



Americans Against Legalizing Marijuana

October 21, 2025

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Andrew N. Ferguson

Chairman of the Federal Trade Commission.

Federal Trade Commission

600 Pennsylvania Avenue, NW

Washington, DC 20580

Re: The False Claims about CBD

Dear Secretary Kennedy, Dr. Makary, Attorney General Bondi, Administrator Cole and Chairman Ferguson

You all have a role in approving medicines and/or enforcing FDA medicine and food laws.

Cannabidiol (CBD) is a concentrated oil of the cannabis plant. Cannabis industry advertisements claim it is perfectly safe and legal, but CBD has many negative side effects. In the rush by the cannabis industry to convince consumers to use CBD, there has been little consideration of the health and safety concerns that must be addressed.

Enclosed is our research paper on CBD and other research.

We respectfully request that you enforce the FDA food and drug laws to protect consumers.

Sincerely yours,

Carla D. Lowe

President

Scott Chipman

Vice President

AMERICANS AGAINST LEGALIZING MARIJUANA
RESEARCH PAPER
www.aalm.info

October 21, 2025

CBD IS NOT SAFE AS A MEDICINE OR A FOOD UNLESS IT ACQUIRES FDA APPROVAL

Cannabidiol (CBD) and Tetrahydrocannabinol (THC) come from the cannabis plant. A pure form of CBD (Epidiolex) is approved by the FDA as a medicine for two rare disorders to be used only under proper medical protocols. Other CBD products sold as medicines, or food or food supplements that are not approved by the FDA are Black-Market and are illegally trafficked and sold in violation of federal FDA laws. In addition, CBD cosmetics must be properly labeled under FDA law and not be adulterated by deleterious substances. [1]

CBD is a concentrated oil of the cannabis plant. Cannabis industry advertisements claim it is perfectly safe, but CBD has negative side effects and may interfere with work performance and safety and the functioning of medications and may be contaminated. In the rush to convince consumers to use CBD, there has been little consideration of the concerns that must be addressed.

BLACK-MARKET CBD IS NOT APPROVED BY THE FDA

Black-Market CBD is not administered with any federally approved medical protocols as are prescription drugs and there may be no warnings for how they interact with other drugs, or whether they have dangerous side effects.

Under the federal Food, Drug and Cosmetic Act it's illegal to introduce THC and CBD into the food supply, or to market them as dietary supplements. It is not safe to do so unless approved by the FDA. [2]

MULTIPLE STUDIES SHOW BLACK MARKET CBD PRODUCT CONTAMINATION

The FDA has tested the chemical contents of many Black-Market CBD products and many were found to not contain the levels of CBD they claimed to contain. [3] Black-Market CBD often contains THC and/or contaminants such as pesticides, heavy metals, bacteria, and fungus. [4] Synthetic CBD use has caused adverse reactions, including altered mental status, seizures, confusion, and loss of consciousness. [5]

CBD CAUSES PHYSICAL DISEASE AND SAFETY RISKS

The marijuana industry has touted CBD as a “wonder drug.” * They may claim it is perfectly safe and legal and can be used for all that ails you or makes you uncomfortable physically. People are consuming CBD under the misapprehension that it is safe to do so. It is not. CBD has known health risks based on FDA clinical studies in humans and other clinical reports. The known adverse reactions include:

1. Hepatocellular Injury (liver injury) - inflammation or damage to cells
2. Somnolence and Sedation
3. Suicidal Behavior and Ideation
4. Hypersensitivity Reactions - allergic reactions
5. Negative interaction with anti-epilepsy drugs such as Tegretol, Dilantin, Luminal, Solfoton, Tedral, Primidone (anti-seizure)
6. Interactions with immunosuppressive drugs used in transplants or chemotherapy and with warfarin.
7. CBD use can impair kidney function and cause anemia. [6]

CBD AND PREGNANCY

The FDA strongly advises that during pregnancy and while breastfeeding women should not use CBD or THC. They may put themselves or their baby at serious risk by using these marijuana products. [7] CBD products may also be contaminated with substances that may pose a risk to the fetus or breastfed baby such as pesticides, heavy metals, bacteria, and fungus. Studies in laboratory animals show male reproductive toxicity, including in the male offspring of CBD-treated pregnant females. This includes decrease in testicular size, inhibition of sperm development, and decreased testosterone. [8]

TAKING CBD CAN BE DANGEROUS WHEN DRIVING OR USING MACHINERY

Recent FDA studies show that CBD can cause sleepiness, sedation and that may make operating a motor vehicle or machinery dangerous after consuming CBD products.[9]

CBD AND WORK PERFORMANCE

CBD has side effects including drowsiness, decreased appetite, diarrhea, transaminase elevations, fatigue, feeling unwell (malaise), rash, difficulty sleeping (insomnia, disordered sleep, and poor-quality sleep), infections, somnolence, decreased appetite, diarrhea, and asthenia. A recent FDA report states that CBD can cause sleepiness, sedation and that may make operating a motor vehicle or machinery dangerous after consuming CBD products.[10] These side effects can endanger employees and public safety.

THE USE OF CBD MAY CAUSE EMPLOYEES TO HAVE A POSITIVE DRUG TEST RESULTS FOR THC.

CBD use may cause positive drug test results. A truck driver lost his job when he tested positive for THC on a drug test after being told by the CBD manufacturer that the CBD product had no THC. Illegally selling THC in medicine or food products is marijuana trafficking and is racketeering. The driver sued under the Racketeer Influenced and Corrupt Organizations Act (RICO). The US Supreme Court recently held in the case that RICO lawsuits can be used in such cases. *Medical Marijuana v. Horn*, 145 S.Ct. 931 (2025)

DANGERS TO HEALTH

In another federal lawsuit, the plaintiff bought CBD relying on advertising that the products had “No Heavy Metals or Insecticides.” The CBD failed laboratory testing for heavy metals, including copper, nickel, lead and for total yeast and mold. Lead can cause poisoning, speech and language problems, neurologic toxicity and reproductive problems. Mold can cause allergic and respiratory problems and yeasts can cause infection in people with compromised immune systems. [11] Another CBD product was recalled due to lead contamination. The recall stated that acute lead poisoning could cause pain, muscle weakness, paresthesia, abdominal pain, nausea, vomiting, diarrhea, constipation, poor appetite, weight loss, symptoms associated with encephalitis, metallic taste in the mouth, shock, hemolysis, and kidney damage. [12] Use of Black-market CBD can injure employee health and work performance.

