Hemp-Derived THCs:
A Discussion on Public Health, Policy, and Enforcement

Presenters:
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Agenda:

1. Introduction;
2. Scientific Overview of Delta-8 THC;
3. Legal Overview of Delta-8 THC; and
4. Policy and Enforcement Issues and Solutions
Scientific Overview of Delta-8 THC

- One of over 100 cannabinoids produced naturally by the cannabis plant;
- Not found in significant amounts in the cannabis plant;
- As such, concentrated amounts of delta-8 THC are typically manufactured from hemp-derived cannabidiol (CBD); and
- Not evaluated by FDA for safe use, in any context.
Scientific Overview of Delta-8 THC

- FDA has received adverse event reports
- Delta-8 THC manufacturers may use potentially harmful household chemicals to synthesize it
- The final product may have potentially harmful by-products related to chemicals used in the process
- Manufacturing may occur in unregulated conditions, resulting in presence of unsafe contaminants
Why are we Concerned?

- Increase in ADR’s to FDA and nation’s poison control centers
- Contamination/manufacturing concerns
- Variability in formulations and labeling
- Other cannabinoid and terpene content
- Variable delta-8 concentrations
- If labeled as “hemp products,” consumers may assume non-psychotropic
- Concern @ marketing for therapeutic uses
  - Violation of federal law
  - Puts consumers at risk, as products have not been proven as safe or effective
  - Patients may use in lieu of approved therapies to treat disease

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>❑ Delta-8 THC is a cannabinoid naturally occurring in the hemp plant as defined in the 2018 Farm Bill;</td>
<td>❑ Delta-8 THC does not naturally occur in commercially viable amounts in the hemp plant;</td>
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<td>❑ Delta-8 THC is also a double bond isomer of delta-9 THC which is produced by the hemp plant;</td>
<td>❑ DEA’s August 2020 IFR clarified that synthetic THCs still remain schedule I controlled substances;</td>
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<td>❑ The 2018 Farm Bill legalizes isomers that do not contain delta-9 THC concentrations that exceed 0.3% on a dry-weight basis;</td>
<td>❑ No delta-8 THC on the market is produced via direct extraction from the hemp plant;</td>
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<td>❑ Delta-8 THC is not a controlled substance under the Federal Analogue Act because THCs found in hemp are excepted from the CSA by virtue of the 2018 Farm Bill.</td>
<td>❑ All delta-8 THC available through unregulated channels is made in a laboratory by converting hemp-derived CBD through a chemical process to delta-8 THC;</td>
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<td>❑ Moreover, the effects of delta-8 THC on the central nervous system are not substantially similar to those of delta-9 THC.</td>
<td>❑ This conversion is “synthesis”, making delta-8 THC produced from CBD a synthetic THC;</td>
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<tr>
<td>❑ Delta-8 THC is also a controlled substance analogue under the Federal Analogue Act.</td>
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It doesn’t matter . . .
National poison control centers received 661 exposure cases of delta-8 THC products between January 2018 and July 31, 2021, 660 of which occurred between January 1, 2021, and July 31, 2021. Of the 661 exposure cases:

- 41% involved unintentional exposure to delta-8 THC and 77% of these unintentional exposures affected pediatric patients less than 18 years of age.
- 39% involved pediatric patients less than 18 years of age.
- 18% required hospitalizations, including children who required intensive care unit (ICU) admission following exposure to these products.
This is a Public Safety Issue

All-Natural, Plant Based

Our Delta-8 products are derived from the hemp plant and CBD, which is a cannabinoid found in the hemp plant. The National Cancer Institute defines Delta 8 as "an analogue of tetrahydrocannabinol with... appetite-stimulating, analgesic, and neuroprotective properties".

Enhanced Research & Development

Our advanced history in the Hemp and CBD industries have allowed us to innovate while focusing our priorities on purity, quality and safety.

Lab Tested Extracts

We strive to ensure the quality and purity of every batch by submitting our extracts for third-party lab testing. For more information on our lab testing, feel free to reach out or visit our Lab Results page.
Preventing the “Whack-a-Mole” Approach

Delta-10

Delta-8 THC

THC-P

HHC

THC-O
Available Products on the Market

THC-O PRODUCTS

Bearly Legal’s all new THC-O-Acetate also known as Delta-8-Acetate, DELTA-X, Pur-Infinite vape tanks and cartridges are absolutely amazing. Similar to delta-8-THC, THC-O Acetate delivers a powerful punch of effects that are quite delightful, but much more potent!

Stronger & longer lasting than D8 or D10 but fully federally farm bill compliant. Bearly Legal’s THCO Tanks are made for the connoisseurs of Delta-THC extracts and rare and exotic cannabinoids.

D8 THC-O typically gives a relaxing & Indica feeling, with a calming warmth and head buzz immediately. No VG, PG, PEG, Vitamin E, MCT, or any other cutting agents. This is a pure and very concentrated distillate. Extracts of only the highest quality standards and quality is guaranteed, to be what is advertised or money back guarantee.

Source: https://www.bearlylegalhemp.com/
We’re all in this Together

Protecting Public Safety

Preventing Youth Access

Coordinated Policy

FACT SHEET
Emerging Public Health Concern: Delta-8 THC

- 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.
Differing State Approaches

1) Outright Prohibition;

2) Moving Delta-8 THC into Regulated Marijuana Programs; or

3) Regulate Within State’s Hemp Program.
Unification Across the States

• Immediate Action

• Attorney General Involvement

• Legislative Fix
Regulatory Tug-of-War
Thank You!

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