



**Written Testimony of:**

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**Before the:**

House Committee on Oversight and Accountability  
Health Care and Financial Services Subcommittee

**July 27, 2023 hearing on:**

“Hemp in the Modern World: The Yearslong Wait for FDA Action”

Chairwoman McClain, Ranking Member Porter, and Members of the Subcommittee, thank you for inviting me to testify today. My name is Gillian Schauer, and I am the Executive Director of the Cannabis Regulators Association (referred to as CANNRA). CANNRA is a non-partisan association of government agencies that regulate cannabis and hemp across 45 states and U.S. territories. We are an association of comprised entirely of current government officials who are in the trenches implementing cannabis and hemp policy in their states and territories. We convene and support governments so they can learn from each other, identify best practices in policy, and troubleshoot challenges. Prior to serving as the first Executive Director of CANNRA, I spent more than a decade working with federal agencies – including CDC and the National Institutes of Health - on cannabis-related policy, research, and public health. I went on to consult directly with state and municipal regulatory agencies. I have a PhD in Behavioral Science and a master’s in public health.

**Because of a broad definition of hemp in the 2018 Farm Bill, we have seen an explosion of hemp-derived products that are intoxicating, that are not safe for consumers, and that can appeal to and be accessed by youth.** This is one of the biggest issues facing cannabis and hemp regulators today. Red states, blue states - every state is grappling with the public health and safety risks that come from unregulated intoxicating hemp-derived cannabinoid products. We commend you on holding a hearing on “hemp in the modern world” and for including a regulatory perspective at this hearing. Given their unique experience implementing policy, state, territorial, municipal, and tribal regulators must have a seat at the table for any regulatory discussions about hemp or cannabinoid products.

**The Issue**

1. Modern hemp products extend well beyond fiber, grain, and feed. **Today, a significant portion of the marketplace is consumable hemp-derived products that contain THC and other intoxicating cannabinoids found in the *Cannabis sativa L.* plant – which is the same plant species for hemp as for marijuana or cannabis.** These hemp-derived compounds extend well beyond CBD, though CBD is commonly used as a source material for manufacturing hemp-derived intoxicating products.

- **Hemp-derived products on the market today often contain THC levels that meet or exceed the levels permitted in state marijuana or cannabis marketplaces**, including products with high levels of delta-9 THC<sup>1,2</sup> – the primary component in the cannabis plant that gets you high, and THCA<sup>3</sup> – which readily converts to delta-9 THC when heated or combusted. Other intoxicating cannabinoids - like delta-8 THC, THC-O-Acetate, H4-CBD, THCP, and HHC, which are often prohibited in state-regulated marijuana markets due to safety, are also widely available in the hemp marketplace.
- **The current hemp marketplace also includes cannabinoid products that are expressly prohibited by state marijuana regulators because they appeal to youth or have dangerously high levels of THC or other intoxicating cannabinoids.** For example, in Minnesota, a hemp-derived product called “Death by Gummy Bears”<sup>4</sup> contained 100 mg delta-9 THC per serving and 2500 mg per package. Servings sizes and package limits in state-regulated marijuana markets are typically 10mg/serving, 100mg per package.<sup>5</sup> Another online hemp-derived edible product is being marketed as the “largest legal THC gummy in history” and contains - in a single gummy - 3,000 mg of delta-9 THC per serving and 20,000 mg per package,<sup>6</sup> 200 times more than would be allowed in an adult use marijuana market. Other products mimic commercially available food products and appeal to youth.<sup>7,8,9</sup>
- **Some of the cannabinoids found in so-called “hemp” products are not found in nature and have never been studied for human consumption or safety.** Some of these products are made synthetically and contain nothing that came from a hemp or marijuana plant. These newly developed, unstudied products are widely available across the country online, and in gas stations and grocery stores, with no federally required testing for contaminants, no required packaging and labeling to tell consumers what is in the products or how they were manufactured, and no federal age-gating to ensure that intoxicating products are only sold to adults. This is in direct contrast to state-regulated marijuana or cannabis markets, which are regulated with consumer safety and youth prevention at the forefront.

## **2. Unregulated and often intoxicating hemp-derived cannabinoid products can pose serious risk to consumers, including:**

- ***A lack of testing and tracking for consumer safety:*** Products – whether intoxicating or not – may have contaminants that can be harmful to human health. Some of these contaminants result from the chemical manufacturing process required to convert CBD into intoxicating compounds and are known to be toxic or are unidentified and unstudied in humans. Some of these contaminants may be present on or in the plant (e.g., heavy metals, microbials, pesticides). Unlike products in state-regulated marijuana markets that are subjected to contaminants testing and track and trace systems to facilitate quick recalls in the case of adverse events, no required testing or system to recall products or notify consumers in the case of adverse events exist federally for cannabinoid hemp products.

- ***A dangerous lack of consumer awareness and education:*** Consumers may not know that the hemp products they are purchasing can have an intoxicating effect or result in a positive drug test. In states like Oklahoma and Texas, where adult-use or recreational cannabis consumption is not legal, consumers can purchase untested, unregulated hemp-derived intoxicants that mimic the effects of high potency THC products at CBD shops and gas stations. These types of products are also available in states with regulated adult-use markets but are sold outside of the regulatory structure due to their designation as “hemp” and are available for purchase online and delivered through the mail. Consumers are not only being misled intentionally, they can experience potential health risks from consuming and inhaling products that have not been properly tested or regulated.
- ***Product packaging and forms that appeal to children and mimic existing commercial food and candy products.*** Whereas state marijuana markets are highly regulated in terms of product form and packaging to prevent accidental consumption of products by children, intoxicating hemp products exist in a range of forms (some that mimic commercially available food and candy items) and are sold with packaging that may appeal to children. The national poison centers documented more than 2,000 cases of exposure to hemp-derived delta-8 THC between January 2021 and February 2022: 40% of those cases involved unintentional exposure to delta-8 THC and 82% of those cases were in pediatric patients. 70% of all cases required a healthcare facility evaluation and 8% of those resulted in admission to a critical care unit.<sup>10,11,12</sup>
- ***Inaccurate and incomplete product labeling.*** Hemp-derived products are not subject to federal packaging and labeling requirements and often do not include accurate and complete ingredient and labeling information, or information about how the product was manufactured. For example, the State of Maryland conducted a study of hemp-derived products available at retail establishments in the state in 2022.<sup>13</sup> Only 3 out of 25 (12 percent) of the hemp-derived products purchased across the state included warning statements that the product may be impairing or intoxicating, despite every product containing high levels of THC. In addition, THC potency levels for all hemp-derived products tested fell outside the standard 10 percent variance that is acceptable in all regulated marijuana and cannabis markets, meaning what was in the product was not what was on the label. A study by researchers at Johns Hopkins tested 105 topical CBD products and found that only 24% were accurately labeled for CBD, and many products contained THC and did not advise consumers on the label.<sup>14</sup>

**3. The federally unregulated hemp-derived cannabinoid marketplace undermines state-regulated marijuana markets which have been set up to protect consumers and prevent youth access.** Counter to state-regulated marijuana markets, intoxicating hemp-derived products cost less to produce and sell because there are no manufacturing or testing standards, or product quality and safety requirements in place to protect consumers. Intoxicating hemp-derived products are available without added state-excise taxes, in mainstream locations where consumers - including minors - can purchase other goods and services. Consumers can purchase these products using credit cards (vs. the cash-based state-marijuana markets) and can have them delivered through the mail across state lines. When compared to state-regulated marijuana markets, the current cannabinoid hemp market is effectively an alternative unregulated market for intoxicating cannabinoids, with lower barriers to entry and access due to a complete lack of consumer safety and public health regulations.

## Regulatory Considerations

- 1. States and territories face significant challenges regulating or restricting the sale of intoxicating hemp-derived products.** Absent federal regulation of hemp-derived products, or even clarification on the legality of these products under federal law, states are limited in their ability to protect consumers and prevent youth access. States cannot easily regulate interstate commerce of hemp or online markets without federal intervention and enforcement. The overly broad federal definition of “hemp” in the farm bill has led to the exploitation of a seemingly endless permutation of loopholes.<sup>15</sup> The resulting intoxicating so-called “hemp” products can be naturally occurring, partially synthetic, or totally synthetic and are produced under the guise of federal legality, making it extremely difficult for states to protect public health and maintain safe, well-regulated medical and adult-use marijuana markets.
- 2. Hemp-derived cannabinoid products are not just one thing. They exist in many forms with many different active ingredients.** Cannabinoids function the same whether they come from “hemp” or “marijuana”. State regulations often take a holistic view and classify and regulate intoxicating hemp products in the same manner as marijuana. In some states, Attorney General’s offices have been engaged in trying to protect consumers. Low-THC hemp products are often left available to the general public under these regulatory frameworks. **But how low-THC is defined matters greatly.** Unless Congress intends to legalize marijuana under the guise of “hemp,” low THC thresholds should be nonintoxicating to a majority of people, and substantially lower than what we see in marijuana markets (which range from 5-10 mg THC/serving and 50-100 mg THC/package). The state of Oregon published a review of the science to help guide these levels.<sup>16</sup>
- 3. The current landscape of hemp-derived cannabinoid products warrants urgent federal action and regulation.** Despite what many consumers may assume when purchasing a commercial product, **the production and sale of hemp-derived cannabinoid products is not regulated federally.** Federal hemp regulation stops at the border of the farm. Finished hemp products are not regulated federally for contaminants, ingredients, cannabinoid content, mode of consumption or product type, packaging and labeling, or serving size. **This is in stark contrast to the state-regulated cannabis frameworks,** which aim to prioritize public and consumer safety by requiring product testing, ingredient disclosure and compliance, adherence with accepted product types, inclusion of specific packaging and labeling – including warnings and child resistant packaging and serving size and package limits for intoxicating cannabinoids.
- 4. A comprehensive federal regulatory framework that addresses all hemp-derived cannabinoids is urgently needed.** This framework cannot just focus on CBD. It must be a framework that includes the cannabinoid hemp products we see in the field today – including intoxicating products being converted from CBD, and products being manufactured from whole-plant CBD products that contain many other cannabinoids (some potentially intoxicating, some not) that must be regulated. A federal regulatory framework must account for the many ways cannabinoid hemp products are consumed – as foods, beverages, vaped products, and smoked products. It must acknowledge that many of the same compounds from the *Cannabis sativa L.* plant are being regulated in states as state legal – but federally illegal marijuana. A narrow regulatory focus only on specific cannabinoids (e.g., CBD alone) will leave gaps that will most certainly be exploited and continue to pose risks to consumers and public health.

**5. A federal regulator with a background in public health and consumer safety (like FDA) is urgently needed for hemp-derived cannabinoid products, including but not limited to CBD.** The 2018 Farm bill did not clearly name a regulator for finished cannabinoid hemp products. A regulator should be promptly identified, authorized, and funded, with a short and specified timeframe to:

- Provide clear boundaries and definitions for the products that will be regulated, including combusted and aerosolized products, which do not fit into existing federal food, dietary supplement, or cosmetics regulatory pathways.
- Set minimum requirements for processing and manufacturing, ingredients, modes of consumption and product types, testing, packaging and labeling, and serving size (among other elements).
- Establish and implement an education and enforcement approach to ensure compliance.
- Conduct consumer education about legal products.

As an association of state regulators, **CANNRA is not encouraging the re-criminalization of cannabinoid hemp products, but rather comprehensive regulation that accounts for the potential product risks and the existing markets that states have carefully architected for marijuana.** States have demonstrated that thoughtful regulatory frameworks can protect consumers and public health and move us away from the harms of prohibition. As state regulators know well, these are complex regulatory questions that will require a regulator to be nimble and course correct as more scientific information comes out.

### Conclusion

Whether through the Farm Bill or another priority piece of legislation, a broad regulatory framework is urgently needed to address hemp-derived cannabinoid products. **Congress has an opportunity to learn from the approaches that states have taken to set a thoughtful and comprehensive federal regulatory framework.** The regulation of hemp-derived products is complex and nuanced, and state regulators understand those nuances better than anyone. CANNRA's state cannabis and hemp regulators, who work every day regulating cannabinoids and implementing frameworks that protect consumers, public health, and markets, stand ready to engage with members of Congress to provide valuable insight from members' states and jurisdictions and to inform a federal regulatory framework that does the same.

I want to thank members of the committee who have reached out to speak directly with their hemp and cannabis regulator, and I want to extend an invitation to connect any of you with your state cannabis and hemp regulator, if you do not already know them. We look forward to being a resource to Congress on this important topic. Thank you for inviting me to speak on behalf of CANNRA to share a state regulatory perspective.

Respectfully,



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## ABOUT CANNRA

The Cannabis Regulators Association (CANNRA) is a nonpartisan, non-profit (501c4) association of high-level government officials involved in cannabis regulation across 45 states and U.S. territories, and Canada. CANNRA does not have any nongovernmental members. CANNRA was founded in late 2020 and stemmed from regular convenings cannabis regulators were holding to share learnings, identify best practices, and troubleshoot challenges.

### CANNRA's Mission and Principles:

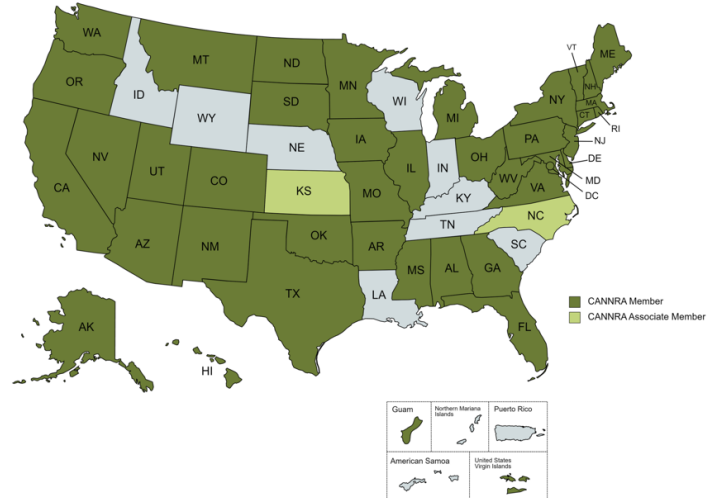
CANNRA's mission is to convene, educate, and support governmental agencies responsible for implementing cannabis policies and regulations. We accomplish this by fostering collaboration and coordination to identify and share best practices that safeguard public health and consumer safety, promote equity, and create regulatory certainty for industry participants. We seek out a diversity of perspectives on regulatory issues related to cannabis and work with a wide array of stakeholders. CANNRA strives to harmonize regulatory approaches where possible, while acknowledging that the same cannabis policy does not work in all places and that governmental jurisdictions have unique populations, politics, geography, and needs.

### CANNRA Members:

U.S. CANNRA members include the primary cannabis regulatory agencies in the following states and U.S. territories: AL, AK, AR, AZ, CA, CO, CT, DE, DC, FL, GA, GUAM, HI, IL, IA, KY, ME, MD, MA, MI, MN, MO, MS, MT, NV, NH, NJ, NM, NY, ND, OH, OK, OR, PA, RI, SD, TX, USVI, UT, VT, VA, WA, and WV. CANNRA members represent states and territories with a variety of cannabis policies in place. More than half of CANNRA members have joined at a level that allows multiple state agencies to participate in CANNRA, extending beyond the primary regulatory agency and including state departments of agriculture, transportation, public health, behavioral health, revenue, and environment (among others). In addition to states with regulatory programs for medical or adult use cannabis, we have two non-voting, associate state members that do not yet regulate cannabis but want to learn more about the regulatory approach for cannabis: KS and NC. Internationally, Health Canada has joined CANNRA as an international non-voting member agency.

### Leadership and Committees:

CANNRA operates through a 7-member board that consists of cannabis regulators representing a diversity of state cannabis regulatory programs in terms of policies and geography. We have more than a dozen topic-based committees spanning virtually all facets of cannabis regulation. Committees are co-chaired by staff from cannabis regulatory agencies and other associated governmental agencies.







April 17, 2023

The Honorable Kevin McCarthy  
Speaker of the House  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Hakeem Jeffries  
Minority Leader  
U.S. House of Representatives  
Washington, D.C. 20515

The Honorable Chuck Schumer  
Majority Leader  
U.S. Senate  
Washington, D.C. 20510

The Honorable Mitch McConnell  
Minority Leader  
U.S. Senate  
Washington, D.C. 20510

### **Re: Urging Federal Action to Address Hemp-Derived Cannabinoid Product Regulation**

The Cannabis Regulators Association, a nonpartisan association representing cannabis and hemp regulatory agencies from more than 40 member states and U.S. territories, urges federal action to provide a regulatory framework for hemp-derived cannabinoid products. These products currently lack federal manufacturing, testing, and labeling requirements, and they pose consumer safety and public health risks. In the absence of federal regulation, state government agencies have borne the brunt of the efforts to effectively regulate cannabinoid hemp products.

The Agriculture Improvement Act of 2018 (the Farm Bill) was drafted with a focus on agricultural commodities and non-intoxicating hemp products. However, the language of the bill created a thriving market for intoxicating cannabinoid products that fit within the definition of “hemp.” State cannabis and hemp regulators have observed three primary loopholes that businesses are using to justify the manufacture or sale of intoxicating hemp-derived products:

- **“0.3% loophole”:** While the threshold of 0.3% delta-9 THC (tetrahydrocannabinol) by weight is a small amount of THC in a hemp plant, when applied to hemp-derived products (e.g., chocolate bars, beverages, etc.) which can weigh significantly more, 0.3% by weight can amount to hundreds of milligrams of THC. For example, a 50-gram chocolate bar at 0.3% THC would have around 150 mg of THC (30 times the standard 5 mg THC dose established by the National Institute on Drug Abuse). A family sized pack of cookies weighing 20 oz can contain around 1700 mg of THC using the 0.3% THC threshold.
- **“THCA loophole”:** The 0.3% threshold specifically applies to “delta-9 THC.” As written, it does not include delta-9 THCA (the precursor to THC). Hemp plants produce a much greater amount of THCA than THC, and THCA readily converts into THC when smoked, heated, or combusted. Most states with medical or adult-use cannabis programs define “total THC” to capture the total intoxicating potential of cannabis by combining the amount of THC with the potential of THCA that can convert into THC. Despite some states’ efforts

to address this issue within regulated markets, many hemp businesses are selling “THCA hemp” flower that contains less than 0.3% delta-9 THC but has a total THC concentration of 15% to 20%. This so-called “hemp” is indistinguishable from marijuana flower.

- **“Derivatives loophole”:** The definition of hemp also includes “all derivatives” of the cannabis plant. As a result, many hemp businesses are taking CBD (cannabidiol) derived from hemp and chemically converting it into intoxicating cannabinoid derivatives like delta-8 THC, THCO acetates, and HHC (hexahydrocannabinol). This loophole appears to be an unintended outcome of copying catch-all language from the Controlled Substances Act and is resulting in chemically derived compounds that have not been well-studied for human safety.

While intoxicating cannabinoid hemp products present significant consumer safety and public health risks, the unregulated manufacture and sale of non-intoxicating cannabinoid hemp products can also pose potential risks. In considering the reauthorization of the Farm Bill, Congress should consider the experiences of state cannabis and hemp regulators who have grappled with these regulatory issues.

**CANNRA has identified several key considerations as the Farm Bill language is revised and cannabinoid hemp product regulation is debated:**

- Explicitly separating regulation of conventional agricultural and industrial hemp (e.g., food, fiber, seed, grain) from regulation of cannabinoid hemp products, and clarifying the definition of hemp in the Farm Bill to state that the 0.3% THC threshold only applies to plants, not to finished products;
- Having federal regulations that set a floor, while allowing states to implement more restrictive regulations without being preempted by federal law;
- Identifying appropriate limits for THC and other cannabinoids in finished products, including approaches that address full-spectrum products (which can contain high amounts of THC), approaches to determine a threshold for THC at which a majority of people will not be intoxicated, and approaches to prevent the sale of any potentially intoxicating cannabinoid product to minors;
- Addressing “total THC” (including THCA) in hemp regulations generally, rather than just in the context of pre-harvest crop testing;
- Implementing labeling requirements that inform consumers of the cannabinoid composition of the products they purchase, including the total milligrams of THC in the serving size and product;
- Implementing manufacturing and testing requirements on all cannabinoid hemp products to ensure that products are free from contaminants and potentially harmful byproducts;
- Regulating intermediate and finished-product manufacturers, including safe harbor for crude or in-process hemp extracts that exceed 0.3% THC in the manufacturing process but are ultimately processed into federally compliant finished products;
- Regulating the manufacture and sale of semisynthetic “derivative” products (e.g. products derived chemically from materials sourced from hemp) in a way that ensures consumer safety;
- Developing a regulatory approach to address the manufacture of any synthetic (e.g., cannabinoids made chemically) and biosynthetic (e.g., cannabinoids derived from genetically modified yeast or algae) cannabinoids or products to ensure consumer safety;
- Engaging essential federal agencies that should have regulatory oversight over cannabinoid hemp products, including not only the US Department of Agriculture, but also the Food and Drug Administration, the Environmental Protection Agency, and if a tax mechanism is being considered, the Alcohol and Tobacco Tax & Trade Bureau.

As discussions about revisions to the Farm Bill continue, it is vital to include cannabis and hemp regulators at the table as a group of government officials with direct regulatory experience related to cannabinoid products. Federal engagement is urgently needed to support states in the regulation of these products and to protect public health and consumer safety. CANNRA stands ready to serve as a resource as discussions about the Farm Bill reauthorization continue, and a regulatory framework is considered for hemp-derived cannabinoid products.

Respectfully,



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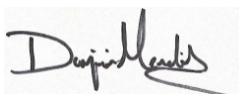
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### CANNABIS REGULATORS ASSOCIATION

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# Considerations in Establishing Cannabinoid Limits for Hemp Products

## Rationale for Rulemaking

Oregon Liquor and Cannabis Commission

December 27, 2021

## Impetus for Rulemaking

In 2021, the Oregon Legislature passed House Bill 3000 ([Oregon Laws 2021, Chapter 542](#)) to address several issues related to cannabis, including:

- Directing the Oregon Liquor and Cannabis Commission (OLCC) to establish cannabinoid limits above which an industrial hemp commodity or product becomes an “adult use cannabis item.” Products that exceed these limits can continue to be sold on the general market for hemp products in Oregon (outside the OLCC-regulated marijuana market), but cannot be sold to minors.
- Directing OLCC to establish cannabinoid limits for industrial hemp commodities or products generally. Products that exceed these limits cannot be sold to consumers under Oregon law.

These issues are related, but distinct. The language about “adult use cannabis items” addresses the concern that minors could purchase hemp products containing potentially-intoxicating quantities of tetrahydrocannabinol (THC<sup>1</sup>), the substance primarily responsible for the “high” that marijuana produces. The language about hemp items generally addresses the concern that hemp products are currently legally allowed to contain larger quantities of THC than are permitted in Oregon’s adult use marijuana and medical marijuana programs based on a limit of 0.3% total THC:

**Table 1.**

What does 0.3% look like?		
	Hemp Potency Limit	Adult-Use Marijuana Limit <sup>2</sup>
20 g pack of gummies:	60 mg $\Delta^9$ -THC	50 mg $\Delta^9$ -THC
85 g bar of chocolate:	255 mg $\Delta^9$ -THC	50 mg $\Delta^9$ -THC
12 oz beverage:	>1,000 mg $\Delta^9$ -THC	50 mg $\Delta^9$ -THC

Any limits that OLCC establishes will only apply to sales to minors and sales to consumers under Oregon law. These limits have minimal impact on an Oregon hemp business’s ability to compete in the hemp market in other states. The only cannabinoid limit on industrial hemp products and commodities exported from Oregon is that they cannot exceed 0.3% total THC, in accordance with the limit in federal law.

## Current Regulatory Landscape

The term “cannabis” refers broadly to plants in the genus *Cannabis*, family Cannabaceae. Cannabis regulations generally distinguish between low-THC plants or products made from low-THC plants (“hemp”) and high-THC plants or products made from high-THC plants (“marijuana”).

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<sup>1</sup> Throughout these rules, “THC” generally refers to “total  $\Delta^9$ -THC,” which is calculated by adding the concentration of  $\Delta^9$ -THC and  $0.877 \times \Delta^9$ -THCA. Much of the THC in the cannabis plant occurs in the form of  $\Delta^9$ -THCA, a generally non-intoxicating substance, which converts to the more intoxicating  $\Delta^9$ -THC when exposed to heat.

<sup>2</sup> This table is based on the limits that are currently in effect. OLCC draft rules propose to increase the THC limit for marijuana edibles to 100 mg per container in 2022.

In 2018, hemp was removed from the United States federal schedule of controlled substances by the Agriculture Improvement Act of 2018, also referred to as the “2018 Farm Bill” (Public Law 115–334). This represented a significant expansion of privileges that were implemented through the Agricultural Act of 2014, which allowed the establishment of agricultural pilot programs for the cultivation of industrial hemp (Public Law 113–79).

The 2018 Farm Bill defines hemp as including “all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” This means that products and commodities made from hemp are also removed from the schedule of controlled substances. Many hemp businesses have interpreted “derivatives” to also include substances created synthetically from hemp extracts, which has led to a proliferation of semisynthetic cannabinoids (“artificially derived cannabinoids”) being incorporated into products sold to consumers. The range of artificially derived cannabinoids currently being sold include semisynthetic versions of naturally-occurring cannabinoids as well as novel cannabinoids that have no history of human use. Some artificially derived cannabinoids are marketed for their intoxicating effects, while others are marketed as health and wellness products.

In the context of hemp plants and flower, hemp industry advocates have argued that the federal limit of 0.3% THC is not adequately based in science. The number comes from a study of a wide variety of cannabis plants grown in Canada under less-than-ideal conditions (Small & Beckstead 1973a; Small & Beckstead 1973b), and one of the authors of that study has come out in support of increasing the THC limit for hemp plants (Israel 2018). But if the 0.3% THC limit for plants is inadequately scientific, a 0.3% THC limit for consumer products is even less so. As shown in Table 1, above, allowing 0.3% THC in foods or supplements allows these products to contain extremely impairing amounts of THC. Scientifically-grounded assessments of the acceptable non-impairing concentration of THC in foods, presented below, result in concentrations that are orders of magnitude smaller than 0.3%. In establishing 0.3% THC as the limit for hemp products generally, rather than the limit for THC in hemp plants, it is not clear that any consideration was given to the quantities of THC that consumers might be exposed to.

While the 2018 Farm Bill removed hemp from the federal schedule of controlled substances, it also “explicitly preserved” the authority of the U.S. Food and Drug Administration (FDA) “to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act” (Gottlieb 2018). In a written response to the passage of the 2018 Farm Bill, FDA Commissioner Scott Gottlieb noted:

**“Additionally, it’s unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.** This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it’s illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.” (Gottlieb 2018; emphasis added)

This means that all foods and supplements containing CBD or THC are federally illegal, even when derived from legally-grown hemp. The only exception to this is foods that are derived from parts of the hemp plant that may not contain CBD or THC. The FDA has evaluated Generally Recognized as Safe (GRAS) notices for certain products derived from hemp seed and had no questions regarding the conclusion that the use of the products as described in the notices is safe (FDA 2021a; Gottlieb 2018). The notices specified that THC was present in the food products only as a trace contaminant at very low levels: No more than 4 mg/kg (0.0004%) in hulled hemp seeds and no more than 10 mg/kg (0.001%) in hemp seed oil (Keefe 2018a; Keefe 2018b).

The FDA has reiterated their position that foods and supplements containing CBD or THC are unlawful several times, however, businesses that manufacture or sell these prohibited products have generally not faced any consequences. The FDA appears to be restricting its enforcement action to sending warning letters to companies that sell CBD products with claims that the product can prevent, diagnose, treat, or cure serious diseases (FDA 2019; FDA 2021a; FDA 2021b).

It is important to note that the FDA's position on this is specific to CBD and THC, because they are active ingredients in drugs. It does not apply to hemp derivatives and products generally. Other hemp-derived substances may be eligible for use in foods or dietary supplements if they have a GRAS determination, or if the FDA responds favorably to a new dietary ingredient (NDI) notification. OLCC staff are not aware of any GRAS determinations or NDI notifications related to any other hemp cannabinoids. It seems that the only thing preventing the FDA from evaluating other hemp cannabinoids as dietary ingredients is the fact that no manufacturer has yet submitted notifications for these ingredients.

While foods and supplements containing CBD, THC, or other hemp-derived cannabinoids currently violate federal law, Oregon's laws are less restrictive. With the proliferation of hemp in Oregon prior to the passage of the 2018 Farm Bill, Oregon law was crafted with the intent that hemp-derived ingredients would not be prohibited in foods. Oregon Revised Statutes (ORS) 571.272(2) declares that "For purposes of ORS chapter 616 [laws pertaining to food and other commodities], the [Oregon Department of Agriculture (ODA)] may not consider industrial hemp or industrial hemp commodities or products to be an adulterant." With the passage of House Bill 3000 in 2021, this statute was amended to give ODA the authority to consider artificially derived cannabinoids to be an adulterant. To date, ODA has not yet exercised that authority.

This is the context in which OLCC entered rulemaking: There are a wide variety of cannabinoid hemp commodities and products available to consumers, including minors, that are subject to regulation by the FDA under the FD&C Act and the Public Health Service Act. These products are almost universally not in compliance with those regulations. Currently, the only limit on cannabinoid content for these products under Oregon law is that they may not exceed 3 mg/g (0.3%) total  $\Delta^9$ -THC, which allows hemp products to contain quantities of THC that far exceed the levels permitted in Oregon's adult use marijuana program.

## Rationale for Differentiating Sales to Minors and Adults

As mentioned above, there were two related but distinct motivations for directing OLCC to set cannabinoid content limits for minors and for hemp products generally:

- Minors should not be able to purchase products that contain an intoxicating quantity of THC.

- Considering Oregon’s robustly-regulated market for high-THC cannabis products, hemp products sold to consumers should not have quantities of THC that are on par with or exceed Oregon’s limits on THC in adult use marijuana products.

In addressing products sold to minors, it is important that THC should not be present in the products in a quantity that may be intoxicating. In addressing products sold to adults, who may purchase high-THC marijuana products through a licensed adult use marijuana retailer, it is not necessarily critical to limit the products to a non-intoxicating amount of THC.

When considering cannabinoid limits for sale to adults, it is important to bear in mind that a significant share of the cannabinoid hemp product market consists of “full-spectrum” products – products that contain CBD, THC, other cannabinoids, and other naturally-occurring substances from hemp in approximately the same proportion that they occur in the hemp plant. CBD and THC in hemp exist in proportion to one another. Even high-CBD low-THC plants may produce THC in proportion to CBD at approximately a 1:20 ratio (Zirpel *et al.* 2018). That means full-spectrum hemp products that contain large concentrations of CBD will also have elevated levels of THC.

This makes it impossible to set a THC limit that prohibits the sale of intoxicating hemp products without also prohibiting the sale of full-spectrum hemp products. Conversely, allowing full-spectrum hemp products necessarily means setting a THC limit that is high enough for some intoxicating hemp products to also be sold.

Differentiating between cannabinoid limits for sales to minors and sales to adults recognizes the importance of continuing to allow full-spectrum hemp products to be sold to adults without also allowing the sale of large amounts of THC to minors.

## THC Limits for Sales to Minors

During the rulemaking process, OLCC heard concerns that minors should not be purchasing *any* quantity of THC. One major drawback to setting the threshold at zero is that it would be impractical to enforce. With a limit of zero, a testing lab might use a method with a relatively high threshold for detection or quantification of THC and consequently “not find” THC even when a significant amount might be present.

Setting a specific limit, either on a percentage basis or a milligram-per-container basis, and requiring a certificate of analysis to show the laboratory can detect at that level, provides more assurance that adult use cannabis items will not be sold to minors.

In order to establish a non-intoxicating THC threshold, it is instructive to consider the limits that are currently in place for alcohol in products sold to minors, as well as work that has been done internationally to establish safe thresholds for the presence of THC in foods.



## Comparison to Alcohol

Alcohol may be present in small quantities in foods and beverages other than alcoholic beverages. In order to be considered “non-alcoholic,” a food or beverage can contain no more than 0.5% alcohol by volume. A minor may purchase non-alcoholic foods and beverages that contain this small amount of alcohol.

