LEGISLATIVE REPORT

Hemp-Derived Non-Delta-9-Tetrahydrocannabinol Products

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Maryland Medical Cannabis Commission
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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 20th and November 17th. 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

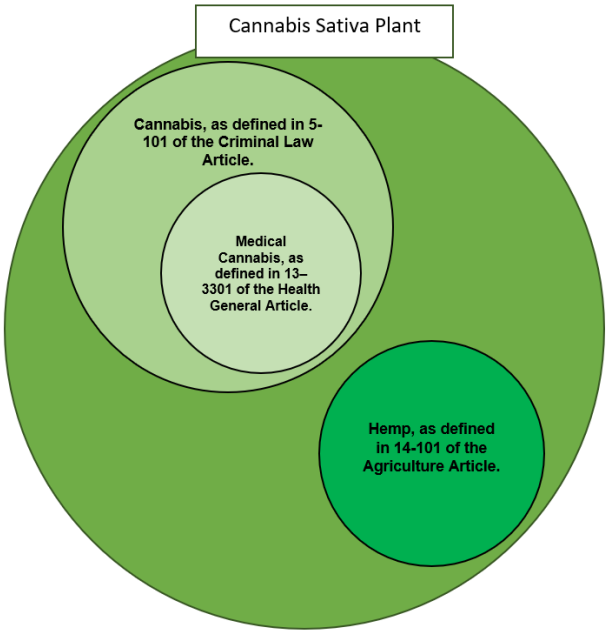
The Cannabis Sativa Plant and Existing Legal Definitions

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 §14-101of 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.[1] 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

[1] 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[2]. 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.[3] 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.

[2] 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/

[3] 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[4], and National Industrial Hemp Council[5] have issued warnings about the unknown safety profile and health risks of unregulated delta-8-THC. The FDA[6] and CDC[7] 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."[8]

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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[4] 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

[5] 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

[6] 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

[7] 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

[8] 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,[9] 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, tetrahydrocannabibutol (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.

[9] S.O. Vanegas et al., "Assessment of Dependence Potential and Abuse Liability of Δ8-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."[10] 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,

[10] 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.*[11]

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).

[11] 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

	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	Count
Product Type	V	G	V	G	G	V	V	V	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

	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	Count
Not Safe for Children and/or 21+																										15
Do not use if Pregnant or Breastfeeding																										11
Delayed Effect																										4
Not Evaluated/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 preforming this analysis was different than the ITL used by the Commission in the testing of these products, providing a third data point.

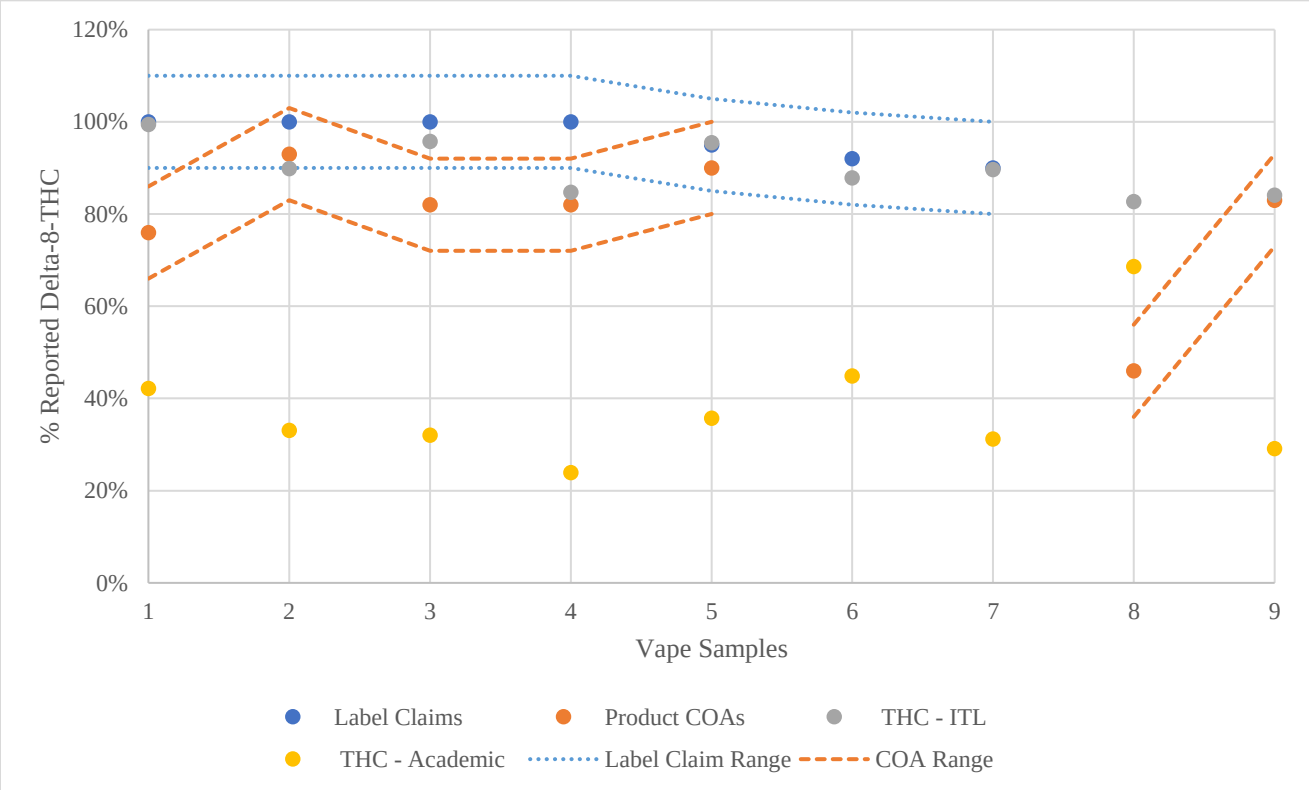
The most notable finding from the laboratories' analysis was the inconsistency of potency results. Generally, a 10% variance would be acceptable for product potency results. This level of accuracy was often achieved from the ITL testing of vape products, where the results were within this range in five 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

