


Covering Cannabis as a Health Benefit: What Consumers Need to Know

Stacey Worthy, Esq., Aimerd Alliance



1

About

Aimerd Alliance is a nonprofit health policy organization that works to protect and enhance the rights of health care consumers and providers



2

Preview

- Definitions and background
- Federal law
- State law
- Mandated coverage of marijuana
- Recommendations



3

Definitions



- **Cannabis**: products derived from cannabis sativa plant; 540 chemical substances
- **Tetrahydrocannabinol (THC)**: substance primarily responsible for altered effects on person's mental state
- **Marijuana**: cannabis products that contain substantial amounts of THC (more than 0.3%)
- **Hemp**: cannabis products that contain low concentrations of THC (0.3% or less)
- **Cannabinoids**: any of over 100 chemical constituents of hemp or marijuana. THC and CBD are two most common
- **Cannabidiol (CBD)**: cannabinoid derived from hemp or marijuana or synthetic version

AIMEDALLIANCE

4

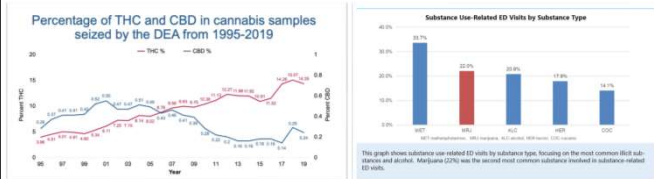
Cannabis Products Are Everywhere



AIMEDALLIANCE

5

Cannabis Potency vs. ED Visits



AIMEDALLIANCE

Source: Potency Monitoring Program, Quarterly Report #146

6

Health Consequences

THE NEGATIVE HEALTH EFFECTS OF MARIJUANA

- 1/10 develop marijuana use disorder
- American Heart Association: increased risk of heart attacks, strokes, impaired heart functioning
- Use during pregnancy linked to problems with attention, memory, problem-solving skills, behavior problems in children
- Frequent marijuana use in high doses can cause anxiety and paranoia
- In adolescents, marijuana use can result in
 - Impaired short-term memory, concentration, attention span, and problem-solving skills
 - Alterations in motor control, coordination, judgment, reaction time, and tracking
 - Negative effects on lung function and higher rates of psychosis
 - Higher likelihood of drug dependence or addiction in adulthood
- University of Colorado Hospital in Denver study:
 - Marijuana-related emergency room visits tripled after state allowed recreational sales
 - 2-3 patients / day with severe vomiting, anxiety, and psychosis

AIMEDALLIANCE Source: Nora D. Volkow, MD, Susan D. Baker, PhD, Wilson M. Compton, MD, and Susan R.B. Weisz, PhD, N. Engl. J. Med. 2014; 370:2219-2227, June 5. <http://www.nytimes.com/2014/06/05/health/marijuana-use.html>

7

Is CBD Harmful?

- Non-FDA-approved products may contain high levels of THC and harmful metals, toxins, and mold
 - E.g., "spice" or "K2" in vape oils
- NC HHS alert (March 2018)
 - Increase in ED visits linked to vaping CBD oil
 - Over 30 reports
 - Altered mental status, hallucinations, seizures, loss of consciousness, rapid heartbeat
- Could pose risks in pregnant women and children
- Candies can be enticing to children

AIMEDALLIANCE

8

Is CBD Harmful?

Case study: Can CBD oil shrink lung cancer tumors?

Army releases warning on dangers of 'CBD' vape oils

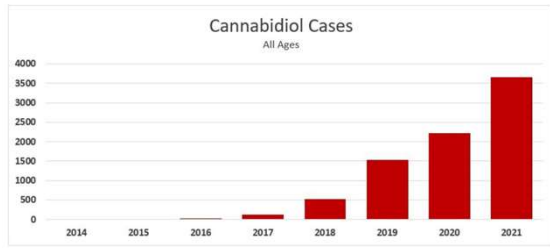
Vaping marijuana associated with more symptoms of lung damage than vaping or smoking marijuana

7 Californians hospitalized in ICU after vaping cannabidiol or CBD oils

AIMEDALLIANCE

9

Rates of CBD-Related Poisonings



American Association of Poison Control Centers
Accessed 11/30/2020



10

Delta-8-THC

NORTH CAROLINA NEWS

Delta 8 is legal, but for how long? NC retailers, hemp organizations want to see regulations

CHARLOTTE, N.C. (WJZY) - Getting high off hemp. There's a popular new strain that gets you high like marijuana, and it's totally legal due to a loophole in the federal farm bill.

