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# The Bloom of Hemp: CBD Oils in the Community Pharmacy

## NCPA 2018 Annual Convention

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## Disclosure

Alex Capano is employed as Medical Director for Ecofibre Industries, which wholly owns Ananda Professional. The conflict of interest was resolved by peer review of the content.

Jonathan Miller is an employee with Frost Brown Todd, LLC. This conflict of interest has been resolved by peer review of the content.

Todd Halpern is an employee with Venable LLP. This conflict of interest has been resolved by peer review of the content.

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## Learning Objectives

1. Review the potential therapeutic benefits of CBD oil and counseling points.
2. Outline legal considerations of selling CBD oil in community pharmacies.
3. Examine marketing tactics and associated risks with CBD oils.

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## History of Hemp

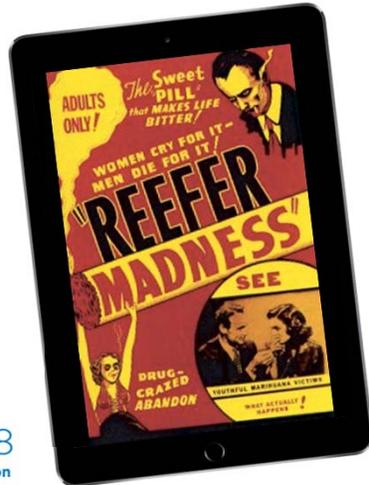
- ✓ Continuous use for > 8,000 years
- ✓ Grown by George Washington, used by Thomas Jefferson
- ✓ In US Pharmacopeia until 1937
- ✓ Marihuana Tax Act & Prohibition
- ✓ Act opposed by American Medical Association



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# Marihuana Tax Act of 1937



- According to the **Congressional Research Service**: this was hastily enacted in response to the introduction of morphine & opioids.

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# Hyperbole Everywhere!



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## Hemp Seed Oil

- Exceptionally rich in polyunsaturated fatty acids
- Omega-3 & Omega -6
  - Linolenic Acid,  $\alpha$ -linolenic acid, gamma-linolenic acid\*
- Antithrombotic
- Anti-inflammatory
- Anti-asthmatic
- Immunomodulatory  
(autoimmune disorders, RA, etc.)



(Deferne, 1996; Rose, 1991; Rose, 1997)

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## Full-Spectrum Hemp Extract

- The benefits of hemp-seed oil  
PLUS cannabinoids.
- Cannabinoids: CBD, THC, CBN, CBG,  
etc.
- Cannabinoids are derived from the  
flower of the hemp plant.



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## The Endocannabinoid System (ECS)

- Not widely taught in medical, nursing or pharmacy schools (~13 percent)
- Present in all humans - receptors exist throughout the body (brain, digestive system, lymphatic system, etc.)
- Responsible for homeostasis
  - Regulation of breath, inflammation, immune response, mood, pain, GI motility, neuroprotection, hormonal balance, sleep/wake cycle, blood pressure, tumor surveillance, and reproduction
- Can be activated by going for a run, i.e.. "runner's high"



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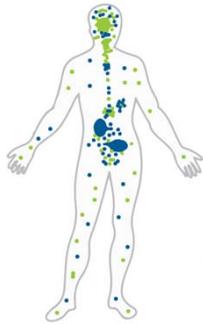
## The Endocannabinoid System (ECS)

- ✓ CB1 and CB2 expression is altered by the endocannabinoid system
- ✓ Increased expression can be beneficial in certain disease states, such as neuropathic pain and multiple sclerosis, by decreasing symptoms and even slowing disease progression
- ✓ Effects mood, regulates body temperature, controls inflammation, and more.
- ✓ **Statement from the NIH:** modulating the ECS "may have therapeutic potential in almost all diseases affecting humans."

