

National Mental Health and Substance Use Policy Laboratory

Cannabidiol (CBD) – Potential Harms, Side Effects, and Unknowns

August 8, 2023



SAMHSA
Substance Abuse and Mental Health
Services Administration

Housekeeping

- We have made every attempt to make today's presentation secure. If we need to end the presentation unexpectedly, we will follow-up using your registration information.
- Have a question for the speakers? Email ebprc@samhsa.hhs.gov
- At the end of today's webinar, please complete a brief survey.
- Following the session, you will receive an email on how to access a certificate of attendance; must attend at least 30 minutes.
- This event is closed captioned! To view captions, click the arrow beside the CC box at the bottom of your screen, and choose "Show Subtitles."
- Follow us on social media:


@PTTCNetwork



Please Note:
This session is recorded and all materials will be posted on pttcnetwork.org within 1 week.

Purpose of the PTTC Network

 Improve implementation and delivery of effective substance use prevention interventions

 Provide training and technical assistance services to the substance use 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.



PTTC Network Approach

Develop and disseminate tools and strategies needed to improve the quality of substance abuse prevention efforts

Provide intensive technical assistance and learning resources to prevention professionals in order to improve their understanding of

- prevention science,
- how to use epidemiological data to guide prevention planning, and
- selection and implementation of evidence-based and promising prevention practices.

Develop tools and resources to engage the next generation of prevention professionals.



PTTC

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

PTTC Network

**PTTC Network
Coordinating Office**
University of Missouri
- Kansas City

REGION 10
Northwest
PTTC
University of
Washington

REGION 8
Mountain
Plains
PTTC
University of
Utah

REGION 5
Great Lakes
PTTC
University of
Wisconsin-
Madison

REGION 2
Northeast
& Caribbean
PTTC
Rutgers
University

REGION 1
New
England
PTTC
AdCare
Maine

REGION 9
Pacific
Southwest
PTTC
University of
Nevada,
Reno

REGION 3
Central
East
PTTC
Danya
Institute

**National Hispanic and Latino
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National Latino Behavioral
Health Association

**National American Indian
and Alaska Native PTTC**
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REGION 4
Southeast
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Medicine

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South
Southwest
PTTC
University of
Oklahoma

Pacific Ocean

Commonwealth of Northern Marianna Islands

Guam

Republic of the Marshall Islands

Republic of Palau

Federated States of Micronesia

American Samoa

Hawaiian Islands

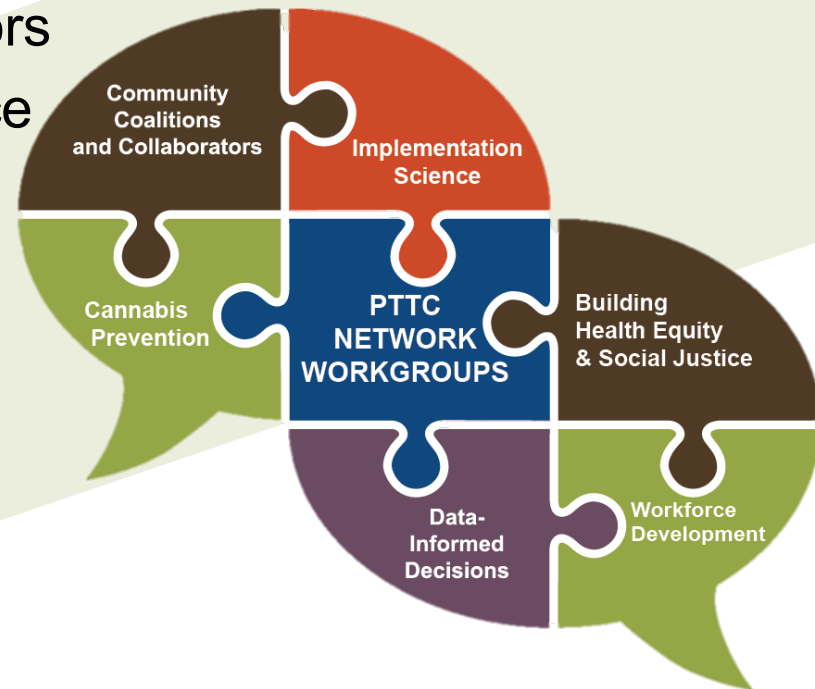
Puerto Rico

U.S. Virgin Islands

Focus Areas and Working Groups

Learn more: <https://pttcnetwork.org/centers/global-pttc/pttc-areas-focus>

1. Community coalitions and collaborators
2. Building Health Equity & Social Justice
3. Data-informed decisions
4. Implementation Science
5. Cannabis Prevention
6. Workforce Development