		Label Claim		**Product COAs**	
Testing Laboratory		**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.					

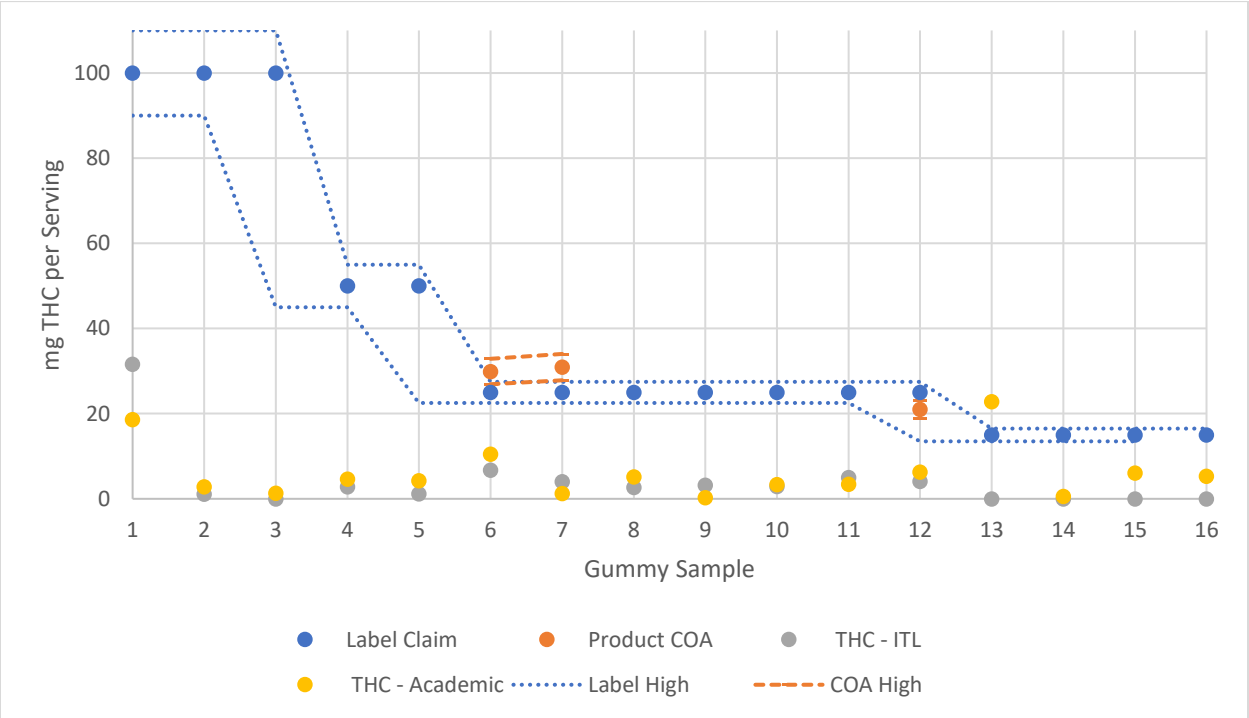
Exhibits 5 and **6** (on the following pages) compare the two Commission test results to the product label claims and product COAs (when applicable). These exhibits have also layered over the acceptable error range of 10% discussed above. As shown above in **Exhibit 4**, there were more instances of 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.[12] 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:

[12] 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.[13] 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

[13] 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 17th 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 contaminates 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 contaminates, including: (i) microbials; (ii) heavy metals; (iii) pesticides; (iv) solvents; (v) reagent residuals; and (vi) bleaches. The specific contaminates to be tested for should be established in regulations and consistent with other states' testing protocols. A list of contaminates 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 Commissions 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 20th Meeting
- The Network for Public Health Law – Eastern Region
    - Presented during October 20th Meeting
- Vincente Sederberg
    - Presented during November 17th 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 20th – 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 17th at 1PM
  - MMCC Staff to share proposed statutory revisions/definitions by October 28th

Synthetic Cannabinoids from hemp: Isomers and Derivatives of Δ9-THC

Chad Johnson, Ph.D.

