

# CBD: What You Need to Know in the Era of Commercial Cannabis

Scott M. Gagnon, MPP, PS-C

Director, New England Prevention Technology Transfer Center

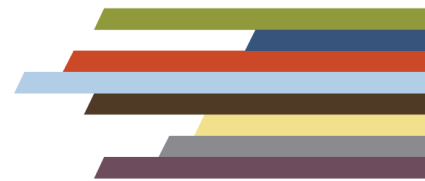
September 28<sup>th</sup>, 2023



New England (HHS Region 1)

PTTC

Prevention Technology Transfer Center Network  
Funded by Substance Abuse and Mental Health Services Administration



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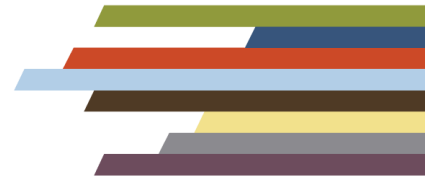
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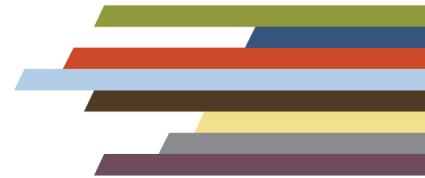
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# About the New England PTTC

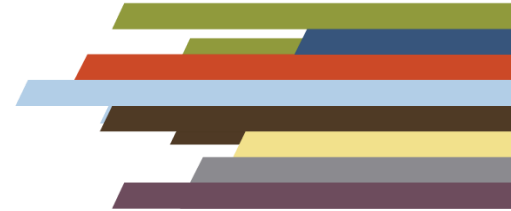




Housed and administered by:



Partner organizations:

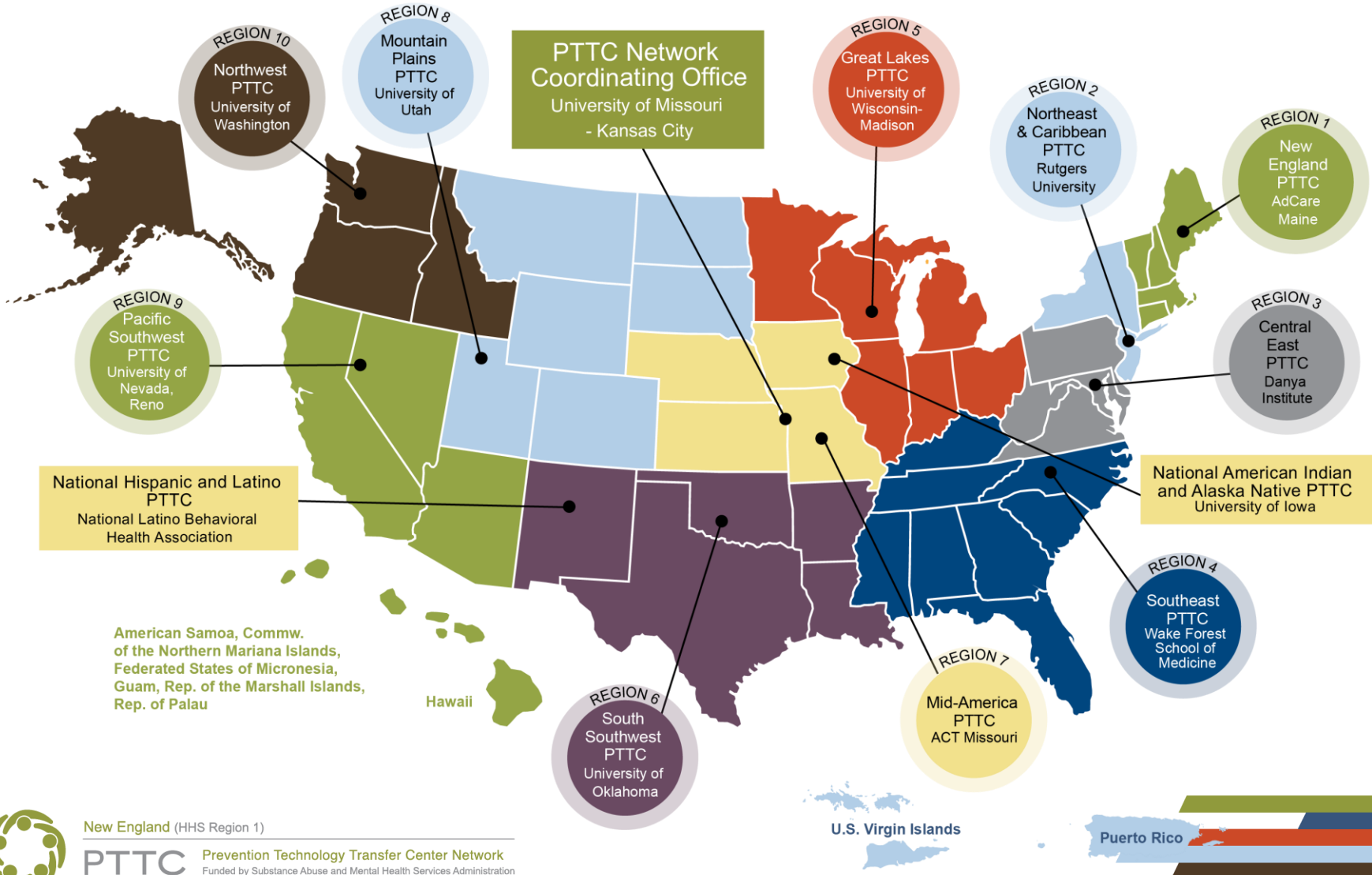




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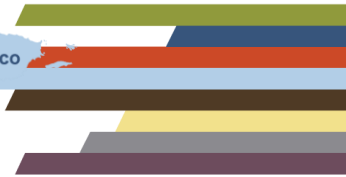
## PTTC Network



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# New England Prevention Technology Transfer Center

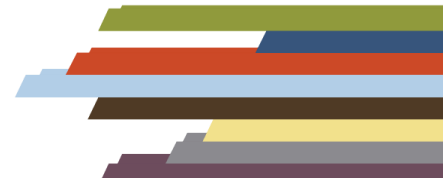


Improve implementation and delivery of effective substance misuse prevention interventions



Provide training and technical assistance services to the substance misuse prevention field

- Tailored to meet the needs of recipients and the prevention field
- Based in prevention science and use evidence-based and promising practices
- Leverage the expertise and resources available through the alliances formed within and across the HHS regions and the PTTC Network.



# Wide range of training & T/A services

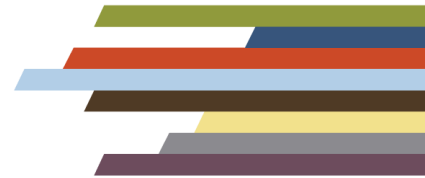
- Newsletters, updates and news from SAMHSA, and other informational products
- In-person trainings
- Live and recorded webinars
- Self-paced online courses
- Tailored intensive technical assistance
- Learning Communities
- Resource development: Literature reviews, implementation guides, infographics, white papers, etc.



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The use of affirming language inspires hope.

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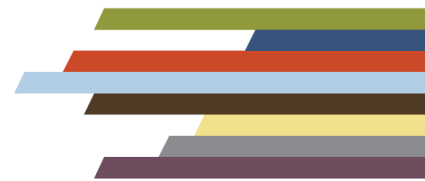
LANGUAGE MATTERS.

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**Words have power.**

PEOPLE FIRST.

The PTTC Network uses affirming language to promote the application of evidence-based and culturally informed practices.

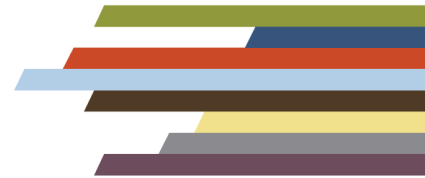




# Discussion about Terminology

## Cannabis vs Marijuana

- The field remains divided and unsettled on the usage of these terms
- “Marijuana” is enshrined in Federal drug policy and in drug policy in many states while in some legalized states “Cannabis” has been codified into policy.
- Some audiences don’t understand what “cannabis” refers to, which can complicate community education efforts
- Clear history and background of discriminatory and racist policies and practices entwined with “marijuana”
- “Cannabis” can be seen as the industry’s attempt to normalize and impact perceptions of the drug amongst the general public



# Acknowledgement

This presentation includes content originally developed by SAMHSA's National Mental Health and Substance Use Policy Laboratory for a national webinar on CBD held on August 8<sup>th</sup>, 2023.