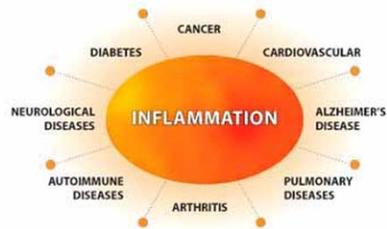
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## The Endocannabinoid System



CB1  
CB2

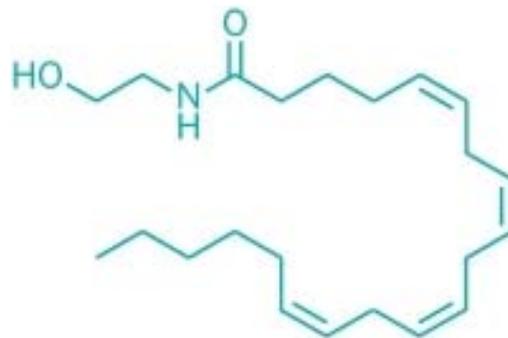


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## The Endocannabinoid System (ECS)

- Activation of the ECS through cannabinoids
- Endogenous cannabinoids
  - Anandamide, 2-AG
- Exogenous Cannabinoids
  - Plant derived
  - CBD, THC, CBG, CBN, THCv, etc.



Anandamide

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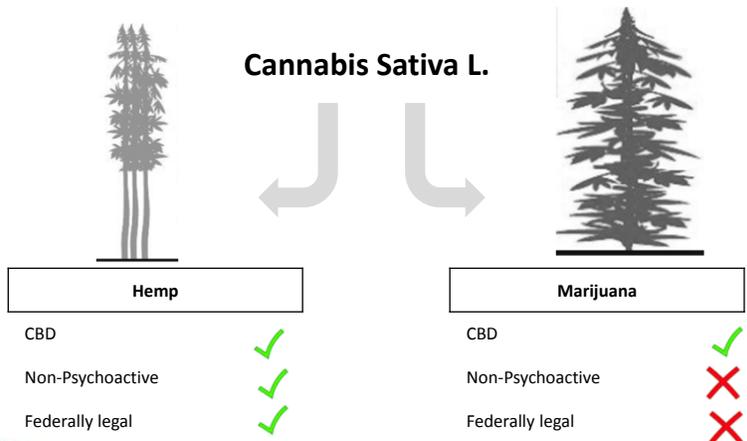
# CBD vs. THC

- CBD:
  - Not psychoactive
  - Will not (and *cannot!*) get you high
  - Anti-inflammatory, pain relieving, immunomodulating, anti-anxiety, etc.
- THC
  - The compound that elicits the high in marijuana
  - Highly regulated
  - Federally illegal
  - Can induce anxiety & psychosis

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# Hemp vs. Marijuana



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Legal production and sale of hemp was signed into law by President Obama in 2014



## CBD and other Rare Cannabinoids

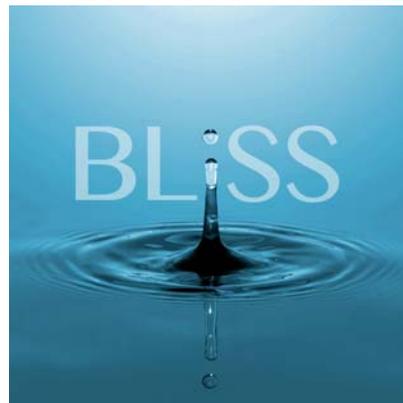
- Not psychoactive
- Used as anti-epileptic, anti-inflammatory, analgesic, anti-emetic, anxiolytic and anti-psychotic
- Inhibits THC-induced adverse reactions (ie. Anxiety, psychosis, intoxication)
- \*May\* inhibit tumor growth
  - Demonstrated by multiple studies on human cancer cells (\*NOT enough research!)
- Neuroprotective

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## CBD & Anandamide

- Named after Sanskrit word – Ananda - “bliss”
- Directly correlated with improved mood, reduction of depression and anxiety responses.
- Endogenous levels are low and the half-life is rapid

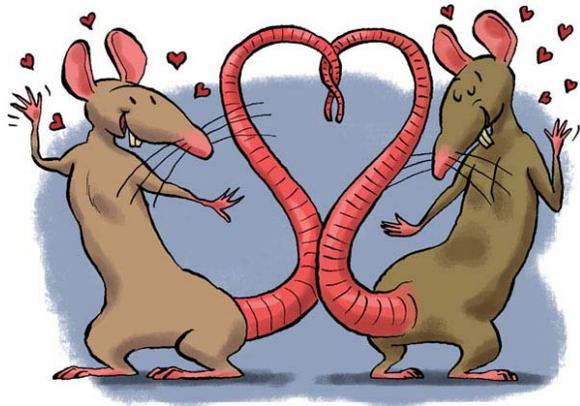


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## CBD, Anandamide & Oxytocin

