



TEXAS CBD Today

FALL 2018

News from licensed CBD producer Compassionate Cultivation



Contact Us

General info

texasoriginalcc.com or 512-614-0343

Prescribers and patients 512-467-4118

On social media @CBDTexas

Compassionate Cultivation

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What's Inside

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- 3 Compare regulated Texas products vs. online products
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Introduction to Cannabidiol for Epilepsy

Approximately 30 percent of people with epilepsy don't respond well to conventional treatments, but cannabidiol (CBD), a non-psychoactive compound found in the cannabis plant, has emerged as a promising alternative treatment option.

Research indicates CBD treatments may decrease the frequency of convulsive seizures in some patients suffering with intractable epilepsy, and numerous patients and caregivers have come forward

across the country in recent years reporting positive responses with integrated use of CBD, which is typically refined into an oil form and ingested.

The state of Texas created a medical cannabis program in 2015 with the passage of the Compassionate Use Act, which allows licensed dispensing organizations to grow cannabis and manufacture CBD products for treatment of intractable epilepsy.



Cannabis oil made at Compassionate Cultivation's Texas facility is refined into special formulations containing precise amounts of the plant compounds cannabidiol (CBD) and low amounts of psychoactive tetrahydrocannabinol (THC).

How the Texas Compassionate Use Act Works for Patients and Physicians

The Compassionate Use Registry of Texas (CURT) is the state-run platform used by physicians and licensed dispensing organizations to provide low-THC medical cannabis (CBD oil) to patients who hold a valid prescription.

PATIENT REQUIREMENTS

1. Be a permanent resident of Texas.
2. Have a diagnosis of intractable epilepsy.
3. Hold a valid prescription from a CURT-registered physician.

PHYSICIAN REQUIREMENTS

1. Must specialize in the field of examining, diagnosing and treating epilepsy.
2. Be registered with CURT as a prescribing physician.
3. Document patient prescriptions in the CURT database, including patient information and their treatment plan.

Essential Info on Adding Patient Treatment Plans Into the State Registry

The first step for physicians is to enroll with the state as a prescriber. Visit the Texas Department of Public Safety (DPS) Compassionate Use Registry Portal. Click the "Physician Registration" link located under the "Licensing" tab and follow the instructions. (See our complete registration how-to online at texasoriginalcc.com/physicians)

Your treatment plan must include: patient's name and date of birth; their prescribed dosage; the means of administration ordered; total amount of low-THC cannabis

required to fill patient's prescription; and how you will monitor patient's symptoms, tolerance and reactions.

Acquire a secondary approval by a fellow CURT-registered physician, and note the physician's CURT username; he or she is not required to have contact with the patient.

It should be noted that a patient can see a CURT-registered physician solely for the purpose of receiving a CBD oil prescription, while retaining their existing relationship with their primary physician/neurologist.

FIRST-TIME PRESCRIPTION ORDERS & REFILLS

To fill a prescription, patient (or guardian) must contact the licensed dispensing organization by phone to confirm the order details and set up a time for pickup at the dispensary or schedule a delivery. Please allow up to one week for deliveries.

CONTACT COMPASSIONATE CULTIVATION

Prescribers and Patients:
call 512-467-4118

For general info, 512-614-0343
Email: info@texasoriginalcc.com

Why It's Better to Stay In-State With Compassionate Cultivation

OUTSIDE OF TEXAS

Products often utilize industrial hemp grown and processed overseas from places like China and Ukraine.

No mandatory quality-control guidelines.

No purity testing standards.

Uncertainty about whether products are contaminated with heavy metals or pesticides, or if they actually contain the CBD levels they claim.

Anything shipped into Texas containing detectable amounts of THC is illegal, according to the Texas Department of Public Safety.

Since 2015, FDA has issued 40 warning letters to online CBD companies about products not containing amount of CBD on product labels and making unwarranted health claims.

Study by Penn Medicine published in the Journal of the American Medical Association (November 2017) found that nearly 70 percent of CBD-based products being sold online are mislabeled.

Need-based patient assistance program, and discounts for military families and in-dispensary pickup.

No pesticides used in plant cultivation.

Solvent-free extraction process to make CBD oil.

Transparency in test results, ingredients and labeling that meet or exceed all state regulations.