Leads:

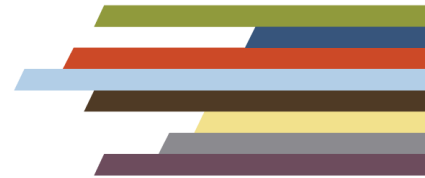
- Krishnan Radhakrishnan, SAMHSA
- Amy Berninger, ABT Associates



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# What We'll Cover...

Introduction to cannabis plant, CBD and how it is different from THC:

What started the CBD explosion

Marketing and availability

Usage prevalence rates and demographics

How over-the-counter CBD is used

Adverse effects of pure CBD

Potential harms of over-the-counter CBD

Populations of special concern

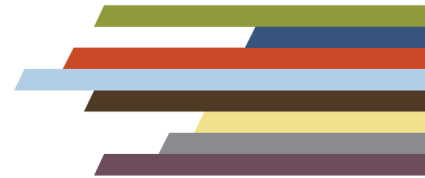
Concluding remarks, tips, and action steps



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## SAMHSA ADVISORY

Substance Abuse and Mental Health  
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FEBRUARY 2023

### CANNABIDIOL (CBD) – POTENTIAL HARMS, SIDE EFFECTS, AND UNKNOWNNS

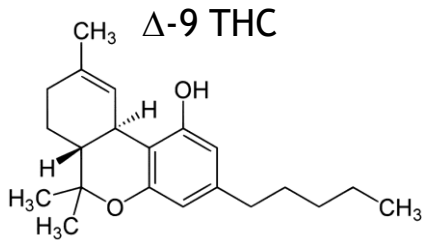
The use of non-Food and Drug Administration (FDA)-approved cannabidiol, or CBD, has gained attention in recent years, as CBD is becoming increasingly popular and is being marketed for various health conditions.<sup>1</sup> A poll of American adults aged 18 years and older found that 14 percent reported using CBD products in 2019, and a similar poll conducted in 2020 found that as many as 1 in 3 adults reported using CBD products.<sup>2,3</sup> However, non-FDA-approved, commercial CBD products marketed to the public and available over the counter differ significantly in composition from those used in clinical studies,<sup>4</sup> and there is limited evidence to support their safety.<sup>5</sup> The public should be aware of the misconceptions surrounding CBD products, as well as the potential harms and risks associated with their use.

#### Key Messages

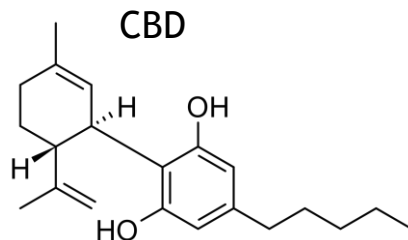
- Cannabidiol (CBD) and delta-9-tetrahydrocannabinol (delta-9 THC) are two of many chemical compounds called cannabinoids that are found in the cannabis plant. CBD, which in its pure form does not produce any psychoactive effects,<sup>6,7</sup> is typically derived from the hemp plant. Nevertheless, CBD products, except for the prescription medication Epidiolex,<sup>1,8</sup> are not FDA-approved, so despite being marketed extensively, there are no federal standards for their content, purity, or potency<sup>9</sup>
- The concentration of CBD may be more or less than advertised and, because of a lack of quality control, the manufacturing process may introduce harmful biological and chemical contaminants, including the psychoactive THC.<sup>14</sup> The lack of safety standards, accuracy in labeling, and quality control may lead to additional concerns for unintended intoxication, particularly among children.
- Since federal restrictions on growing cannabis plants that contain low amounts of delta-9 THC were removed in 2018, CBD has become widely available in a range of products and formulations, including topicals, fabric, food, and beverages.<sup>10</sup>
- In 2020, as many as one-third of American adults reported using CBD products.<sup>2</sup>
- CBD has been marketed as a treatment for a range of health conditions in recent years; however, there is a lack of evidence to support many of these claims.<sup>5</sup>
- Potential risks and harms associated with CBD use include adverse drug interactions, liver toxicity, and reproductive and developmental effects.
- Delta-9 THC or delta-9 THC-contaminated products may be sold as CBD. Labeling of these products may be unclear or misleading, posing a potential threat to a user's current or prospective employment, produce inaccurate medical test results, or cause unintended drug interactions.
- More clinical research is needed to determine if CBD products are safe and effective treatments for the conditions for which they are marketed.<sup>1</sup>