Study at UC Irvine



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## CBD & Opioid Reduction

- Why?
  - CBD is an effective analgesic
  - CBD is safe when used as an adjunct
  - CBD may reduce opioid craving and withdrawal symptoms



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## CBD & Opioid Reduction

- **JAMA's systematic review of cannabinoids analgesia.<sup>1</sup>**
  - Supported by **high-quality evidence for *marked pain relief***
- **Meta-Analysis from the National Academies of Science, Engineering & Medicine**
  - "*Conclusive or substantial evidence*" of cannabinoids' efficacy in pain relief
- **Petzke's Systematic Review on Cannabinoids & Pain**
  - Conclusion: Cannabinoids effective for pain relief

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## CBD & Opioid Reduction



### Human, Double-blind, placebo controlled RCT:

Statistically significant reduction in heroin cravings after one dose of CBD at 1 hr, 24 hrs & 7 days

CBD decreased cigarette use among dependent participants.

CBD reduced anxiety in the patients who received it



### CBD & Fentanyl Pharmacokinetic Study

No increased risk of respiratory depression

No increased cardiovascular risk

## CBD & Opioid Reduction

- States with medical cannabis laws: **24.8%** lower mean annual opioid overdose mortality rate
- Medicare Rx for drugs reduced
  - pain, depression, anxiety, nausea, psychoses, seizures and sleep
- Michigan:
  - 64% decrease in opioid use
  - improved quality of life
  - reduction in side effects
- California:
  - 97% of opioid users reported that they “strongly agreed/agreed” that cannabinoids reduced their opioid use

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## CBD & Opioid Reduction

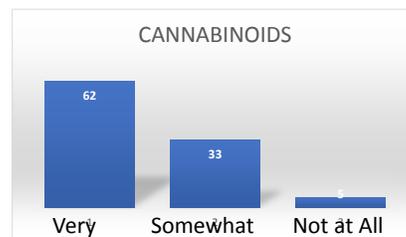
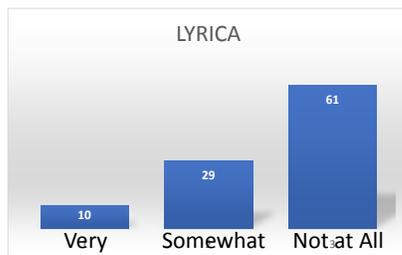
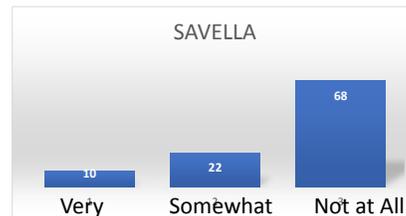
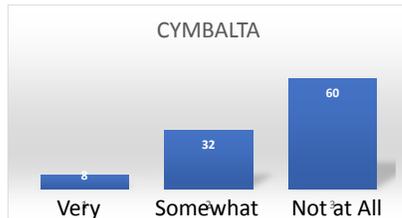
- Maine Medical Center: 1,500 opioid users; patients with chronic pain
- Reduction in:
  - Opioids: 76.7%
  - Anxiety meds: 71.8%
  - Depression meds: 37%
  - Sleep meds: 65.2%
  - Migraine meds: 66.7%
  - Alcohol: 42%



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## National Pain Foundation Study on Fibromyalgia



## Market Analysis: The Brightfield Study

- 1,400 Hemp derived CBD users
- Key Take-Aways:
  - Top Conditions for CBD use: depression, insomnia, anxiety, pain, migraines, arthritis and nausea
  - 84% reported it was extremely effective in reducing their clinical conditions/symptoms
  - 42% substituted CBD completely and eliminated use of traditional medications.
  - 69% : more effective or “much more effective” than other OTC products they’ve tried.
  - 56% reported the same over prescription meds.
  - 90% reported that they were likely to buy again.

