

CANNABINOIDIOL AND COVID WHAT ADDICTION PHYSICIANS NEED TO KNOW

Gregory Bunt, M.D. FASAM, FISAM

Past President, International Society of Addiction Medicine Past President, New York Society of Addiction Medicine Diplomate, Addiction Psychiatry - American Board of Psychiatry and Neurology Clinical Assistant Professor of Psychiatry, NYU School of Medicine











NOTHING TO DISCLOSE



Gregory Bunt, M.D. FASAM, FISAM





A non-psychotomimetic cannabinoid found in the Cannabis species. Most abundant and widely known cannabinoid in cannabis, THC is the cannabinoid responsible for the main psychoactive effects patients are familiar with.

Bears structural similarity to the other natural cannabinoids, including tetrahydrocannabinol, tetrahydrocannabivarin, cannabidiol, and cannabinol, among others.

C B C

MARIJUANA CONTAINS CANNABINOIDS

DELTA-9-TETRAHY

which are a group of terpenophenolic compounds concentrated in the viscous resin of the glandular trichomes on the plant bud. Found in largest quantities in Cannabis varieties indigenous to central Africa, like certain phenotypes from Malawi. It is currently being researched as a treatment for metabolic disorders including diabetes, as well as serving as a potential appetite suppressant.

A mildly-psychoactive cannabinoid that comes about from the degradation of THC, there is usually very little CBN in a fresh plant.

NEF

With respect to the medical potential of the cannabis, CBD may hold the most promise for many serious conditions. CBD is a non-psychoactive cannabinoid that is believed to reduce the psychoactive effects of THC.

THC



WHAT IS CBD?

CBD is an abbreviation for Cannabidiol, a naturally-occurring cannabinoid component found in cannabis that comprises up to 40% of the plant. Cannabidiol is "a cannabinoid devoid of psychoactive effect." After THC (△9-tetrahydrocannabinol), CBD is by-far the most studied natural cannabinoid. According to many researchers, CBD may be the single most important cannabinoid ever discovered.

The reduced psychoactivity of CBD makes it an appealing treatment option for patients seeking anti-inflammatory, anti-pain, anti-anxiety, and anti-psychotic effects without disconcerting lethargy or dysphoria.

CBD is used to promote relaxation and a sense of well-being. It is also shown to be a powerful anti-obsessive: freeing the mind to help the body heal. A simple PubMed search yields over 1,500 papers that discuss the therapeutic actions of CBD.



Therapeutic Effects of Cannabidiol

The Biology and Potential Therapeutic Effects of Cannabidiol

June 24, 2015 presented by Nora D. Volkow, Director, National Institute on Drug Abuse Senate Caucus on International Narcotics Control

Drug Caucus Hearing on Barriers to Cannabidiol Research (United States Senate Caucus on International Narcotics Control)

"Cannabidiol: Barriers to Research and Potential Medical Benefits"

Mr. Chairman, Ms. Chairwoman, and Members of the Senate Drug Caucus, thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this hearing to share what we know about the biology and the potential therapeutic effects of cannabidiol (CBD), one of the main active chemical compounds found in marijuana. In light of the rapidly evolving interest in the potential use of marijuana and its derivative compounds for medical purposes, it is important to take stock of what we know and do not know about the therapeutic potential of CBD.



Background

To date, 23 states and the District of Columbia have passed laws allowing marijuana to be used for a variety of medical conditions. Fifteen additional states have enacted laws intended to allow access to CBD oil and/or high-CBD strains of marijuana. Interest in the potential therapeutic effects of CBD has been growing rapidly, partially in response to media attention surrounding the use of CBD oil in young children with intractable seizure disorders including Dravet syndrome and Lennox-Gastaut syndrome. While there are promising preliminary data, the scientific literature is currently insufficient to either prove or disprove the efficacy and safety of CBD in patients with epilepsy.¹ and further clinical evaluation is warranted. In addition to epilepsy, the therapeutic potential of CBD is currently being explored for a number of indications including anxiety disorders, substance use disorders, schizophrenia, cancer, pain, inflammatory diseases and others. My testimony will provide an overview of what the science tells us about the therapeutic potential of CBD and of the ongoing research supported by NIH in this area.