Cannabis Prevention Working Group

- Britany Wiele, Chair
- Scott Gagnon, Co-Chair
- Michelle Frye-Spray
- Ken Winters
- Susie Villalobos
- Jeanne Pulvermacher
- Deborah Nixon-Hughes
- Taylor Cook

<https://pttcnetwork.org/centers/global-pttc/cannabis-prevention>

The screenshot shows the PTTC website's Cannabis Prevention Priority Area. At the top is the PTTC logo and navigation menu. The main heading is "Cannabis Prevention Priority Area". Below this is a paragraph explaining the group's purpose and a photo of hands holding signs that say "REDUCE YOUR RISK". The "Working Group Chair" is Michelle Frye-Spray and the "Working Group Co-Chair" is Priscilla Glamaesi. A section titled "Network Related Products" features two items: "Teen Marijuana Vaping Climbs Significantly" (with a bar chart showing an increase from 2.9% to 3.2% to 3.9%) and "MARIJUANA MYTHS AND FACTS" (a toolkit). At the bottom, there is a link to "Research, Policies, and Practices: Federal and Community-level Perspectives on Vaping" and a QR code for "Cannabis Pharmacology for Substance Misuse Prevention Practitioners (3-part series on HealthKnowledge.org)".

The use of affirming language inspires hope.

LANGUAGE MATTERS.

Words have power.



PEOPLE FIRST.

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

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Cannabidiol (CBD) – Potential Harms, Side Effects, and Unknowns

August 8, 2023



SAMHSA
Substance Abuse and Mental Health
Services Administration

SAMHSA ADVISORY

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.¹ 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.^{2,3} 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 studies⁴ and there is limited evidence to support their safety.⁵ 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,^{6,7} is typically derived from the hemp plant. Nevertheless, CBD products, except for the prescription medication Epidiolex,^{1, 8} are not FDA-approved, so despite being marketed extensively, there are no federal standards for their content, purity, or potency⁹
- 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.^{5,4} 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.¹⁰
- In 2020, as many as one-third of American adults reported using CBD products.²
- 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.⁵
- 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.¹

Organization of presentation

- Introduction to cannabis plant, CBD and how it is different from THC: chemistry & biology
- 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

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 (Δ -9 THC) and Cannabidiol (CBD). A third, Δ -8 THC, is also being marketed.

Female Cannabis sativa



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

Cannabis female flower

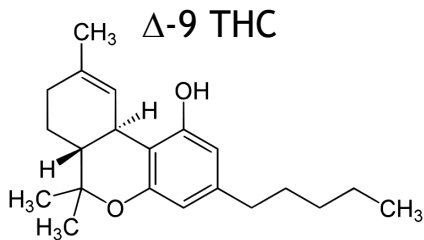


[wikipedia.org](https://en.wikipedia.org/wiki/Cannabis_female_flower)

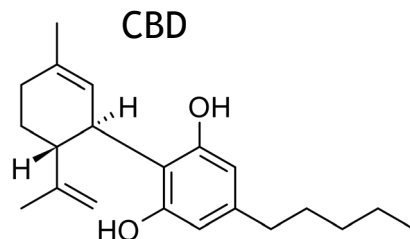
Hemp leaves for sale



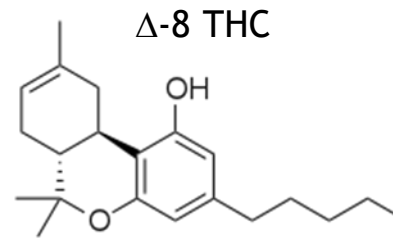
Getty Images



[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

(used with permission)