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## The Brightfield Study

- Pros of Hemp-Derived CBD:
  - Relief without side-effects
  - “It doesn’t get me high”
- Cons of Hemp-Derived CBD:
  - “It doesn’t get me high”
  - Lack of availability
- 67% Bought between 1 & 3 products in the last 2 weeks
- “significantly more likely to purchase branded products via legal and official channels” (...such as your pharmacy!)

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## World Health Organization on CBD



**World Health  
Organization**

- CBD is safe and well tolerated in humans
- Not associated with negative public health effects
- Not associated with abuse potential

World Health Organization, & WHO Expert Committee on Drug Dependence. (2018). WHO Expert Committee on Drug Dependence: thirty-ninth report.

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## The Entourage Effect: Why Whole-Plant, Full-Spectrum Matters

ISOLATE



FULL-SPECTRUM



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## Dosing and Delivery

- Sublingual vs. Oral vs. Topical



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## Drug / Drug Interactions

### CBD interacts with CYP 450

- CYP3A4, CYP2C9, CYP2C19
- Potential inhibition at CYP3A4 & CYP2D6
- Less significant than grapefruit juice?
- Sometimes may inhibit metabolism of other drugs
- Sometimes increases metabolism of other drugs
- Clinically significant?
- Follow-up & Counseling

**GW Pharmaceuticals:** 40mg sativex (1:1 ratio)  
No interaction with other CYP 450, other drugs

### Follow-up Study:

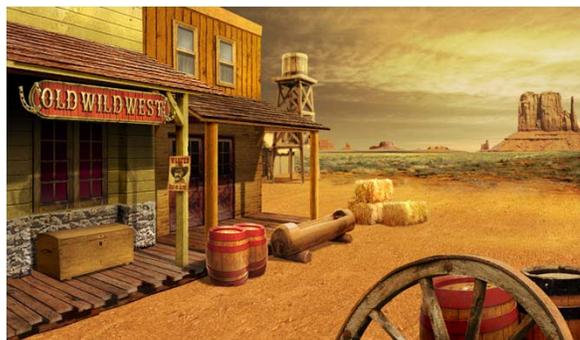
Interaction with anti-epileptic drugs at 35mg CBD  
Resulted in increased side-effects from anti-epileptic drugs  
Reduced dose of anti-epileptic drugs to reverse adverse effects  
Maintained overall reduction in seizure activity  
70% of participants had 50% reduction in overall seizures

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## The Wild West of CBD

- JAMA: 70% of CBD products do not match label (Bon Miller et al., 2017)
- FDA: 91% of products do not match packaging (2016)



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## Certificate of Analysis

### Should:

- Be done by a third party lab
- Include cannabinoid content
- Include tests for pesticides, microbes, chemicals
- Be lot specific

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## Certificate of Analysis

### Cannabinoid Test Results 02/21/2018

Cannabinoid analysis utilizing High Performance Liquid Chromatography (HPLC, QSP 5-4-4-4)

	LOD mg/mL	LOQ mg/mL	mg/mL
THC	0.000034	0.001	1.72
THCa	0.000066	0.001	ND
CBD	0.000057	0.001	7.73
CBDa	0.000038	0.001	0.08
CBN	0.000029	0.001	0.18
CBDV	0.000065	0.001	0.27
CBDVa	0.00003	0.001	ND
CBG	0.000086	0.001	0.23
CBGa	0.000072	0.001	ND
THCV	0.000035	0.001	0.11
Δ8 - THC	0.000083	0.001	0.01
CBC	0.000095	0.001	0.32

Total THC	1.72 mg/ml
Total CBD	7.80 mg/ml
<b>Total Active Cannabinoids:</b>	<b>10.65 mg/ml</b>

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# Letter for Employers & Providers

**Information Regarding Over-the-counter Dietary Supplement Hemp Oil and False-Positive Drug Screens**

Pain is often inadequately treated with currently available drugs, such as opioids. Nevertheless, opioids continue to be used, overused, and even abused, by people seeking to find pain relief. Thus, physicians and patients are seeking new approaches to treat pain that also address concerns about drug abuse.

