VILLAGE OF Lake Villa

AGENDA

VILLAGE OF LAKE VILLA

COMMITTEE OF THE WHOLE – SPECIAL MEETING

Monday, September 8, 2025

6:00 p.m.

1. Call to Order and Roll Call
2. Pledge of Allegiance
3. New Business
    a. Grocery Tax Discussion
    b. Kratom/Delta-8 THC Discussion
    c. Review of Solicitor Regulations
4. Adjournment

DATE: August 28, 2025

TO: Mayor James McDonald and Board of Trustees

FROM: Michael Strong, Village Administrator

RE: **Introduction to Kratom and Delta-8 THC**

Introduction

In recent years, municipal officials in Illinois have had to navigate an increasingly complex marketplace and regulatory landscape that has led to the proliferation of novel psychoactive substances, synthetic drugs, THC products, and synthetic cannabinoids. Many of these items pose significant public health risks as they remain unregulated by federal or state authorities.

Two particularly and increasingly prevalent substances, Kratom and Delta-8 THC, have generated much discussion in Illinois communities over the past several months, due to their growing availability in retail settings such as gas stations, vape shops, and online marketplaces. Their popularity, particularly among youth, has raised significant concerns among public health officials and municipal leaders due to the affects they have on users. Reported side effects from use include hallucinations, vomiting, tremors, anxiety, dizziness, confusion, erratic behavior, aggression, suicidal ideation, psychosis, loss of consciousness, agitation, nausea, tachycardia, elevated blood pressure, seizures, panic attacks, paranoid behavior, non-responsiveness, and impaired cognitive functioning. In severe cases, use of these substances has been linked to death.

Despite the seriousness of these risks, Kratom and Delta-8 remain widely available to consumers. This is due in part to gaps in federal and state regulatory frameworks. Although laws exist that prohibit certain synthetic drugs, manufacturers often alter the chemical composition of their compounds to remain technically outside the scope of those laws. In contrast, cannabis in Illinois is subject to a robust regulatory framework that includes licensing, testing, and age restrictions.

The most immediate and urgent issue for local governments is the challenge posed by these new psychoactive substances, which rapidly evolve and exploit legal loopholes, making it difficult for existing regulatory, forensic, and public health systems to keep up.

The aim of this memorandum is to dig deeper into the nature of two specific psychoactive substances (Kratom and Delta-8 THC), the public health concerns they raise, the responses from other municipalities, and potential regulatory tools for non-home-rule communities.

What are Kratom and Delta-8 THC?

As the landscape of psychoactive substances continues to evolve, local governments face mounting challenges in regulating compounds that fall outside traditional drug control frameworks. Two prominent examples, Kratom and Delta-8 THC, highlight the complexities of the current regulatory "grey zone". Meaning, both substances are widely available, legally ambiguous, and increasingly associated with public health concerns. Before we explore rules or policies, it's important to understand what these substances are and how they're used.

Kratom

Kratom is a tropical tree native to Southeast Asia, where its leaves have been used traditionally for their stimulant and analgesic properties. In the United States, kratom is typically consumed in the form of capsules, powders, or teas. Its two primary active compounds interact with opioid receptors in the brain, producing stimulant effects at low doses and sedative, opioid-like effects at higher doses. Kratom is often used for self-managing opioid withdrawal, but carries risks of addiction, psychosis, livery toxicity, and seizures.

The DEA has classified kratom as a "*Drug and Chemical of Concern*", though it is not currently scheduled under the Controlled Substances Act. The FDA has not approved kratom for any medical use, and has issued multiple warnings about its safety, citing contamination risks and potential for abuse.

In Illinois, kratom is regulated under the Kratom Control Act, which prohibits its sale to individuals under 18 and requires proper labeling. However, the Act does not classify kratom as a controlled substance, nor does it impose testing or quality control standards. This regulatory gap has led to concerns about the unregulated sale of kratom in gas stations, vape shops, and online platforms, often without adequate consumer protections.

Delta-8 THC

Delta-8 THC is a chemical that comes from hemp, which is a type of cannabis plant. It is similar to Delta-9 THC, the chemical in marijuana that makes people feel high. But Delta-8 is made in labs by changing another chemical called CBD. This process uses strong chemicals like acids and solvents, and the final products are not tested for safety.

Delta-8 is sold in many forms, like gummies, vapes, and drinks. These products are often colorful and sweet, which makes them attractive to kids and teens. They are sold in gas stations, vape shops, and online—places where it's easy for young people to get them.

The 2018 Farm Bill made hemp legal, but it didn't clearly say what to do about Delta-8. Because of this, Delta-8 is being sold without the same rules that apply to marijuana.

Marijuana in Illinois is legal for adults over 21, but it must be tested, labeled, and sold in licensed stores. Delta-8 has none of those rules.

Health experts are worried about Delta-8. It can cause confusion, anxiety, and even hallucinations. Some children and pets have gotten sick after eating Delta-8 products by accident. The FDA and other groups have warned that these products are not safe and should not be sold like candy or snacks.

In Illinois, Delta-8 is not explicitly regulated under state cannabis laws, and legislative efforts to address the issue have stalled. As a result, municipalities have begun to explore local regulatory options, particularly in light of concerns about youth access, product safety, and misleading marketing practices.

Why are these Products a Concern?
Now that we know what Kratom and Delta-8 THC are, let's look at why they're raising concerns in communities like ours.

Easy Access for Teens
These products are often sold in gas stations, vape shops, and convenience stores. They're sometimes packaged to look like candy or snacks, which makes them appealing to kids and teens. In some cases, they've been sold to minors as young as thirteen.

Health Risks
- Kratom can cause addiction, hallucinations, and even death in some cases.
- Delta-8 THC has caused poisonings in children who accidentally ate gummies. Some ended up in the ICU with slowed breathing and heart rate.
- Recent reports from the Lake Villa Fire Department indicate that they have responded to a few calls related to the use of psychoactive substances such as Kratom and Delta-8 THC. Although these incidents are infrequent, the symptoms reported by patients include feeling "freaked out" or "panicking" after use. This highlights the potential for severe psychological reactions, even with occasional use, and underscores the importance of addressing the public health risks associated with these substances.

Lack of Regulation
Unlike legal cannabis dispensaries, stores selling Kratom and Delta-8 don't have to follow strict rules. There's no requirement for lab testing, proper labeling, or age checks. This makes it hard for local police to know what's being sold and whether it's safe, the Table 1 includes a comparative overview for these substances

Table 1: Substance Regulation in Illinois: A Comparative Overview

	Cannabis	Delta-8 THC	Kratom
Legal Status	Legal for adults 21+ under the Cannabis Regulation and Tax Act	Legal but unregulated at the state level	Legal for individuals 18+ under the Kratom Control Act
Licensing Required?	Yes – cultivation, processing and retail licenses	No	No
Are products tested?	Yes	No	No
Labeling Requirements	Yes – for potency, pesticides, heavy metals, etc.	No	Minimal – only age restriction and basic labeling
Packaging Requirements	Yes – child resistant, tamper-evident	No	No
Taxation	Yes – state and local	No	No
Advertising Restrictions?	Yes – strict limits on youth-targeted marketing	No	No
Sales Locations	Licensed dispensaries only	Gas stations, vape shops, online	Gas stations, vape shops, online

How are Government Agencies Responding?

Government agencies at the federal, state, and local levels have taken varied approaches to the regulation, or prohibition, of Kratom and Delta-8 THC, reflecting growing concern over public health risks, youth access, and the lack of product oversight.

Federal Response

At the federal level, both substances remain largely unregulated, though agencies have issued warnings:

- The U.S. Food and Drug Administration (FDA) has not approved kratom or Delta-8 THC for any medical use. It has issued multiple public health advisories warning of contamination, misleading marketing, and adverse health effects.
- The Drug Enforcement Administration (DEA) classifies kratom as a “Drug and Chemical of Concern” and has stated that synthetically derived Delta-8 THC is a Schedule I controlled substance, though enforcement has been inconsistent.
- The Federal Trade Commission (FTC) has taken action against companies making unproven health claims about these products.

State-Level Regulation in the Midwest

- **Illinois**: Kratom is legal for individuals 18 and older under the Kratom Control Act, but there is no product testing or licensing. Delta-8 THC is not regulated under the state's cannabis laws, so long as products contain less than 0.3% delta-9 THC by dry weight, creating a legal gray area. In March 2025, legislation was filed at the State to amend the Act (HB1303) to increase the consumption age to 21, impose taxes, and enforce additional regulations pertaining to Kratom. While the timeline for bills that are currently in committee is ambiguous, there seems to be momentum at the State level to approve the bill by fall of 2026. At the local level, several municipalities have enacted bans within their respective communities (see below).
- **Indiana**: Kratom is banned statewide and classified as a Schedule I controlled substance. Delta-8 THC is not clearly legal; the Attorney General has issued an opinion treating it as a controlled substance. A bill (SB 478) proposes regulating Delta-8 through licensing, testing, and age restrictions, but it remains stalled in the state legislature.
- **Wisconsin**: Kratom is banned statewide. Delta-8 THC is not explicitly banned but may be considered illegal if classified as synthetic THC.
- **Michigan**: Kratom is legal, and legislation has been proposed to regulate it under a Kratom Consumer Protection Act. Delta-8 THC is regulated as marijuana and must be sold through licensed dispensaries under the state's cannabis laws.

Local Government Actions

In the absence of consistent state or federal regulation, many municipalities have taken action to protect public health, below is a sample of communities in Illinois that have taken up local regulation.

- **Antioch, IL**: First non-home rule municipality to ban both kratom and Delta-8 THC using its business licensing authority.
- **Rolling Meadows, IL**: Banned both substances using its vape shop/tobacco licensing authority after a one-year monitoring period.
- **Elk Grove Village, IL**: Banned both substances via ordinance using its tobacco licensing authority.
- **Highland Park, IL**: Banned both substances via ordinance using its tobacco shop and smoking related uses within its zoning code.
- **Oak Park, IL**: Enacted regulations on the sale of intoxicating hemp products, which include items like gummies, chips and snacks infused with Delta-8 THC, as well as products containing kratom.
- **Orland Park, IL**: Enacted a broad ban on kratom, Delta-8, and other novel psychoactive substances.

- **Batavia, IL**: Proposed a ban on Delta-8 and similar products after undercover investigations revealed misleading marketing and youth-targeted packaging.
- **Jerseyville, Alton, Glen Carbon, Edwardsville, and Godfrey, IL**: Have all enacted local bans on kratom.

These actions reflect a growing trend among local governments to fill regulatory gaps and respond to community concerns about the safety and accessibility of these substances.

Regulatory Options for Municipalities
While non-home rule municipalities in Illinois do not possess the broad legislative authority granted to home rule communities, they are not without tools to address emerging public health concerns. The Village retains the ability to regulate the sale of substances like Kratom and Delta-8 THC through its existing powers related to business licensing, tobacco licensing, zoning, and public health. The following options outline a potential strategies the Village Board may consider to regulate the availability of these substances:

1. **Establishment of a Tobacco Licensing Program** – The Village could create a local tobacco retailer licensing program that includes Kratom and Delta-8 THC within its scope. This would allow the Village to regulate who may sell these products, impose conditions on their sale (e.g. age restrictions, signage, and packaging) and conduct compliance checks.

2. **Integration with Liquor License Conditions** – The Village may also amend its liquor license ordinance to prohibit any liquor license holder from selling Kratom, Delta-8 THC, or similar substances on the licensed premises. This approach would be particularly effective for regulating gas stations, convenience stores, restaurants/bars/taverns that already operate with a liquor license. However, it would limit regulation on smoke shops or retail businesses that do not possess a liquor license.

3. **Zoning and Land Use Controls** – Through its zoning authority, the Village may restrict where Kratom and Delta-8 THC products can be sold. For example, sales could be prohibited within certain distances of schools, parks, day cares, or residential neighborhoods. Zoning restrictions can help limit youth exposure and concentrate sales in areas that are easier to monitor and enforce.

Policy Questions for Village Board Consideration
As the Village Board evaluates potential regulatory responses, the following questions may guide discussion:

1. Should the Village act now or wait for the outcome of pending state legislation relative to Kratom?

2. If deemed appropriate, should the Village pursue a regulatory framework for these substances?
3. Should the Village align its policy with neighboring communities to ensure regional consistency?
4. What enforcement mechanisms should be employed, and which Village Departments should take the lead?
5. What role should public education and outreach play in any regulatory strategy?

Recommendation
At this stage, staff recommends that the Board use this memorandum as a foundation for discussion and direction. Given the impending legislative action at the state level relative to Kratom, the Village Board may wish to direct staff to monitor the legislation and report back any developments that may align with desired local regulations.

If the Village Board desires to regulate both kratom and delta-8 at this time, doing so through the establishment of a tobacco license would be a prudent and effective approach to pursue at this time.

Following Board direction, staff can prepare draft ordinance language or provide sample ordinances that may be tailored to the Village's policy goals and legal authority concerning the regulation of these substances.