- Popular cannabis compound similar to delta-9
- Produces less intoxicating effect than delta-9 but more than CBD



11

Is Delta-8 Harmful?

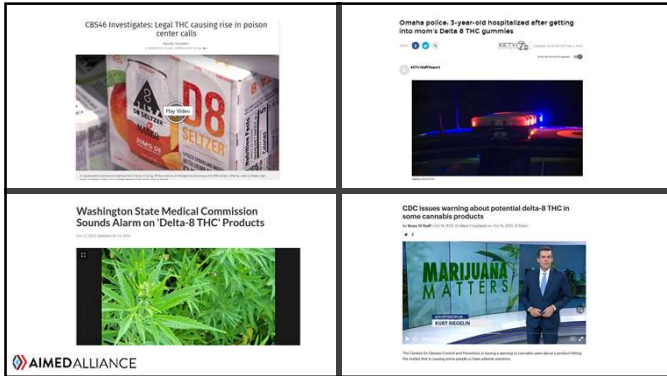
Poison Center warns about dangers of Delta-8-THC



- May not be able to distinguish between hemp- and cannabis-derived delta-8
- Can cause harmful reaction if taken in high doses
- Can be dangerous if taken by a child
 - Two cases of severe adverse reaction in children who ingested father's gummies



12



13

But Are They Legal?

- It depends
 - Federal vs. state law
 - Product in question
 - Activity involved (e.g., research, manufacture)

AIMEDALLIANCE

14

Federal Laws

AIMEDALLIANCE

15

Controlled Substances Act

- Most **cannabis** products and derivatives are Schedule I substances
- High potential for abuse
- No currently accepted medical use
- Illegal to manufacture, distribute, dispense, or possess



16



- Changed how **hemp** is classified under the CSA
- Hemp excluded from definition of marijuana
- Hemp and hemp-derived products (e.g., CBD) must be produced in compliance with the 2018 Farm Bill (i.e., no more than 0.3% THC on a dry weight basis)



17

Food, Drug & Cosmetics Act

- CBD is active ingredient in a prescription drug product approved under FDCA
- Rx medication was approved before Farm Bill was passed
- Under FDCA, no food or supplement products can contain same active ingredient as approved Rx drug



18

FDA's Position on CBD

- Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the component that produces the "high" associated with marijuana use. Much interest has been seen around CBD and its potential related to health benefits.
- Marijuana is different from CBD. CBD is a single compound in the cannabis plant, and marijuana is a type of cannabis plant or plant material that contains many naturally occurring compounds, including CBD and THC.
- The FDA has approved only one CBD product, a prescription drug product to treat two rare, severe forms of epilepsy.
- It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement.
- The FDA has seen only limited data about CBD safety and these data point to real risks that need to be considered before taking CBD for any reason.
- Some CBD products are being marketed with unproven medical claims and are of unknown quality.
- The FDA will continue to update the public as it learns more about CBD.

AIMEDALLIANCE

19

Is Delta-8 Legal?

Delta-8 Legality | Greenway Magazine

- **Federal law:** Under CSA, all THC is Schedule I controlled substance except hemp
 - Delta-8 in cannabis or cannabis-derivative is illegal
 - Delta-8 analogs are illegal
 - Delta-8 in hemp or hemp-derivatives may be legal
- **State law:**
 - Banned or restricted in at least 18 states as of October 15, 2021
 - Others have introduced legislation to ban or restrict

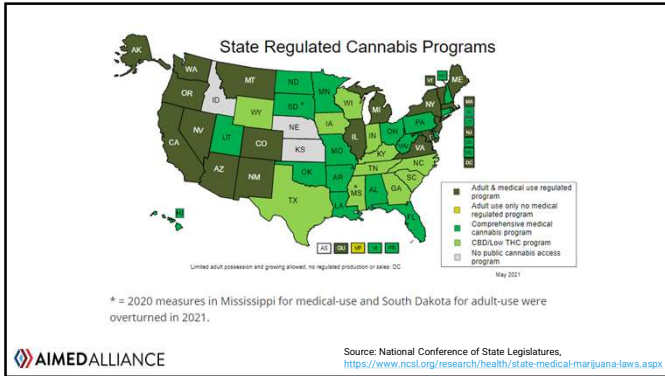
AIMEDALLIANCE

20

State Laws

AIMEDALLIANCE

21



22

"Medical Marijuana"

