Medical Cannabis & the Texas Compassionate Use Program 2025

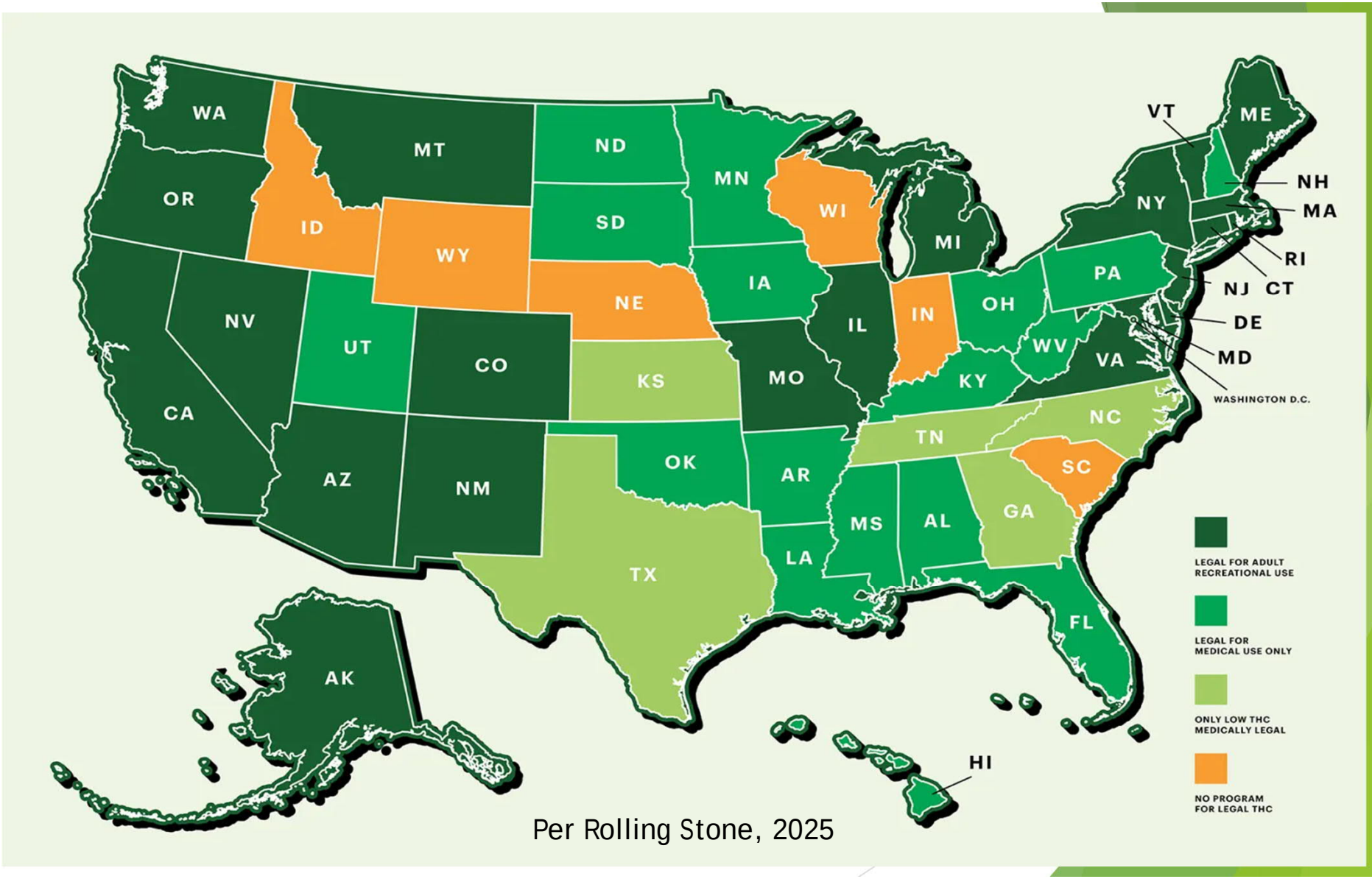
Where have we been, where are we going?

Disclosures

- Speaker Bureau for Jazz Pharmaceuticals (maker of Epidiolex)
- Former CMO for Compassionate Cultivation, licensed dispensary for T-CUP

Agenda

- History of the Texas Compassionate Use program
- Basics of CBD treatment with focus on Epilepsy Rx
- Evidence-based approach to CBD/THC therapy
- Symptom-based therapy & CBD/THC ratios
- Autism, multiple sclerosis, & PTSD: knowns & unknowns
- Terpenes, institutional policy & other challenges



Per Rolling Stone, 2025

Texas's Journey in Medical Cannabis

- The Texas Compassionate Use Act (Senate Bill 339) enacted by the Texas Legislature
- Three dispensaries awarded licenses by the Texas Dept of Public Safety
- First Physician approved by Texas DPS for the Compassionate Use Program
- First Delivery of Medical CBD prescription through the Compassionate Use Program
- Governor Abbott signs Expansion of CUP (HB 3703) inclusive of multiple new indications and rules

HB3703 – What Changed in 2019?

Conditions Added

All epilepsy and "other seizure disorders"
Autism
Multiple sclerosis
Spasticity
Terminal cancer
Amyotrophic lateral sclerosis (ALS)
Incurable neurodegenerative disorders including: Parkinson's, Alzheimer's, and many others*

Administrative Changes

Removed requirement for a second prescriber approval

Registered physician's names will NOT be made public without written authorization

Changes the definition of 'prescribe' to mean 'entering in the CURT database.'

