



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

by David G. Evans, JD

**C**annabidiol (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.<sup>1</sup>

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.”<sup>2</sup>

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.<sup>3</sup>

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.<sup>4</sup>

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](http://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.<sup>5</sup>

### 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.<sup>6</sup>

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%).<sup>7</sup>

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.<sup>8</sup>

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.<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup>

### 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.<sup>12</sup>

### 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).<sup>13</sup> Consumers should not take CBD with Clobazam for seizures.<sup>14</sup> 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.<sup>15</sup> 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.<sup>16</sup>

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.<sup>17</sup>



## Glaucoma Made Worse by Marijuana, THC, and CBD

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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.<sup>1-5</sup> 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.<sup>18</sup> [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.<sup>19</sup>

### 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.<sup>20</sup>



## 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.<sup>21</sup> The CDC also notes that marijuana use by a pregnant woman can have teratogenic effects causing birth defects.<sup>22</sup>

## 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.<sup>23</sup>

## 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.<sup>24</sup>

## 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.<sup>25</sup> The U.S. military has banned the use of hemp/CBD products for military personnel.<sup>26</sup>

## 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.<sup>27</sup> 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."<sup>28</sup>

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