epilepsy, Nausea and Vomiting, Cancer</td>
</tr>
<tr>
<td>CBDV</td>
<td>x</td>
<td>Epilepsy</td>
</tr>
<tr>
<td>THCA</td>
<td>x</td>
<td>Nausea and Vomiting, Epilepsy</td>
</tr>
<tr>
<td>THCV</td>
<td>x</td>
<td>Diabetes, Obesity, Pain, Inflammation, Epilepsy</td>
</tr>
<tr>
<td>THCVa</td>
<td>x</td>
<td>Under investigation</td>
</tr>
<tr>
<td>CBG</td>
<td>x</td>
<td>Glaucoma, Cancer, Inflammation, Anxiety, Huntingdon’s Disease</td>
</tr>
<tr>
<td>CBGA</td>
<td>x</td>
<td>Under investigation</td>
</tr>
<tr>
<td>CBN</td>
<td>x</td>
<td>Anxiety, Insomnia, Epilepsy, Anti-bacterial effects</td>
</tr>
<tr>
<td>CBC</td>
<td>x</td>
<td>Pain, Inflammation, Cancer</td>
</tr>
</tbody>
</table>
Farm Bill passed but the FDA...

- **Hemp** (contains no more than .03% THC) has been removed from the Government’s Controlled Substance Acts.
- However, the **Food and Drug Administration (FDA)** has not approved CBD’s use in food or beverages.
- The FDA controls the regulation of Cannabidiol (CBD),
  NOT the Farm Bill.

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Farming Act

• **Hemp Farming Act of 2018** became law December 20, 2018 removing hemp (defined as cannabis with less than 0.3% THC) from Schedule I controlled substances and making it an *ordinary agricultural commodity.*
Depending on where you live, you may be able to obtain a medical cannabis card for conditions like:

- Alzheimer's – interference with amyloid plaque formation
- Glaucoma – lowers intraocular pressure
- Multiple sclerosis – may relieve painful muscle contractions
- Crohn's Disease/IBD - enhanced gut permeability
- Adverse effects of chemo/Anorexia – appetite-stimulating effects
- PTSD – improvement in symptoms, undergoing further research
- Arthritis – e.g. RA & OA; pain reduction & improvement in mobility
- Epilepsy – e.g. Darvet’s Syndrome
- Chronic pain

<table>
<thead>
<tr>
<th>THC (Tetrahydrocannabinol)</th>
<th>CBD (Cannabidiol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Psychoactive</td>
<td>• Non-psychoactive</td>
</tr>
<tr>
<td>• Analgesic</td>
<td>• Analgesic</td>
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<tr>
<td>• Anti-inflammatory</td>
<td>• Anti-inflammatory</td>
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<tr>
<td>• Antioxidant</td>
<td>• Antioxidant</td>
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<tr>
<td>• Anti-emetic</td>
<td>• Anti-emetic</td>
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<tr>
<td>• Euphoric</td>
<td>• Anxiolytic</td>
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<tr>
<td>• Anti-neoplastic</td>
<td>• Anti-psychotic</td>
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<tr>
<td>• Anti-spasmodic</td>
<td>• Anti-convulsant/spasmotic</td>
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<tr>
<td>• Anti-tremor</td>
<td>• Anti-epileptic</td>
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<tr>
<td>• Appetite Stimulant</td>
<td>• Immunomodulatory</td>
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<td></td>
<td>• Neuroprotective</td>
</tr>
<tr>
<td></td>
<td>• Decrease THC psychoactivity</td>
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</table>
Terms - Hemp

- **CBD** - is from flower only.
- **Hemp oil** - a carrier oil made from seed and/or stalk.
- **Full spectrum** – is from the whole (full) plant.
- **Isolate** – extracts are rendered down to a single molecule – CBD using a variety of post processing steps.

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Hemp extract is code word for CBD (ex. 28 mg per 1 ml serving)

Hemp seed is made from the seed and virtually no CBD; they contain omega 3 & 6

Hemp oil is a carrier or base that they are using - does not have CBD

Hemp stalk is a source of many beneficial phytocannabinoids

Phytocannabinoid may contain some CBD

CBDA – cannabinoid; you won’t know how much is CBD unless you test it.
Drug Testing
What does all this mean?

• SAMHSA (Substance Abuse and Mental Health Services Administration) guidelines.

• Drug tested through urine for THC.

• THC is responsible for marijuana’s psychoactivity and euphoria.

• A consumer who uses a high-quality, scientifically vetted hemp-based product at the standard serving size is highly unlikely to test positive for THC.

• Extremely high doses may result in a positive urine screen.

• Consumers need to be fully informed of the specific regulations posed by their employers.
More than 800 stores in Alabama, California, Colorado, Illinois, Indiana, Kentucky, Maryland, and Tennessee now offer CBD products.