Removes the CBD required minimum—> variable ratios created with low/absent CBD content

* See complete list of qualifying incurable neurogenerative disorders at https://texreg.sos.state.tx.us/public/regviewer$ext.RegPage?sl=R&app=1&p_dir=&p_rloc=369555&p_tloc=&p_ploc=&pg=1&p_reg=369555&ti=25&pt=1&ch=1&rl=61&issue=11/29/2019&z_chk=

Texas's Journey to Cannabis Medicine II

Sept 2019

- New indications open for non-refractory epilepsy, terminal cancer, degenerative disorders
- Variable ratios now allowed

June 2021

- 2nd expansion of TCUP

Sept 2021

- New indication opens for PTSD
- THC max concentration increased

July 2023

- NO new bills passed in 2023 legislative session

July 2025

- 3rd expansion of TCUP

HB3703 – What Changed in 2021?

Conditions Added

PTSD

All forms of cancer (not just terminal)

Chronic pain was NOT approved as an eligible diagnosis but many patients are rx'd utilizing neuropathy as the eligible condition

Administrative Changes

INCREASED THC concentration to max 1% =10 mg/mL

Various changes to prescribing database:

Assignment to specific dispensary not required

Specification of ratio is "optional" therefore CBD & THC dosing may be left up to the patient

HB 46: What Changed in 2025?

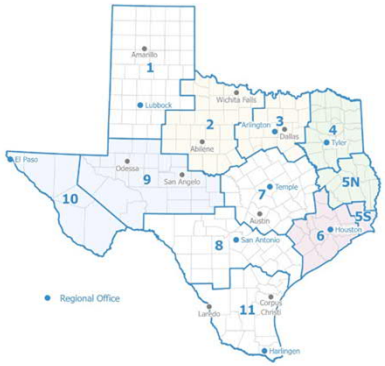
Conditions Added

Chronic pain (>90 day duration)

Traumatic Brain Injury (TBI)

Inflammatory Bowel Diseases

All terminal illness or hospice care



Administrative Changes

Replaced 1% THC cap with maximums:

- 10 mg THC/dose
- 1000 mg per package
- no more than 90 day supply/Rx w 4 RF

New Delivery Methods/Formulations most importantly INHALED delivery

- --will begin this month
- --formulations not defined in HB46 TBD
- --other forms incl suppositories & topicals

Allows satellite storage sites in each Tx public health region

T-CUP today

- Still 3 licensed dispensaries, BUT HB46 requires adding 9 by 12/1/2025 and 3 more by 4/1/2026
  - Compassionate Cultivation
  - Fluent
  - Goodblend
- PTSD is now the most common diagnosis for patients utilizing medical cannabis through T-CUP; chronic pain will likely displace this
- Prescriber registration has increased substantially (350+ listed in CURT), many functioning through online cannabis clinics
- Cost has declined due to permission to outsource CBD production (THC must be manufactured within the dispensary)

Qualifying medical conditions in Texas

- Epilepsy & “other seizure disorders”
- Autism spectrum disorders
- Multiple Sclerosis (MS)
- Spasticity
- Amyotrophic Lateral Sclerosis (ALS)
- Alzheimer Disease & other dementias
- Parkinson Disease
- Post-traumatic Stress Disorder (PTSD)
- Huntington Disease
- >100 other incurable neurodegenerative diseases
- All Cancers

- Traumatic Brain Injury (TBI)
- Chronic Traumatic Encephalopathy CTE

- Chronic Pain
- Crohn’s disease and other inflammatory bowel diseases
- All Terminal diagnoses
- All Hospice Patients

Dept State Health Services- controls conditions

What is cannabis?

Cannabis is a flowering plant

Used for medicinal purposes since 2800 BC in ancient China.

Primary medication in early medical books (pre 1920's)

Contains ~500 naturally occurring chemicals (coffee has over 1,000)

>180 known phytocannabinoids in the cannabis plant

The two most abundant and well known phytocannabinoids:

CBD (cannabidiol) and THC (tetrahydrocannabinol).

discovered 1940 discovered in 1964

What's in a name?

Hemp

- Legal! (Farm Bill 2018)
- <0.3% by weight of THC
- Unregulated by government
- Unknown other ingredients
- Largely untested/ inconsistent

Medical Cannabis

CBD/Low THC

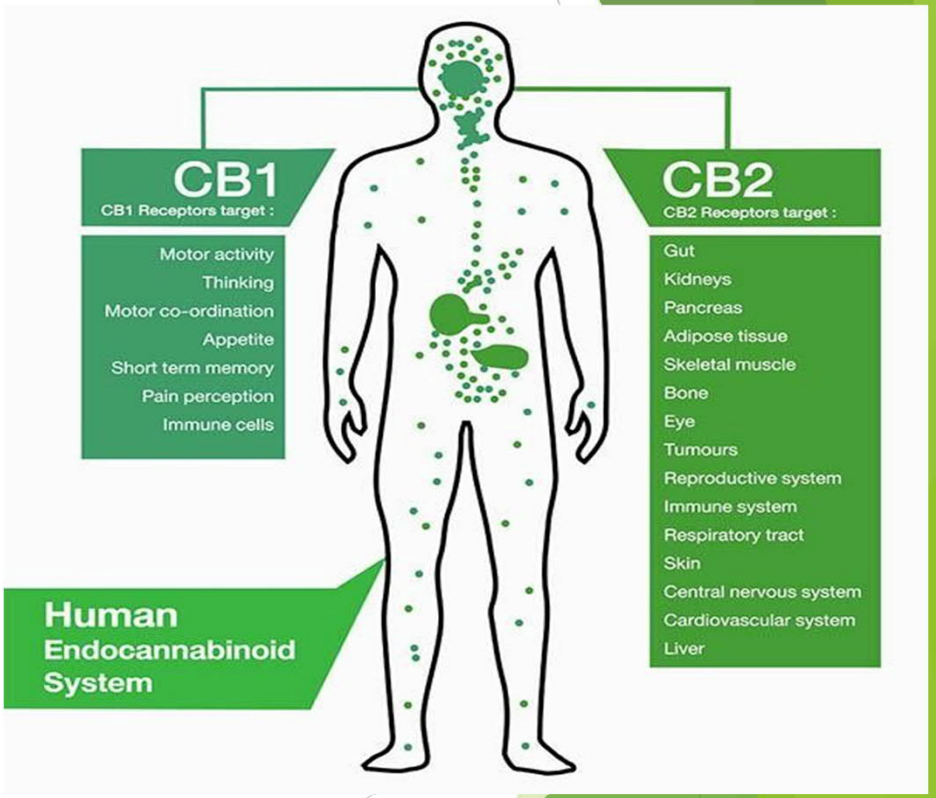
- Legal in Texas under Compassionate Use
- Allows up to 1% THC
- Derived from Cannabis plants
- Heavily regulated by DPS
- Strict testing protocols that are publically available