CBD vs. Δ -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

Δ -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)

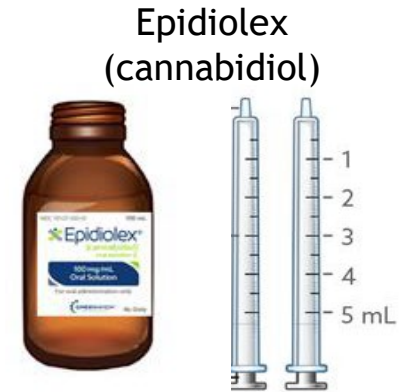
Floral Hemp: From the Field and Greenhouse to CBD



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

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



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

- Over-the-counter (OTC), i.e., commercial-grade, CBD products are not FDA-approved

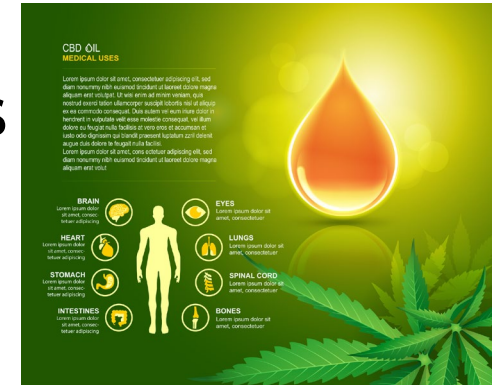


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Marketing and Availability of OTC CBD

- 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

<https://www.singlecare.com/>; <https://www.cannabisbusinesstimes.com/>; <https://cfah.org/>

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 Δ -9 and/or Δ -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 Δ -8 and/or Δ -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

SAMHSAADVISORY
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Next Steps

The PTTC Network is funded through SAMHSA to provide this webinar. As part of receiving this funding we are required to submit data related to the quality of this event.

Please take a moment to complete a brief survey about today's webinar.

Survey:

- The following link will pop up in your browser upon exiting the webinar. You will also receive this link via email.
- <https://ttc-gpra.org/P?s=237490>

Within a week:

- The recording of today's presentation will be available on pttcnetwork.org Cannabis Prevention workgroup page
- Attendees will receive a follow-up email with instructions for downloading a certificate of completion.




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

Walking the Walk in 2022: Embracing SAMHSA Priorities and the Intersection of Harm Reduction, Prevention, and Recovery

Cele Fichter DeSando, MPM


I went to my first 12 step recovery support group meeting in 1976. I was twenty years old and attended the open meeting as part of a community psychology class assignment. I didn't begin working as a prevention specialist for another 10 years but something the lead speaker said has resonated with me for more than 40 years. "It's not enough to talk the talk, you have to walk the walk."

Each year, many of us make New Year's resolutions that never make it past the talking stage. Resolutions and goals take more than words, they need actions that are put into practice. Sometimes, like newly walking toddlers, we take two steps forward, one step back, and an occasional fall along the way. Changing behavior and learning new practices takes time, a plan, support from peers, a way to measure success, and resources from trusted experts.

In 2022, as we develop prevention goals, plans, and resolutions, the Substance Abuse Mental Health Services Administration (SAMHSA) serves as a trusted expert resource with a roadmap of priorities and principles to guide


Featured PTTC Resources

- [Harm Reduction Through a Prevention Lens Resources](#)
PTTC Network Coordinating Office
- [Fentanyl Test Strips: A Grassroots Harm Reduction Strategy](#)
Great Lakes PTTC
- [Preventing Drug Overdoses](#)



HARM REDUCTION THROUGH A PREVENTION LENS

Harm Reduction and Prevention have common goals in reducing the adverse health and social consequences of substance use but exist at different places in the continuum of Universal, Selective, and Indicated Prevention.



HARM REDUCTION AND PREVENTION HAVE COMMON GOALS

TO REDUCE HARM AMONG PEOPLE WHO USE SUBSTANCES, PREVENTION INTERVENTIONS

In the chat

Share one thing
you learned today

THANK YOU!

For more information, contact ebprc@samhsa.hhs.gov