# *Cannabis* (L. common hemp) & cannabidiol (CBD)

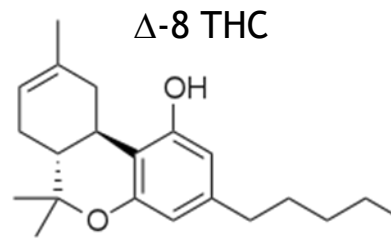
- Cannabis belongs to a small family of flowering plants, Cannabaceae, known as the hemp family.
- Cannabis plants produce around 500 chemicals. Approx. 100 are phytocannabinoids, produced in trichomes growing on female flowers.
- Two common wild cannabinoids are Delta-9 Tetrahydrocannabinol ( $\Delta$ -9 THC) and Cannabidiol (CBD). A third,  $\Delta$ -8 THC, is also being marketed.



[wikipedia.org](https://en.wikipedia.org/wiki/Delta-9_tetrahydrocannabinol)



[wikipedia.org](https://en.wikipedia.org/wiki/Cannabidiol)



[wikipedia.org](https://en.wikipedia.org/wiki/Delta-8_tetrahydrocannabinol)

- Most phytocannabinoids share common structural features.

# Hemp vs. Marijuana

- Under the Agricultural Marketing Act of 1946, as amended by the Agriculture Improvement Act of 2018 (also known as the 2018 Farm Bill):
  - Hemp means a cannabis plant or any part of the plant with a delta-9 THC concentration of  $\leq 0.3\%$  on a dry weight basis.
  - The Farm Bill considers cannabis plants that cannot be classified as hemp, because they contain  $>0.3\%$  delta-9 THC on a dry weight basis, to be marijuana

State Licensed Hemp Farms Sprouting in Rural Levy County



[spotlightonlevycountygovernment.com](http://spotlightonlevycountygovernment.com)

(used with permission)

# CBD vs. $\Delta$ -9 THC

## CBD

- Typically derived from the hemp plant
- No psychoactive effect (i.e., nonintoxicating)
- Mechanism of action complex; interacts weakly with endocannabinoid receptors CB1R & CB2R
- CBD inhibits breakdown of natural endocannabinoids & possibly THC

## $\Delta$ -9 THC

- Typically derived from the marijuana plant
- Produces a psychoactive effect (i.e., intoxicating)
- Binds to both CB1R and CB2R
- CB1R is prominent in CNS (brain and spinal cord), CB2R in rest of body, including immune cells

# CBD Explosion

- On December 20, 2018, the Agricultural Improvement Act of 2018 was signed into law
  - Known as the “2018 Farm Bill”
  - Amended the Agricultural Marketing Act of 1946
  - Legalized the commercial production of hemp



[usda.gov](https://www.usda.gov)

Floral Hemp: From the Field and Greenhouse to CBD



[usda.gov](https://www.usda.gov)



# Where is the product coming from...

- FDA-approved CBD medication (Epidiolex)
- Over-the-Counter (OTC) CBD products
- CBD/Cannabis products from state-sanctioned/regulated dispensaries