- States require provider certification, but few require education
- 2020 study:
 - Providers ill-prepared to answer patients' questions
 - Low knowledge and comfort levels
 - Most reported not receiving education or
- Pretext of bona-fide doctor-patient relationship
 - Certification in 15 minutes or less
 - Money-back guarantee
 - "Everything should be this easy"
 - Discount for bringing a friend

23

Mandated Coverage

AIMEDALLIANCE

24




Legislation

- 6 states introduced bills to mandate health insurance or workers' compensation coverage of marijuana



25


Bill No.	Plans and Programs Covered
HI SB 2586 (2020)	State-regulated plans, HMOs, workers' compensation programs
MA H. 3975 (2019)	State employee health plans, Medicaid MCOs, and other state-regulated plans
ME LD942 (2019)	Government medical assistance programs (i.e., Medicaid) and private health insurers
NJ A. 1708 (2020)	Workers' compensation program, private insurers, health service corporations, hospital service corporations, HMOs, State Health Benefits Program (SHBP), and School Employees' Health Benefits Program
NY SB 2054 (2019)	Exchange plans, Medicaid, CHIP, and workers' compensation
WI SB 377 (2019)	Disability insurance policies; state, county, city, town, and school self-insured health plans



26


Workers' Compensation

- State laws vary on *permissibility* of marijuana coverage
 - Some hold it is permissible and reimbursable treatment (e.g., CT, MN, NJ)
 - Some exempt workers' comp or employers from being required to reimburse (e.g., AZ)
 - Some prohibit reimbursement altogether (e.g., FL, ND)
 - Some deem it outright illegal (e.g., ME)



27

Preemption



- ERISA preempts all state law that
 - Mandate employee benefit structures or their administration
 - Constrain employers or plan fiduciaries to certain choices
 - Prevent uniform administrative practice

AIMEDALLIANCE

28

Preemption

- State laws would likely interfere with national uniform plan administration
 - State laws legalizing use of marijuana vary from state to state
 - Only 6 states have introduced legislation to mandate plan coverage
 - Plan administrators would have to create varying formularies
- States cannot regulate self-funded plans

AIMEDALLIANCE

29


Preemption – CSA Case Law

- Federal law preempts state law if they conflict
- *Bourgoin v. Twin Rivers* (ME 2018)
 - CSA preempted court order mandating workers' comp coverage of marijuana
 - Covering cost of marijuana qualified as aiding and abetting unlawful possession and use of marijuana
- *In re Daniel Wright* (MA 2020)
 - Marijuana's status as a Schedule I controlled substance preempted state from ordering workers' comp insurer to cover
 - Insurers / employers would "not be participating in the patient's use of federally proscribed substance voluntarily"
 - Involuntary risk of prosecution
- *But see, McNeary v. Freehold Township* (NJ 2019); *Vialpando v. Ben's Automotive Svcs.* (NM 2019); *Lewis v. Am. Gen. Media* (NM 2015); *Hager v. M&K Constr.* (NJ 2020)


AIMEDALLIANCE

30

FDCA




- State laws mandating marijuana coverage undermine purpose and intent of FDCA
- Drugs must obtain FDA approval before they can be marketed or distributed in interstate commerce
- If intended to treat medical condition, considered unapproved new drug and illegal under FDCA
- Significant risks to patients due to lack of safety, effectiveness, or quality review



31


Safety Concerns



Investigation finds illegal synthetic marijuana in vape and edible products sold as CBD

PUBLISHED MON, SEP 14 2019 8:00 PM EDT. UPDATED MON, SEP 16 2019 6:54 PM EDT

- Products may be contaminated with undisclosed substance (e.g., THC, heavy metals and toxins, mold)
 - Study found **synthetic, psychoactive adulterants** (e.g., **spice / K2**, and other dangerous illicit substances) in 1/3 of CBD vape oils
 - 2019 study: 70% were "highly contaminated" with heavy metals (e.g., **lead and arsenic, herbicides, and pesticides**)
 - 2020 study from FDA: 49% contained **THC or THCA** at concentrations above the 3.1 mg/serving cut off