This 0.5% threshold for alcohol is not at all comparable with the 0.3% threshold for THC in hemp products because alcohol is much less potent than THC on a weight-to-weight basis. One standard unit of alcohol – a typical 12 fl oz beer, 5 fl oz glass of wine, or 1.5 fl oz portion of distilled spirits – contains 14 g or 14000 mg of alcohol (National Institute on Alcohol Abuse and Alcoholism [NIAAA] 2021). By contrast, a standard unit of THC is only 5 mg (National Institute on Drug Abuse [NIDA] 2021). There is nearly a 3000-fold difference between the weights of these standard units.

The relevant limiting factor with consumption of alcohol from non-alcoholic beverages is the amount of liquid that a person can reasonably drink at one time. A person would have to consume approximately one gallon of liquid at 0.5% to consume one standard unit of alcohol. By contrast, a person would only have to drink one-third of a teaspoon (1.7 ml) of liquid at 0.3% to consume one standard unit of THC.

A threshold for THC equivalent to the non-alcoholic threshold can be derived on a percentage basis, or on a per-container basis by comparison to a typical unit of a non-alcoholic beverage:

- **Percentage equivalence:**  $0.5\% \text{ alcohol} \times (5 \text{ mg THC} \div 14000 \text{ mg alcohol}) = 0.0002\% \text{ THC}$ .<sup>3</sup>
- **Per-container equivalence:** Taking 12 fl oz to be a typical container size for a non-alcoholic beverage,  $12 \text{ fl oz} \times 0.5\% \text{ alcohol} \times 29.5735 \text{ ml/fl oz} \times 0.789 \text{ g/ml} = 1.4 \text{ g alcohol}$ <sup>4</sup>. Since a standard unit of alcohol is 14 g, this means a typical container of a non-alcoholic beverage can contain one-tenth of a unit of alcohol. A standard unit of THC is 5 mg, so one-tenth of a standard unit of THC would be 0.5 mg THC.

Most hemp products have smaller weights than typical non-alcoholic products, which makes a simple percentage limit on THC significantly more restrictive than a milligram-per-container limit for the vast majority of products. For example, under this percent limit, a 1 oz tincture would be limited to approximately 0.06 mg THC.

## Comparison to International Standards

As hemp seed and products derived from hemp seed have become more prevalent in foods, significant work has been done internationally to establish safe levels for residual THC in these foods. While the seeds of hemp do not naturally contain any THC, they are contained within a part of the plant called the calyx, which does contain THC. Some amount of THC transfers from the plant to the seeds in the course of processing (Food Standards Australia New Zealand [FSANZ] 2002). Consequently, several countries that allow hemp seeds and hemp seed oil to be used in foods have established limits or guidance values on the amount of trace THC contamination that may be present in hemp seeds or hemp seed-derived food products to ensure

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<sup>3</sup> The equation is  $[\text{limit of alcohol by volume}] \times \frac{[\text{standard unit of THC}]}{[\text{standard unit of alcohol}]}$

<sup>4</sup> Using the density of pure ethanol in order to convert from volume to mass.

that THC exposure through hemp foods does not pose a risk of intoxication or other adverse consequences. Significantly, these analyses consider exposure for the entire population, not only exposure for adults.

### General guidelines for THC exposure

Several efforts have been made to evaluate appropriate levels of exposure to THC originating from hemp in the food supply.

In general, these evaluations are based on establishing a “lowest observed adverse effect level” (LOAEL) or a “no observed adverse effect level” (NOAEL) for THC, then adjusting that number for safety or uncertainty factors. This provides an estimate the amount of THC that can be consumed in a short period of time without significant health risks to the consumer (Liu & Chen 2003). This may be expressed as an “acceptable daily intake” (ADI), “acute reference dose” (ARfD), “health based guidance value” (HBGV) or “tolerable daily intake” (TDI). The following is a summary of these values from a variety of sources:

- Croatian Food Agency (Hrvatska agencija za hranu [HAH]): 0.5 mg/day ADI<sup>5</sup> (HAH 2011)
- European Food Safety Authority Panel on Contaminants in the Food Chain (EFSA CONTAM Panel): 1 µg/kg bw, equivalent to 0.08 mg for an 80 kg person (EFSA CONTAM Panel 2015; Bundesinstitut für Risikobewertung<sup>6</sup> [BfR] 2018)
- European Industrial Hemp Association (EIHA): 7 µg/kg bw HBGV, equivalent to 0.56 mg for an 80 kg person (EIHA 2021)
- Food Standards Australia New Zealand (FSANZ): 6 µg/kg bw TDI, equivalent to 0.48 mg/day for an 80 kg person (FSANZ 2002; FSANZ 2012)
- Leson Environmental Consulting, in an analysis commissioned by Dr. Bronner’s Magic Soaps and the North American Industrial Hemp Council (NAIHC): 0.5 mg/day ADI (Grotenhermen *et al.* 2001)

The majority of these values are in good agreement, being equivalent to approximately 0.5 mg THC. The EFSA evaluation is an outlier, proposing an ARfD equivalent to less than 0.1 mg THC for an 80 kg person. However, the German BfR supports the EFSA analysis, stating that “exceeding [the ARfD of 1 µg/kg bw] is undesirable from a toxicological point of view, since adverse health effects can no longer be ruled out with the required degree of certainty” (BfR 2021).

It is also worthwhile to consider the data that these analyses used to establish an LOAEL or NOAEL for THC. The following is a non-exhaustive selection of literature that addresses oral THC dosage, impairment, and adverse events:

- A study on the effects of oral THC in 16 healthy human subjects evaluated doses of 0, 5, 10, 15, and 20 mg/person. A dose of 5 mg THC was sufficient to affect the skill performance measures, but subjective intoxication based on self-reporting was indistinguishable from placebo. (FSANZ 2002, citing Chesher *et al.* 1990)

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<sup>5</sup> The English language summary contains a typo, specifying the ADI as 500 mg per day. In the original Croatian text, the correct figure is twice stated as 500 µg/day (e.g. “izračunat je ADI za THC putem hrane i iznosi 500 µg/dan.”).

<sup>6</sup> German Federal Institute for Risk Assessment.

- A study on treatment of anorexia associated with weight loss in patients with AIDS receiving placebo or 2.5 mg THC twice daily orally. Treatment-related adverse events were noted in 43% of patients receiving THC, compared with 13% of patients receiving placebo; 8.3% of patients receiving THC discontinued due to perceived drug toxicity, compared with 4.5% of patients receiving placebo. “Most patients who required dose reduction were able to tolerate the half-dose (one 2.5-mg capsule in the evening).” (Beal *et al.* 1995)
- A follow-up 12 month study involving patients from the previous study (Beal *et al.* 1995) starting with 2.5 mg THC once or twice daily orally and adjusting dosage up or down “based on patient response and side effects.” Dosage was adjusted in 38% of patients, with half of those reducing to 2.5 mg THC once daily and half increasing to between 7.5 and 20 mg daily. 15% of patients discontinued due to perceived drug toxicity. “Adverse events were primarily related to the central nervous system (for example, anxiety, confusion, depersonalization, dizziness, euphoria, somnolence, and thinking abnormality) and occurred in 35 of 93 patients (38%) enrolled in the study. In 19 patients, treatment-related adverse events were the primary or secondary reason for early study discontinuation.” (Beal *et al.* 1997)
- A study on treatment of spasticity in 57 patients with multiple sclerosis using oral cannabis extract with a THC:CBD ratio of 1:0.36. Five patients discontinued due to persistent side effects. “The maximally tolerated THC dose exhibited a bimodal distribution” with the largest numbers of patients consuming 27.5 mg THC daily, 7.5 mg THC daily, or 10 mg THC daily. (Vaney *et al.* 2004)
- A study on appetite and weight in 243 patients with cancer receiving placebo, 2.5 mg THC twice daily orally, or cannabis extract containing 2.5 mg THC and 1 mg CBD twice daily orally. Dose reductions due to adverse events were necessary in 33% of patients receiving THC or cannabis extract (Strasser *et al.* 2006)
- A randomized, double-blind study of the effects of “very-low-dose” oral THC and ethanol in 11 healthy human subjects. Participants did not report feeling any drug effects following administration of 2.5mg THC without any ethanol, but this dose produced “modest effects on subjective ratings, measures of cognitive performance, and physiological measures.” (Ballard & de Wit 2011)

### Specific limits on the concentration of THC in foods

Several countries have established limits or guidance values on the concentration of THC that is allowed in hemp-derived foods:

#### **Belgium**

*Cannabis sativa* is included on a list of plants that are prohibited from being used in foods. This regulation dates back at least to 1997, and was updated as recently as August 2021 (Arrêté Royal 2017; Arrêté Royal 2021). Belgium’s Federal Agency for the Safety of the Foodchain has clarified that this prohibition includes legally-grown hemp, but notes that “a derogation from the prohibition on the manufacture and marketing of these plants as foodstuffs or as components incorporated into foodstuffs may sometimes be requested. The assessment is made on a case-by-case basis, taking into account the THC content of each batch and the other characteristics of the product.” (Federal Agency for the Safety of the Food Chain [FASFC] 2018)

#### **Canada**

Canada allows hemp containing no more than 10 mg/kg THC (0.001%) in natural health products that are subject to the Natural Health Products Regulation rather than the Cannabis Act. Products with more than 10 mg/kg THC are regulated under Canada's federally-legal cannabis framework (Health Canada 2021). Prior to the passage of the Cannabis Act, hemp products containing no more than 10 mg/kg THC were similarly exempt from the Controlled Drugs and Substances Act (Health Canada 2020).

### **Germany**

Germany has not established formal limits on THC content in hemp-derived foods, however the German Federal Institute for Consumer Health Protection and Veterinary Medicine (BfVV<sup>7</sup>) established "guidance values" for THC content in hemp-derived foods in 2000 (BfVV 2000):

- 0.005 mg/kg THC (0.000005%) for non-alcoholic and alcoholic beverages
- 5 mg/kg THC (0.0005%) for edible oils
- 0.15 mg/kg THC (0.000015%) for all other foods

More recently, the German Federal Institute for Risk Assessment (BfR) reconsidered the previously-published guidance values and recommended that they be lowered because it is possible that a person consuming foods with THC content in accordance with the guidance values could ingest a dose of more than 2.5 mg THC per day. Only the guidance value for beverages was considered to be sufficiently conservative. (BfR 2018, BfR 2021)

### **Italy**

In 2020, Italy published the following limits on the concentration of "total THC," defined as the sum of  $\Delta^9$ -THC and  $\Delta^9$ -THCA (Gazzetta Ufficiale 2020):

- 2 mg/kg THC (0.0002%) for hemp seed and hemp seed flour (or other shredded, chopped, or ground preparations)
- 5 mg/kg THC (0.0005%) for hemp seed oil
- 2 mg/kg THC (0.0002%) for foods containing hemp-derived ingredients

### **New Zealand**

In 2012, Food Standards Australia New Zealand (FSANZ) approved an application for low-THC hemp as a food, establishing the following limits on the concentration of THC (FSANZ 2012):

- 5 mg/kg THC (0.0005%) in hemp seed
- 10 mg/kg THC (0.001%) in hemp seed oil
- 0.2 mg/kg THC (0.00002%) in beverages made from hemp seed
- 5 mg/kg THC (0.0005%) in any other hemp seed-derived product

### **Switzerland**

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<sup>7</sup> Bundesinstitut für Gesundheitlichen Verbraucherschutz Und Veterinärmedizin.

Switzerland has established THC limits for foods that include hemp seed since at least 1995 (Das Eidgenössische Departement des Innern<sup>8</sup> [EDI] 1995), although those limits have since been reduced. As of 2016, Switzerland imposes the following limits on THC concentration (EDI 2016):

- 20 mg/kg THC (0.002%) in hemp seed oil
- 10 mg/kg THC (0.001%) in hemp seed
- 5 mg/L THC (approximately 0.00063% by weight based on pure alcohol) in spirits
- 2 mg/kg THC (0.0002%) in baked goods
- 2 mg/kg THC (0.0002%) in pasta
- 1 mg/kg THC (0.0001%) in plant-based foods
- 0.2 mg/kg THC (0.00002%) in alcoholic beverages other than spirits
- 0.2 mg/kg THC (0.00002%) in non-alcoholic beverages
- 0.2 mg/kg THC (0.00002%) in herbal and fruit teas (based on a preparation of 15 g plant material per k kg water; boiling water poured over plant material and temperature held above 85 °C for 30 minutes)

### **Unites States**

The FDA has not yet established any formal limits for THC in hemp-based foods, however FDA has evaluated GRAS notices for hemp seeds and hemp seed oil and concluded that “these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. [...] The GRAS conclusions can apply to ingredients for human food marketed by other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications” (FDA 2021a). The GRAS notices for hulled hemp seed and hemp seed oil specify that the products contain THC below the following concentrations (Keefe 2018a; Keefe 2018b):

- 4 mg/kg THC (0.0004%) in hulled hemp seed
- 10 mg/kg THC (0.001%) in hemp seed oil

### **Conclusion**

On balance, a percentage limit by weight on THC content is likely to be significantly more restrictive than a milligram-per-container limit. In order to minimize the impact on segments of the industry selling products containing minimal amounts of THC while still prohibiting the sale of intoxicating quantities of THC to minors, a milligram-per-serving limit is preferable.

OLCC staff recommend maintaining the limit of 0.5 mg THC per container that was established through temporary rulemaking following the passage of 2021 House Bill 3000. This limit is very well-aligned with limits on the sale of non-alcoholic beverages to minors and with the majority of recommendations on acceptable daily exposure to THC through foods.

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<sup>8</sup> Switzerland’s Federal Department of Home Affairs.

## THC Limits for Sales to Adults

As discussed above, it is not necessarily critical to establish limits such that a product cannot contain an intoxicating quantity of THC when establishing cannabinoid limits for hemp products that are offered for sale to adults. In fact, limiting THC to a non-intoxicating level would effectively prohibit the sale of full-spectrum hemp products to consumers. Full-spectrum products constitute a significant portion of cannabinoid hemp products currently sold in Oregon, so prohibiting these products is not a desirable outcome.

Instead, the primary objectives in limiting THC content in hemp products for sale to adults are:

1. Establishing THC-per-serving limits such that a single serving is relatively unlikely to produce significant impairment in a typical adult consumer.
2. Establishing THC-per-container limits such that a hemp product contains substantially less THC than is permitted in Oregon's adult use marijuana system.

### Per-serving limits

Based on the data evaluated by various countries and other organizations in establishing safe limits of residual THC in hemp food products, the consensus appears to be that the LOAEL is 2.5 mg THC. This is partly because oral doses of THC below 2.5 mg have not been well-studied; it is possible that future studies could establish an LOAEL below 2.5 mg. However, not all studies that involved 2.5 mg found the dose to have an intoxicating effect. In the studies where adverse events related to administration of THC occurred at 2.5 mg, the incidence of adverse events was relatively low. Dr. Ethan Russo, former Director of Research and Development of the International Cannabis and Cannabinoids Institute, has described 2.5 mg THC as "a threshold dose for most people without tolerance" (Skodzinski 2021).

There is evidence that CBD may reduce the impairing effects of THC, although the data are not unanimous on this, and the effect may be dependent on the dose of CBD relative to THC (Ganesh *et al.* 2021; Petitet *et al.* 1998; Solowij *et al.* 2019). If CBD does reduce the effects of THC, full-spectrum products containing both THC and CBD could be better-tolerated than THC alone.

It may also be worthwhile to consider the effect on sensitive persons. There is significant individual variation in sensitivity to THC. In particular, elderly persons have been noted as being potentially more sensitive to the psychoactive effects of THC (Abbot Laboratories 2011).

Whatever per-serving limit is set for THC will ultimately have an impact on the amount of CBD that can be present in a serving of the product. As discussed above, high-CBD low-THC plants will typically contain THC in a ratio of around 1:20 with CBD. In other words, a full-spectrum product will typically contain 20 mg CBD for each milligram of THC that is present. There are many hemp products that aim to provide greater than 20 mg CBD per serving. If THC were limited to 1 mg per serving, doses above 20 mg CBD in full-spectrum hemp products would no longer be viable.

A per-serving limit of 2 mg THC balances the available data on the effects of THC with the concerns of established industry participants making full-spectrum THC products. Available data indicate that a typical adult consumer is relatively unlikely to be significantly impaired in this range. However, it is important that

consumers be adequately informed of the amount of THC they are consuming when using cannabinoid hemp products. OLCC staff are concerned about the lack of clear or consistent labeling standards for hemp products. The risk of accidental overconsumption of THC is significantly higher when a consumer is not able to quickly and easily determine how much THC is present in the product they are consuming.

### Per-container limits

At present, the only state that has established THC limits per-container for hemp products is Alaska, which limits THC content in a hemp product to no more than 50 mg under 11 Alaska Administrative Code (AAC) [§40.415](#). This is identical with the current limit for THC in adult use marijuana edibles in Oregon, but significantly lower than Oregon's limit for THC in adult use tinctures. In order to effectively accomplish the objective of establishing THC-per-container limits such that a hemp product contains substantially less THC than is permitted in Oregon's adult use marijuana system, it seems necessary to differentiate per-container limits for different categories of products, analogous to the THC limits for adult use marijuana products.

One basis for comparing the relative amounts of THC in hemp and marijuana products is to consider the amount of THC present in the plants. Hemp is limited by definition to no more than 0.3% total THC. By contrast, approximately 90% of marijuana in Oregon's adult use market contains 15% total THC or greater. This means that, for flower products, marijuana is typically at least 50 times more potent than legal hemp flower.

Considering this in the context of edibles, tinctures, and topicals:

- Marijuana edibles will be able to contain up to 100 mg THC in 2022. One-fiftieth of this limit would be 2 mg THC per container, which equates to approximately 40 mg CBD in a full-spectrum edible product. This seems unnecessarily restrictive and could contribute to significant packaging waste for products reformulated to stay below 2 mg THC per container. In this product category, it is more realistic to limit hemp products to one-tenth or one-fifth the amount of THC allowed in marijuana edibles: A limit of 10 mg THC would allow full-spectrum edibles with approximately 200 mg CBD, while a 20 mg THC limit would allow full-spectrum edibles with approximately 400 mg CBD. OLCC staff recommend a limit of 20 mg THC per container for hemp edibles and other cannabinoid hemp products (excluding tinctures and topicals).
- Marijuana tinctures can contain up to 1,000 mg THC. One-fiftieth of this limit would be 20 mg THC per container, which equates to approximately 400 mg CBD in a full-spectrum tincture product. This seems unnecessarily restrictive and could contribute to significant packaging waste for products reformulated to stay below 20 mg THC per container. In this product category, it is more realistic to limit hemp products to one-tenth the amount of THC allowed in marijuana tinctures: A limit of 100 mg THC would allow full-spectrum hemp tinctures with approximately 2,000 mg CBD. OLCC staff recommend a limit of 100 mg THC per container for hemp tinctures.
- Marijuana topicals can contain up to 6% THC by weight. One-fiftieth of this limit would be 0.12% THC. However, considering the low central bioavailability of THC when applied topically, there does not appear to be a compelling reason to limit hemp topicals beyond the statutory limit of 0.3% total THC by weight. The 0.3% THC limit is one-twentieth of the limit for THC in marijuana topicals. OLCC staff recommend no specific limit on the number of milligrams per container for hemp topicals.

Regardless of the maximum per-container limits established by OLCC, ORS 475B.254 (as amended by 2021 House Bill 3000) limits hemp products to no more than 0.3% total THC. In cases where the 0.3% limit is more restrictive than the milligram-per-container limit, the 0.3% total THC limit applies. For example, a 1 fl oz tincture weighing 25 g is limited to no more than 75 mg THC, even if OLCC establishes a limit of 100 mg THC per container for tincture products.

## Artificially Derived Cannabinoids

In House Bill 3000, the Oregon Legislature defined “artificially derived cannabinoids” explicitly in terms of how they are created: “a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the plant Cannabis family Cannabaceae.” There is no reference in the definition to whether the artificially derived cannabinoid has an intoxicating effect. Other parts of the bill, such as the definition of “adult use cannabinoid” specifically delineate when they are referring to the subset of artificially derived cannabinoids which are intoxicating<sup>9</sup>. From this, it can be inferred that the entire set of artificially derived cannabinoids includes all cannabinoids made through the methods described in the definition, not just the subset of those substances that may have an intoxicating effect.

Intoxicating artificially derived cannabinoids were included in the definition of “adult use cannabinoid” out of concern that they might be legally included in products sold to minors or used to circumvent the potency limits that apply to  $\Delta^9$ -THC in marijuana products. However, there are broader concerns applicable to all artificially derived cannabinoids, and it is the understanding of OLCC staff that these broader concerns are the reason that Section 17 of House Bill 3000 directs OLCC to establish limits on the cannabinoid content of hemp products, including: “The maximum concentration of any other cannabinoid, adult use cannabinoid **or artificially derived cannabinoid** that is permitted in a single serving of an industrial hemp product” (emphasis added). For these reasons, OLCC has considered both intoxicating and non-intoxicating artificially derived cannabinoids in the context of this rulemaking.

Entirely separate from any concerns about dosage, toxicity, or intoxicating potential, there is cause for concern related to impurities that may result from the manufacturing process by which an artificially derived cannabinoid is made:

- The process of synthesizing an artificially derived cannabinoid can employ a wide range of solvents and reagents. If adequate steps are not taken to remove residual solvents or reagents from the reaction product, a consumer could be exposed to the residual solvents or reagents. Marijuana and hemp products are subject to certain required compliance testing under Oregon law, but this compliance testing does not encompass all solvents that may be used in the production of an artificially derived cannabinoid, and they do not encompass any reagents at all. Further, it is impractical to generate a comprehensive list of solvents and reagents of concern because of the wide variety of synthetic routes that may be used to generate any number of artificially derived cannabinoids from a cannabis starting material.

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<sup>9</sup> E.g. “any artificially derived cannabinoid that is reasonably determined to have an intoxicating effect.”



- No chemical reaction is 100% efficient. In nearly every chemical reaction, some amount of side-reaction products<sup>10</sup> will also be created. The side-reaction products will differ depending on the specific reaction conditions, including the reagents, solvents, temperature, pressure, and atmosphere. The required compliance testing for hemp and marijuana in Oregon is based on the concerns presented by cannabis itself and processes that may be used to extract cannabinoids from cannabis. They do not encompass any side-reaction products that result from synthetic manipulation of a cannabis-derived starting material, nor is it practical to encompass side-reaction products of concern that could be generated by all possible syntheses that might use a cannabis-derived starting material.

OLCC staff have heard comments that these risks may be mitigated through implementation of a purity standard, such as requiring that all artificially derived cannabinoids be at least 97% pure. Unfortunately, this is not an adequate solution. Knowing that impurities make up no more than 3% of the product is only reassuring when it is known that the impurities are not harmful when consumed at that level. Without knowing the identity of the side-reaction products, which will vary depending on the specific synthetic route employed by the manufacturer, the potential toxicity of the side-reaction products also remains largely unknown

There are also practical complications to implementing a purity standard: At present, Oregon's OLCC-licensed, ORELAP<sup>11</sup>-accredited laboratories are not necessarily accredited for detection or quantification of any artificially derived cannabinoids, nor are their accredited methods sufficiently sensitive to report a purity level above 97% with a high degree of confidence.

Considering the potential risks, and the current inability to mitigate those risks through required compliance testing, it is appropriate to defer to the ordinary regulatory processes that would apply to any other novel synthetic material being introduced into a food or dietary supplement. The FDA generally regulates the introduction of novel synthetic ingredients into foods or dietary supplements, and provides multiple routes:

- GRAS determination: A business can make the determination that an ingredient is generally recognized as safe (GRAS), meaning that there is a reasonable certainty of no harm under the conditions of its intended use (21 CFR 170.30). The business may voluntarily submit notice of the GRAS determination to the FDA, allowing the FDA to evaluate the manufacturer's basis for making the GRAS determination, but the business is not required to notify FDA when they make a GRAS determination.
- NDI notifications: Prior to including a "new dietary ingredient" in a dietary supplement that will be introduced into interstate commerce, the manufacturer or distributor of the supplement or ingredient is required to submit notification to the FDA, including information about the basis for concluding that there is a reasonable expectation of safety for the use of the ingredient. This requirement does not apply to an ingredient that has been present in the food supply as an article used for food in a form in which the food has not been chemically altered. (21 CFR 190.6)

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<sup>10</sup> A product other than the desired product.

<sup>11</sup> Oregon Environmental Accreditation Program, the agency that accredits cannabis testing laboratories in Oregon.

To date, there is no evidence that manufacturers of artificially derived cannabinoids or products containing artificially derived cannabinoids are complying with these requirements prior to including their artificially derived cannabinoids in foods or supplements that enter into interstate commerce. Anecdotally, manufacturers and industry advocates justify this non-compliance by asserting that the FDA will not fairly consider any information about cannabis-derived ingredients. That assertion ignores two important facts: First, that active involvement by the FDA is not necessarily required if the manufacturer has sufficient evidence that there is a reasonable certainty of no harm to make a GRAS determination; and second, that the FDA has not yet been given the opportunity to evaluate a new dietary ingredient notification for an artificially derived cannabinoid because no such notification has been submitted.

The FDA's publicly-stated position is that CBD and THC specifically are excluded from being considered a dietary supplement under 21 USC 321 (ff)(3)(B), which states that the term "dietary supplement" does not include an article approved as a new drug or authorized for investigation as a new drug. It is on this basis that the FDA recently objected to NDI notifications for two dietary supplements containing full-spectrum hemp extracts (Welch 2021a; Welch 2021b). This exclusion does not apply to artificially derived cannabinoids unless they are an approved new drug or authorized for investigation as a new drug. Until an NDI notification is submitted for such an artificially derived cannabinoid, any assertions about the FDA's response to such a notification remains conjecture.

OLCC staff recommend that non-intoxicating artificially derived cannabinoids should not be permitted in products sold to consumers until they meet one of the established regulatory standards for affirming that there is a reasonable expectation of safety or certainty of no harm. Recognizing that products containing the artificially derived cannabinoid cannabidiol (CBD) are already prevalent in Oregon's cannabinoid hemp market, staff recommend that these products should continue to remain available, absent evidence of harm to consumers, for a period of 18 months while they work to establish a GRAS determination or complete an NDI notification, but limit these products to Oregon's more closely-regulated marijuana market where clear labeling standards apply and the Cannabis Tracking System provides a mechanism for effectively tracking a product recall should a recall become necessary. Oregon would not be alone in having regulations that effectively prohibit artificially derived cannabinoids in the general market for hemp products; the Colorado Department of Public Health and Environment (CDPHE 2021) has publicly clarified that "chemically modifying or converting any naturally occurring cannabinoids from industrial hemp is non-compliant with the statutory definition of "industrial hemp product."

OLCC staff further recommend that intoxicating artificially derived cannabinoids should not be permitted in products sold to consumers absent evidence of a reasonable expectation of safety or certainty of no harm. Should such evidence become available, OLCC could engage in further rulemaking to establish concentration and serving size limits and allow specific artificially derived cannabinoids to be present in products based on the evidence.

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**LEGISLATIVE REPORT**

*Hemp-Derived Non-Delta-9-Tetrahydrocannabinol Products*

**December 2022**

**Maryland Medical Cannabis Commission**

Tiffany Randolph, Esq., Chair

William Tilburg, JD, MPH, Executive Director

<b>Section</b>	<b>Page #</b>
I. <b>Introduction</b> .....	2-3
II. <b>Background</b> .....	3-7
<i>The Cannabis Sativa Plant and Existing Legal Definitions</i> .....	3
<b>Exhibit 1:</b> Visual representation of Maryland Statutory Definitions for Cannabis, Medical Cannabis, and Hemp .....	4
<i>2018 Farm Bill</i> .....	4-5
<b>Exhibit 2:</b> Actual and Projected Product Potency: Finished Food Products on a 0.3% dry-weight THC Basis .....	5
<i>Proliferation of Non-delta-9-THC Products</i> .....	5-6
<i>Federal Response</i> .....	7
<i>Lack of Enforcement of FDA Regulations</i> .....	7
III. <b>Public Health and Safety Concerns</b> .....	8-10
IV. <b>Commission Research and Study Activities</b> .....	10-24
<i>Commission Study and Analysis of Commercially Available Products</i> .....	10-15
<b>Exhibit 3:</b> Consumer Safety Information and Warning Labels.....	11
<b>Exhibit 4:</b> Share of Test Results within Acceptable Error Range: Label Claims and Product COAs .....	12
<b>Exhibit 5:</b> Vape Product Potency: Label Claims, Product COAs, and Test Results.....	13
<b>Exhibit 6:</b> Edible Product Potency: Label Claims, Product COAs, and Test Results.....	14
<i>Research and Monitoring of Other States</i> .....	15-18
Colorado.....	15-18
Virginia .....	18-19
<i>Other States Regulation of Hemp-Derived Products</i> .....	20-23
Oregon.....	20
West Virginia .....	20-22
Florida.....	22-23
New York.....	23-24
V. <b>Commission Stakeholder Engagement and Feedback</b> .....	24-26
<i>Survey Results</i> .....	24-25
<i>Other Feedback and Recommendations</i> .....	25-26
VI. <b>Recommendations</b> .....	26-30
1. Align product regulations with the health and safety risks of the product. ....	27-29
2. Require certain hemp-derived products to be subject to laboratory testing, packaging and labeling, therapeutic claims standards and other product safety measures.....	29-30
3. Only allow for sales of certain products in licensed, regulated establishments.....	30
4. Expand public health messaging and resources established under Chapter 26 of the Acts of 2022 to include any THC Product.....	30-31
VII. <b>Conclusion</b> .....	31
VIII. <b>Appendices</b> .....	31



## I. Introduction

### *Legislative Mandate – Regulation of Non-delta-9 THC Products*

Chapters 511 and 512 of the Acts of 2022 require the Maryland Medical Cannabis Commission (“Commission”) to study and make recommendations on the classification and regulation of tetrahydrocannabinols (THC), other than delta-9-THC, that are artificially, synthetically, or naturally derived and manufactured products containing delta-8 and delta-10-THC. **Delta-9-THC** is the compound most associated with intoxication or psychoactive effects of cannabis, and is currently regulated within the Maryland Medical Cannabis Program solely for medical purposes. With the ballot referendum to legalize adult-use cannabis beginning July 1, 2023, approved by Maryland voters in the November general election, delta-9 products for adult use (known as adult-use cannabis) will be overseen by the State under a new adult-use regulatory framework.

**By way of scientific background, delta-8 and delta-10-THC are isomers of delta-9. Isomers** are defined as compounds with the same formula, but with a difference in the arrangement of atoms. In the instances of delta-9 compared to delta-8 and delta-10, the difference is the placement of a carbon double-bond (in the eighth, ninth, or tenth place for delta-8, delta-9, or delta-10, respectively). Throughout the Commission’s research, concerns were also raised around **derivative** compounds. **Derivatives** are compounds produced from or related to another compound, and may share less of a molecular similarity than isomers (e.g., another compound of note, hexahydrocannabinol or HHC is a derivative of THC, as it adds hydrogen to the compound, through a process called hydrogenation). The term **derivative** may also reference using cannabidiol (CBD) compounds to create delta-8-THC. In this instance, the delta-8 created would be a *derivative* of CBD, and an *isomer* of delta-9-THC.

The Commission conducted this study in consultation with the Maryland Department of Agriculture, the Maryland Hemp Coalition, the Maryland State Police - Forensic Sciences Division, U.S. Cannabis Council, and the Maryland Healthy Alternatives Association. The Commission further sought input from stakeholders in Maryland’s existing medical cannabis industry, testing laboratories, and other State partners at the Maryland Department of Health’s Office of Food Protection and the Maryland Poison Center (See *Appendix A* for list of consultants and stakeholders who contributed to the Commission’s study). This report and recommendations have also been informed by national best practices from other states’ regulatory frameworks and expert opinions on hemp regulations.

The Commission began its study by acquiring commercially available delta-8-THC products in the State and providing samples to two different laboratories to test the products for potency, heavy metals, and residual solvents. Commission compliance staff also evaluated the product’s packaging, label claims, available Certificates of Analysis (COAs) and safety information.

