Adverse Event Reports Involving Delta-8 Tetrahydrocannabinol (THC) Products from the FDA CFSAN Adverse Event Reporting System (CAERS), 2021

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Introduction

- Cannabis products containing delta-8 THC, a psychoactive and intoxicating isomer of delta-9 THC, became readily available in late 2020 and rapidly gained popularity among consumers.
- The FDA is aware of the growing concerns surrounding delta-8 THC products and first issued a Consumer Update in September 2021 to notify the public about the serious health risks of delta-8 THC.
- Many delta-8 products sold online and in stores currently are being marketed as foods and dietary supplements, although these products have not been evaluated by the FDA for safe use in any context.
- Furthermore, since the natural amount of delta-8 THC in hemp is very low, manufacturers convert other cannabinoids in hemp, like cannabidiol (CBD), into delta-8 THC, using potentially harmful chemicals.
- Little data exist on the toxicity of delta-8 THC products, and real-world data from adverse events can be a useful tool in providing safety information.
- The FDA CFSAN (Center for Food Safety and Applied Nutrition) Adverse Event Reporting System (CAERS) is a post-marketing surveillance system that receives and monitors adverse event (AE) and product complaint (PC) reports for foods, dietary supplements, cosmetics, and infant formula.
- While the reports submitted to CAERS vary in quality, review of these adverse event reports may help increase our understanding of potential health effects associated with delta-8 THC products.

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

Materials and Methods

CAERS receives adverse event reports via MedWatch, Safety Reporting Portal (SRP), Field Accomplishments and Compliance Tracking System (FACTS), emails, and telephone calls. Adverse events are coded to terms in the Medical Dictionary for Regulatory Activities (MedDRA). One CAERS adverse event report can have multiple outcomes.

We queried the CAERS database for reports that contain “delta-8” in product names, ingredients, or narratives. We extracted the CAERS ID, age, sex, ethnicity, race, outcomes, symptoms, CFSAN product type, and System Organ Classes (SOCs). We assessed the reports and provided descriptive statistics.

Results and Discussion

- In 2021, CAERS received 77 reports involving delta-8 THC-containing products. Of the 77 delta-8 THC reports, 54 (70%) reports appertained to delta-8 THC-containing food products (e.g., brownies, cookies, and candy bars), and 23 (30%) reports pertained to products marketed as dietary supplements. Thirteen (17%) reports were submitted by law enforcement, 58 (75%) by consumers, and 6 (8%) by health care professionals.
- Of the 77 delta-8 THC reports received, 58 (76%) were adverse events only, 6 (8%) were product complaints only, and 13 (17%) were for both adverse events and product complaints (**Fig. 1**).

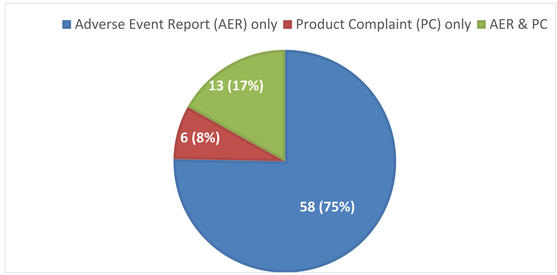


Figure 1. Count of delta-8 THC reports CAERS received in 2021 by AER only, PC only, and both (AER & PC).

- Next, we performed a descriptive analysis of the delta-8 THC reports CAERS received in 2021 (**Table 1**).

Age* (years)	Median	39
(N=64)	Mean	38
	Range	[2.6-68.6]
Sex*	Female	38
(N=70)	Male	32
Ethnicity*	Hispanic/Latino	4
(N=62)	Not Hispanic/Latino	58
Race*	Asian	1
(N=62)	Black or African American	2
	White	55
	Multiracial	4
Outcomes**	Death	0
(N=69)	Disability	8
	Hospitalization	21
	Life threatening	5
	Medically important	36
	Patient visited ER	15
	Patient visited healthcare provider	6
	Required Intervention	7
	Other seriousness	7
*Not all complainants reported the relevant information.		
**A complainant can have one or more outcomes.		

Table 1. Descriptive Characteristics of delta-8 THC adverse event reports.