EXPLORING THE LEGAL LANDSCAPE OF DELTA-8 THC AND SIMILAR CANNABIS PRODUCTS

PUBLIC HEALTH LAW CENTER
at Mitchell Hamline School of Law

PRESENTERS

Dr. Gillian Schauer, PhD, MPH
Executive Director
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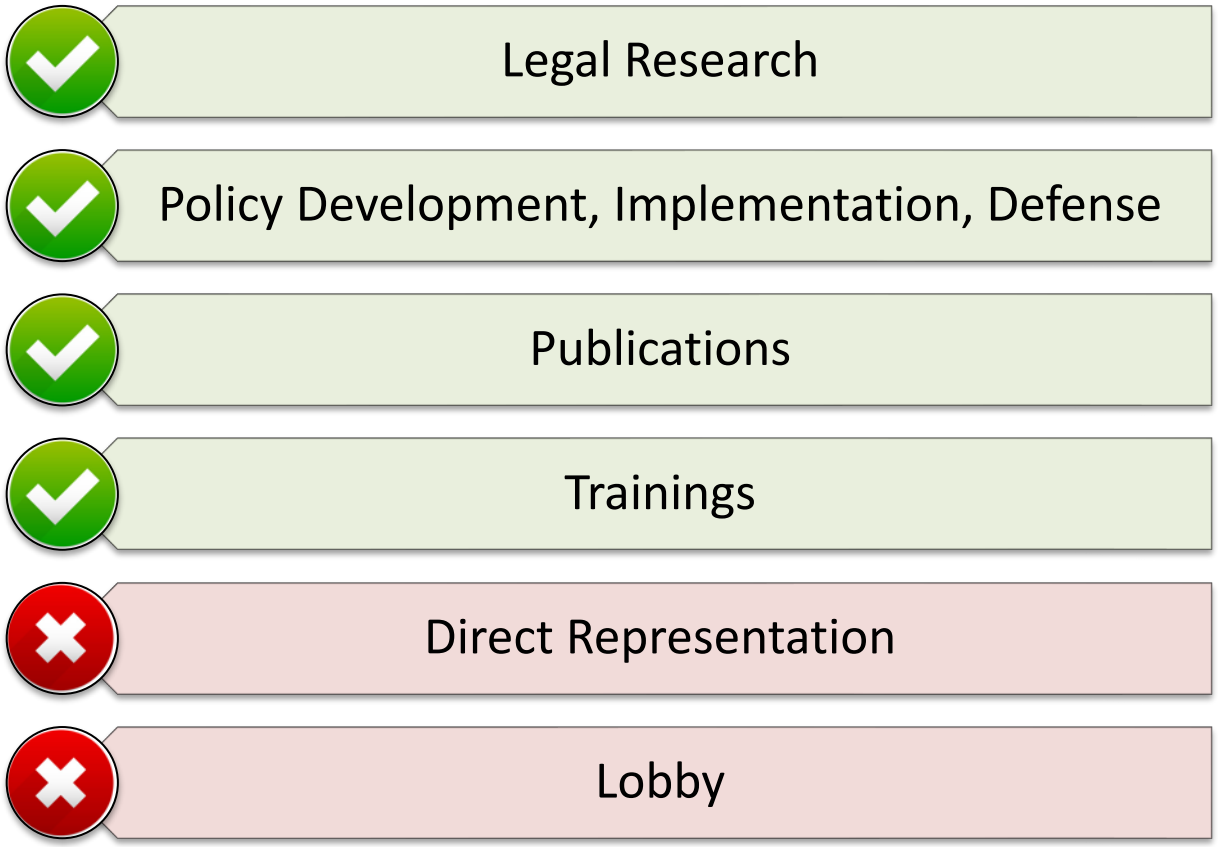
PUBLIC HEALTH LAW CENTER
at Mitchell Hamline School of Law

PUBLIC HEALTH LAW CENTER
COMMERCIAL TOBACCO CONTROL TEAM

PUBLIC HEALTH LAW CENTER
at Mitchell Hamline School of Law

LEGAL TECHNICAL ASSISTANCE



PHLC's cannabis-related work is funded through the Robert Wood Johnson Foundation.

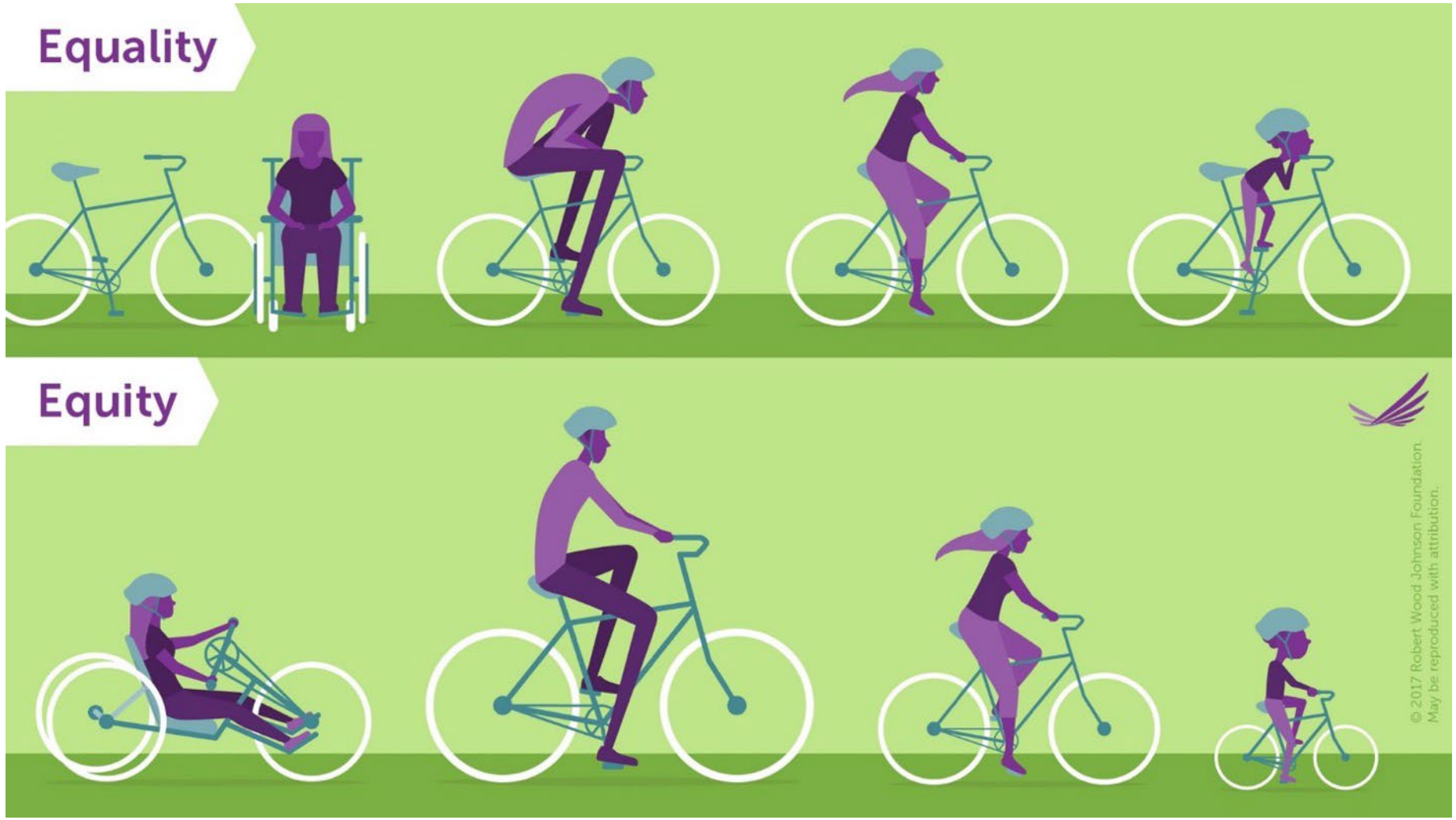

Equality
Equity
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Image credit: Sam Bradd https://drawingchange.com/gathering-wisdom-visuals-for-a-healthy-future/

OVERVIEW

- What is Delta-8 THC and how is it regulated (or not)?
- What are the lessons to be learned about regulation of new*(-ish)* products, such as Delta-8 THC and similar cannabis-derived products?
- What do public health advocates need to understand about Delta-8 THC and how does it apply to commercial tobacco work?
- Practical steps to take in your state or community to protect public health

Delta-8 THC and other Hemp-Derived Cannabinoids: Health and Consumer Safety Considerations

Gillian Schauer, PhD, MPH
Executive Director
Cannabis Regulators Association (CANNRA)

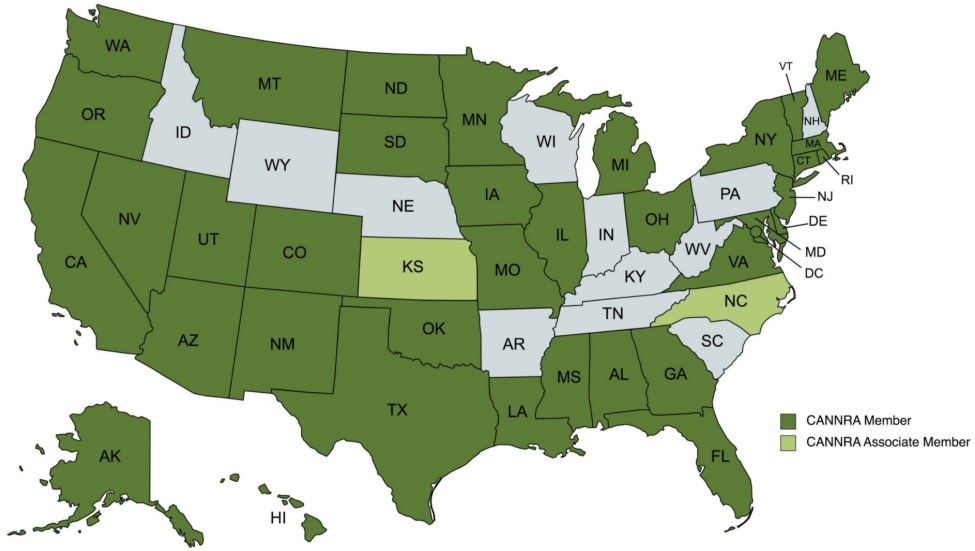
Presentation for the Public Health Law Center, June 16, 2022

Brief Overview of CANNRA

- A **national nonpartisan nonprofit organization of government officials involved in cannabis regulation** in more than 40 states and territories.
- Not an advocacy group; **takes no formal position for or against cannabis legalization**.
- Mission and goals are to:
  - Equip policymakers with unbiased information from the front lines of cannabis legalization.
  - To identify and share best practices that safeguard public health and safety, promote equity, and promote regulatory certainty for industry participants.
  - To harmonize policy across jurisdictions where possible.
- More than a dozen committees spanning the breadth of cannabis policy topics.
- Funded primarily by member agencies; no non-governmental membership.
- An affiliate of the Council of State Governments (CSG).

CANNRA

CANNABIS REGULATORS ASSOCIATION



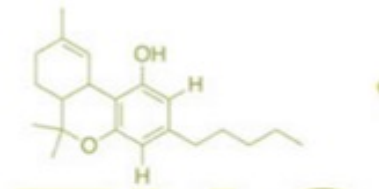
www.cann-ra.org

Disclosures and Disclaimers

I do not have anything to disclose.

This presentation is my own and does not necessarily represent an official position of CANNRA or of any of the state agencies with whom I work.

>100 Cannabinoids



THC

JANUARY 18, 2021 9:00AM ET

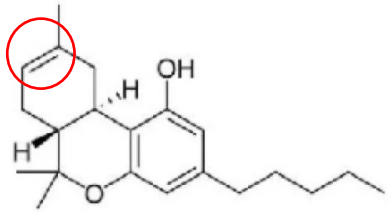
How Some THC Is Legal — For Now

Delta-8-THC — a less-potent cousin of famed Delta-9-THC — is legal enough to sell in most states. But how does it work? And will the DEA shut it down?

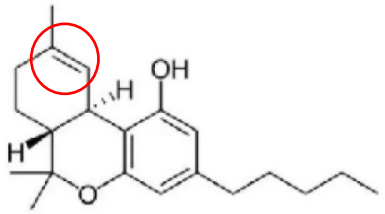
By SETH KING

What are Delta-8, 9, and 10 THC?

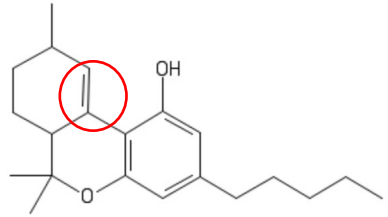
- THC has several isomers (delta-8, delta-9, delta-10)
- Delta-8 and Delta-10 are chemically different from Delta-9 THC by the location of one double bond
- Also psychotropic
  - The World Health Organization estimates D8 is 50-75% as potent as D9)



delta-8-THC



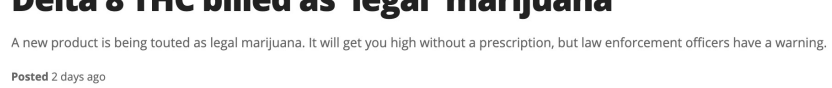
delta-9-THC



Delta-10-THC

Why hasn't delta-8 been a focus of the market until recently?

- Most states regulating cannabis have defined THC as Delta-9 THC
- Other isomers only naturally present in the plant in small quantities
- 2018 farm bill --> hemp/CBD
  - CBD can be synthetically converted into delta-8, delta-9, or delta-10 THC using solvents (e.g., benzene, ethanol) and acids (e.g, sulfuric acid, nitric acid, etc.).
- Farm bill leaves Delta-8 (and other THC isomers) in a gray area of legality (largely outside of regulatory control at present)



Federal laws and guidance on the topic

- **2018 Farm Bill:**

"The plant species Cannabis Sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, **isomers**, acids, salts, and salts of isomers, whether growing or not, **with a delta-9 THC concentration** of not more than 0.3% on a dry weight basis."