CBD Biology and Therapeutic Rationale

CBD is one of more than 80 active cannabinoid chemicals in the marijuana plant.^{III} Unlike the main psychoactive cannabinoid in marijuana, tetrahydrocannabinol (THC), CBD does not produce euphoria or intoxication.^{IIII,V,V} Cannabinoids have their effect mainly by interacting with specific receptors on cells in the brain and body: the CB1 receptor, found on neurons and glial cells in various parts of the brain, and the CB2 receptor, found mainly in the body's immune system. The euphoric effects of THC are caused by its activation of CB1 receptors. CBD has a very low affinity for these receptors (100 fold less than THC) and when it binds it produces little to no effect. There is also growing evidence that CBD acts on other brain signaling systems, and that these actions may be important contributors to its therapeutic effects.^{III}

Preclinical and Clinical Evidence

Rigorous clinical studies are still needed to evaluate the clinical potential of CBD for specific conditions.ⁱ However, preclinical research (including both cell culture and animal models) has shown CBD to have a range of effects that may be therapeutically useful, including anti-seizure, antioxidant, neuroprotective, anti-inflammatory, analgesic, anti-tumor, anti--psychotic, and anti-anxiety properties. Adverse Health Effects of Marijuana Use Nora D. Volkow, M.D., Ruben D. Baler, Ph.D., Wilson M. Compton, M.D., Susan R.B. Weiss, Ph.D. N Engl J Med 2014; 370:2219-2227June 5, 2014DOI: 10.1056/NEJMra1402309



THE NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

Dan L. Longo, M.D., Editor

Adverse Health Effects of Marijuana Use

Nora D. Volkow, M.D., Ruben D. Baler, Ph.D., Wilson M. Compton, M.D., and Susan R.B. Weiss, Ph.D.

N LIGHT OF THE RAPIDLY SHIFTING LANDSCAPE REGARDING THE LEGALIZAtion of marijuana for medical and recreational purposes, patients may be more likely to ask physicians about its potential adverse and beneficial effects on health. The popular notion seems to be that marijuana is a harmless pleasure, access to which should not be regulated or considered illegal. Currently, marijuana is the most commonly used "illicit" drug in the United States, with about 12% of people 12 years of age or older reporting use in the past year and particularly high rates of use among young people.¹ The most common route of administration is inhalation. The greenish-gray shredded leaves and flowers of the *Cannabis sativa* plant are smoked (along with stems and seeds) in cigarettes, cigars, pipes, water pipes, or "blunts" (marijuana rolled in the tobacco-leaf wrapper from a cigar). Hashish is a related product created from the resin of marijuana flowers and is usually smoked (by itself or in a mixture with tobacco) but can be ingested orally. Marijuana can also be used to brew tea, and its oil-based extract can be mixed into food products.

The regular use of marijuana during adolescence is of particular concern, since use by this age group is associated with an increased likelihood of deleterious consequences² (Table 1). Although multiple studies have reported detrimental effects, others have not, and the question of whether marijuana is harmful remains the subject of heated debate. Here we review the current state of the science related to the adverse health effects of the recreational use of marijuana, focusing on those areas for which the evidence is strongest.

ADVERSE EFFECTS

RISK OF ADDICTION

Despite some contentious discussions regarding the addictiveness of marijuana, the evidence clearly indicates that long-term marijuana use can lead to addiction. Indeed, approximately 9% of those who experiment with marijuana will become addicted³ (according to the criteria for dependence in the *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition [DSM-IV]). The number goes up to about 1 in 6 among those who start using marijuana as teenagers and to 25 to 50% among those who smoke marijuana daily.⁴ According to the 2012 National Survey on Drug Use and Health, an estimated 2.7 million people 12 years of age and older met the ria for dependence on marijuana, and 5.1 million people met the criteria for dependence on any illicit drug⁴ (8.6 million met the criteria for dependence on alcohol⁴). There is also recognition of a bona fide cannabis withdrawal syndrome⁵ (with symptoms that include irritability, sleeping difficulties, dysphoria, craving, and anxiety), which makes cessation difficult and contributes to relapse. Marijuana use by adolescents is particularly troublesome. Adolescents' increased vulnerability to adverse long-term outcomes from marijuana use is probably related From the National Institute on Drug Abuse, National Institutes of Health, Bethesda, MD. Address reprint requests to Dr. Volkow at the National Institute on Drug Abuse, 6001 Executive Blvd., Rm. 5274, Bethesda, MD 20892, or at nvolkow@nida.nih.gov.