We make consistent, highly pure CBD medicine at our state-of-the-art facility in Manchaca, 10 miles southwest of downtown Austin.

Exceptional customer service in assisting patients, answering questions and fulfilling orders via pickup or statewide delivery.

Each batch of CBD medicine is lab-tested to ensure products are free from heavy metals, pesticides and contaminants.

CBD Oil Comparison of Compassionate Cultivation and Popular OTC Products

%(mass/mass)

Actual measured contents of CBD and THC for Compassionate Cultivation products, compared with various CBD products purchased elsewhere by patients. Values represent a random sample analyzed by industry standard HPLC methods using a Restek Raptor ARC-18 and standards obtained from Restek. Analysis performed and reported by third-party testing lab.

Compassionate Cultivation	CBD	THC	CBD:THC	CBN	CBDA	THCA
CCTX Lone Star Peppermint MCT	10.38	0.45	23:1	0.11	0.00	0.04
CCTX Lone Star Cherry MCT	10.00	0.45	22:1	0.11	0.00	0.04
CCTX Lone Star Unflavored MCT	10.08	0.45	22:1	0.12	0.00	0.04
CCTX Lone Star Unflavored Safflower	10.39	0.49	21:1	0.00	0.00	0.00
Others	CBD	THC	CBD:THC	CBN	CBDA	THCA
CW Plus Mint Chocolate (Hemp) 100mL	1.71	0.05	36:1	0.03	0.00	0.00
CW Plus Mint Chocolate (Hemp) 30mL	1.71	0.05	36:1	0.03	0.00	0.00
Palmetto Harmony (1) 100mL	1.70	0.06	28:1	0.03	0.05	0.00
Palmetto Harmony (2)	1.56	0.05	31:1	0.00	0.00	0.00
CW Advanced Olive Oil	6.55	0.20	33:1	0.00	0.00	0.00
CW Advanced Chocolate Mint	5.51	0.16	34:1	0.00	0.00	0.00

Our Mission

Compassionate Cultivation is a 100% Texan, state-licensed medical cannabis company dedicated to growing, processing and dispensing the purest, highest-quality CBD medicine to help reduce the suffering of qualifying patients in the Lone Star State.

WHERE THE MAGIC HAPPENS

Inside Compassionate Cultivation's Austin-Area Headquarters

Cutting-Edge Cultivation

Compassionate Cultivation's high-quality cannabis strains are grown from seed through harvest utilizing a strict nutrient management program, integrated pest management systems and horticultural techniques to ensure our plants receive the proper elements, nutrients and care for optimal growth. At our indoor cultivation facility, we adhere to strict sanitation guidelines and utilize

high-tech controls and sensors to monitor the environment and conserve energy during the growth process.

Our selected CBD-rich cultivars are processed to yield products with less than 0.5 percent THC and at least 10 percent CBD, adhering to guidelines set out under the Compassionate Use Act.

—Taylor Kirk, Director of Cultivation



Photo: Bobby Scheidemann

State-of-the-Art Processing



Photo: Chris Reichman, Sum & Substance Photography

We utilize a hydrocarbon-free, high-purity CO₂ extraction process to extract pure plant oil from our feedstock. The process is finely tailored through manipulations in temperature and pressure to optimize the capture of components of interest, and performed in a certified, semi-automated, closed-loop system to facilitate the recapture of over 90 percent of the CO₂ used. After extraction, a series of purification, distillation and chromatography steps are implemented, resulting in oil products with cannabinoid purities as high as 99 percent.

—Geoff Young, Director of Processing at lab partner Xabis

About the Texas Compassionate Use Act

This state law enacted in 2015 created guidelines for a medical cannabis program. Under the CUA, the state licensed three businesses, including Compassionate Cultivation, to grow cannabis plants and process them into low-THC products rich in non-psychoactive cannabidiol (CBD) specifically for patients with intractable epilepsy. State-registered physicians can create treatment plans and prescribe CBD products to patients who are permanent Texas residents. Compassionate Cultivation opened the state's first licensed dispensary location in February 2018 and also offers delivery services statewide.



Compassionate Cultivation's Austin-area facility encompasses all aspects of modern medical cannabis cultivation, processing, testing and retail sales.