- **DEA Clarification in Federal Register Vol. 85 No. 163, Aug. 21, 2020:**

"All synthetically derived tetrahydrocannabinols remain schedule I controlled substances."

- **Ninth Circuit Appellate Court decision, May 2022:**

Trademark copyright case over Delta-8 vape products – defendant appealed initial ruling on the grounds that Delta-8 hemp was not legal under the farm bill. The Ninth Circuit Court held that the "Plain and unambiguous" text of the Farm Bill indicated that delta-8 THC products were lawful. But also added that "Regardless of the wisdom of legalizing delta-8 products, this Court will not substitute its own policy judgement for that of Congress."

What are we seeing on the market?

- Delta-8 products being advertised in mainstream outlets nationwide
- Increasingly, Delta-10 products, HHC, THC-O-Acetate, and others
- Largely vapes/oils, edibles
- Marketed as a “high without the mental side effects” (e.g., paranoia)
- Marketed with medicinal claims
- Available online, in hemp markets, in state-regulated marijuana markets

What are the potential health and safety risks?

Areas of public health concern:

- **THC isomers and other hemp-derived cannabinoids like HHC and THCO are psychotropic and impairing**
- **Consumer awareness:**
  Issues with packaging, labeling, warnings
- **Youth access issues**:
  Widely available online and in hemp markets
- **Processing and testing:**
  Contaminants and byproducts, total THC testing, testing records for recalls
- **Undermines the regulated market**

Poison Center Reports on Delta-8 Products

MICHIGAN POISON CENTER
WAYNE STATE UNIVERSITY

FACT SHEET
Emerging Public Health Concern: Delta-8 THC

- Delta-8 tetrahydrocannabinol (THC) is a cannabinoid component of *Cannabis sativa*. This chemical is distinct from delta-9 THC, the main psychoactive compound found in marijuana.
- Delta-8 THC can be extracted and made from cannabidiol (CBD) in the hemp plant. However, its effects on the body are different from CBD.
- Although less psychoactive than delta-9 THC, delta-8 THC has psychoactive properties that can cause clinically significant toxicity.
- Federally, delta-8 THC is unregulated since it is different from delta-9 THC.
- Delta-8 THC appeals to youth seeking a 'legal high'. It is available as fruit-flavored gummies and in vape solution. The colorful fruit-flavored gummies can be attractive to young children.
- Recently in a nearby state, two cases of severe adverse reactions to delta-8 THC have been reported in children.
  - The children ingested their father's gummies, purchased at a vape shop.
  - They became symptomatic with deep sedation and slowed breathing with initial increased heart rate progressing to slowed heart rate and blood pressure.
  - Both children were admitted to the intensive care unit for further monitoring and oxygen supplementation.
- Exposures to delta-8 THC have also been reported in adults with products that were mistaken for CBD-like products. These exposures led to symptoms consistent with cannabinoid intoxication.
- Delta-8 THC can cause symptoms similarly observed during cannabinoid intoxication, including:
  - Lethargy
  - Uncoordinated movements, decreased psychomotor activity
  - Slurred speech
  - Increased heart rate progressing to slowed heart rate
  - Low blood pressure
  - Difficulty breathing
  - Sedation
  - Coma
- Long-term effects of using delta-8 THC are unknown.
- There is no specific antidote. Treatment is largely symptomatic and supportive care.
- Clinicians should be vigilant in observing patients presenting with marijuana-like symptoms who do not report a marijuana exposure or history of use.
  - Symptomatic patients should be questioned about their use of CBD or delta-8-THC products.
  - It is unclear whether delta-8-THC can be detectable or cross-reacts during routine testing for delta-9-THC.

Seek help for Substance Use Disorder as soon as possible. Call the Substance Abuse and Mental Health Services Administration (SAMHSA) at 800-662-HELP (4357), or visit www.FindTreatment.gov to locate support and assistance for Substance Use Disorder in your community.

For those who have questions about drug safety or any substance call your Michigan Poison Center at

1-800-222-1222

550 E. Canfield, Suite # 354
Detroit, Michigan 48201

www.mipoisonhelp.org

THIS IS AN OFFICIAL WEST VIRGINIA SUBSTANCE ABUSE ALERT: # WV003

WEST VIRGINIA POISON CENTER

SUBSTANCE ABUSE ALERT #WV003

TO: Hospital emergency departments, community health providers, law enforcement agencies, Director, WV Emergency Medical Services, Regional Medical Directors, emergency medical services personnel, local health departments, WV Office of Drug Control Policy, WV Office of Epidemiology and Prevention Services, State Epidemiology Outcomes Workgroup members, local health departments, WV Board of Education

FROM: Elizabeth J. Scharman, Pharm.D., DABAT, BCPS, FAACT; Director, West Virginia Poison Center

DATE: March 10, 2021

DISTRIBUTION: As deemed appropriate within each agency receiving this alert

Reported Cases of Adverse Reactions to Delta-8-THC Products in West Virginia

Description:

Delta-8-THC is a cannabinoid component of *Cannabis sativa* that is a double bond isomer of Delta-9-THC, the psychotropic component of marijuana. It can be synthesized from CBD. It's actions on the body are not similar to CBD. Although less psychotropic than delta-9-THC, it does have psychotropic properties and is marketed for its psychotropic effects in fruit flavored candy gummies and vape solution.

It is promoted as being legal since it is not delta-9-THC and can be extracted and concentrated from the CBD in the hemp plant. However, some would argue that the fact it has to be synthesized into its final form puts it legality into question.

Demographics:

In March 2021, two cases of adverse reactions to Delta-8-THC products were reported in adults. In both cases it was mistaken for a product like CBD. In neighboring states, cases are also being reported that have included children requiring Intensive Care Unit admissions after exposure.

In addition to people having unintended consequences from what they thought was CBD, this drug will appeal to adults and adolescents seeking a "legal high". The fruit-flavored gummies are attractive to small children.

Patient Presentation:

Practitioners should be on the lookout for patients presenting with marijuana-like symptoms who do not report/or a parent or caregiver does not report, a marijuana exposure. Symptomatic individuals should be asked about their use of CBD or delta-8-THC products.

Delta-8-THC does not elute in the same place as delta-9-THC so the ability to detect, and cross reactivity with the different laboratory tests that hospitals use to detect delta-9-THC, is not characterized fully.

There is no specific antidote. The West Virginia Poison Center is available 24 hours a day for toxicology consultations.

Reporting:

Please report cases of acute delta-8-THC toxicity to the WV Office of Drug Control Policy as you would overdoses from other drugs of abuse.

WEST VIRGINIA POISON CENTER

SUBSTANCE ABUSE ALERT #WV003

TO: Hospital emergency departments, community health providers, law enforcement agencies, Director, WV Emergency Medical Services, Regional Medical Directors, emergency medical services personnel, local health departments, WV Office of Drug Control Policy, WV Office of Epidemiology and Prevention Services, State Epidemiology Outcomes Workgroup members, local health departments, WV Board of Education

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- Although less psychoactive than delta-9 THC, delta-8 THC has psychoactive properties that can cause clinically significant toxicity.

- Federally, delta-8 THC is unregulated since it is different from delta-9 THC.

- Delta-8 THC appeals to youth seeking a 'legal high'. It is available as fruit-flavored gummies and in vape solution. The colorful fruit-flavored gummies can be attractive to young children.

- Recently in a nearby state, two cases of severe adverse reactions to delta-8 THC have been reported in children.
  - The children ingested their father's gummies, purchased at a vape shop.
  - They became symptomatic with deep sedation and slowed breathing with initial increased heart rate progressing to slowed heart rate and blood pressure.
  - Both children were admitted to the intensive care unit for further monitoring and oxygen supplementation.

- Exposures to delta-8 THC have also been reported in adults with products that were mistaken for CBD-like products. These exposures led to symptoms consistent with cannabinoid intoxication.

- Delta-8 THC can cause symptoms similarly observed during cannabinoid intoxication, including:
  - Lethargy
  - Uncoordinated movements, decreased psychomotor activity
  - Slurred speech
  - Increased heart rate progressing to slowed heart rate
  - Low blood pressure
  - Difficulty breathing
  - Sedation
  - Coma

- Long-term effects of using delta-8 THC are unknown.

Increases in Availability of Cannabis Products Containing Delta-8 THC and Reported Cases of Adverse Events

Distributed via the CDC Health Alert Network
September 14, 2021, 10:00 AM ET
CDCHAN-00451

Summary

The purpose of this Health Alert Network (HAN) Health Advisory is to alert public health departments, healthcare professionals, first responders, poison control centers, laboratories, and the public to the increased availability of cannabis products containing delta-8 tetrahydrocannabinol (THC) and the potential for adverse events due to insufficient labeling of products containing THC and cannabidiol (CBD).

Background

Marijuana, which can also be called weed, pot, or dope, refers to all parts of the plant *Cannabis sativa L.*, including flower, seeds, and extracts with more than 0.3% delta-9 tetrahydrocannabinol (THC) by dry weight. Any part of the cannabis plant containing 0.3% or less THC by dry weight is defined as hemp.[1] The cannabis plant contains more than 100 cannabinoids, including THC, which is psychoactive (i.e., impairing or mind-altering) and causes a "high".[2] CBD is another active cannabinoid found in the cannabis plant that is not psychoactive and does not cause a "high".

FDA Actions to Date

FDA NEWS RELEASE

FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products

Violations Include Marketing Unapproved New Drugs, Misbranding, Adding Delta-8 THC to Food Products

Share | Tweet | Linkedin | Email | Print

For Immediate Release: May 04, 2022

Cannabis-Derived Products Data Acceleration Plan

Share | Tweet | Linkedin | Email | Print

Content current as of:
10/16/2021

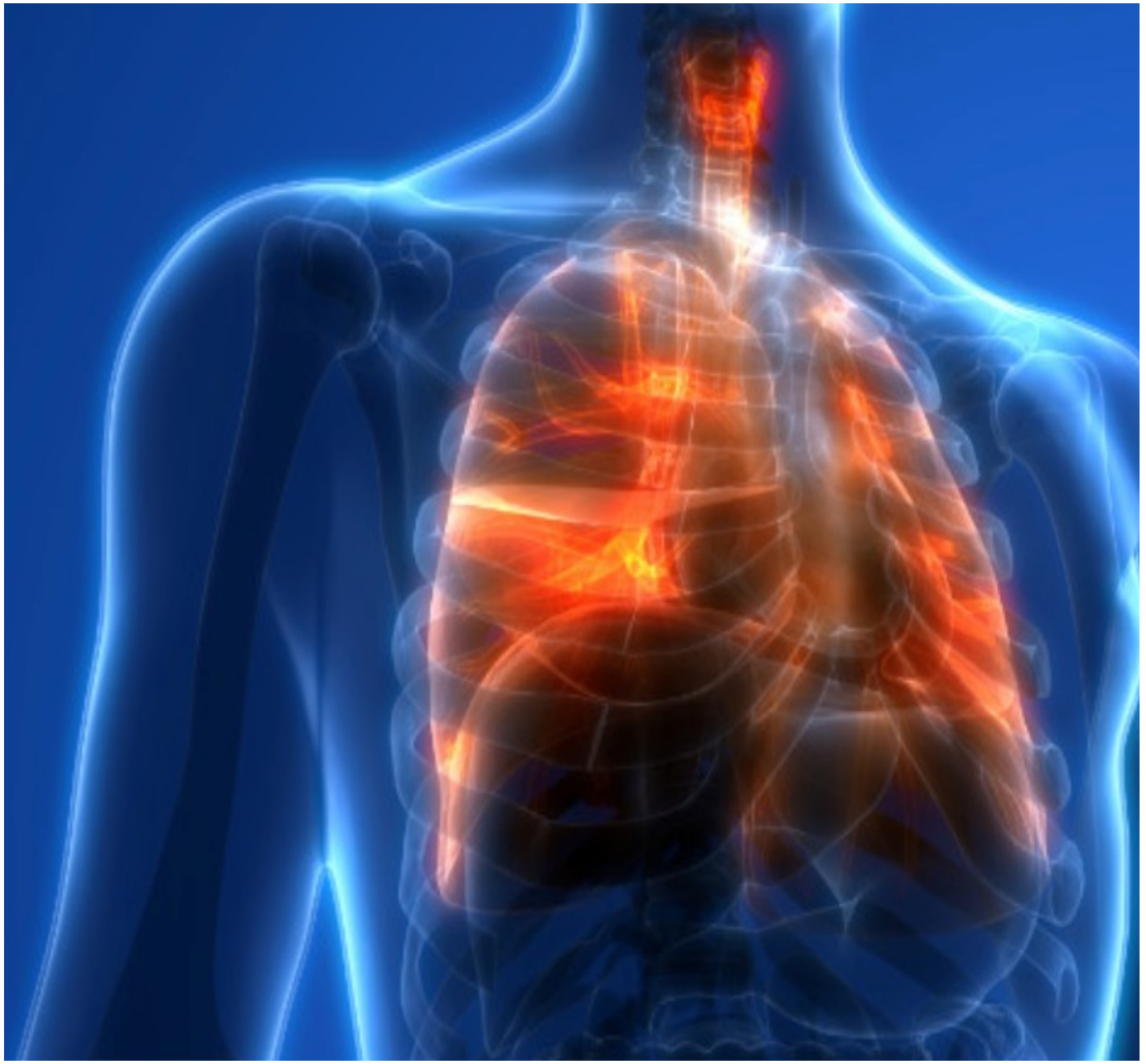
U.S. Cannabis Council report on Delta-8

- Tested 16 Delta-8 products obtained legally from the market
- Testing conducted by ProVerde labs
- Findings:
  - All contained Delta-8 THC
  - Some contained Delta-9 THC (with a mean concentration of more than 10 times the USDA hemp limit of 0.3%)
  - Lead was detected in 4/16 samples
  - Other metals (e.g., copper, chromimum, nickel) detected in 7/16 samples
  - Residual solvents detected in a majority of samples
  - 7-10 compounds in each sample were of unknown identification

US CANNABIS COUNCIL

A cautionary tale:
E-Cigarette and Vaping Lung Injury (EVALI)

- Peaked in 2019
- 68 confirmed deaths across 29 states and DC; 2,807 hospitalizations across 50 states and DC
- Largely unregulated products from illicit or informal sources
- Unsafe byproducts and diluents (Vitamin E Acetate was named as one cause)
- Labeling and recall issues in a number of states



Delta-8 yesterday and today….

