

CBD: What Physicians Need to Know to Keep Patients Safe

By Carie Sherman

Cannabidiol, commonly referred to as CBD. is marketed as a "miracle drug." People seeking relief from everything from social anxiety and addiction to chronic pain and cancer have looked to CBD products to heal.

It's a booming market. In 2020, the global market was valued at 2.8 billion and experts predict its continued growth. It's also a product market that's largely unregulated. From false claims of efficacy to poor quality, buyers of CBD products should beware. While the potential benefits for patients exist, medical science is somewhat lacking in evidence due to marijuana's historical and current classification as a schedule 1 substance.

> A 2019 Gallup poll revealed that 1 in 7 adults in the U.S. have used CBD. The same poll indicates that CBD is used by people seeking relief from pain (40%), anxiety (20%), insomnia (11%), and arthritis (8%).1

WHAT IS CBD?

CBD is one of hundreds of naturally occurring compounds found in marijuana (cannabis). Unlike tetrahydrocannabinol (THC), CBD doesn't make the user feel

intoxicated, Advocates of CBD believe it's a natural remedy for common ailments.

CBD oil is widely praised for a long list of potential benefits. Patients using CBD oil have experienced relief for anxiety, epilepsy and symptoms related to cancer and treatment side effects. Researchers are performing clinical studies in a number of areas and across a number of conditions, including sleep disorders, neuropathy, diabetes, PTSD, arthritis and more. CBD can be purchased as a concentrate, capsule, edible, tincture, isolate and vape oil. It's also found in skin and hair products.

According to a report from the World Health Organization, "In humans, CBD exhibits no effects indicative of any abuse or dependence potential...To date, there is no evidence of public health related problems associated with the use of pure CBD."2

However, the CBD industry isn't held to the strict regulations that govern pharmaceuticals. And although researchers are currently working to improve our scientific understanding of how CBD works in the human body and how it impacts





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QUESTIONS PHYSICIANS SHOULD CONSIDER BEFORE RECOMMENDING CBD

- 1. Do you have an established, documented physician-patient relationship?
- 2. Have you completed an in-person medical evaluation?
- Have you discussed and documented the risks and benefits of CBD oil?
- 4. Do you have a treatment agreement in place and documented in the medical record?
- 5. Do you have a relationship with a CBD company (i.e., will you benefit financially from patients using a CBD product)?
- **6.** Do you need a special license or certificate to recommend CBD?

Adapted from Tips for Minimizing Liability via Federation of State Medical Boards¹⁵



SAMPLE CBD TREATMENT AGREEMENT

For a sample CBD treatment agreement, please visit the Forms Library on our website at **profsolutions.com.**

certain conditions, there is a need for providers to support their patient's decision-making as it relates to treatment with CBD.

IS THE SAFETY OF CBD LARGELY ASSUMED?

Cannabis and its derivatives have a long history of recreational use. Is it possible this assumed safety could be dangerous to some patients? Some researchers say yes, citing use growing by more medically complicated patients. "Recognition that this general benignancy of CBD is perhaps only applicable to younger, healthier individuals using cannabis recreationally creates a tremendous patient safety concern in this new era." 3

Because CBD is technically a supplement, there is growing concern among physicians that patients may not disclose their use of CBD. Physicians, particularly those managing medically complex patients, should ask about CBD during the intake process and document responses on health history forms.

IS CBD PREVENTIVE MEDICINE?

Inflammation plays a huge role in a number of diseases and conditions, so it's no wonder researchers are hard at work studying the compound. The known anti-inflammatory properties of CBD suggest its use may prevent disease; however, most of the data is the result of animal studies. Bradley E. Alger, PhD, studies endocannabinoids. "With complex actions in our immune system, nervous system and virtually all of the body's organs, the endocannabinoids are literally a bridge between body and mind. By understanding this system, we begin to see a mechanism that could connect brain activity and states of physical health and disease."

HOW DOES CBD WORK IN THE BODY?

In the early 90s, researchers discovered the endocannabinoid system in the human body.
Researchers still have a lot to learn about the system itself, but experts know that the system is involved in major body functions, such as appetite, memory, sleep and mood.

The system has three parts that function in the body (regardless of use of CBD): receptors, enzymes and endocannabinoids.

- Receptors are found throughout the body and are what the endocannabinoid binds to.
- There are many enzymes involved but only two types break down endocannabinoids.
- Endocannabinoids keep the body's systems functioning properly.

THE RELATIONSHIP OF RECEPTORS AND ENDOCANNABINOIDS

The central nervous system receptor (CBI) is responsible for movement, pain, appetite, memory and mood. The peripheral nervous system receptor (CB2) influences pain and inflammation. After the enzymes break down the cannabinoids, the endocannabinoids try to bind with the receptors. CBD is not shown to attach to the receptor, but it has been shown to influence it. This receptor activation is how researchers believe CBD benefits the body.

MORE RESEARCH IS NEEDED

There's enough evidence to support the need for data-driven research to help us understand CBD and its impact on the human body. As researchers work to help guide us, it's important for providers to stay SUMMER 2021 PAGE 3

informed to best support patients interested in exploring the potential health benefits associated with CBD.

