

US could back 1st pot-derived medicine, and some are worried

June 19 2018, by Kathleen Foody And P. Solomon Banda



In this April 23, 2018, photo, Meagan Patrick kisses her daughter, Addelyn Patrick, 5, in the playroom at Realm of Caring in Colorado Springs, Colo. Addelyn was born with a brain malformation and suffers from multiple forms of seizures. The U.S. Food and Drug Administration is expected to decide soon whether to give its first approval to a prescription drug made from the marijuana plant. But parents, including Meagan, who have used other products containing chemicals from the plant to treat their children's severe forms of epilepsy are feeling more cautious than celebratory. (AP Photo/Thomas Peipert)

A British pharmaceutical company is getting closer to a decision on whether the U.S. government will approve the first prescription drug derived from the marijuana plant, but parents who for years have used cannabis to treat severe forms of epilepsy in their children are feeling more cautious than celebratory.

The U.S. Food and Drug Administration is expected to decide by the end of the month whether to approve GW Pharmaceuticals' Epidiolex. It's a purified form of cannabidiol—a component of cannabis that doesn't get users high—to treat Dravet and Lennox-Gastaut syndromes in kids. Both forms of epilepsy are rare.

Cannabidiol's effect on a variety of health conditions is frequently touted, but there is still little evidence to back up advocates' personal experiences. The U.S. Drug Enforcement Administration has long categorized cannabis as a Schedule I drug, a category with "no currently accepted medical use and a high potential for abuse." That strictly limits research on potential medical uses for cannabis or the chemicals in it, including cannabidiol, or CBD.

But for years, parents desperate to find anything to help their children have turned to the [marijuana](#)-based products made legal by a growing number of states.

Meagan Patrick is among the parents using CBD to treat symptoms in their children. She moved from Maine to Colorado in 2014 so she could legally get CBD for her now-5-year-old daughter, Addelyn, who was born with a brain malformation that causes seizures.



In this April 23, 2018, photo, Addelyn Patrick, 5, sits inside a teepee in the playroom at Realm of Caring in Colorado Springs, Colo. Addelyn was born with a brain malformation and suffers from multiple forms of seizures. The U.S. Food and Drug Administration is expected to decide soon whether to give its first approval to a prescription drug made from the marijuana plant. But parents, including Addelyn's mother Meagan Patrick, who have used other products containing chemicals from the plant to treat their children's severe forms of epilepsy are feeling more cautious than celebratory. (AP Photo/Thomas Peipert)

"My child was dying, and we needed to do something," Patrick said.

As for the potential approval of a pharmaceutical based on CBD, she said fear is her first reaction.

"I want to make sure that her right to continue using what works for her is protected, first and foremost. That's my job as her mom," Patrick said.

Advocates like Patrick became particularly concerned when GW Pharmaceuticals' U.S. commercial business, Greenwich Biosciences, began quietly lobbying to change states' legal definition of marijuana, beginning in 2017 with proposals in Nebraska and South Dakota.



In this April 23, 2018, photo, Lacie Lloyd works in the call center at the Realm of Caring Foundation in Colorado Springs, Colo. The organization fields calls from all over the world and offers advice about medical cannabis. The Realm of Caring Foundation, an organization co-founded by Paige Figi said it maintains a registry of about 46,000 people worldwide who use cannabidiol, or CBD. (AP Photo/Thomas Peipert)

Some worried the company's attempt to ensure its product could be

legally prescribed and sold by pharmacies would have a side effect: curtailing medical marijuana programs already operating in more than two dozen states.

The proposals generally sought to remove CBD from states' legal definition of marijuana, allowing it to be prescribed by doctors and supplied by pharmacies. But the change only applies to products that have FDA approval.

Neither Nebraska nor South Dakota allows medical use of marijuana, and activists accused the company of trying to shut down future access to products containing cannabidiol but lacking FDA approval.

GW Pharmaceuticals never intended for the changes to affect other [marijuana products](#), but they are necessary to allow Epidiolex to be sold in pharmacies if approved, spokesman Stephen Schultz said.



In this April 23, 2018, photo, a map on the wall marks some of the places where people have sought advice from Realm of Caring Foundation in Colorado Springs, Colo. The Realm of Caring Foundation, an organization co-founded by Paige Figi said it maintains a registry of about 46,000 people worldwide who use cannabidiol, or CBD. (AP Photo/Thomas Peipert)

He would not discuss other places where the company will seek changes to state law. The Associated Press confirmed that lobbyists representing Greenwich Biosciences backed legislation in California and Colorado this year.

"As a company, we understand there's a significant business building up," Schultz said. "All we want to do is make sure our product is accessible."