N Engl J Med 2014;370:2219-27. DOI: 10.1056/NEJMral402309 Copyright © 2014 Massachusetts Medical Society.

CBD: CLINICAL CONSIDERATIONS

Source THC Content Efficacy Tolerability Safety Dosing

IS CBD oil legal?



Why The Hemp Industry Is Suing The DEA Over CBD Oil | HIA vs. DEA



Hemp businesses and consumers could soon be celebrating the end of the DEA's attempts to prevent Americans from producing or selling cannabidiol (CBD) extracts.

On Dec 14, 2016, the <u>DEA published a new rule</u> establishing a new drug code for "marijuana extracts."

The rule states that extracts from the "genus cannabis" plant containing *any cannabinoid* "will continue to be treated as Schedule I controlled substances."

CAN YOU GET HIGH FROM CBD OR HEMP OIL?

SODIOL

Pre-Filled Disposable Vaporizer

Powerful Antioxidant, Non-Psychoactive

Research Has Shown CBD May Help With:

- Focus
- Concentration
- Pain Relief
- Seizures

- Epilepsy
- Nausea
- Inflammation
- Anxiety / Depression

THE FOLLOWING DOCTORS ARE PROMOTING THE BENEFITS OF CBD





Dr. Bonni Goldstein is currently the Medical Director of Canna-Centers, a medical practice devoted to educating patients about the use of cannabis for serious and chronic medical conditions. Dr. Richard Besser is ABC News' Chief Health and Medical Editor and formerly the acting director of the American Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry. Sanjay Gupta, MD is an American neurosurgeon and an assistant professor of neurosurgery at Emory University School of Medicine and associate chief of the neurosurgery service at Grady Memorial Hospital in Atlanta, Georgia.



University of California San Francisco



OSHER CENTER FOR INTEGRATIVE MEDICINE

HARVARD MEDICAL SCHOOL AND BRIGHAM AND WOMEN'S HOSPITAL

The Osher Collaborative for Integrative Medicine comprises an international group of <u>seven academic</u> <u>Centers</u>

Integrative Healthcare Symposium Annual Conference

Learn, Engage and Improve your Patients' Overall Health FEBRUARY 23-25, 2027 | NEW YORK HILTON MIDTOWN, NY





UF Health Integrative Medicine Conference Botanicals and Supplements: Safe, Sensible and Effective Use





Collaboration in Action: Advancing Integrative Health through Research, Education, Clinical Practice and Policy "The leading conference on Integrative Medicine and Health.

May 8-11, 2018 Baltimore Marriott Waterfront For more details, visit:

internationalcongress.imconsortium.org

visit:

Senator Barbara Mikulski The longest serving woman in the United States Congress, Senator Mikulski is from the State of Maryland, host to this Congress, and a strong proponent of Integrative Medicine.

Special Guest Speaker

Meet the Invited Plenary Speakers









Peter Wayne, PhD Associato Professor of Modione, Haviard Medical School (Director of Research, Cahre Center for Indegrative Modione, Birgham and Womens Medione, Birgham and Womens Associata and Harvard Medical School

Helene M. Langevin, MD Professor in Residence of Mediene, D Harvard Medical School, Director, Osher Center for Integrative Medicine, Brigham and Wenner, Hospital and Harvard T Medical School

Fabrizio Benedetti, MD Steve ircotor, Conter for Hypoxia, Platoau Rosà Lats, Plateau Rosà, Italy witzertand, Professor, University of unin Modical School, Neuroscionce Dept, Turin, Italy

MD, MPH Alessio Fasano, MD dione and Professor of Podatrice, Harved Kold tor, VCU School, Director, Center for Celas thy Virginia Research and Treathent; Crief, Divisio Podietric Gastroenterslog and Nutrit

FORMS OF CBD

- Pharmaceutical grade
- Cannabis Dispensary
- OTC
- Internet

Hemp oil CBD < 10 mg CBD 25-50 mg

THC 0.0% THC< 0.3% THC> 0.3% THC> 3.0%

CANNABIS RELATED MEDICATIONS



Marinol / Dronabinol	Synthetic Delta-9 THC
Sativex	THC (delta-9-tetrahydrocannabinol) CBD (cannabidiol)
Nabilone / Cesamet	Synthetic cannabinoid similar to THC
Dexanabinol	Synthetic non-psychotropic cannabinoid that blocks NMDA receptors
Epidiolex®	Pure plant-derived Cannabidiol (CBD)

Rimonabant / Synthetic chemical that blocks endocannabinoids **Acomplia**





















Supplement Facts

MEDTERRA

CBD CEL CAPSULES 25MG

Serving Size: 1 Softgel Servings Per Container: 30

Amount Per Serving	%Daily Value		
Calories	5		
Total Fat	0.5 g	<1%*	
Hemp Extract (Aerial Plant Parts) (Cannabidiol (CBD) 50 mg)	75 mg	+	

* Percent Daily Values are based on a 2,000 calorie diet. * Daily Value not established.