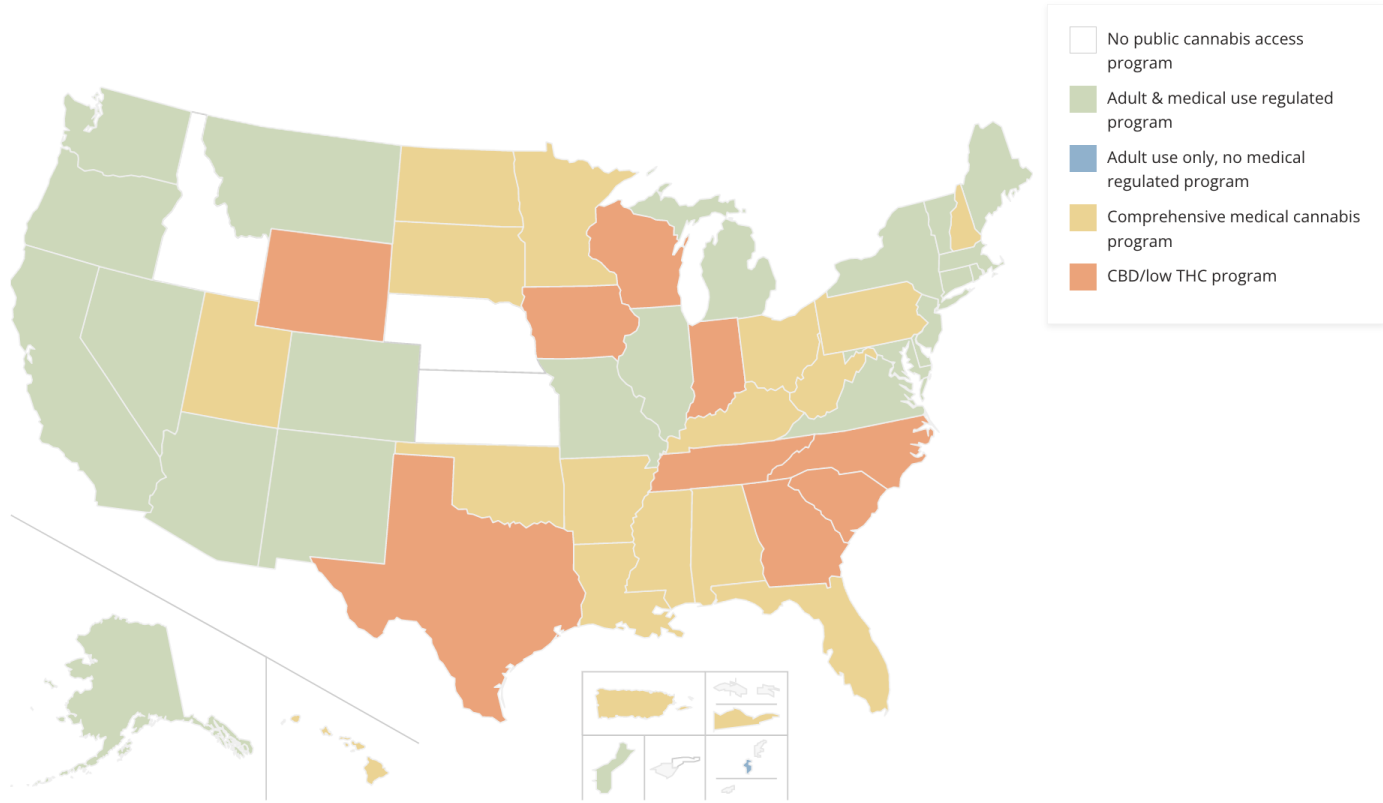
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# State Regulated Cannabis Programs, April 2023

Switch View ▾



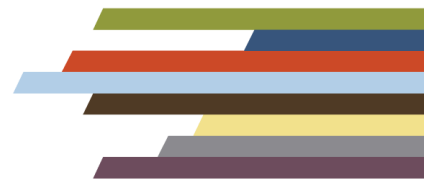
Source: <https://www.ncsl.org/health/state-medical-cannabis-laws>



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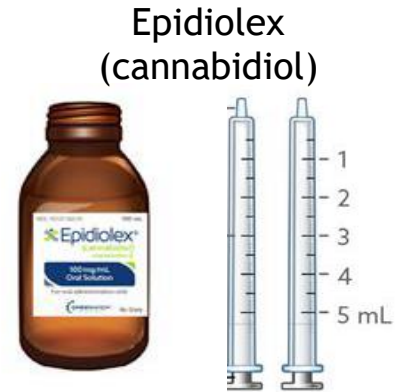
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# Pharmaceutical- and commercial-grade CBD

- Only one CBD product is FDA-approved, Epidiolex
  - Pharmaceutical-grade CBD, for epilepsy
  - Only available with a valid prescription
  - Administered orally with an oral syringe
- Over-the-counter (OTC), i.e., commercial-grade, CBD products are not FDA-approved



[fda.gov](https://www.fda.gov)

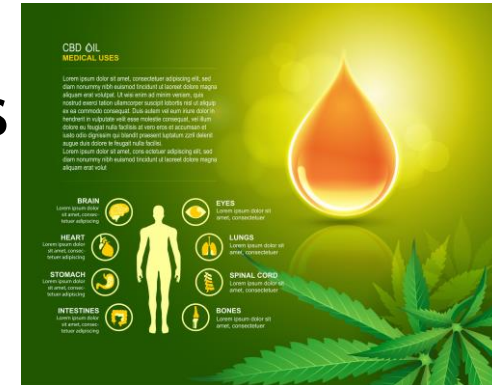


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# Marketing and Availability of OTC CBD