People buying CBD should be warned about the known adverse reactions to CBD. They should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that CBD does not affect them adversely (e.g., impaired judgment, thinking or motor skills). Use of CBD may increase the risk of suicidal thoughts and behavior. Hypersensitivity reactions can occur with use of CBD. It is not known if CBD is safe and effective in children under 2 years of age. FDA clinical trials of CBD did not include any patients aged above 55 years. CBD for elderly people could be dangerous due to the greater frequency of decreased liver or cardiac function, and of concomitant disease or other drug therapy.[13]

The DOT has issued the following warning about CBD use by those employees who are subject to federal drug testing requirements.

It is important for all employers and safety-sensitive employees to know:

1. The Department of Transportation requires testing for marijuana and not CBD.
2. The labeling of many CBD products may be misleading because the products could contain higher levels of THC than what the product label states. The Food and Drug Administration (FDA) does not currently certify the levels of THC in CBD products, so there is no Federal oversight to ensure that the labels are accurate. The FDA has

cautioned the public that: “Consumers should beware purchasing and using any [CBD] products.” The FDA has stated: “It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement.” Also, the FDA has issued several warning letters to companies because their products contained more CBD than indicated on the product label.

3. The Department of Transportation’s Drug and Alcohol Testing Regulation, Part 40, does not authorize the use of Schedule I drugs, including marijuana, for any reason. Furthermore, CBD use is not a legitimate medical explanation for a laboratory-confirmed marijuana positive result. Therefore, Medical Review Officers will verify a drug test confirmed at the appropriate cutoffs as positive, even if an employee claims they only used a CBD product.

It remains unacceptable for any safety-sensitive employee subject to the Department of Transportation’s drug testing regulations to use marijuana. Since the use of CBD products could lead to a positive drug test result, Department of Transportation-regulated safety-sensitive employees should exercise caution when considering whether to use CBD products.[14]

FDA REPORTS

To make a report to the FDA about CBD being used as a medicine or as a food or food supplement go to:

<https://www.accessdata.fda.gov/scripts/email/oc/buyonline/english.cfm#whattoreport>

The CDC warns that:

Adverse Effects of THC- or CBD-Containing Products

If consumers experience adverse effects of THC- or CBD-containing products that are an immediate danger to their health, they should call their local or regional poison control center at 1-800-222-1222 or 911 or seek medical attention at their local emergency room and report the ingredients of products they have consumed to healthcare providers. [15]

* The marijuana industry referred below to here are those who illegally, negligently or fraudulently produce, market, or distribute marijuana or CBD

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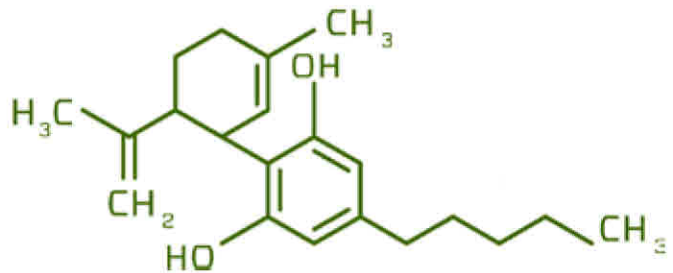
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September/October 2020

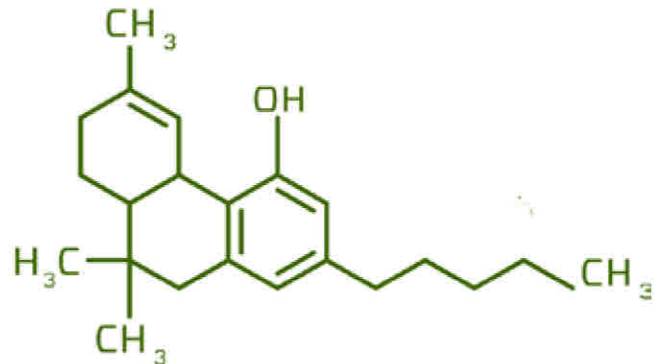
National Cannabis Review: Are CBD & THC Valid Medicines?



CBD
CANNABIDIOL

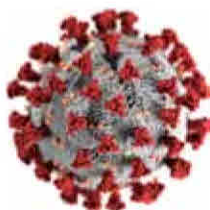


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FACULTY RESEARCH UPDATE



COVID-19 REPORT: Testing & Physician Wellness



Medical Fraud, Mislabeling, Contamination: All Common in CBD Products

by David G. Evans, JD

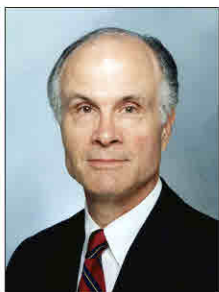
Cannabidiol (CBD) is an oil derived from the cannabis plant. It is touted as a “wonder drug.” Advertisements claim it is perfectly safe and legal and can be used for all that ails you or makes you uncomfortable mentally or physically. People are consuming it under the misapprehension that it is safe, however, CBD has negative side effects and may interfere with the functioning of other medications and may be contaminated.

Consumer demand for CBD has increased due to aggressive marketing and fraudulent health claims. In the rush to market CBD, there has been little consideration of the concerns that must be addressed before CBD is given full acceptance. This article will explore those concerns.



Is CBD Legal?