Other Ingredients: Extra Virgin Olive Oil, Vegetarian Softgel (Modified Com Starch, Glycerin, Carrageenan, Sorbitol, & Purified Water), Chlorophyllin.

5 Traps to Know When Buying CBD Oil Online

Trap #1 – Watch Out for Low CBD Oil Prices

Trap #2 – Don't Buy CBD Oil That Cures Everything

CBD oil must be lab tested and refined to find the perfect combination to treat different medical conditions.

Trap #3 – Look for the Non-Psychoactive Stamp

The first thing to look for when browsing an online CBD store is for the Non-Psychoactive seal of approval. CBD oil does not contain THC, or it contains extremely low levels. Also, by law, it is illegal to shop psychoactive substances.

Trap #4 – The Extraction Method and Lab Testing of CBD Oil

It's important to make sure that the manufacturer of the CBD oil is a licensed pharmacist that understands what they are doing when formulating CBD products. When extracting CBD from the hemp plant it is best to use productive extraction processes such as CO2; a low temperature, high-pressure technique. Once the extraction is complete, its is important that the company uses a third party lab to test raw compounds. This guarantees that you are getting an unbiased opinion of the CBD oil from a third party lab.

Trap 5 – Lack of Transparency on the Site

Always best to check the fine print and the depth of the seller's website. A reliable and trustworthy manufacturer will have no problems showing the exact ingredients of their products and also their lab tests.

https://www.marijuanabreak.com/buy-cbd-oil-tips

The first CBD hemp oil product of its kind, RSHO-X[™] is a completely THC-free version of our customer favorite Real Scientific Hemp Oil[™]. Since RSHO-X[™] contains absolutely no THC, the compound in cannabis that gets users high, it has become the CBD supplement of choice for parents of small children, first responders, competitive athletes, or anyone subject to a drug test. In fact, RSHO-X[™] is the first cannabinoid supplement available that meets the rigid drug testing restrictions set forth by the World Anti-Doping Agency (WADA). Each 4 oz bottle comes with 1000 mg of CBD and absolutely no THC.



CBD FOR ATHLETES

What Can CBD Do For Athletes?

Years of scientific research has revealed that cannabinoids such as CBD interact with the body's endocannabinoid system (ECS). The ECS is a complex system that works within the body and controls a variety of biological processes like appetite, immune responses, mood, and sleep. The ECS also contains a network of cannabinoid receptors found in the brains and digestive systems of all mammals. By connecting with the two main types of cannabinoid receptors, CB1 and CB2, which are found on cells throughout the body, CBD interacts with the endocannabinoid system, helping it in striving to achieve homeostasis—the body's natural state of balance.

Athletes claim that their post-routine recovery period is shorter.

Once the workouts, exertion, and competitions are over, athletes use CBD in topical form. Simply rub or roll a CBD topical on the sore or aching muscle area. Because our CBD hemp oil products are categorized as dietary supplements in the United States, we comply with the FDA's <u>DSHEA guidelines</u> and cannot endorse any specific medical benefits of CBD or our hemp oil.

We encourage you to browse thousands of reputable studies regarding CBD published online and talk with your doctor to see if a CBD supplement is right for you



The World Anti-Doping Agency (WADA) was established in 1999 as an international independent agency composed and funded equally by the sport movement and governments of the world. Its key activities include scientific research, education, development of anti-doping capacities, and monitoring of the <u>World Anti Doping Code (Code</u>)– the document harmonizing anti-doping policies in all sports and all countries.



A world where all athletes can compete in a doping-free sporting environment.

Our Core Values

Integrity

•We are the guardian of the values and spirit inherent in the Code.

We are impartial, objective, balanced and transparent.
We observe the highest ethical standards and <u>avoid improper</u>

influences or conflicts of interests that would undermine our independent and unbiased judgment.