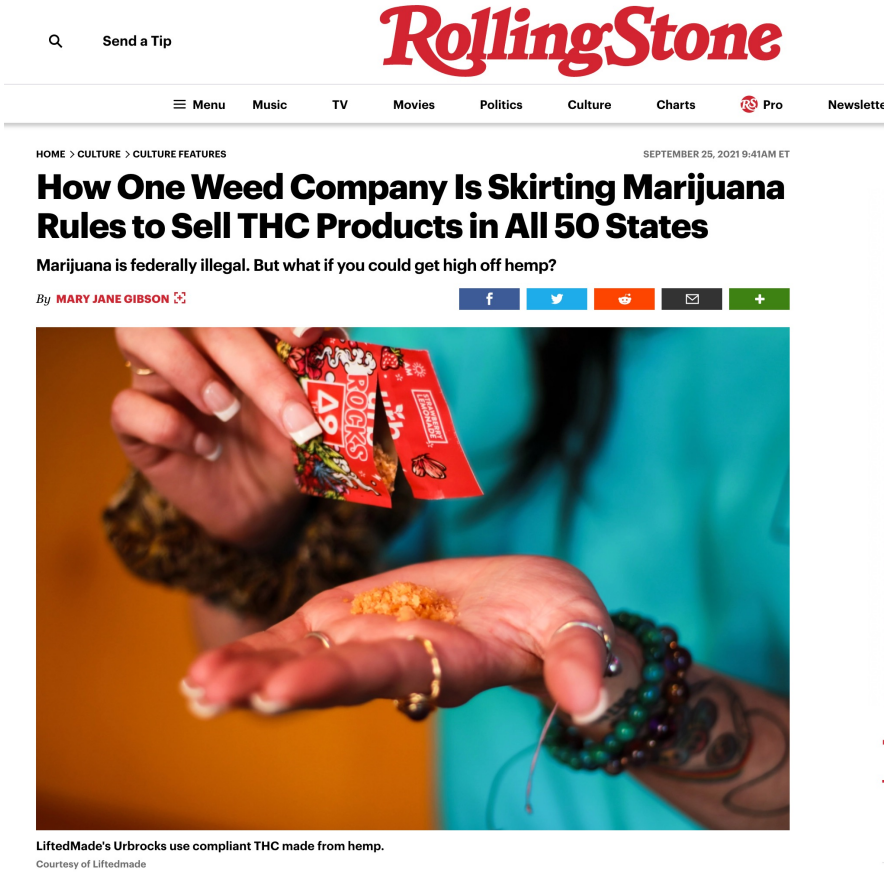
??? tomorrow….

THC-O Acetate
Hexahydrocannabinol
THC-P
THC-V

Quantity of Legal Delta-9 THC in hemp products

- 0.3% Delta-9 THC in dry weight can result in a much higher proportion of THC in concentrated form.

A collaboration between Urb Finest Flowers and Delta Extrax! Introducing Premium Delta 9 THC Gummies. These 6-gram gummies feature 10mg of hemp-derived Delta-9 THC. These gummies are a fully legal hemp product under the 2018 Hemp Farm Bill as they contain 0.1% delta-9-THC.



Delta-9 THC in legal hemp products

- Excerpt from testimony by OLCC on HB 3000 in 2021 session

  - High-THC hemp edibles can legally be sold to consumers in Oregon, including minors, as long as they are below 0.3% Delta-9-THC.

(item pictured is not a marijuana or hemp item)

What does 0.3% look like? "Fun Size" of gummies		
	Hemp Potency Limit	**Adult-Use Marijuana Limit**
20 g pack of gummies	60 mg Δ^9-THC	50 mg Δ^9-THC

Policy approaches other states have pursued

- Allow these products on both markets.
- Outlaw these products on both markets.
- Regulate these products within the context of the hemp regulatory framework.
- Outlaw these products in the hemp market but allow on the regulated cannabis/marijuana market.

Challenges in regulation of hemp

- Highly technical subject that legislatures often don’t fully understand
  - Disagreement on how to define “impairing” and where to draw the line
  - What to do about non-natural synthetics (like THCO, HHC)?
  - What to do about biosynthetically derived cannabis?
- Different agencies regulating hemp and cannabis
- Public health testimony often missing from legislative discussions

Conclusions

- CBD is being chemically converted into a number of impairing cannabinoids – some that exist in nature and some that do not.
- Hemp-derived products have a range of public health and consumer safety concerns, including availability to youth
- Safety profiles are unavailable/do not exist for a number of the new hemp-derived cannabinoids that are entering the market
- Federal regulatory inaction has pushed this issue to the states
- State regulation of hemp looks different from state to state
- Public health has a role to play in education and policy

Questions?

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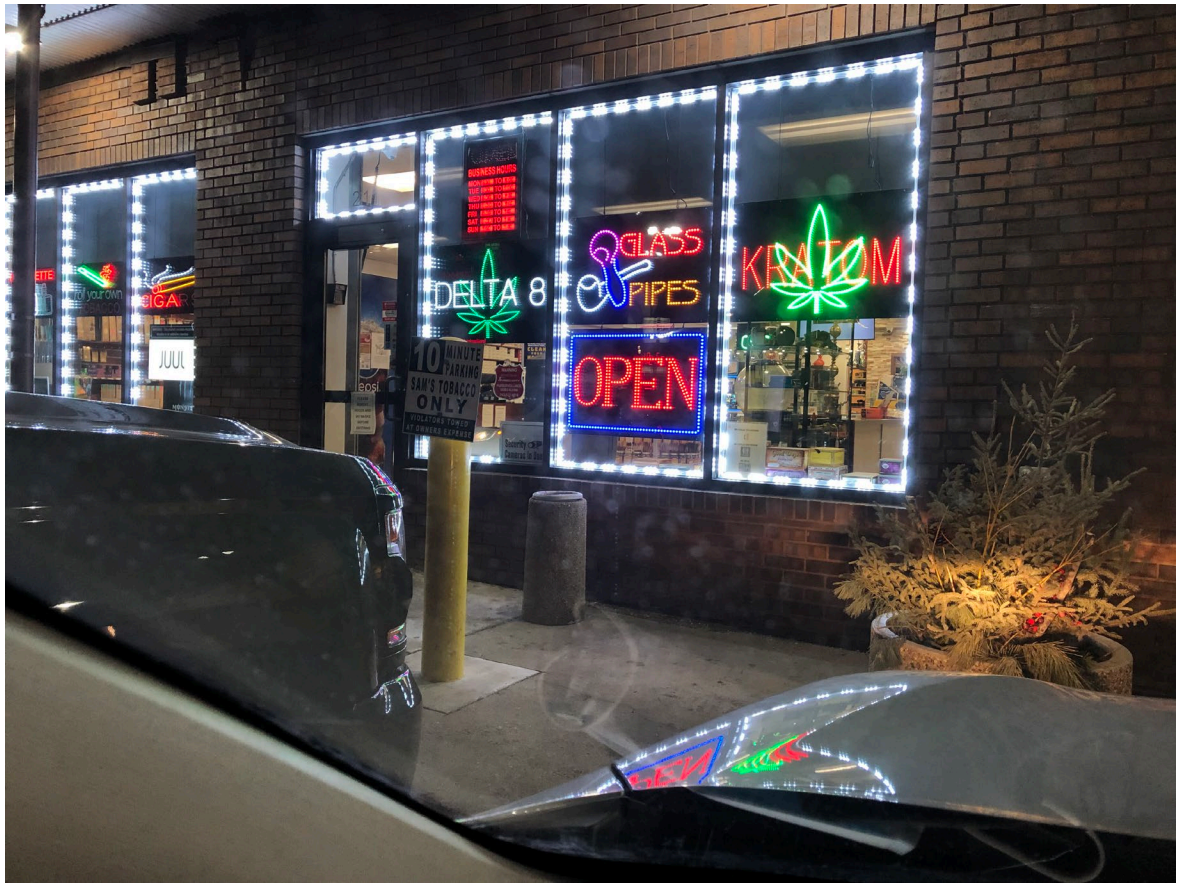
WHAT DO PUBLIC HEALTH ADVOCATES NEED TO UNDERSTAND ABOUT DELTA-8 THC AND HOW IS IT RELEVANT TO COMMERCIAL TOBACCO PREVENTION?



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WHAT DO DELTA-8 AND SIMILAR PRODUCTS LOOK LIKE?

Delta-8 THC and similar products are sold as:

- food/beverages,
- e-cigarettes, &
- combustibles

Photo Credit: Association for Nonsmokers-MN (ANSR)

Photo Credit: Association for Nonsmokers-MN (ANSR)

Photo Credit: Association for Nonsmokers-MN (ANSR)

Photo Credit: Association for Nonsmokers-MN (ANSR)

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DELTA-8 THC AND SIMILAR INTOXICATING SUBSTANCES

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FDA warning: https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc

WHERE ARE DELTA-8 THC & SIMILAR PRODUCTS SOLD?

St. Paul, MN
(Photo: PHLC)

Mall of America, Bloomington, MN
(Photo: PHLC)

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WHAT CAN PUBLIC HEALTH ADVOCATES AND COMMUNITIES DO?

- Determine if these products are regulated at the state level and which state agencies are/should be charged with regulating these products
  - Identify the reporting or complaint process

- Public Awareness
  - Inform communities about possible dangers of Delta-8 products, and issue policy briefs and guidance

WHAT CAN PUBLIC HEALTH ADVOCATES AND COMMUNITIES DO?

- Work with state cannabis regulators:
  - Share information with regulators about what is on the market and any concerns or challenges faced
  - Report manufacture and sales violations to appropriate regulators
    - State Board of Pharmacy
    - State Dept. of Agriculture
    - State Attorney General and Law enforcement
- Urge greater federal regulation for health and safety
  - Food, Drug, and Cosmetic Act enforcement--health claims, food additives, drugs

WHAT CAN PUBLIC HEALTH ADVOCATES AND COMMUNITIES DO?

- Identify the intersections with other state or local laws:
  - **Drug regulations**
  - **Food regulations**
  - **Clean indoor air/smoke-free policies**—state/local depends on definitions of smoking. May cover bud version and/or e-cig versions.
    - Similarly, individual policies for smoke-free parks, workplaces, housing, schools and other locations should revisit their definitions to ensure that smoking any of these products is covered.
  - **Point of Sale commercial tobacco regulations**—state or local restrictions or regulations on sale may fall under the definitions of electronic smoking device—but may not cover edibles and other forms of products.

MINNESOTA EXAMPLE

- The Minnesota Department of Agriculture has indicated that **food products containing delta-8 are not legal for sale in Minnesota**. (Gummies, candy, chips, etc.)

- The Minnesota Board of Pharmacy has indicated that **non-food delta-8 products are also not legal for sale because they are intoxicating**.

- The Minnesota Clean Indoor Air Act **prohibits smoking and vaping Delta-8 products anywhere smoking is prohibited under the Act**.

Mall of America, Bloomington MN
(Photo: PHLC)

MINNESOTA'S CLEAN INDOOR AIR ACT COVERS "SMOKING" ANY DELTA-8 PRODUCT

- The Minnesota Clean Indoor Air Act:
  - "Smoking" means inhaling, exhaling, burning, or carrying any lighted or heated cigar, cigarette, pipe, or any other lighted or heated product containing, made, or derived from nicotine, tobacco, *marijuana, or other plant, whether natural or synthetic*, that is intended for inhalation. Smoking includes carrying or using an activated electronic delivery device, as defined in section 609.685. (emphasis added) Minn. Stat. Sec. 144.413 Subd. 4 (2020)

- Under the MCIAA, smoking is prohibited in virtually all indoor public places and places of work.

LOCAL SMOKE-FREE LAWS AND INDIVIDUAL SMOKE-FREE POLICIES MAY ALSO COVER "SMOKING" DELTA-8 PRODUCTS

- Local smoke-free laws:
  - Minnesota Clean Indoor Air Act allows local jurisdictions to enact laws and regulations that are stronger and more protective than the state law.
  - Many Minnesota local jurisdictions have enacted stronger smoke-free laws covering outdoor areas, including parks and recreation areas, and prohibiting smoking in tobacco and vape shops.