The Commission convened two public meetings as part of this study on October 20<sup>th</sup> and November 17<sup>th</sup>. During the first meeting, the Commission provided an overview of the legislative mandate for the study and the framework for the meetings. There was also a presentation on the chemistry and pharmacology of hemp-derived THC products and another on the federal landscape and other states’ solutions to the regulation of non-delta-9-THC products. (See *Appendix B* for the October 20 meeting agenda and presentations).

In between these meetings, the Commission distributed a survey to the consultants named in Chapters 511 and 512 and other interested stakeholders to solicit feedback about the manner in which non-delta-9-THC products should be classified and regulated. The format of the survey permitted the consultants to submit narratives and supplemental materials in addition to responding to survey questions.

During the second meeting, the Commission shared the results of the survey and presented preliminary laboratory testing findings of non-delta-9-THC products tested in Maryland. There was also a presentation on Colorado’s hemp task force and proposed framework for the regulation of non-delta-9 products. (See *Appendix C* for the November 17 meeting agenda and presentations).

This report establishes the need for regulation of psychoactive hemp-derived THC products, considers other states’ approaches, and makes policy recommendations to implement a regulatory framework in Maryland.

## **II. Background**

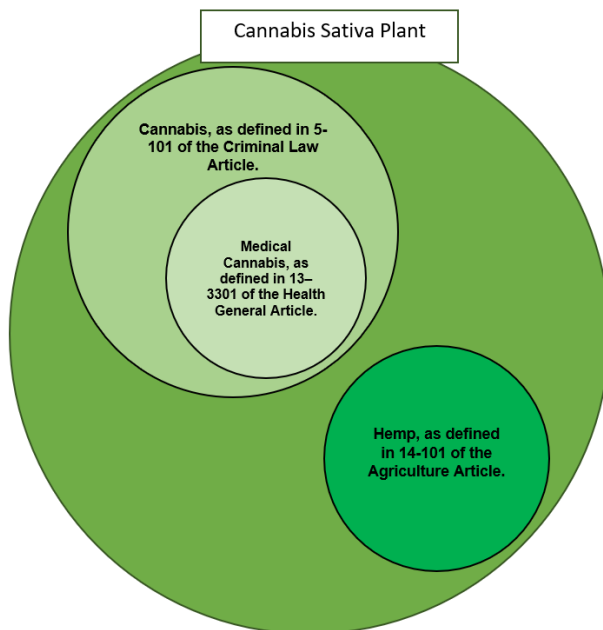
### ***The Cannabis Sativa Plant and Existing Legal Definitions***

When discussing hemp or cannabis, whether used for recreational, medical, or industrial purposes such as to manufacture rope and other fibers, it is all in reference to, and processed from, the same plant: *Cannabis sativa L.* As discussed later in this report, the federal government, and certain states including Maryland, have initially used the concentration of delta-9-THC within the plant to differentiate between hemp or cannabis varieties of this plant.

Maryland’s current definitions for Cannabis (Criminal Law Article § 5-101), Medical Cannabis (Health – General Article §13-3301), and Hemp (Agriculture Article §14-101) are all legislatively intended to be exclusive of one another. Both the “cannabis” and “medical cannabis” definitions note that “hemp as defined in §14-101 of the Agriculture Article” is excluded from each of these definitions. Similarly, the “hemp” definition states that “*“Hemp” does not include any plant or part of a plant intended for a use that is regulated under Title 13, Subtitle 33 of the Health – General Article.*” Hemp products are currently defined in statute as “a product grown in accordance with Subtitle 3 of this title ” (meaning in accordance with the Hemp Farming Program under Title 14 of the Agriculture Article).

The cannabis and hemp definitions relate to one another in Maryland statute are shown in **Exhibit 1**, below.

**Exhibit 1: Visual representation of Maryland Statutory Definitions for Cannabis, Medical Cannabis, and Hemp**



**2018 Farm Bill**

The passage of the federal Agriculture and Nutrition Improvement Act (“2018 Farm Bill”) legalized hemp, which is defined as the Cannabis sativa L. plant that contains less than 0.3% delta-9-THC on a dry weight basis. Currently, whether a product is defined as hemp is based on how much delta-9-THC is present. However, this created a regulatory gap where other psychoactive THC isomers are not considered in federal or State law when determining product regulations. Neither the 2018 Farm Bill nor Maryland law address other THC isomers, including delta-8 and delta-10, that provide a similar psychoactive effect or “high” to delta-9. Initially, this regulatory gap did not present an issue, because delta-8 and the other THC isomers occur naturally in the cannabis plant only in very trace amounts, and manufactured hemp-derived THC products were not widely commercially available.

To further compound matters, using the percentage of THC on a dry weight basis is a poor system to determine potency for finished products. “Low THC” is relative depending upon the type of product. No more than 0.3% delta-9-THC by dry weight, meaning in dried plant material, is a very small amount of THC. However, in foods and beverages, which weigh more than dried plant material, 0.3% can be a lot of THC, and therefore, can be quite intoxicating. **Exhibit 2** shows the weight in grams of standard food products, and suggests what amount of THC would be allowed with that serving size if a 0.3% standard was used uniformly. For additional context, **Exhibit 2**

shows examples of edible products approved by the Commission and calculates these products' potency using the same percent of THC standard. For reference, the current per serving and per package potency limits for edibles in Maryland's medical cannabis program is 10 milligrams (mg) and 100 mg THC, respectively. For further context, there is only one adult-use state that allows more than 150 mg THC for edible packages.

**Exhibit 2: Actual and Projected Product Potency: Finished Food Products on a 0.3% dry-weight THC Basis**

	Product	Weight (g)	Potential THC Content (mg)	Actual mg THC	Actual % of THC
Approved MMCC Products	MMCC Gummy #1	50	150	100	0.20%
	MMCC Gummy #2	7.1	21.3	10	0.14%
	MMCC Chocolates #1	45	135	100	0.22%
	MMCC Chocolates #2	36.8	110.4	100	0.27%
	MMCC Discos #1	45	135	100	0.22%
Standard Product Sizes	Fun Size Candy Bar	17	51		
	Standard Size Candy Bar	50	150		
	Sharing Size Candy Bar	93	279		
	Fruit Snacks Pouch	26	78		
	Potato Chip Snack Bag	28	84		

As shown above, allowing finished products to be up to 0.3% THC by dry weight can significantly increase the potency of a given product. Given that a relatively small amount of THC is often considered to have an intoxicating effect, using the dry-weight standard on a finished product, regardless of the type of THC, is clearly imperfect and outside of the legislative intent of either State or federal law.

***Proliferation of Non-delta-9-THC Products***

According to the National Association of State Departments of Agriculture, after the 2018 Farm Bill cleared the way for legal hemp production, there was an overproduction of hemp which caused prices to plummet.<sup>1</sup> Businesses considered other ways to better monetize hemp plants which led to the manufacture of delta-8, delta-10-THC, and other similar psychoactive THC products from

<sup>1</sup> Runestad, T. (2021, March 18). *Delta-8 THC is saving the sagging CBD biz*. Natural Products INSIDER. Retrieved December 19, 2022, from <https://www.naturalproductsinsider.com/ingredients/delta-8-thc-saving-sagging-cbd-biz>

CBD found in the hemp plants<sup>2</sup>. Manufactured non-delta-9-THC is commonly sold in edible products and vape cartridges. Many hemp and CBD producers across the country exploited this very specific federal definition of hemp by producing products that contain laboratory-created THC isomers. Consequently, there has been a proliferation of CBD products containing the THC isomer referred to as delta-8-THC. Other commonly sold hemp derivatives include delta-10-THC, THC-O-acetates, THCP, HHC, HHC-O-acetate, HHCP, and CBN.

It is important to note that this report is largely not concerned with products containing *only* CBD sold in the State (or products with very trace amounts of intoxicating compounds). While research and federal regulation on the overall safety of CBD is still unknown, it is generally viewed as non-intoxicating. The focus of this report is on potential intoxicating products and compounds that necessitate a regulatory framework for the health and safety of Marylanders. Further, in an assessment conducted as part of this report, it appears that products containing only CBD may make up a large share of consumable hemp-derived products available in the State. When reviewing two online retailers based in Maryland, the Commission found that over one-third of these products sold would be unaffected by any regulations and recommendations contained in this report. The review of products available by purported compound is found in *Appendix D*.

Manufacturers have identified cost-effective ways to chemically convert CBD, which is not psychoactive, into delta-8, delta-10, and other psychoactive THC isomers. To perform this conversion, manufacturers use a harsh chemical extraction process known as isomerization in which the CBD is dissolved in a solvent and mixed with acid, and then the mixture is maintained at a temperature of at least 100 degrees Celsius and stirred for 24 to 48 hours. This highly technical chemical process can lead to the creation of other cannabinoids and by-products not naturally found in cannabis. These by-products may include hazardous solvents such as heptane, hexane, sulfuric acid, and hydrochloric acid.<sup>3</sup> Furthermore, delta-8-THC and other THC isomers are known to produce psychoactive effects similar to those caused by delta-9-THC. There are currently a wide range of intoxicating hemp products being sold in Maryland and throughout the U.S.

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<sup>2</sup> Helmer, J. (2021, May 12). 6 strategies hemp industry members are pushing to overcome oversupply. Cannabis Business Times. Retrieved December 28, 2022, from <https://www.cannabisbusinesstimes.com/article/6-strategies-overcoming-hemp-oversupply-legislation-exports-delta-8-thc/>

<sup>3</sup> Erickson, B. E. (2021, August 30). *Delta-8-THC craze concerns chemists*. cen.acs.org. Retrieved December 19, 2022, from <https://cen.acs.org/articles/99/i31/Delta-8-THC-craze-concerns.html>

### ***Federal Response***

The U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), U.S. Hemp Authority<sup>4</sup>, and National Industrial Hemp Council<sup>5</sup> have issued warnings about the unknown safety profile and health risks of unregulated delta-8-THC. The FDA<sup>6</sup> and CDC<sup>7</sup> issued public health advisories on delta-8 in September 2021, citing the increased availability of these products and the potential for adverse events due to insufficient labeling of products containing THC and CBD.

The FDA further expressed concern about the marketing of these products, including online marketing, that is appealing to children, and contamination of products due to unsafe methods of manufacturing (e.g., use of dangerous solvents and acids). It is also notable that the U.S. Hemp Roundtable (USHR), a nonprofit business advocacy organization, while not supportive of a strict ban on delta-8-THC, instead supports regulation of the cannabinoid in a similar manner to adult-use cannabis. The USHR issued a statement against “marketing delta-8-THC products under the guise of the hemp name, for any intoxicating value or euphoric effect” calling it “irresponsible.”<sup>8</sup>

### ***Lack of Enforcement of FDA Regulations***

With the removal of hemp from the Controlled Substances Act, the 2018 Farm Bill placed the regulation of foods, beverages, dietary supplements, and cosmetics that contain cannabinoids like CBD, under the FDA through the FDA’s enforcement of the federal Food, Drugs, and Cosmetic Act (FD&C Act). The FDA stated that CBD and THC cannot be added to any food that is sold in interstate commerce and that CBD and THC cannot be marketed as dietary supplements, even if they are derived from hemp.

A wide array of hemp-derived foods, beverages, and dietary supplements containing CBD, THC, or other cannabinoids that are not in compliance with FDA regulations are being sold online and in retail stores. To date, the FDA has taken minimal enforcement action limited to a small number of manufacturers or sellers of hemp-derived products when there were health claims that put the product into the category of an unapproved drug.

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<sup>4</sup> Robertson, B. (2021, March 25). U.S. HEMP AUTHORITY ANNOUNCES IT WILL NOT CERTIFY “HEMP” PRODUCTS THAT ARE MARKETED FOR INTOXICATION. US Hemp Roundtable. Retrieved December 28, 2022, from <https://hempsupporter.com/news/u-s-hemp-authority-announces-it-will-not-certify-hemp-products-that-are-marketed-for-intoxication>

<sup>5</sup> PR Newswire. (2021, September 30). NIHC makes policy statement on delta-8 THC. NIHC Makes Policy Statement on Delta-8 THC. Retrieved December 28, 2022, from <https://www.prnewswire.com/news-releases/nihc-makes-policy-statement-on-delta-8-thc-301389257.html>

<sup>6</sup> FDA. (2022, May 4). FDA issues warning letters to companies illegally selling CBD and delta-8 THC products. U.S. Food and Drug Administration. Retrieved December 12, 2022, from <https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products>

<sup>7</sup> Centers for Disease Control and Prevention. (2021, September 14). Han archive - 00451. Centers for Disease Control and Prevention. Retrieved December 12, 2022, from <https://emergency.cdc.gov/han/2021/han00451.asp>

<sup>8</sup> Wiard, K. (2021, March 8). For Immediate Release: Statement on Marketing Hemp Products. US Hemp Roundtable. Retrieved December 28, 2022, from <https://hempsupporter.com/news/for-immediate-release-statement-on-marketing-hemp-products>

### III. Public Health and Safety Concerns

The lack of testing and regulation of delta-8 and similar THC isomers raises a number of significant health and safety concerns. Specifically, the Commission is concerned about the potential levels of intoxication from unregulated products, ability for youth to access products, lack of standardization across packaging and labeling and testing for product potency and purity, unfounded therapeutic claims, lack of manufacturing best practices and other public health implications.

- **Impairing and unregulated** – Even though delta-8 and similar psychoactive hemp-derived THC products can be as intoxicating, if not more, than delta-9-THC, the products commonly contain no warning statements about the potential for impairment. These products are entirely unregulated and can pose serious health risks. Many of these compounds are still under-researched. However, a study published in the *Journal of Drug and Alcohol Dependence* and shared with the Commission as part of stakeholder engagement suggests that delta-8 produces similar effects to delta-9,<sup>9</sup> including in terms of potential of dependence and abuse liability. Other compounds, derivatives, and isomers that can be made from hemp-derived CBD include delta-10, HHC, THC-O-Acetate, tetrahydrocannabitol (THCB), and tetrahydrocannabiphorol (THCP). As part of the study conducted by the Commission, stakeholders and staff were briefed on these other isomers and derivatives by the Co-Director of the University of Maryland School of Pharmacy's master's program in Medical Cannabis Science and Therapeutics. Some of these substances were identified as wholly synthetic when others only appear in trace amounts in the plant. While delta-8 or delta-10 is sometimes identified as slightly less intoxicating than delta-9, some of these compounds are more potent than delta-9. These slides used to discuss these compounds are including in this report under *Appendix B*.
- **Youth access** – Delta-8 products are widely available online and at retail establishments from gas stations to grocery stores, most commonly without any age restrictions. In response, the General Assembly passed an age restriction on sales of products containing delta-8 or delta-10 in 2022 (see Criminal Law Article §10-108). This provision took effect on July 1, 2022. To date, the Commission is unaware of any enforcement action of this provision by State or local law enforcement.
- **Lack of packaging and labeling standards** – There are currently no federal standards requiring labels to disclose the total THC content of hemp-derived products or to warn consumers that the product may be intoxicating and may have potential health dangers.

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<sup>9</sup> S.O. Vanegas et al., “Assessment of Dependence Potential and Abuse Liability of  $\Delta$ 8-Tetrahydrocannabinol in Mice,” *Drug and Alcohol Dependence* 240 (2022): p. 09640, <https://doi.org/10.1016/j.drugalcdep.2022.109640>.

Further, there are no prohibitions against packaging and labeling products in a manner that may be attractive to minors.

- **No verified testing** – Delta-8 products are not required to undergo laboratory or quality control testing prior to sale. Consumers are unable to verify product potency (including whether they contain delta-9-THC), the ingredients included, or if the products contain heavy metals, solvents, pesticides, or other harmful contaminants. Analyses performed by independent laboratories indicate that few COAs for CBD and other hemp-derived THC products are accurate, and that package labels often grossly misstate the amount of CBD, delta-8-THC, delta-9-THC, and other THC isomers that are present in a product. In 2021, Virginia Commonwealth University analyzed dozens of delta-8 products and found “an alarming lack of safety standards, accurate labeling, and quality control.” Products the university evaluated commonly were “two, three, 10 times more concentrated with delta-8 than what the package claims.”<sup>10</sup> Moreover, in most cases, nothing is known about the health effects of the product’s impurities, and there is little scientific research in the U.S. or internationally on the safety and efficacy of products containing delta-8 and other similar THC isomers.
- **False or misleading therapeutic claims** – There has been no oversight of therapeutic claims that are made pertaining to delta-8 and similar THC products. False and misleading therapeutic claims can harm consumers. Former FDA Commissioner Scott Gottlieb stated that “Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.”
- **Uncontrolled or unsanitary manufacturing settings** – There are currently no health and safety standards for receipt, storage, processing, handling, testing, or transport of these products, and no regulatory oversight to ensure product safety and quality. Absent manufacturing standards, harmful solvents and acids like heptane, hexane, cyclohexane, toluene, sulfuric acid, hydrochloric acid, and p-toluene sulfonic acid are commonly used in the production of delta-8. These methods can be hazardous to the individuals manufacturing the product, as well as the consumer.
- **Potential for dangerous public health impacts** – There has been a sharp increase in the number of poison control calls, emergency department visits, pediatric ICU admissions,

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<sup>10</sup> McNeill, B. (2021, December 15). VCU Lab Testing delta-8 products finds misleading labeling, lack of safety standards. VCU News. Retrieved December 12, 2022, from <https://news.vcu.edu/article/2021/12/vcu-lab-testing-delta-8-products-finds-misleading-labeling-lack-of-safety-standards>



and adverse event reports to the FDA related to delta-8-THC products. The FDA received 104 reports of adverse events in patients who consumed delta-8-THC products between December 1, 2020, and February 28, 2022. Of these 104 adverse event reports:

- 77% involved adults, 8% involved pediatric patients less than 18 years of age, and 15% did not report age.
- 55% required intervention (e.g., evaluation by emergency medical services) or hospital admission.
- 66% described adverse events after ingestion of delta-8-THC-containing food products (e.g., brownies, gummies).
- Adverse events included hallucinations, vomiting, tremor, anxiety, dizziness, confusion, and loss of consciousness.

National poison control centers received 2,362 exposure cases of delta-8-THC products between January 1, 2021 (i.e., date that delta-8-THC product code was added to database), and February 28, 2022. Of the 2,362 exposure cases:

- 58% involved adults, 41% involved pediatric patients less than 18 years of age, and 1% did not report age.
- 40% involved unintentional exposure to delta-8-THC and 82% of these unintentional exposures affected pediatric patients.
- 70% required health care facility evaluation, of which 8% resulted in admission to a critical care unit; 45% of patients requiring health care facility evaluation were pediatric patients.
- *One pediatric case was coded with a medical outcome of death.*<sup>11</sup>

#### **IV. Commission Research and Study Activities**

##### ***Commission Study and Analysis of Commercially Available Products***

As part of its study of the regulations of non-delta-9-THC products, the Commission purchased 25 hemp-derived THC products commercially available in the State, eight inhalable products (e.g., vape cartridges or pens) and 17 ingestible products (e.g., edibles). These purchases were made at tobacco stores, gas stations, and hemp or CBD retailers. Purchases were made across five jurisdictions (Prince George’s, Montgomery, Frederick, and Anne Arundel Counties and Baltimore City).

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<sup>11</sup> FDA. (2022, May 4). *5 things to know about delta-8 tetrahydrocannabinol – delta-8 THC*. U.S. Food and Drug Administration. Retrieved December 12, 2022, from <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc>

The purpose of these purchases was to identify a baseline of non-delta-9-THC products available throughout the State with respect to their potency, purity, and labeling standards. Findings from this analysis are discussed in greater depth below.

### Product Availability, Information & Warning Labels

Before evaluating the products, it is significant to note that Commission staff who purchased delta-8 and delta-10 products had their IDs checked at less than one-half of the retail establishments. This is important considering that at the time of the purchases, the 21 or older age restriction for the purchase of delta-8 and delta-10 products established under Criminal Law Article §10-108 was already in effect under State law.

Seventeen out of 25 of the products did include some type of warning, but the content of these warning statements varied significantly. When warning labels did appear, most referenced the 21 or older age restriction or directed consumers to store these products away from children. Several others stated that the products should not be used by anyone who may be pregnant or breastfeeding, or that product use may cause impaired driving. Fewer made explicit mention that these products may induce impairment or other psychoactive effects. Label font size and location often varied as well.

In terms of other consumer safety information, only 11 products displayed an expiration date. COAs were available for 10 products. **Exhibit 3** (below) shows the distribution of these types of consumer safety information across the products sampled by the Commission.

### Exhibit 3: Consumer Safety Information and Warning Labels

	Product Sample																					Count					
	A1	B1	C1	D1	E1	F1	G1	H1	I1	J1	K1	L1	M1	N1	O1	P1	Q1	R1	S1	T1	U1	V1	W1	X1	Y1		
Product Type	V	G	V	G	G	V	V	V	G	G	G	G	G	G	G	G	G	G	G	G	V	V	V	V	G	G	
Exp. Date																											11
COA																											10
Warning Labels																											17
Count	2	1	1	1	1	2	2	1	2	2	2	1	2	1	1	2	0	0	0	3	3	2	1	2	3		

	Warning Type																					Count					
	A1	B1	C1	D1	E1	F1	G1	H1	I1	J1	K1	L1	M1	N1	O1	P1	Q1	R1	S1	T1	U1	V1	W1	X1	Y1		
Not Safe for Children and/or 21+																											15
Do not use if Pregnant or Breastfeeding																											11
Delayed Effect																											4
Not Evaluate d/Approved by FDA																											9
Impaired Driving																											10
Can Cause Intoxication/Psychoactive																											3
Count	0	4	5	3	3	4	4	3	2	1	1	0	1	0	0	5	0	0	0	4	4	2	0	3	3		

Note: Products Q1, R1, and S1 contained a symbol that could be interpreted as a warning, but no words explicitly warning about the product.

**Product Potency, Homogeneity, COAs and Label Accuracy**

Another vector of analysis for the purpose of this study was to determine the potency of commercially available products, how potency corresponded to potency claims on the package labeling or under the product’s COA. The Commission’s research included two separate laboratories testing products with varied methods of analysis. Initially, products were analyzed at an academic laboratory specializing in hemp and synthetic cannabinoids. Separate samples were also sent to a State-registered independent testing laboratory (ITL) for medical cannabis products. Additionally, whenever the product contained a COA, the laboratory performing this analysis was different than the ITL used by the Commission in the testing of these products, providing a third data point.

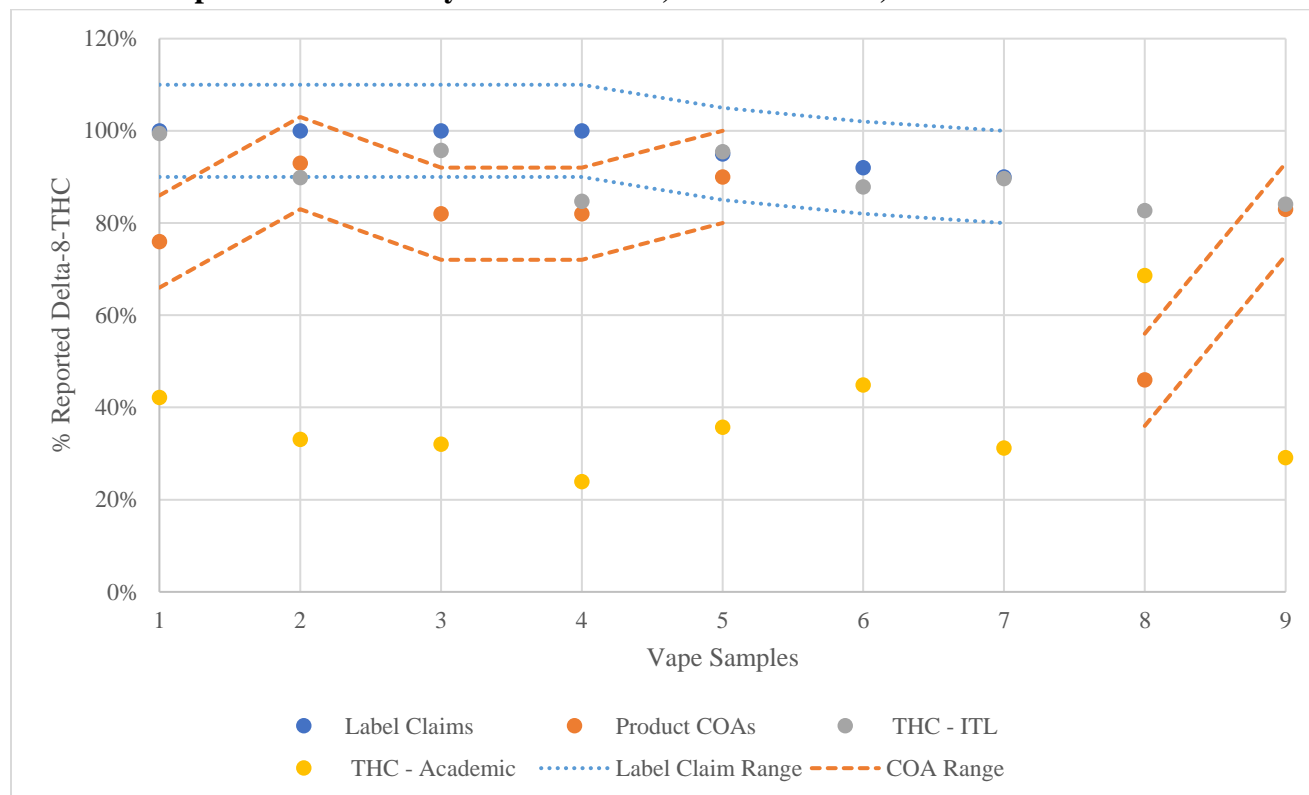
The most notable finding from the laboratories’ analysis was the inconsistency of potency results. Generally, a 10% variance would be acceptable for product potency results. This level of accuracy was often achieved from the ITL testing of vape products, where the results were within this range in five of seven product’s label claims, and four of seven product’s COAs. However, neither the academic laboratory, nor the ITL, identified a single instance where edible products’ potency results were within 10% of either a product’s label claim or COA. The instances of Commission-studied laboratory results aligning with product-based claims or laboratory analysis is shown in **Exhibit 4** (below).

**Exhibit 4: Share of Test Results within Acceptable Error Range: Label Claims and Product COAs**

Testing Laboratory		Label Claim		Product COAs	
		ITL	Academic	ITL	Academic
Vape products within acceptable error of +/- 10%	%	71%	0%	57%	0%
	#	5/7	0/7	4/7	0/7
Gummy products within acceptable error of +/- 10%	%	0%	0%	0%	0%
	#	0/17	0/17	0/3	0/3
Note: Products that did not contain COAs or make label claims pertaining to potency were not evaluated.					

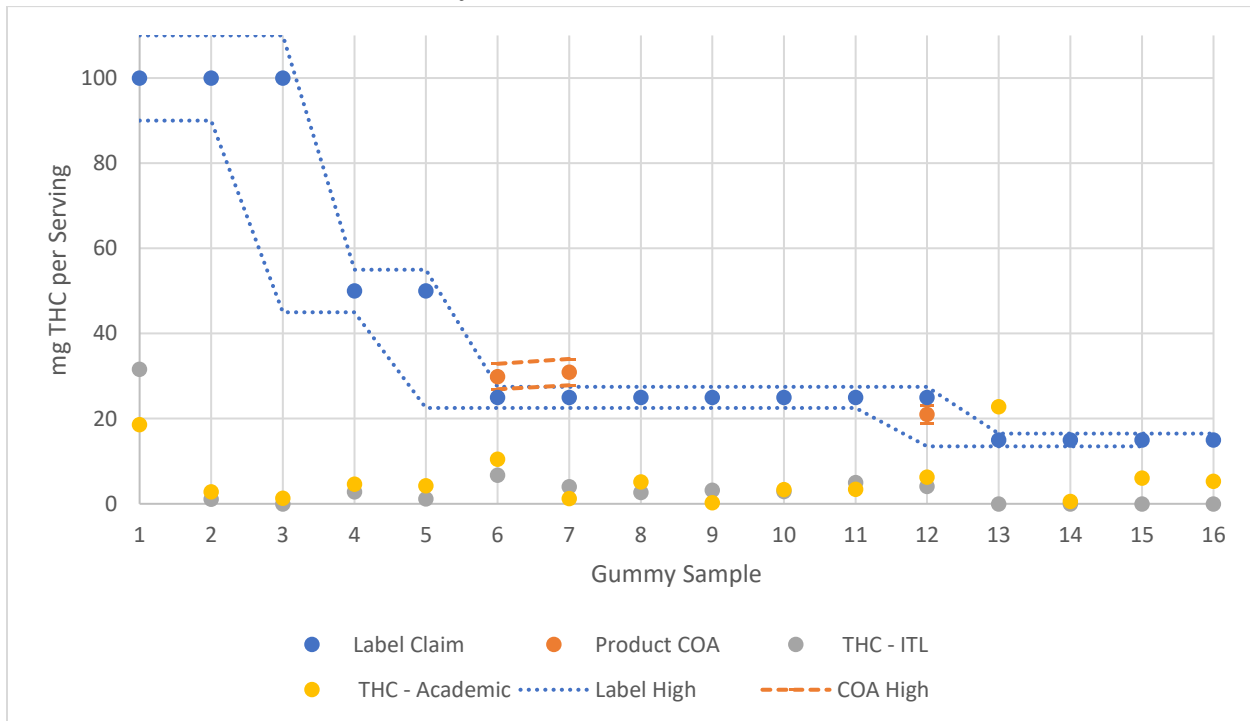
**Exhibits 5** and **6** (on the following pages) compare the two Commission test results to the product label claims and product COAs (when applicable). These exhibits have also layered over the acceptable error range of 10% discussed above. As shown above in **Exhibit 4**, there were more instances of accuracy in the inhalable products purchased. This is largely consistent with what the Commission would expect, considering that the oil used in vape products is often more homogeneous than sampling results from gummies or other edible products.

### Exhibit 5: Vape Product Potency: Label Claims, Product COAs, and Test Results



For the edible products, shown in **Exhibit 6** on the next page, the Commission would also note that all these products purported to have a delta-8-THC content of greater than 10 mg per serving. As discussed above in this report, delta-9-THC is the compound currently regulated by the Commission and considered to be intoxicating. However, as previously indicated, recent research has suggested that delta-8 and other THC isomers and derivatives can also have intoxicating or psychoactive effects. While the present statutes and regulations only consider delta-9-THC, the current THC limit for edibles in the State’s medical cannabis program is 10 mg per serving and 100 mg per container. The Commission is concerned that some packages being sold in the State contain significantly more non-delta-9-THC isomers and derivatives than would be allowed in the regulated cannabis market. For example, three edible products purchased for this study purported to contain 100 mg delta-8-THC *per serving* and over 1,000 mg per container. In fact, every edible product purchased as part of this study would not be allowed under the State’s existing medical cannabis laws. All edible products purported to have more than the 10 mg per serving limit, and 13 of 16 edible products had greater than 100 mg per container. The Commission would like to further emphasize that the products purchased as part of this study are not extremes or outliers. In fact, from online retailers in Maryland, one can easily find products purporting to contain over 2,000 mg of THC per container, twice the amount of THC in any product reviewed here. One product that is currently being sold online in the State claims to have 3,500 mg THC per container, the equivalent of at least 35 Commission-regulated edibles packages combined. This product is currently on sale for \$17.95 per package.

**Exhibit 6: Edible Product Potency: Label Claims, Product COAs, and Test Results**



Another concern that arose in our testing around product potency was the homogeneity of products, or how similar two different servings, packaged together were to one another in terms of potency. In this instance, the Commission also found inconsistencies, and some significant variance of THC content within products found in the same package. While this test was not conducted for all edible products sampled, the initial results suggest that manufacturing and packaging products in such a way that ensures homogeneity will be an important regulatory consideration for the State.

In the Commission’s stakeholder meetings, research was shared regarding the best method for conducting potency testing of hemp products. A white paper shared by representatives of the hemp industry suggested that Gas Chromatography–Mass Spectrometry (GCMS) as an analytical method is better suited for determining potency than High-Performance Liquid Chromatography (HPLC). While this report will not opine on the respective merits of either analytical method, this ongoing debate in the scientific community and industry does underscore the importance of technical authorities, and regulations to ensure that testing is done at high-quality laboratories equipped to use the best, most accurate, and up-to-date methods and standards.