There are claims that CBD from hemp used as a medicine or food is always legal. This is not accurate. The Agriculture Improvement Act of 2018 changed federal law regarding the production and marketing of hemp. Hemp is defined as cannabis and its derivatives with extremely low (less than 0.3% a dry weight basis) concentration of the THC. These changes removed hemp from the federal Controlled Substances Act, which means that it will no longer be an illegal substance under federal law. However, Congress explicitly preserved the FDA's authority to regulate these products under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. These compounds are subject to the same requirements as FDA-regulated products containing any other substance regardless of the source of the substance. Cannabis products claiming in their marketing materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of



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diseases must go through the FDA drug approval process for human or animal use before they are legally marketed.¹

As stated by the FDA Commissioner:

“Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.”²

CBD products that are not approved by the FDA and are sold as medicines, or as food, or cosmetics are “black-market” and are illegally trafficked and sold. This includes those sold in reputable stores, restaurants, and other places that don’t have FDA approval to do so. Black-market CBD products have not been evaluated by the FDA to determine if they are safe as foods or effective or safe for any medical use, and if safe, what the proper dosage would be. In addition, they are not administered with any federally approved medical protocols as are prescription drugs and there may be no warnings for how they interact with other drugs, or whether they have dangerous side effects.³

A pure form of CBD is approved by the FDA as a medicine for two rare seizure disorders. Its approval was based on well-controlled FDA clinical trials. This is a purified form of CBD in a reliable dosage form and a reproducible route of delivery. Since it is manufactured according to FDA standards by a reliable company that has followed the rules, we can assume it is free from adulterants and contaminants. Its side effects and other clinical data are publicly available. This type of data is not provided by the black-market CBD products.⁴

There are a number of papers discussing the pros and cons of CBD as a medicine that can be viewed on the National Library of Medicine website at www.nlm.nih.gov. Some studies, notwithstanding their many deficiencies, provide some support for the hypothesis that CBD may exert some beneficial effects, but it has yet to be proven to be both effective and safe. FDA quality studies with purified CBD are warranted. However, clinical data does not support some

claimed uses of CBD for Parkinson’s disease, schizophrenia, cancer palliation and treatment, chronic pain and spasticity, depression, anxiety disorder, insomnia, and inflammation. There is insufficient evidence to rate effectiveness of CBD for Bipolar disorder, Crohn’s disease, diabetes, dystonia, Huntington’s disease, multiple sclerosis (and its muscle spasms, tiredness, bladder control, the ability to move around, or well-being and quality of life), schizophrenia, nerve damage in the hands and feet (peripheral neuropathy) and other conditions.⁵

CBD Mislabeling and Contamination

Studies suggest that black-market CBD is not very reliable or safe. In 2020, the FDA did a study on products that claimed to have a specific amount of CBD and those claimed amounts were compared to the FDA testing results. Of the 102 products that indicated a specific amount of CBD, 18 products (18%) contained less than 80% of the amount of CBD indicated, 46 products (45%) contained CBD within 20 percent of the amount indicated, and 38 products (37%) contained more than 120 percent of the amount of CBD indicated. Of great concern is that 49% of the products tested contained THC.⁶

The *Journal of the American Medical Association* published a letter demonstrating the results of “undercover” purchases of CBD. Of 84 samples tested, THC was detected in 21%. There were other defects in the mislabeled products. Only 30.95% were accurately labeled. Accuracy of labeling depended on product type, with vaporization liquid most frequently mislabeled (87.50%) and oil most frequently labeled accurately (45.0 %). THC was detected (up to 6.43 mg/mL) in 18 of the 84 samples tested (21.43%).⁷

A Johns Hopkins researcher tested CBD products. Testing showed 44 products (59%) had detectible levels of CBD, but the average ratio of THC to CBD was 36-to-1. Only one product had a 1-to-1 ratio, which some research suggests is associated with fewer side effects and improved clinical benefit compared with higher ratios of THC to CBD. The testing indicated the edible cannabis products may have very little CBD.⁸

A study published by the National Institute of Health showed that products were mislabeled



with 26% containing less CBD than labeled and 43% containing more, indicating a high degree of variability and poor standardization of online products. Notably, the oil-based products were more likely to be accurate (45% compared to 25% for tincture and 12.5% for vaporization liquid) and had a smaller percentage of deviation. Oil based products also had a higher range of concentration. In addition to CBD mislabeling, THC was detected in 21% of samples. This study also notes that products containing THC could have sufficient enough concentrations to produce intoxication in children.⁹

In a recent federal lawsuit, the plaintiff bought CBD products relying on advertising that the products had “No Heavy Metals or Insecticides.” The products failed laboratory testing for heavy metals, including copper, nickel, and lead and also for total yeast and mold. Lead can cause poisoning, speech, and language problems, neurologic toxicity, and reproductive problems. Mold can cause allergic and respiratory problems, and yeasts can cause infection in people with compromised immune systems.¹⁰ On July 28, 2020, another CBD product was recalled due to lead contamination. The recall noted that acute lead poisoning could cause pain, muscle weakness, paresthesia, abdominal pain, nausea, vomiting, diarrhea, constipation, poor appetite, weight loss, symptoms associated with encephalitis, metallic taste in the mouth, shock, hemolysis, and kidney damage.¹¹

False Medical Claims

Examples of false claims for CBD can be taken from FDA and Federal Trade Commission (FTC) warning letters to CBD companies. In order to make claims of treatment or medical use, products must obtain approval from the FDA after submitting their data. False claims include using CBD to treat: alcoholism, Alzheimer’s disease, arthritis, autism, blood pressure and heart rate, cancer, chronic traumatic encephalopathy, cardiovascular disease, chemotherapy-induced hearing loss, colitis, concussions, depression, diabetes, leukemia, liver inflammation, lupus, Lyme disease, neurological damage, Parkinson’s disease, stroke, schizophrenia, traumatic brain injury (TBI), and tumors.¹²

CBD Negative Side Effects and Drug Contraindications

There may be interactions between CBD and immunosuppressive drugs used in transplants or

chemotherapy and with warfarin as there may be the potentiation of anticoagulant effects with marijuana, including CBD. CBD may interact with other medicines, including prescription and over-the-counter medicines, vitamins, herbal supplements, and any cannabis-based products. CBD may affect the way other medicines work, and other medicines may affect how CBD works.