INDIVIDUAL SMOKE-FREE POLICIES MAY ALSO COVER "SMOKING" DELTA-8 PRODUCTS

- Individual smoke-free policies
  - Workplaces
  - Smoke-free housing
  - Smoke-free schools

COMMERCIAL TOBACCO POINT OF SALE REGULATIONS MAY APPLY TO SOME PRODUCTS

- "Electronic delivery device" means any product containing or delivering nicotine, lobelia, or any other substance, whether natural or synthetic, intended for human consumption through inhalation of aerosol or vapor from the product. Electronic delivery device includes but is not limited to devices manufactured, marketed, or sold as electronic cigarettes, electronic cigars, electronic pipe, vape pens, modes, tank systems, or under any other product name or descriptor. Electronic delivery device includes any component part of a product, whether or not marketed or sold separately. Electronic delivery device excludes drugs, devices, or combination products, as those terms are defined in the Federal Food, Drug, and Cosmetic Act, that are authorized for sale by the United States Food and Drug Administration. (Minn. Stat. § 609.685, subd. 2 (c)

- "Tobacco-related devices" means cigarette papers or pipes for smoking or other devices intentionally designed or intended to be used in a manner which enables the chewing, sniffing, smoking, or inhalation of aerosol or vapor of tobacco or tobacco products. Tobacco-related devices include components of tobacco-related devices which may be marketed or sold separately. (Minn. Stat. § 609.685, subd. 2 (b))

TOBACCO SALES REGULATIONS MAY APPLY TO SOME PRODUCTS (ELECTRONIC SMOKING DEVICES)

- **No sales under age 21** (Minn. Stat. § 461.12, subd. 2)
- **No self-service sales**, unless a retail store has an entrance that opens directly to the outside, derives at least 90 percent of gross revenue from the sale of licensed products, and no person under age 21 is present or permitted to enter at any time (Minn. Stat. § 461.18, subd. 1)
- **No vending machine sales**, unless the vending machine is located in a facility that cannot be entered at any time by persons under age 21 (Minn. Stat. § 461.18, subd. 2)
- **Require child-resistant packaging** for sale of a liquid intended to be used with electronic delivery devices, whether or not it contains nicotine (Minn. Stat. § 461.20)
- **No sales from a moveable place of business** or kiosk (Minn. Stat. § 461.21)
- **Required signage** to communicate that any sales to persons under age 21 are illegal and subject to penalties (Minn. Stat. § 461.22, subd. 1)
- **Require age verification** for sales to persons under age 30 (Minn. Stat. § 461.22, subd. 2)

PUBLIC HEALTH LAW CENTER RESOURCES

COMMERCIAL TOBACCO & MARIJUANA

Decriminalization of marijuana is an important step towards health equity and repairing the damage to communities and individuals caused by punitive and discriminatory drug laws. Many states have legalized or are considering legalizing the use and sale of marijuana for medical and recreational purposes, but despite general public support, legalization and regulation of marijuana presents many public health, safety, and social justice challenges. Although marijuana and commercial tobacco differ, many of the strategies used to regulate them are similar, as are the regulatory obstacles these strategies present. Public health advocates and tobacco control professionals must be able to address the policy impacts of recreational marijuana use on hard-won tobacco control laws and other measures to protect public health.

MARIJUANA USE BY EMPLOYEES: DRUG-FREE POLICIES AND THE CHANGING LEGAL LANDSCAPE

TOBACCO, RECREATIONAL MARIJUANA, AND THE SHIFTING PREROGATIVES OF USE

MARIJUANA IN MULTI-UNIT RESIDENTIAL SETTINGS

THERE IS NO CONSTITUTIONAL RIGHT TO SMOKE OR TOKE

TOKING, SMOKING & PUBLIC HEALTH: LESSONS FROM TOBACCO CONTROL FOR

Search Commercial Tobacco an

VIDEOS

Cannabis Regulation: High Time for a Public Health & Equity Approach →

What if Marijuana Were NOT a Schedule 1 Drug?: Legal and Policy Implications →

Marijuana Mayhem: Regulatory Lessons from Tobacco Control →

Palliative Care versus Harmful Exposure: Secondhand Medical Marijuana Smoke in Multi-Unit Housing →

PUBLIC HEALTH LAW CENTER at Mitchell Hamline School of Law / MARIJUANA

WHAT'S THE DEAL WITH DELTA-8 THC?

Frequently Asked Questions

Cannabis is a species of plant containing hundreds of different chemical compounds known as cannabinoids.[1]

The two most prevalent cannabinoids are cannabidiol (CBD), a non-psychoactive compound, and Delta-9 tetrahydrocannabinol (THC), the compound responsible for the psychoactive effects experienced when using marijuana.[2] Delta-8 THC, on the other hand, is a compound not naturally occurring in significant amounts in the cannabis plant. Instead, concentrated amounts are manufactured through a chemical extraction process from hemp-derived CBD.[3] Often marketed as "weed lite" or "diet weed," Delta-8 THC is estimated to be 50 to 75 percent as psychoactive as Delta-9 THC, and is frequently sold and marketed as an intoxicating product.[4]

Delta-8 THC is widely available in a variety of products, such as gummies, tinctures, candies, vape pens, oils, and beverages, and is often found online and in convenience stores, gas stations, tobacco product shops, CBD shops, and other retail establishments. The growing popularity of Delta-8 products has raised concerns regarding legal sale and manufacture and health and safety risks, particularly to youth, and spurred a rare health warning by the CDC in September 2021.[5] This fact sheet addresses a few frequently asked questions about Delta-8 THC products, including regulatory options.

Photo: Association for Nonsmokers — MN (ANSR)

www.publichealthlawcenter.org

PUBLIC HEALTH LAW CENTER at Mitchell Hamline School of Law

https://www.publichealthlawcenter.org/topics/commercial-tobacco-control/commercial-tobacco-and-marijuana

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REGULATION OF KRATOM IN AMERICA: UPDATE

SEPTEMBER 2022

WHAT IS KRATOM?

Kratom is an herb that is derived from a leafy Southeast Asian tree, known formally as *Mitragyna speciosa*. The tree is native to a number of countries, including Indonesia, Malaysia, and Thailand and is a member of the coffee family. Kratom contains two psychoactive compounds, mitragynine and 7-hydroxymitragynine; both compounds bind to μ-opioid receptors in the brain and produce a pharmacological response that is similar to those produced by other μ-opioid agonists, such as morphine.

Historically, individuals began ingesting kratom in the 19th century. Farmers in Southeast Asia traditionally used kratom to boost their productivity and as a substitute for opium. When consumed in small doses, kratom produces a mild stimulant effect; in moderate to high amounts, kratom produces opioid like effects. At very high doses it acts like a sedative.

THE USE OF KRATOM IN AMERICA

Soldiers returning from the Vietnam war and immigrants from Southeast Asia introduced kratom to America. However, it was not until the past 15 years that kratom use started to become more mainstream. An estimated 11 to 15 million Americans consume kratom products regularly.[1] In the U.S., kratom can be purchased online and in head shops, gas stations, and corner stores. Kratom is relatively inexpensive, selling for nine to 20 dollars per ounce on the internet. The kratom industry generated $1.3 billion in sales in 2019.[2]

Typically sold as a bitter powder, individuals consume kratom by swallowing capsules or using the powder to make tea. In a survey of 2,798 kratom users conducted by researchers at Johns Hopkins University School of Medicine, individuals cited pain relief, treating anxiety and depression, and managing opioid dependance as reasons for using kratom.[3] Of those who use kratom to manage opioid dependence, 87 percent reported relief from opioid withdrawal symptoms.[4] As kratom's use rose in the U.S., so did calls to poison control centers about kratom exposures. In 2011, poison control received 13 calls nationwide related to kratom exposure; in 2017, the number of calls skyrocketed to 682.[5] With respect to adult kratom exposure cases occurring between 2011 to 2017, 32 percent of cases resulted in an admission to a healthcare facility, and 52 percent of cases resulted in a serious medical outcome, such as seizure, respiratory distress, or slow heartrate.[6]

KRATOM REGULATION AT THE FEDERAL AND STATE LEVELS

Despite kratom's mainstream presence for a relatively short period in the U.S., its use has managed to cause much controversy. Federal regulators and kratom organizations are at odds about the potential dangers (or lack thereof)

[1] "Policy Brief: What is Kratom?," American Kratom Association, last modified January 2021, https://assets.website-files.com/61858fcec654303987617512/619ddeac793d144d09fbc28a_aka-policy-brief-1---what-is-kratom-jan-2021.pdf.
[2] Paul Georgia, "The Human and Economic Impacts of the Kratom Industry in the United States," American Kratom Association, last modified September 24, 2021, https://drive.google.com/file/d/1ChyAKfdOrWzckau9kKwWti1F47D0WjUO/view.
[3] Albert Garcia-Romeu, et al., "Kratom (*Mitragyna speciosa*): User Demographics, Use Patterns, and Implications for the Opioid Epidemic," *Drug and Alcohol Dependance* 208 (March 2020), https://doi.org/10.1016/j.drugalcdep.2020.107849.
[4] *Id.*
[5] Sara Post, et al., "Kratom Exposures Reported to United States Poison Control Centers: 2011-2017," *Clinical Toxicology* 57, no. 10 (February 2019): 847-854, https://doi.org/10.1080/15563650.2019.1569236.
[6] *Id.*

of kratom and how kratom should be regulated. In addition to battles on the federal level, several states banned, or considered banning, kratom products.

The federal government's positions and actions toward kratom

In 2009, nine people died in Sweden over the course of a 12-month period after consuming a kratom product known as "Krypton."[7] Subsequent testing showed that the kratom product at issue contained a toxic level of the opioid tramadol.[8] With the deaths in Sweden and the increase in kratom consumption in the U.S., the U.S. Food and Drug Administration (FDA) became concerned about the use of kratom due to the FDA's limited knowledge about kratom's safety and effect on consumers. In 2012, the FDA identified kratom on an "import alert" for unapproved drugs, which it subsequently affirmed by another import alert in 2014.[9] As a result of these alerts, the FDA seized more than 25,000 pounds of raw kratom, worth more than $5 million, in California during September 2014.[10] In January 2016, the FDA seized approximately 90,000 bottles of dietary supplements containing kratom in Illinois, and in August 2016, the FDA seized more than 100 cases of kratom products worth more than $150,000 in California.[11] Most recently, in May 2021, U.S. Marshals, at the FDA's request, seized more than 207,000 units of dietary supplements containing kratom valued at approximately $1.3 million.[12]

On August 31, 2016, the U.S. Drug Enforcement Agency (DEA), published a notice of intent to list kratom's two psychoactive compounds, mitragynine and 7-hydroxymitragynine, as Schedule I controlled substances under the emergency scheduling provisions of the Controlled Substances Act.[13] The kratom community was outraged by this decision. In September 2016, kratom organizations organized the "March for Kratom" at the White House and convinced 51 members of Congress on both sides of the aisle to sign a letter against the DEA's proposal.[14] Additionally, kratom supporters sent a petition containing more than 145,000 signatures to President Obama against the DEA's proposal.[15] As a result of the backlash, the DEA withdrew the scheduling notice on October 13, 2016, and instead, opened a public comment period to solicit comments regarding the scheduling of mitragynine and 7-hydroxymitragynine. It stated that it would receive a scientific and medical evaluation and scheduling recommendation from the FDA.[16] Interested parties submitted over 23,000 comments, with 99.1 percent of them opposing the ban.[17]

In October 2017, the FDA renewed its interest in scheduling kratom's two psychoactive compounds and submitted an "eight-factor" analysis to the DEA.[18] A month later, the FDA announced a public health advisory on kratom, asserting that kratom was associated with 36 deaths and has similar effects and dangers to other opioids.[19]

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[7] "Swedish Docs Identify Deadly Legal Drug," *The Local*, December 29, 2010, https://www.thelocal.se/20101229/31134/.
[8] *Id.*
[9] "FDA and Kratom," U.S. Food and Drug Administration, last modified April 27, 2022, https://www.fda.gov/news-events/public-health-focus/fda-and-kratom.
[10] *Id.*
[11] *Id.*
[12] "FDA Announces Seizure of Adulterated Dietary Supplements Containing Kratom," U.S. Food and Drug Administration, last modified October 29, 2021, https://www.fda.gov/news-events/press-announcements/fda-announces-seizure-adulterated-dietary-supplements-containing-kratom.
[13] "DEA Announces Intent to Schedule Kratom," Drug Enforcement Administration, last modified August 20, 2016, https://www.dea.gov/press-releases/2016/08/30/dea-announces-intent-schedule-kratom.
[14] Steven Nelson, "Dozens of Congressmen Ask DEA Not to Ban Kratom Next Week," *U.S. News*, September 23, 2016, https://www.usnews.com/news/articles/2016-09-23/45-congressmen-ask-dea-not-to-ban-kratom-next-week.
[15] "Please do not make Kratom a Schedule I Substance," We the People, last accessed August 17, 2022, https://petitions.obamawhitehouse.archives.gov/petition/please-do-not-make-kratom-schedule-i-substance/.
[16] Withdrawal of Notice of Intent to Temporarily Place Mitragynine and 7-hydroxymitragynine into Schedule I, 81 Fed. Reg. 70,652 (Oct. 13, 2016).
[17] " Review Of DEA Kratom Public Comments Shows Strong Support Among Vets, Doctors, Cops And Seniors For Coffee-Like Herb," *PR Newswire*, February 2, 2017, https://www.prnewswire.com/news-releases/review-of-dea-kratom-public-comments-shows-strong-support-among-vets-doctors-cops-and-seniors-for-coffee-like-herb-300401575.html.
[18] "Leading Scientists Strongly Reject FDA 8-Factor Analysis Of Kratom, Call Upon The DEA And NIDA To Reexamine FDA Claims," *PR Newswire*, November 28, 2018, https://www.prnewswire.com/news-releases/leading-scientists-strongly-reject-fda-8-factor-analysis-of-kratom-call-upon-the-dea-and-nida-to-reexamine-fda-claims-300757232.html. The eight factors to be considered in permanently scheduling a substance as controlled are identified in 21 U.S.C. § 811(c).
[19] "Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom," U.S. Food and Drug Administration, last modified April 5, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fda-advisory-about-deadly-risks-associated-kratom.