- OTC CBD products are often marketed as therapies for many health conditions
- Many of these claims are unproven and the health effects of products unknown
- The FDA has been unable to evaluate and approve these products for their marketed use
  - Limited data to support their effectiveness
  - THC and CBD products are excluded from the dietary supplement definitions
  - A new regulatory pathway for CBD is needed

## CBD Oil: Medical Uses Claimed in Marketing



Getty Images

# Marketing and Availability of OTC CBD (cont'd)

- Availability varies by state, depending on regulations
- OTC CBD products are available throughout the United States
  - Online retailers
  - “Brick and mortar” retailers (e.g., drugstores, grocery stores, convenience stores, gas stations)
- Most CBD sales—greater than 60%—are made online.

CBD online shopping



Getty Images

# Who uses OTC CBD (US statistics)?

Age group	Used CBD in last 2 years	Ever used CBD
Adults	25%	33%
18 - 29	20%	40%
30 - 49	16%	32%
50 - 64	11%	23%
65+	8%	15%

- 64% are familiar with CBD and/or CBD products
- Nearly half (46%) of CBD users are millennials
- Women use CBD slightly more than men: 52% are female
- Almost half (48%) of users live with children under 18
- 47% think the government regulates CBD
- 22% do not trust CBD
- In 2020, CBD products generated over \$5 billion in sales

# How is OTC CBD used?

CBD comes in many different forms:

- Food items: chocolate, gummies, other candy
- Beverage items: CBD-infused sodas, water, tea
- Smokable items: smokable flower; vapes—cartridge, e-cig.
- Topicals: lotions, balms, gels, cosmetics, etc.
- Oils: tinctures with a dropper or as a gelcap
- Transdermally: skin patch
- Eye drops
- Suppositories
- Pet products



Getty Images

# Adverse Effects of Pure CBD

Most common adverse reactions:

- Sleepiness, worsened with alcohol
- Decreased appetite
- Diarrhea
- ↑ liver enzymes, dose related & esp. if also taking Valproate
- Fatigue, malaise, & weakness
- Rash
- Insomnia, sleep disorder, and poor quality sleep
- Infections

Also, ↑ risk of drug-drug interactions

Additional Information applies to pregnant and breastfeeding women

([from fda.gov](https://www.fda.gov))



# Potential Harms Associated with OTC CBD

What about commercial-grade (OTC) CBD?



Getty Images

# OTC CBD: Caveat Emptor

Harms associated with OTC CBD use include:

- Adverse events
  - Seriousness depends on several factors
- Unreliable labeled concentration, i.e., dose
  - Research suggests CBD product labeling largely inaccurate
- Unreliable purity, with harmful contaminants
  - Purity concerns due to unsafe manufacturing practices
- Contaminated with THC
  - Unlabeled  $\Delta$ -9 and/or  $\Delta$ -8 THC may be present
- Unproven health claims
  - May delay right diagnosis and treatment
- CBD-related emergency room visits increasing
  - Visits due to intentional and unintentional use

# Populations of Special Concern

- Pregnant and breastfeeding women
  - Lack of human research, but FDA is continuing to collect and study data on harmful effects
  - Animal studies suggest high dose CBD causes reproductive system problems in male fetuses
  - CBD contaminants, including THC, may pose risk to developing fetus or breastfed baby
  - FDA strongly advises against the use of CBD in any form during pregnancy or while breastfeeding
- Children
  - Unintended intoxication

# Concluding Remarks

- CBD is increasingly available, in various forms
- However, only one CBD product, Epidiolex, is FDA-approved for treating seizures
- The FDA has not approved any OTC CBD
- The CBD marketplace is largely unregulated
- Nevertheless, CBD is marketed for various ailments, despite limited evidence of effectiveness

# Concluding Remarks (cont'd)

- OTC CBD is widely mislabeled & is of questionable purity
- Biological & chemical contaminants found in CBD samples
- CBD may also contain  $\Delta$ -8 and/or  $\Delta$ -9 THC
- Children are especially vulnerable to CBD & must not be given OTC CBD
- Pregnant & breastfeeding women should also avoid CBD products