Marijuana

- Illegal federally, legal in some states
- THC content varies average ~15%-20%
- Unregulated/untested
- Usually don't know the source
- Could contain other ingredients/heavy metals & pesticides

The Endocannabinoid System (ECS)

- Made up entirely of CB1 & CB2 receptors
  - CB1 & CB2 receptors span the entire body
  - CB1 & CB2 receptors span each body system
- Supplementing endogenous cannabinoids with exogenous cannabinoids affects each person differently



*https://www.google.com/search?q=endocannabinoid+system&sxsrf=AJOqlzWUR24mphFpSVMV3SNoEM6XQHkN6g:1677523349885&source=lnms&tbm=isch&sa=X&ved=2ahUKEwi6_y6rbb9AhXyk2oFHVDrBvYQ_AUoAXoECAIQAw&biw=1440&bih=789&dpr=2#imgrc=PMaujYVOQ2tVbM

Epidiolex: FDA-approved cannabis therapy

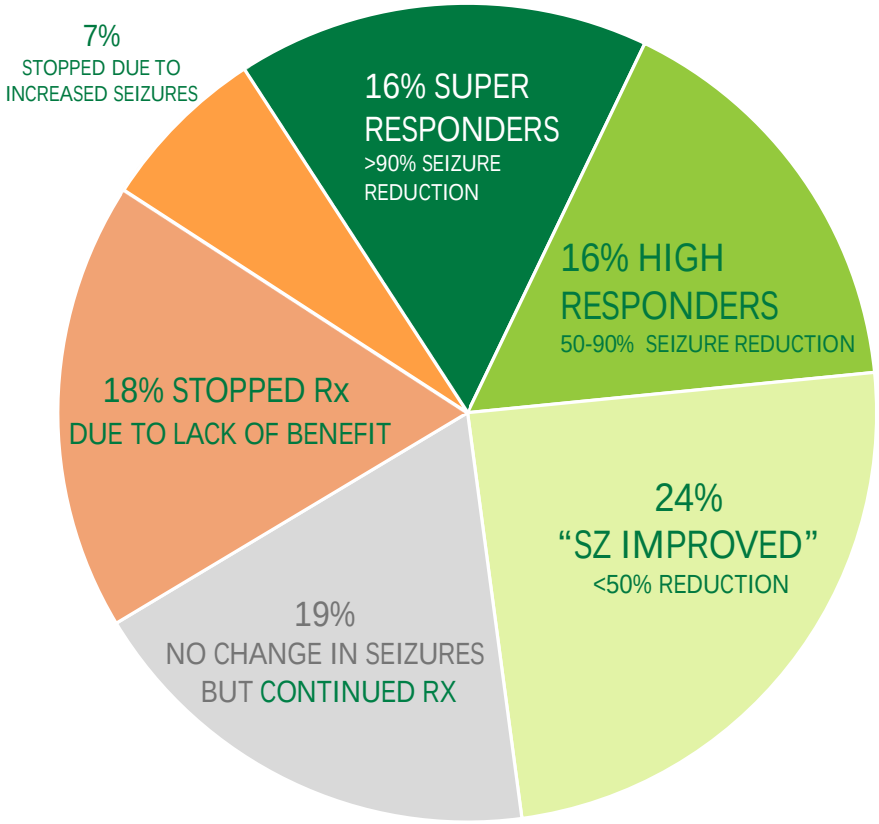
- CBD only (NO THC)
- FDA-approved in 2018 for epilepsy Dravet Syndrome & Lennox-Gastaut Syndrome
- FDA-approved in 2020 for Tuberous Sclerosis
- Studies provide proof of efficacy in refractory epilepsy as adjunctive therapy & dosing that can guide utilization of dispensary CBD
- Rarely effective as monotherapy, but constrained to very refractory patient populations
- Well-tolerated & may replace other medications in polytherapy
- Combination with clobazam is important (European indication requires both)

Cannabidiol Phase III Studies Lennox-Gastaut

> 50% reduction of drop seizures	39% of patients taking 20 mg/kg/day cannabidiol 36% of patients taking 10 mg/kg/day cannabidiol 14% of patients taking placebo
>75% reduction of drop seizures	25% at 20 mg/kg/day 11% at 10 mg/kg/day 3% of placebo
5 % of the high-dose group were free of drop seizures	

Cannabidiol in patients with seizures associated with Lennox-Gastaut syndrome (GWPCARE4): a randomised, double-blind, placebo-controlled phase 3 trial. Thiele EA et al. Lancet. 2018 Mar 17;391(10125):1085-1096. doi: 10.1016/S0140-6736(18)30136-3. Epub 2018 Jan 26.

