

# Marijuana-based drug gets positive review from US agency

17 April 2018, by Matthew Perrone



This May 23, 2017, file photo shows GW Pharmaceuticals' Epidiolex, a medicine made from the marijuana plant but without THC. The medicine reduced seizures in children with severe forms of epilepsy and warrants approval in the United States, health officials said Tuesday, April 17, 2018. (AP Photo/Kathy Young, File)

A closely watched medicine made from the marijuana plant reduces seizures in children with severe forms of epilepsy and warrants approval in the United States, health officials said Tuesday.

British drugmaker GW Pharmaceuticals is seeking permission to sell its purified form of an ingredient found in cannabis—one that doesn't get users high—as a medication for rare, hard-to-treat seizures in children. If successful, the company's liquid formula would be the first government-approved drug derived from the cannabis plant in the U.S.

The Food and Drug Administration's approval would technically limit the treatment to a small group of epilepsy patients. But doctors would have the option to prescribe it for other uses and it could

spur new pharmaceutical research and interest into other cannabis-based products. Man-made versions of a different marijuana ingredient have previously been approved for other purposes.

The FDA posted its review of the experimental medication Epidiolex ahead of a public meeting Thursday when a panel of outside experts will vote on the medicine's safety and effectiveness. It's a non-binding recommendation that the FDA will consider in its final decision by late June.

Patients taking the treatment had fewer seizures, according to the FDA's internal review posted online. Scientists concluded that GW Pharmaceutical's submission "appears to support approval" despite some potential side effects including risks of liver injury.

More than two dozen states allow marijuana use for a variety of ailments, but the FDA has not approved it for any medical use. In 2016, the agency recommended against easing federal restrictions on marijuana. The U.S. continues to classify marijuana as a high-risk substance with no medical use, alongside other illicit drugs like heroin and LSD.

For years, desperate patients and parents have pushed for wider access to medical marijuana products for a host of conditions including pain, post-traumatic stress disorder and epilepsy, with only anecdotal stories and limited studies on their side.

But studies conducted by GW Pharmaceuticals have begun to change that picture.

Across three studies involving more than 500 patients, Epidiolex generally cut the number of monthly seizures by about 40 percent, compared with reductions between 15 and 20 percent for patients taking a dummy medicine.

Most patients in the study were already taking at least three other medications to try and control their seizures.



In this Feb. 14, 2018, file photo, marijuana plants are displayed at a dispensary in Berkeley, Calif. U.S. health officials say a closely watched medicine made from the marijuana plant significantly reduces seizures in children with severe forms of epilepsy and warrants approval in the U.S. The Food and Drug Administration posted its review Tuesday, April 17, of the experimental medication ahead of a public meeting later this week. (AP Photo/Marcio Jose Sanchez, File)

Epidiolex is essentially a pharmaceutical-grade version of cannabidiol, or CBD oil, which some parents have used for years to treat children with epilepsy. CBD is one of more than 100 chemicals found in the cannabis plant and it doesn't contain THC, the ingredient that gives marijuana its mind-altering effect.

CBD oil is currently sold online and in specialty shops across the U.S., though its legal status remains murky. Most producers say their oil is made from hemp, a plant in the cannabis family that contains little THC and can be legally farmed in a number of states for clothing, food and other uses.

A doctor who treats children with epilepsy says it's important to have an FDA-approved version of CBD.

"I think it needs to be approved because everyone is using it across the internet without knowing the safety ... and no one is watching the interactions with other drugs," said Dr. Joan Conry of Children's National Health System in Washington, who was not involved in the studies.

Conry and other researchers say it's not yet clear why CBD reduces seizures in some patients.

GW Pharmaceuticals makes its drug from cannabis plants that are specially bred to contain high levels of CBD. It's seeking approval for two rare forms of childhood epilepsy—Dravet and Lennox-Gastaut syndromes.

Common side effects included diarrhea, vomiting, fatigue and sleep problems. FDA reviewers flagged a more serious issue with potential liver injury, but said doctors could manage the risk by monitoring patients' enzyme levels.

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