ADVISING PATIENTS ON HOW TO TAKE CBD

Because CBD can be inhaled, ingested, or applied topically, it can be found in a number of different products. Oral formulations may be advisable over inhaling CBD, as there is growing evidence of vaping causing lung injury. Dosing should be started low and considered on an individual patient's basis.

FACTS AND MYTHS CLINICAL RESEARCH HAS FOUND BENEFITS OF CBD USE.

Fact: Clinical studies have confirmed that CBD reduces the levels of proinflammatory cytokines, inhibits T cell proliferation, induces T cell apoptosis and reduces migration and adhesion of immune cells.⁴

A 2019 literature review found evidence of the value of CBD, showing it to have a "calming effect" on the central nervous system in neuropsychiatric disorders such as epilepsy, anxiety, and schizophrenia.⁵ In addition, it's been documented that CBD can also impact chronic pain.⁶

CBD as a "cure" for cancer has also been popularized in recent years, yet the claim remains largely unsubstantiated. There is evidence to suggest that nausea and vomiting can be lessened through the use of CBD.

Pre-clinical and clinical evidence also supports a role for CBD as a novel treatment for anxiety disorders. A study demonstrated "the potential of CBD to produce anxiolytic-like effects in pre-clinical models and the potential of CBD to induce acute anxiolytic effects when administered as a single dose in healthy volunteers and individuals with SAD."⁷

THERE ARE NO SIDE EFFECTS OR ADVERSE EVENTS ASSOCIATED WITH CBD.

Myth: Although CBD is known to be non-intoxicating and non-habit forming, there are known side effects. One-third of CBD users report non-serious side effects, including dry mouth, euphoria, hunger, irritated eyes and fatigue.⁸

Adverse events have also been reported. In animals, CBD adverse events included developmental toxicity, embryo-fetal mortality, central nervous system inhibition and neurotoxicity, hepatocellular injuries, spermatogenesis reduction, organ weight alterations, male reproductive system alterations and hypotension, although at doses higher than recommended for human pharmacotherapies.9 In addition, animal studies have shown the potential for elevated liver enzymes, though at higher doses than typical human consumptions.

In humans, adverse events include the potential for drug-drug interactions. CBD acts like grapefruit, by inhibiting the cytochrome P450 system.

Tacrolimus is an immunosuppressive drug used with heart, liver, and kidney transplant patients. In a research study, it was deemed to have clinically significant negative outcomes due to CBD's interference with the ability to metabolize it.¹⁰

- Studies also suggest an interaction between blood thinners (warfarin) and CBD, which are also metabolized by the cytochrome P450 system.¹¹
- A 2021 review found evidence of CBD interacting with anti-epileptic drugs, antidepressants, opioid analgesics, and THC.
 Additionally, it's been shown to interact with acetaminophen and alcohol.¹²

LACK OF REGULATION COULD LEAD TO PATIENT HARM.

Fact: The general lack of regulation is making it increasingly difficult to determine what's safe.

- Mislabeling. A study by Penn Medicine found mislabeling of 70% of CBD products sold online. Marcel Bonn-Miller. PhD, an adjunct assistant professor of Psychology in Psychiatry and the lead author on the study, believes the mislabeling of cannabidiol products is a direct result of inadequate regulation and oversight. "The big problem, with this being something that is not legal at the federal level, is that the needed quality assurance oversight from the Food and Drug Administration is not available."13
- False Medical Claims. The FDA and Federal Trade Commission (FTC) have sent warning letters to many CBD companies about false claims for medical use, including its efficacy in treating "alcoholism, Alzheimer's disease, arthritis, autism, blood pressure and heart rate, cancer, chronic traumatic encephalopathy, cardiovascular disease,

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- 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."¹⁴
- Dosage. Due to a lack of clinical studies, it's difficult for doctors to confirm safe, beneficial dosage levels.
 Researchers have studied oral dosaging ranging from 100-800mg per day.

CBD OIL IS LEGAL.

Myth: CBD can be derived from hemp or marijuana. At the federal level, only CBD derived from hemp (with THC of less than 0.3 percent) is legal. However, CBD oil, even if derived from hemp, is not legal in all states. Some states require a license for medical use, so it's important to consider the regulations in your own state. Contact your state board for questions or guidance.

ENCOURAGING PATIENTS TO BE SAVVY CONSUMERS IS IMPORTANT.

Fact: It's always important to check the label to understand what you're purchasing; this can be difficult when labels are intended as product marketing. Some general guidance includes:

- CBD oil can be derived from hemp or from marijuana.
 If you live in a state where marijuana is legal, you may be able to purchase CBD oil with higher levels of THC which may cause a psychoactive effect and/or cause THC to show up on a drug test.
- Ensure the label mentions
 "cannabidiol" or hemp extract.
 Some products marketed as
 CBD may only list hempseed
 oil, hemp seeds, or cannabis
 seed oil. While they may each
 have their own set of health
 benefits, CBD and its
 benefits are not present
 in these products.
- Always check the product for any known allergies and follow the manufacturer's dosage recommendations.

Even if you are not prescribing medical cannabis or CBD products, your patients may be using it. As a provider, understanding medical cannabis and CBD products is beneficial, regardless of the laws in your state. This includes knowledge of the potential uses, adverse effects, and risks associated with using. Document and discuss the pros and cons of use, monitor for improvements and/or potential adverse effects and consider how medical cannabis and CBD products could affect medications you are prescribing and adjust them accordingly.

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