CBD may decrease how fast the liver metabolizes the drug. This may possibly increase the effects and side effects. CBD may potentially interact in a negative way with anti-epileptic drugs such as: carbamazepine (Tegretol), phenytoin (Dilantin), phenobarbital (Luminal, Solfoton, Tedral), primidone (anti-seizure). Users should be cautious before taking CBD with: sedatives, herbs, and supplements that cause drowsiness, seizure medications, drugs that are broken down and changed by the liver. People should be cautious with using Brivaracetam (Briviact), Eslicarbazepine (Aptiom), and Everolimus (Zostress).¹³ Consumers should not take CBD with Clobazam for seizures.¹⁴ The use of CBD along with these drugs might increase the effects and side effects of the drugs.

Adverse Reactions

The adverse reactions to CBD include: hepatocellular injury, somnolence and sedation, suicidal behavior and ideation, hypersensitivity reactions—allergic reactions, negative interaction with anti-epilepsy drugs (such as Tegretol, Dilantin, luminal, Solfoton, Tedral, primidone), interactions with immunosuppressive drugs used in transplants or chemotherapy and with warfarin. CBD use can impair kidney function and cause anemia.¹⁵ Black market CBD is generally sold without warnings about adverse reactions.

The side effects of CBD can include: drowsiness, decreased appetite, diarrhea, transaminase elevations, fatigue, feeling unwell (malaise), rash, difficulty sleeping (insomnia, disordered sleep, and poor-quality sleep), infections, somnolence, decreased appetite, diarrhea, and asthenia.¹⁶

Research shows that more than 40% of children with epilepsy who were given CBD orally had adverse events that included THC like symptoms. The research challenged the widely accepted premise that CBD is not intoxicating.¹⁷



Glaucoma Made Worse by Marijuana, THC, and CBD

by John C. Hagan III, Ophthalmologist Eye, MD

Normal Vision



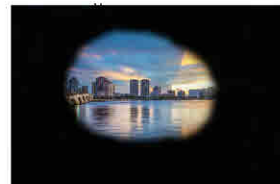
Early Glaucoma



Advanced Glaucoma



End Stage Glaucoma



Source: <https://www.graceandvision.com.au/eye-conditions/glaucoma/>

Although glaucoma is a listed indication for issuing sham medical marijuana cards, the most recent evidence is that cannabis in either tetrahydrocannabinol (THC) or cannabidiol (CBD) are both harmful to the eye and have a deleterious effect on glaucoma.¹⁻⁵ CBD has been shown to increase intra-ocular pressure (IOP) the fundamental problem with most forms of glaucoma; while THC lowers IOP but the effect is transient and therapeutically worthless. Chronic cannabis use causes damage and loss of retina ganglion cells as does the disease glaucoma. Moreover, ganglion cells are central nervous system tissue, like the cells of the brain, and may serve as a surrogate marker for brain cell loss. This might account for neurological problems associated with heavy cannabis use such as memory loss, lethargy and poor motivation, permanent IQ loss in youthful users, aggression, psychosis, etc. Half a century of research has found no benefit to any cannabis products in ophthalmology. Use of sham medical marijuana, CBD or any form of cannabis is not recommended for glaucoma or any other eye condition by the American Academy of Ophthalmology or the Glaucoma Society. No physician should ever recommend cannabis use for any of the many forms of glaucoma.

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Glaucoma

A recent study suggests that CBD doesn't lower eye pressure but instead raises it. High eye pressure is the primary risk factor for glaucoma, a leading cause of blindness.¹⁸ [Editor's Note: see sidebar.]

Warnings

Black Market CBD may be sold without warnings being provided. People should be warned about the known adverse reactions to CBD. People should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that CBD does not affect them adversely (e.g., impaired judgment, thinking, or motor skills). Use of

CBD may increase the risk of suicidal thoughts and behavior. Hypersensitivity reactions can occur with use of CBD. It is not known if CBD is safe and effective in children under two years of age. FDA clinical trials of CBD did not include any patients aged above 55 years. CBD for elderly persons could be dangerous due to the greater frequency of decreased liver or cardiac function, and of concomitant disease or other drug therapy.¹⁹

Vehicle Operation

A recent FDA report states that CBD can cause sleepiness, sedation, and that may make operating a motor vehicle or machinery dangerous after consuming CBD products.²⁰



CBD and Pregnancy

The FDA strongly advises that during pregnancy and while breastfeeding, women should not use CBD or THC. They may put themselves or their baby at serious risk by using these marijuana products. CBD products may also be contaminated with substances that may pose a risk to the fetus or breastfed baby such as pesticides, heavy metals, bacteria, and fungus. Studies in laboratory animals show male reproductive toxicity, including in the male offspring of CBD-treated pregnant females. This includes decrease in testicular size, inhibition of sperm development, and decreased testosterone.²¹ The CDC also notes that marijuana use by a pregnant woman can have teratogenic effects causing birth defects.²²

Drug Tests

CBD may affect drug test results. A truck driver lost his job when he tested positive for THC on a drug test after being told by the manufacturer that a CBD product had no THC.²³

Recent CBD Lawsuits

There are many recent lawsuits filed against CBD manufacturers and more are on the way. They were filed after the FDA issued a series of warning letters that such products, unless approved by the FDA, are neither safe or effective for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body. Some of the cases allege that the manufacturers' CBD products made false medical claims or were mislabeled as dietary supplements or there were false claims as to the amount of CBD present in the product. A California case claims that the company engaged in false and deceptive practices and that their products could not be sold legally. A Massachusetts case claimed that many of the defendant's products had significantly lower levels of CBD than advertised. A California case claimed that the defendant company made false claims that CBD could help the symptoms of autism and that could treat illnesses such as hepatitis, cancer, and Tourette syndrome. A New York case alleges false medical claims for marijuana and for violations of the federal securities laws. A Florida case alleged that CBD has "been touted as having numerous

positive health effects." CBD has been used to treat conditions such as "anxiety, sleep disorders, and chronic pain." In selling the products with significantly less CBD, plaintiff claimed the Defendants "are cheating every consumer who buys the products by that amount." The Federal Trade Commission recently petitioned to enjoin a CBD company from disseminating false or unsubstantiated advertisement claims in connection sale of a product that purportedly treats, prevents or reduces the risk of COVID-19 and products that purportedly treat cancer.²⁴