Response to Lonestar CBD in epilepsy patients: Retrospective IRB-approved chart review study

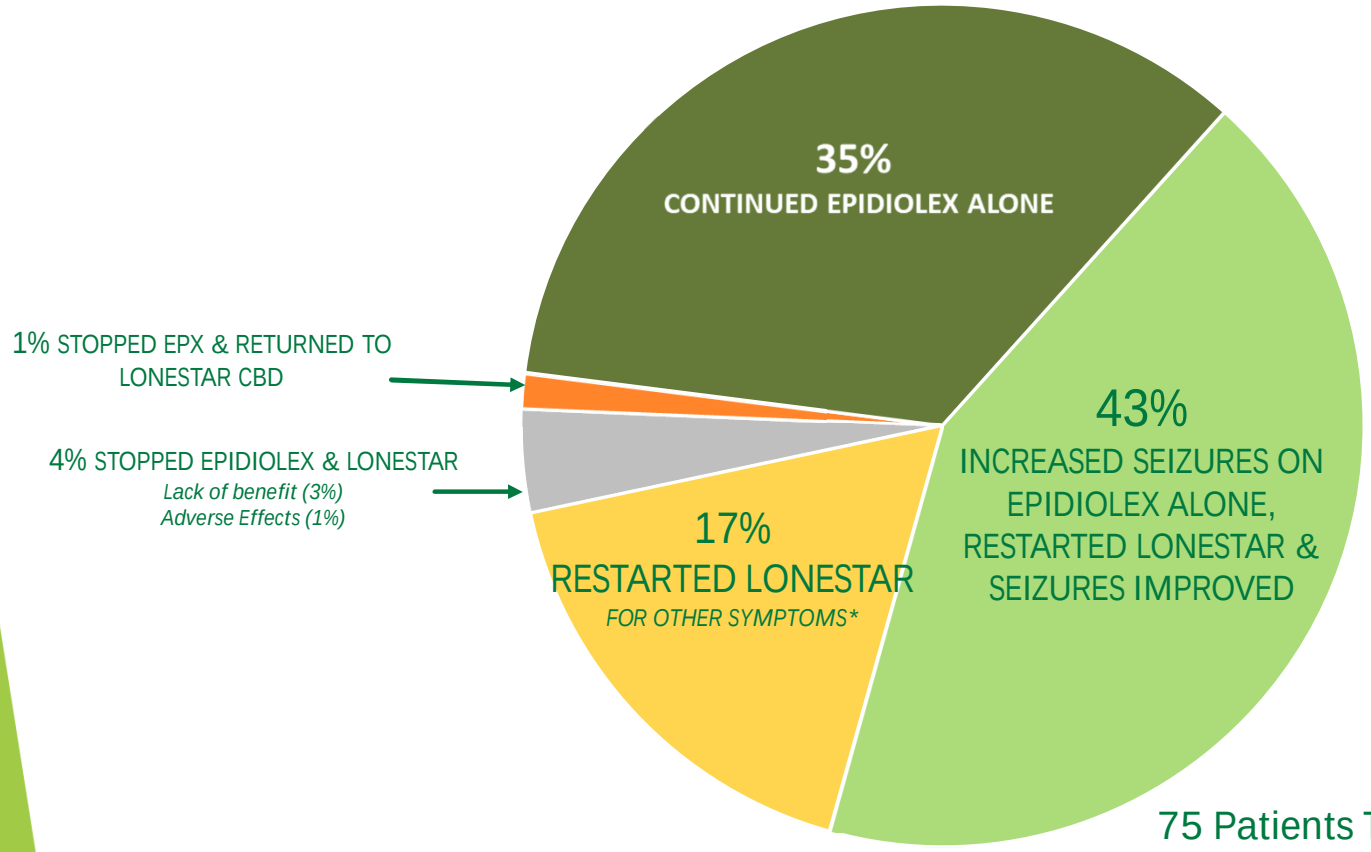


- **OTHER REPORTED BENEFITS**
  - Increased alertness/communication
  - Less rescue medication
  - Better sleep
  - Decreased anxiety
  - Decreased behavior issues
  - Increased appetite
  - Happier demeanor
  - Calming effect
  - Decrease in constipation
- **SIDE EFFECTS REPORTED**
  - Somnolence or insomnia
  - Diarrhea
  - GI upset
  - Agitation/aggressive behavior

Karen Keough's patient cohort 2/2018-2/2020
135 patients treated, 1-22 months follow-up

Lonestar CBD/THC + Epidiolex Treatment Outcomes

Patients that transitioned from Lonestar CBD to Epidiolex



Karen Keough's patient cohort 2/2018-2/2020

75 Patients Total
Follow-Up: 2-24 Months

Do all T-CUP products contain THC?

Yes!

In Texas the CBD:THC content is presented in ratios

CBD	:	THC
20	:	1
3	:	1
1	:	1
0	:	1

All of these ratios must keep to the allowable 10mg per dose

Do All T-CUP cannabis products contain CBD?

NO!!!

*Not all of them.

Despite being a CBD/ Low THC state some dispensary products do not contain CBD.

Examples: CBG, CBN, and 0:1 formulations

Possible side effects:

- Fatigue/somnolence
- GI upset
- Soft Stools
- Insomnia
- Aggression

Most severe side effects:

- Vomiting
- Psychosis

(Backes, 2017)

CN&CA Utilization of Cannabis Therapy

- Cannabis therapy clinic run by NP Liz Cross
- Most of our 12 physicians are registered in T-CUP
- Some patients are shared w other neurologists and we solely provide their cannabis therapy
- Most common conditions we treat
  - Epilepsy (adding THC to Epidiolex or for patients who cannot access Epidiolex)
  - Autism Spectrum Disorder (for behavior/aggression)
  - Spasticity/dystonia