Cannabinoids, including cannabidiol (CBD), are natural chemicals found in hemp that have pain-fighting properties. CBD has been scientifically shown to be safe and effective in treating pain and is virtually absent of abuse potential. Therefore, in an effort to curb the use of opioids, over-the-counter and legal hemp-derived dietary supplements containing CBD are being recommended more and more by physicians as complementary and adjunctive agents useful for treating pain.

Legal industrial hemp contains only a fraction of THC (i.e. tetrahydrocannabinol) a psychoactive compound found in marijuana. The federal limit for hemp THC content is 0.3 percent, and in accordance with the 2014 U.S. Farm Bill, hemp grown in Kentucky is routinely tested to ensure that its THC level falls at or below the legal limit.

Activation of the body's CB1 (i.e. cannabinoid-1) receptor is responsible for THC's psychoactive properties. In contrast, CBD does not activate the CB1 receptor in the same manner as THC. This is why CBD is considered to be non-psychoactive. In other words, CBD will not cause intoxication or a "high."

However, because of the fat-soluble nature of THC and other cannabinoids found in hemp oil, accumulation and excretion of hemp oil byproducts can result in a positive drug test for THC. Thus, since hemp oil can be legally sold in stores as a dietary supplement, consumption of hemp oil products (i.e. CBD from hemp) may be a viable explanation for "false-positive" detection of THC (i.e. marijuana) in drug screens.

For more information, please contact your patient's pharmacist or Ananda Professional's Medical Director at [alex.capano@anandaohemp.com](mailto:alex.capano@anandaohemp.com).

Sincerely,  
 Alex Capano, DNP, CRNP  
 Medical Director, Ananda Professional  
 Senior Fellow, The Institute of Emerging Health Professions at Thomas Jefferson University  
 Faculty, The Lambert Center for the Study of Medicinal Cannabis & Hemp at Thomas Jefferson University

References:  
 (1) The ON Risk Manag. 2008 Feb; 4(1) Cannabinoids in the management of difficult to treat pain.  
 (2) Epilepsy & Behavior Volume 79, Part B, May 2017, Pages 288-291: The legal status of cannabis (marijuana) and cannabidiol (CBD) under U.S. law.

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# COA from CBD company X.

From a 60ml bottle labeled "500mg CBD"

ID	Weight %	Conc.
10-THC	ND	ND
11-THC	ND	ND
CBD	0.28 wt%	2.51 mg/mL
CBN	ND	ND
CBC	ND	ND
CBG	ND	ND
CBV	ND	ND
THCA	ND	ND
CBDA	ND	ND
CBGA	ND	ND
Total	0.28 wt%	2.51 mg/mL
Max CBD	0.28 wt%	2.51 mg/mL

What is the actual amount of CBD in the bottle?

Is it full-spectrum?

What about pesticides?

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## Conclusions

- Hemp-derived CBD may be an effective option for many patients
- Excellent Safety Profile
- Profitability and Health Promotion
- Only Some CBD is Legal
- Full-Spectrum is Best
- Check the COA!

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## Questions?

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## Where We are Today

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## DEA Regulation

### Controlled Substances Act: Schedule I

Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation...

(23) Marihuana...

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## “Marihuana” (CSA)

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*

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## Hemp Farming Act of 2018 (S. 2667)

Amend CSA Definition of Marijuana to exclude “Hemp”:

“the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids...with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”

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## FDA Regulation

### “Dietary Supplement”

Does NOT include a product containing:

an article that has been (1) approved as a new drug; or (2) “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,” unless the product was first marketed as a dietary supplement or as a food.

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## FDA Regulation

### GW Pharmaceuticals

- FDA approved Epidiolex (CBD) New Drug Application in June 2018
- Clinical trials announced at least as early as 2006, and possibly earlier

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## FDA Regulation



### WARNING LETTER

#### Unapproved New Drugs and Misbranded Drugs

Although you market "CBD All-Natural Hemp Oil" as a dietary supplement, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. Under that provision, if an article (such as CBD) 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 outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD.

The existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex.<sup>[1]</sup> FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR § 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the Act [21 U.S.C. § 355]. FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act, but you may present FDA with any evidence that has bearing on this issue.

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## FDA Regulation

### 13. Is it legal, in interstate commerce, to sell a food to which THC or CBD has been added?

A. No. Under section 301(l) of the FD&C Act, it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the Act) or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not called our conclusions into question.

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## Miscellaneous Issues

- Financial Institutions / Banks / Credit Card Processors
  - Visa / Mastercard Rules
- Pharmacy Licenses
- Insurance

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## What's on the Horizon...

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## History of Hemp

- Leading Cash Crop from Founders Through Early 20<sup>th</sup> Century
- Reefer Madness and Prohibition
- Emerging Science Distinguishing between Hemp and Marijuana
- Legality of Imports – 9<sup>th</sup> Circuit Decision in HIA v/DEA

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## 2014 Farm Bill/Pilot Program Regimen

- Kentucky Leads Way in 2012
- McConnell and the 2014 Farm Bill
- Federal Lawsuits to “Free the Seed”
- FDA Q&A
- 2016 Omnibus Law
- 40 State Pilot Programs

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## Current Legal Status

- Hemp-Derived CBD Must be Less than 0.3% THC and Produced in Legal Program
- No Disease Remediation Claims
- Some States Offer Medical Route – Limited
- States Moving Toward Permanent Legalization
- Remaining FDA Concerns

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## Who is the U.S. Hemp Roundtable?

- A coalition of dozens of hemp companies and all the industry's major national grassroots organizations.
- Working to pass bi-partisan legislation in U.S. Congress that would establish hemp as an agricultural commodity, and remove regulations as a controlled substance.
- Efforts include an aggressive, targeted, grass-tops lobbying campaign
- Mission includes facilitating information exchange, development of a self-regulatory organization (SRO), and long-term legislative advocacy on other major policy issues.

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## Board of Directors



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Van Dyke Holdings

WILLIAMS  
 RANCH  
 COMPANY



## Member Organizations

- AgTech Scientific
- American Herbal Products Association
- AnaviiMarket
- Atalo
- Atlas St. Ventures
- BotanacorServices
- Canna-Pet
- Cream
- Elemental Processing
- Eurofins
- General Hemp
- Gotham Green Partners
- Green Wellness Life
- Harrod's Creek Farm
- Hempure
- Hemp Industries Association
- Hemp Today
- Irwin Naturals
- Medterra
- MHR Brands
- National Hemp Association
- North American Industrial Hemp Council
- S&H Hemp
- Unique Food Works
- Virginia Industrial Hemp Coalition
- Vote Hemp
- Zelios

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## Membership Levels

### Board of Directors

This membership level provides for participation in the governance of the organization and includes voting rights, and hiring and budget decisions in addition to general member benefits.

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### Voting

This membership level includes a voice in the development of all Roundtable policies, including the key decisions on legislative language and policy priorities.

### Non-Voting

This membership level includes participation in calls and meetings, and a voice to express their ideas and concerns, but not able to cast votes.

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## Federal Legislation



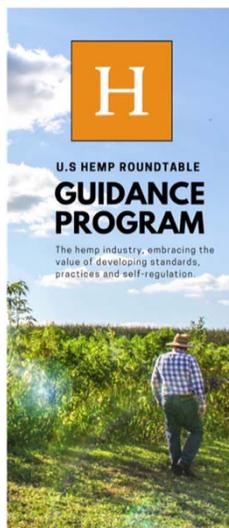
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- Hemp Farming Act of 2018
  - Senate Bill 2667; House Bill 5485
- Agricultural Improvement Act of 2018
  - Senate Farm Bill

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## SRO/Guidance Program

- Standards and practices for the hemp industry
- Development of a self-regulated organization by 2019



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## State-By-State Efforts

State	Complete	In Progress
CA		Yes
FL		Yes
IN	Yes	
MI		Yes
MO	Yes	
OH		Yes
OK		Yes
TN	Yes	
TX		Yes
UT		Yes
WA		Yes

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**Our next battle** → **FDA**



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**Questions?**

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