**Presence of Heavy Metals, Residual Solvents, and other Contaminants**

The final prong of the Commission’s analysis of products was to test for certain contaminants. The list of specific contaminants tested for is found in *Appendix E* and derived largely from the standards used currently for medical cannabis products. While some contaminants were detected, all products would have met the existing standards for medical cannabis. However, the

Commission believes that, if testing is implemented in the State, the residual solvent panel will need to be expanded to capture solvents that may be used in the manufacturing process. As discussed above, the isomerization process of these products can be very different than simple extraction that is often done in the medical cannabis market. Other states that have implemented testing for hemp products test for over 20 residual solvents, while the Commission’s initial testing panel only included six solvents. These other testing standards used in both Florida and New York are also listed in *Appendix E*.

### ***Research and Monitoring of Other States***

Absent federal regulation or clarification as to whether delta-8 and other THC isomers created through chemical processes are lawful under federal law, a growing number of states have taken steps to prohibit or regulate hemp-derived products containing delta-8 or other THC isomers. Since 2019, at least 21 states have laws specifically governing delta-8 and/or other THC isomers, several of which have implemented outright bans of delta-8 and similar products. The remaining jurisdictions have required these products to meet certain regulatory requirements or standards. Some of these regulations and recommendations were the product of task forces and workgroups, while others were developed directly by the legislature or regulatory body themselves. (See *Appendix F* entitled “Regulation of Cannabinoid Hemp Products in Select Adult-Use Cannabis States” which was developed by the University of Maryland Francis King Carey School of Law in support of the Commission’s study.)

Colorado, Virginia, and Maryland are among states that have established studies or task forces to evaluate the regulation of psychoactive non-delta-9-THC products and make recommendations. Commission staff throughout the interim closely monitored other State workgroups or task forces that have also been weighing best practices for the regulation on intoxicating hemp-derived THC products.

Following an update on state task forces, this report will highlight other states that have elected to implement a robust regulatory pathway and framework for hemp-derived THC products, including Oregon, West Virginia, Florida, and New York.

### **Colorado**

Colorado has established an extensive task force comprised of representatives across the hemp and marijuana industries in the state to study intoxicating hemp products and make recommendations to the general assembly by January 1, 2023, as directed by SB 22-205. Since July 2022, Colorado has held 20 public meetings for over 50 hours cumulatively, staffed by the State’s Marijuana Enforcement Division (MED).

Ultimately, the Intoxicating Hemp Task Force in Colorado supported a regulatory framework as follows:

- The 2018 Farm Bill exempted hemp from the Controlled Substances Act (CSA) but expressly preserved the FDA’s authority to regulate hemp and products containing hemp ingredients under the FD&CA, as well as other product safety laws and regulations.
- The FDA, the federal agency charged with implementing the FD&CA and other safety laws, has failed to execute its responsibilities to regulate consumable products containing hemp ingredients after the passage of the 2018 Farm Bill. As the FDA continues to delay evaluating the safety of hemp ingredients and establishing a regulatory pathway for hemp ingredients in consumer products, it has also failed to enforce existing product safety regulations (except where products make egregious therapeutic claims).
- Despite the FDA’s inaction, the legalization of hemp has allowed businesses to develop and innovate novel cannabinoids that are beneficial consumer products. The absence of FDA enforcement also created an active market for THC-based intoxicating hemp products that are not compliant with federal product safety standards nor subject to state cannabis regulations. As previously stated, these products often have higher levels of THC than are permitted in cannabis retail stores, are often produced using chemical synthesis without regulatory oversight, and many do not meet fundamental safety-based manufacturing, processing, and retail standards.
- The federal partial step towards cannabis legalization by decriminalizing cannabis plants with a low THC concentration while maintaining prohibition on high-THC varieties has exacerbated the need for regulation and enforcement around product manufacturing, testing, labeling, and other safety standards. Until all cannabis is fully federally legalized or the FDA sufficiently addresses the issue, states must act to fill the existing regulatory gap that has allowed the proliferation of unsafe, intoxicating products and created significant confusion for consumers, regulators, and law enforcement. State action should be grounded in core federal product safety standards for the relevant consumer goods. Those regulations are founded on fundamental components of product safety to ensure products are safe for their intended use and not adulterated. These are also the most likely regulatory standards that will be imposed when the FDA or Congress finally acts, many of which are already incorporated at the state level in Colorado and other jurisdictions through state-level food and drug laws. This should include:
  - Consumable products fall within specifically designated categories with respective safety standards, specifically food and dietary supplements.
  - A food ingredient must be safe under the conditions of its intended use and must have demonstrated safety prior to entering the market, including meeting Current Good Manufacturing Practices (“cGMP”). Dietary supplements are

intended to supplement the diet and contain at least one dietary ingredient, which are also subject to safety standards.

- Substances at intoxicating levels, intended to be used for intoxication or inebriation, or produced through unsafe processes generally do not meet safety standards for foods or dietary supplements. Accordingly, there are no warning labels on foods nor are their age-gates for foods and dietary supplements. Instead, the most-used product intended for intoxication, alcohol, falls under specialized regulations to appropriately address safety concerns including production, potency levels, labeling, marketing, packaging, and age-gating.
- Ingredients for all food and dietary supplements must meet specific safety profiles.
- It is the responsibility of product manufacturers to demonstrate safety and compliance of marketing of their products internally or through formal channels prior to a product's introduction into the market and not the government's role to prove that something is unsafe unless it is challenging that business's safety determination.

Additionally, the task force seeks to define the following terms in either statute or regulation to best regulate hemp-derived products in a way that protects public health and safety:

- **Intoxicating:** Using Colorado's existing definition of "intoxication" and then applying this definition to potentially intoxicating hemp-products.
  - Criminal Code § 18-1-804. "Intoxication" as used in this section means a disturbance of mental or physical capacities resulting from the introduction of any substance into the body.
- **Total THC:** is defined in Colorado regulations as:
  - The sum of the percentage by weight of Delta-9-tetrahydrocannabinolic acid (D9-THCA) multiplied by 0.877,
  - Plus the percentage by weight of Delta-8-tetrahydrocannabinol (D8-THC),
  - Plus the percentage by weight of Delta-9-tetrahydrocannabinol (D9-THC),
  - Plus the percentage by weight of Exo-tetrahydrocannabinol (Exo-THC),
  - Plus the percentage by weight of Delta-10-tetrahydrocannabinol (D10-THC).
- Differentiate in regulation or statute between "**Consumable Hemp Products**" and other products not intended for human consumption. Create a higher regulatory barrier for those consumable products to protect health and safety.
- Establish certain cannabinoids as generally recognized as safe, such as Cannabidiol (CBD), Cannabigerol (CBG) or cannabinol (CBN) and create a group of



“**Novel Cannabinoids**” that are not initially recognized as safe, either through statute, regulations, or FDA recognition.

With these principles and definitions in mind, the task force moved forward on a framework for regulation of these products that contained the following policy recommendations:

1. **Regulate THC in Hemp Products:** Create a basic permissible limit of total THC content for hemp products that is low enough to prohibit the widespread sale of intoxicating products. Create a transition period for compliance of this standard, and a regulatory pathway for approval if above this threshold but determined to be non-intoxicating by the regulatory body.
2. **Novel Cannabinoids:** Change existing statute and regulations to expressly permit known, safe, cannabinoid including anything that has been certified as GRAS (Generally Recognized as Safe) or NDI (New Dietary Ingredients) by the FDA; require products containing these compounds to meet certain manufacturing standards and safeguards (e.g., cGMP). Here again, the recommendation was to create a process to allow authorization and approval for products that fall outside this initial, established framework. This framework is suggested to be based on existing FDA criteria for evaluation of NDI and GRAS.
3. **Enforcement:** Enforce the law against in-state, as well as out-of-state persons violating the law and guidelines established and create a system for identifying and reporting unsafe or intoxicating products. Further, support and fund public education campaigns around youth-access and make the distinction between intoxicating and non-intoxicating hemp products.

### **Virginia**

The Commonwealth of Virginia’s legislature tasked the Virginia Department of Agriculture and Consumer Services to assemble a task force to study industrial hemp products with other State agencies and stakeholders. By way of two public meetings and with public comment periods held over the summer of 2022, and six hours of listening sessions with the Commonwealth’s existing hemp growers, processors, and dealers, the Secretary of Agriculture and Forestry drafted and submitted a report on hemp products that asserted the following principles:

- Unregulated cannabis products (e.g., intoxicating hemp products containing THC) are cause for concern within the Commonwealth.

- The 2018 Farm Bill’s hemp provisions were the result of advocacy in support of hemp fiber and grain production opportunities. Congress established the delta-9-THC limit in the definition of hemp to allow for the production of hemp fiber and grain but also maintain the prohibition on production of intoxicating cannabis, and, at the time the legislation was enacted, delta-9-THC was the primary cannabinoid known to have an intoxicating effect.
- Since the enactment of the 2018 Farm Bill, the U.S. hemp industry’s interest in growing hemp for its fiber or grain shifted to an interest in growing high-CBD varieties of hemp for edible and inhaled product production. Within the past few years, a portion of the hemp product industry has further shifted to the production of edible and inhaled THC products using hemp-derived CBD; however, the primary type of THC in these products is not delta-9-THC, but instead delta-8-THC or delta-10-THC, among others. Delta-8-THC has an intoxicating effect similar to that of delta-9-THC, the cannabinoid in marijuana that produces a “high;” however, the legal status of delta-8-THC is gray given its connection to hemp, which was removed from the federal CSA by the federal 2018 Farm Bill. A delta-8-THC product has a delta-9-THC concentration that is less than 0.3% but typically has a delta-8 THC concentration that is intoxicating.

In addition to these background findings, the report identified three areas of consensus or majority support amongst their State agency, regulators, and stakeholders:

1. Protecting consumers, especially children, from dangerous products is paramount.
2. Copycat candy products should be banned from sale, and stiff criminal penalties should exist for anyone manufacturing, selling or distributing those products in the Commonwealth of Virginia.
3. Regulation of some form of THC products intended for human consumption should exist.

Under these broad points of consensus, the report submitted by the task force made the following recommendations:

1. Assess a product’s legality using its Total THC concentration;
2. Coordinate cannabis regulation and enforcement;
3. Require a permit to sell certain hemp products;
4. Establish civil penalties for non-compliance, selling without a permit, and manufacturing or selling a product outside of established standards; and
5. Address the sale of edible hemp products in restaurants.

## *Other States Regulation of Hemp-Derived Products*

### **Oregon**

The Oregon Liquor and Cannabis Commission (OLCC) was tasked by their legislature to study and make recommendations on product restrictions. After considering international standards, other state positions, and equivalent methodologies with other products, the OLCC recommended the following restrictions on products:

- A 0.5 THC mg limit per container for products to be sold widely, without any sort of age-gating or other restrictions.
- A per serving limit of 2 mg THC to be sold to adults and per package limits of 20 mg of THC for edibles and transdermal products.
- 100 mg THC limit for tincture products.
- Regardless of the maximum per-container limits established by OLCC, Oregon regulations limits hemp products to no more than 0.3% total THC concentration. In cases where the 0.3% limit is more restrictive than the mg per container limit, the 0.3% total THC limit applies.
  - For example, a 1 fl oz tincture weighing 25 g is limited to no more than 75 mg THC, even with the 100 mg tincture limit established by the OLCC.
- Further, Oregon entirely bans both intoxicating and non-intoxicating artificially-derived cannabinoids. In House Bill 3000, the Oregon Legislature defined “artificially-derived cannabinoids” explicitly in terms of how they are created: “a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the plant Cannabis family Cannabaceae.”
  - For certain non-intoxicating, artificially-derived cannabinoids currently on the market in Oregon (namely, CBN), OLCC recommended allowing these products to remain available in the State’s more regulated marijuana market until certification for their safety can be provided to make these products more widely available.

### **West Virginia**

West Virginia’s hemp program establishes registration and permitting requirements for the production and sale of hemp-derived products. All retail facilities, including online locations, are required to register with the Department of Agriculture to sell hemp products in West Virginia. Each retail establishment site must register annually and pay a \$100 fee to sell hemp-derived products in West Virginia.

West Virginia also requires hemp products and producers to be registered in the State. To register a product, a manufacturer must provide information on the origin of the raw hemp, a copy of the product label, and a COA. Certain hemp fiber products such as rope, fiber, and paper are exempted from these registration requirements. Other exemptions exist for ingredients that have been GRAS certified by the FDA.

Specific labeling requirements in West Virginia include:

- Hemp products for human consumption as a food or dietary supplement shall be labeled in accordance with FDA guidelines for food or dietary supplement labeling.
- Hemp products intended for topical absorption by humans shall be labeled in accordance with FDA guidelines for Cosmetic Products Warning Statements.
- Hemp products shall not contain disease or drug claims on the label that are not approved by the FDA.
- The product lot on the label must be traceable to the plant origin.
- Hemp products meant for animal consumption shall be labeled and comply with the West Virginia Commercial Feed Law, West Virginia Code §19-14-1 et seq.
- Hemp seed products intended for cultivation shall be labeled in accordance with the West Virginia Seed Law, West Virginia Code §19-16-1 et seq.
- Product labels must be clear and legible.
- Labels must be printed in English.
- The following labeling is forbidden:
  - Unless at least 51% of the hemp in the product is grown in the state of West Virginia, the hemp product cannot be labeled as a West Virginia hemp product.
  - The product may not be attractive to children, including by:
    - The use of cartoons.
    - The use of images popularly used to advertise to children.
    - The imitation of a candy label.
  - The label may not include false or misleading information. This includes untrue or unproven information that leads consumers to have an inaccurate impression.
  - The label cannot include the use of the word “organic” unless referencing certified organic products that have been certified as organic in accordance with the National Organic Program, as provided for by the USDA.
  - Labels will be considered misbranded when a West Virginia Department of Agriculture analysis finds the claim is above or below 20% of the cannabinoid amount declared on the label, excluding any tetrahydrocannabinols.

The COA for all products shall include the following information:

- A batch or lot number identification.
- The date the COA was received.

- The method of analysis for each test conducted.
- The product name.

The COA for all hemp products must also list the cannabinoid profile by the percentage of dry weight, and include THC and CBD content.

A manufacturer must provide a COA for each finished hemp product that is registered, except for products that are verified to contain no detectable amounts of all cannabinoids. Products that only contain hemp ingredients that have been given GRAS status by the FDA are exempt from the COA requirements but not the requirement to register annually.

West Virginia's framework was shared with the Commission by Maryland hemp industry stakeholders as a model for the Commission to evaluate in this study as an example of meaningful legislation and appropriate regulations that work towards the safety of the consumers and the development of the hemp industry.<sup>12</sup> The Commission incorporates best practices from West Virginia's model into the recommendations found later in this report.

### **Florida**

Florida also regulates hemp products by differentiating between hemp products for human consumption, which includes both inhalation and ingestion. Florida regulations further differentiate between hemp extract and the hemp plant itself.

Rule 5K-4.034 of the Florida Administrative Code governs hemp extract for human consumption and places product testing and labeling requirements on hemp products sold in the state. These regulations list several prohibited substances including Vitamin E acetate, which was the main ingredient that resulted in adverse outcomes during the EVALI crisis, limits on over 60 pesticides, 21 different residual solvents, four heavy metals, biological impurities and mycotoxin limits on products in the state (See *Appendix E* for list of solvent, heavy metals, and other impurities tested). In some instances, the limits are different for products to be ingested or inhaled. Compliance testing is done by Florida's regulatory agency. When these regulations were implemented, Florida reported lead levels exceeding the regulatory standard in 6%-8% of samples, and the presence of lead in over one in five products tested.

In statute, the legislature also required COAs for all products sold in the state and required the packaging to include:

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<sup>12</sup> More information on West Virginia's Hemp program can be found here: [WVDA Hemp Products](#); West Virginia's *Hemp Product Guide* was directly shared with the Commission, and can be found here: [WV Hemp Products Guide](#); West Virginia's Administrative Rule 61-30 was also shared directly with the Commission. An updated version of this rule can be found here: [Notice of Proposed Rule: 61-30](#)

- A scannable barcode or quick response code linked to the COA of the hemp extract batch by an independent testing laboratory;
- The batch number;
- The Internet address of a website where batch information may be obtained;
- The expiration date; and
- The number of milligrams of each marketed cannabinoid per serving.

Additionally, regulation prohibits labels or advertisements from containing claims indicating the product is intended for diagnosis, cure, mitigation, treatment, or prevention of disease, rendering it a drug as defined in 21 U.S.C. 321(g)(1).

Florida further regulates these hemp products for human consumption by requiring permitting for “Hemp Food Establishments” and only allows these products to be sold in permitted establishments. This is an annual registration that carries a \$650 permitting fee. These permits exist for both retail and wholesale establishments. The permitting and product regulations are enforced by the Florida Department of Agriculture and Consumer Services Division of Food Safety. Hemp retailers or distributors must also be able to show on request that the hemp products were developed or manufactured from an “Approved Source” which is statutorily defined as a manufacturer that meets local, state or federal regulatory and food safety standards. All hemp products intended for ingestion must be manufactured by an approved source. Separate permitting exists for products intended for inhalation.

Florida’s framework was also shared with the Commission by Maryland hemp industry stakeholders as a model for the Commission to evaluate in this study as an example of meaningful legislation and appropriate regulations that work towards the safety of the consumers and the development of the hemp industry.<sup>13</sup> The Commission incorporates best practices from Florida’s model into the recommendations found later in this report.

### **New York**

The State of New York established a separate licensing structure and set of regulations for cannabinoid hemp products. New York uses the standard of products intended for human consumption for their definition of cannabinoid hemp products. New York’s standard for human consumption also includes topical applications. The state has regulations for cultivators, cannabinoid hemp processors, and cannabinoid hemp retailers.

For hemp processors, the manufacture and extraction of hemp must comply with cGMP, and products must be laboratory tested and maintain a COA. The regulations also specifically prohibit

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<sup>13</sup> More information on Florida’s Hemp program can be found here: [FDACS Hemp/CBD In Florida](#); Florida’s *Hemp Extract of Ingestion and Inhalation* document was directly shared with the Commission and can be accessed here: [Hemp Extract for Ingestion and Inhalation](#)

the use of delta-8 or delta-10-THC that was created through isomerization as well as other synthetic cannabinoids in the processing of cannabinoid hemp products.

New York established pesticide limits for 67 pesticides, 21 residual solvents, four heavy metals, biological impurities, and mycotoxins (See *Appendix E* for list of solvent, heavy metals, and other impurities tested). The list of contaminants is largely consistent with Florida's restrictions discussed above; however, acceptable limits vary between some compounds. Hemp processors are required to sample and test products in accordance with the regulations and the laboratories conducting the testing must maintain ISO/IEC 17025 accreditation. This is the same accreditation Maryland, and many states require for cannabis testing laboratories.

Labeling requirements include a nutrition or supplement information panel, ingredients' list, serving sizes and cannabinoid content, expiration date, and a link to the COA. Packaging also may not display cartoon characters or candy imitations in such a way that would be marketed or appealing to children. The packaging must also be tamper resistant and contain the following warning labels:

- Keep out of reach of children;
- The product contains THC;
- The product has not been evaluated by the FDA for safety or efficacy;
- Those who are pregnant or nursing should consult their healthcare provider before use; and
- If the product is an inhalable cannabinoid hemp product, a warning stating that smoking or vaporizing is hazardous to your health.

The cannabinoid hemp retailer licensing is required to sell products both in-person and online in New York. This license must be posted in the store in a way that is visible to consumers, and the cost of this license is \$300 per location annually.

Additional regulations prevent hemp products, retailers, or processors from making false or misleading claims, or any claims that the product can, or is intended to, diagnose, cure, mitigate, treat, or prevent disease. Further, these products are restricted from presenting as a cannabis or medical cannabis product or as appealing to minors.

## **V. Commission Stakeholder Engagement and Feedback**

### ***Survey Results***

The Commission solicited stakeholder feedback through a survey developed by Commission staff and direct outreach. Not all stakeholders elected to participate in the survey, but any written responses and recommendations made by stakeholders, including those submitted outside of the

survey, have been incorporated into the report. (See *Appendix G* for stakeholder written responses and recommendations.)

One area of consensus, both in survey responses and written comments was the need for product testing and labeling standards. In a written submission to the Commission, the Maryland Healthy Alternatives Association and the Maryland Hemp Coalition wrote in support of hemp-derived product regulation stating: “Establish guidelines, standards and regulation for hemp extract and hemp extract products in regards to: Licensing; Distribution; Labeling/packaging; Production/processing; Purity/potency testing; Inspections; Reporting; [and] Enforcement/violations.”

This was consistent with the survey respondents who recommended that products should be tested for: heavy metals; product potency; chemical impurities; and microbiological impurities. In terms of labeling, survey respondents universally recommended requiring warning labels, a list of ingredients and a COA. In terms of production and processing, again as recommended by the hemp industry representatives, respondents selected cGMP as a standard that should be implemented in the manufacturing, production and/or storage of these products.

Survey respondents universally supported a standard of total THC to evaluate products. However, this position was not shared by representatives of the State’s hemp industry.

The final component of the survey asked respondents to consider various THC product potency limits and corresponding regulatory requirements based on THC concentration. All respondents selected 0.3 mg THC or less as a threshold for which hemp-derived products should not be subject to strict regulatory oversight. Products under this standard would broadly be considered non-intoxicating. Additionally, every response recommended aligning the regulation of cannabis products with hemp products, suggesting support for parity between the two regulatory structures.

### ***Other Feedback and Recommendations***

#### **Align regulations with neighboring jurisdictions**

In addition to supporting regulations pertaining to licensing, product testing, inspections, and reporting as discussed above, the hemp industry representatives expressed support for aligning Maryland regulations with neighboring states. This report highlighted regulatory frameworks in two of Maryland’s neighbors: Virginia and West Virginia. The Commission’s recommendations to the General Assembly in the following section adopt best practices from these states, as well as other leaders in the space to craft a regulatory framework that will be in the best interest of Marylanders, while being consistent with feedback received throughout this process.



### **Require Department of Agriculture regulate all hemp-derived products**

One recommendation from hemp industry representatives that has not been incorporated into the Commission's recommendations is designating the Maryland Department of Agriculture (MDA) as the regulatory body for all hemp-derived finished products and establishing a hemp advisory council to advise the Department in developing its rules governing hemp-derived products. This recommendation was submitted to the Commission and shared at the November 17<sup>th</sup> public meeting, and is included in *Appendix G*. Under the hemp industry proposal, the Maryland Department of Agriculture would be required to regulate the cultivation, manufacture, and sale of all hemp-derived products, including intoxicating products containing THC isomers. The Commission does not take a position on whether one State agency should be solely responsible for regulating finished hemp-derived products, including those products that are highly intoxicating, or if so, which State agency should take primacy. Under current law, MDA does not regulate finished products intended to be consumed or inhaled by humans, or intoxicating products intended for human consumption or inhalation. At present, the Maryland Department of Health regulates finished food, drug, and dietary supplement products in the State, the Alcohol and Tobacco Commission regulates vape products containing THC isomers and other cannabinoids derived from hemp, and the Medical Cannabis Commission regulates intoxicating cannabis- and hemp-derived products manufactured or sold by medical cannabis businesses (note: the Medical Cannabis Commission staff and regulatory authority will transition to the Alcohol and Tobacco Commission in 2023 pursuant to Chapter 26 of the Acts of 2022). Further, MDA expressed a disinterest in gaining regulatory authority over these hemp-derived products during the production of this report.

### **Implement Specific Product Testing Requirements**

The Commission received research submitted by stakeholders recommending product testing, but specific approaches to product testing and contaminant limits were not proposed. Therefore, the Commission's recommendations on product testing ultimately reflect best practices from other states and the existing medical cannabis program.

## **VI. Recommendations**

Hemp and cannabis are each derived from the *Cannabis sativa* plant. Delta-9 THC is the intoxicating compound most prevalent in cannabis, but the isomers and derivatives of delta-9-THC (e.g., delta-8, delta-10) also produce intoxicating and impairing effects and pose similar public health implications as delta-9 due to potential impurities. The State adopted its existing definition of cannabis, which expressly excludes hemp and products derived from hemp, to draw a distinction between plants and products that are intoxicating (cannabis) and those that are not (hemp). However, with advances in chemistry, non-intoxicating cannabinoids that are prevalent in hemp (e.g., CBD) can be chemically converted into highly intoxicating THC isomers and derivatives. Yet, under existing State law products containing these potentially highly intoxicating THC

isomers and derivatives are not subject to any health or safety standards governing their manufacture or sale – unlike nearly identical products containing delta-9-THC. Therefore, the Commission makes the following recommendations to ensure that potentially intoxicating compounds and products are subject to manufacturing, testing, health and safety standards, regardless of the source of the initial biomass.

### **1. Align product regulations with the health and safety risks of the product.**

Many states have attempted to regulate hemp products based on whether the product may present a greater risk to public health and safety. In determining whether a product may present a greater risk to public health and safety, and therefore, should be subject to greater regulation, states most commonly have focused on whether: (1) a cannabinoid is naturally occurring or artificially derived, (2) a product is intoxicating or impairing, and/or (3) the product is intended for human consumption. These policy considerations can be used separately or in tandem to create a broad regulatory framework that aims to best protect Marylanders. These policy considerations are derived from other states’ models and established best practices:

- **Synthetically Derived v. Naturally Derived:** Delta-8 and delta-10 are naturally occurring cannabinoids, but each can also be created by chemically converting CBD into THC. Cannabinoids that are created through this isomerization process are commonly referred to as synthetically or artificially derived. One of the more challenging aspects of regulating delta-8, delta-10 and other similar cannabinoids is that those cannabinoids created through isomerization are identical to those naturally occurring in the plant but may have been created using harmful solvents, which can residually remain in the end product. Further, the proliferation of other compounds that are not naturally occurring in the cannabis plant (e.g., THC-O-Acetate) creates additional public health uncertainty and concerns. Some states, such as Oregon, have banned synthetic products or processes. Alternatively, other jurisdictions such as West Virginia, consider whether a cannabinoid is naturally occurring or non-naturally occurring within their regulatory framework. Accordingly, products containing delta-8, delta-9, or delta-10 may be permitted in the state, but products containing tetrahydrocannabinol acetate, THC-O, ATHC, exo-THC, and delta-8-O are prohibited from being sold in the state. Given the possibility of harmful solvents when products are made through a synthetic process, the Commission recommends establishing testing criteria to evaluate the safety of these products.
- **Intoxicating v. Non-Intoxicating:** Other states, such as Colorado and Virginia in their recently established hemp task forces, have recommended that the standard for regulation within hemp-derived products be a determination of whether the product is intoxicating. This position is supported by the U.S. Hemp Roundtable - a national coalition of hemp

companies seeking standards and regulation around hemp and CBD products. In response to Virginia’s Task Force proposal, they stated that “the Roundtable continues to advocate for a regulatory framework that distinguishes non-impairing, non-intoxicating hemp products from intoxicating, impairing products sold under the guise of hemp, and more importantly protects consumers by assuring access to quality, regulated products”. Their written statement also supports a Total THC concentration to assess products, and the use of this standard to determine if the products are intoxicating. General Counsel Jonathan Miller, on behalf of the U.S. Hemp Roundtable was consistent in their written position during his August 7 testimony to Virginia’s hemp task force, stating that “when we worked on the 2014 and 2018 Farm Bill, the underlying theme was that hemp was non-intoxicating and that marijuana and adult-use cannabis was intoxicating” and that “hemp and hemp products like CBD could be sold at retail to consumers with regulation [and] then the intoxicating compounds would be limited to adult-use cannabis markets and more strictly regulated and limited to adults.” He further went on to state that “When working on the 2014-2018 farm bill(s), we were working with the science and policy knowledge at that time and came up with a measurement of 0.3% delta-9-THC or less and we weren’t aware of what delta-8 or delta-10 or many other compounds ... [mentioned earlier in the hearing] at the time.” Therefore, to be consistent with the Congressional intent, and general use of hemp products relative to cannabis products, those products that are determined to be intoxicating should not be considered hemp, or at the very least have a regulatory framework that achieves parity with cannabis regulations, given their potential for intoxication and impairment.

How states elect to determine whether hemp-derived products are intoxicating can vary. Some states, such as Oregon, have elected to establish specific THC benchmarks on products to establish the basis of understanding for when a product would be considered to cause intoxication. Oregon’s research and subsequent regulations found that 0.5 mg total THC *per container* would be considered non-intoxicating. Above this threshold, Oregon capped THC concentration for edible products at 2.0 mg THC per serving and 20 mg THC per container. This created a framework where hemp-products that had some intoxicating effects could be sold, but with greater regulation, packaging requirements, and other restrictions.

- **Consumable v. Non-Consumable:** Hemp products that are intended for human consumption pose a greater concern to the public health, safety, and well-being than those products that are used for the manufacturing of fiber, rope, textiles, or many of the other industrial uses for hemp products. The Commission recommends that products sold to end users be regulated more stringently than those used for an industrial purpose. Further, regulations could differentiate between products for inhalation and ingestion rather than topical applications in humans or the end-users. Some compounds and contaminants act

differently in the body when ingested rather than inhaled, making the method of administration an important regulatory consideration. As discussed earlier, both Florida and New York have instances of different regulatory standards for products for ingestion versus inhalation. New York considers topical application consumable as well, while Florida does not. Further, Maryland's experience and response to the 2019 lung injury (EVALI) crisis, which was attributed to vape products containing Vitamin E Acetate and claimed the lives of at least 68 Americans and caused serious lung injury in thousands of others, underscores the importance of regulating products differently based on the method of administration.

## **2. Require certain hemp-derived products to be subject to laboratory testing, packaging and labeling, therapeutic claims standards and other product safety measures.**

**Laboratory testing:** The Commission recommends that the General Assembly adopt the Hemp Industry Association's position on testing of hemp-derived products for safety to include testing for the presence of certain contaminants, including: (i) microbials; (ii) heavy metals; (iii) pesticides; (iv) solvents; (v) reagent residuals; and (vi) bleaches. The specific contaminants to be tested for should be established in regulations and consistent with other states' testing protocols. A list of contaminants tested for by Florida and New York are included in *Appendix E* of this report.

**Packaging and labeling:** The Commission recommends establishing minimum packaging and labeling requirements for certain hemp products (e.g., intoxicating product, consumable/inhalable products). For example, packaging should include a universal symbol indicating that the product contains THC and should not display a cartoon, color scheme, image, graphic or feature that may make the package attractive to children. Package labels should include: (i) warning statements governing safe use and secure storage of the product; (ii) a list of THC and other cannabinoid ingredients or additives; and (iii) a COA displaying the laboratory testing results of the product. These requirements are consistent with the current requirements for cannabis products in Maryland and across the country.

**Therapeutic claims:** The federal and state standard for making any therapeutic or medical claims is the claim must: (i) be supported by substantial clinical evidence or data; and (ii) include information on the most significant side effects or risks associated with the use of the product. This standard should be expressly extended to include hemp-derived products.

**Federal manufacturing standards:** Federal good manufacturing practices standards should be applied to the manufacture of hemp-derived products sold in Maryland, when possible. Certified good manufacturing practices (cGMP) are the national standard governing the

manufacturing of drugs and food in the United States, and best practices for the manufacture of dietary supplements. Expressly extending cGMP requirements to the manufacture, storage, and distribution of hemp-derived products would ensure product quality and consumer safety. Absent the explicit use of federal cGMP standards, the State should establish other product safety standards to govern the manufacture, storage, and distribution of these products. Another use of federal standards occurs in West Virginia, where products that only contain hemp ingredients that have been given GRAS (Generally Recognized as Safe) status by the FDA are exempt from providing a COA. GRAS is a designation given by the FDA that indicates a substance added to food is considered safe under conditions of its intended use. Currently, dehulled hemp seed, hemp seed oil, and hemp seed protein are designated GRAS by the FDA.