Co-Director, Masters in Medical Cannabis Science and Therapeutics

Outline

- Basics of Pharmacology
- Isomer vs. derivative
- Isomers + derivatives of Δ9-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

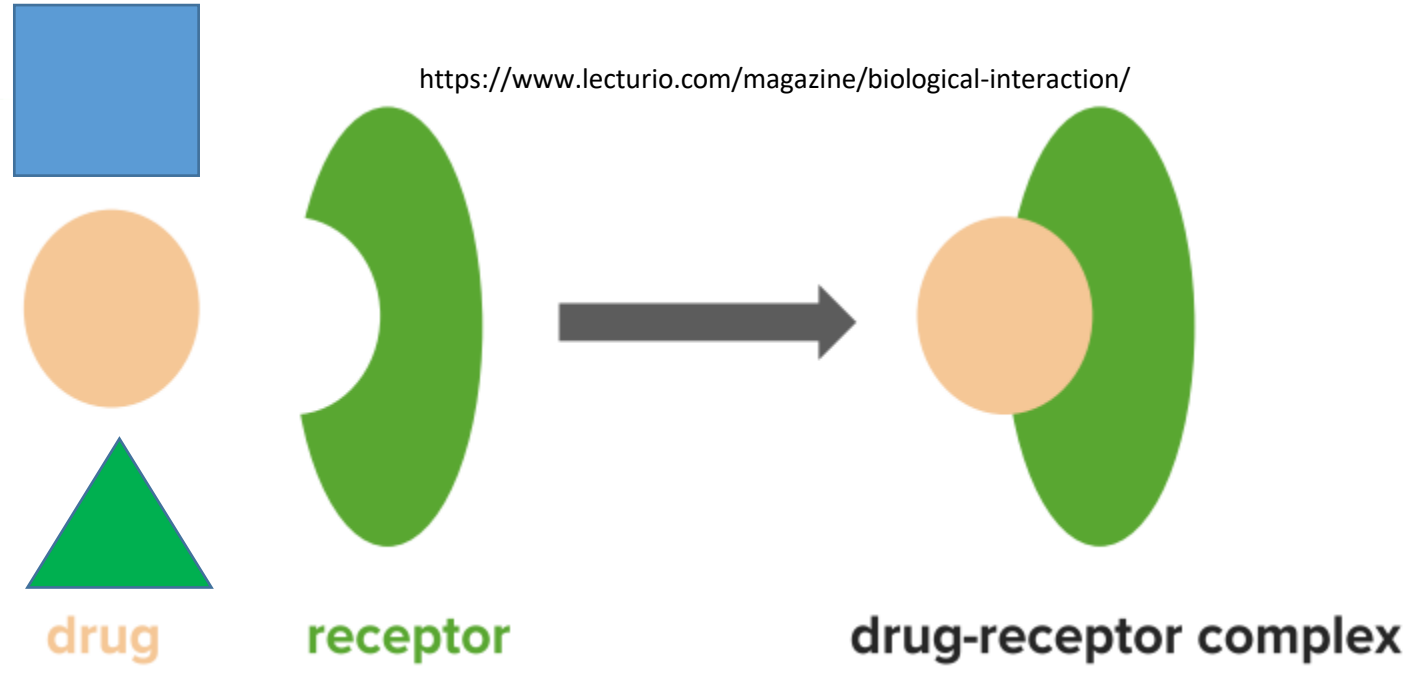
Affinity

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)