Government Bans on CBD Use

The federal Department of Transportation has issued a warning that CBD use can show up as a positive THC result on a drug test.²⁵ The U.S. military has banned the use of hemp/CBD products for military personnel.²⁶

The Future of CBD and the FDA

The FDA is currently undertaking a large long-term study of black-market CBD products to understand the characteristics of CBD products in order to make informed decisions about how best to protect public health. The FDA will report again on the results from both the near and long-term studies when complete data sets are available.²⁷ On July 21, 2020, the FDA stated that in regard to CBD and other cannabinoids:

"The FDA believes the drug approval process represents the best way to ensure that safe and effective new medicines, including any drugs that contain cannabis or cannabis-derived compounds, are available to patients in need of appropriate medical therapy."²⁸

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Disclosure

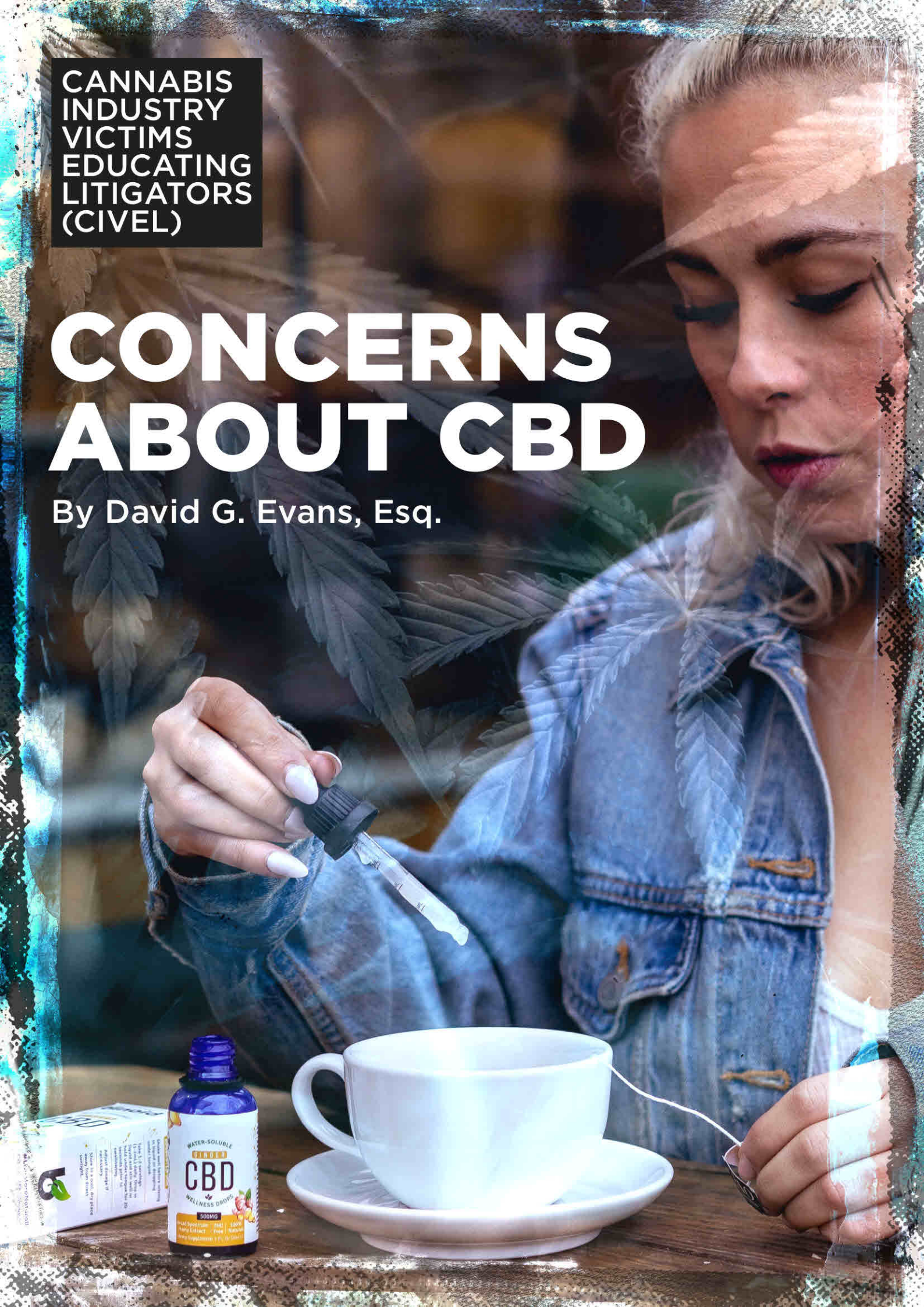
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CONCERNS ABOUT CBD

By David G. Evans, Esq.



The marijuana industry referred to here are those who illegally, negligently or fraudulently produce, market, or distribute marijuana.

WHAT IS CBD?

Cannabidiol (CBD) is a derivative of marijuana and one of the main active ingredients in the marijuana plant. There are two types of CBD. There is Epidiolex, a pure form of CBD approved by the FDA as a medicine but only for the treatment of two seizure syndromes. There is also non-FDA approved CBD that is defined as “Commercial CBD” for the purposes of this paper. Commercial CBD used as a medicine or in food is illegal under federal law and in some states.¹

