Oversold?
Will cannabis oil live up to its hype for epilepsy patients in Texas?

For many Texas patients with intractable epilepsy, the ability to obtain cannabis oil legally since February has been a blessing.

For one family in the Rio Grande Valley, "this is the first time their child has been seizure-free," says Sindi Rosales, CEO of the Epilepsy Foundation of Central & South Texas. The reduction in seizures is just tremendous. It's something they have never experienced. So they are ecstatic about the potential.

That's the good news. The bad news is not all patients are responding as positively to the treatment. Physicians say this is predictable: Not all anti-seizure medicines help all patients.

Unfortunately, this good news/bad news dynamic doesn't match some of the hype that preceded cannabis oil's arrival in Texas. While most patients and physicians never will deal with this exotic script, its introduction has met with a great deal more hoopla than most medications.

"People in the general public think this is exceptionally effective and totally safe, so the patient expectation is very high," said Karen C. Keough, MD, an Austin pediatric neurologist and one of only 30 Texas physicians registered so far to prescribe cannabis oil legally. "That's compounded by the political controversy about whether marijuana in general, and [cannabis oil] in particular, should be out there."

Quality conundrum
The Texas Legislature paved the way for dispensing cannabis oil in 2015 by passing the Compassionate Use Act (tma.tips/CompassionateUse). It legalized the sale of only cannabidiol, or CBD, which is non-euphoric and has low levels of tetrahydrocannabinol (THC), the psychoactive element in marijuana. The Texas Medical Association at the time testified in favor of further study on the use of marijuana products as medicine.

CBD has been touted as helping with a variety of medical problems, including epileptic seizures, post-traumatic stress disorder, and multiple sclerosis. Texas' Compassionate Use Act allowed the use of CBD for one narrow medical condition: refractory epilepsy.

Seventeen states permit CBD use for medical reasons. (See map, page 33.) So far, only three dispensaries are licensed in Texas: Compassionate Cultivation, located in Manchaca near Austin; Cansorium Texas (or Knox Medical), in Schulenburg; and Surterra Wellness in Austin.

M. Scott Perry, MD, the medical director of neurology at Cook Children's Medical Center in Fort Worth, said the law passed amid a lot of hype about the effectiveness of CBD. People posted success stories on social media about CBD ending their seizures, and those victories were amplified in the news.

Scientific studies done since then, and experience among patients in other states showed that CBD helped a small subset of patients with chronic seizures, Dr. Perry noted. "It's definitely another tool in the toolbox. But if you base it on what people saw in the beginning, which was that everybody on Facebook was seizure-free -- it's not that good," he said.

People can order cannabis oil from a variety of out-of-state companies over the Internet, which is illegal in Texas but not uncommon. But Dr. Perry said most of the companies involved do not have the same production standards or abilities as pharmaceutical companies. That means the quality in some cases may vary not just from brand to brand, but from bottle to bottle.

"While all CBD oils are high in CBD, they're also different," Dr. Perry explained. "One might have 99 percent of CBD and the other might have 97 percent of CBD and 3 percent of something else, and that 3 percent of something else is important."

Dr. Perry said that 3 percent can be small amounts of other substances in the cannabis plant — most of which have not been studied, making it impossible to tell if they’re good or bad for seizure patients.

Dr. Keough has tried to address this concern by working directly with one of the Texas dispensaries, Compassionate Cultivation. She was personally involved in the operational planning for extraction and medicine production to make sure the oil would be produced consistently. She said it is essential for prescribers and patients to have confidence that the medicine contains the ingredients at the concentration on the label, every time.
"There will be none of this, ‘I don’t know what’s in the bottle, and is it going to be the same the next time I get a bottle?’" she said. "That’s why the availability of Texas-sourced CBD is a game-changer."

Dr. Keough serves as Compassionate Cultivation's chief medical officer, and acknowledges she has a small financial stake in the company. She says her role is comparable to physicians who advise pharmaceutical companies about best practices.

Ms. Rosales of the Epilepsy Foundation said the biggest problem so far with cannabis oil is that only about 30 physicians can prescribe it statewide. She says these physicians have to commit to doing more work because virtually everything about cannabis oil — like figuring out correct dosages — is experimental.

"The physicians who have been working on this have just been tremendous," she said. "They are having to make extra phone calls and reach out to people like myself or to the dispensaries. There's just a lot more involvement than the typical script."

Another problem is the price. Morris Denton, the CEO of Compassionate Cultivation, said most of his clients currently pay less than $200 a month for their prescriptions because physicians tend to start with conservative dosages as they monitor the effects. He said that is likely to rise as physicians adjust dosages over time to suit their patients, likely putting average prescription prices in the $350- to $600-a-month range.

However, Valerie Coffman, a licensed vocational nurse and epilepsy coordinator at the Kelsey-Seybold Clinic in Houston, said prescriptions easily could cost at least $1,000 — and CBD is not covered by insurance in Texas.

Nevertheless, she said, people are eager to try it.

"I still have parents who are ready to move forward with it because they're just looking for something that will offer [their children] some relief," she said.

**Something new**

Dr. Perry said patients with epilepsy may be excited about cannabis oil now, but that excitement may soon be transferred to another product. Drugmaker Greenwich Biosciences is expected to get U.S. Food and Drug Administration (FDA) approval for a pharmaceutical-grade version of CBD called Epidiolex this summer. Assuming that happens, the oils produced by the dispensaries still might have value for experimental purposes, but physicians and patients are more likely to turn to an FDA-approved drug that is covered by insurance.
Mr. Denton, the CEO of Compassionate Cultivation, says the introduction of Epidiolex is not necessarily a bad thing for his company. He said all cannabis products are currently listed as Schedule I drugs — meaning they are dangerous and have no medicinal value — by the U.S. government. The success of Epidiolex would show that is not the case.

"From my perspective, I'm rooting for [Epidiolex],” Mr. Denton said. "Because if the FDA says, sure, CBD has medicinal value, then CBD has medicinal value for not just epilepsy, but a variety of other medical conditions, as well."

Meanwhile, Texans with epilepsy remain eager to try cannabis oil. Michael Newmark, MD, a neurologist at the Kelsey-Seybold Clinic in Houston, said he has one patient already taking it and four others about to start. He said the one who is taking it went from several seizures a day to being seizure-free in the first three weeks. He'd love for that success to continue, but it's much too early to draw conclusions.

"Seizures and epilepsy are a chronic condition, and we go through peaks and valleys all the time,” Dr. Newmark said. "So we're looking for not only seizure freedom in the next few weeks but in the next few months."

Dr. Perry at Cook Children's in Fort Worth said he's encouraged about cannabis oil, but he spends a lot of time managing his patients' expectations.

"I found when I get done having the conversation with the families about the science and which drugs work, most of them are not as gung-ho about [cannabis oil] at the end," he said. "They're like, 'You're right — why don't I try something else in the meantime.'"

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