American Bar Association TM American Bar Association

americanbar.org/groups/litigation/committees/mass-torts/articles/2023/summer2023-cannabis-mass-tort-litigation-whats-on-the-horizon/

April 07, 2023 **Articles**

Cannabis Mass Tort Litigation: What's on the Horizon?

All the elements are there: a growing body of scientific research into the safety and potential therapeutic uses of cannabis, heightened media attention, and a patchwork of regulatory requirements.

By Cara Edwards, Lucas Przymusinski, Jarred Reiling, and Mary Grace Braun

Policy makers, regulators, the media, and the American public are paying ever more attention to the rapidly growing cannabis industry. As of November 16, 2022, 37 states and the District of Columbia have legalized the medical use of cannabis products, and 21 states and the District of Columbia have legalized the recreational use of marijuana. Some analysts "expect the industry could grow to $75 billion in sales by 2030, surpassing soda, among other industries."

Meanwhile, a key component of public discourse and action surrounding cannabis has focused on health and safety. Recent developments include a new federal law expanding cannabis research (preceded by an urging to increase scientific knowledge about cannabis), safety alerts issued by the Food and Drug Administration (FDA), state enforcement action focusing on edibles resembling kid-friendly food products, and extensive media coverage about adverse effects of cannabis products.

Underpinning all of this is the need for clear guidance on cannabis policy from the federal government—and especially from Congress. Earlier this year, the FDA denied three petitions that had called on it to allow cannabidiol (CBD) products to be marketed as dietary supplements. In so doing, the agency urged Congress to act, affirming that "a new regulatory pathway for CBD is needed that balances individuals' desire for access to CBD products with the regulatory oversight needed to manage risks. The agency is prepared to work with Congress on this matter." However, with a deeply divided Congress, it is unclear what can be accomplished any time soon. A comprehensive federal approach to regulate cannabis is likely still a long way off.

Meanwhile, class actions involving cannabis are also on the rise. Such actions are brought primarily under state consumer protection and public nuisance statutes. As further explained below, we expect it will not be long before mass tort litigation involving cannabis products follows. The unique regulatory and legal position of cannabis products brings to mass tort litigation unique issues and questions. These include such factors as the federal legality of certain cannabis products, proving causation, and other concerns.

Background

Marijuana, and its derivatives, is a Schedule I drug under the Controlled Substances Act (CSA) and is illegal to possess or distribute under U.S. federal law. *See* 21 U.S.C. § 802(16). This classification extends essentially to "all parts of the plant *Cannabis sativa L.*," as well as synthetic equivalents and extracts. *See* 21 C.F.R. §§ 1308.11(d)(31), (d)(58). Tetrahydrocannabinol (THC) and CBD are the two most familiar of these cannabis extracts; others are THC-O, CBG (cannabigerol), and CBN (cannbinol).

The Agricultural Improvement Act of 2018 (the 2018 Farm Bill) removed "hemp" (defined as any cannabis plant or extract with a delta-9 THC "concentration of not more than 0.3 percent on a dry weight basis"; *see* 7 C.F.R. § 990.1) from Schedule I of the CSA. At the time the 2018 Farm Bill was passed, two versions of cannabis were generally available in the United States: marijuana (cannabis with a delta-9 THC concentration greater than 0.3 percent) and hemp (cannabis with a delta-9 THC concentration of 0.3 percent or less).

The legal status of cannabinoids other than “hemp” and “marijuana” is less clear. While the 2018 Farm Bill focused on hemp and related delta-9 THC levels, it did not expressly address delta-8 THC, another cannabis extract. Delta-8 THC, like delta-9 THC, is a psychoactive substance found in the *Cannabis sativa* plant. Unlike delta-9 THC, though, delta-8 THC is not found in as significant amounts in the cannabis plant; delta-8 THC products are usually manufactured from concentrated amounts of delta-8 THC that in turn have been derived from hemp.

Delta-8 THC products began to proliferate in 2019 due to a perception that they potentially fall within the CSA exclusion in the 2018 Farm Bill. The Drug Enforcement Administration (DEA) has taken the position that delta-8 THC is synthetically derived due to its method of manufacturing and that “[a]ll synthetically derived tetrahydrocannabinols remain schedule I controlled substances.” 85 Fed. Reg. 51,639, 51,641 (Aug. 21, 2020). The same goes for other extracts, including THC-O, as the DEA explained in a February 2023 letter. Meanwhile, several states have taken steps to either ban or restrict delta-8 THC and THC-O. And in another twist, in a trademark dispute, the Ninth Circuit cast doubt on whether the DEA’s position is consistent with the CSA as amended by the 2018 Farm Bill. *See A.K. Futures v. Boyd Street Distro*, 35 F.4th 682 (9th Cir. 2022).