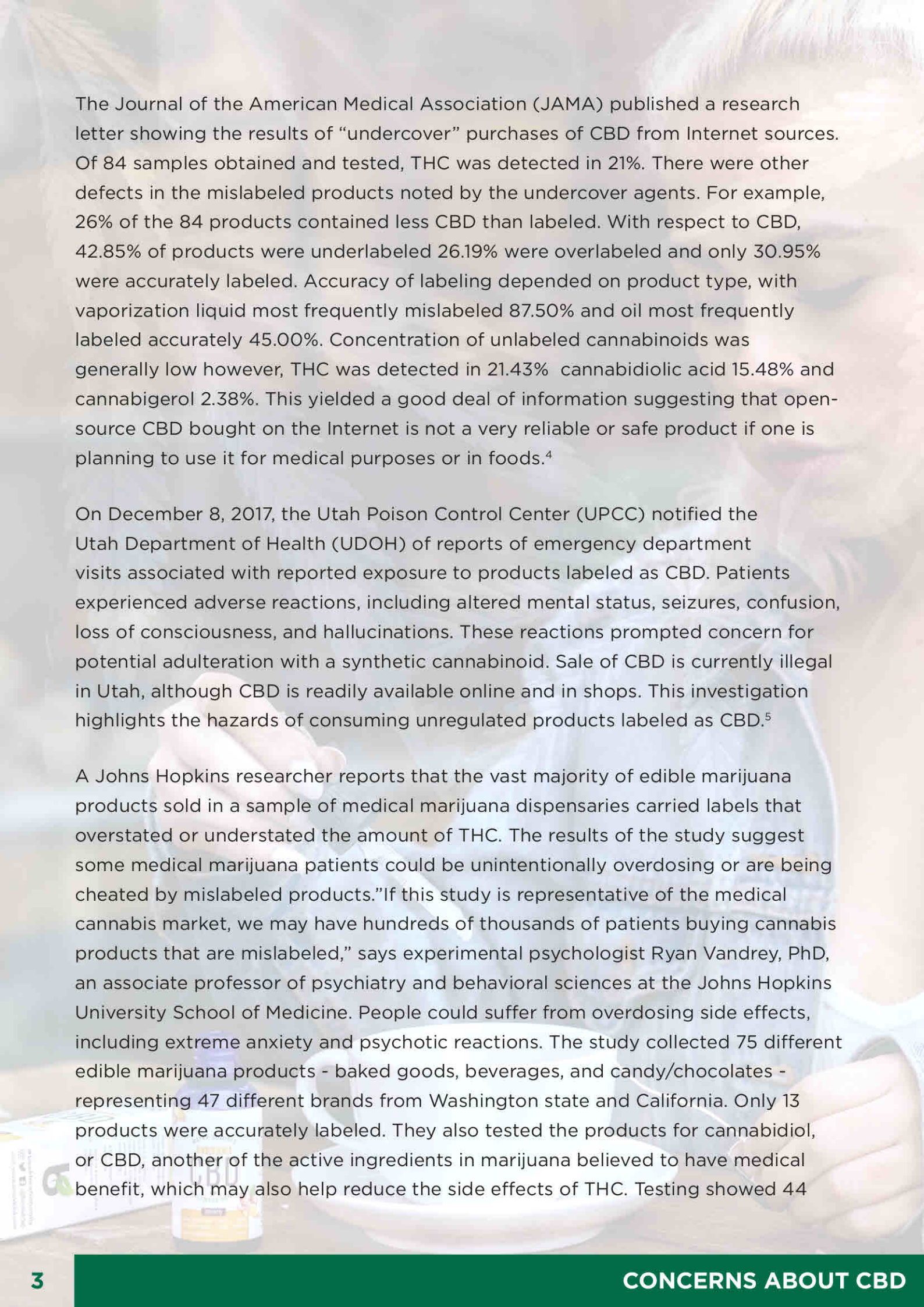
The chemical in marijuana that causes the high (and many of its other effects) is delta-9 tetrahydrocannabinol, or THC. But there are over 100 other cannabinoid chemicals in the plant; CBD is one of those. Different cannabinoids can have very different biological effects.²

FALSE CLAIMS FOR CBD

The marijuana industry has touted commercial CBD as a “wonder drug.” They may claim it is perfectly safe and legal and can be used for all that ails you or makes you uncomfortable physically. People are consuming large amounts under the misapprehension that it is safe to do so. It is not safe to do so. It has negative side effects and may interfere with the functioning of other medications.

Multiple Studies Show That Commercial CBD Products May Not Be Pure and May Have Negative Side Effects

The Food and Drug Administration (FDA) has issued several warning letters to firms that market Commercial CBD that they are selling CBD illegally. These products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease. The FDA has also tested the chemical content of cannabinoid compounds in CBD, and many were found to not contain the levels of CBD they claimed to contain.³ Consumers should beware purchasing and using any such products.

A person is shown from the chest up, holding a small bottle of CBD oil over a white bowl. The person has light-colored hair and is wearing a light-colored shirt. The background is slightly blurred, showing a wooden surface and some other items. The text is overlaid on the image.

The Journal of the American Medical Association (JAMA) published a research letter showing the results of “undercover” purchases of CBD from Internet sources. Of 84 samples obtained and tested, THC was detected in 21%. There were other defects in the mislabeled products noted by the undercover agents. For example, 26% of the 84 products contained less CBD than labeled. With respect to CBD, 42.85% of products were underlabeled 26.19% were overlabeled and only 30.95% were accurately labeled. Accuracy of labeling depended on product type, with vaporization liquid most frequently mislabeled 87.50% and oil most frequently labeled accurately 45.00%. Concentration of unlabeled cannabinoids was generally low however, THC was detected in 21.43% cannabidiolic acid 15.48% and cannabigerol 2.38%. This yielded a good deal of information suggesting that open-source CBD bought on the Internet is not a very reliable or safe product if one is planning to use it for medical purposes or in foods.⁴

On December 8, 2017, the Utah Poison Control Center (UPCC) notified the Utah Department of Health (UDOH) of reports of emergency department visits associated with reported exposure to products labeled as CBD. Patients experienced adverse reactions, including altered mental status, seizures, confusion, loss of consciousness, and hallucinations. These reactions prompted concern for potential adulteration with a synthetic cannabinoid. Sale of CBD is currently illegal in Utah, although CBD is readily available online and in shops. This investigation highlights the hazards of consuming unregulated products labeled as CBD.⁵