“These products include topicals such as creams, sprays, roll-ons, lotions and salves. We are not selling any CBD-containing supplements or food additives. We have partnered with CBD product manufacturers that are complying with applicable laws and that meet CVS’s high standards for quality,” CVS statement.
Psychoactive (Personal) vs Non-Psychoactive (Medical)

Cannabinoids

Delta-9-THC "PSYCHOACTIVE"

CBD "NOT PSYCHOACTIVE"
THC/CBD Effects on the Developing Brain????

- Unreliable Delivery System
- Unknown Absorption
- Products Containing THC
- Drug Interactions
- Contaminants
- Dosing
- Confusion of Legality
- Cannabis Use Disorder
Brain's Chemical

Anandamide

Drug

THC

Source: NIDA
Endocannabinoids are the body’s endogenous cannabinoids.

“The Bliss Molecules”

Anandamide (Sanskrit ananda inner bliss) is one endocannabinoid. It is found in chocolate (though there is some controversy over whether the small quantity has any effect on the body). It is about as potent as THC.
THC – Actions

• THC has a wide number of pharmacological actions, some of which have been known since antiquity.

• Anxiolytic / Sedative (CB1)
• Analgesic (CB1)
• **Anticonvulsant** (CB1)
• Appetite Stimulant (CB1)
• Anti-emetic (CB1)
• Anti-inflammatory / Immune Suppressant (CB2)
• ETC.
Cell Destruction Occurs with both THC and CBD: The Result is Suppressed Immune Function

Impact of Addiction

- MARIJUANA:

16 y.o.
2 year history of daily abuse
underside surface view of prefrontal and temporal lobe activity

Normal

© 2006 Amen Clinics Inc
Psychoactive (Personal) vs Non-Psychoactive (Medical)

Cannabinoids

Delta-9-THC
“PSYCHOACTIVE”

CBD
“NOT PSYCHO ACTIVE”
CBD Structure

- Converted from CBDa by heating.
CBD – Pharmacological Actions

• Well Documented:
  • Anti-seizure effects

• Suggested:
  • Analgesic (acute and chronic pain)
  • Antipsychotic
  • Anxiolytic
  • Anti-cancer
  • Anti-inflammatory
CBD Pharmacology

• CBD does act via the endocannabinoid system as usually defined.

• It does not activate CB1 or CB2 receptors - or mimic 2AG, anandamide or any known endocannabinoid.

• It may interact with the endocannabinoid system indirectly, e.g. antagonizes CBD1 receptors and inhibits FAAH (?).

• What receptors does it bind to?
CBD
Endogenous
Ligand?

• Effects of CBD are said to be “pleotropic”. It acts on many different receptors.

• Unclear whether there is an endogenous ligand.

• Except for the chemical messengers related to its various receptors (5 HT, opioids, etc.)
CBD – Receptors?

A very confused field. It has been reported to act on:
- CBD does NOT act on the CB1 or CB2 receptors
- Instead it acts on the following:
  - 5 HT 1A – partial agonist (anxiolytic? antidepressant?)
  - Adenosine receptors – agonist (anxiolytic?)
  - TRPV1 - weak agonist, desensitizes (analgesia?)
  - Mu and delta opiate receptors – allostERIC modulator (analgesic?)
  - PPAR – agonist (anticancer?)
  - GPR55 – antagonist (effect?)
  - ETC, ETC
Oral Cannabidiol Does Not Produce a Signal for Abuse Liability in Frequent Marijuana Smokers

• The data indicate that CBD has low potential for abuse; however, it currently remains unclear if CBD is safe for long-term use or clinically useful for the treatment of any of the disease conditions currently under investigation. However, this study may help inform U.S. regulatory decisions if CBD shows medicinal promise in clinical trials.

CBD- Is It Safe to Take????
BUYER BEWARE!!!!!

BTW a 2OZ bottle of pure CBD oil will cost more than the $24.95. It is an expensive extraction process!!!!
CBD Extraction

Extraction Methods

**CO₂ extraction.** The supercritical (or subcritical) CO₂ method uses carbon dioxide under high pressure and extremely low temperatures to isolate, preserve, and maintain the purity of the medicinal oil. This process requires expensive equipment and a steep operational learning curve. But, when done well the end product is safe, potent, and free of chlorophyll.
Other Extraction Methods

- Steam Distillation
- Hydrocarbon Solvent Extraction
- Natural Solvent Extraction
Costs of Production and Extraction of CBD

**Cultivation Costs:** $5,000 per acre

Following decortication, the extraction is conducted to access the cannabinoids, flavonoids, terpenes, etc. Two of the most popular ways that extraction occurs include CO2 and ethanol. A CO2 extraction machine is estimated to cost between $135,000 and $150,000.

**Costs of example products:** $59.99-187.99 per 30 ml
Hemp CBD Scorecard by Center for Cannabis Safety

Only 4 companies out of 40 companies made an “A”

nearly half of the companies made a D or F.

