Take Heed: FDA & CDC Release Health Alerts About Delta-8 THC

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Authors:

Andrea Hope J. Steel

The FDA and CDC each issued warning notices to the public regarding Delta-8 THC products on September 14, 2021, many of which are marketed as hemp products (and include some non-obvious references to other novel cannabinoids that may have similar effects and marketing). Both notices state most of the delta-8 THC products on the market have been "synthetically converted" from CBD but fail to address the fundamental stakeholder question as to the legality of these products. The major concerns noted were adverse events following consumption (many from inadvertent intoxication), marketing to and use by minors, and the potential presence of harmful by-products and unsafe manufacturing practices.

With increased state and federal attention on these products, there is also an increased risk to industry participants beyond that of criminal liability, such as FDA/FTC enforcement, banking and insurance obstacles, and civil liability claims. We recently discussed some of these on our Hemp Legally Speaking podcast episodes.

FDA Consumer Alert

The FDA consumer alert indicates we may begin to see enforcement action taken against companies marketing these products in deceptive ways and/or with unsubstantiated health claims. The notice lists five "Things to Know" about the serious health risks of delta-8 THC:

- Delta-8 THC products have not been evaluated or approved by the FDA for safe use and may be marketed in ways that put public health at risk.
- The FDA has received adverse event reports involving delta-8 THC-containing products.
- Delta-8 THC has psychoactive and intoxicating effects.

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- Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC claimed in the marketplace.
- Delta-8 THC products should be kept out of the reach of children and pets.

Tracking recent data from within the last year (following the publication of the DEA Interim Final Rule which added confusion to the delta-8 legality question), more than a dozen hospital or emergency room visits and hundreds of calls to poison control were reported. Many of these incidents were due to unintended exposure, especially among youth. Of the more than 660 poison control calls, 39% involved minors and 18% resulted in hospitalization.

Because these products concentrate delta-8 THC in amounts much higher than found naturally occurring in the plant, the FDA notes historical cannabis data cannot be relied upon for safety indicators. The manufacture of delta-8 THC in economically feasible amounts requires a conversion where the FDA warned some may be using potentially unsafe chemicals during the process, and the result may contain potentially harmful by-products. Because of the lack of regulation in the consumable hemp arena, manufacturing may be taking place in unsanitary facilities that increase the risk of contamination. Many of these products are marketed in unscrupulous ways, appealing to children, and even animal poison control centers have seen a significant uptick in accidental exposure among pets.

CDC Health Alert

The CDC health alert puts healthcare workers and the public on notice. It focuses on the recent increases in adverse health events from delta-8 THC consumption now being tracked and monitored. It also reiterates many of the sentiments of the FDA consumer notice as well, and provides lists of recommendations for consumers, health departments/poison control centers, retailers, and healthcare providers.

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In addition to the poison control calls also noted in the FDA notice, the CDC alert included a review of emergency room visits where delta-8 THC was mentioned in the primary complaint. This review indicated that the vast majority of these visits (73%) were concentrated in mostly southern states without adult-use access to marijuana. In these regions, delta-8 THC products are often marketed as hemp products, which can be confusing to consumers under the impression all hemp products are not psychoactive, leading to accidental intoxication.

The CDC alert points out that a lack of consistent testing requirements means some of these products might not be tested for contaminants such as heavy metals, solvents, or pesticides, which may potentially have harmful effects. It also makes mention of delta-10 THC and THC-O acetate, reiterating the concern that health effects are unknown due to a lack of research.

The CDC's recommendations for the public include awareness that these delta-8 THC products:

- May be intoxicating;
- May contain misleading labeling which only reports delta-9/CBD concentrations and leaves out potency concentrations of other cannabinoids that may be intoxicating; and
- Should be stored away from children.

Retailers are encouraged to be transparent with consumers about the potential for intoxication and include all forms of THC and other psychoactive ingredients on the labels.

For the healthcare industry, recommendations include:

- Increasing awareness among healthcare workers about these products and their psychoactive qualities, including those in states where only hemp marketplaces are permitted;
- Encouraging the use of the newly-created poison center control codes where delta-8 THC exposure has been reported;
- Urging regulators to require all forms of THC ingredients be listed on the product labels;

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- Offering community-based organizations use this data to raise awareness about the potential negative health effects of delta-8 THC and other cannabis derivatives that may be of concern;
- Requesting healthcare workers ask about delta-8 exposure when patients present with THC-like intoxication; and
- Consulting with toxicologists and local poison control where necessary, as detection of use can be difficult and there is no antidote for THC intoxication – only supportive care and symptom treatment.

Final Thoughts & Takeaways

While the question of legality remains unanswered, the reports of adverse health events are alarming and stakeholders should take heed. The health alerts are rapidly being disseminated nationwide and an uptick in regulatory crackdowns may ensue.

For those entrenched in the cannabis industry, these health concerns over delta-8 THC products are not new. However, to our knowledge, this is the first formal statement from a federal agency regarding Delta-8 THC, and we got two in one day. While it is not surprising these alerts came about after reports of health and safety concerns, it is disappointing the consumable hemp industry remains largely unregulated and without uniform standards as we continue to wait for action at the federal level. Until then, the industry needs to self-regulate to protect consumers in addition to ensuring business continuity.

The notices are also carefully worded and repeatedly refer to delta-8 THC products as "synthetically converted" as opposed to "synthetically derived" (though the CDC notice does make this reference once). The term "synthetically derived" instantly drums up the DEA Interim Final Rule from August 2020 that notably stated all "synthetically derived" THCs are controlled substances no matter the THC concentration, differentiating them from "materials that are derived from the cannabis plant." The precise choice of words highlights the challenge of categorizing products derived from a plant and then converted via synthesis.

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Businesses working with delta-8 THC products are encouraged to promptly analyze their risks and take appropriate mitigation measures which may include changes to manufacturing practices, testing methods, and packaging and labeling. For more information, reach out to one of the authors of this article.

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