•We develop policies, procedures and practices that reflect justice, equity and integrity.



https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf Cannabidiol Critical Review Report Expert Committee on Drug Dependence Fortieth Meeting Geneva, 4-7 June 2018

The United Nations Conventions on international drug control treats extracts from the cannabis plant somewhat differently than marihuana or tetrahydrocannabinols. The creation of a new drug code in the DEA regulations for marihuana extracts will allow for more appropriate accounting of such materials consistent with treaty provisions.

The Single Convention on Narcotic Drugs, 1961 ("Single Convention") and the 1971 Convention on Psychotropic Substances ("Psychotropic Convention") provide for the international control of marihuana constituents. Many of the CSA's provisions were drafted to comply with these Conventions. The CSA includes schemes of drug scheduling and procedures for adding, removing, and transferring drugs among the schedules that are similar, in some ways, to those in the Single Convention. With respect to those drugs that are subject to control under the Single Convention, the CSA mandates that DEA control such drugs in a manner that will ensure the United States meets its obligations under the Single Convention. <u>21</u> <u>U.S.C. 811(d)(1)</u>.

According to WHO, CBD is not addictive or toxic



In the report, WHO says that CBD offers medical benefits without the potential risk of addiction. The report notes: "In an animal drug discrimination model, CBD failed to substitute for THC. In humans, CBD exhibits no effects indicative of any abuse or dependence potential."

The WHO report says CBD has "been demonstrated as an effective treatment for epilepsy" in adults, children, and animals. In addition, the report indicates that there is preliminary evidence showing that CBD could be beneficial in treating many diseases including alzheimer's disease, cancer, psychosis, parkinson's disease, and other conditions.



PHENOMENON

VAPE ADDITIVE

昭朝

配

CBD Oil May Help With The Following...

✓ Kills or slows bacteria growth (Antibacterial) ✓ Reduces blood sugar levels (Anti-diabetic) ✓ Reduces inflammation (Anti-inflammatory) Reduces risk of artery blockage (Anti-ischemic) ✓ Reduces seizures and convulsions (Anti-epileptic) ✓ Inhibits tumor/cancer cell growth (Anti-proliferative) ✓ Treats psoriasis (Anti-psoriatic) ✓ Suppresses muscle spasms (Antispasmodic) ✓ Promotes bone growth (Bone stimulant) ✓ Tranquilizing, used to treat psychosis (Anti-psychotic) ✓ Relieves anxiety (Axiolytic) ✓ Relieves pain (Analgesic) Protects nervous system degeneration (Neuroprotective) ✓ Reduces contractions in the small intestine (Intestinal Anti-prokinetic)

FDA sends warning letters to CBD companies, including Colorado's CW Hemp

FDA U.S. FOOD & DRUG

Dear Mr. Stanley:

WARNING LETTER

VIA SIGNATURE CONFIRMED DELIVERY

October 31, 2017

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.cwbotanicals.com (redirects to www.cwhemp.com) in August 2017 and has determined that you take orders there for the products "Everyday Dietary Supplement," "Everyday Plus Dietary Supplement," "Everyday Advanced Dietary Supplement" and "Charlotte's Web Gel Pen," which you promote as products containing cannabinoids, including cannabidiol (CBD). We have also reviewed your website at the internet address www.theroc.us, and your social media websites at www.facebook.com/CWHempOfficial and www.twitter.com/CWHemp; these websites direct consumers to your website, www.cwhemp.com, to purchase your products.

FDA Targets Country's Largest Cannabidiol Producer In Warning Over Cancer Claims

The U.S. Food and Drug Administration <u>sent letters</u> on Tuesday to four cannabis companies, warning them against making medical claims about cannabidiol (CBD). The agency also took issue with the businesses marketing CBD products as dietary supplements.

The FDA's warning letters targeted companies in California, Florida and Colorado: Natural Alchemist, Greenroads Health, That's Natural! and the Stanley Brothers, who produce CBD products under CW Botanicals and CW Hemp.

https://www.fda.gov/news-events/public-health-focus/fdaregulation-cannabis-and-cannabis-derived-productsincluding-cannabidiol-cbd

Potential harm, side effects and unknowns fda.gov

1.CBD has the potential to harm you, and harm can happen even before you become aware of it.