What to do with ratios: EVIDENCE-FREE ZONE

- 20:1 form = 20 mg CBD/1 mg THC 10 mg/kg solution or edibles w same ratio
  - Used for epilepsy as high CBD content is relevant to Epidiolex treatment
  - Weight-based dosing throughout lifespan
  - Adjunctive therapy with clobazam is synergistic
- 3:1 form 15 mg CBD/5 mg THC
  - First non-20:1 ratio introduced, rarely utilized but can be relevant for other dx
- 1:1 form (self-explanatory)
  - Used for spasticity, behavior/aggression and pain disorders
  - CBD counterbalances THC and MIGHT counteract some feared AE of THC like psychosis
- 0:1 form –JUST THC—but prescription in CURT still includes the “”0” designation
  - Some patients find this more impactful than 1:1 form for same symptoms
  - Useful for adding THC to Epidiolex—unclear how much this helps but I’ve seen it matter

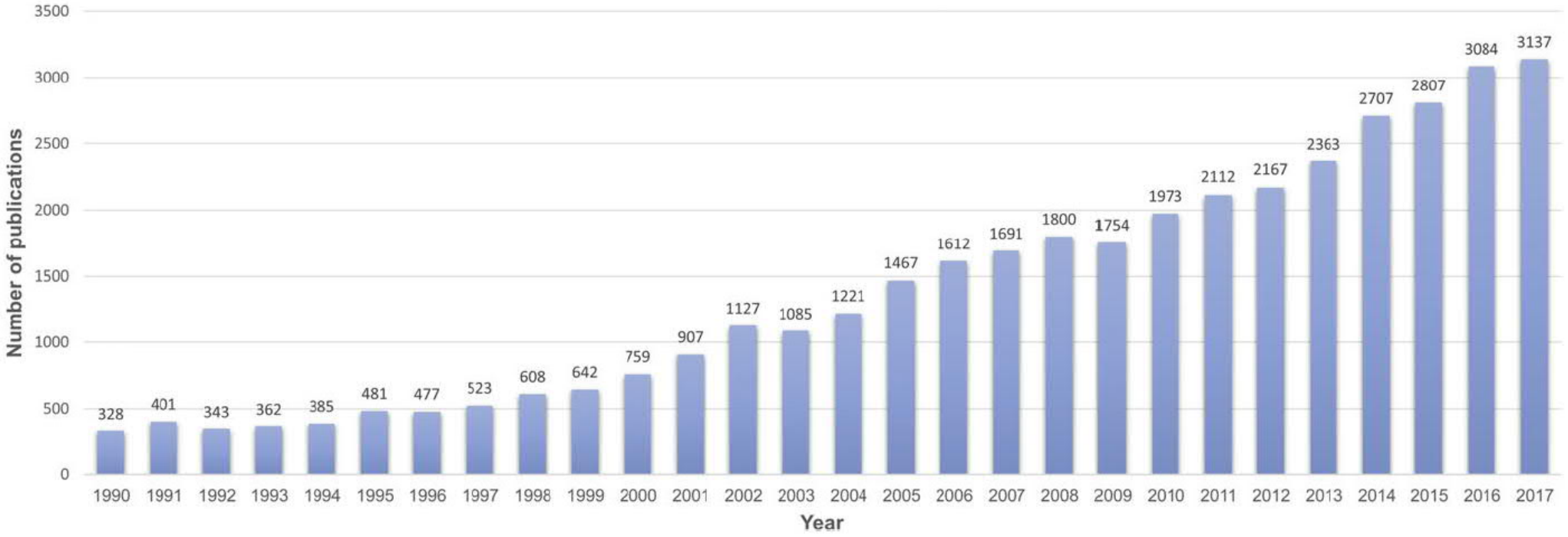
BJCP British Journal of Clinical Pharmacology

Medical cannabis: aligning use to evidence-based medicine approach

Lihi Bar-Lev Schleider, Ran Abuhasira and Victor Novack

Cannabis Clinical Research Institute, Soroka University Medical Center and Faculty of Health Sciences, Ben-Gurion University of the Negev, Israel