On February 6, 2018, the FDA issued a statement increasing the number of kratom-associated deaths to 44.[20] The FDA also announced through this statement that it developed a new technology, called the Public Health Assessment via Structural Evaluation (PHASE) model, that could "simulate, using 3-D computer technology, how the chemical constituents of a substance are structured at a molecular level, how they may behave inside the body, and how they can potentially affect the brain."[21] Based on the data obtained from the PHASE model, the FDA stated "[it felt] confident in calling [the] compounds found in kratom, opioids."[22]

In July 2018, the FDA concluded that numerous kratom products contained extremely high amounts of salmonella.[23] According to the FDA, as of the end of May 2018, 199 cases of salmonellosis in 41 states were associated with kratom consumption.[24] Due to the outbreak, multiple kratom products were voluntarily recalled, but the FDA issued a mandatory recall order against one kratom supplier who failed to cooperate with the voluntary recall.[25] The trouble with kratom products continued in April 2019, when the FDA discovered 30 different kratom products that contained nickel and lead in amounts exceeding the safe exposure limit for oral daily drug intake.[26] In June 2019, the FDA issued warning letters to two kratom marketers and distributors, Cali Botanicals and Kratom NC, "for illegally selling unapproved, misbranded kratom-containing drug products with unproven claims about their ability to treat or cure opioid addiction and withdrawal symptoms."[27] These companies also made claims "that kratom can protect you against cancer," and that it can treat, among other disorders, migraines, ADHD/ADD, depression, and arthritis.[28] In July 2022, the FDA, jointly with the Federal Trade Commission, issued similar warning letters to four companies selling unapproved kratom products for the treatment or cure of opioid use disorder and withdrawal symptoms.[29]

The World Health Organization's position on kratom

In July 2021, the World Health Organization (WHO) announced that it would conduct a pre-review of kratom while at its annual Expert Committee on Drug Dependence (ECDD) meeting.[30] The ECDD is an independent, international group of 12 experts in the field of drugs and medicines tasked with reviewing the public health impact of psychoactive substances and making recommendations to the international community.[31] The ECDD

[20] "Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's scientific evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse," U.S. Food and Drug Administration, last modified April 5, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-scientific-evidence-presence-opioid-compounds.
[21] *Id.*
[22] *Id.*
[23] "Statement from FDA Commissioner Scott Gottlieb, M.D. and FDA Deputy Commissioner for Foods and Veterinary Medicine Stephen Ostroff, M.D., on the ongoing risk of salmonella in kratom products," U.S. Food and Drug Administration, last modified July 2, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-fda-deputy-commissioner-foods-and-veterinary.
[24] *Id.*
[25] *Id.*
[26] "Laboratory analysis of kratom products for heavy metals," U.S. Food and Drug Administration, last modified April 3, 2019, https://www.fda.gov/news-events/public-health-focus/laboratory-analysis-kratom-products-heavy-metals.
[27] "FDA issues warnings to companies selling illegal, unapproved kratom drug products marketed for opioid cessation, pain treatment and other medical uses," U.S. Food and Drug Administration, last modified June 25, 2019, https://www.fda.gov/news-events/press-announcements/fda-issues-warnings-companies-selling-illegal-unapproved-kratom-drug-products-marketed-opioid.
[28] *Id.*
[29] "FDA Roundup: July 5, 2022," U.S. Food and Drug Administration, last modified July 5, 2022, https://www.fda.gov/news-events/press-announcements/fda-roundup-july-5-2022.
[30] "Five New Psychoactive Substances to be Considered for International Control by 44th ECDD Meeting," United Nations Office on Drugs and Crime, last accessed August 17, 2022, https://www.unodc.org/LSS/Announcement/Details/601d676a-ec14-48df-8333-f167d7997baf.
[31] "Expert Committee on Drug Dependence: About Us," World Health Organization, last accessed August 17, 2022, https://www.who.int/groups/who-expert-committee-on-drug-dependence/about.

conducts a pre-review of a substance to determine whether current information justifies a critical review by the committee.[32] A pre-review is only a preliminary analysis of a substance, and the findings do not determine whether the substance under review should be scheduled.[33]

On July 23, 2021, the FDA put out a request for comments on the "abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use" of kratom and the other six substances set to be reviewed during the ECDD's October 2021 meeting.[34] The FDA planned to consider the comments in preparing a response from the U.S. to the WHO regarding the misuse and diversion potential of the substances up for review.[35] The WHO then used the information provided by the U.S., as well as information from other countries, when considering whether to recommend a substance be subject to international restrictions.[36] In addition to the public comments requested by the FDA, Senator Mike Lee (R-UT) and Representative Mark Pocan (D-WI) sent a letter to the Secretary of the U.S. Department of Health and Human Services and the U.S. Ambassador to the United Nations asking that the U.S. oppose any effort to add kratom to the list of internationally controlled substances.[37] The letter stated that there is no conclusive evidence that would warrant the U.S. voting in favor of international scheduling of kratom and that more research is needed to better understand kratom's safety profile.[38]

In December 2021, the ECDD released a summary of its assessments, findings, and recommendations from the October 2021 meeting.[39] In an 11-1 decision, the committee determined that there is insufficient evidence to recommend a critical review of kratom.[40] The committee recommended that kratom instead continue to be under surveillance by the WHO Secretariat, which it has been since 2020.[41]

The American Kratom Association's positions

Established in 2014, the American Kratom Association (AKA) is a Virginia-based non-profit corporation that advocates on behalf of American kratom users. The AKA opposes the attempts by the FDA and the DEA to schedule kratom and strongly disagrees with the FDA's assertions that kratom is a dangerous substance with a high potential for abuse. As opposed to opioids, the AKA asserts that the pattern of use and the abuse potential for kratom is similar to unscheduled substances, like caffeine.[42] Additionally, the AKA claims that no fatal overdoses are associated with pure kratom.[43] The organization alleges that none of the 44 deaths reported by the FDA

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[32] 44th Expert Committee on Drug Dependance: Substances for review, last accessed August 17, 2022, https://cdn.who.int/media/docs/default-source/2021-dha-docs/v2.annex1_final_44th-ecdd-list-of-substances.pdf?sfvrsn=83978385_1&download=true#:~:text=The%20purpose%20of%20a%20pre,a%20substance%20should%20be%20changed.
[33] *Id.*
[34] International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; . . . Kratom (mitragynine, 7-hydroxymitragynine). . . Request for Comments, 86 Fed. Reg. 39,038 (July 23, 2021).
[35] *Id.*
[36] *Id.*
[37] Letter from Sen. Michael Lee and Rep. Mark Pocan, to Linda Thomas-Greenfield, U.S. Ambassador to the U.N., and Xavier Becerra, Sec'y of the Dep't of Health and Hum. Serv. (Oct. 19, 2021), available at https://s3.documentcloud.org/documents/21093913/lee-pocan-191021-kratom-letter-to-unhhs.pdf.
[38] *Id.*
[39] Expert Comm. on Drug Dependance, Summary of Assessments, Findings, and Recommendations of the 44th ECDD (2021), available at https://cdn.who.int/media/docs/default-source/controlled-substances/44ecdd_unsg_annex1.pdf.
[40] *Id.*
[41] *Id.*
[42] Jack E. Henningfield, et al., "The Abuse Potential of Kratom According the 8 Factors of the Controlled Substances Act: Implications for Regulation and Research," *Psychopharmacology* 235 (December 2017): 573-589, 575, https://doi.org/10.1007/s00213-017-4813-4.
[43] *Id.* at 583.

display any cause that is consistent among all the cases or that can be specifically linked to the use of kratom.[44] Moreover, the AKA argues that the FDA did not take into consideration polydrug use, adulterated kratom, or underlying physical or mental health issues when determining whether the primary cause of death was due to kratom.[45]

It is important to note that despite the AKA's disagreements with the FDA, the AKA is not opposed to the regulation of kratom; rather, it is opposed to the FDA's current suggestions. One of the AKA's stated missions is to protect consumers from adulterated kratom products. With this mission in mind, the AKA supports FDA regulations that would ensure the safety and purity of kratom products and is open to the FDA development of labeling guidelines for kratom. Additionally, the AKA supports minimum age of procurement laws for kratom products and child resistant packaging.

With kratom currently largely unregulated, the AKA developed a good manufacturing practices (GMP) program to increase the safety of kratom products. In order for a manufacturer of kratom products to qualify for the program, and thus be listed as such on the AKA website, the manufacturer must commit to following strict manufacturing and processing requirements and be verified by a pre-approved, independent auditor. If the manufacturer qualifies for the GMP program, then they must also complete annual independent audits to remain in the program. The AKA's GMP program also requires an initial program registration fee and an annual re-certification fee. The factors on which the AKA focuses when determining whether to accept a manufacturer into the GMP program include the presence of standard operating procedures; proper recordkeeping; an adverse event reporting system; truthful marketing practices; and the implementation of a compliance program. As of August 2022, there are 43 AKA GMP qualified vendors.[46] In addition to the GMP program, the AKA supports a truth in labeling compliance program. This program is a form of self-regulation that encourages kratom consumers to report potential kratom product marketing violations to the AKA. The AKA will then submit these reports to the FDA, so that the FDA can investigate, and if necessary, take action against kratom vendors "who use impermissible health claims to mislead consumers about the actual benefits of using [an] otherwise safe food product."

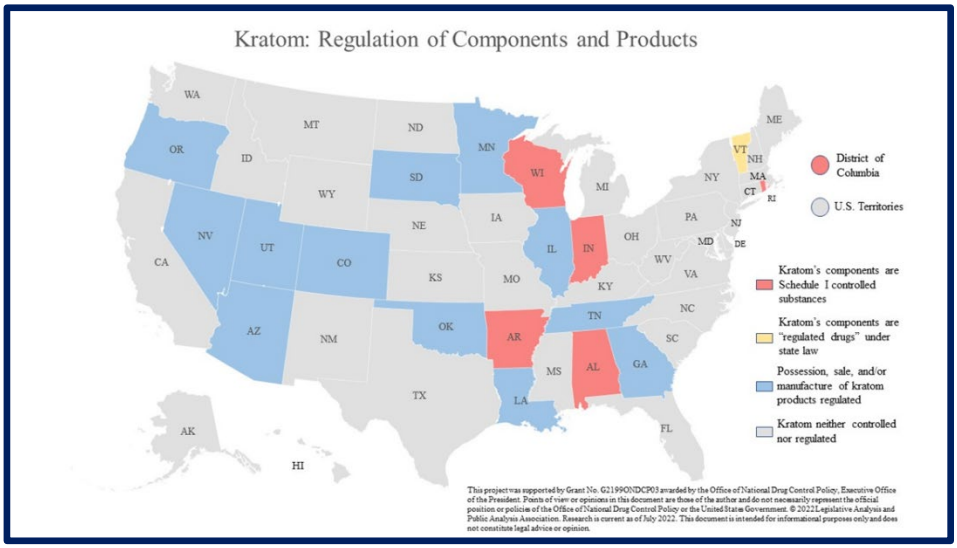
Kratom laws on the state and local levels

In addition to federal regulatory battles, some state and local governments have implemented regulatory controls on kratom. In six states (Alabama,[47] Arkansas,[48] Indiana,[49] Rhode Island,[50] Vermont,[51] and Wisconsin[52]) and the District of Columbia,[53] kratom's psychoactive components are controlled substances.[54] A handful of cities and counties also ban kratom, including: San Diego, California; Sarasota County, Florida; and Denver, Colorado.[55] To encourage states to stop short of enacting a total ban, the AKA developed model state legislation under which a dealer of kratom products may not legally prepare, distribute, or sell a kratom product that is adulterated or

[44] Jane Babin, "FDA Fails to Follow the Sciences on Kratom," *American Kratom Association*, August 2018, 13, https://docs.wixstatic.com/ugd/9ba5da_54f08e1805c34c108ad7199481507d88.pdf.
[45] *Id.*
[46] "AKA's GMP Qualified Vendors," American Kratom Association, last accessed August 18, 2022, https://www.americankratom.org/gmp-qualified-vendors.
[47] ALA. CODE § 20-2-23 (West 2022).
[48] ARK. ADMIN. CODE § 007.07.2 (West 2021).
[49] IND. CODE. ANN. § 35-48-2-4 (West 2022) (mitragynine and 7-hydroxymitragynine are included in the definition of "synthetic drug." (Ind. Code Ann. § 35-31.5-2-321 (West 2022). All synthetic drugs are Schedule I controlled substances).
[50] Rhode Island Dept. of Health, Notice of Designation of Controlled Substance (May 31, 2017), https://docs.wixstatic.com/ugd/9ba5da_9836aee2b9f04a30b55fe480fe3c6ff4.pdf.
[51] 12-5 VT. CODE R. § 23:7.0 (West 2022).
[52] WIS. STAT. ANN. § 961.14 (West 2022).
[53] The legal status of kratom in the District of Columbia (D.C.) appears unclear. Please see LAPPA's Kratom: Summary of State Laws, available here, for more information.
[54] In Vermont, kratom's components are "regulated drugs," making them generally illegal except as specifically allowed. VT. STAT. ANN. tit. 18, § 4205 (West 2022). In the remaining jurisdictions, kratom components are Schedule I controlled substances.
[55] For more information on the legality of kratom in states and local jurisdictions, please refer to LAPPA's 50-state review of kratom laws, available at https://legislativeanalysis.org/kratom-summary-of-state-laws/.

contaminated with a dangerous non-kratom substance. Additionally, kratom products may not be legally sold without labels containing the amount of mitragynine and 7-hydroxymitragynine contained in the product. The model law also bans the sale of kratom products to individuals under the age of 18 and proposes that violations of the above provisions would result in a misdemeanor.