### **3. Only allow for sales of certain products in licensed, regulated establishments.**

Requiring manufacturers and retailers of certain hemp-derived products to be licensed and conducting compliance inspections on these businesses will improve product quality and safety, reduce youth access, and assist with any applicable tax collection. Licensing allows the State to monitor where products are manufactured and sold in order to conduct compliance checks. Similarly, sanctions against licenses (e.g., reprimand, suspension or revocation) are more effective than fines or other penalties at improving regulatory compliance. In particular, sales-to-minors checks conducted by state and local entities for similar age-restricted products such as alcohol, cannabis, and tobacco are extremely effective at improving business compliance and reducing youth access and use. As discussed in the Commission's study, one of the initial findings was the lack of identification checks at retail establishments where THC product purchases were made.

### **4. Expand public health messaging and resources established under Chapter 26 of the Acts of 2022 to include any THC Product.**

The Public Health Advisory Council was established by Chapter 26 of the Acts of 2022 to study and make ongoing recommendations on an array of public health impacts of cannabis use and mitigation of youth use of, misuse of, and addiction to cannabis, including through the implementation of public health campaigns on cannabis. Consistent with the Commission's earlier recommendations, messaging around health and safety of cannabis products should be expanded to include and consider any products containing THC, regardless of the initial plant source.

Public education campaigns and health education are critical components to educating parents and youth about the risks associated with THC products. The educational campaigns should inform the public on the dangers and potentially intoxicating nature of hemp-derived THC products. A disproportionate number of poison control calls and adverse event reports to the FDA and CDC related to these products involve minors. Of the calls specifically for delta-8 received by

National Poison Centers from January 2021 to February 2022, 41% involved pediatric patients, and 82% of all unintentional exposures were of pediatric patients.

Ongoing public health developments and recommendations on potentially intoxicating hemp-derived THC products should be monitored and studied by the Cannabis Public Health Advisory Council.

## **VII. Conclusion**

The Commission extends its gratitude to the Maryland General Assembly for their leadership on this issue, by partnering with the Commission to identify the challenges facing the State from unregulated non-delta-9-THC products and addressing this complex problem with the passage of Chapters 511 and 512 of the Acts of 2022. The Commission believes that the information, research, and recommendations contained in this report will allow the General Assembly to continue to enact policy to benefit the health and safety of all Marylanders. The Commission would also like to thank the researchers, stakeholders, other State agencies who contributed feedback, expertise, and information to this report.

## **VIII. Appendices**

The following pages contain the report appendices. The first three appendices (*Appendices A, B, and C*) pertain to the public stakeholder meetings held by the Commission over the research of this report. The next two appendices add additional context in terms of product testing and availability (*Appendices D and E*, respectively). *Appendix F* contains more extensive research on certain states' regulatory frameworks. All stakeholder feedback that was provided as a part of the Commission's work, including responses to draft recommendations that were shared with stakeholders in advance of this report's submission, are compiled into *Appendix G*.

## **Appendix A: Stakeholders, Presenters and Entities Consulted with During Commission's Study of Non-Delta-9-THC Products**

### **Stakeholders Named in Section (II) of Chapters 511 & 512**

- Maryland Medical Cannabis Commission
- Maryland Department of Agriculture
- Maryland Hemp Coalition
- Forensic Sciences Division in the Department of State Police
- U.S. Cannabis Council
- Maryland Healthy Alternatives Association

### **Other Invited Guests, Presenters and Experts in the State**

- Maryland School of Pharmacy master's in Medical Cannabis Science and Therapeutics
  - Presented during October 20<sup>th</sup> Meeting
- The Network for Public Health Law – Eastern Region
  - Presented during October 20<sup>th</sup> Meeting
- Vincente Sederberg
  - Presented during November 17<sup>th</sup> Meeting
- Maryland Poison Center
- Maryland Wholesale Cannabis Trade Association (CANMD)
- Maryland Medical Dispensary Association (MDMDA)
- Maryland Independent Testing Laboratories
- Maryland Department of Health - Food Protection

**Chapter 511/512 Report on Regulation of Non-Delta-9 THC Products  
Meeting #1  
Thursday, October 20<sup>th</sup> – 1PM  
Held Virtually & Livestreamed**

- **Welcome and Introductions** (5 minutes)
- **Summary of Ch. 511/512, and legislative report mandate** (5 minutes)
  - MMCC Staff
- **Presentation on chemistry / pharmacology of hemp-derived products** (30 minutes)
  - Dr. Chad Johnson, Co-Director of the University of Maryland School of Pharmacy's Master of Science in Medical Cannabis Science and Therapeutics
- **Questions** (5 minutes)
- **Presentation by on legal background, federal authority, and other states' solutions** (20 minutes)
  - Mathew Swinburne, J.D., Associate Director, The Network for Public Health Law - Eastern Region & The University of Maryland Francis King Carey School of Law
- **Questions** (5 minutes)
- **Discussion of presentations** (15 minutes)
- **Next Steps** (5 minutes)
  - Next meeting: November 17<sup>th</sup> at 1PM
  - MMCC Staff to share proposed statutory revisions/definitions by October 28<sup>th</sup>



# Synthetic Cannabinoids from hemp: Isomers and Derivatives of $\Delta^9$ -THC

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Chad Johnson, Ph.D.

Co-Director, Masters in Medical Cannabis Science and Therapeutics

# Outline

- Basics of Pharmacology
- Isomer vs. derivative
- Isomers + derivatives of  $\Delta^9$ -THC—chemistry and pharmacology

# Cannabinoids

Receptors:

CB1 and CB2

CB1 – neuroactive effects (located in the brain predominantly)

CB2 – major effects are the immune system (located peripherally predominantly)

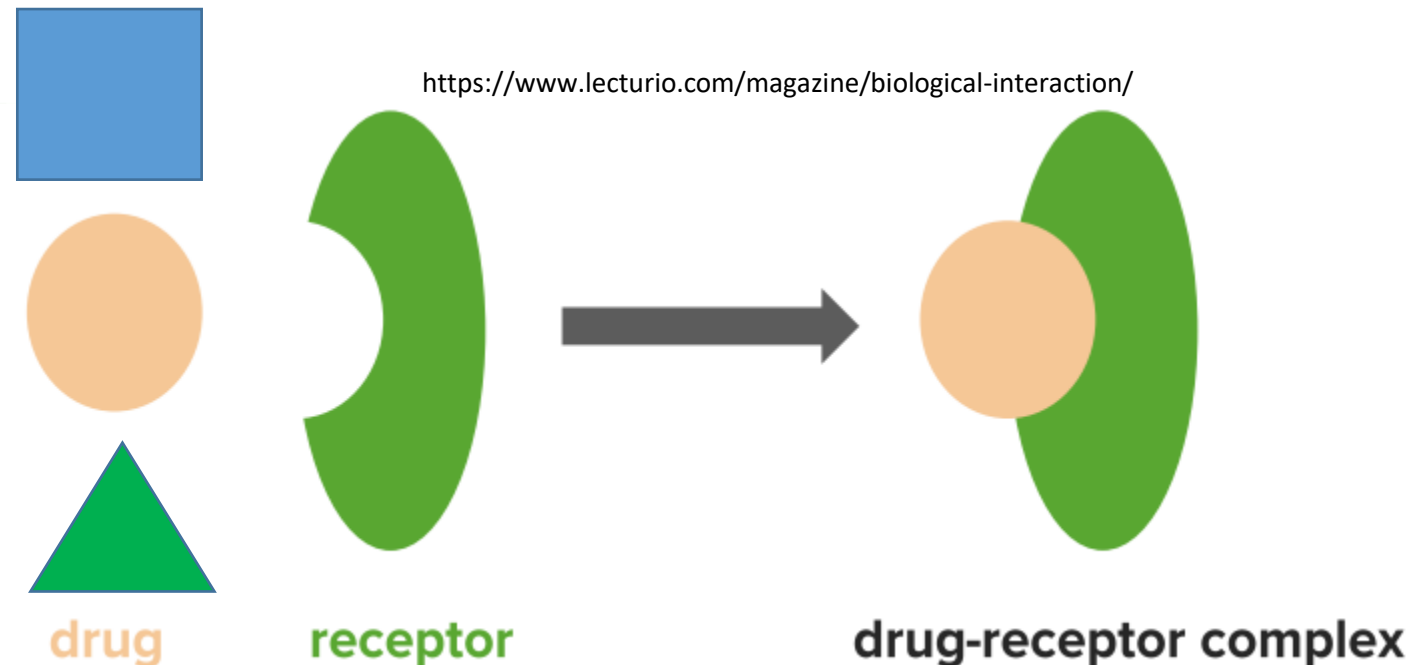
7-Transmembrane G-Protein Coupled Receptors

# Affinity

**Proteins that recognize “drugs”** and transmit a message from outside the cell to the inside

Affinity = Binding = Recognition

Higher affinity=less drug needed to send the message (generally)



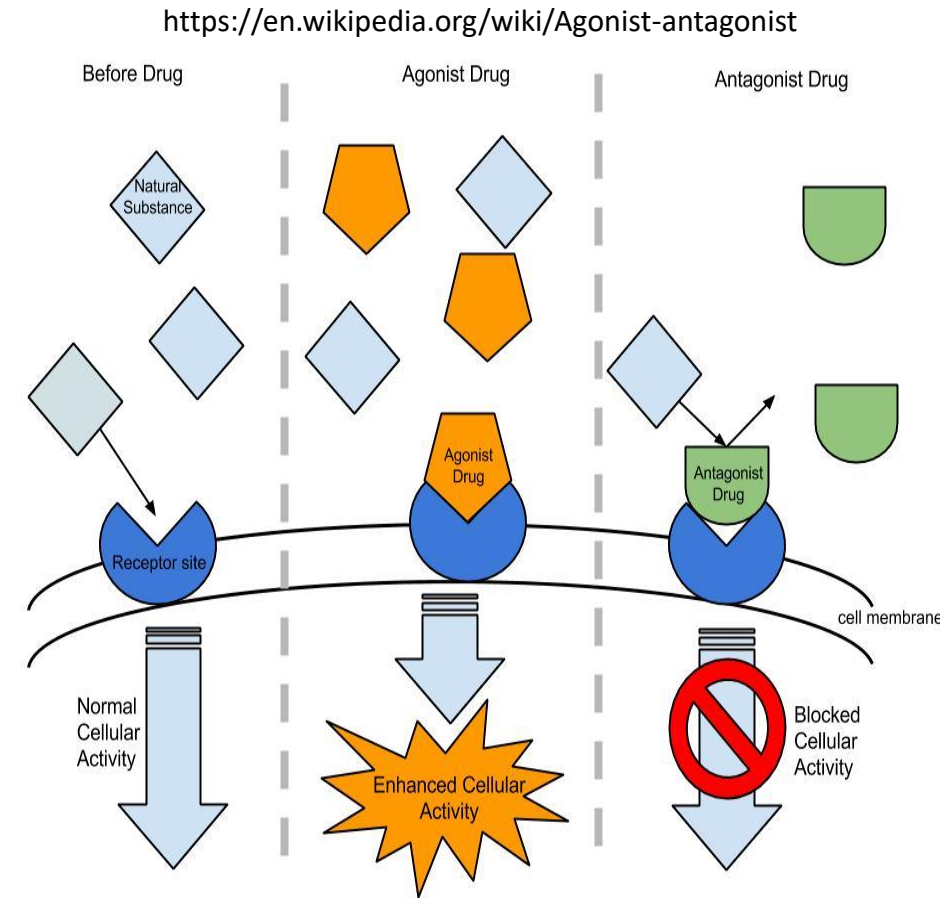
# Efficacy

Proteins that recognize “drugs” and **transmit a message from outside the cell to the inside**

Binding is required—Affinity!

Can activate (agonist) or not activate (antagonist)

How much they activate is efficacy



# Potency

Proteins that recognize “drugs” and transmit a message from outside the cell to the inside

Can activate (agonist) or not activate (antagonist)

**How much drug is required for activation=POTENCY**

## Summary

Receptors and enzymes are both proteins, but have differing functions

Receptors recognize drugs (affinity)

Drugs can activate (high efficacy) = agonist

**or**

not activate (low efficacy) = antagonist

How much drug is required = potency

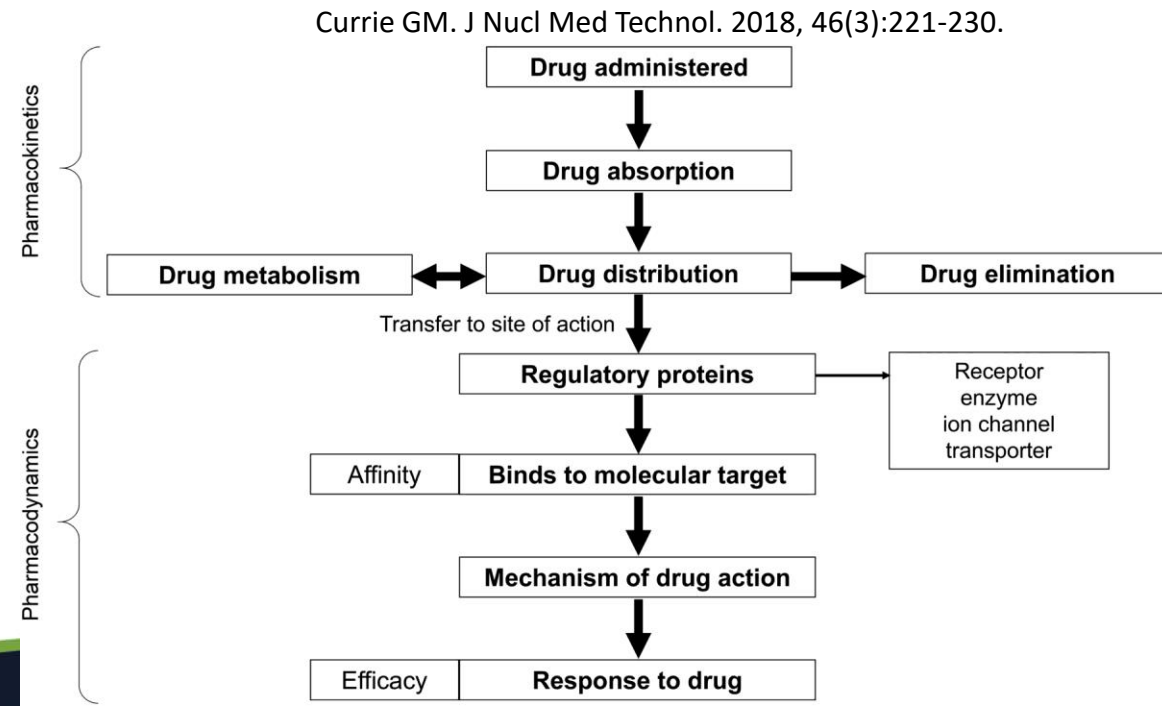
# Pharmacokinetics and Pharmacodynamics

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# Pharmacokinetic (PK) Foundational Concepts

- *Pharmacokinetics* is the science of the kinetics of drug absorption, distribution, metabolism and elimination (**ADME**)
- **PK** tells us how quickly a drug is **absorbed** in the body
- *This a good predictor of how quickly the **pharmacodynamic (PD)** [what the drug does to the body] effect will start.*
- **PK** tells us how a drug is **distributed** in the body.
- *This tells us that the drug will reach its receptor to yield a **PD** effect*
- **PK** tells us how quickly or slowly a drug is **metabolized** or **excreted**
- *This tells us how often we should administer a drug, e.g. twice a day, once a day, etc.*



# Route of administration matters!

- Smoking is the most common (quick onset, easier to titrate)
- Oral admin (longer onset, first-pass metabolism)
- We would expect the liver to render a drug inactive—but that isn't always the case...



**Smoking**

*Onset: 5–10 minutes  
Duration: 2–4 hours*



**Vaporisation\***

*Onset: 5–10 minutes  
Duration: 2–4 hours*



**Oral (other)**

*Onset: 60–180 minutes  
Duration: 6–8 hours*



**Topical**

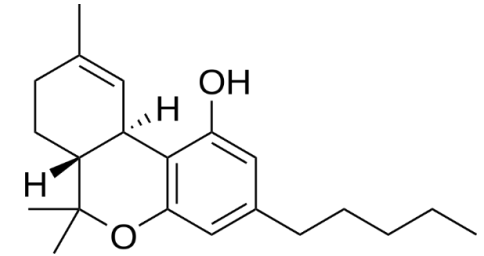
*Onset: Variable  
Duration: Variable*



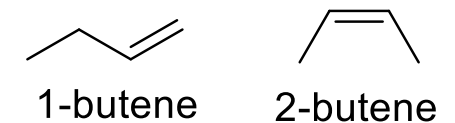
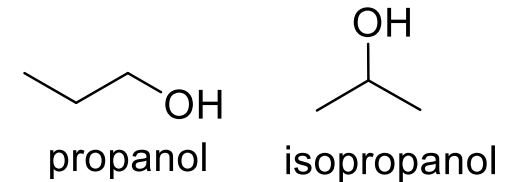
**Oro-mucosal**

*Onset: 15–45 minutes  
Duration: 6–8 hours*

# “Isomers” and “Derivatives” of $\Delta 9$ -THC



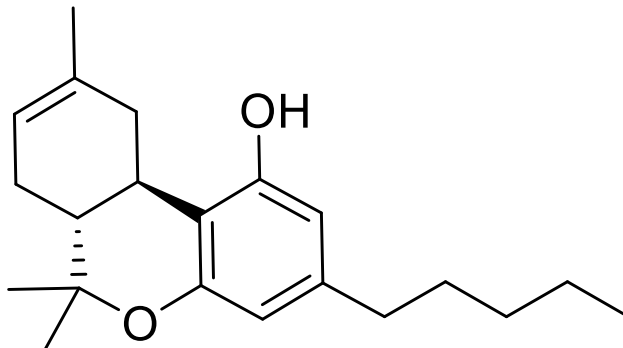
An “**isomer**” has the same chemical formula, but different connectivity of the atoms within the molecule.



A “**derivative**” does NOT have the same chemical formula (but could have similar connectivity!).

# $\Delta 8$ -THC, $\Delta 9$ 's "Legal" Younger Sibling...

- $\Delta 8$  can be produced from hemp (CBD)—hence was placed in a legal “gray” area
- Legalization of CBD led to overproduction of hemp (2018 Farm Bill...)
- What do growers do? Find a way to make their "hemp" more profitable.

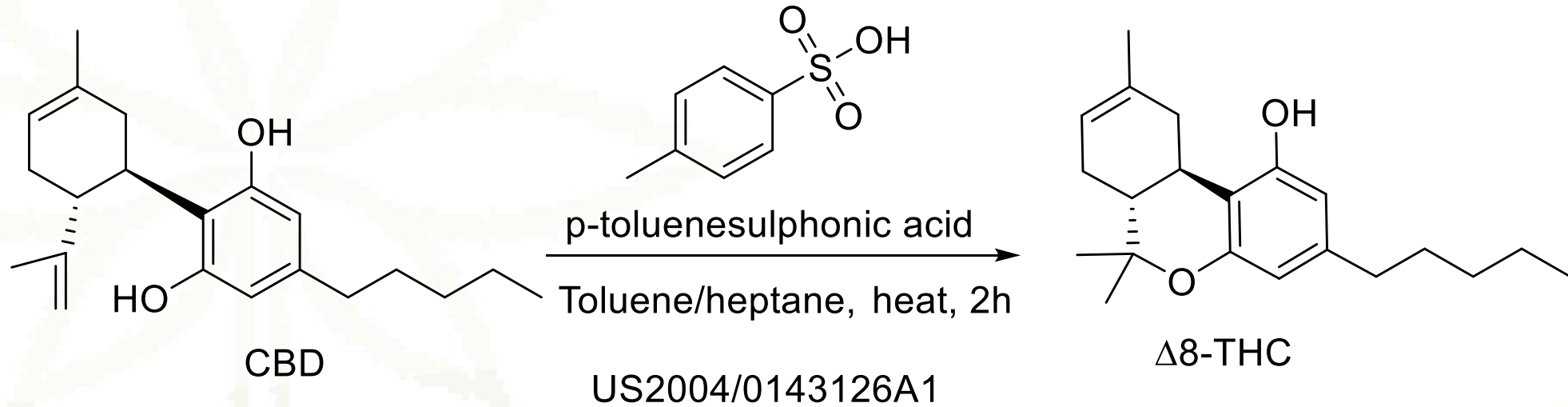
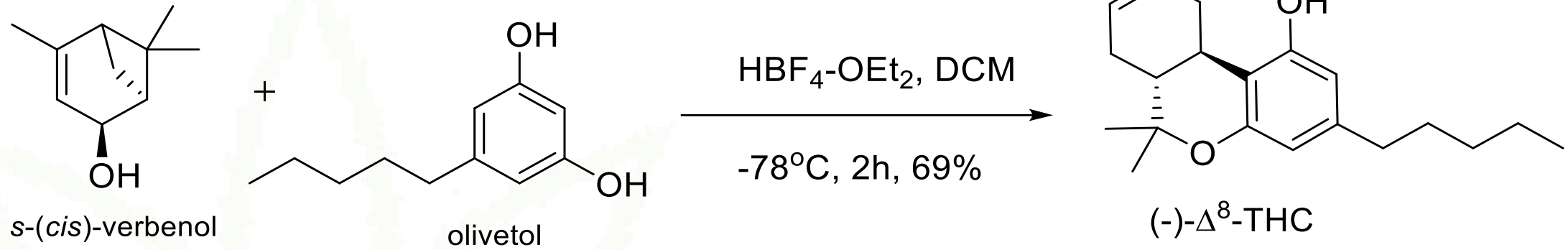


## $\Delta 8$ , cont.

- Only occurs at minimal levels in the plant ( $\leq 1\%$ )
- It has similar activity to  $\Delta 9$ -THC, but slightly less potent—yet it is marketed as hemp!
- Purification/QC issues
- *AK Futures LLC vs Boyd St Distro LLC* (early summer 2022)



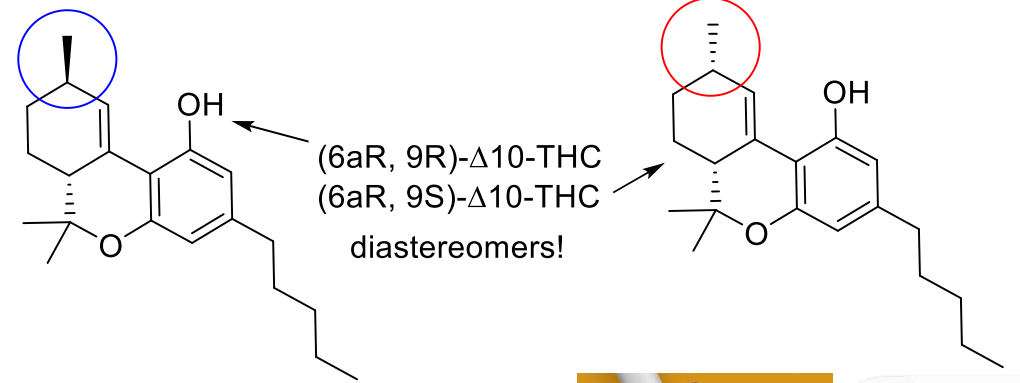
# MS in Medical Cannabis Science and Therapeutics



# Abuse Liability of $\Delta 8$ ?

- Vanegas et al. Drug and Alcohol Dependence. 2022, 240, 109640
- They found that:
  - Acute and chronic effects of  $\Delta 8$  resemble  $\Delta 9$
  - “Classical” cannabinoid effects mediated by CB1 receptor
  - Tolerance (and cross tolerance) develops to WIN55,212
  - $\Delta 8$  substitutes for  $\Delta 9$  in drug discrimination assays
  - Withdrawal symptoms develop from  $\Delta 8$  (physical dependence)

# $\Delta$ 10-THC

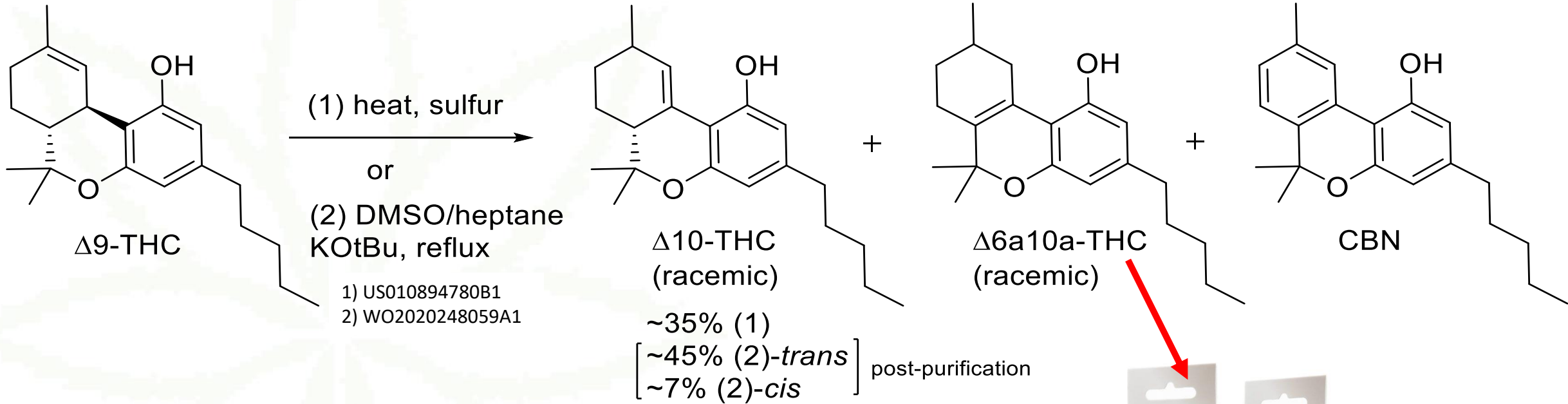


- **Not natural**
- Same legal issues as  $\Delta$ 8...
- 9R-isomer shows higher potency
- Both show much weaker ( $\mu$ M) potency than  $\Delta$ 9 (similar to  $\Delta$ 8)—very few studies done
- Purification/QC issues





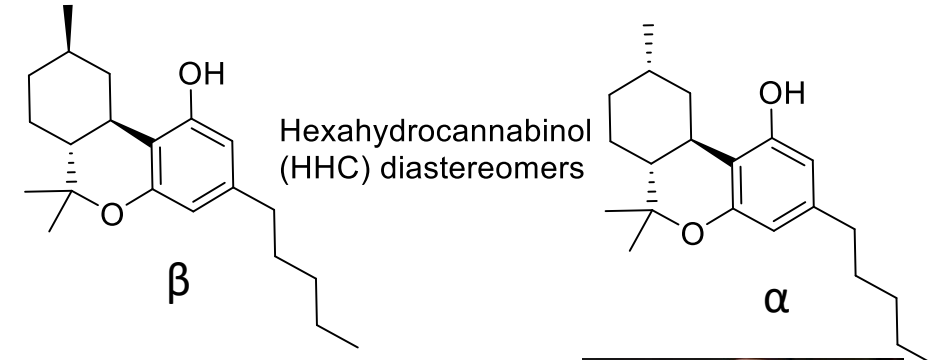
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**Conclusion: Purification is needed!**



# Hexahydrocannabinol (HHC)

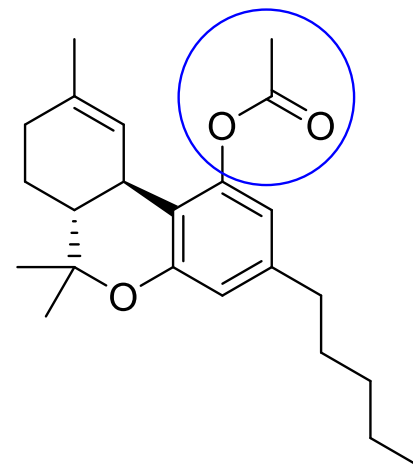


- Hydrogenated derivative of THC—only trace amounts from the plant
- Can be easily made from citronellal and olivetol
- Primarily sold in vape carts (not widely available...yet)
- Is legal to buy/sell/use for now—once again, a legal loophole
- 9 $\beta$  enantiomer=more active
- Purification/QC issues



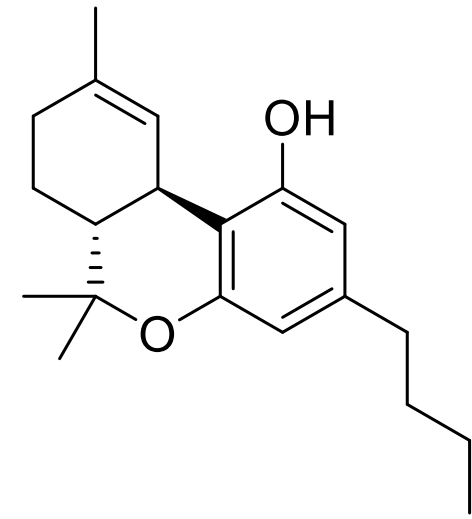
# THC-O-Acetate (THCO)

- Synthetic
- Still agonist at CB1/CB2, but increased potency (3-4x)
- Originally investigated as a possible non-lethal incapacitating agent (Edgewood Arsenal experiments) in mid-late 1900s (2x more likely at higher doses to produce ataxia)
- Not scheduled at the Federal level—legal loophole



**VERY FEW STUDIES DONE TO ESTABLISH SAFETY**

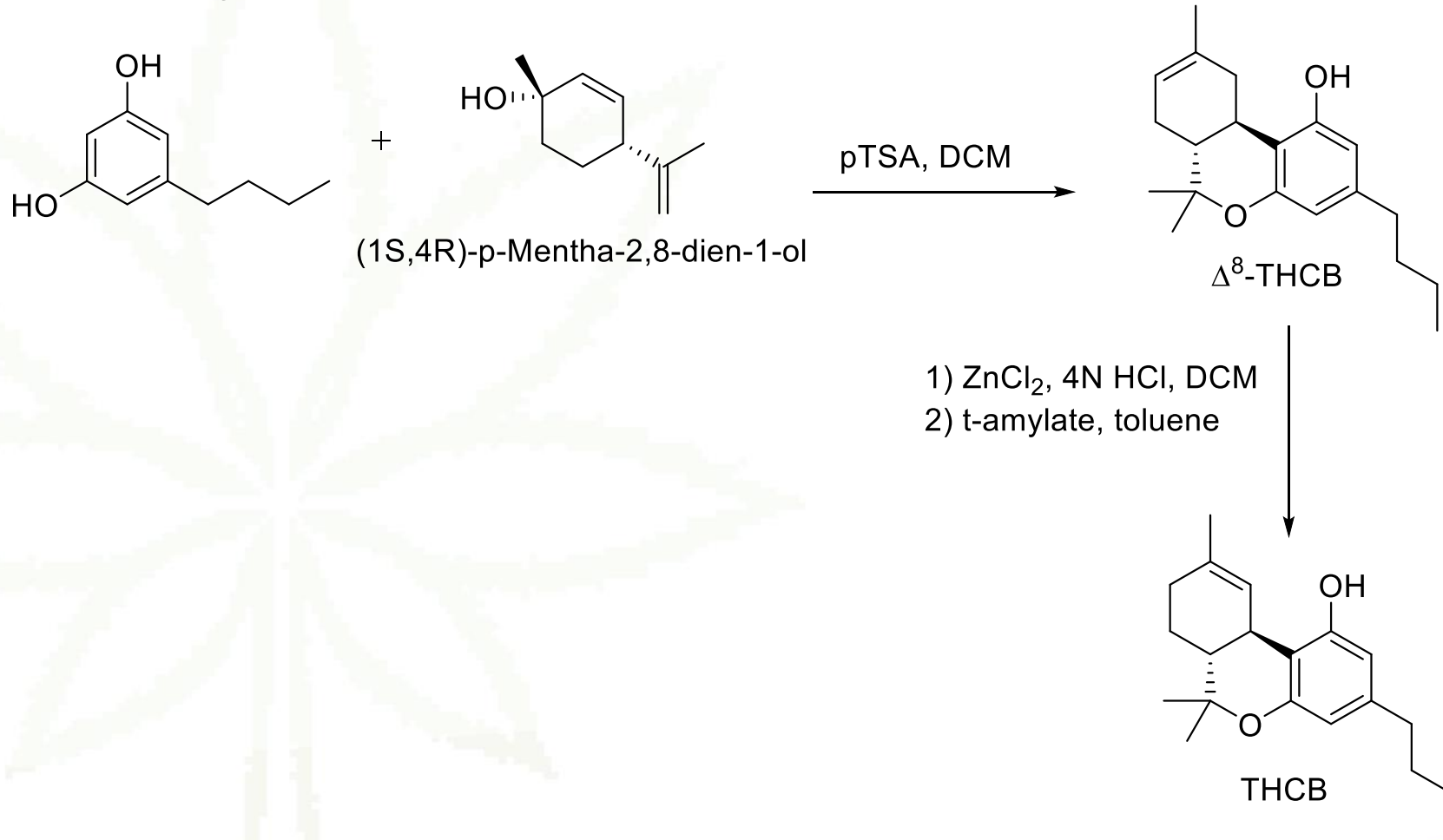
# Tetrahydrocannabibutol (THCB)



- Isolated from the plant, but in small quantities
- Similar binding affinity to CB1/CB2 (low nM range) as  $\Delta 9$ , moderate efficacy in mice (tetrad test: spontaneous activity [hyperlocomotion], analgesia, changes in body temp, and latency for moving)
- $\Delta 8$  version known as JWH-130

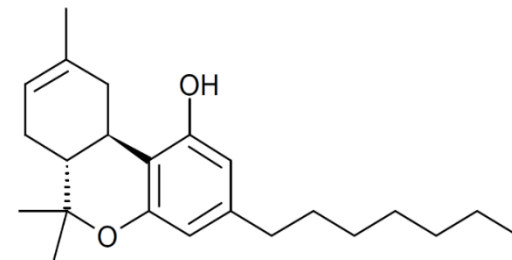
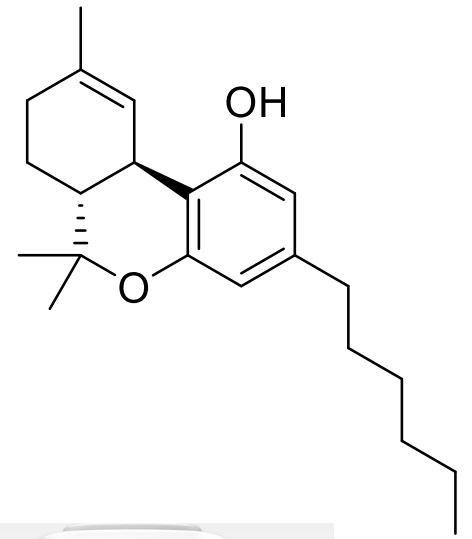


# THCB synthesis



# Tetrahydrocannabiphorol (THCP)

- Potent, synthetic derivative of  $\Delta 9$ —isolated only in trace amounts from the plant (Citti et al. *Nature*, 2019)
- CB1/CB2 agonist (~30x higher affinity for CB1, ~10x for CB2)
- Purification/QC issues (again)
- The  $\Delta 8$ -isomer is known as JWH-091



# What to do now?

- The more we know the better...are more isomers/derivatives on the rise?
- What products are out there? Are they validated for QC/purity?
- Research is needed to establish:
  - ADME
  - Safety
  - Dosing
- Regulation?

