

# FDA approves country's first medicine made from marijuana



The Food and Drug Administration on Monday approved the country's first drug derived from marijuana, a medication that treats two rare and devastating forms of epilepsy.

The drug, GW Pharmaceuticals' Epidiolex, is made of cannabidiol, or CBD, a component of marijuana that does not give users a high. It is given as an oil, and in clinical trials, it was [shown to reduce](#) the number of seizures by about 40 percent in patients with Dravet or Lennox-Gastaut syndromes.

"This approval serves as a reminder that advancing sound development programs that properly evaluate active ingredients contained in marijuana can lead to important medical therapies," FDA Commissioner Scott Gottlieb said in a statement. "And, the FDA is committed to this kind of careful scientific research and drug development."

The FDA's decision [was expected](#). FDA officials had indicated they supported approving Epidiolex, and an advisory panel had unanimously recommended it get the green light. There was some concern about the drug's effects on the liver, but experts have said this risk could be addressed by doctors as they monitor their patients during treatment.

Before GW can market Epidiolex, though, the Drug Enforcement Administration [will have to reclassify CBD](#), which in this case, because it comes from marijuana, [is considered a Schedule I drug](#), meaning it has no medical value and a high risk of abuse. The agency is expected to do so within 90 days.

"This approval is the culmination of GW's many years of partnership with patients, their families, and physicians in the epilepsy community to develop a much needed, novel medicine," GW CEO Justin Gover said in a statement. "These patients deserve and will soon

have access to a cannabinoid medicine that has been thoroughly studied in clinical trials, manufactured to assure quality and consistency, and available by prescription under a physician's care."

A company representative said the list price for the medication had not been set yet.

Patients with Lennox-Gastaut and Dravet syndromes, which typically emerge in the first few years of life, can suffer from debilitating and recurrent seizures, sometimes dozens a day. One in five patients is estimated to die before they are 20 years old.

There are six other drugs approved to treat seizures associated with Lennox-Gastaut, but none approved for Dravet.

Although Epidiolex was only approved for the two specific conditions, analysts expect doctors to prescribe it off label for a variety of epileptic diseases. It comes from a proprietary strain of cannabis grown by GW that has been bred to have high levels of CBD and low levels

The FDA has previously approved synthetic medications that resemble or are identical to THC. The drugs are listed as Schedule II and Schedule III, meaning they have medicinal value but also potential for abuse.

Many families have moved to states where marijuana is legal medically or recreationally so they could treat their children with CBD on their own. But experts have said that having a regulated medication with standard dosing and supply is crucial for patient safety, a sentiment echoed by Gottlieb in his statement Monday.

Gottlieb also used the approval to vouch for the years-long clinical development of Epidiolex as a model for bringing products made from marijuana to the market. The FDA is willing to help companies that want to pursue such research programs, he said, but they need to prove their products work and are safe with data from clinical trials.

"This is an important medical advance," Gottlieb said. "But it's also important to note that this is not an approval of marijuana or all of its components. This is the approval of one specific CBD medication for a specific use. And it was based on well-controlled clinical trials evaluating the use of this compound in the treatment of a specific condition. Moreover, this is a purified form of CBD. It's being delivered to patients in a reliable dosage form and through a reproducible route of delivery to ensure that patients derive the anticipated benefits. This is how sound medical science is advanced."

Gottlieb hinted at additional enforcement actions against companies that sell unregulated CBD products with medical claims that aren't backed up by evidence. The FDA has previously sent warning letters to companies that hyped their products as cancer or Alzheimer's fighters.

"Marketing unapproved products, with uncertain dosages and formulations, can keep patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases," he said.