- 1. CBD can cause liver injury.
- 2. CBD can affect how other drugs you are taking work, potentially causing serious side effects.
- 3. Use of CBD with alcohol or other drugs that slow brain activity, such as those used to treat anxiety, panic, stress, or sleep disorders, increases the risk of sedation and drowsiness, which can lead to injuries.
- 4. Male reproductive toxicity, or damage to fertility in males or male offspring of women who have been exposed, has been reported in studies of animals exposed to CBD.
- 2.CBD can cause side effects that you might notice. These side effects should improve when CBD is stopped or when the amount used is reduced.
 - 1. Changes in alertness, most commonly experienced as somnolence (drowsiness or sleepiness).
 - 2. Gastrointestinal distress, most commonly experienced as diarrhea and/or decreased appetite.
 - 3. Changes in mood, most commonly experienced as irritability and agitation.
- 3.There are many important aspects about CBD that we just don't know, such as:
 - 1. What happens if you take CBD daily for sustained periods of time?
 - 2. What level of intake triggers the known risks associated with CBD?
 - 3. How do different methods of consumption affect intake (e.g., oral consumption, topical, smoking or vaping)?
 - 4. What is the effect of CBD on the developing brain (such as on children who take CBD)?
 - 5. What are the effects of CBD on the developing fetus or breastfed newborn?
 - 6. How does CBD interact with herbs and other plant materials?
 - 7. Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?



Judge Jeanine Pirro Heavenly Rx



John Boehner: From Speaker of the House to Cannabis Pitchman



"The advances Doctor Oz has made in the CBD industry are remarkable. I wouldn't believe it if I hadn't had the chance to try it out for myself. After using CANNAPRO CBD for two weeks I was already feeling like



Says He Has Nothing to Do With CBD Products

Tom Hanks Slams 'False' Ad That Claims He Endorses CBD

Not only did these CBD companies allegedly use false quotes from the actor but they're also accused of using the Clint Eastwood name in the metadata of some of the websites selling the products, which would help to bring the sites up if somebody were to do a web search for <u>Clint Eastwood</u>. The two lawsuits filed in Los Angeles claim false endorsement, trademark infringement, and violation of common law.

Needless to say, this seems like it will be pretty simple and clear in court. Either Clint Eastwood made such statements or he didn't and it should be pretty easy to prove one way or the other. It certainly wouldn't be the first time a company tried to borrow the name of a famous person without permission, but obviously it runs a pretty serious risk.

And it seems like this isn't that unusual a practice. **The Wrap** reports that Ellen Degeneres and **Sandra Bullock** have filed similar lawsuits in the past. In addition, **Tom Hanks** has called out at least one ad for CBD products that used his likeness and a quote that claims to be from him. Hanks was unequivocal that he had never said such a thing.







DOSAGE AND ADMINISTRATION

Obtain serum transaminases (ALT and AST) and total bilirubin levels in all patients prior to starting treatment. (2.1, 5.1) • See Full Prescribing Information for titration.

Seizures Associated with Lennox-Gastaut Syndrome or Dravet Syndrome •

The recommended starting dosage is 2.5 mg/kg by mouth twice daily (5 mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day)

Based on individual clinical response and tolerability, EPIDIOLEX can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day).

1 kg = 2.2 lbs 70 kg = 155 lbs

Table 3: Adverse Reactions in Patients Treated with EPIDIOLEX in Controlled Trials of LGS and DS

Adverse Reactions EPIDIOLEX 10 mg/kg/day 20 mg/kg/day N=75 % N=238 % N=227

Hepatic Disorders Transaminases elevated	8	16	3
Gastrointestinal Disorders Decreased appetite	16	22	5
Diarrhea	9	20	9
Weight decreased	3	5	1
Gastroenteritis	Ο	4	1
Abdominal pain, discomfort	3	3	1
Nervous System Disorders			
Somnolence	23	25	8
Fatigue, malaise, asthenia	11	12	4
Lethargy	4	8	2
Sedation	3	6	1
Irritability, agitation	9	5	2
Aggression, anger	3	5	<1

<u>Hepatic Disorders</u> transaminases elevated

Placebo 3%

10 mg/kg 8 %

20 mg/kg

16 %



Yasmin Hurd, PhD DIRECTOR, ADDICTION INSTITUTE AT MOUNTSINAI

CBD Reduces Craving and Anxiety in People With Heroin Use Disorder

Mount Sinai study highlights the potential of cannabidiol as a treatment option for opioid abuse New York (May 21, 2019)

Cannabidiol (CBD) reduced cue-induced craving and anxiety in individuals with a history of heroin abuse, suggesting a potential role for it in helping to break the cycle of addiction, according to research conducted at the Icahn School of Medicine at Mount Sinai and published May 21 in the *American Journal of Psychiatry*. The study also revealed that CBD tended to reduce physiological measures of stress reactivity, such as increased heart rate and cortisol levels, that are induced by drug cues.