17 companies were not USDA certified and could not provide verification that their products were truly organic.

www.centerforfoodsafety.org
New Products for 2020
Edibles
Edibles and The Law

• Can THC or CBD products be sold as dietary supplements?
  A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement.
  There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.
  Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements.
Pharmacology

- CBD
  - Antibacterial
  - Inhibits cancer cell growth
  - Neuro-protective
  - Promotes bone growth
  - Reduces seizures and convulsions
  - Reduces blood sugar levels
  - Reduces function in the immune system
  - Reduces inflammation
  - Reduces risk of artery blockage
  - Reduces small intestine contractions
  - Reduces vomiting and nausea
  - Relieves pain
  - Relieves anxiety
  - Slows bacterial growth
  - Suppresses muscle spasms
  - Tranquilizing
  - Treats psoriasis
  - Vasorelaxant

- CBC
  - Inhibits cancer cell growth
  - Promotes bone growth
  - Reduces inflammation

- CBCA
  - Reduces inflammation
  - Treats fungal infection

- Δ9-THCA
  - Aids sleep
  - Inhibits cancer cell growth
  - Reduces vomiting and nausea

- Δ9-THC
  - Reduces vomiting and nausea
  - Relieves pain
  - Stimulates appetite
  - Suppresses muscle spasms

- Δ8-THC
  - Reduces pain

- THCV
  - Reduces pain

- CBG
  - Reduces inflammation
  - Relieves pain
  - Slows bacterial growth

- CBGA
  - Reduces inflammation
  - Promotes bone growth
  - Slows bacterial growth

- CBDA
  - Reduces inflammation
  - Promotes bone growth
  - Slows bacterial growth

- CB
  - Reduces inflammation
  - Promotes bone growth
  - Slows cancer cell growth
CBD Products on the Rise

• However, CBD research has been restricted because the Drug Enforcement Administration classifies it as an illegal substance, and researchers in the United States are required to have a license to possess and study the compound.

• To date, FDA has approved one drug containing a highly purified form of CBD, Epidiolex, based on clinical trials that showed the drug reduced seizures in children with two rare forms of epilepsy. From that clinical trial, researchers also know CBD can trigger adverse side effects, such as diarrhea and fatigue. Patients who participated in the trials had higher rates of infection, sleep problems, and depressed appetite.
Concerns about safe CBD products

FDA said most CBD products currently sold in the United States are unregulated and untested. The agency noted that its own testing has shown some products do not contain the amounts of CBD they claim to contain, while some CBD products contain toxic metals, pesticides, and THC.

FDA also noted that some available data has sparked concerns about potential harms associated with CBD products, including changes to male fertility, diarrhea, drowsiness, liver injury, mood changes, and possible interactions with other drugs.
Concerns about CBD Safe Products

• CBD companies have been waiting for direction from FDA on how to label and market their products. "They keep telling us they're going to come out with guidance, and they don't," Ridenour said, adding, "They just tell us what not to do. We're ready to comply with anything they throw at us.”

• Even a critical review by the World Health Organization (WHO) recently reported that CBD is a promising treatment for a number of medical conditions, is well tolerated, has a good safety profile, and doesn’t appear to be a risk for abuse, dependence, or other public-health related problems. In other words, even the WHO thinks CBD is A-OK.

• But wait just a second...............
Concerns about CBD Safe Products

- High dose side effects:
- Tiredness
- Decreased appetite
- Gastrointestinal problems
- Altered liver enzymes (see following section for more on liver enzymes)
- Other issues include:
  - Pesticides and heavy metals from bad farming practices
  - High levels of THC (more than desired)
  - Synthetic cannabinoids
  - Any kind of contaminants (mold, bacteria, rancidity, etc)
Concerns about CBD Safe Products

Drug to Drug Interactions:
- HIV medications
- Warfarin
- Anticonvulsants
- Chemotherapy
- Liver Disease: elevated liver enzymes
- Low Blood Pressure: orthostatic hypotension, increased risk of falls
- Conception: Lower fertility rates
- Pregnancy and Breastfeeding; Passes to the placenta to unborn fetus
The FDA Safety Warnings

• CBD has the potential to harm you, and harm can happen even before you become aware of it.
  • CBD can cause liver injury.
  • CBD can affect the metabolism of other drugs, causing serious side effects.
  • Use of CBD with alcohol or other Central Nervous System depressants increases the risk of sedation and drowsiness, which can lead to injuries.

• CBD can cause side effects that you might notice. These side effects should improve when CBD is stopped or when the amount ingested is reduced.
  • Changes in alertness, most commonly experienced as somnolence (drowsiness or sleepiness).
  • Gastrointestinal distress, most commonly experienced as diarrhea and/or decreased appetite.
  • Changes in mood, most commonly experienced as irritability and agitation.

• There are many important aspects about CBD that we just don’t know, such as:
  • What happens if you take CBD daily for sustained periods of time?
  • What is the effect of CBD on the developing brain (such as children who take CBD)?
  • What are the effects of CBD on the developing fetus or breastfed newborn?
  • How does CBD interact with herbs and botanicals?
  • Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?

• It will take time to discover these answers and others that will arise-so buyer be aware!!!

Questions