Another important factor to take into account is the recent expansion of access to cannabis clinical research through the Medical Marijuana and Cannabidiol Research Expansion Act, signed into law in December 2022. Before December 2022, access to cannabis clinical research was sharply limited in the U.S. The act rolls back federal restrictions on marijuana research while promoting development of FDA-approved pharmaceuticals incorporating marijuana and CBD. This means that the potential therapeutic benefits of cannabis are increasingly being studied and will contribute to the growing body of current knowledge. Also, adverse events will continue to be documented.

Cannabis and the Potential for Mass Tort Litigation

Mass tort litigation involves “at least 100 civil tort actions arising from a single accident or use of or exposure to the same product or substance, each of which involves a claim in excess of $50,000 for wrongful death, personal injury or physical damage to or destruction of tangible property.” Mass tort cases have long been expansive, yet the size and number of mass tort multidistrict litigations continues to increase. In 2013, for instance, there were 73 active multidistrict litigations; this year, there are 300, and 90 percent are mass tort cases.

What prompts such an increase? The formula is familiar. Mass tort litigation generally starts with some triggering event, such as regulatory action, new data or study publications, or a widely covered adverse event. The triggering event then leads to extensive media coverage, which in turn sparks widespread advertising by the plaintiffs’ bar. The result: a growing volume of claims and plaintiffs.

The history of the Agent Orange mass tort litigation is instructive. This chemical herbicide was widely used by the U.S. military in its herbicidal warfare program, Operation Ranch Hand, during the Vietnam War. In 1970, in a move that received significant attention in the media, the Department of Defense suspended all use of Agent Orange in Vietnam, partly because the Department of Agriculture had begun restricting some domestic uses of its chemical ingredients. By the late 1970s, extensive media coverage was being given to the purported long-term adverse health effects of these chemicals, such as birth defects, cancers, kidney diseases, and nervous disorders. On January 8, 1979 a group of U.S. military veterans brought a class action lawsuit alleging they were adversely affected by Agent Orange, in the U.S. District Court for the Southern District of New York. In May 1979, the case was consolidated into a multidistrict litigation in the Eastern District of New York. In 1985, the court approved an opt-out class settlement under which corporate defendants paid $180 million into a settlement fund.

Today, we are seeing what may well be the start of an era of multidistrict litigations for cannabis products, with a slowly growing narrative that suggests cannabis may cause harm. These are some recent events:

- The FDA and the U.S. Centers for Disease Control and Prevention have issued a number of safety advisories relating to cannabis products. For example, on September 14, 2021, the Centers for Disease Control issued a safety advisory about “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).” On May 4, 2022, the FDA similarly issued an advisory flagging the “serious health risks” of delta-8 THC and stating that the FDA has received adverse event reports that delta-8 THC has psychoactive and intoxicating effects, that such products often involve the use of potentially harmful chemicals, and that such products should be kept out of the reach of children and pets.
- The FDA has issued an increasing number of warning letters to companies that market unapproved new drugs that allegedly contain CBD. In May 2022, the FDA issued warning letters to five companies for selling products labeled as containing delta-8 THC, citing violations related to drug misbranding linked to health claims involving the products and the addition of delta-8 THC in foods such as gummies, chocolate, and chewing gum.

- There has been no shortage of media coverage about certain dangers arising from cannabis products—most notably, a media narrative about the rise of children accidentally eating edibles. On January 3, 2023, for instance, *Forbes* published an article about the seeming rise in such events, reporting the "more than 3,054 calls to poison control centers about cannabis exposure in kids under the age of 6 after inadvertently consuming an edible in 2021," which is up from just 207 reports in 2017, marking an "increase of 1,375%." As possible explanations, the article pointed to the "increasing legalization of marijuana, children spending more time at home and having more opportunities to find cannabis-infused treats and clinicians having more experience treating cases." Similar articles have also been posted by the *New York Times*, the *Washington Post*, and other major media outlets.
- In addition, we are seeing some state attorneys general bringing civil and criminal cases against unlicensed retailers selling cannabis products. As recently as February 2023, Connecticut Attorney General William Tong sued five Connecticut retailers for alleged violations of the Connecticut Unfair Trade Practices Act over the sale of illegal delta-8 THC products that mimic popular youth-oriented snacks and candies.

These events have not triggered mass tort litigation to date, but we expect it is a matter of time before cannabis product users come forward alleging injuries or adverse health conditions as a result of cannabis use.