A Johns Hopkins researcher reports that the vast majority of edible marijuana products sold in a sample of medical marijuana dispensaries carried labels that overstated or understated the amount of THC. The results of the study suggest some medical marijuana patients could be unintentionally overdosing or are being cheated by mislabeled products.”If this study is representative of the medical cannabis market, we may have hundreds of thousands of patients buying cannabis products that are mislabeled,” says experimental psychologist Ryan Vandrey, PhD, an associate professor of psychiatry and behavioral sciences at the Johns Hopkins University School of Medicine. People could suffer from overdosing side effects, including extreme anxiety and psychotic reactions. The study collected 75 different edible marijuana products - baked goods, beverages, and candy/chocolates - representing 47 different brands from Washington state and California. Only 13 products were accurately labeled. They also tested the products for cannabidiol, or CBD, another of the active ingredients in marijuana believed to have medical benefit, which may also help reduce the side effects of THC. Testing showed 44

products (59%) had detectible levels of CBD, but the average ratio of THC to CBD was 36-to-1. Only one product had a 1-to-1 ratio, which some research suggests is associated with fewer side effects and improved clinical benefit compared with higher ratios of THC to CBD. What the testing indicates that a lot of what's available in the edible cannabis market may have very little CBD.⁶

Another report published by the National Institute of Health showed that products were mislabeled with 26% containing less CBD than labeled and 43% containing more, indicating a high degree of variability and poor standardization of online products. Notably, the oil-based products were more likely to be accurate (45% compared to 25% for tincture and 12.5% for vaporization liquid) and had a smaller percentage of deviation. Oil based products also had a higher range of concentration. In addition to CBD mislabeling, THC was detected in 21% of samples. This study also notes that products containing THC could have sufficient enough concentrations to produce intoxication in children.⁷

CBD NEGATIVE SIDE EFFECTS

Drug Contraindications

CBD oil may potentially interact in a negative way with anti-epilepsy drugs such as:

1. carbamazepine (Tegretol)
2. phenytoin (Dilantin)
3. phenobarbital (Luminal, Solfoton, Tedral)
4. primidone (anti-seizure)⁸

There are interactions with CBD and immunosuppressive drugs used in transplants or chemotherapy and there are interactions with warfarin as there may be the potentiation of anticoagulant effects with marijuana, including CBD.⁹

Common Side effects

The most common side effects of CBD can include:

- Sleepiness
- Decreased appetite
- Diarrhea
- Change in liver function
- Fatigue
- Malaise
- Asthenia (weakness or lack of energy)
- Rash
- Insomnia
- Sleep disorder
- Poor quality sleep
- Infections
- CBD also interacts with some other seizure medicines.
- Nausea or vomiting
- Dizziness
- Anxiety or depression
- Changes in appetite/weight¹⁰

Research published in the journal *Cannabis and Cannabinoid Research* shows that more than 40% of children with epilepsy who were given CBD orally had adverse events that included THC like symptoms. The research challenged the widely accepted premise that CBD is not intoxicating.¹¹

Glaucoma

A recent study suggests that CBD doesn't lower eye pressure but raises it. High eye pressure is the primary risk factor for glaucoma, a leading cause of blindness. Glaucoma damages the optic nerve at the back of the eye. Glaucoma is linked to a buildup of pressure inside the eye. The increased pressure can damage the nerve, leading to permanent vision loss.¹²

Even Epidiolex Has Negative Side Effects

In June, 2018, the FDA approved Epidiolex® (cannabidiol, CBD) oral solution for the treatment of seizures associated with two rare, severe forms of epilepsy - Lennox-Gastaut syndrome and Dravet syndrome - in people two years of age or older. The FDA approved a purified form of CBD. The FDA was quick to note however, that this is not an approval of marijuana or all of its components. This is the approval of one specific CBD medication for a specific use. And it was based on well-controlled clinical trials evaluating the use of this compound in the treatment of a specific condition. Moreover, this is a purified form of CBD. It's being delivered to patients in a reliable dosage form and through a reproducible route of delivery to ensure that patients derive the anticipated benefits. This is how sound medical science is advanced. However, use should not be taken lightly due to the number of side effects that are being seen with this product.¹³

We must assume that since it is manufactured according to FDA standards, by a reliable manufacturer, that it is free from contaminants. This purity is not guaranteed by the commercial CBD products that are not manufactured according to FDA standards.

Even Epidiolex has risks. Other CBD products share these risk but the marijuana industry has for the most part not warned about those dangers to those people who use their CBD products. The below information, unless cited otherwise, comes from the FDA-required package insert warnings and precautions for Epidiolex.¹⁴ The most common warnings are about:

1. Hepatocellular Injury (liver injury)
2. Somnolence and Sedation
3. Suicidal Behavior and Ideation
4. Hypersensitivity Reactions
5. Withdrawal of Antiepileptic Drugs

Liver Injury

Epidiolex can cause liver enzymes to be elevated. Elevated liver enzymes can indicate inflammation or damage to cells in the liver because inflamed or injured liver cells leak higher than normal amounts of certain chemicals, including liver enzymes, into the bloodstream, which can result in elevated liver enzymes on



blood tests. It is important to measure hepatic (pertaining to the liver) laboratory values and having them evaluated by the healthcare provider before treatment with Epidiolex and periodically during treatment. There may be signs or symptoms suggestive of hepatic dysfunction such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine, loss of appetite, itching, fever, feeling unwell, unusual tiredness, unusual darkening of the urine or right upper stomach area pain or discomfort. Commercial CBD that is not approved by the FDA is sold all over the United States without warnings about liver damage.¹⁵

Somnolence and Sedation

People should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that Epidiolex does not affect them adversely (e.g., impaired judgment, thinking or motor skills). Other medicines (e.g., clobazam) or alcohol may increase sleepiness. Commercial CBD is sold all over without such warnings.

Suicidal Thinking and Behavior

Use of Epidiolex, may increase the risk of suicidal thoughts and behavior. Commercial CBD is sold without warnings about this.