Several state laws contain similarities to the AKA's model law. In 12 states, the possession, sale, manufacture, and distribution of kratom products is regulated. Of these 12 states, seven of them (Arizona, Colorado, Georgia, Nevada, Oklahoma, Tennessee, and Utah) also have requirements for kratom product labels, such as requiring a list of the product's ingredients and stating the amount of mitragynine and 7-hydroxymirtragynine contained in the product. In the other five states (Illinois, Louisiana, Minnesota, Oregon, and South Dakota), there are no product labeling requirements. In all 12 states where the possession, distribution, sale, or manufacture of kratom products is regulated, the regulation contains age restrictions. In eight states (Arizona, Georgia, Illinois, Louisiana, Minnesota, Nevada, Oklahoma, and Utah), kratom products are restricted to individuals over the age of 18. In the other four states (Colorado, Oregon, South Dakota, and Tennessee), the age restriction is age 21 and older. See the map below for a visual representation of state laws.



During 2021 and 2022, 28 states introduced legislation related to kratom. Of those 28 states, 21 states introduced legislation to regulate the possession, distribution, sale, or manufacture of kratom products in some fashion. Two states (Louisiana and West Virginia) introduced legislation to make kratom's components Schedule I controlled substances. Five states (Kentucky, Mississippi, New Jersey, Pennsylvania, and Washington) introduced dueling pieces of legislation—that is, state legislators introduced at least one bill to make kratom components Schedule I controlled substances and at least one bill to regulate the possession, distribution, sale, or manufacture of kratom products. The conflictive nature of the proposed legislation underscores the controversies involving kratom and differing perspectives of its use and safety.

CONCLUSION

The differing perspectives on the efficacy and safety of kratom use has resulted in a complex regulatory landscape. While federal agencies and kratom consumer advocacy groups continue to argue over the best way to regulate kratom and protect public health, states and local governments have begun to regulate kratom in some fashion. As the popularity of kratom products increases, states continue to introduce kratom related legislation ranging from making kratom a controlled substance to establishing labeling requirements for kratom manufacturers and distributors. The controversies around kratom will likely continue until scientists can provide consumers and policymakers with more information about kratom's pharmacological effects.

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ABOUT LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces timely model laws and policies that can be used by national, state, and local public health, public safety, and substance use disorder practitioners who want the latest comprehensive information on law and policy as well as up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to fact sheets. Examples of topics on which LAPPA has assisted stakeholders include law enforcement/community engagement, naloxone laws, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.

For more information about LAPPA, please visit: https://legislativeanalysis.org/.

Kratom

WHAT IS KRATOM?

Kratom is a tropical tree native to Southeast Asia. Consumption of its leaves produces both stimulant effects (in low doses) and sedative effects (in high doses), and can lead to psychotic symptoms, and psychological and physiological dependence. Kratom leaves contain two major psychoactive ingredients (mitragynine and 7-hydroxymytragynine). These leaves are crushed and then smoked, brewed with tea, or placed into gel capsules. Kratom has a long history of use in Southeast Asia, where it is commonly known as thang, kakuam, thom, ketum, and biak. In the U.S., the use of kratom has increased markedly in recent years.

Kratom tree

How is it used?

Mostly used by oral ingestion in the form of a tablet, capsule, or extract. Kratom leaves may also be dried or powdered and ingested as a tea, or the kratom leaf may be chewed.

What are the effects?

At low doses, kratom produces stimulant effects with people reporting increased alertness, physical energy, and talkativeness. At high doses, people experience sedative effects. Kratom consumption can lead to addiction.

Several cases of psychosis resulting from use of kratom have been reported, where individuals addicted to kratom exhibited psychotic symptoms, including hallucinations, delusion, and confusion.

Leaf of kratom tree

What does it do to the body?

Kratom's effects on the body include nausea, itching, sweating, dry mouth, constipation, increased urination, tachycardia, vomiting, drowsiness, and loss of appetite. Users of kratom have also experienced anorexia, weight loss, insomnia, hepatotoxicity, seizure, and hallucinations.

Kratom capsules

What is its legal status?

Kratom is not controlled under the Controlled Substances Act; however, there may be some state regulations or prohibitions against the possession and use of kratom. FDA has not approved kratom for any medical use. In addition, DEA has listed kratom as a Drug and Chemical of Concern.

FDA STATEMENT

Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds

For Immediate Release:

December 20, 2018

Statement From:

Scott Gottlieb, M.D.
Commissioner of Food and Drugs - Food and Drug Administration (May 2017 - April 2019)

Today, the Agriculture Improvement Act of 2018 was signed into law. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as cannabis (*Cannabis sativa L.*), and derivatives of cannabis with extremely low (less than 0.3 percent on a dry weight basis) concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC). These changes include removing hemp from the Controlled Substances Act, which means that it will no longer be an illegal substance under federal law.

Just as important for the FDA and our commitment to protect and promote the public health is what the law *didn't* change: Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. In doing so, Congress recognized the agency's important public health role with respect to all the products it regulates. This allows the FDA to continue enforcing the law to protect patients and the public while also providing potential regulatory pathways for products containing cannabis and cannabis-derived compounds.

We're aware of the growing public interest in cannabis and cannabis-derived products, including cannabidiol (CBD). This increasing public interest in these products makes it even more important with the passage of this law for the FDA to clarify its regulatory authority over these products. In short, we treat products containing cannabis or cannabis-derived compounds as we do any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of the source of the substance, including whether the substance is derived from a plant that is classified as hemp under the Agriculture Improvement Act. To help members of the

public understand how the FDA's requirements apply to these products, the FDA has maintained a webpage (/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd) with answers to frequently asked questions, which we intend to update moving forward to address questions regarding the Agriculture Improvement Act and regulation of these products generally.

In view of the proliferation of products containing cannabis or cannabis-derived substances, the FDA will advance new steps to better define our public health obligations in this area. We'll also continue to closely scrutinize products that could pose risks to consumers. Where we believe consumers are being put at risk, the FDA will warn consumers and take enforcement actions.

In particular, we continue to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds. Among other things, the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce. This is the same standard to which we hold any product marketed as a drug for human or animal use. Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.

Additionally, it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.

We'll take enforcement action needed to protect public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and are being marketed in violation of the FDA's authorities. The FDA has sent warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure

serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

While products containing cannabis and cannabis-derived compounds remain subject to the FDA's authorities and requirements, there are pathways available for those who seek to lawfully introduce these products into interstate commerce. The FDA will continue to take steps to make the pathways for the lawful marketing of these products more efficient.

These pathways include ways for companies to seek approval from the FDA to market with therapeutic claims a human or animal drug that is derived from cannabis. For example, in June 2018, the FDA approved a drug, Epidiolex (/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms), that contains cannabis-derived CBD for the treatment of seizures associated with two rare and severe forms of epilepsy. That approval was based on adequate and well-controlled clinical studies, which gives prescribers confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

In addition, pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process. However, the FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.

It should also be noted that some foods are derived from parts of the hemp plant that may not contain CBD or THC, meaning that their addition to foods might not raise the same issues as the addition of drug ingredients like CBD and THC. We are able to advance the lawful marketing of three such ingredients today. We are announcing that the agency has completed our evaluation of three Generally Recognized as Safe (/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food) (GRAS) notices related to hulled hemp seeds, hemp seed protein and hemp seed oil and that the agency had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for these uses without food additive approval, provided they comply with all other requirements and do not make disease treatment claims.

Given the substantial public interest in this topic and the clear interest of Congress in fostering the development of appropriate hemp products, we intend to hold a public meeting in the near future for stakeholders to share their experiences and challenges with these products, including information and views related to the safety of such products.

We'll use this meeting to gather additional input relevant to the lawful pathways by which products containing cannabis or cannabis-derived compounds can be marketed, and how we can make these legal pathways more predictable and efficient. We'll also solicit input relevant to our regulatory strategy related to existing products, while we continue to evaluate and take action against products that are being unlawfully marketed and create risks for consumers.

At the same time, we recognize the potential opportunities that cannabis or cannabis-derived compounds could offer and acknowledge the significant interest in these possibilities. We're committed to pursuing an efficient regulatory framework for allowing product developers that meet the requirements under our authorities to lawfully market these types of products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC

Español (/consumers/articulos-para-el-consumidor-en-espanol/5-cosas-que-debe-saber-sobre-el-delta-8-tetrahidrocannabinol-o-delta-8-thc)

Delta-8 tetrahydrocannabinol, also known as delta-8 THC, is a psychoactive substance found in the *Cannabis sativa* plant, of which marijuana and hemp are two varieties. Delta-8 THC is one of over 100 cannabinoids produced naturally by the cannabis plant but is not found in significant amounts in the cannabis plant. As a result, concentrated amounts of delta-8 THC are typically manufactured from hemp-derived cannabidiol (CBD).

It is important for consumers to be aware that delta-8 THC products have not been evaluated or approved by the FDA for safe use in any context. They may be marketed in ways that put the public health at risk and should especially be kept out of reach of children and pets.

Here are 5 things you should know about delta-8 THC to keep you and those you care for safe from products that may pose serious health risks:

1. Delta-8 THC products have not been evaluated or approved by the FDA for safe use and may be marketed in ways that put the public health at risk.

The FDA is aware of the growing concerns surrounding delta-8 THC products currently being sold online and in stores. These products have not been evaluated or approved by the FDA for safe use in any context. Some concerns include variability in product formulations and product labeling, other cannabinoid and terpene content, and variable delta-8 THC concentrations. Additionally, some of these products may be labeled simply as “hemp products,” which may mislead consumers who associate “hemp” with “non-psychoactive.” Furthermore, the FDA is concerned by the proliferation of products that

contain delta-8 THC and are marketed for therapeutic or medical uses, although they have not been approved by the FDA. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of federal law, but also can put consumers at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns because patients and other consumers may use them instead of approved therapies to treat serious and even fatal diseases.

2. The FDA has received adverse event reports involving delta-8 THC-containing products.

The FDA received 104 reports of adverse events in patients who consumed delta-8 THC products between December 1, 2020, and February 28, 2022. Of these 104 adverse event reports:

- 77% involved adults, 8% involved pediatric patients less than 18 years of age, and 15% did not report age.
- 55% required intervention (e.g., evaluation by emergency medical services) or hospital admission.
- 66% described adverse events after ingestion of delta-8 THC-containing food products (e.g., brownies, gummies).
- Adverse events included, but were not limited to: hallucinations, vomiting, tremor, anxiety, dizziness, confusion, and loss of consciousness.

National poison control centers received 2,362 exposure cases of delta-8 THC products between January 1, 2021 (i.e., date that delta-8 THC product code was added to database), and February 28, 2022. Of the 2,362 exposure cases:

- 58% involved adults, 41% involved pediatric patients less than 18 years of age, and 1% did not report age.
- 40% involved unintentional exposure to delta-8 THC and 82% of these unintentional exposures affected pediatric patients.
- 70% required health care facility evaluation, of which 8% resulted in admission to a critical care unit; 45% of patients requiring health care facility evaluation were pediatric patients.
- One pediatric case was coded with a medical outcome of *death*.

3. Delta-8 THC has psychoactive and intoxicating effects.

Delta-8 THC has psychoactive and intoxicating effects, similar to delta-9 THC (i.e., the component responsible for the “high” people may experience from using cannabis). The FDA is aware of media reports of delta-8 THC products getting consumers “high.” The FDA is also concerned that delta-8 THC products likely expose consumers to much higher levels of the substance than are naturally occurring in hemp cannabis raw extracts. Thus, historical use of cannabis cannot be relied upon in establishing a level of safety for these products in humans.

4. Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC claimed in the marketplace.

The natural amount of delta-8 THC in hemp is very low, and additional chemicals are needed to convert other cannabinoids in hemp, like CBD, into delta-8 THC (i.e., synthetic conversion). Concerns with this process include:

- Some manufacturers may use potentially unsafe household chemicals to make delta-8 THC through this chemical synthesis process. Additional chemicals may be used to change the color of the final product. The final delta-8 THC product may have potentially harmful by-products (contaminants) due to the chemicals used in the process, and there is uncertainty with respect to other potential contaminants that may be present or produced depending on the composition of the starting raw material. If consumed or inhaled, these chemicals, including some used to make (synthesize) delta-8 THC and the by-products created during synthesis, can be harmful.
- Manufacturing of delta-8 THC products may occur in uncontrolled or unsanitary settings, which may lead to the presence of unsafe contaminants or other potentially harmful substances.

