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**POTENTIAL LITIGATION RISKS
ASSOCIATED WITH ARTIFICIAL
FLAVORS IN THE KENTUCKY
CBD AND DELTA-8
THC INDUSTRIES**

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As attorneys and insurance professionals in the cannabis industry are aware, with legalization efforts for cannabis and cannabis-related products (such as CBD and Delta-8 THC) for medical and recreational use in approximately 34 states, consumers are experiencing an exploding range of new and different products for legal cannabis consumption. Legislative efforts to legalize marijuana in Kentucky have stalled yet again in 2021. Nevertheless, CBD (made from hemp), and Delta-8 THC (a controversial cannabis extract whose legality is widely disputed) are available to the public in the Commonwealth.

In purchasing and using these products, many consumers prefer the experience of vaping. As would be the case with any type of inhalation product, consumers and retailers have a natural interest in safety for CBD or Delta-8 vapes. Vaping safety in general is a concern that in recent years has come to a head in the e-cigarette vaping industry, with a wave of litigation by consumers against Juul Labs related to its e-cigarette products. Importantly, some of the same concerns expressed by consumers and regulators in the e-cigarette industry also have potential effects for the CBD and Delta-8-THC indus-

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tries, including the use of artificial flavors previously identified by National Institute for Occupational Safety (NIOSH) and others as potential health risks in the inhalation setting.

This article will briefly cover the legal, health, and regulatory history of artificial flavor products of concern, and explain current litigation concerns (including the Juul litigation) about consumer use of these ingredients in CBD and Delta-8 vaping products, with an eye toward consumer education as well as legal and risk management.

A GROWING INDUSTRY

Over the past twenty years, ballot measures for the legalization of medicinal and recreational cannabis have swept across the United States. California was the first state to legalize medical marijuana in 1996, and Washington and Colorado became the first two states to legalize recreational use in 2012.¹ Following in the footsteps of these progressive pioneering states, 19 other states have since legalized adult recreational cannabis use, and 36 states have legalized medicinal cannabis use.²

With the widespread legaliza-

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tion of cannabis, a new market has emerged offering consumers a variety of products for cannabis consumption, including vaping products. Similar to the explosive growth of e-cigarettes, the use of a vaping device to consume cannabis products has skyrocketed in recent years, with vaping products now accounting for more than 30% of legalized cannabis sales.³ The rise in popularity of vaping cannabis is not surprising. Vaping cannabis offers consumers many of the same conveniences as e-cigarettes offer nicotine users, including portability, clean consumption without ash, and access to flavored cartridges. However, the similarities between vaping cannabis and e-cigarettes do not end there. Cannabis cartridges may have more in common with nicotine vaping products than consumers and retailers imagine due to the lack of federal regulations and testing of artificial flavors in cannabis vapes.

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Even among states that have not yet legalized medicinal or recreational cannabis, many have passed measures permitting the use of cannabidiol (CBD) and/or Delta-8 derived from federally-compliant hemp plants. CBD is a non-in-

“Regardless of whether Delta-8 products continue to be available in Kentucky, it is undisputed that CBD products will continue to be legally available to consumers, including as CBD vaping products.”

toxicating cannabinoid extracted from the hemp plant.⁴ Studies have suggested that CBD helps with a variety of health issues including seizures, anxiety, insomnia, and chronic pain.⁵ Kentucky first legalized the use of hemp-derived medicinal CBD in 2014.⁶ In 2017, hemp-derived CBD products with 0.3% THC or less became legal for all consumers in the Commonwealth.⁷

Like CBD, Delta-8 is a cannabinoid derived from the hemp plant that causes psychoactive effects similar to that of THC, the active ingredient in marijuana.⁸ The legality of Delta-8 is widely contested in Kentucky. The Kentucky Department of Agriculture recently issued a letter declaring that Delta-8 is illegal under state and federal laws, which allegedly only create a narrow exemption re-scheduling hemp-derived products containing 0.3% or less of Delta-9 tetrahydrocannabinol (commonly known as simply as “THC”), and do not create such an exemption for Delta-8.⁹ However, hemp growers across the Commonwealth argue that because this exemption does not explicitly prohibit or even address Delta-8, the substance is legal.¹⁰ Most recently, a Kentucky hemp industry trade organization filed a lawsuit in July 2021 attempting to enjoin the Commonwealth

from seizing Delta-8 products following initial police raids targeting the product.¹¹ Nevertheless, while this legal and regulatory debate plays out, Delta-8 is still widely available throughout Kentucky.

A FLAVORED PAST

Regardless of whether Delta-8 products continue to be available in Kentucky, it is undisputed that CBD products will continue to be legally available to consumers, including as CBD vaping products. Flavored vaping devices and e-cigarettes containing nicotine were originally promoted as an alternative to cigarettes without harmful chemicals and carcinogens. While many of the artificial flavors used in nicotine vapes have long been recognized as safe ingredients in food products, recent scientific literature suggests that inhalation of some of these ingredients can harm the lungs.¹² Citing this research, over 900 lawsuits have been filed against e-cigarette manufacturers, including JUUL Labs, Inc. The lawsuits allege that Juul used appealing, kid-friendly flavors to market a product that would create and sustain a nicotine addiction without the stigma associated with cigarettes.¹³ These flavors include vanilla, cucumber, cool mint, and mango, which consumers allege contain artificial flavors and ingredients that are not safe for inhalation.

