

Cannabidiol (CBD) Medicinal Properties

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The curative properties of Cannabidiol (CBD) has many advocates with diverse medical claims, a long history of use, and claims of efficacy with testimonials for specific cures for a large variety of general conditions. CBD has been reported to cure and/or ameliorate a host of medical problems including sleep disorders, anxiety, pain relief, and epileptic seizures. These anecdotal cures and reliefs from symptoms are made with very little evidence to back them up. Few studies have been performed that would shed light on the science to substantiate the claims. Now with the accessibility of material and the widespread production of CBD oil, there are many products sold over the counter. However only one formulation has been tested through a Food and Drug Administration (FDA) protocol and been subjected to clinical trials to show safety and efficacy for specified medical conditions. June 28, 2018, the FDA approved the first drug, Epidiolex, and thus far is the only one. Epidiolex (cannabidiol) is an oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. London-based GW Pharmaceuticals, the manufacturer of Epidiolex, has said it will charge \$32,500 a year for the treatment, in line with other medications for intractable epilepsy. This drug contains a highly purified CBD oil derived directly from the marijuana plant *cannabis sativa*. Besides Epidiolex, all other products are made, purified, and distributed without any clearance or approval from the FDA.

The DEA has scheduled THC and the CBD derived from it as a Schedule 1 drug. The FDA has scheduled Epidiolex as Schedule 5 and placed the requirement that the THC content must be less 0.1%. Also, of significance in the determination of safety and dependency, Epidiolex was tested in a human physical dependence study. A dose of cannabidiol 1500 mg/day (750 mg twice daily) was administered to adults for 28 days. Following drug discontinuation, no signs or symptoms of withdrawal were shown in patients over a 6-week period. This study suggests that cannabidiol does not produce physical dependence. The drug Epidiolex is essentially pure CBD with less than 0.1% THC. Some CBD products are sold with medical claims that have not been demonstrated and production processes that cannot verify the contents or the purity of the end products. The wide reach of the internet and other marketing and distribution organizations have facilitated the sale of these products, often referred to as "over the counter nutraceuticals" or "generic food products", which claim to not be regulated by the Drug Enforcement Agency (DEA) or the FDA. It is illegal to sell and distribute products that have not been approved through the required regulatory agencies that contain medical claims.

Hemp, a strain of the *cannabis sativa* plant, is now legal with the signing of the Farm Bill into law by president Trump in 2018. However, the director of the FDA Commissioner Scott Gottlieb issued the following statement: "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."

He further stated: "At the same time, we recognize the potential opportunities that cannabis or cannabis-derived compounds could offer and acknowledge the significant interest in these possibilities. We're committed to pursuing an efficient regulatory framework for allowing product developers that meet the requirements under our authorities to lawfully market these types of products." The DEA still considers it a schedule 1 drug. The future will likely contain a lot of news and some clarifications on how to proceed with these issues.

THC and CBD are widely distributed throughout the United States and Canada without claims of safety, purity, or efficacy. The purity component for both products are not regulated by any oversight, nor are standard measures of purity required for the sale of these items. Pain is one of the most common cited reasons for the use of CBD, however, the claims for pain relief are anecdotal and not demonstrated in clinical trials as of this writing. The only product approved for sale with FDA claims is Epidiolex. The sale and use of THC in certain states has been voted as legal, however, THC is still listed as a Schedule 1 Drug by the DEA. The FDA's position is that THC and CBD must meet the requirements under its authorities to lawfully market any types of products in the United States of America.

References:

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