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# Regulation of Hemp Derived THC Products

*Mathew Swinburne, J.D.*

*Associate Director*

*The Network for Public Health Law-Eastern Region*

# Presentation Outline

**Thank you to Annie Carver and Robert Stenzel**

- 1. 2014 Agricultural Bill**
- 2. 2018 Agriculture Bill**
- 3. FDA Authority**
- 4. FDA Action**
- 5. State Responses**
- 6. Court Involvement**

# 2014 Agriculture Bill

## Created the Hemp Pilot Program

- Defined industrial hemp as cannabis with a Delta-9-THC concentration of not more than 0.3% on a dry weight basis.
- Allowed the cultivation of hemp for research purposes in states that had laws permitting the cultivation of hemp.
- Restricted to institutions of higher learning and state departments of agriculture.
- Only covered states not tribal governments or territories.
- Hemp was still a schedule I drug on the Controlled substance Act.
- Involved less federal oversight and restrictions than the 2018 Farm Bill and many states choose to remain in the program until it expired in Dec 2021.



# 2018 Agriculture Bill

- Legalized hemp as an agricultural product.
- Removed Hemp from the Controlled Substance Act (no longer Schedule I substance).
- No longer restricted to research.
- Includes states, tribal governments, and territories.
- Permitted in interstate commerce.
- States could develop their own hemp cultivation programs or utilize the USDA system. (most states have chosen to develop their own programs).
- Retained the FDA authority to regulate the products derived from hemp. (7 USC 1639r)**



# 2018 Farm Bill-Hemp Defined

*the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis (7 USC 1620c)*



50 grams x 0.3%=150mg

# FDA Authority

## Food Drug and Cosmetic Act

- ❑ **Food**-Adulteration (may render it injurious to health)
- ❑ **Food Additive**-must petition FDA for approval. Safe for intended use
- ❑ **Dietary Supplement**-Structure function claims-well being claims, nutrient deficiency disease, . . .
- ❑ **Drug**-Diagnosis, cure, mitigation, treatment, or prevention of disease claims.

**No regulations for hemp derived products**



# FDA Response

## *Consumer Update: 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC (Dec. 2021).*

1. Delta-8 THC products have **not been evaluated or approved by the FDA** for safe use and may be marketed in ways that put the public health at risk.
2. The FDA has received **adverse event reports** involving delta-8 THC-containing products.
3. Delta-8 THC has **psychoactive and intoxicating effects**
4. Delta-8 THC products often involve use of **potentially harmful chemicals** to create the concentrations of delta-8 THC claimed in the marketplace.
5. Delta-8 THC products should be kept out of the reach of children and pets.



# FDA Warning Letters

Issued warning letters to five companies for selling Delta-8 THC products in violation of the FDCA (May 2022)

1. **Unapproved New Drug:** based on diagnosis, cure, mitigation, treatment, or prevention of disease claims.
  - “Delta-8 THC can be used to suppress the immune response in your body. If a patient is suffering from autoimmune diseases, Delta-8 THC will offer some relief and support. Some of these diseases include lupus, HIV/AIDS, and multiple sclerosis.”
2. **Misbranded drugs**-inadequate directions for safe use
3. **Adulterated Food**
  - No food additive regulation authorizes the use of Delta-8 THC.
  - Use of unauthorized food additive has adulterated the food products.



# New York- Separate Licensing System

- ❑ NY Cannabis Control Board and the Office of Cannabis Management tasked with regulating **cannabinoid hemp**.
- ❑ **Cannabinoid hemp**: any product processed or derived from hemp, that is used for human consumption including for topical application for its cannabinoid content, that does not contain more than 0.3% THC.
  - 0.3% THC by weight is delta-9.
  - Prohibit the addition of THC isomers-Delta-8 and Delta-10.
- ❑ **Age Restriction**: retailers cannot sell inhalable cannabinoid hemp product or flower product to anyone under 21.
- ❑ **Created a Hemp Specific Licensing System**
  - **Cultivators** (Department of Agriculture).
  - **Cannabinoid hemp processor**: licensed to extract hemp extract and/or manufacture cannabinoid hemp products.
  - **Cannabinoid Hemp Retailer**: licensed to sell cannabinoid hemp products, including via the internet, to consumers in New York State.

**Office of  
Cannabis  
Management**



# New York- Separate Licensing System

- ❑ **Product Restrictions**: cannot contain alcohol (liquor, wine, beer, cider, . . . ), tobacco or nicotine, cannot be in the form of an injectable, inhaler, cigarette, cigar or pre-roll.
  - **Food or beverage**: 25 mg of total cannabinoids per individually packaged product.
  - **Dietary supplements**: 3,000 mg of total cannabinoids per product, with no more than 75 mgs per individual serving.
- ❑ **Packaging**: imitate a candy label or use cartoons or other images popularly used to advertise to children, tamper-evident, light minimizing
- ❑ **Labeling**: ingredients, cannabinoid profile, warnings (not evaluated by FDA, keep away from children, pregnant or breastfeeding, . . . )
- ❑ **Testing**: pesticides, metals, residual solvents, biologicals, mycotoxins, cannabinoids



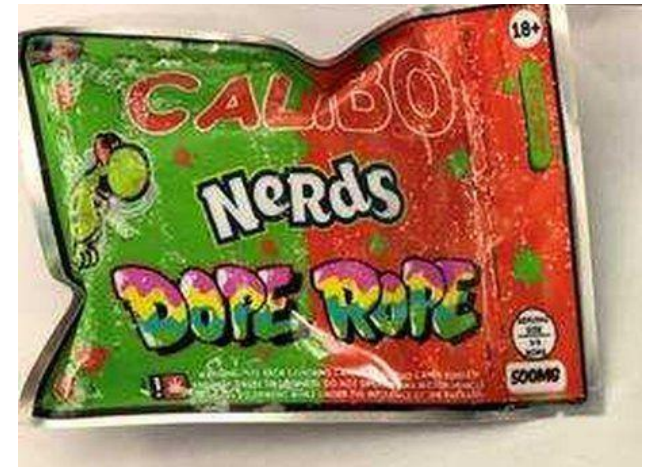
# Minnesota-Unlicensed Adult-Use Market

- ❑ Legalized the sale of products with THC if derived from hemp. **Do not require a license to sell.**
- ❑ Must be 21 years of age to purchase.
- ❑ **THC Restrictions**
  - Looks at all THC isomers (Delta-7, Delta-8, Delta-9, . . . .)
  - All products are limited to 0.3% of THC by weight.
  - Edibles further limited 5 mg per serving and 50 mg per package
  - Selling products that exceed these limits a criminal offense



# Minnesota-Unlicensed Adult-Use Market

- ❑ **Products:** prohibit human, cartoon, animals and fruits shapes; cannot resemble a food brand primarily consumed by children product, serving demarcations, cannot be made by apply cannabinoid extract to commercially available food.
- ❑ **Packaging:** opaque, child resistant, tamper evident, cannot appeal to children, and cannot resemble commercially available food products.
- ❑ **Labeling:** restrict product claims (see e.g., curative claims), warning: “Keep the product away from children”, cannabinoid profile
- ❑ **Testing:** products must be tested for mold, heavy metals, pesticides, fertilizers, solvents, cannabinoid profiles, and THC levels.



# Oregon- No License but Product Limits

- ❑ **Cannabinoid Hemp Product:** intended for human consumption-edible, topical, transdermal, . .and contains cannabinoids from Industrial Hemp.
  - Subject to the same product testing as cannabis products.
  - Do not require a license to sell these products.
  - Products cannot have synthetic cannabis derivatives (see e.g., Delta-8 THC)
- ❑ **Product Delta-9 THC limits**
  - Edibles and Transdermal patches 2mg/serving a 20mg/container
  - Tinctures 100mg/container
  - All products limited to 0.3% THC by weight.
- ❑ **Age restriction:** Must be 21 years of age to purchase a hemp product with 0.5 mg or greater of THC.
- ❑ **Adult-Use Cannabis Retailers and Medical Dispensaries** can sell Cannabinoid Hemp Products, but products are subject to all the cannabis product packaging, labeling, and testing requirements.

## Michigan-Include in Licensed Cannabis Market

- ❑ **With the rise in hemp derived intoxicating cannabinoids, transferred hemp product authority to Cannabis Regulatory Agency**
- ❑ **All THC isomers included in the state definition of THC.**
- ❑ **Products containing THC isomers can only be sold as part of the state's licensed adult-use or medical markets.**



# Colorado-Task Force

**Industrial hemp product:** finished products containing industrial hemp that is for human use or consumption and is a cosmetic, dietary supplement, food, food additive, contains a delta-9 concentration of 0.3%

- ❑ Do not need a “hemp license” to sell or manufacture but manufactures must complete register with the state.
- ❑ **CO Department of Public Health & Environment (CDPHE)-Notice (May 2021):** Prohibited chemical modification or converting of naturally occurring cannabinoids (Delta-9, Delta-8, . . .)

## **CO Senate Bill 22-205**

- ❑ Give CDPHE the authority to ban synthetic derived intoxicating THC isomers
- ❑ Created a **task force** to study intoxicating hemp products and make policy recommendations
- ❑ **20 members:** representatives from state government, experts in marijuana and industrial hemp regulation, licensed marijuana industry, industrial hemp industry, testing laboratories, and a representative of a county or district public health agency
- ❑ Differentiation between Synthetic/Semi-Synthetic cannabinoids.
- ❑ Report due to the general assembly by January 1, 2023.

## AK Futures LLC v. Boyd Street Distro LLC et al 35 F.4th 682 (May 19, 2022)

- ❑ Delta-8 product trademark case in the 6th Circuit
- ❑ Defense argued not entitled trademark protections because only lawful products qualify for trademark protection and delta-8 is not a lawful product.
- ❑ Court Held that Delta-8 was a legal product under federal law
- ❑ **Definition:** all derivatives, extracts, [and] cannabinoids—sweeping reach
- ❑ Statute is unambiguous and precludes a distinction based on manufacturing method (synthetic).





## KENTUCKY HEMP ASSOCIATION et al, v. RYAN QUARLES et al.



### **KENTUCKY DEPARTMENT OF AGRICULTURE**

Dr. Ryan F. Quarles, Commissioner

#### KY Dept. Agriculture-Guidance Letter

- Delta-8 is schedule I drug under KY and Federal Law
- The manufacture and marketing of products containing Delta-8 THC, in any quantity or concentration level, remains prohibited by federal law and state law.
- Failure to heed this guidance could result in the revocation of your hemp license and expose you to the risks of prosecution by federal, state, and local law enforcement agencies
- Subsequent criminal enforcement actions by the Kentucky State Police

#### Court Reasoning

- Federal Definition: hemp includes **all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers.**
- Delta-8 is a derivative of hemp and excluded from state and federal CSA.
- Legal product in KY.

Thank you for you time.

**Mathew Swinburne**  
**Associate Director**  
**The Network for Public Health Law-**  
**Eastern Region**

**[mswinburne@law.umaryland.edu](mailto:mswinburne@law.umaryland.edu)** or  
**[mswinburne@networkforphl.org](mailto:mswinburne@networkforphl.org)**



**Chapter 511/512 Report on Regulation of Non-Delta-9 THC  
Products  
Meeting #2  
Thursday, November 17<sup>th</sup> – 1PM  
Held Virtually & Livestreamed**

- **Welcome and Impact of Referendum on Non-Delta-9 THC Regulations (5 minutes)**
  - Will Tilburg, MMCC
- **Overview of Feedback Thus Far (5 minutes)**
  - Andrew Garrison, MMCC
- **Laboratory Testing Findings (10 Minutes)**
  - Lori Dodson, MMCC
- **Presentation on Colorado's Task Force and Consensus Framework (20 minutes)**
  - Jordan Wellington, Vicente Sederberg
  - Jen Flanagan, Vicente Sederberg
- **Questions (5 minutes)**
- **Discussion of Presentations and Framework (15 minutes)**
- **Next Steps (5 Minutes)**
  - Christi Megna, MMCC




# Ch. 511/512 Mandated Report Meeting #2

Thursday, November 17<sup>th</sup>

1PM-2:30PM



# Today's Meeting

- Welcome & Impact of Question 4 on Work Ahead
  - Points of Consensus Around Existing Feedback
  - MMCC Preliminary Test Results of Commercially Available Hemp-Products in Maryland
  - Presentation and Discussion of Colorado's SB22-205 Consensus Proposal
    - Jordan Wellington & Jen Flanagan, Vicente Sederberg
  - Discussion of Presentations
  - Next Steps
- 



# Question 4's Impact on Non-Delta-9-THC Products and Regulations

Will Tilburg, MMCC Executive Director



# Points of Consensus Thus Far

- Using a total THC Content when determining product regulations; specifically, one that includes isomers and derivatives of THC.
- Testing hemp-derived products to include:
  - Presence of Heavy Metals
  - Microbiological Impurities
  - Product Potency
  - Chemical Impurities
- Labeling on Hemp-derived products to include:
  - Warning Labels
  - List of non-CBD or THC Ingredients or Additives
  - Certificate of Analysis
- Using FDA's cGMP standards in product manufacturing.

# Open Questions

- Variation of regulation / framework on product type.
- Sales locations, permitting, or other retail restrictions.
- Exact guardrails on product potency available for consumption.
- Jurisdiction of regulatory and enforcement authority within State government.
- Laboratories authorized to conduct hemp-product testing.
  - DEA Certification, MMCC Authorized ITLs, Labs with ISO Certifications Consistent with MMCC Standards.



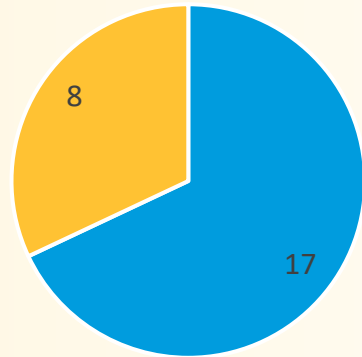


# MMCC Laboratory Testing Preliminary Findings for Commercially Available Hemp- Products in Maryland

Lori Dodson, MMCC Senior Advisor

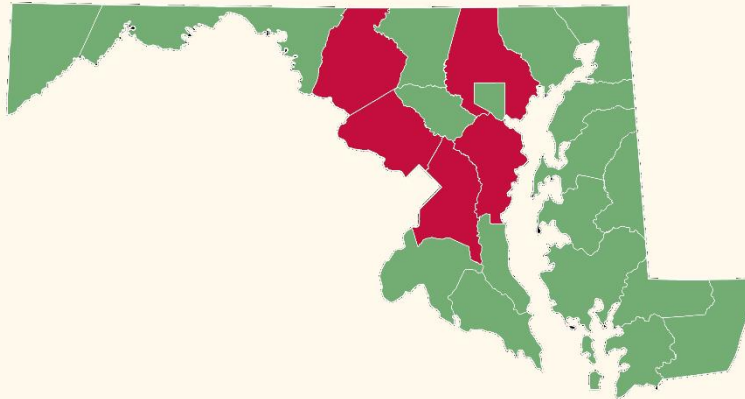


# Delta-8 Study Demographics



■ Gummies ■ Vapes

## Products Purchased Across 5 MD Counties



IDs Checked on **50%** of Purchases

# Packaging and Labeling



**44%**  
Included  
Expiration  
Dates

**60%**  
Included  
Warning  
Statements



Extraction Technician: CB  
Analytical Chemist: Altitude

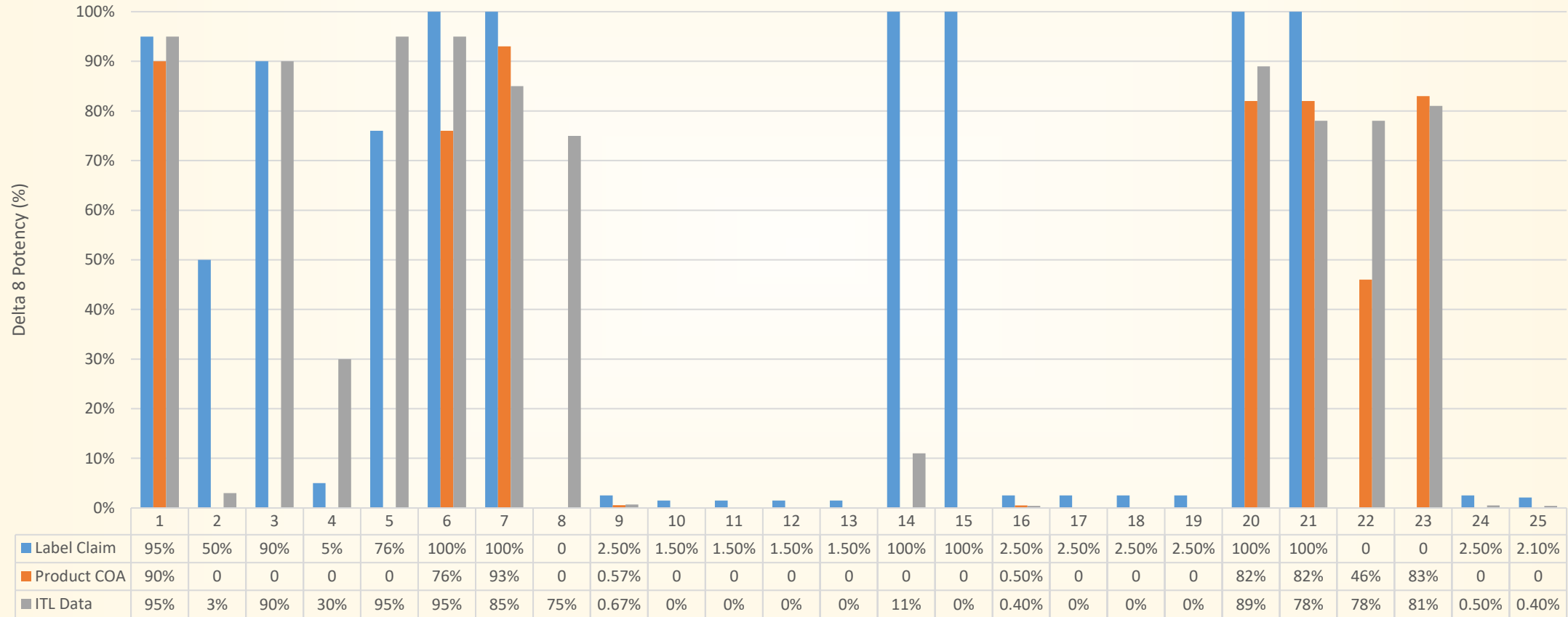
Cannabinoid Profile			
Cannabinoids (HPLC)	LOD (mg/mL)	%	Results
			mg/mL
Cannabidivarin (CBDV)	<0.0828		
Cannabidiolic Acid (CBD-A)	<0.0828		
Cannabigerolic Acid (CBG-A)	<0.0828	0.05	0.441
Cannabigerol (CBG)		1.76	17.2
Cannabidiol (CBD)			
Tetrahydrocannabivarin (THCV)	<0.0828		
Cannabinol (CBN)	<0.0828	0.06	0.551
delta 9-Tetrahydrocannabinol (THC)	<0.0828		0.409

Extraction Technician: CB  
Analytical Chemist: Altitude

Terpene Profile	
Terpene	Results
	ug/g
alpha-Borneol	
alpha-Terpinolene	
Borneol and (-)-Borneol	
gamma-Terpinene	
linalyl Acetate	
linalool	
limonene	
pinene	
terpinolene	
trans-Caryophyllene	74.9
Humulene	19.1
beta-Caryophyllene	
beta-Pinene	


**44%** Included Certificates of Analysis

# Potency of Delta-8 Comparisons – Preliminary Data



Hemp Sample

Label Claim Product COA ITL Data



# Colorado's SB22-205 Task Force on Intoxicating Hemp and Tetrahydrocannabinol Products Consensus Proposal

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Jen Flanagan, Vicente Sederberg





Next Steps:

Report due to MDGA by January 1, 2023



# Regulatory Framework

## SB22-205 Intoxicating Hemp Task Force



- **Ground state policy in federal best-practices**
- Hold consumable products to higher safety standards
- Provide businesses the opportunity to demonstrate safety of products
- Protect proprietary business information from public records requests
- Allow for regulatory flexibility in scientific and policy development
- Prioritize current public safety issues through enhanced enforcement, public reporting mechanisms, and public education campaigns
- Establish a realistic timeline for implementation and compliance



# Definitions: Intoxication

Striking the right balance between statutory and regulatory definitions will be the key to success.

## Define 'intoxication' / not 'intoxicating cannabinoids'

*Intoxication occurs from consumption above a specific threshold*

- Define intoxication and leverage existing state law
- Identify cannabinoids that have the potential to cause intoxication
- Establish the levels at which some cannabinoids can become intoxicating, alone or collectively

**Core Concept: Potentially Intoxicating Cannabinoid**

# Definitions: Total THC

Define 'Total THC' in regulation, not statute

*Any definition will need to be adjusted as science evolves*

- Include all forms of THC
- Create the statutory authority for the appropriate agency to define the formula used to calculate Total THC
- Establish similar authority for other cannabinoids capable of causing intoxication and for combinations of cannabinoids, as needed
- Paramount that definitions on the marijuana and hemp codes mirror each other

# Definitions: Separate Consumables

Create a definition for 'Consumable Hemp Product(s)'

*More stringent product safety regulations should apply to consumables*

- Hemp products intended for human consumption should have a higher regulatory threshold to protect public health.
- Separating the intended use of hemp will allow for regulations that are customized to the risks associated with that product and avoids unintentionally imposing unnecessary restrictions on non-consumable products.

# Definitions: Novel Cannabinoids

- Novel Cannabinoid Any cannabinoid that:
  - Is not listed in statute as initially approved safe for sale (ex: CBD, CBG, CBN)
  - Does not have GRAS or NDI approval; OR
  - Has not been assessed by the appropriate regulatory agency for safety and intoxication profiles

Under our proposal, a regulated pathway for safe and legal products containing novel cannabinoids is created around federal best practices of requiring producers to demonstrate safety through scientific findings.

# Policy Recommendations #1: THC in Hemp Products

Address the riskiest products on the market first

*Provide reasonable timeframes for businesses to comply*

## *Phase 1 – Statutory Changes*

- Adjust definition of THC
- Require compliance with existing laws
  - Air quality controls and cGMP
- Establish initial THC limits for all consumables
  - Serving, ratios, package

## *Phase 2 – Regulatory Implementation*

- Appropriate regulatory agency establish THC limits in regulation at a level conservative enough to prohibit products reasonably assumed to cause intoxication
- Create an approval process (next slide)
- Transition period for compliance

Permissible THC limits (mg) for hemp products should be based on existing safety data:  
-- Low enough to effectively prohibit sale of intoxicating products  
-- Address public safety issues presented by such products

# Policy Recommendations #1: THC in Hemp Products

## Approval of Non-Intoxicating Hemp Products

*Products that meet basic safety standards may exceed regulatory and statutory limits*

- The appropriate regulatory agency would approve products for sale that exceed THC levels based upon data provided by the manufacturer
- Framework should be based on FDA standards and best practices
- Consideration of product form, manufacturing process, cannabinoid profile and ratios, safety and intoxication data, data typically required for a GRAS or NDI submission, product testing, marketing and labeling

As during Phase 1, compliance with other existing laws would also be expected

# Policy Recommendations #2: Novel Cannabinoids

Create a structure that can evolve with science

*Require compliance with state or federal product safety standards*

- *Phase 1 – Statutory Changes*
  - Expressly permit known safe cannabinoids
  - Manufacturing standards and safeguards
  - Allow anything with GRAS or NDI
- *Phase 2 – Regulatory Implementation*
  - The appropriate regulatory agency will create a process for assessing the safety profile and intoxicating potential of novel cannabinoids in hemp products, as well as limits for potentially intoxicating cannabinoids

Timeline allows regulatory agencies to continue gathering feedback from stakeholders and prepare for implementation and gives hemp companies the time to adhere to compliance requirements.

# Policy Recommendations #2: Novel Cannabinoids

## Approval of Novel Cannabinoids

*Require compliance with state or federal product safety standards*

- Rely on existing FDA criteria for evaluation, without requiring final FDA approval
- The appropriate regulatory agency will establish a process for the assessment of novel cannabinoids to determine whether they are safe for consumption or cause intoxication at certain levels
- Empower state regulators to consider and reconsider classification of cannabinoids in the future, in consultation with scientific experts
- Synthetic and semi-synthetic cannabinoids permissibility is base upon safety

- Product form and method of delivery
- Description of manufacturing process
- Cannabinoid profile, ratio, naturally occurring
- Evidence about non-intoxication
- GRAS / NDI / equivalent
- cGMP standards and compliance

Safe and non-intoxicating = permitted ingredient in both industrial hemp products and consumable hemp products

Potentially unsafe / intoxicating = maybe used as permitted ingredient at established levels or approval (ex: THC)

Unsafe = prohibited entirely as hemp ingredient



# Policy Recommendations #3: Enforcement

## Sufficient funding for enforcement and education

*Without oversight and enforcement, even the best policies can be ineffective*

- Enforcement against in-state and out-of-state actors violating the law
- System for identifying and reporting unsafe or intoxicating products
- Public education campaigns with specific messaging toward curbing youth access

# Summary and Implementation

- *Legislative*
  - Legislation setting initial statutory THC limits, effective by January 2024
  - Initial statutory list of approved cannabinoids
- *Regulatory*
  - Regulations with approval process and new THC limits
  - Regulations for assessing novel cannabinoids
- *Implementation*
  - Compliance required with new THC levels, novel cannabinoid assessments, and approval processes required

# Conclusions

Reaffirms policy of two clear lanes:

- Intoxicating cannabis products = marijuana
- Non-intoxicating cannabis products = hemp

Prioritizes public safety by permitting synthetic and semi-synthetic cannabinoids based upon best practice assessments

This proposal:

- Brings together elements of preceding frameworks put forward by hemp and marijuana stakeholders
- Incorporates ideas from the legislative session
- Leaves room for consideration and resolution of policy items in the future
- Does not impose a hard cap on THC
- Creates opportunity for regulators and the cannabis industries to adapt while prioritizing public health and safety
- Will support innovation in the hemp industry
- Is consistent with the legislative intent of the Farm Bill and state's policy priorities

# Thank You



## Appendix D – Review of Online Retailers

		<u>Maryland Online Retailer 1</u>		<u>Maryland Online Retailer 2</u>	
		<b>Number of Products</b>	<b>Share of Total Products</b>	<b>Number of Products</b>	<b>Share of Total Products</b>
<u>Product Category*</u>					
<b>Potentially Intoxicating Products</b>	Delta-8-THC	313	31%	62	21%
	Delta-9-THC	90	9%	6	2%
	Delta-10-THC	44	4%	21	7%
	THC-O	69	7%	13	4%
	Hemp Flower and Pre-Rolls	66	6%	57	19%
	Other Potentially Intoxicating Compounds (e.g. THC-P, THC-V, HHC, THCh, & THCjd)	64	6%	10	3%
<b><i>All THC/Potentially Intoxicating Products</i></b>		<b>646</b>	<b>64%</b>	<b>169</b>	<b>57%</b>
<b>Non- Intoxicating Products</b>	CBD - Gummies & Edibles	141	14%	50	17%
	CBD - Topicals	109	11%	25	8%
	CBD - Oils and Tinctures	70	7%	36	12%
	CBD - Soft gels & Capsules	13	1%	2	1%
	CBD - Pets	32	3%	7	2%
	CDB - Vape	6	1%	10	3%
<b><i>All CBD Products</i></b>		<b>371</b>	<b>36%</b>	<b>130</b>	<b>43%</b>
<b><u>All Products Available</u></b>		<b>1017</b>	<b>100%</b>	<b>299</b>	<b>100%</b>

**\*Note:** Product categories reviewed using retailer’s online marketplace for products. MMCC staff did not individually verify label claims, or compound types sold within an individual product category. This data is intended to be illustrative as to the number of products impacted by the proposed regulations, and the share of these products in the State’s existing retail landscape. The MMCC is aware that certain products may contain both CBD and hemp-derived THC. An individual product with multiple compounds may be double counted in this analysis, if they are marketed by the retailer under multiple categories.

## Appendix E: Hemp-Product Contaminant Testing and Restrictions

<b><u>Residual Solvents (Limits in parts per million, or ppm)</u></b>			
<b>Contaminant</b>	<b>Florida Restrictions for Hemp Products</b>	<b>New York Restrictions for Hemp Products</b>	<b>MMCC Product Restrictions*</b>
1,2-Dichloroethane	2 ppm	5 ppm	
1,1-Dichloroethene	8 ppm	8 ppm	
Acetone	750 ppm	5,000 ppm	
Acetonitrile	60 ppm	410 ppm	
Benzene	1 ppm	2 ppm	2 ppm
Butane	5,000 ppm	2,000 ppm	5,000 ppm
Chloroform	2 ppm	60 ppm	
Ethanol	5,000 ppm	5,000 ppm	5,000 ppm
Ethyl Acetate	400 ppm	5,000 ppm	
Ethyl Ether	500 ppm	5,000 ppm	
Ethylene Oxide	5 ppm	5 ppm	
Heptane	5,000 ppm	5,000 ppm	5,000 ppm
Hexane	250 ppm	290 ppm	290 ppm
Isopropyl Alcohol	500 ppm	5,000 ppm	
Methanol	250 ppm	3,000 ppm	
Methylene Chloride	125 ppm	600 ppm	
Pentane	750 ppm	5,000 ppm	
Propane	5,000 ppm	5,000 ppm	5,000 ppm
Toluene	150 ppm	890 ppm	890 ppm
Trichloroethylene	25 ppm	80 ppm	
Xylenes, Total (ortho-, meta-, para-)	150 ppm	2,170 ppm	2,170 ppm

**\*Note:** Hemp Products tested as a part of this study by an MMCC-Certified Independent Testing Laboratory were *only* tested using the MMCC’s existing panel of contaminants, highlighted throughout this Appendix. As shown, states that have developed a testing panel for Hemp products specifically have expanded their contaminants and impurities tested for given the nature of the production process.