Cannabis Mass Tort Litigation Would Raise Unique Issues

Mass torts typically involve product liability, negligence, or intentional tort claims. Product liability is a likely focus for cannabis litigation. Three types of claims exist for product liability, each of which aims to hold parties accountable for products that cause harm. Here are possible ways that cannabis claims could be brought regarding each of these three types:

Manufacturing defects occur when a product has been manufactured improperly. Potential cannabis manufacturing defect claims could focus on the presence of chemicals or other harmful pesticides in unprocessed cannabis. There are also risks of contracting fungal infection or even bacterial infection from contaminated cannabis or from exposure to heavy metals in contaminated soil or groundwater.

Design defects occur when there is an inherent flaw in the design of the product itself. Potential areas of focus for cannabis products are child-resistant packaging, products designed to resemble familiar kid-friendly food products, products with high THC levels, and vape hardware that leaches heavy metals.

Finally, *warning defects* occur when the manufacturer fails to provide appropriate instructions on how to use a product or fails to warn consumers about its inherent risks. Such failure-to-warn claims arising from cannabis products would likely focus on dosage warnings for both

medical and recreational use, as well as issues regarding labeling and packaging—particularly where manufacturers do not abide by applicable state and local regulations. Failure-to-warn claims could also arise when children or pets accidentally ingest a cannabis product and are injured by it.

Applying these common concepts to mass tort litigation may prove challenging and thought-provoking when cannabis is involved. Also notable is how applying these concepts may vary depending on the type of cannabis product involved (for instance, recreational as opposed to medical, THC as opposed to CBD). A few examples:

- **Limited scientific knowledge regarding safety complicates failure to warn claims.** Some side effects of cannabis use (intoxication, lassitude) may be considered obvious, and for others, the relatively limited availability of scientific information makes it more difficult to have actual or constructive notice of a particular side effect. Also, for medical marijuana products, these unknowns complicate the role of the learned intermediary doctrine, especially because physicians typically recommend, rather than prescribe, a cannabis product for a patient.
- **Limited scientific knowledge also complicates the use of expert testimony to show causation.** With more unknowns than knowns, expert testimony evidence will be even more prone to disputes than it already is; under either the *Daubert* or *Frye* standards, scant scientific precedent will make the task of evaluating whether evidence is reliable or scientifically valid much more difficult for judges.
- **Some cannabis product users also use other products, which complicates proving causation.** For example, studies have examined the co-use of cannabis and alcohol, the co-use of cannabis and tobacco, and the use of all three. Furthermore, there is little information available about the interactions between cannabis and other medications.
- **The lack of uniform testing standards would complicate manufacturing and design defect claims.** Currently, cannabis testing is performed under differing regulatory frameworks among states that have legalized cannabis. While concepts like testing for potency and contaminants are common, the standards and methodologies vary significantly. Further, one study showed that over 50 percent of delta-9 THC products derived from hemp are mislabeled, among other discrepancies. Given all these variables, it could be challenging to show liability on the part of a particular manufacturer.

- **The legal status of some cannabis products under federal law creates potential preemption issues.** For example, the FDA has made clear that it is currently illegal under the Food, Drug, and Cosmetic Act to market THC and CBD by adding it to a food or labeling it as a dietary supplement because THC and CBD have been approved as active ingredients in drugs. *See* 21 U.S.C. §§ 321(ff)(3)(B), 331(ll). For a product liability action related to these products, plaintiffs would have to overcome complex preemption arguments (e.g., whether a theory of liability depends entirely on a violation of the Food, Drug, and Cosmetic Act).

When considered in combination, these concepts—largely centered around the lack of uniform legal and regulatory standards in the cannabis industry—collectively could present unique issues that make litigating these claims more difficult.

Conclusion

Cannabis mass tort litigation is on the horizon. All the elements are there: a growing body of scientific research into the safety and potential therapeutic uses of cannabis, heightened media attention, and a patchwork of regulatory requirements. However, the path forward will wind through uncharted territories, marked by unique issues such as difficulties in proving causation, inconsistencies in legal standards based on differing regulatory frameworks, and expansions of scientific data that will affect the strength of claims. Amid all the uncertainty, litigators would be wise to keep abreast of the growing body of research, developments in state and federal regulations, and current claims and defenses populating this landscape.
Cara Edwards and Lucas Przymusinski are partners and Jarred Reiling is of counsel at DLA Piper in New York, New York, and Mary Grace Braun is an associate at DLA Piper in San Diego, California.

here.