Cannabidiol for the Reduction of Cue-Induced Craving and Anxiety in Drug-Abstinent Individuals With Heroin Use Disorder: A Double-Blind Randomized Placebo-Controlled Trial <u>Yasmin L. Hurd</u>, Ph.D., <u>Sharron Spriggs</u>, M.A., <u>Julia Alishayev</u>, R.P.A., <u>Gary Winkel</u>, Ph.D., <u>Kristina Gurgov</u>, R.P.A., <u>Chris Kudrich</u> et al Published Online:21 May 2019<u>https://doi.org/10.1176/appi.ajp.2019.18101191</u>

The Difference between CBD and THC

There are two main natural compounds found in marijuana: cannabidiol (CBD) and tetrahydrocannabinol (THC). Each act very differently in the brain.

- •THC is a psychoactive compound and is an agonist, or activator, of the cannabinoid 1 (CB1) receptor this is what produces a "high", or a sense of euphoria
- •CBD is a nonintoxicating compound, and binds weakly, if at all, to the CB1 receptor, causing no high, and does not cause dependence

THC is associated with many of the negative effects of marijuana, including difficulty with thinking and problem-solving, impaired memory, hallucinations, and psychosis.¹ Some research suggests that CBD can aid in the treatment of chronic pain, insomnia, and anxiety, but more investigation is needed.

What did this study find?

The study by Hurd *et. al.* found that CBD has the potential to help patients deal with environmental cue-induced craving and anxiety by reducing heart rate and the levels of stress hormones brought on by the sights, sounds, and people that trigger them. Researchers conducted the study with 42 people in good health between the ages of 21 and 65 who had heroin use disorder. All the participants had to be abstinent from heroin both at the start of and during the 4-week timeframe of the study. **Administering controlled amounts of CBD resulted in significantly reduced cravings and anxiety, compared to placebo**. These effects also lasted up to 7 days after the initial administration of CBD. In addition, CBD reduced the environmental cue-induced physiological measures of increased heart rate and salivary cortisol levels. Importantly, researchers found no significant effects on cognition and no serious side effects.



June 13, 2019 By <u>Mark Gold, MD</u>

Addiction Policy Forum is excited to announce our newest initiative, <u>Research You Can Use</u> This partnership with <u>Dr. Mark Gold</u>, a world-renowned expert in addiction and psychiatry, will highlight cutting-edge research related to addiction prevention, treatment, and recovery that may help transform policy and practice.



Can CBD Help in the

Treatment of and Recovery from Opioid Use Disorder?

Cannabidiol for the Reduction of Cue-Induced Craving and Anxiety in Drug-Abstinent Individuals With Heroin Use Disorder: A Double-Blind Randomized Placebo-Controlled Trial **Citation:** Hurd, Y.L., Spriggs, S., Alishayev, J, Winkel, G., Gurgov, K., Kudrich, C., Oprescu, A.M., Salsitz, E., (2019) *The American Journal of Psychiatry*

Would you consider prescribing cannabidol (CBD) off-label for treating pain?





Would you consider prescribing cannabidol (CBD) off-label for treating traumatic

Would you consider prescribing cannabidol (CBD) off-label for treating insomnia?





Would you consider prescibing cannabidol (CBD) off-label for treating opiate

Total Results: 86

Would you consider recommending hemp oil with cannabidol (CBD) but no THC for treating pain?



Would you consider recommending hemp oil with cannabidol (CBD) but no THC for treating insomnia?



Would you consider recommending hemp oil with cannabidol (CBD) but no THC for treating traumatic stress?



Would you consider recommending hemp oil with cannabidol (CBD) but no THC for treating opiate addiction?



Total Results: 80





SUMMARY OF CLINICAL ISSUES

Questions About Source Questions About THC Content Questions About Efficacy Questions About Tolerability Questions About Safety Questions About Dosing

Concerns About Unproven Medical Claims Viewpoints of ASAM Colleagues