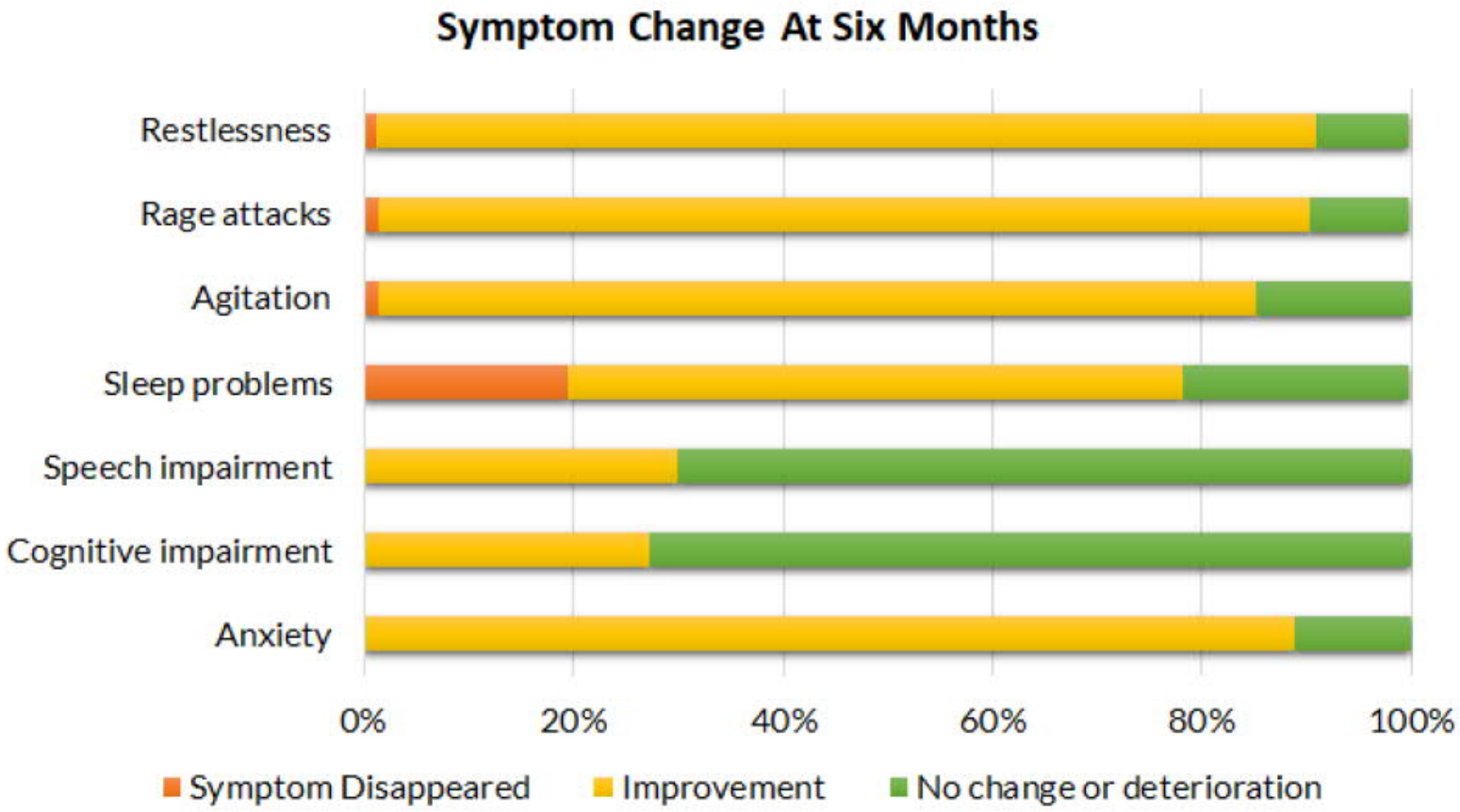
Cannabis and evidence-based medicine



Observational Study for Autism

- 53 patients age 4–22 years Rx cannabidiol median of 66 days (30-588).
- 30% solution of 20:1 CBD/THC formulation
- Median Dose: THC 7 mg/day (range 4-11); CBD 90 mg/day (range 45-143)
- Results: (parental report on 3 point scale: improved/no change/worse
  - Self-injury and rage attacks (*n* = 34) improved in 67.6% and worse in 8.8%.
  - Hyperactivity (*n* = 38) improved in 68.4%, no change in 28.9% and worse in 2.6%.
  - Sleep problems (*n* = 21) improved in 71.4% and worse in 4.7%.
  - Anxiety (*n* = 17) improved in 47.1% and worse in 23.5%.
- Adverse effects, mostly somnolence and change in appetite, were mild.

*Frontiers in Pharmacology, 09 January 2019: Clinical Pharmacology and Toxicology Unit, Assaf Harofeh Medical Center, Tel Aviv, Israel; Autistic Spectrum Disorder Clinic Assaf Harofeh Medical Center, Tel Aviv, Israel


Symptom Change At Six Months
Restlessness
Rage attacks
Agitation
Sleep problems
Speech impairment
Cognitive impairment
Anxiety
0%
20%
40%
60%
80%
100%
Symptom Disappeared
Improvement
No change or deterioration

Multiple Sclerosis & Medical Cannabis

- Wide acceptance of cannabis in MS community
  - 20-60% of patients use cannabis
  - 50-90% state they would consider

- Some RPCTs of cannabis demonstrate favorable response
  - THC/CBD 1.1:1 (Sativex) oral spray is approved in Europe for spasticity in MS
  - US trial discontinued d/t failure to meet predefined end-points on a spasticity rating scale

J Neurol, NSU & Psych; 83:11

Summary of Systematic Review for **CLINICIANS**

AMERICAN ACADEMY OF NEUROLOGY.

EFFICACY AND SAFETY OF THE THERAPEUTIC USE OF MEDICAL MARIJUANA (CANNABIS) IN SELECTED NEUROLOGIC DISORDERS

2014

Do cannabinoids relieve spasticity in patients with multiple sclerosis (MS)?

Strong evidence	Oral cannabis extract (OCE) is established as effective for reducing patient-reported scores (**2 Class I studies**).
Moderate evidence	OCE is probably ineffective for reducing objective measures at 12 to 15 weeks (**1 Class I study**).
	THC is probably effective for reducing patient-reported scores (**1 Class I study**).
	THC is probably ineffective for reducing objective measures at 15 weeks (**1 Class I study**).
	Nabiximols is probably effective for reducing patient-reported symptoms at 6 weeks (**1 Class I study**) and probably ineffective for reducing objective measures at 6 weeks (**1 Class I study**).
Weak evidence	OCE is possibly effective for reducing objective measures at 1 year (**1 Class II study**).
	THC is possibly effective for reducing objective measures at 1 year (**1 Class II study**).
Insufficient evidence	Smoked marijuana is of uncertain efficacy (**insufficient evidence**).

PTSD & Medical Cannabis

AIMS Neuroscience

AIMS Neurosci. 2021; 8(3): 414–434.
Published online 2021 May 13. doi: 10.3934/Neuroscience.2021022

PMCID: PMC8222769
PMID: 34183989

Cannabis in the management of PTSD: a systematic review

Yasir Rehman,[1,2,3,*] Amreen Saini,[4] Sarina Huang,[5] Emma Sood,[4] Ravneet Gill,[4] and Sezgi Yanikomeroglu[5]

>10 observational studies with no comparators, only 1 randomized control trial
>Generally report a reduction in overall PTSD symptoms and improved QOL
>Adverse effects: dry mouth, headaches, and psychoactive effects (agitation/euphoria)
>Occasional patients experiencing a worsening of symptoms.