Advanced Laboratory Testing



Photo: Chris Reichman, Sum & Substance Photography

Product transparency is a key component to providing the quality and consistency of our medicine. Our facility is outfitted with over \$1 million of advanced lab equipment and utilizes state-of-the-art instrumentation and analytical methods to fully characterize each product and provide quality assurance to the patient. All of our products are free of any heavy metals, microbials and chemical contaminants, and they're labeled to clearly state the cannabinoid compositions, enabling patients to know they are using consistent medicine.

—Jason Hamilton, Director of Analytical Testing and Quality Assurance, Xabis

Texas' First Licensed Dispensary

With our Feb. 8 grand opening, Compassionate Cultivation's Austin-area dispensary became the first licensed medical cannabis dispensary to open its doors in the state of Texas. Our patient-friendly dispensary, located at 12701 Lowden Lane in Manchaca, is open to the public, although the purchase of cannabis-based medicine is limited to registered patients and legal guardians. Compassionate Cultivation's expert staff are equipped to answer any questions, as well as provide patient consultations, physician outreach resources and detailed information on our products and retail merchandise. Our high-quality CBD products are available at our dispensary location and through our delivery service, which accommodates patients across the state.

—Compassionate Cultivation Staff



Photo: Compassionate Cultivation Staff

GET THE LATEST CBD NEWS ON
COMPASSIONATE CULTIVATION'S BLOG:
[TEXASORIGINALCC.COM/BLOG](https://www.texasoriginalcc.com/blog)

CBD Dosing Recommendations and Guidelines for Treatment of Intractable Epilepsy

**DR. KAREN KEOUGH, PEDIATRIC NEUROLOGIST & EPILEPTOLOGIST;
CHIEF MEDICAL OFFICER, COMPASSIONATE CULTIVATION**

Determining a patient's ideal dose and formulation for cannabis-based medications is fairly similar to the process for dosing any new pharmaceutical medications.

Like most new medications, dosage recommendations for cannabidiol (CBD) medicines are best established according to existing scientific research, careful integration of high-quality anecdotal evidence, and incorporation of individual patient outcomes as we develop experience. The biggest difference is that CBD medicines don't start out with a dosing range approved by the FDA. Although newly FDA-approved drugs include dose ranges approved in clinical trials, the real-world dosing ranges become apparent as more patients use the medication and as prescribers and patients get a better sense of the dosing they need.

GENERAL GUIDELINES FOR CBD DOSING

The dose-finding process will be different for each patient. Because the Texas program is new, there is a limited knowledge base for physicians at this time; it will grow as more patients join the program and prescribers gain a better understanding of what works and how patients tolerate CBD treatment. Each patient will need

to discover the dosing amount that works best for them. This is what the titration process is all about. I devised these guidelines based on published data from clinical trial results, and have refined the approach based on experience with nearly 100 patients I have written prescriptions for since February 2018. This is a starting point, with the expectation that some patients may require higher doses.

DOSING RECOMMENDATIONS

For each patient, CBD dosing will depend on the following:

- » Formulation of product (e.g. CBD concentration, THC concentration). Compassionate Cultivation's Lone Star product is 100 mg/ml CBD with 5 mg/ml THC (0.5%).
- » Patient characteristics, including weight, age and the number and type of medications the patient is already taking. One common seizure medication often used in refractory patients that has a strong interaction with CBD is clobazam (Onfi). Patients taking Onfi should start on lower CBD doses and be titrated more gradually even if Onfi is the only other seizure medication the patient is taking when initiating CBD treatment.
- » Initial dose and rate of titration both need to be considered.
- » Medically sensitive patients, such as those under two years of age or those taking multiple concomitant seizure medications, should be started at a lower dose and titrated more slowly. Less sensitive patients can be started at a somewhat higher initial dosage.

Dose increments of <0.1ml are not feasible to measure, so round to 0.1 ml instead of 0.05 ml increments. The half-life is long, so once/day dosing is fine for small doses; split to twice/day if volume makes oral absorption difficult or if the dose starts to cause sleepiness.

Doses should be given in cheek or under tongue ideally; if swallowed, should be given with some fatty food to increase absorption.