32


Unsubstantiated Therapeutic Claims & Adverse Events

WARNING LETTER

Noetic Nutraceuticals
MARC5-CMS 607572 – MAY 15, 2020

"We are getting a lot of questions about whether CBD (Hemp Extract) can help with the Coronavirus (COVID-19). The short answer is YES, it certainly can help. Now, let's be clear. It is not seen as a cure, but CBD has properties (anti-bacterial, anti-viral, and anti-inflammatory) that can aid with symptoms and help a person stay healthy to fight off illness. In order to fight disease and illness, we need our immune system to be functioning properly and many studies have shown that CBD can aid with this. . . . Less stress= less pain= a higher functioning immune system. Taking a daily CBD supplement. . . can only help."

- State laws incentivize purchase of marijuana that are often deceptively marketed
- Some sellers have made unsubstantiated therapeutic claims
 - Federal judge issued permanent injunction against NY company for selling "organic hemp seed oil" to "suppress the growth of cancer"
- Lack of rigorous scientific data
- Have resulted in adverse events
 - American Heart Association: marijuana can increase risk of heart attacks and strokes



33

Drug-Free Workplace Act (DFWA)

- Non-FDA-approved marijuana products can result in impairment in the workplace
- If employee is impaired at work, employer may face liability under DFWA
- DFWA requires good faith effort to keep drug free workplace; requirement hard to meet if forced to cover marijuana
- No exceptions for employers subject to state law



34


Risk of Litigation

- Employers generally permitted to adopt drug-free workplace policies and may terminate employee who is impaired while in the workplace
- If employer conducts drug testing, it may be unclear whether employee is currently using marijuana on the job or off the job
- However, some states have marijuana anti-discrimination laws that may protect employees from being fired if using marijuana off the job for medical purposes
- Some courts have ruled in favor of the employee



35

OSHA

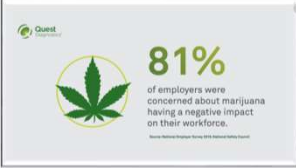


- State laws could expose employers to liability under Occupational Safety and Health Act
- Imposes duty on employers to offer workplace free from recognized hazards that could cause death or serious physical harm
- OSHA has strongly supported measures that contribute to a drug-free environment
- Employer may still have a general duty to protect against hazards
- Violations include civil penalties of up to \$70K and imprisonment



36

Workforce Changes



- Negative impact on labor productivity and income-earning ability
- Workplace impairment
 - Poses risk for those in safety-sensitive jobs (operating heavy machinery)
 - Study of postal workers: Employees who tested positive for marijuana on pre-employment urine drug tests had
 - 55% more industrial accidents
 - 85% more injuries
 - 75% greater absenteeism
- Use of marijuana can result in disciplinary action or loss of job
 - Tests may be unreliable; even some gas chromatography-mass spectrometry tests cannot distinguish between CBD and THC

AIMEDALLIANCE

37

Legal Troubles for Consumers



- Testing positive for THC can result in loss of certain civil liberties
- Many tests cannot distinguish between products (e.g., THC vs. CBD)
- Tests may be unreliable

AIMEDALLIANCE

38

reason

A 69-Year-Old Great-Grandmother Was Arrested at Disney World for Carrying CBD Oil

By Staff Writer/Editor

Utah woman says her legal CBD use has put her at risk of losing custody of her daughters

Transport topics

Fired Truck Driver Sues Cannabidiol Company After Using Product

AIMEDALLIANCE

Legal Troubles for Consumers

- Arrest
- Loss of child custody
- Loss of job
 - Dept of Transportation: CBD use not legitimate medical explanation for laboratory-confirmed THC+ result
- Loss of benefits (e.g., workers' compensation)

39

Recommendations

- Know the laws in your state
- Encourage states not to cover non-FDA-approved marijuana products
- If legislation introduced in your state, contact state legislatures
 - States include HI, MA, ME, NJ, NY, and WI
- Educate employees / public on risks of marijuana
- Encourage employers to adopt a clear impairment in the workplace policy to set expectations



40

Thank You

-  policy@aimedalliance.org
-  (202) 559-0380
-  @AimedAlliance



41