- All adverse event reports were reviewed, with follow-up review for some adverse event reports by a CFSAN Medical Officer. The Medical Officer provided a severity assessment per 21CFR312.32(a) and a causality assessment using the World Health Organization-Uppsala Monitoring Center (WHO-UMC) causality assessment system.
- Of the 23 delta-8 THC adverse event reports more closely reviewed by a CFSAN Medical Officer, 14 (61%) were deemed serious adverse events, and 9 (39%) non serious adverse events. Causality assessment resulted in “probable association,” “possible association” or “insufficient information” for most of these reports **(Table 2)**. Sometimes it was difficult for CFSAN Medical Officers to fully evaluate causality due to various reasons such as missing important information in the report, the use of multiple products by the complainant, too many ingredients in one product, etc.

Causality Assessment	Serious AER	Non-Serious AER	Total AERs
Certain	0	0	0
Probable	4	4	8
Possible	6	3	9
Unlikely	0	0	0
Insufficient information	4	2	6
Unrelated	0	0	0
Total AERs	14	9	23

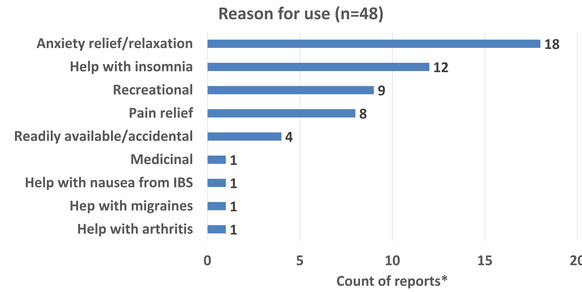
Table 2. Severity Assessment and Causality Assessment of delta-8 THC adverse event reports (n=23).

- Summary of System Organ Class (SOC) for the adverse events involving delta-8 THC products from 71 adverse event reports indicated these adverse events span a wide range of organ systems with psychiatric disorders, nervous system disorders, and gastrointestinal disorders being the top 3 (**Table 3**).

System Organ Classes (SOCs)	Counts
Psychiatric disorders	45
Nervous system disorders	38
Gastrointestinal disorders	24
General disorders and administration site conditions	22
Cardiac disorders	13
Investigations	9
Injury, poisoning and procedural complications	8
Respiratory, thoracic and mediastinal disorders	8
Vascular disorders	4
Skin and subcutaneous tissue disorders	2
Eye disorders	2
Metabolism and nutrition disorders	2
Ear and labyrinth disorders	1
* A complainant can describe multiple adverse events that span multiple SOCs.	

Table 3. System Organ Classes (SOCs) for delta-8 THC adverse event reports (n=71).

- Regarding the reason for use, there were 48 reports in which the complainants self-reported at least one condition for using delta-8 THC products. In terms of frequency, the top four reasons for using delta-8 THC products reported were for anxiety relief, help with insomnia, recreation, and pain relief (**Fig. 2**).



* A patient can have multiple reasons for using the delta-8 THC products.

Figure 2. Reasons why complainants used delta-8 THC products (n=48).

Conclusions

- In 2021, CAERS received 77 reports involving delta-8 THC-containing products.
- Among these 77 reports:
  - 54 (70%) reports appertained to delta-8 THC-containing food products (e.g., brownies, cookies, and candy bars), and 23 (30%) reports pertained to products marketed as dietary supplements.
  - 13 (17%) reports were submitted by law enforcement, 58 (75%) by consumers, and 6 (8%) by health care professionals.
  - 58 (76%) were adverse events only, 6 (8%) were product complaints only, and 13 (17%) were for both adverse events and product complaints.
  - Psychiatric disorders, nervous system disorders, and gastrointestinal disorders were the top three reported SOCs.
  - Anxiety relief, help with insomnia, recreation, and pain relief are the top 4 reasons for using delta-8 THC products.
  - Causality can be difficult to fully evaluate if there is important information missing in the report, use of multiple products by the complainant, and/or too many ingredients in one product.
- While the reports submitted to CAERS vary in quality, review of adverse event reports help provide needed real-world data.
- Continuing assessments of reports along with efforts to improve the quality of reporting information may help increase our understanding of potential health effects associated with delta-8 THC products.