## Appendix E

<b><u>Heavy Metals (limits in parts per billion, or ppb)</u></b>			
<b>Contaminant</b>	<b>Florida Restrictions</b>	<b>New York Restrictions</b>	<b>MMCC Product Restrictions*</b>
Cadmium	500 ppb for <i>Ingestion</i> ; 200 ppb for <i>Inhalation</i> .	500 ppb for <i>Ingestion</i> ; 200 ppb for <i>Inhalation</i> .	500 ppb for <i>Ingestion</i> ; 400 ppb for <i>Inhalation</i> .
Lead	500 ppb for <i>Ingestion</i> or <i>Inhalation</i> .	1,000 ppb for <i>Ingestion</i> ; 500 ppb for <i>Inhalation</i> .	500 ppb for <i>Ingestion</i> ; 1,500 ppb for <i>Inhalation</i> .
Arsenic	1,500 ppb for <i>Ingestion</i> ; 200 ppb for <i>Inhalation</i> .	1,500 ppb for <i>Ingestion</i> ; 200 ppb for <i>Inhalation</i> .	1,500 ppb for <i>Ingestion</i> ; 400 ppb for <i>Inhalation</i> .
Mercury	3,000 ppb for <i>Ingestion</i> ; 200 ppb for <i>Inhalation</i> .	1,500 ppb for <i>Ingestion</i> ; 100 ppb for <i>Inhalation</i> .	3,000 ppb for <i>Ingestion</i> ; 200 ppb for <i>Inhalation</i> .

<b><u>Biological Impurities (CFU = Colony Forming Unit)</u></b>			
<b>Contaminant</b>	<b>Florida Restrictions</b>	<b>New York Restrictions</b>	<b>MMCC Product Restrictions</b>
STEC E. coli	1 CFU per gram.	None present.	1 CFU per gram.
Salmonella	1 CFU per gram.	None present.	none present
Total Combined Yeast and Mold	100,000 CFU per gram for <i>Ingestion</i> or <i>Inhalation</i> .	<103 CFUs per gram.	100,000 CFU per gram
Other	Aspergillus niger, Aspergillus fumigatus, Aspergillus flavus, Aspergillus terreus, 1 CFU per gram.	Total plate count for aerobic bacteria, <104 CFUs per gram.	Total plate count for aerobic bacteria, <100,000 CFUs/gram.
<b><u>Mycotoxins (Limits in parts per billion, or ppb)</u></b>			
<b>Contaminant</b>	<b>Florida Restrictions</b>	<b>New York Restrictions</b>	<b>MMCC Product Restrictions†</b>
Total Aflatoxin (B1, B2, G1, G2),	20 ppb.	20 ppb.	20 ppb.
Ochratoxin	20 ppb.	20 ppb.	20 ppb.

**\*Note:** Hemp Products tested as a part of this study by an MMCC-Certified Independent Testing Laboratory were *only* tested using the MMCC’s existing panel of contaminants, highlighted throughout this Appendix. As shown, states that have developed a testing panel for Hemp products specifically have expanded their contaminants and impurities tested for given the nature of the production process.

**†Note:** While the MMCC’s existing product panel for Microbiological Impurities and Mycotoxins is consistent with other states testing protocols for hemp products, these tests were not conducted as part of this study.



## CANNABIS

# Regulation of Cannabinoid Hemp Products in Select Adult-Use Cannabis States


## Regulation of Cannabinoid Hemp Products

### I. Introduction:

The federal government legalized hemp as an agricultural commodity in the 2018 Farm Bill. Hemp is defined as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”<sup>1</sup> While the Farm Bill created a regulated pathway for the cultivation of hemp, it did not create a regulatory system for products derived from hemp. However, it explicitly preserved the authority of the Food and Drug Administration (FDA) over products derived from hemp.<sup>2</sup> Unfortunately, the FDA has not created regulations specific to these products or utilized its existing authority to regulate drugs, dietary supplements, and other categories of products to much effect.<sup>3</sup> This lack of regulation is a public health concern from a product and consumer safety standpoint. Some hemp derived products contain high levels of intoxicating cannabinoids and others have not been tested for dangerous contaminants including heavy metals and pesticides. As a result, states have begun to craft their own regulatory systems.

This resource focuses on hemp derived products intended for human consumption with a particular focus on those marketed for their cannabinoid profiles. The resource examines the regulatory approaches of five states: Colorado, Michigan, Minnesota, New York, and Oregon. Below, the resource provides summaries of each state’s regulatory system. These summaries explore nine key policy variables. First, they





identify which state agencies hold regulatory authority. Second, they summarize the licensing requirements for the sale of hemp derived products. Third, they review any age restrictions placed on the purchase of hemp derived products. Fourth, they examine potency restrictions placed on hemp derived products. These potency restrictions focus on tetrahydrocannabinol (THC). Fifth, the summaries identify the THC profile used in the state's measurements. Does the state only regulate delta-9 THC or does it include other THC isomers? Sixth, the summaries examine labeling requirements for these products. Do states require specific information pertaining to cannabinoids, the manufacturer, health warnings, ingredients, and/or allergens? Seventh, the summaries identify specific packaging requirements for hemp derived products. Do states have measures intended to decrease the appeal to children? Do states require tamper evident or child resistant packaging? Eighth, the summaries look to see if there are specific product restrictions that focus on safety and decreasing the product's appeal to children. Finally, they review the product testing standards used to evaluate cannabinoid profiles and contaminants.

## II. State Summaries

### Colorado


**Regulatory Agency:** The Colorado Department of Agriculture has been given authority over the regulation of hemp production.<sup>4</sup> The manufacturing, packaging, and distribution of Industrial Hemp Products is regulated by Colorado Department of Public Health and Environment.<sup>5</sup> Industrial Hemp Products distributed through the licensed marijuana industry are also subject to regulation by the Marijuana Enforcement Division.<sup>6</sup> In addition, Colorado created a task force to study intoxicating hemp products and make legislative and rule recommendations. The task force is composed of 20 representatives including, but not limited to, the representatives from state government, experts in marijuana and industrial hemp regulation, licensed marijuana industry, industrial hemp industry, testing laboratories, and a representative of a county or district public health agency. The task force is required to submit their analysis and recommendations concerning the regulation of industrial hemp to the general assembly by January 1, 2023.<sup>7</sup>

**Licensing:** Colorado does not require a license to manufacture or sell industrial hemp products. However, to manufacture industrial hemp products a party must register with the Colorado Department of Public Health and Environment.<sup>8</sup>

**Age Restrictions:** Colorado has not set an age restriction on industrial hemp products.

**Potency Restrictions:** Industrial hemp products are finished products containing industrial hemp that is for human use or consumption and is a cosmetic, dietary supplement, food, or food additive that contains a maximum delta-9 concentration of 0.3%.<sup>9</sup> While this is the statutory definition, the product testing standards look at maximum total THC concentration of 0.3%.<sup>10</sup> Total THC incorporates tetrahydrocannabinolic acid (THCA) and various THC isomers.<sup>11</sup>

**THC Profiles:** While product testing standards evaluate total THC, the Colorado Department of Public Health and Environment banned the chemical modification or conversion of naturally occurring cannabinoids. This includes processes that create THC isomers (see e.g., Delta-8 and Delta-10).<sup>12</sup>



**Labeling:** The Colorado Department of Public Health and Environment has created specific labeling requirements for industrial hemp products. Labels for these products must include:

1. The total THC content per serving and total THC content per individual finished product package;
2. The manufacturing address or a qualifying phrase which states the firm's relation to the product (e.g., “manufactured for” or “distributed by”);
3. A net weight statement;
4. A list of ingredients, in descending order of predominance by weight;
5. The identity of each isolated cannabinoid as an ingredient and the amount labeled in milligrams or when using a broad or full spectrum product, label the total amount in milligrams; and
6. Allergens identified and listed separately.

With regards to health claims, these products must be qualified and follow the Federal Trade Commission (FTC) and FDA regulations and guidance. Also, an industrial hemp product can not include any claims that it can, or is intended to, diagnose, cure, mitigate, treat, or prevent disease.<sup>13</sup>

**Packaging Requirements:** Product packaging must be food-grade or Generally Regarded as Safe (GRAS).<sup>14</sup>

**Product Restrictions:** Industrial Hemp products are not subject to specific product restrictions.


**Product Testing:** Industrial hemp products are subject to product testing requirements created by the Colorado Department of Public Health and Environment. These standards test for select microbial contaminants, mycotoxins, pesticides, heavy metals, and residual solvents. The standards also test for the product's total THC levels.<sup>15</sup> In addition to these standards, if a Retail Marijuana Store or Medical Marijuana Dispensary wishes to sell an industrial hemp product, the product must pass all required testing pursuant to the regulated marijuana testing program (4-100 Series Rules) at a Retail Marijuana Testing Facility.<sup>16</sup>

## **Michigan**

**Regulatory Agency:** In 2022, the governor of Michigan issued a reorganization order that vested authority to regulate hemp growers in the Michigan Department of Agriculture and Rural Development, while transferring all other regulation of hemp to the newly renamed Cannabis Regulatory Authority (CRA).<sup>17</sup>

**Licensing:** To sell finished cannabinoid hemp products, a party must have a hemp processor handler license or be licensed as part of the state's cannabis program.<sup>18</sup>

**Age Restrictions:** There is no age restriction placed on the purchase of hemp derived products.



**Potency Restrictions:** Michigan’s only restriction is that hemp products contain no more than 0.3% THC on a dry-weight or per volume basis. However, the state indicates that the Cannabis Regulatory Agency will set total THC limits for hemp products, but these levels have yet to be set.<sup>19</sup>

**THC Profiles:** Michigan includes all forms of THC when evaluating THC levels. The state defines THC as tetrahydrocannabinol acid, regardless of whether it is artificially or naturally derived. In addition, the definition captures structural, optical, and geometric isomers of THC.<sup>20</sup>

**Labeling:** Hemp products are not subject to specific labeling requirements. However, the CRA has been given authority to draft regulations for the cultivation, processing, distribution, and sale of hemp products.<sup>21</sup> Also, the CRA has developed extensive labeling and packing requirements for marijuana products that could serve as a basis for future regulations.<sup>22</sup>

**Packaging Requirements:** Hemp products are not subject to specific packaging requirements. However, the CRA has been given authority to draft regulations for the cultivation, processing, distribution, and sale of hemp products.<sup>23</sup>

**Product Restrictions:** Hemp products are not subject to specific product restrictions. However, the CRA has been given authority to draft regulations for the cultivation, processing, distribution, and sale of hemp products.<sup>24</sup>

**Product Testing:** Hemp products are not subject to product testing. However, Michigan requires preharvest testing to measure THC concentration.<sup>25</sup>

## **Minnesota**

**Regulatory Agency:** The Minnesota Board of Pharmacy has been granted regulatory authority.<sup>26</sup>

**Licensing:** Minnesota does not require licensing of hemp derived product manufacturers, distributors, or retailers.<sup>27</sup>


**Age Restriction:** Products containing “any cannabinoid or tetrahydrocannabinol extracted or otherwise derived from hemp” may not be sold to any person under the age of 21.<sup>28</sup>

**Potency Restrictions:** THC is the only intoxicating cannabinoid that is permitted to be sold.<sup>29</sup> All hemp derived products are limited to 0.03% of any THC by dry weight.<sup>30</sup> In addition, edible cannabinoid products are restricted to 5mg of any THC per serving and 50mg of any THC per package.<sup>31</sup>

**THC Profile:** When evaluating the THC potency of a hemp derived product, Minnesota includes all forms of THC.<sup>32</sup>

**Labeling:** Minnesota requires that hemp derived products be labeled with the following information:

1. The name, location, contact phone number, and website of the manufacturer;
2. The name and address of the laboratory used to test the product;

- 
3. An accurate statement of the amount or percentage of cannabinoids found in each unit of the product; and
  4. A statement that the product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the FDA

This information must be prominently and conspicuously displayed in terms that are easily read and understood. This information can be displayed on the product package or a scannable bar code or matrix barcode that links to the manufacturer’s website. In addition, Minnesota prohibits any claims that the product may be used to prevent, treat, or cure a disease or that it alters the structure or function of the human body, unless such claim has been approved by the FDA.<sup>33</sup> Edible cannabinoid products have additional labeling requirements. The labeling for these products must also include serving size, a cannabinoid profile for each serving, an ingredient list, allergen information, and a warning to keep the product away from children.<sup>34</sup>

**Packaging requirements:** Minnesota has packaging requirements for edible cannabinoid products. Packaging for these products must be opaque, child resistant, tamper evident, cannot resemble commercially available food products, and cannot be packaged in a way to reasonably mislead a consumer to believe that it contains anything but an edible cannabinoid product.

**Product Restrictions:** Minnesota has special product restrictions for edible cannabinoid products. The restrictions focus on minimizing the appeal of these products to children. These products cannot resemble or be the cartoon representation of real or fictional humans, animals, or fruit. Edible cannabinoid products cannot resemble a food brand primarily consumed by children and they cannot be created by adding cannabinoids to existing candy or snack food. In addition, these products need clearly demarcated servings.<sup>35</sup>


**Product Testing:** Hemp product manufacturers are required to submit representative samples to “an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the board.”<sup>36</sup> The testing must be consistent with industry standards for herbal and botanical substances. At a minimum, this requires the testing to check that the product:

1. Contains the amount or percentage of cannabinoids listed on the product label;
2. Does not contain more than trace amounts of any mold, residual solvents, pesticides, fertilizers, or heavy metals; and
3. Does not contain more than 0.3 percent of any THC.<sup>37</sup>

While the statute indicates that the Pharmacy Board will adopt standards for testing, it has not addressed the issue of permissible contaminant levels. The term “trace amounts” has not been defined in statute, regulation, or guidance document. While manufacturers are required to conduct testing prior to selling the product in Minnesota, they are not required to provide test results to the Minnesota Pharmacy Board prior to sale. However, they must provide the results when requested by the Board.<sup>38</sup>

## **New York**

**Regulatory Agency:** The New York Cannabis Control Board and the Office of Cannabis Management tasked with regulating cannabinoid hemp products.<sup>39</sup>



**Licensing:** New York has created a licensing system for cannabinoid hemp products that is separate for the state's licensed marijuana markets. Cultivators of hemp are licensed through the New York Department of Agriculture.<sup>40</sup> While cannabinoid hemp product processors and retailers are licensed through the Office of Cannabis Management.<sup>41</sup>

**Age Restriction:** Retailers may not sell inhalable cannabinoid hemp products or flower products to anyone under 21.<sup>42</sup>

**Potency Restrictions:** Products are limited to 0.3% of delta-9 THC.<sup>43</sup> In addition, New York limits the total amount of cannabinoids that may be in a product. Cannabinoids include any hemp-derived phytocannabinoid, including THC, tetrahydrocannabinolic acid (THCA), and CBD.<sup>44</sup> Edible products are limited to 25 mg of total cannabinoids. Products that qualify as dietary supplements under federal law are limited to 3,000 mg per package and 75 mg per serving.<sup>45</sup>


**THC Profile:** THC levels refer only to delta-9 THC. New York bans the addition of synthetic cannabinoids, or cannabinoids created through isomerization, including delta 8-THC and delta 10-THC.<sup>46</sup>

**Labeling:** New York has extensive labeling requirements for cannabinoid hemp products. All products must provide the following information:

1. A list of all ingredients;
2. The number of servings;
3. The milligrams per serving and the milligrams per package of: CBD, "Total THC" which includes detectable levels of total Delta 9-THC, Delta 8-THC, and Delta 10- THC, and any other marketed cannabinoid;
4. The expiration date if applicable;
5. The lot or batch number;
6. The name of the cannabinoid hemp processor or out of state manufacturer, packer, or distributor,
7. A scannable bar code or QR code linked to a certificate of analysis;
8. The hems country of origin; and
9. A means for reporting serious adverse events.<sup>47</sup>

In addition, products that are ingested, including sublingual and oral absorption, must have a nutritional or supplement fact panel based on the number of servings.<sup>48</sup> New York also requires a series of warnings for cannabinoid hemp products. All products must have warnings that advise: to keep the product out of the reach of children, that the product is made from hemp and may contain THC, that the product is not approved by the FDA, and pregnant and nursing individuals should consult their healthcare provider before using. Inhalable products must also have a warning that smoking or vaporizing presents health risks.<sup>49</sup> In addition, products must have clear serving and use instructions.<sup>50</sup> Finally, New York mandates that required information must be at least 4.5-point font, with some selected items bolded or in one font size larger.<sup>51</sup>

**Packaging:** New York has packaging requirements that focus on addressing youth exposure to cannabinoid hemp products. First, packaging is prohibited from imitating a candy label and from using cartoons or other images that are attractive to children. However, New York adds a layer of complexity to this prohibition by prohibiting imagery that is attractive to individuals under 21 for inhaled products and imagery that is attractive



to individuals under 18 for all other products.<sup>52</sup> Next, all cannabinoid hemp products must have tamper-evident packaging that minimizes exposure to oxygen and light.<sup>53</sup>

**Product Restrictions:** New York has implemented several product safety restrictions. Cannabinoid hemp products cannot contain liquor, wine, beer, cider, or meet the definition of alcoholic beverage under New York' Alcohol Beverage Control Law. They cannot contain tobacco or nicotine. They cannot be an injectable, inhaler, cigarette, cigar, or pre-roll. In addition, the products must be shelf stable and prepackaged. They cannot be added to consumable products at the point of sale.<sup>54</sup> In addition, cannabinoid hemp products with multiple servings must have a clear method of denoting a serving size (see e.g., individually wrapped or premeasured).<sup>55</sup> Inhalable cannabinoid hemp products are subject to special requirements pertaining to prohibited ingredients and safety measures for electronic vaporization devices.<sup>56</sup> Finally, cannabinoid hemp products cannot be made into cosmetics.<sup>57</sup>

**Product Testing:** Cannabinoid hemp processors must contract with an independent commercial laboratory to test their hemp extract and products.<sup>58</sup> To qualify as a testing laboratory for cannabinoid hemp products, the laboratory must be certified under the medical cannabis program or meet a series of metrics set by regulation.<sup>59</sup> In addition, New York set product limits on a broad spectrum of pesticides, residual solvents, heavy metals, biologicals, and mycotoxins.<sup>60</sup>

## **Oregon**


**Regulatory Agency:** The Oregon Department of Agriculture, the Oregon Health Authority, and the Oregon Liquor and Cannabis Commission (OLCC) share regulatory authority over hemp derived products.

**Licensing:** The Oregon Department of Agriculture licenses hemp growers and hemp handlers.<sup>61</sup> Hemp handlers are the licensed parties that are permitted to process hemp into various products.<sup>62</sup> However, no specific license is required to sell cannabinoid hemp products.<sup>63</sup> However, hemp and cannabinoid hemp products can be sold by OLCC licensed marijuana retailers. However, licensed hemp growers and hemp handlers must be certified by the OLCC before they can sell their products to OLCC licensed business.<sup>64</sup> In addition, a marijuana processor can obtain an endorsement that allows them to also function as hemp handlers.<sup>65</sup>

**Age Restriction:** Adult-use cannabis items cannot be sold to anyone under the age of twenty-one, unless it is part of the licensed medical cannabis market. Consumable hemp products are adult-use cannabis items if they contain more than a total of 0.5 mg of delta-9 THC, any other THC isomer, THCA, or any cannabinoid advertised as having an intoxicating effect.<sup>66</sup>

**Potency Restrictions:** All cannabinoid hemp products are subject to a 0.3% total delta-9 THC limit. However, edible products and transdermal products are limited to 2 mg total delta-9 THC per serving and 20 mg per container. Hemp tinctures are subject to a 100 mg of total delta-9 THC limit per container.<sup>67</sup>

**THC Profile:** Oregon evaluates product potency based on total delta-9 THC.<sup>68</sup> This number is calculated by adding the mass of delta-9 THC to 0.877 times the mass of delta-9 tetrahydrocannabinolic acid (THCA).<sup>69</sup> Cannabinoid hemp products may not contain any artificially derived cannabinoids.<sup>70</sup> These cannabinoids are created by a chemical reaction that changes the molecular structure of any substance from the



cannabis plant. It does not include naturally occurring chemicals that have been separated from the plant or cannabinoids that are produced by decarboxylation of a naturally occurring cannabinoid acid without the use of a chemical catalyst.<sup>71</sup> This restriction would prohibit the conversion of CBD into a THC isomer.

**Labeling:** Labeling requirements for hemp derived products are based on the category of product and use the existing labeling protocol established by OLCC for the licensed cannabis market. However, there are a few modifications to this standard. First, hemp products must use the hemp symbol rather than the universal symbol used for marijuana products. Second, hemp products do not need to provide the same product warnings as marijuana products. Instead, hemp products must use the following warning: “This product is derived from hemp and could contain THC. Keep out of the reach of children.” Third, hemp products that are not intended for oral consumption must have an additional warning on the label that states “DO NOT EAT” in bold capital letters.<sup>72</sup>

**Packaging:** Consumable hemp products are subject to the same packaging requirements as marijuana products in the licensed cannabis market.<sup>73</sup> As a result, they must be packaged in a container that is resealable and child resistant. In addition, the packaging may not be attractive to children or contain any untruthful or misleading content.<sup>74</sup> Packaging is deemed attractive to minors if it includes (1) cartoons, (2) a design, brand, or name that resembles a non-cannabis consumer product of the type that is typically marketed to minors, (3) symbols or celebrities that are commonly used to market products to minors, (4) images of minors, or (5) words that refer to products that are commonly associated with minors or marketed by minors.<sup>75</sup>

**Product Restrictions:** If a cannabinoid hemp product is created by an OLCC licensed marijuana processor it is subject to specific product restrictions. First, it cannot by its shape, design, or flavor appeal to minors. Second, it cannot resemble non-cannabis/hemp products primarily marketed and consumed by children. Third, products cannot be in the shape of animals, vehicles, people, or character. Fourth, products cannot be created by applying cannabinoid concentrate or extract to commercially available snacks and candy. Fifth, products cannot contain Dimethyl Sulfoxide.<sup>76</sup> Hemp handlers with a certificate to sell their products to OLCC licensed business are required to comply with the same standards.<sup>77</sup> However, the same product restrictions do not appear for hemp handlers selling their products outside the OLCC licensed system.

**Product Testing:**

Oregon’s product testing standards for hemp derived products are based on the category of product and use the existing testing protocol established by the state health department for the licensed cannabis market. These testing protocols are required prior to the sale of the product to the consumer. Currently, every process lot of hemp concentrates or extracts intended for human consumption are tested for solvents, pesticides, select cannabinoids, and mycotoxins.<sup>78</sup> Starting in March of 2023, these products will also be tested for heavy metals and microbiological contaminants.<sup>79</sup> However, certain hemp concentrates made only using food grade animal fat or food grade plant-based oil are subject to less stringent testing protocol.<sup>80</sup> Hemp cannabinoid products, which include edible and topical products, are subject the same select cannabinoid testing and microbiological contaminants as cannabinoid products in the licensed cannabis market.<sup>81</sup> Industrial hemp derived vapor products are currently tested for solvents, pesticides, select cannabinoids, and mycotoxins.<sup>82</sup> Starting in March of 2023, these products will also be tested for heavy metals and microbiological contaminants.<sup>83</sup>

This document was developed by Mathew R. Swinburne, J.D., Associate Director for the Network for Public Health Law-Eastern Region. The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.

Updated: December 14, 2022

<sup>1</sup> 7 U.S.C. § 1639o.

<sup>2</sup> 7 U.S.C. § 1639r.

<sup>3</sup> The FDA has issued warning letters to a small sample of companies that have marketed hemp derived products with illegal health claims and inaccurate listing of cannabinoids. See Food and Drug Administration, Warning Letters and Test Results for Cannabidiol-Related Products, available at <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>.

<sup>4</sup> COLO. REV. STAT. § 35-61-113.

<sup>5</sup> 6 COLO. CODE REGS. § 1010-21:7.

<sup>6</sup> See e.g., 1 COLO. CODE REGS. § 212-3:6-105 (setting additional product testing standards for industrial hemp products sold at marijuana retailers).

<sup>7</sup> COLO. REV. STAT. § 44-10-201

<sup>8</sup> See COLO. REV. STAT. § 25-5-426 (requiring registration); See also Colorado Department of Public Health and Environment, Manufactured Food, Industrial Hemp, or Storage Facility Registration, available at <https://drive.google.com/file/d/1gayiLhfxLI7K2HQX15bRcZYYGlgFC8bD/view>.

<sup>9</sup> COLO. REV. STAT. § 25-5-426, see also 1 COLO. CODE REGS. § 212-3:1-115.

<sup>10</sup> 6 COLO. CODE REGS. § 1010-21:7.

<sup>11</sup> See 6 COLO. CODE REGS. § 1010-21:4 (defining total THC as 0.87(THCA)+THC); See also 1 COLO. CODE REGS. § 212-3:1-115 (defining total THC to include various THC isomers and THCA).

<sup>12</sup> Colorado Department of Public Health and Environment, *Re: Production and/or Use of Chemically Modified or Converted Industrial Hemp Cannabinoids*, (May 14, 2021) available at <https://hempindustrydaily.com/wp-content/uploads/2021/05/CDPHE.pdf>.

<sup>13</sup> 6 COLO. CODE REGS. § 1010-21:7.

<sup>14</sup> *Id.*

<sup>15</sup> See 6 COLO. CODE REGS. § 1010-21:7 (providing testing standards for industrial hemp products).

<sup>16</sup> See 1 COLO. CODE REGS. § 212-3:6-105 (retail cannabis), see also 1 COLO. CODE REGS. § 212-3:5-105 (medical cannabis).

<sup>17</sup> MICH. COMP. LAW § 333.27002.

<sup>18</sup> MICH. COMP. LAW § 286.847; See also Michigan Cannabis Regulatory Agency, Processing Hemp FAQs, available at <https://www.michigan.gov/cra/sections/hemp-processing/hemp-processing-faqs>.



<sup>19</sup> MICH. COMP. LAW § 333.27953.

<sup>20</sup> *Id.*

<sup>21</sup> MICH. COMP. LAW § 333.27958.

<sup>22</sup> **See** MICH. ADMIN. CODE R 420.504 (providing labeling and packing restrictions for marijuana products).

<sup>23</sup> MICH. COMP. LAW § 333.27958.

<sup>24</sup> *Id.*

<sup>25</sup> MICH. COMP. LAW § 286.854.

<sup>26</sup> MINN. STAT. § 151.72

<sup>27</sup> MINN. STAT. § 151.72 subdiv. 3, *See also* Minnesota Board of Pharmacy, Hemp Derived Products Frequently Asked Questions June 30, 2022, *available at* [https://mn.gov/boards/assets/Hemp%20Derived%20Products%20FAQ\\_tcm21-532612.pdf](https://mn.gov/boards/assets/Hemp%20Derived%20Products%20FAQ_tcm21-532612.pdf).

<sup>28</sup> MINN. STAT. § 151.72 subdiv. 3(c).

<sup>29</sup> MINN. STAT. § 151.72 subdiv. 3(a), *see also* Minnesota Board of Pharmacy, Hemp-Derived Cannabinoid Products Guidance August 24, 2022, *available at* [https://mn.gov/boards/assets/Hemp%20Derived%20Products%20Guidance\\_Final\\_tcm21-538705.pdf](https://mn.gov/boards/assets/Hemp%20Derived%20Products%20Guidance_Final_tcm21-538705.pdf).

<sup>30</sup> *Id.*

<sup>31</sup> MINN. STAT. § 151.72 subdiv. 5.

<sup>32</sup> MINN. STAT. § 151.72, *see also* Minnesota Board of Pharmacy, Hemp Derived Products Frequently Asked Questions June 30, 2022, *available at* [https://mn.gov/boards/assets/Hemp%20Derived%20Products%20FAQ\\_tcm21-532612.pdf](https://mn.gov/boards/assets/Hemp%20Derived%20Products%20FAQ_tcm21-532612.pdf).

<sup>33</sup> MINN. STAT. § 151.72 subdiv. 3(c).

<sup>34</sup> MINN. STAT. § 151.72 subdiv. 5.

<sup>35</sup> MINN. STAT. § 151.72 subdiv. 5(e).

<sup>36</sup> MINN. STAT. § 151.72 subdiv. 5(c).

<sup>37</sup> MINN. STAT. § 151.72 subdiv. 4(a).

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> N.Y. CANNABIS LAW § 10 (Power and authority of Cannabis Control Board); N.Y. CANNABIS LAW § 11 (Power and authority of Office of Cannabis Management).

<sup>41</sup> N.Y. AGRIC. AND MKTS. LAW § 509.

<sup>42</sup> N.Y. CANNABIS LAW § 92(Processor), N.Y. CANNABIS LAW § 93 (Retailer).

<sup>43</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.16.

<sup>44</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.8 (a)(2) *available at* [https://cannabis.ny.gov/system/files/documents/2021/11/part\\_114\\_cannabinoid\\_hemp\\_regulation\\_11-10-21.pdf](https://cannabis.ny.gov/system/files/documents/2021/11/part_114_cannabinoid_hemp_regulation_11-10-21.pdf)

<sup>45</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.1(c).

<sup>46</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.8(10)(b).

<sup>47</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.8(a)(11).

<sup>48</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.9(a).

<sup>49</sup> *Id.*

<sup>50</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.9(f).

<sup>51</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.9(d).

<sup>52</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.9(g).

<sup>53</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.9(b).

<sup>53</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.9(c).

<sup>54</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.8.

<sup>55</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.8.(c)

<sup>56</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.8.(d)

<sup>57</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.1(d).

<sup>58</sup> N.Y. CANNABIS LAW § 105.

<sup>59</sup> N.Y. COMP. R. & REGS. TIT. 9, § 114.10(b)

<sup>60</sup> N.Y. COMP. R. & REGS. TIT. 9, § §114.10(f-j)

<sup>61</sup> See OR. ADMIN. R. 603-048-0125 (hemp growers), see also OR. ADMIN. R. 603-048-0150 (hemp handlers).

<sup>62</sup> OR. ADMIN. R. 603-048-0150.

<sup>63</sup> OR. ADMIN. R. 845-025-3320, see also Oregon Liquor and Cannabis Commission, Marijuana and Hemp, available at <https://www.oregon.gov/olcc/marijuana/Pages/Selling-Hemp.aspx#:~:text=In%20Oregon%2C%20no%20specific%20license,to%20sell%20cannabinoid%20hemp%20products.>

<sup>64</sup> See OR. ADMIN. R. 845-025-2705 (covering the certification of hemp handlers); see also OAR 845-025-27009 (covering the certification of hemp growers).

<sup>65</sup> OR. ADMIN. R. 603-048-0150.

<sup>66</sup> OR. ADMIN. R. 845-026-0300.

<sup>67</sup> OR. ADMIN. R. 845-026-0400 Table 3.

<sup>68</sup> *Id.*

<sup>69</sup> OR. ADMIN. R. 333-064-0100(4).

<sup>70</sup> OR. ADMIN. R. 845-026-0400.

<sup>71</sup> OR. ADMIN. R. 333-064-0100(3).

<sup>72</sup> OR. ADMIN. R. 845-025-7140.

<sup>73</sup> OR. ADMIN. R. 845-025-7020.

<sup>74</sup> *Id.*

<sup>75</sup> OR. ADMIN. R. 845-025-1015.

<sup>76</sup> See OR. ADMIN. R. 845-025-3220 (providing product restrictions).

<sup>77</sup> OR. ADMIN. R. 845-025-2755.