The plaintiffs in the Juul lawsuit cited a 2016 study which analyzed the ingredients in some of the most popular vaping flavors.¹⁴ The study found the concentration of artificial flavoring in nicotine vaping e-liquids to be of toxicological concern, particularly with flavors using diacetyl, acetyl propionyl (AP), and benzaldehyde.¹⁵

Diacetyl and AP are diketones, which are naturally occurring in many foods, including butter and beer. Artificial diketones are a key component in artificial butter flavorings.¹⁶ Decades before artificially flavored e-liquids, studies suggested that occupational inhalation exposure to diacetyl in the food production industry was associated with respiratory diseases including obliterative bronchiolitis (BO) and exertional dyspnea.¹⁷ BO, sometimes referred to as “popcorn lung,” is a rare pulmonary disease characterized by inflammation, narrowing, or obliteration of bronchioles in the lung. The connection between diacetyl and BO was first investigated in 1985 when NIOSH was called to a microwave popcorn factory to investigate after two young, previously healthy non-smoking employees were diagnosed with BO.¹⁸ NIOSH’s investigation noted the presence of diacetyl and other chemicals in the factory but could not definitively determine the cause of the employees’

“As a result of these studies, the Food and Drug Administration (FDA) and FEMA have issued guidance stating that the use of artificial flavors in vaping products should be rigorously studied before they are used in any e-liquids.

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illness.¹⁹

In 2000, NIOSH was called to investigate a microwave popcorn plant in Missouri after nine workers from the plant had been diagnosed with BO.²⁰ A three-year study of those workers’ occupational exposures determined that inhalation of butter flavoring chemicals poses a serious risk for occupational lung disease.²¹ In December 2003, NIOSH issued a safety alert to businesses that may have used butter flavoring.²² The safety alert suggested implementing safeguards, like the use of personal protective equipment, and requested the employers notify and caution worker of the risks.²³

NIOSH and other private actors have continued to conduct research on the suspected link between diacetyl and other diketone flavorings and lung disease. The research has produced some direct and indirect evidence suggesting a link between exposure to flavor-related compounds and excessive lung function declines under certain conditions.²⁴ A flavoring manufacturers trade organization, the Flavor Extract Manufacturers Association (“FEMA”), has indicated that heating diacetyl will increase volatility and air concentrations.²⁵

Much like nicotine e-liquids, there are dozens of CBD and Delta-8 e-liquid flavors widely accessible on the consumer market, including smooth vanilla, watermelon, mango, and strawberry. Research conducted in 2015 found the presence of diacetyl, AP, and acetoin in vape flavors such as Cupcake, Fruit Squirts, Wakiki Watermelon, Cotton Candy Tutti Frutti, and Blue Water Punch.²⁶

With increased awareness of the potential risks associated with inhalation of artificial flavors, many e-liquid manufacturers and retailers have released statements that their products do not contain diacetyl or AP. However, a 2015 study investigated the diacetyl and AP content in a variety of sweet-flavored nicotine vaping liquids and found that many e-liquids contained diacetyl and AP.²⁷ Diacetyl was detected in 110 of the 159 samples and AP was detected in 53 samples.²⁸ 52 samples had levels of diacetyl that exceeded the limits for occupational exposure recommended by NIOSH.²⁹ Notably, these diketones were detected in samples from manufacturers who explicitly stated that they were not present in their e-liquids.

As a result of these studies, the Food and Drug Administration (FDA) and FEMA have issued guidance stating that the use of artificial flavors in vaping products should be rigorously studied

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before they are used in any e-liquids.³⁰ Despite this guidance, and due to a lack of uniform regulation, it is still normal practice for manufacturers of e-liquids to sell cartridges without a full ingredient list. Even the most cautious CBD and Delta-8 e-liquid consumers risk unintentional exposure to diacetyl and AP.

RISK MANAGEMENT FOR CBD AND DELTA-8 INDUSTRY PLAYERS

Because of the lack of regulation around artificial vape flavorings, manufacturers and retailers of flavored CBD and Delta-8 vaping products are vulnerable to similar litigation that has plagued the nicotine vaping industry. As such, manufacturers and those in the CBD and Delta-8 industry should take measures to ensure their protection. Hemp growers should include indemnity agreements in their contracts with industry purchasers if litigation should arise. While CBD and Delta-8 have not been singled out to date as the components of vaping products that raise safety concerns, this defense will not prevent growers from being sued in the first place.

To control litigation risk, e-liq-

uid manufacturers should consider including indemnity agreements in purchases from flavor manufacturers. For example, these indemnity agreements could contractually require that all flavor manufacturers certify that their products do not contain diacetyl or AP and could also require the manufacturers to identify any diketone components capable of producing diacetyl as a byproduct.

In any contract with e-liquid manufacturers, flavor manufacturers should explicitly state whether or not diacetyl, AP, or any diketone components capable of producing diacetyl as a bi-product are present in the flavors when used in a vaping device. Like e-liquid manufacturers, flavor manufacturers should consider the allocation of litigation risk in transactions, specifically related to the risks associated either with worker exposure at the e-liquid manufacturer's operation, or in a consumer lawsuit. For example, terms and conditions of any sale could explicitly indicate which party to the transaction bears the risk associated with either workers' compensation or personal injury litigation.

In summary, the CBD and Delta-8 industries should closely monitor the nicotine vaping litigation and proactively adapt their

practices to avoid future liability. Through forward looking measures, the industry can ensure a bright future as its popularity continues to soar.



Mark is a seasoned litigator and senior partner who mitigates risk and delivers results to his clients by partnering

with them to understand the needs of their business, recognizing the nuances specific to each product or service, and counseling them through contentious situations from the inception of a claim through the finality of litigation.

As managing attorney for the Fort Mitchell, KY office, and Co-Chair of Reminger's Workers' Compensation practice group, Mark specializes in defending employers, commercial businesses and decision-makers, from formulating and implementing a national strategy in multijurisdictional litigation to managing multiple-suit, mass-tort, large class actions and workers' compensation litigation.

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