



# MEDICAL MARIJUANA FAQ'S

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## Frequently asked questions about cannabidiol (CBD) and children with epilepsy

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(NOTE: The Epilepsy Foundation of Colorado provides this information as a public service, but we do not make treatment recommendations. Treatment decisions should be made by patients and family members based on appropriate consultation with physicians and careful consideration of each individual case. The Epilepsy Foundation of Colorado is not affiliated with any entities involved in producing or marketing CBD-based products.)

#### ***What is the medical marijuana product known as Charlotte's Web?***

Charlotte's Web is a extract made from cannabis plants and administered in liquid form. Its popular name refers to Charlotte Figi, the child with Dravet syndrome whose seizures decreased after she began taking this product. It is produced in Colorado by the Stanley brothers and sold at their Colorado Springs dispensary.

#### ***Does Charlotte's Web give children a "high" as is the typical result with other forms of medical marijuana?***

No, because Charlotte's Web has a low level of THC, the psychoactive component of marijuana that makes users high. In fact, its THC level is so low (0.3% or less) that the Colorado Department of Agriculture has classified Charlotte's Web as hemp rather than marijuana, making it eligible to be transported across state lines under federal law. (This change, combined with the fact that 16 states have passed laws permitting the use of low-THC cannabis products with children, has greatly reduced the flow of families relocating to Colorado to access products containing CBD.)

#### ***Is medical marijuana legal for children?***

Yes. In Colorado, cannabis-related products may be obtained for children with the recommendation of two doctors (as opposed to one doctor for adults). Presumably it would be difficult to get two doctors' approval for a young child to take a form of marijuana that is high in THC, although Dr. Kelly Knupp of Children's Hospital Colorado reports having seen children with epilepsy who have taken high-THC products.

#### ***What is the evidence that CBD is having a positive effect in controlling seizures among children with intractable epilepsy?***

The most extensive study thus far is led by Orrin Devinsky of New York University. In this study, 261 children with severe epilepsy received Epidiolex, a medication containing CBD, for at least three months at 16 U.S. sites. According to family logs, 47% of these patients had at least a 50% seizure reduction at three months and 9% were seizure-free. On the other hand, 16% of patients stopped treatment due to lack of efficacy or an

adverse effect. More information on this and other studies is available at <http://www.npr.org/sections/health-shots/2015/12/07/458818829/marijuana-extract-may-help-some-children-with-epilepsy-study-finds>

Researchers at Children’s Hospital Colorado found that 33% of 75 pediatric epilepsy patients using a CBD-related treatment experienced at least a 50% seizure reduction.

Dr. Margaret Gedde, who has followed hundreds of children with epilepsy using CBD-related treatments, reported in an observational study (not independently verified) that 60% achieved a seizure reduction of 50% or more.

No results of a randomized controlled trial are available yet. This type of research is the standard used to determine efficacy of medications.

***Are there medical marijuana treatments for children with epilepsy other than Charlotte’s Web?***

Yes. Other marijuana dispensaries in Colorado are also offering products reported to be high in CBD and low in THC. The best-known alternative is Haleigh’s Hope, associated with Jason Cranford and the Boulder-based Flowering Hope Foundation.

The breadth of applications has also expanded. CBD oils are now available in gels or patches as well as in oil form. Action by Congress to clarify that a product classified as “industrial hemp” in its own state can be transported across state lines has also impacted the market. At least six companies, located in Kentucky and South Carolina as well as Colorado, are marketing nationally hemp oils that are reportedly high in CBD and low in THC.

Epidiolex, the medication being used in Dr. Devinsky’s study, is made by GW Pharmaceuticals, a British company. It is high in CBD and contains no detectable THC. GW Pharmaceuticals has obtained permission from the Food and Drug Administration to make Epidiolex available as an Investigational New Drug (IND) by application from physicians wishing to prescribe it. Sixteen physicians are participating in the study, but none of them are in Colorado. A randomized trial is now occurring to determine the efficacy of this product for children with epilepsy.

***Are all these products basically the same?***

No. Epidiolex is refined to eliminate the psychoactive THC completely; other products have low levels of THC. There is considerable debate as to whether THC or other chemicals in marijuana could have an “entourage effect,” i.e., working in combination to provide medical benefits not obtained from taking pure CBD.

***Under what circumstances might this treatment be considered?***

Given the lack of rigorous medical evidence at this point, the use of Charlotte’s Web or similar treatments by children with epilepsy is recommended only for severe, intractable cases that have not responded to other, more established medications. Any child taking cannabis-related products should be closely monitored by a physician. Parents of children with severe, intractable epilepsy may understandably be tempted to take desperate measures. But when asked what he thought parents should know, Jason Cranford said, “Tell them not to wean their child off other drugs, without a doctor’s oversight, based on what some other parent who doesn’t know their child is telling them on Facebook.”

***What are the known side effects of Charlotte’s Web or other cannabis-related products generally in children?***

The most commonly reported side effects in the Epidiolex study have been drowsiness, diarrhea, and decreased appetite. Increased seizures and convulsions have occurred in a small number of cases. Long-term effects are an open question. Marijuana use in children has been shown to have negative effects on the brain, but we do not know whether treatments containing little or no THC will have any long-term side effects.

***How do I know what is actually in the product I am buying?***

That can be a challenge. No pharmaceutical-grade medical marijuana is available in Colorado. No FDA testing or oversight is required; the FDA has issued warning letters to some producers (not in Colorado) after testing their products and finding that they did not contain the CBD claimed on the label. Beginning later in 2016, Colorado will require testing of medical marijuana products for THC, but not for CBD. The Stanley- and Cranford-led operations have used both in-house and third-party testing processes in an attempt to ensure that Charlotte's Web and Haleigh's Hope have consistent chemical content. Other growers and dispensaries may also claim to offer forms of marijuana that are high in CBD and low in THC, but parents cannot arrange for their own lab testing in Colorado, because marijuana testing labs are not permitted to test samples from private citizens. Families considering the use of cannabis-related products should make sure that they are comfortable with the process by which the product's quality and consistency are achieved. Dr. Gedde encourages asking for lab reports showing the product's composition. She indicated confidence in the consistency of both Charlotte's Web and Haleigh's Hope.

***Does medical insurance cover CBD-based products as a treatment for children with epilepsy?***

Not yet. As a result, families can expect to pay for it themselves. As of 2014, the cost of Charlotte's Web ranged from \$100 to \$600 per month, depending on dosage level and patient weight. Many Charlotte's Web patients receive financial assistance from the Realm of Caring Foundation ([info@theroc.us](mailto:info@theroc.us) or 719-347-5400), which is related to the Stanleys' organization. Haleigh's Hope is priced at 9 cents per milligram; according to Cranford, the average patient dose costs \$150 per month (contact information: [www.floweringhope.co](http://www.floweringhope.co) or 719-368-7963).

If the efficacy of Epidiolex or other cannabis-related products could be documented through clinical trials, they might become eligible for insurance coverage in the future. Although the Drug Enforcement Administration currently classifies marijuana as a Schedule I controlled substance (which means that it has no currently accepted medical use in the United States), Marinol, a drug prescribed for side effects of chemotherapy that contains THC, is classified separately as Schedule III. GW Pharmaceuticals hopes that Epidiolex would be similarly reclassified if the FDA approves its use following clinical trials.