Industry lobbyists in those states said they take company officials at their word, but they still insisted on protective language ensuring that recreational or medical marijuana, cannabidiol, hemp and other products derived from cannabis plants won't be affected by the changes sought by GW Pharmaceuticals.

Patrick Goggin, an attorney who focuses on industrial hemp issues in California, said the company would run into trouble if it tried to "lock up access" to marijuana-derived products beyond FDA-approved drugs.



In this Monday, April 23, 2018, photo, Lukas Inman sits on the couch at his home in Colorado Springs, Colo. Inman suffers from a rare and severe form of epilepsy called Lennox-Gastaut Syndrome. A British pharmaceutical company is getting closer to a decision on whether the U.S government will approve the first prescription drug derived from the marijuana plant, but parents, including Lukas,' who for years have used cannabis to treat severe forms of epilepsy in their children are feeling more cautious than celebratory. (AP Photo/Thomas Peipert)

"People need to have options and choices," he said. "That's the battle here."

Legal experts say the changes are logical. Some states' laws specifically prohibit any product derived from the marijuana plant from being sold in pharmacies. The FDA has approved synthetic versions of another cannabis ingredient for medical purposes but has never approved marijuana or hemp for any medical use.

A panel of FDA advisers in April unanimously recommended the agency approve Epidiolex for the treatment of severe seizures in children with epilepsy, conditions that are otherwise difficult to treat. It's not clear why CBD reduces seizures in some patients, but the panel based its recommendation on three studies showing significant reduction in children with two forms of epilepsy.

Denver-based attorney Christian Sederberg, who worked on the GW Pharmaceuticals-backed legislation in Colorado on behalf of the marijuana industry, said all forms of marijuana can exist together.



In this Monday, April 23, 2018, photo, Alex Inman holds a bottle of THC-infused oil in Colorado Springs, Colo. Inman's teenage son, Lukas, suffers from a rare and severe form of epilepsy called Lennox-Gastaut Syndrome. A British pharmaceutical company is getting closer to a decision on whether the U.S government will approve the first prescription drug derived from the marijuana plant, but parents, including Lukas,' who for years have used cannabis to treat

severe forms of epilepsy in their children are feeling more cautious than celebratory. (AP Photo/Thomas Peipert)

"The future of the industry is showing itself here," Sederberg said. "There's going to be the pharmaceutical lane, the nutraceutical (food-as-medicine) lane, the adult-use lane. This shows how that's all coming together."

Alex and Jenny Inman said they won't switch to Epidiolex if it becomes available, though their son Lukas has Lennox-Gastaut syndrome.

Alex, an information technology professional, and Jenny, a preschool teacher, said it took some at-home experimentation to find the right combination of doctor-prescribed medication, CBD and THC—the component that gives marijuana users a high—that seemed to help Lukas with his seizures.

"What makes me a little bit nervous about this is that there's sort of a psyche amongst patients that, 'Here's this pill, and this pill will solve things,' right? It works differently for different people," Alex Inman said.



In this Monday, April 23, 2018, photo, syringes used to administer CBD oil sit on the kitchen counter of the Inman family in Colorado Springs, Colo. Lukas Inman, 19, suffers from a rare and severe form of epilepsy called Lennox-Gastaut Syndrome. The Inmans moved from Maryland to Colorado in 2015 after doctors recommended a second brain surgery for Lukas' seizures. Luke's and other parents and advocates for cannabidiol, CBD, said children respond differently to a variety of strains. (AP Photo/Thomas Peipert)

The Inmans moved from Maryland to Colorado in 2015 after doctors recommended a second brain surgery for Lukas' seizures. The couple and other parents and advocates for CBD said children respond differently to a variety of strains.

The Realm of Caring Foundation, an organization co-founded by Paige Figi, whose daughter Charlotte's name is attached to the CBD oil Charlotte's Web, said it maintains a registry of about 46,000 people worldwide who use CBD.

For Heather Jackson, who said her son Zaki, now 15, benefited from CBD and who co-founded the foundation, Epidiolex's approval means insurers will begin paying for treatment with a cannabis-derived product.

"That might be a nice option for some families who, you know, really want to receive a prescription who are going to only listen to the person in the white coat," Jackson said.



In this Monday, April 23, 2018, photo, Lukas Inman, 19, interacts with his father in Colorado Springs, Colo. Inman suffers from a rare and severe form of epilepsy called Lennox-Gastaut Syndrome. A British pharmaceutical company is getting closer to a decision on whether the U.S government will approve the first prescription drug derived from the marijuana plant, but parents, including Lukas,' who for years have used cannabis to treat severe forms of epilepsy in their children are feeling more cautious than celebratory. (AP Photo/Thomas Peipert)

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