<sup>78</sup> See OR. ADMIN. R. 603-048-2330 (referencing existing testing protocol); see also OR. ADMIN. R. 333-007-0330 (providing testing protocol).

<sup>79</sup> OR. ADMIN. R. 333-007-0330.

<sup>80</sup> OR. ADMIN. R. 603-048-2330.

<sup>81</sup> OR. ADMIN. R. 603-048-2340.

<sup>82</sup> OR. ADMIN. R. 333-007-0342.

<sup>83</sup> *Id.*



MARYLAND  
**HEALTHY**  
ALTERNATIVES ASSOCIATION

Maryland Medical Cannabis Commission  
849 International Drive Suite 450,  
Linthicum, MD 21090

Dear Andrew Garrison and MMCC Staff,

As members of the Maryland Healthy Alternatives Association and hemp industry stakeholders, we feel that the survey titled "Chapters 511/512 Feedback Form" does not provide adequate opportunities for us to express our input in a supportive and thorough manner. It is important that our input regarding the hemp-derived products under review is taken into consideration to further our mission of protecting the public's access to safe natural alternatives to pharmaceuticals in Maryland. We hope that this letter will assist us in conveying our perspective on the matter rather than the survey that asks for preselected responses. To best qualify our industry's thoughts on this important issue, we must be able to explain our position in more detail. Thank you for taking the time to consider our thoughts on this issue.

As members of the hemp industry, we firmly believe that our invaluable expertise on the current review of hemp-derived products is essential for a complete study. We were at the forefront of creating and marketing these products, and we have a deep understanding of their benefits for supporting individual wellness and well-being. It is our responsibility to advocate for these products and ensure they are evaluated fairly and accurately. We urge the review committee to take our perspective seriously and understand the vital role that these products play in our industry and in the lives of consumers. It is important that they are not unjustly restricted or banned based on inaccurate information or outdated stigma. Our industry deserves a fair chance to thrive and offer these valuable, natural alternatives to the market. We stand behind our products, their safety, and their effectiveness as beneficial wellness aids.

During the last legislative session we were very happy that Senator Feldman and Delegate Pena-Melnyk took an interest in this issue and we were very excited to work with them through this study group to help make recommendations towards a plan for regulation of these products. We as the hemp industry want regulation that protects consumer safety and we are grateful to them for addressing this issue and working with us. However as we represent the industry being discussed, we were very disappointed that we had no role in the development of the agenda nor the development of the survey.

Any study that takes place must include a balanced sample which is crucial for obtaining reliable results. We are concerned this study's solicited parties are heavily weighted towards the medical and adult-use cannabis industry, with only 27% having direct involvement in the hemp industry. This disparity raises important questions about potential bias in the outcomes of this research. Additionally, federal laws currently treat hemp and cannabis as separate industries with different economic interests. This further complicates the already skewed sample, as each group may have different motivations and interpretations of the results. To truly understand the topic at hand and obtain unbiased conclusions, it is imperative to solicit a more evenly distributed range of participants from both industries.

The hemp industry has long fought for recognition and legitimacy. The recent survey, which requests suggestions for THC limits without acknowledging the possibility of not limiting THC at all is concerning to many hemp industry stakeholders and consumers. By only offering predetermined options up to 25 mg in the drop down menus, the survey suggests that anything above that level is too high - though there is plenty of evidence to suggest otherwise. Consumers should have the freedom to choose products with higher THC levels if they so desire, as long as they are properly informed and able to use them responsibly. Any regulation should prioritize safety while also allowing for a diverse and thriving market.

When it comes to setting limits on cannabis consumption, it's important to remember that every individual is unique. Variables such as tolerance levels, body type, and medical conditions can all play a role in how a person might react to cannabis. It's also important to consider the interactions between cannabis and the endocannabinoid system, which plays a vital role in various bodily functions. Aside from these personal factors, there are also considerations to be made about the specific cannabinoids present in the product being consumed and the method of consumption (i.e. flower, edibles, vaporizer). Ultimately, taking all of these variables into account is crucial for establishing safe consumption guidelines for cannabis users. Unfortunately, this level of consideration was not given when creating the survey on consumption limits - equal input from the hemp industry should have been sought out beforehand to contribute to the creation of this survey.

The survey also requests the respondent to choose from a list of compounds (developed in part from Dr. Chad Johnson from the University of Maryland School of Pharmacy) which should be considered when determining the tetrahydrocannabinol (THC) content of a product. We, the hemp industry, believe that congressional intent was clear on this point through the actions made in the 2018 Farm Bill and the amendments made to the Controlled Substance Act by the Agricultural Improvement Act of 2018. To clarify, the 2018 Farm Bill defined hemp as:

The plant "Cannabis sativa L. and any part of the plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis" [7 U.S.C.1639o(1)]

Also, the Agricultural Improvement Act of 2018 amended the Control Substance Act (CSA) in two ways:

1. CSA definition of “marihuana” to exclude hemp
2. All tetrahydrocannabinols in hemp are removed from the CSA’s definition of “tetrahydrocannabinols”

- “Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946”

The recent ruling by the U.S. Court of Appeals for the Ninth Circuit serves as a reminder that Congress carefully considered its definition of hemp, including only delta-9 THC in its THC content measurement for hemp and hemp products. This intent was further solidified through actions taken by Congress, such as allowing for overall delta-9-THC levels to not exceed 0.3% on a dry weight basis and mandating that hemp be grown in accordance with a state or tribal plan approved by the U.S. Secretary of Agriculture. This decision was not made arbitrarily, but rather based on extensive research and consultation with experts in the field. The ruling also reflects a respect for the authority and judgment of Congress in making decisions related to hemp and its regulation. As the court states, this is a decision made by Congress and should not be overruled by any other agency or study group. In order to stay within legal limits, it is crucial to adhere to this congressional definition of hemp and include only delta-9 THC when measuring THC content. Any other decision to redefine hemp is an attempt to circumnavigate a federal law.

The survey's questions regarding the regulation of hemp-derived products and "other isomers or derivatives of THC" overlook another important issue in current cannabis science: the inability to accurately determine whether certain cannabinoids are naturally occurring or not. While it may be easy to distinguish between THC and CBD, as they are the most well-known and widely studied cannabinoids, there are hundreds more that have yet to be fully understood. The limitations of current technology and testing standards make it impossible to determine with certainty whether these cannabinoids occur naturally in the hemp plant or not. This lack of scientific understanding renders the survey's predetermined responses insufficient for data needed to provide a clear answer. It is important for any regulatory decisions to be based on solid scientific evidence, rather than subjective opinions. With all the above considered we, the Maryland Healthy Alternatives Association, on behalf of the hemp industry and consumers of hemp products cannot provide our answers in a manner that does our perspective justice. The Maryland hemp industry and hemp industry stakeholders agree that meaningful legislation and appropriate regulations are needed to ensure consumer safety. A plan has been drafted by vested parties in the Maryland hemp industry with goals such as:

Establish a Hemp Advisory Council to provide advice and expertise to the Maryland Department of Agriculture (MDA) with respect to plans, policies, and procedures applicable to the administration of the state hemp program. Allowing for the MDA to retain regulatory control over these agricultural products, as intended by Congress.

Define or redefine specific terms that allow for a clarified understanding of hemp extracts, hemp extract products, and hemp-derived cannabinoids.

Set age restrictions for hemp extracts, hemp extract products and retail establishments.

Establish guidelines, standards and regulation for hemp extract and hemp extract products in regards to:

- Licensing
- Distribution
- Labeling/packaging
- Production/processing
- Purity/potency testing
- Inspections
- Reporting
- Enforcement/violations
- Align with neighboring states to encourage interstate commerce while bolstering the regional economy and the developing hemp industry

It's important to have sensible regulations in place for any industry, and the hemp industry is no exception. However, calls for a complete ban on hemp products or for the regulation of hemp in the same way as Schedule One drugs are misguided and could ultimately harm both consumers and small businesses. While it's necessary to address any public safety concerns, many of the claims about such a crisis remain unsubstantiated. In addition, it would be inappropriate for a regulatory body with conflicting economic interests to lead the conversation on how to best regulate hemp products. Instead, perspectives from experts in the field as well as stakeholders from the hemp industry must be considered in order to create fair and effective regulations that protect consumers without stifling innovation and small business growth.

The Maryland Healthy Alternatives Association and industry stakeholders are eager to work with the Maryland Department of Agriculture and the Maryland Legislature to improve current hemp

regulations. This collaboration will encourage a thriving hemp industry in Maryland, bringing economic opportunities and access to new products for consumers. We look forward to discussing ways to streamline the regulatory process and increase support for farmers, producers, and retailers. These efforts will bring positive change to the state's hemp industry and help it reach its full potential.

Thank you for considering our perspective on this important issue. We are available for further conversation on this topic as needed.

Sincerely,

The Maryland Healthy Alternatives Association

Daniel Simmonds

Nicholas Patrick

## Appendix G: Stakeholder Feedback



November 2, 2022

Maryland Medical Cannabis Commission  
849 International Drive Suite 450,  
Linthicum, MD 21090

Dear Andrew Garrison and MMCC Staff,

We the Maryland Hemp Coalition and hemp industry stakeholders are writing this letter to clearly provide our input with regard to the survey titled “Chapters 511/512 Feedback Form”. The limited multiple choice options do not provide us options that accurately reflect the hemp industry’s perspective. Additionally, some concerns with respect to the process employed by this study group are listed below.

The Maryland Hemp Coalition exists “to cultivate a robust and thriving hemp industry in Maryland”. We firmly believe our input on this topic, in regards to the hemp-derived products currently under review in this study, is of utmost importance. The products under review were created by the hemp industry in response to the health and wellness market demand of our communities.

Our first concern is the lack of involvement or correspondence with myself, Levi Sellers, as the designated representative for Maryland’s hemp industry. In a letter dated January 13, 2022 from Will Tilburg addressed to the Maryland legislature, his plea for this study group included a concern of a “potential public health crisis”. It is vital to a study of this magnitude to consult and include the hemp industry itself for input on how to handle such an important matter. Therefore, it has become even more apparent that the subsequent survey received without the hemp industry’s input, is partial to a particularly desired outcome by those involved in crafting said survey.

Secondly, only about 27% of the parties chosen to participate in this study group have a direct involvement with the hemp industry. The remaining parties have a direct involvement with the medical/adult-use cannabis industry. With this point alone any outcome from this study will be skewed in favor of the medical/adult-use cannabis industry.

Thirdly, it appears that even as a participant in the study, the hemp industry is not treated as a participant but more like an invited witness. An agenda was previously created for the “first meeting” without hemp industry input. And, as previously stated, the development of the “Chapter 511/512 Feedback Form” survey questionnaire which was sent to members of the study group, was also compiled without the hemp industry input.

After review of the aforementioned “feedback form” or survey, it is apparent that there is an intentional outcome that is not in the best interest of the hemp industry, hemp industry stakeholders, or the consumers that rely on the access of these products in a free and legal market. For example, the survey includes a spreadsheet attachment that requests suggestions for predetermined THC limits that the respondent thinks “would create the best regulatory framework”. There is no flexibility built into this question with respect to



scientific methods or consideration of bio-chemical ratios between CBD and THC, which can greatly reduce any risk of psychotropic responses in humans.

Furthermore, the survey is flawed. For example, this same question offers a limited range of THC from which to choose, between 0.0mg and 30.0 mg, but, the options available upon responding only go up to 25 mg. These are just a few instances where limitations have been set on the respondent and a pre-determined outcome is suggested.

Establishing limits like these on any products containing cannabinoids should be based on science. Given the past prohibition of hemp and cannabis in general, we lack the important research needed to make these science-based determinations. Making these determinations at this point would be pure speculation.

Due to the unique differences in individuals (tolerance, body type, and medical conditions, etc.) or bio-individuality, this topic is biologically nuanced. Additionally it should be noted that the ratios of cannabinoids to THC that are typical to hemp products are unique and need addressing as such. These facts should have been incorporated into the survey.

The survey also requests the respondent to choose from a list of compounds (developed in part from Dr. Chad Johnson from the University of Maryland School of Pharmacy) which should be considered when determining the tetrahydrocannabinol (THC) content of a product. However, the congressional intent was clear on this point through the actions made in the 2018 Farm Bill and the amendments made to the Controlled Substance Act by the Agricultural Improvement Act of 2018. To clarify, the 2018 Farm Bill defined hemp as:

The plant “Cannabis sativa L. and any part of the plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a **delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis**” [7 U.S.C. 1639o(1)]

Also, the Agricultural Improvement Act of 2018 amended the Controlled Substance Act (CSA) in two ways:

1. CSA definition of “marihuana” to exclude hemp
2. All tetrahydrocannabinols in hemp are removed from the CSA’s definition of “tetrahydrocannabinols”
  - “Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946”

These actions by the US Congress clearly show their intent was only to include delta-9 THC when considering the THC content for hemp and hemp products. As a panel of the U.S. Court of Appeals for the Ninth Circuit states, in the 3-0 ruling, “this Court will not substitute its own policy judgment for that of Congress”, we believe this study groups outcome should reflect the same.

Several other questions throughout the survey request input on the level of regulation of hemp-derived products, when compared to similar cannabis-based products. While also requesting input specifically on “products containing other isomers or derivatives of THC that are not naturally occurring in the hemp plant”. It is well known in both the hemp industry as well as the medical/adult-use cannabis industry that not all cannabinoids, in the plant Cannabis sativa L., can be isolated or tested for using current technology and testing standards, to determine if said cannabinoids are naturally occurring or not. Another point

highlighting that these predetermined responses were not developed with a scientific approach.

Due to the discriminating nature of the pre-selected survey questions and response, the hemp industry is unable to provide clear input and feedback through the “Chapter 511/512 Feedback Form”. The Maryland hemp industry and hemp industry stakeholders agree that meaningful legislation and appropriate regulations are needed to ensure consumer safety. A plan has been drafted by vested parties in the Maryland hemp industry with goals such as:

- o Establish a Hemp Advisory Council to provide advice and expertise to the Maryland Department of Agriculture (MDA) with respect to plans, policies, and procedures applicable to the administration of the state hemp program. Allowing for the MDA to remain regulatory control over these agricultural products, as intended by Congress.
- o Define or redefine specific terms that allow for a clarified understanding of hemp extracts, hemp extract products, and hemp-derived cannabinoids.
- o Set age restrictions for hemp extracts, hemp extract products and retail establishments
- o Establish guidelines, standards and regulation for hemp extract and hemp extract products in regards to:
  - Licensing
  - Distribution
  - Labeling/packaging
  - Production/processing
  - Purity/potency testing
  - Inspections
  - Reporting
  - Enforcement/violations
- o Align with neighboring states to encourage interstate commerce while bolstering the regional economy and the developing hemp industry

Most claims regarding a public safety crisis have gone unsubstantiated and can be addressed with basic regulations (as highlighted above), yet it seems that adult-use and medical cannabis operators are calling for a complete and total ban on sales of hemp-derived products, or for hemp to be regulated in a similar manner as a Schedule One narcotic. It is appropriate to regulate cannabinoids but unnecessary to go from seemingly “unregulated” to “Schedule One narcotic”. As it is inappropriate for a regulatory body with conflicting economic interests to be leading a study for regulating a currently competitive industry’s products.

The Maryland Hemp Coalition and industry stakeholders look forward to working with the Maryland Department of Agriculture and the Maryland Legislature to improve the current Maryland Hemp regulations that allows for a robust and thriving hemp industry, appropriately regulated, in Maryland.

Thank you all again for your time and please feel free to contact us for future conversations on this topic.

Sincerely,

A handwritten signature in black ink, appearing to read "MWS" with a stylized flourish.

Maryland Hemp Coalition

Matthew "Levi" Sellers

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MARYLAND HEMP COALITION



November 16, 2022

Maryland Medical Cannabis Commission  
849 International Drive Suite 450,  
Linthicum, MD 21090

Dear Mr. Tilburg,

On behalf of the Maryland Healthy Alternatives Association, the Maryland Hemp Coalition, and our constituencies, thank you for the opportunity to offer further input and specific policy recommendations for the Maryland Medical Cannabis Commission. We believe that recommendations from the hemp industry will help resolve current and future concerns regarding hemp extracts, hemp extract products, and hemp-derived cannabinoids and will aid in crafting meaningful legislation and appropriate regulations that work towards the safety of the consumers and the development of the hemp industry.

Attached, you will find our recommendations for language to establish a Hemp Advisory Council (Attachment A). Due to the short turn around allotted to us and given the volume of information we need to provide, we will be following up shortly with proposed standards for hemp extract and hemp products in the areas of licensing, distribution, packaging/labeling, and testing and amended definitions for COMAR 15.01.17.02.

Thank you again for the opportunity to submit these recommendations, and we look forward to seeing how they are incorporated into the Maryland Medical Cannabis Commission's final report.

Sincerely,

Three handwritten signatures in black ink are displayed. The first signature is for Matthew "Levi" Sellers, the second is for Daniel Simmonds, and the third is for Nicholas Patrick.

Matthew "Levi" Sellers, Daniel Simmonds, & Nicholas Patrick

Maryland Hemp Coalition & Maryland Healthy Alternatives Association

**ATTACHMENT A: ESTABLISHMENT OF A HEMP ADVISORY COUNCIL**

The Department of Agriculture has the authority to regulate all hemp products and hemp extracts as an agricultural commodity for the purpose of consumer protection and public safety.

To assist with this responsibility a Hemp Advisory Council should be formed to provide advice and expertise to the Department of Agriculture with respect to plans, policies, and procedures applicable to the administration of the state hemp program. Below is suggested as a representation for establishing this council, modeled after the example provided by the Florida Department of Agriculture.

§14–308

(a) Established. –

1. There is a Hemp Advisory Council.
2. The purpose of the Council is to advise the Department with respect to plans, policies, and procedures applicable to the administration of the Program.

(b) Membership. –

(c) The Council shall consist of 15 members, including:

- i. Two representatives of the Governor;
- ii. Two representatives of the Maryland State Senate;
- iii. Two representatives of the Maryland House of Delegates;
- iv. Two representatives of the Secretary of Agriculture;
- v. The President of the Maryland Farm Bureau or their designee;
- vi. The Secretary of the Department of State Police or their designee;
- vii. A representative from the Maryland Hemp Coalition; and
- viii. A representative from the Maryland Healthy Alternatives Association.

## Appendix G: Stakeholder Feedback



MARYLAND  
**HEALTHY**  
ALTERNATIVES ASSOCIATION



December 27, 2022

Maryland Medical Cannabis Commission  
849 International Drive Suite 450,  
Linthicum, MD 21090

Dear Mr. Garrison and MMCC Staff,

On behalf of the Maryland Hemp Industry and our constituencies, thank you for the opportunity to offer input and recommendations on the draft report of the Maryland Medical Cannabis Commission (MMCC) on non-delta-9-THC products in accordance with Chapters 511/512. We believe that recommendations from the Hemp Industry will assist the Maryland Legislature in crafting meaningful legislation and appropriate regulations. We were pleased to see a number of the recommendations included in your draft align with what the Hemp Industry has been advocating for, as we also request meaningful legislation and appropriate regulations to ensure consumer safety with regard to these hemp-derived cannabinoids and products. However, we would like to express concerns about significant unintended consequences from well-intended regulations that could negatively impact the Maryland Hemp Industry, including many small and minority-owned businesses. Additionally, we are disappointed with the very limited time we were given to review and respond to the draft report. We hope that the MMCC will incorporate the hemp industry's input into the final report that will be submitted to the legislature.

As hemp cultivators, retailers, and advocates, we here at the Maryland Hemp Coalition and the Maryland Healthy Alternatives Association feel that the US Hemp Roundtable is no longer working towards the interests of everyday hemp farmers, but rather to advance the economic interests of large, multi-state cannabis corporations and their Boards of Directors. This is unfortunate because it means that their recommendations are less reliable for the original intended audience: small-scale hemp farmers and small hemp businesses across America. This is indicative of a long standing issue within the industry, with hemp and cannabis groups as a whole across all states struggling with conflicts of interest due to their dependency on funds from larger partners. Furthermore, this conflict of interest has created a schism within the industry, making it so state-run organizations can no longer agree with many of the Roundtable's suggestions, further solidifying our belief that they have been irreparably compromised. We completely reject any suggestions from the US Hemp Roundtable as they have strayed from their original mission in favor of pandering to large, multi-state cannabis operations.

As stated above, the Maryland Hemp Industry agrees with many of the draft reports recommendations. These include: requirements for third-party laboratory testing for the presence of certain contaminants; proper labeling and packaging; age-gating of certain hemp-derived products; and expanding the Public Health Advisory Council messaging around health and safety of cannabis products that should be expanded to include and consider any products containing THC or isomers of THC, regardless of the initial plant

source. Additionally, we agree that products sold to end users should be regulated more stringently than those used for industrial purposes, as this has been the model for products in other industries as well. All of these are good examples of meaningful legislation and appropriate regulations that align with the Hemp Industries recommendations.

Unfortunately, we do have concerns in regard to determining requirements based on terms like “synthetic processes” and “Total THC”. A common misconception of hemp-derived cannabinoids is that they are “synthetic”, due to the manufacturing processes performed in a laboratory. As mentioned in your draft report some states have banned “synthetic products or processes”, but this has led to significant unintended consequences from well-intended regulations. The “synthetic” argument was rejected by a three-judge panel of the Ninth Circuit stating, “the source of the product — not the method of manufacture — is the dispositive factor for ascertaining whether a product is synthetic.”

These manufacturing processes are similar to methods used to produce well-known and existing products in the free market, as we mentioned during the second meeting of the study group. Like vitamin supplements, which can be derived from natural plant/animal sources or also more efficiently derived from a process of isomerization. For example, both Vitamin A and Vitamin C can either be derived from a natural source, fish liver oil or citrus fruits, or more efficiently isomerized from acetone or keto acid. These isomerized vitamins have regulations in place to ensure consumer safety, as we all can agree hemp-derived products should as well.

We must also disagree with the recommendation proposed by the Maryland Medical Cannabis Commission with regards to establishing a "Total THC" standard for determining whether a hemp-derived product is intoxicating or not. The 2018 Farm Bill does not prohibit the derivation of Delta 8 or other THC isomers from hemp, nor the enhancement of products with these compounds. It also states that Delta-9-THC is the only limiting factor for hemp and hemp products. This reality was recently reinforced in March 2022 when a 3-0 ruling was issued by the panel of the U.S. Court of Appeals for the Ninth Circuit who declared, “this Court will not substitute its own policy judgment for that of Congress.” Therefore, resources should not be put into creating standards based on something Congress has already decided upon but should instead focus on how best to ensure all related safety regulations are being followed. In congruence with this ruling and clear congressional intent, we advise against determining requirements based on these terms.

The potential for intoxication presents an important factor when deciding how to regulate the sale of hemp-derived cannabinoid products created for consumption. However, it should not be the sole measure used in determining their legality. Rather, it can be used to inform certain conditions on the sale of these products. Such restrictions may include age-gating, testing guidelines and certification, packaging requirements, and labeling requirements. It is important to consider that most of these products offer a lower level of intoxication than those supplied via the Medical and Adult use cannabis markets; consumers are purchasing these items for that precise reason. Effective regulation should reflect this, balancing both safety considerations with consumer needs.

Quality assurance is a core principle we stand by when it comes to hemp-derived products. We firmly believe all products should be rigorously tested and held to the highest standard possible. That’s why we support the MMCC’s recommendations regarding the implementation of the Hemp Industry Association’s position on testing of hemp-derived products for safety to include testing for the presence of certain contaminants, including: (i) microbials; (ii) heavy metals; (iii) pesticides; (iv) solvents; (v)

reagent residuals; and (vi) bleaches. These tests are paramount for an accountable hemp industry and improved safety standards for consumers, so that quality can never be put into question. We hope this initiative will also increase trust from customers in our products, who will know that what they're purchasing is safe and meets the highest standard on offer.

We wholeheartedly agree with the MMCC's recommendations regarding the proper labeling, packaging and marketing of hemp-derived products containing Delta 8 THC and other THC isomers. Child resistant packaging should be a priority in order to keep these products out of the hands of minors. Warning labels should also be included, ensuring that consumers are aware of the contents and legal restrictions associated with purchasing these products. Additionally, labels should not be made overly attractive so as to not be alluring to minors who may come in contact with them. Following these guidelines will ensure that these products are responsibly handled by lawful consumers 21 years of age and older and out of reach from those legally ineligible for usage.

In regards to the Poison Control Center calls referenced at the end of the draft report, we would ask that the MMCC provide the data they used to reach those numbers. From our cursory research, we believe that the numbers of adverse effects involving minors in the report are greatly inflated. In the October 2022 meeting of the MMCC, Bruce Anderson from Maryland Poison Control Center stated:

...the way that we [Poison Control] are able to report on products is based on the codes that exist...since Delta 8 is a relatively new product there isn't specific coding that is great for capturing this information. It's reportable, but it's not easy to report on. So the information may not be entirely pristine from the reports that we are getting. What that means is there may be individuals that are working poison centers that are doing their best to code this situation that they are dealing with, which is like a 911 call, and they may select a generic code that lumps in with all the other cannabis products. ***So the specifics about Delta 8 are probably not ideally captured in the poison center data.***

It is therefore incorrect for the MMCC draft report to assign a percentage to Delta-8 calls, when the Maryland Poison Control Center itself said that they were not confident in the numbers.

While we are not opposed to licensing for retailers and processors or Federal manufacturing standards like current Good Manufacturing Processes (cGMP), we would like to know more about how the MMCC is recommending that these will be implemented. We need to ensure that neither the new licensing nor the cGMP create an additional barrier to entry for small and minority-owned businesses. We would also like to know which entity will be charged with establishing, regulating, and managing the licensing process and cGMP. Our recommendation is that the Department of Agriculture, with assistance from a Hemp Advisory Council that includes representatives from a variety of agencies as well as members of the Maryland Hemp industry, should be the regulatory entity who oversees this, as has been successfully done in other states.

We believe that the requirement for cGMP could be costly for small and minority-owned businesses, although we know that this is not the intent of the MMCC. Ensuring that products manufactured in Maryland meet the highest standards of safety and quality is something the Hemp Industry takes very seriously. To this end, we propose that the draft report be amended to recommend that any product not produced using cGMP standards or given GRAS status by the FDA must have a valid certificate of analysis (COA) readily available to demonstrate full transparency as to the absence of contaminants. This allows



consumers to rest assured that a high level of safety and integrity has been maintained in the manufacturing process which is absolutely essential for continued trust in the product.

We are heartened that Senator Feldman and Delegate Pena-Melnyk have taken the initiative to create this working group in order to tackle an issue that is becoming increasingly important in Maryland. We commend their dedication to this issue and extend our sincere appreciation for their willingness to engage with us. We also recognize the effort that the MMCC put into this report and thank them for their work. We welcome the opportunity to work alongside the MMCC and the General Assembly and actively participate in developing sound legislation that not only promotes public safety but further develops the Hemp Industry within our state's borders.

Sincerely,

Three handwritten signatures in black ink are displayed horizontally. The first signature on the left is 'MWS', the middle one is 'DS', and the one on the right is 'NP'.

Matthew "Levi" Sellers, Daniel Simmonds, & Nicholas Patrick

Maryland Hemp Coalition & Maryland Healthy Alternatives Association



Andrew Garrison  
Director of Policy  
Maryland Medical Cannabis Commission

Dear Mr. Garrison,

I am writing today on behalf of the Maryland Wholesale Medical Cannabis Trade Association (CANMD). Thank you for the opportunity to comment on the MMCC draft recommendations to the legislative report in accordance with Chapters 511/512. It is unfortunate that CANMD could not participate in the public stakeholder meetings, and we are happy to participate in any future discussions on this matter. Please include CANMD's comments in the appendix to the final report.

#### CANMD RESPONSE TO MMCC DRAFT HEMP PRODUCTS RECOMMENDATIONS

##### GENERAL COMMENTS:

As hemp and cannabis are each derived from the Cannabis Sativa plant, all cannabinoids for human consumption, whether naturally occurring or synthetically derived, should be regulated and tested by the same standards to ensure public health and safety and avoid confusion to operators, law enforcement and consumers. These CANMD comments are specific to cannabis and hemp products for human consumption in any form; topical, oral, inhalation or ingestion, rather than industrial hemp used to manufacture other products such as fiber, rope, textiles and other hemp products.

The current laws and regulations, and the broad differentiation of them, around consumable hemp products and legal cannabis products, have led to an explosion of the illicit market and created a public health issue for Marylanders with increased adverse outcomes, non-existent testing, inaccurate labeling of unregulated products, and devalues the licenses of legitimate industry operators.

The continued bi-furcation of using the terms hemp vs. cannabis is misleading and confusing to the public overall. Adjusting the nomenclature to hemp means industrial hemp and industrial hemp products. Using the term cannabis for all consumable hemp-derived and cannabis products will provide better clarity and understanding for the industry, legislators, law enforcement, regulators, and consumers universally.

Moreover, the regulation and enforcement authority of consumable hemp-derived and cannabis products, whether through a natural or synthetic process, should be placed under one agency. The single agency should be responsible for establishing universal testing standards and industry regulations for licensing, manufacturing and retail sales and actively participate in the discovery and enforcement action against untested products and unlicensed and illicit operators and businesses.

Following the outline of the MMCC draft, more detailed comments are below.

**1. Align product regulations with the health and safety risks of the product.**

All cannabinoids for human consumption should be regulated to the same standards. There should be no differentiation of standards between naturally occurring vs. synthetically derived,

non-intoxicating vs. intoxicating or impairing, or medical vs. adult-use products. All cannabinoids need regulation for testing, packaging, warnings and consumer information.

There may be differences in the testing standards and tolerance levels between types of consumption methods; however, the standards should be applied equally across the entire cannabis/hemp industry for a given method. Holding licensed medical cannabis products to a higher regulatory standard will result in lower quality non-medical products and reduced assurances of public health and safety, and higher prices to the consumer for tested and more safe products.

**2. Require certain hemp-derived products to be subject to laboratory testing, packaging and labeling, therapeutic claims standards and other product safety measures.**

CANMD recommends that the General Assembly adopt standards on the testing of consumable hemp-derived products for safety that mirror the medical cannabis testing standards regarding (i) microbials; (ii) heavy metals; (iii) pesticides; (iv) solvents; (v) reagent residuals; (vi) bleach and (vii) potency.

CANMD recommends establishing minimum packaging and labeling requirements for consumable hemp products that mirror the requirements for medical cannabis products.

CANMD agrees with the MMCC recommendation that the federal and state standard for making any therapeutic or medical claim is expressly extended to include all consumable cannabis and hemp-derived products.

CANMD agrees with the MMCC recommendation that the certified good manufacturing practices (cGMP) standard be extended to include the manufacture, storage and distribution of consumable hemp-derived products to ensure product quality and consumer safety. Before requiring all ingredients for consumable hemp products be given GRAS (Generally Recognized as Safe) status by the FDA and not require a COA, the GRAS list needs to be updated to include products typically included in the manufacture of consumable hemp and cannabis products that are currently not included as GRAS due to the Federal classification of cannabis. (i.e., terpenes, cannabinoids, etc.)

**3. Only allow for sales of certain products in licensed, regulated establishments**

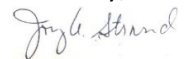
CANMD agrees that manufacturers and retailers of certain consumable hemp-derived products be licensed and undergo compliance inspections that mirror the medical cannabis regulations. Certain exceptions could apply and should be minimal, based on the health risk to the Maryland population, and only pertain to which retail outlets can sell products of low health risk, like CBD-only products. Manufacturing, testing, packaging and warning standards should remain the same as for other consumable hemp-derived and cannabis products.

**4. Expand public health messaging and resources established under Chapter 26 of 2022 to include any THC Product**

Public education campaigns and health education programs should continue to be ongoing and include information for parents, youth and all consumers about the use and risk of all cannabis products, especially THC and other intoxicating products. These education programs must be broadened to help increase understanding of the complexities and differentiation between cannabinoid products and their various effects.

Again, thank you for the opportunity to comment. Please contact me with any questions or needed clarification.

Sincerely,

A handwritten signature in cursive script that reads "Joyce Strand".

Executive Director  
CANMD

cc: CANMD Executive Committee