# For More Information

- The advisory is available on the SAMHSA Store: <https://www.samhsa.gov/resource/ebp/advisory-cbd-potential-harms-side-effect-unknowns>
- For more information, contact [ebprc@samhsa.hhs.gov](mailto:ebprc@samhsa.hhs.gov)

**SAMHSAADVISORY**  
Substance Abuse and Mental Health  
Services Administration

FEBRUARY 2023

**CANNABIDIOL (CBD) – POTENTIAL HARMS, SIDE EFFECTS, AND UNKNOWNNS**

The use of non-Food and Drug Administration (FDA)-approved cannabidiol, or CBD, has gained attention in recent years, as CBD is becoming increasingly popular and is being marketed for various health conditions.<sup>1</sup> A poll of American adults aged 18 years and older found that 14 percent reported using CBD products in 2019, and a similar poll conducted in 2020 found that as many as 1 in 3 adults reported using CBD products.<sup>2,3</sup> However, non-FDA-approved, commercial CBD products marketed to the public and available over the counter differ significantly in composition from those used in clinical studies,<sup>4</sup> and there is limited evidence to support their safety.<sup>5</sup> The public should be aware of the misconceptions surrounding CBD products, as well as the potential harms and risks associated with their use.

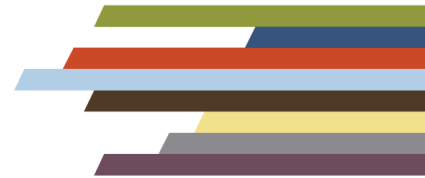
**Key Messages**

- Cannabidiol (CBD) and delta-9-tetrahydrocannabinol (delta-9 THC) are two of many chemical compounds called cannabinoids that are found in the cannabis plant. CBD, which in its pure form does not produce any psychoactive effects,<sup>6,7</sup> is typically derived from the hemp plant. Nevertheless, CBD products, except for the prescription medication Epidiolex,<sup>1,8</sup> are not FDA-approved, so despite being marketed extensively, there are no federal standards for their content, purity, or potency<sup>9</sup>
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- Since federal restrictions on growing cannabis plants that contain low amounts of delta-9 THC were removed in 2018, CBD has become widely available in a range of products and formulations, including topicals, fabric, food, and beverages.<sup>10</sup>
- In 2020, as many as one-third of American adults reported using CBD products.<sup>2</sup>
- CBD has been marketed as a treatment for a range of health conditions in recent years; however, there is a lack of evidence to support many of these claims.<sup>5</sup>
- Potential risks and harms associated with CBD use include adverse drug interactions, liver toxicity, and reproductive and developmental effects.
- Delta-9 THC or delta-9 THC-contaminated products may be sold as CBD. Labeling of these products may be unclear or misleading, posing a potential threat to a user's current or prospective employment, produce inaccurate medical test results, or cause unintended drug interactions.
- More clinical research is needed to determine if CBD products are safe and effective treatments for the conditions for which they are marketed.<sup>1</sup>

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# Tips and Action Steps



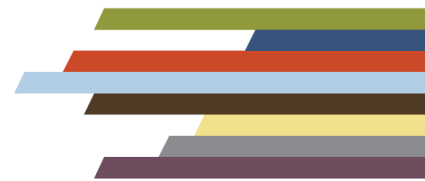
# For Community Coalitions, Prevention, and Treatment Leaders

- Work with local health departments, regulatory agencies, and medical providers to disseminate the latest evidence on the risks and therapeutic potential of CBD, including that which is unknown
- Educate community partners and community members, including adolescents and young adults, about the short- and possible long-term effects associated w/ CBD use
- Implement evidence-based programs to prevention non-FDA-approved CBD use by youth and young adults



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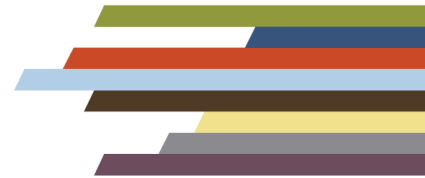
# For Healthcare Providers

- Encourage additional clinical research on the effects of CBD
- Learn about potential interactions of CBD with alcohol and prescription and over-the-counter medications
- Educate patients on the potential risks and harms associated with CBD use, including interactions with prescription drugs, dietary supplements, alcohol, and illicit drugs.