Higher doses have been utilized in some clinical trials, but may not be necessary in all patients to achieve good seizure control. These higher doses may be well tolerated, but we need more experience with the Lone Star product to understand the ranges our patients need for optimal response with minimal side effects.

LOW DOSE INITIATION IN CHILDREN

- » 0.5 mg/kg/day, minimum dose 10 mg = 0.1 ml.
- » Increase every 1-2 weeks by 0.5-1 mg/kg/day, rounding to nearest 10 mg (0.1 ml increments) as long as side effects don't interfere.
- » Target dose 2-10 mg/kg/day; average is 2-6 mg/kg/day.

LOW DOSE IN ADULTS (OR CHILDREN WEIGHING >50 KG)

- » 25 mg twice daily.
- » Increase every 1-2 weeks by 25 mg/dose.
- » Target dose 100-300 mg twice daily if tolerated, or stop sooner if seizures stop or side effects prevent further dose increases.

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For the complete Dosing Guidelines document, as well as full references for research and clinical trials on CBD treatment, please visit texasoriginalcc.com/physicians.

As with every new medication, conservative initial titration and slow dosage increases will minimize the chance of severe side effects, and avoid reaching a dose beyond that necessary to gain control of seizures.

WEIGHING CBD RESEARCH AGAINST THE HYPE

A Pediatrician Learns to Embrace Cannabis as Medicine

BY KAREN KEOUGH, MD

For people suffering from intractable epilepsy, I believe cannabis is medicine—a conviction I developed gradually based on anecdotal evidence, and more recently from empirical research.



I didn't always see cannabis this way. When you're entrenched in the treatment of epilepsy, it's inevitable that you'll encounter cannabidiol (CBD), one of the active cannabinoid compounds found in cannabis. But when my patients first came to me years ago with the idea that CBD could be a game-changer, my initial reaction was to tell them, "Don't believe what you're seeing on the news."

When Compassionate Cultivation—one of only three businesses awarded a license in Texas to grow CBD-rich, low-THC cannabis—approached me in early 2017 to ask if I would work with them, I immediately agreed to offer input, but I had to dig deeper on the question of a more public declaration of support.

There's still a fair bit of stigma regarding cannabis in the medical world, and I had to better understand what was known and not yet known. After doing more research and discussing the idea with my partners at Child Neurology Consultants of Austin, I came to the conclusion that I did very much want to be involved.

More rigorous data has finally started trickling out, including trial

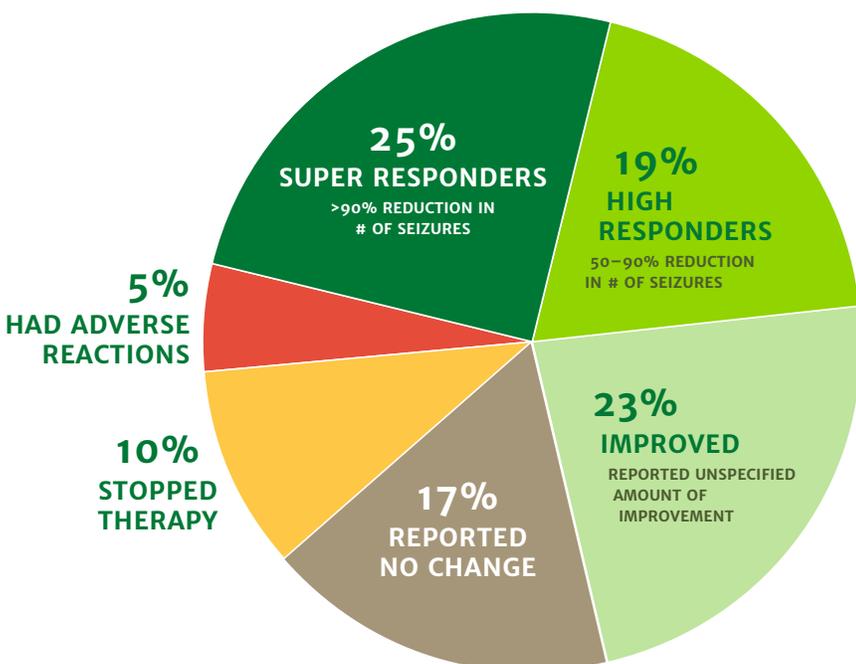
results on drug-resistant seizures published in 2017 in the *New England Journal of Medicine*. That publication meant everything because it legitimized the effectiveness of CBD for the treatment of epilepsy at an unprecedented level of scientific proof. There are many controlled studies in the works on the efficacy of CBD, including a collaboration between the National Institute on Neurological Disorders and Stroke and the National Institute on Drug Abuse.