Hypersensitivity

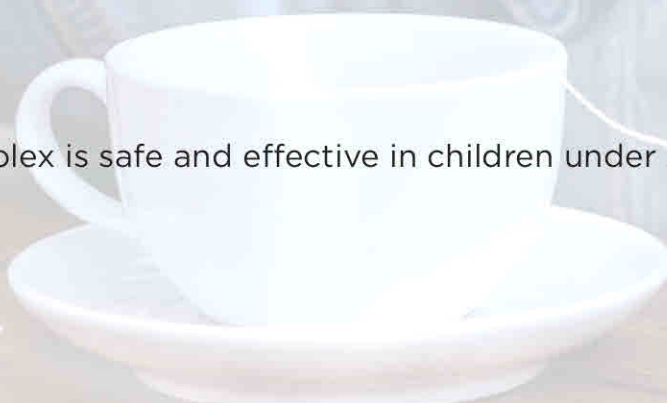
Hypersensitivity reactions can occur with use of Epidiolex. This is when the body reacts with an exaggerated immune response to a foreign agent such as in anaphylaxis or allergy. People need to be warned about this.

Withdrawal of Antiepileptic Drugs

Epidiolex should be gradually withdrawn to minimize the risk of increased seizure frequency and status epilepticus.

Children

It is not known if Epidiolex is safe and effective in children under 2 years of age.



Interactions with other medications

Epidiolex may interact with other medicines, including prescription and over-the-counter medicines, vitamins, herbal supplements, and any cannabis-based products. Epidiolex may affect the way other medicines work, and other medicines may affect how Epidiolex works. People should not use CBD until they are evaluated by a health care provider.

Drug tests

Epidiolex may affect drug test results.

Adverse Reactions

Adverse reactions include:

- somnolence
- decreased appetite
- diarrhea
- transaminase elevations (liver problems)
- fatigue
- malaise
- asthenia (loss of strength and energy)
- rash
- insomnia
- sleep disorder
- poor quality sleep;
- infections.¹⁶

Pregnancy

There is not adequate data on the developmental risks associated with Epidiolex use by in pregnant women. Administration of CBD to pregnant animals produced evidence of developmental toxicity such as increased embryofetal mortality in rats and decreased fetal body weights in rabbits; decreased growth, delayed sexual maturation, long-term neurobehavioral changes, and adverse effects on the reproductive system in rat offspring.



There are not good data on the presence of cannabidiol or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Epidiolex and any potential adverse effects on the breastfed infant from Epidiolex or from the underlying maternal condition.

Geriatric Use

Clinical trials of Epidiolex did not include any patients aged above 55 years to determine whether or not they respond differently from younger patients. Dose selection for elderly persons should be cautious reflecting the greater frequency of decreased liver or cardiac function, and of concomitant disease or other drug therapy.

CONCLUSION

Epidiolex, a purified form of CBD has some risks and should only be used while medically supervised. Commercial CBD has many risks but may not have any safeguards.

ABOUT THE AUTHOR

David G. Evans, Esq., is Senior Counsel for the Cannabis Industry Victims Educating Litigators (CIVEL) who educate lawyers on how to make the marijuana industry accountable to their many victims. Mr. Evans was a plaintiff's litigator in personal injury and employment law cases. Attorneys who desire more information can contact Mr. Evans at seniorcounsel@civel.org. The CIVEL website is: www.civel.org

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DOT OFFICE OF DRUG AND ALCOHOL POLICY AND COMPLIANCE NOTICE



The Agricultural Improvement Act of 2018, Pub. L. 115-334, (Farm Bill) removed hemp from the definition of marijuana under the Controlled Substances Act. Under the Farm Bill, hemp-derived products containing a concentration of up to 0.3% tetrahydrocannabinol (THC) are not controlled substances. THC is the primary psychoactive component of marijuana. Any product, including “Cannabidiol” (CBD) products, with a concentration of more than 0.3% THC remains classified as marijuana, a Schedule I drug under the Controlled Substances Act.

We have had inquiries about whether the Department of Transportation-regulated safety-sensitive employees can use CBD products. Safety-sensitive employees who are subject to drug testing specified under 49 CFR part 40 (Part 40) include: pilots, school bus drivers, truck drivers, train engineers, transit vehicle operators, aircraft maintenance personnel, fire-armed transit security personnel, ship captains, and pipeline emergency response personnel, among others.

It is important for all employers and safety-sensitive employees to know:

1. The Department of Transportation requires testing for marijuana and not CBD.
2. The labeling of many CBD products may be misleading because the products could contain higher levels of THC than what the product label states. The Food and Drug Administration (FDA) does not currently certify the levels of THC in CBD products, so there is no Federal oversight to ensure that the labels are accurate. The FDA has cautioned the public that: “Consumers should beware purchasing and using any [CBD] products.” The FDA has stated: “It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement.”* Also, the FDA has issued several warning letters to companies because their products contained more CBD than indicated on the product label. **i
3. The Department of Transportation’s Drug and Alcohol Testing Regulation, Part 40, does not authorize the use of Schedule I drugs, including marijuana, for any reason. Furthermore, CBD use is not a legitimate medical explanation for a laboratory-confirmed marijuana positive result. Therefore, Medical Review Officers will verify a drug test confirmed at the appropriate cutoffs as positive, even if an employee claims they only used a CBD product.

It remains unacceptable for any safety-sensitive employee subject to the Department of Transportation’s drug testing regulations to use marijuana. Since the use of CBD products could lead to a positive drug test result, Department of Transportation-regulated safety-sensitive employees should exercise caution when considering whether to use CBD products.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies. This policy and compliance

notice is not legally binding in its own right and will not be relied upon by the Department as a separate basis for affirmative enforcement action or other administrative penalty. Conformity with this policy and compliance notice is voluntary only and nonconformity will not affect rights and obligations under existing statutes and regulations. Safety-sensitive employees must continue to comply with the underlying regulatory requirements for drug testing, specified at 49 CFR part 40.

February 18, 2020

ⁱ* What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD: *The FDA is working to answer questions about the science, safety, and quality of products containing cannabis and cannabis-derived compounds, particularly CBD.*" <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>

^{**} <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>