5. Delta-8 THC products should be kept out of the reach of children and pets.

Manufacturers are packaging and labeling these products in ways that may appeal to children (gummies, chocolates, cookies, candies, etc.). These products may be purchased online, as well as at a variety of retailers, including convenience stores and gas stations, where there may not be age limits on who can purchase these products. As discussed above, there have been numerous poison control center alerts involving pediatric patients who were exposed to delta-8 THC-containing products. Additionally, animal poison control centers have indicated a sharp overall increase in accidental exposure of pets to these products. Keep these products out of reach of children and pets.

Why is the FDA notifying the public about delta-8 THC?

A combination of factors has led the FDA to provide consumers with this information. These factors include:

- An uptick in adverse event reports to the FDA and the nation’s poison control centers.
- Marketing, including online marketing of products, that is appealing to children.
- Concerns regarding contamination due to methods of manufacturing that may in some cases be used to produce marketed delta-8 THC products.

The FDA is actively working with federal and state partners to further address the concerns related to these products and monitoring the market for product complaints, adverse events, and other emerging cannabis-derived products of potential concern. The FDA will warn consumers about public health and

safety issues and take action, when necessary, when FDA-regulated products violate the law.

How to report complaints and cases of accidental exposure or adverse events:

If you think you are having a serious side effect that is an immediate danger to your health, call 9-1-1 or go to your local emergency room. Health care professionals and patients are encouraged to report complaints and cases of accidental exposure and adverse events to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Call an FDA Consumer Complaint Coordinator (/safety/report-problem-fda/consumer-complaint-coordinators) if you wish to speak directly to a person about your problem.
- Complete an electronic Voluntary MedWatch form (https://www.accessdata.fda.gov/scripts/medwatch/) online or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.
- Complete a paper Voluntary MedWatch form (/media/85598/download) and mail it to the FDA.
- To report adverse events in animals to the FDA's Center for Veterinary Medicine, please download and submit Form FDA 1932a found at: www.fda.gov/ReportAnimalAE (/animal-veterinary/report-problem/how-report-animal-drug-and-device-side-effects-and-product-problems).

FDA Issues Warning Letters: FDA, FTC Continue Joint Effort to Protect Consumers Against Companies Illegally Selling Copycat Delta-8 THC Food Products (/news-events/press-announcements/fda-ftc-continue-joint-effort-protect-consumers-against-companies-illegally-selling-copycat-delta-8)

Warning Letters: Warning Letters and Test Results for Cannabidiol-Related Products (/news-events/public-health-focus/warning-letters-cannabis-derived-products)

For more information about Delta-8 THC: CDC HEALTH ALERT NETWORK (HAN) (https://emergency.cdc.gov/han/2021/han00451.asp)

The American Association of Poison Control Centers (AAPCC) maintains the National Poison Data System (NPDS), which houses de-identified case records of self-reported information collected from callers during exposure management and poison information calls managed by the country's poison control centers (PCCs). NPDS data do not reflect the entire universe of exposures to a particular substance as additional exposures may go unreported to PCCs; accordingly, NPDS data should not be construed to represent the complete incidence of U.S. exposures to any substance(s). Exposures do not necessarily represent a poisoning or overdose and AAPCC is not able to completely verify the accuracy of every report. Findings based on NPDS data do not necessarily reflect the opinions of AAPCC.

NORML®
Working to Reform Marijuana Laws

NORML's Guide to Delta-8 THC and Other Novel Cannabinoids

Dale Gieringer, Ph.D, Director, California NORML

A number of novel cannabinoids have begun to appear in both state-regulated cannabis products and in non-regulated products derived from hemp. These substances do not possess the same extensive record of safe use and scientific research as do the more familiar cannabinoids typically found in marijuana and hemp, namely Delta-9 THC and CBD. A popular example is Delta-8 THC, which is now available from numerous cannabis and hemp outlets, sometimes under the false pretense that it is a legal hemp product.

What is Delta-8 THC?

Delta-8 THC is an isomer, or minor chemical variant, of Delta-9 THC. It occurs only at minuscule levels in natural cannabis. High levels of Delta-8 THC are produced artificially by chemically converting CBD or Delta-9 THC through a process known as isomerization. All Delta-8 THC products are manufactured by some form of chemical conversion.

What Does Delta-8 THC Do?

Delta-8 THC is psychoactive, but weaker than Delta-9 THC according to users' reports. Only a handful of human subjects have been tested with Delta-8 THC in scientific studies. Therefore, little is known about its long-term safety, its consumption at high dosages, or its medicinal effects. However, given its chemical similarity to Delta-9 THC and its presence in natural cannabis, the safety of Delta-8 THC is thought by most experts to be similar to that of other cannabinoids.

What's a Safe Source of Delta-8 THC?

It's important that Delta-8 THC products be carefully tested for impurities. Delta-8 THC extracts often contain high levels of Delta-9 THC, which is hard to separate out. In addition, the chemical conversion process can produce high levels of other impurities, especially in products derived from CBD.
In some states, products advertised as containing Delta-8 THC are available from state-regulated cannabis dispensaries. In these jurisdictions, these products ought to be subject to the same testing and purity requirements as are other cannabis products prior to being brought to market. However, most Delta-8 THC products are manufactured from hemp-derived CBD and sold through unregulated grey market sources like convenience stores, smoke shops, and gas stations. These products are not reliably tested, and have been found to contain many impurities.

NORML therefore strongly advises consumers to obtain Delta-8 THC products only from state-regulated cannabis manufacturers, NOT from the unregulated hemp market.

Is Delta-8 THC Federally Legal?

While some individual states have taken steps to outlaw the sale of hemp-derived, delta-8-products, others have yet to offer any legal guidance. In 2022, a three-judge panel of the Ninth Circuit Court of Appeals ruled that federal law does not explicitly prohibit the manufacture and sale of delta-8-THC products, regardless of how they are manufactured, as long as the products are initially sourced from either hemp or a cannabinoid extracted from hemp. While the Court failed to weigh in on whether it was

the explicit intent of Congress to legalize such products, it acknowledged that if the 2018 Farm Act inadvertently created a loophole, "then it is for Congress to fix its mistake."

Other Cannabinoids

Numerous other minor cannabinoids and cannabinoid derivatives have been identified, a few of which have begun to appear on the market. None have been tested at significant dosages in humans. NORML strongly advises consumers against using products that are not approved and tested through state-legal cannabis programs.

Delta-10 THC is a synthetic isomer of Delta-9 THC said to be weaker than Delta-8 THC. Delta-10 is one of several isomers (Delta-6, Delta-7, etc) that do not occur naturally in cannabis, but instead are manufactured by labs. None have been tested for safety and efficacy in human studies. Another new synthetic cannabiniod, THC-O acetate, is reputed to be stronger than Delta-9 THC. Consumers are strongly advised to avoid potent cannabinoid derivatives on account of their potential toxicity. Though Delta-10 and THC-O acetate are available from some gray market sources, NORML does not endorse commercial sale of these or other new synthetic cannabinoids until more research on their safety and purity has been performed.

Synthetic Delta-9 THC products manufactured from hemp-derived CBD have been circulating on the unregulated market. Consumers are strongly advised to avoid these products, as they are not properly tested; they are illegal and apt to contain impurities.

Other Natural Cannabinoids

A number of other weak or non-psychoactive cannabinoids common to the cannabis plant are now available on the market in legal states. These include CBG, CBN, THC Acid, CBD Acid, and others. There also exist naturally occurring “-varin” varieties of cannabinoids, such as THCV, CBDV, etc. They are most likely safe to consume, as users have been exposed to them for many years, though generally only at low concentrations. They may also have therapeutic benefits, although these have yet to be firmly established in controlled human studies. State-regulated cannabis products are a safe source of natural cannabinoid extracts.

Terpenes

Terpenes are naturally occurring compounds that contribute to the taste and odor of cannabis. They have been shown to contribute to the medicinal effects and “high” of cannabis. They have been found effective at low levels $\ll$1% in the plant, but there’s no evidence that higher dosages are helpful. Manufacturers sometimes add terpenes to their products to improve their flavor, taste and medicinal effects. This is fine so long as they use terpenes at modest dosages that occur naturally in the plant. While the terpenes in cannabis are generally safe to consume orally, consumers should beware that artificially concentrated terpenes could produce irritating or toxic effects when smoked or vaped.

DATE: August 28, 2025

TO: Mayor James McDonald and Board of Trustees

FROM: Michael Strong, Village Administrator

RE: **Solicitor Regulations – Legal Landscape and Public Education Strategy**

Background

This past summer, staff experienced a noticeable uptick in door-to-door solicitor activity. While some of this activity has been routine, we've received a growing number of resident complaints, ranging from solicitors ignoring clearly posted "No Soliciting" signs to reports of individuals knocking on doors well after 9:00 p.m. In a few cases, residents have described their interactions as "abrasive", rude and/or overly aggressive.

Understandably, this has raised concerns about safety, privacy, and the overall quality of life in our neighborhoods. In response, we have taken a closer look at what tools are available to us under Illinois law and federal constitutional principles to address these concerns and understand where our authority is limited.

Understanding the Legal Landscape

Regulating solicitation is a delicate balance for municipalities. Under the First Amendment, both commercial and non-commercial solicitors (such as political, educational or religious groups) enjoy strong protection. Courts have consistently ruled that municipalities cannot impose outright bans on door-to-door solicitation. However, they are allowed to regulate the time, place, and manner of these activities, provided those regulations are content-neutral and narrowly tailored to serve a significant governmental interest.

Recent and longstanding case law makes clear that even seemingly reasonable regulations may not survive constitutional scrutiny:

- *Watchtower Bible & Tract Society v. Village of Stratton* (2002): Struck down a permit requirement for religious and political canvassers.
- *Ohio Citizen Action v. City of Englewood* (2012): Invalidated a 6 p.m. to 9 a.m. ban on door-to-door canvassing.
- *Reed v. Town of Gilbert* (2015): Held that content-based distinctions in sign regulations are unconstitutional, a principle likely to apply to solicitation ordinances.
- *Norton v. City of Springfield* (2015): Reinforced that even topical distinctions in speech regulation are subject to strict scrutiny.
- A 2019 federal case against Downers Grove resulted in a settlement and a finding that the Illinois Vehicle Code's restriction on street solicitation was unconstitutional.

Given this legal backdrop, we believe that any attempt to expand or enforce solicitation regulations beyond what is currently permitted would likely be vulnerable to a First Amendment challenge.

Village Code Amendments – Key Changes from the 2021 Ordinance
In 2021, the Village of Lake Villa adopted Ordinance No. 2021-05-01, which significantly restructured and modernized its regulations on peddlers, solicitors, and mobile vendors. Key changes included:

- Consolidation and Repeal: The Village repealed Chapter 8 ("Peddling Prohibited") of Title 5 and Chapter 9 ("Solicitors") of Title 3, replacing them with a new, unified Chapter 9 titled "Peddlers and Solicitors."
- Defined Categories: The ordinance clearly defines terms such as "peddler," "solicitor," "mobile food vendor," and "temporary vendor," distinguishing between commercial and non-commercial activities.
- Licensing Requirements: Peddlers and temporary vendors must obtain a license, submit to background checks, and provide detailed business and personal information. Licenses must be visibly displayed during operations.
- Operating Restrictions: Peddlers are prohibited from operating between 10:00 p.m. and 9:00 a.m., using sound devices after 6:00 p.m., or parking in one location for more than one hour without moving at least one block away.
- Solicitor Trespass Provisions: Residents may post "No Soliciting" signs (minimum 4" x 4") to prohibit entry. Solicitors who ignore such signage or fail to leave when asked are considered trespassers under the ordinance.

These updates were designed to align Village regulations with constitutional standards while still providing residents with tools to protect their privacy and safety.

A Potential Path Forward

Given the constitutional limitations on regulating solicitation, and the Village's 2021 Ordinance updates that already reflect current legal standards, our most effective strategy is to focus on resident empowerment, proactive communication, and consistent enforcement support. This approach will help residents understand their rights, take meaningful action to protect their privacy, and feel supported by the Village.

Staff would propose a three-pronged strategy:

1. **Newsletter Communication**: The upcoming Village newsletter will include a dedicated section explaining:
    - Residents' rights under the Village Code and the First Amendment.
    - How to properly post "No Soliciting" signage.
    - What to do if a solicitor ignores signage or behaves inappropriately.
    - When and how to contact the police for assistance.

2. **Direct Outreach to HOAs**: The Village will contact homeowners associations directly to educate their board members on the current ordinance and legal framework. This will enable HOA leadership to share accurate information with residents and help ensure consistent messaging across neighborhoods.

3. **Sticker Distribution**: The Village will purchase and make available "No Solicitor" stickers to residents at Village Hall. These stickers meet the Ordinance's visibility requirements and serve as a clear notice to solicitors that they are not welcome on the resident's premises.

Recommendation

Due to constitutional protections and recent Village Code amendments, staff does not recommend additional regulatory restrictions at this time. Instead, our focus should remain on empowering residents through education, visibility tools, and clear communication to ensure that residents are well-informed and supported in asserting their rights.

We recommend the Village Board endorse this approach and authorize staff to begin implementation immediately.