I encourage my fellow physicians and prescribers to review this important research. I myself have gone from cautioning patients not to expect too much from CBD, to realizing that, for many patients, CBD not only meets their needs but exceeds our expectations.

Dr. Karen Keough, M.D., is a Board Certified Child Neurologist and Epileptologist at Child Neurology Consultants of Austin. She is also the Chief Medical Officer for Compassionate Cultivation. This column was originally published on TribTalk, a publication of The Texas Tribune.

Patient Response to CBD Medicine

EMPIRICAL RESULTS FROM DR. KAREN KEOUGH, AS OF 9/29/2018*



OTHER REPORTED BENEFITS

- » Increased alertness
- » Increased speech
- » Developmental gains
- » Less rescue medication
- » Better sleep
- » Decreased anxiety
- » Decreased behavior issues
- » Marked improvements in cognition
- » Increased appetite
- » Happier demeanor
- » Calming effect
- » Decrease in GI issues

VERY LOW SIDE EFFECTS REPORTED

- » Somnolence
- » Sleepiness
- » Diarrhea
- » GI upset

* Based on 77 out of 96 patients on treatment between 2 and 7 months.

Product Information

Lone Star is a panel of condition-specific cannabidiol (CBD) tinctures that are specifically formulated and lab-tested to treat qualifying patients with intractable epilepsy under the Texas Compassionate Use Act.

Formulated with high CBD levels, low levels of psychoactive tetrahydrocannabinol (THC) and minimal inactive ingredient additives, the Lone Star line is produced using hydrocarbon-free, high purity CO₂ extraction processes and rigorous state-of-the-art testing to ensure consistent medicine that is free of heavy metals, microbials and chemical contaminants.

As part of Compassionate Cultivation's commitment to transparency, test results are publicly available.



ACTIVE INGREDIENTS (SINGLE CONCENTRATION)

100 mg CBD per 1 mL of tincture
5 mg THC per 1 mL of tincture

SIZES

7.5 mL (750 mg CBD / 37.5 mg THC)
15 mL (1500 mg CBD / 75 mg THC)
30 mL (3000 mg CBD / 150 mg THC)

PRICES

7.5 mL: \$105
15 mL: \$200
30 mL: \$380

Note: The retail cost for a single milligram of CBD is approximately 13 cents.

FLAVORS

Cherry, Mint, Unflavored

INGREDIENTS

CO₂ extracted cannabis oil
USP-grade coconut MCT oil*
Food-grade essential oil flavoring

**Safflower oil is available for patients with an aversion to MCT oil. All safflower oil products are unflavored.*

PACKAGING

Tamper-evident, child-resistant clear glass bottle labeled with traceability and dosing information

Box is also fully labeled with traceability, dosing, manufacturer and nutritional information

1 mL medical-grade syringe

Patient slip includes dosing information, plus patient specifics, conversion chart and product overview

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HIGHER DOSE INITIATION IN CHILDREN

- » 1 mg/kg/day, minimum 10 mg = 0.1 mL.
- » Increase every 1-2 weeks by 1 mg/kg/day, as long as side effects do not interfere.
- » If side effects are a problem, go up more gradually with more time between dose increases.
- » Target dose 2-10 mg/kg/day, average is 2-6 mg/kg/day.

HIGHER DOSE IN ADULTS (OR CHILDREN WEIGHING >50 KG)

- » 50 mg twice daily.
- » Increase every 1-2 weeks by 50 mg/dose.
- » Target dose 100-300 mg twice daily if tolerated, or stop sooner if seizures stop or side effects prevent further dose increases.

PATIENT DISCOUNTS / FINANCIAL ASSISTANCE

There is a 10% discount for in-dispensary pickup (cannot be combined with other discounts).
Military families receive a 10% discount with valid proof of service (active or retired).