

## Marijuana-derived drug OK'd for rare epilepsy disorders

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The Food and Drug Administration (FDA) has approved the first marijuana-derived drug to treat two rare forms of epilepsy.

Epidiolex oral solution from GW Pharmaceuticals plc is expected to be available in the fall to treat Lennox-Gastaut syndrome and Dravet syndrome in patients 2 years of age and older.

Both epilepsy disorders begin in childhood, can include multiple types of seizures and impact children's development. Dravet syndrome is not treatable with any other FDA-approved drugs.

"The difficult-to-control seizures that patients with Dravet syndrome and Lennox-Gastaut syndrome experience have a profound impact on these patients' quality of life," Billy Dunn, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research, said in a [news release](#). "In addition to another important treatment option for Lennox-Gastaut patients, this first-ever approval of a drug specifically for Dravet patients will provide a significant and needed improvement in the therapeutic approach to caring for people with this condition."

Epidiolex contains highly purified cannabidiol, which comes from the cannabis sativa plant but does not cause intoxication, according to the FDA. When taken with other medications during three randomized, double-blind clinical trials, Epidiolex reduced the frequency of seizures more effectively than a placebo.

The most common side effects included sleepiness, elevated liver enzymes, decreased appetite, diarrhea, rash, weakness, trouble sleeping and infections. Like other epilepsy drugs, serious risks include suicidal thoughts or attempts, depression, aggression and panic attacks. Epidiolex also may cause liver injury, according to the FDA.

Under federal law, cannabidiol is classified as a Schedule I substance with no medical use. However, GW Pharmaceuticals said it expects the Drug Enforcement Administration to reschedule it within 90 days so that it can be prescribed to patients.

The Academy said in a [2015 policy statement](#) that it opposes medical marijuana that is not FDA-approved but "strongly supports research and development of pharmaceutical cannabinoids."

Renee A. Shellhaas, M.D., FAAP, a member of the AAP Section on Neurology, called Epidiolex approval an advance for children with difficult seizure disorders.

"Epidiolex was evaluated in carefully designed studies in order to meet FDA requirements," she said via email. "It will be a big step forward for physicians to be able to prescribe an FDA-approved form of cannabidiol to their patients."