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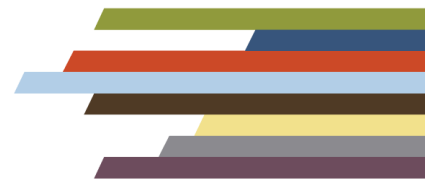
# For Parents, Caregivers, and the General Public

- Talk with children about the risks and harms of using products that contain CBD
- Do not allow children to use over-the-counter CBD products
- Consult a healthcare provider before using any CBD product
- Be aware that the risk of CBD products containing delta-9 and/or delta-8 THC is unknown and use of these products could impact employment drug screenings
- Do not use CBD concurrently with medications, alcohol, or illicit drugs



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# Reporting Adverse Reactions to FDA

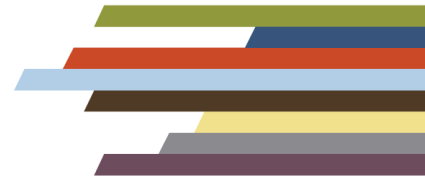
Individuals who experience adverse events as a result of using CBD products can report them to the FDA through their MedWatch Safety Information and Adverse Event Reporting Program

Link: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>



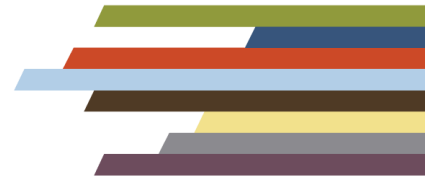
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# **Cannabis-related training and technical assistance products from New England PTTC**





# FOCUS ON CANNABIS PREVENTION

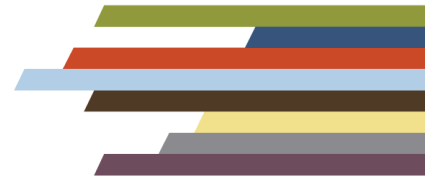
## INSIDE THIS RESOURCE

- [Cannabis Health Advisories](#)
- [Toolkits](#)
- [Resources specific to each New England State](#)
- [Resources provided by Federal Agencies](#)
- [National Resources](#)
- [Recent Journal and Research Articles](#)
- [School Admin and Policy Setting](#)
- [Hubs related to Cannabis Prevention](#)
- [Social Media Kits or Posts](#)
- [Where to Find Laws/Policies \(Federal and State Level\)](#)



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# Microlearning Series

## Microlearning Vaping Series

- Nicotine and the Adolescent Brain
- Neurobiology of Cannabis
- The Appeal of Vaping
- Public Health Concerns of Vaping

## Microlearning Cannabis Prevention Series

- Impairment
- Messaging & Communication
- THC, CBD, and Hemp
- Local and Organizational Policy



# Two New PTTC Courses on Cannabis,

## Cannabis Pharmacology.

Presented by Dr. Hayden Center

- Module 1: The Effects of Cannabis
- Module 2: Cannabis and the Adolescent Brain
- Module 3: Cannabis Pharmacology

## Preventing Underage Cannabis Use: Risk/Protective Factors & Effective Communication

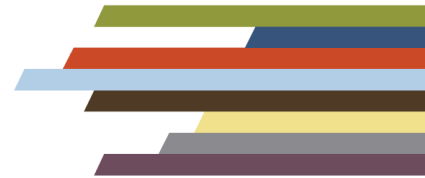
Presented by Gisela Rots



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# Questions?

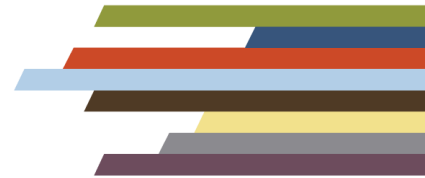
- Do you have any experiences or challenges with clients or people you work with related to CBD?
- Are there other areas of training that would be helpful for you in your work related to CBD or THC?



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# Contact Info:

For all your prevention training and technical assistance services, please be in touch!

- Scott M. Gagnon, MPP, PS-C [sgagnon@adcareme.org](mailto:sgagnon@adcareme.org) - Director
- Erin Burnett [eburnett@adcareme.org](mailto:eburnett@adcareme.org) – Co-Director
- Sarah Johnson [sjohnson@adcareme.org](mailto:sjohnson@adcareme.org) – Training and Technical Assistance Coordinator

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Website:

- [pttcnetwork.org/NewEngland](http://pttcnetwork.org/NewEngland)



New England (HHS Region 1)

PTTC

Prevention Technology Transfer Center Network  
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