

Epilepsy

[Epilepsy](#) is a central nervous system disorder characterized by uncontrollable twitching of the arms or legs and/or seizures. One in 26 Americans will develop epilepsy during their lifetime, according to statistics published by The Epilepsy Foundation. Conventional treatment to mitigate symptoms of this disorder includes medications or sometimes surgery. Nonetheless, even with conventional treatment, an estimated 30 percent of people with epilepsy continue to experience seizures.

Epileptics frequently report gaining subjective relief from cannabis-based interventions.¹ In recent years, increased focus has been paid to the use of cannabis-based therapies by adolescents with severe forms of pediatric epilepsy.

Parents of epileptic children have long advocated in favor of the therapeutic efficacy of cannabis, in particular the use of CBD-rich products, in media reports² and in scientific surveys.³⁻⁴

A growing number of studies are now available in the scientific literature acknowledging CBD's anti-seizure activity in adolescent patients. For example, a retrospective chart review of children and adolescents who were given oral cannabis extracts in a Colorado epilepsy center reported mitigation in seizure frequency in up to 57 percent of subjects.⁵ Additional benefits reported included: improved behavior/alertness (33 percent), improved language (10 percent), and improved motor skills (10 percent).

Israeli researchers in 2016 retrospectively evaluated the effects of CBD oil in a multicenter cohort of 74 patients with intractable epilepsy. Participants in the trial were resistant to conventional epilepsy treatment and were treated with CBD extracts for a period of at least three months. Extracts in the study were provided by a pair of Israeli-licensed growers and were standardized to possess a CBD to THC ratio of 20 to 1. Investigators reported: "CBD treatment yielded a significant positive effect on seizure load. Most of the children (89 percent) reported reduction in seizure frequency. ... In addition, we observed improvement in behavior and alertness, language, communication, motor skills and sleep."⁶

They concluded, "The results of this multicenter study on CBD treatment for intractable epilepsy in a population of children and adolescents are highly promising. Further prospective, well-designed clinical trials using enriched CBD medical cannabis are warranted."

In the fall of 2013, the United States Food and Drug Administration granted orphan drug status to imported, pharmaceutically standardized, plant-derived CBD (aka Epidiolex) extracts for use in experimental pediatric treatment. Clinical trials assessing the safety and efficacy of the treatment in children with severe forms of the disease, such as Dravet syndrome, began in 2014.⁷ Results from several of these trials have become available in recent years.

Clinical trial results publicized in April 2015 at the 67th Annual Meeting of the American Academy of Neurology reported that the administration of these extracts decreased seizure frequency by 54

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percent over a 12-week period in children with treatment-resistant epilepsy.⁸ Trial data reported in the fall of 2015 at the American Epilepsy Society's annual meeting further reported that the adjunctive use of Epidiolex was associated with long-term seizure relief in 40 percent of adolescent subjects.⁹ Open-label trial data reported in the journal *Lancet Neurology* reported a median reduction in seizures in adolescent patient treated with Epidiolex that approached 40 percent. Authors concluded, "Our findings suggest that cannabidiol might reduce seizure frequency and might have an adequate safety profile in children and young adults with highly treatment-resistant epilepsy."¹⁰ Preliminary data provided from one such state-sponsored trial, provided by the University of Alabama at Birmingham in 2016, reported that an estimated 90 percent of subjects with pediatric epilepsy showed "some improvement" following CBD treatment.¹¹

Clinical trial data has also shown Epidiolex treatment to mitigate seizure frequency and be well tolerated in the treatment of Lennox-Gastaut Syndrome, a rare and severe form of epilepsy.¹²⁻¹³ Epidiolex/CBD treatment is also associated with improved symptoms and reduced prescription drug intake in pediatric patients with febrile infection-related epilepsy syndrome (FIRES), a devastating form epilepsy affecting normal children after a febrile illness,¹⁴ as well as with seizure reduction in patients with Tuberous sclerosis complex-induced epilepsy.¹⁵

Observational data published in the journal *Epilepsia* concludes that 70 percent of children administered Epidiolex adjunctively with clobazam experience a greater than 50 percent decrease in seizure frequency. "CBD is a safe and effective treatment of refractory epilepsy in patients receiving CLB treatment," authors reported.¹⁶ Additional clinical trials of Epidiolex, along with several state-sponsored trials using CBD extracts, are ongoing.

Overall, "most studies suggest anticonvulsant effects of CBD, and consider most adverse effects to be mild," reviewers wrote in the *Journal of Epilepsy Research* in 2017.¹⁷

As a result of this growing body of evidence, the Epilepsy Foundation of America has resolved for "changes to state laws to increase access to medical marijuana as a treatment option for epilepsy, including pediatric use as supported by a treating physician."¹⁸ An NDA submission to the US Food and Drug Administration for Epidiolex is pending.¹⁹

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