Inflammatory Bowel Disease

- Cannabis does NOT induce clinical remission NOR reduce inflammation
- RCTs suggest it may improve patient-reported symptoms and QOL
- Recent meta-analysis showed statistically-significant decrease in clinical disease activity in Crohn's disease but not in UC; QOL improved in both
- RCT evidence is rated "low to moderate"
- Adverse events are more common in cannabis groups. But typically mild (dizziness, fatigue & attention disturbance)
- Lack of standardized dosing, formulation & route limits clinical recommendations

J Neural Transm (Vienna). 2022 Oct;129(10):1247-1256. doi: 10.1007/s00702-022-02529-x.
Epub 2022 Jul 20.

Randomized controlled trials on the use of cannabis-based medicines in movement disorders: a systematic review

P Oikonomou [1], W H Jost [2]

- RCTs have failed to show improved motor symptoms in PD, HD, Tourette
- Some have shown improved QOL, anxiety, sleepy and levodopa-induced dyskinesias
- Safety & tolerability results have been favorable
- Observational/retrospective studies suggest improvements in pain, cramping, dyskinesias and MAY reduce opiate use
- NOT confirmed in RCTs

**Cannabis should not replace standard medical therapies for cancer

Cannabis and Cannabinoids in Adults With Cancer: ASCO Guideline

Ilana M Braun [1], Kari Bohlke [2], Donald I Abrams [3], Holly Anderson [4], Lynda G Balneaves [5], Gil Bar-Sela [6], Daniel W Bowles [7], Peter R Chai [8], Anuja Damani [9], Arjun Gupta [10], Sigrun Hallmeyer [11], Ishwaria M Subbiah [12], Chris Twelves [13], Mark S Wallace [14], Eric J Roeland [15]

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PMCID: PMC11730458 NIHMSID: NIHMS2043915 PMID: 38478773

Outcome	Certainty of the Evidence	Direction of Effect	Recommendation
Chemotherapy-induced nausea and vomiting[22,24–26]	Moderate for dronabinol and nabilone; low for THC:CBD extract	Benefit	Weakly in favor (see recommendation 3.1)
Total symptom burden in adults with advanced cancer[21]	Low for high-dose oral CBD	—[a]	Weakly against (see recommendation 3.2)
Cancer pain[27,28]	Moderate for nabiximols	—[a]	None
Sleep, in patients with chronic cancer pain[29]	Moderate for oral cannabinoids (nabiximols or nabilone)	—[a]	None
Low weight or poor appetite[30,31]	Low for dronabinol, nabilone, THC/CBD extract, THC	—[a]	None
Quality of life[21,30,32]	Low for THC, THC/CBD, dronabinol, nabilone, and CBD	None or small detrimental effect	None
Anxiety and depression[33]	Very low for THC, THC:CBD, dronabinol, nabilone, nabiximols	—[a]	None

Institutional/Policy response to CBD use

Epidiolex administration sometimes remains controversial despite FDA approval:

Home health care agency employees

School nurses

Inpatient facilities

Licensed dispensary products may have limitations for administration by nurses, although this is improving

Hospitals sometimes make policies that even exclude T-CUP prescribed treatment

Administration by family members may be discouraged/restricted even in cases where medication has been known to be essential for seizure control

What does the Texas Board of Nursing say?

"Board staff periodically receive questions about whether or not a licensed nurse may administer low-THC cannabis prescribed by physicians. The Nursing Practice Act (Texas Occupations Code, Chapter 301) and Board rules are written broadly so all nurses can apply them in various practice settings… the nurse may administer the low-THC cannabis in accordance with prevailing standards of safe nursing care."

2019

https://www.bon.texas.gov/pdfs/newsletter_pdfs/2019/October2019.pdf

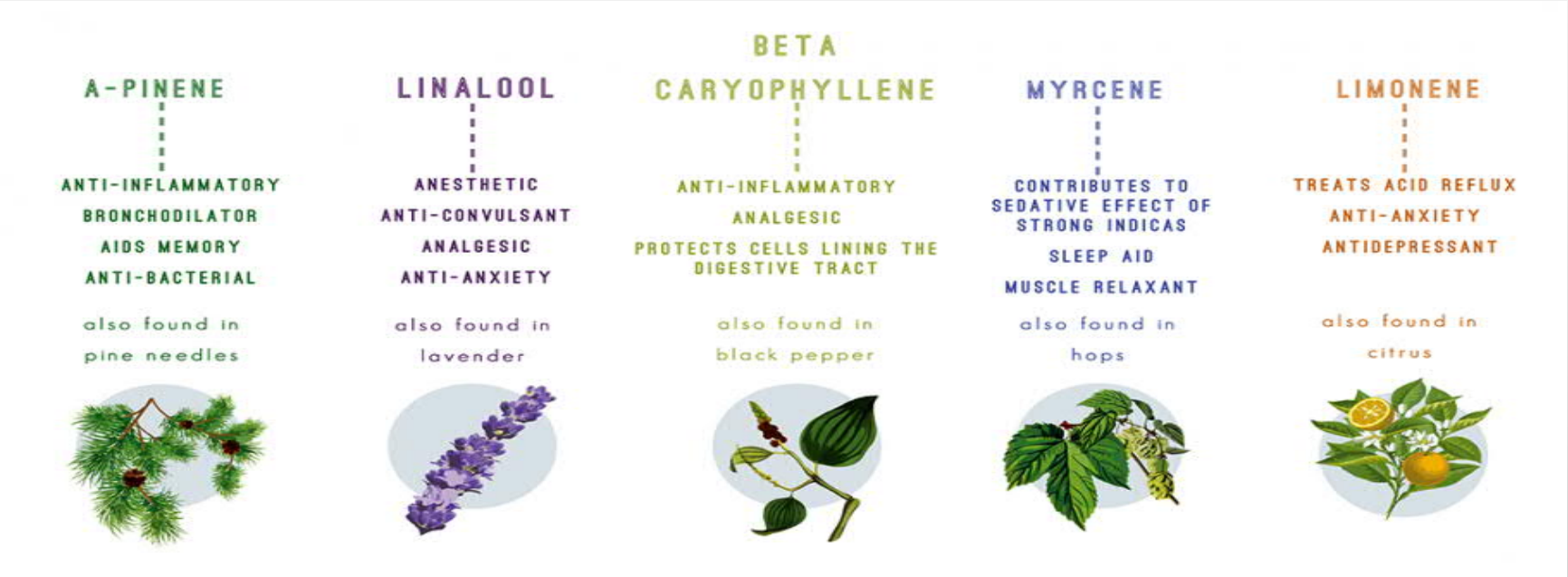
What does the Texas Association of School Boards say?

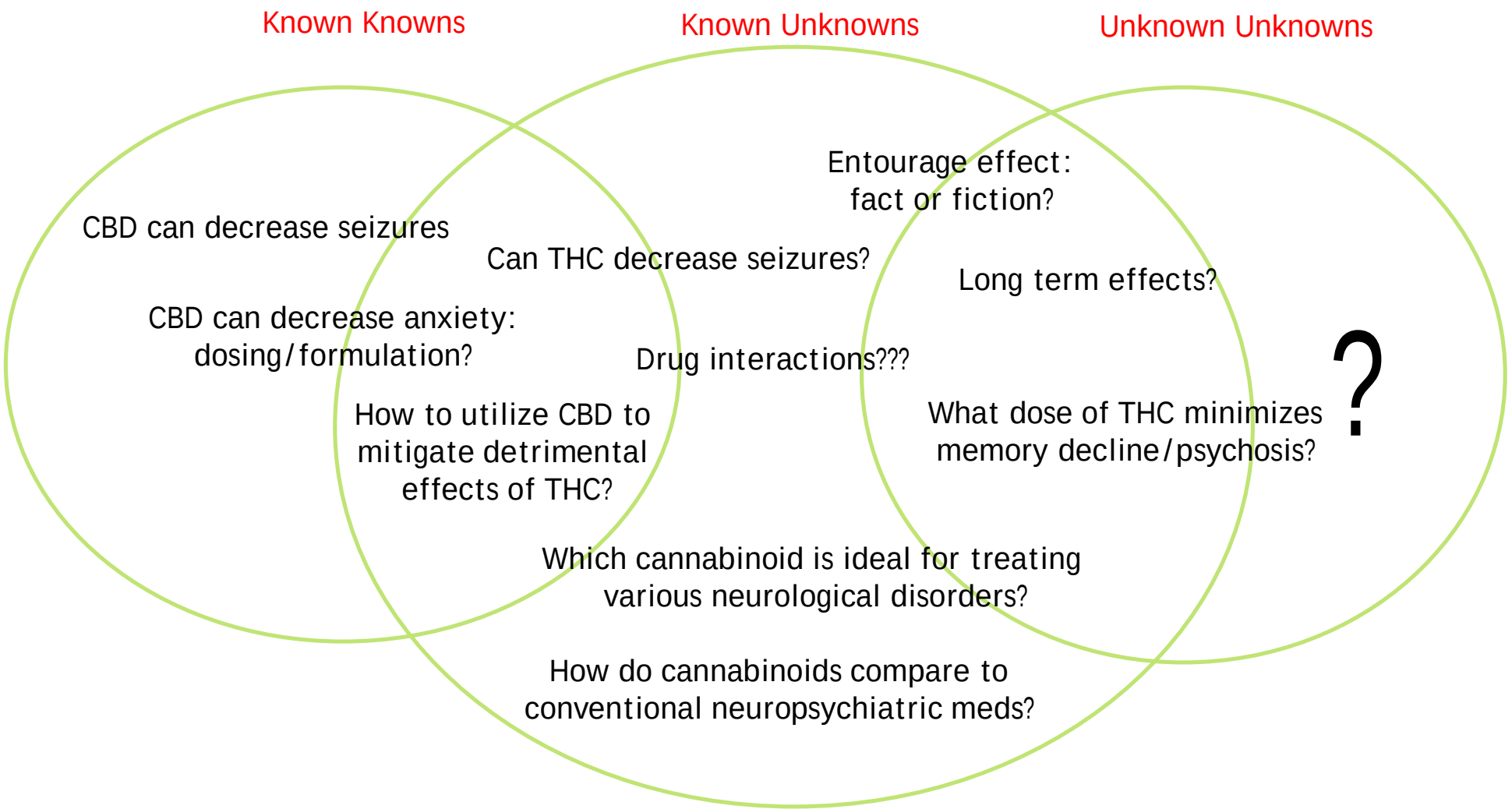
Can Students take prescription medical cannabis at school?

- A school district may NOT adopt or enforce any rule that prohibits a patient's access to low-THC cannabis pursuant to the Act, which enables authorized physicians to prescribe low-THC, high-CBD cannabis to patients suffering from certain conditions or using a product with less than 0.3% by weight.
- Students with a condition such as autism, spasticity or a seizure disorder are entitled to legally use CBD products under the Texas Compassionate Use Act.
- Student's IEP or Section 504 plan should address when the CBD is needed and who will administer it to the student.

https://www.tasb.org/services/legal-services/tasb-school-law-esource/students/documents/legal-questions-about-cbd-in-schools.pdf

Common Cannabis Terpenes




Known Knowns
Known Unknowns
Unknown Unknowns
CBD can decrease seizures
CBD can decrease anxiety: dosing/formulation?
How to utilize CBD to mitigate detrimental effects of THC?
Can THC decrease seizures?
Drug interactions???
Which cannabinoid is ideal for treating various neurological disorders?
How do cannabinoids compare to conventional neuropsychiatric meds?
Entourage effect: fact or fiction?
Long term effects?
What dose of THC minimizes memory decline/psychosis?
?