https://www.lecturio.com/magazine/biological-interaction/



Efficacy

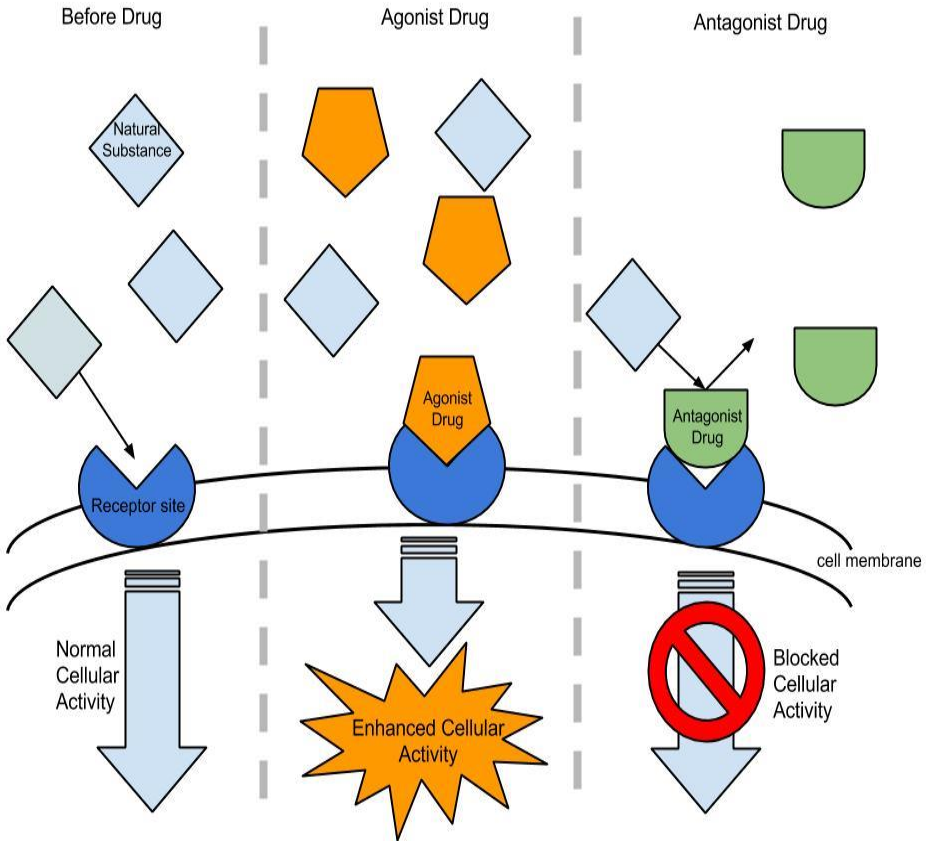
Proteins that recognize “drugs” and **transmit a message from outside the cell to the inside**

Binding is required—Affinity!

Can activate (agonist) or not activate (antagonist)

How much they activate is efficacy

https://en.wikipedia.org/wiki/Agonist-antagonist



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

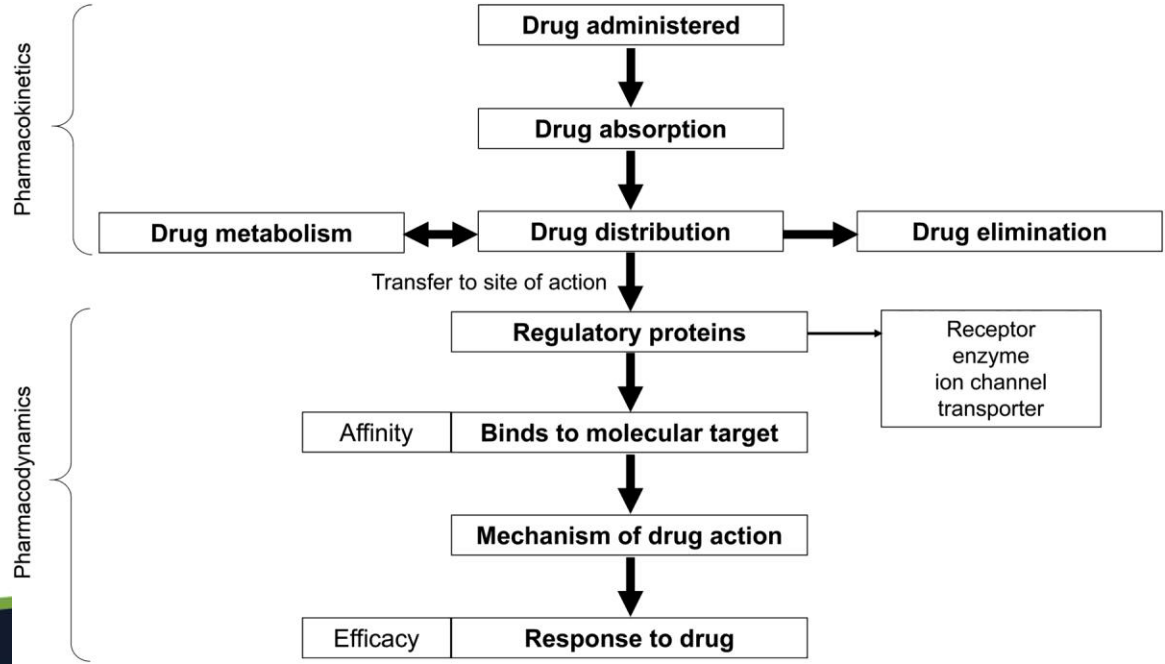
Pharmacokinetics and Pharmacodynamics

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,*

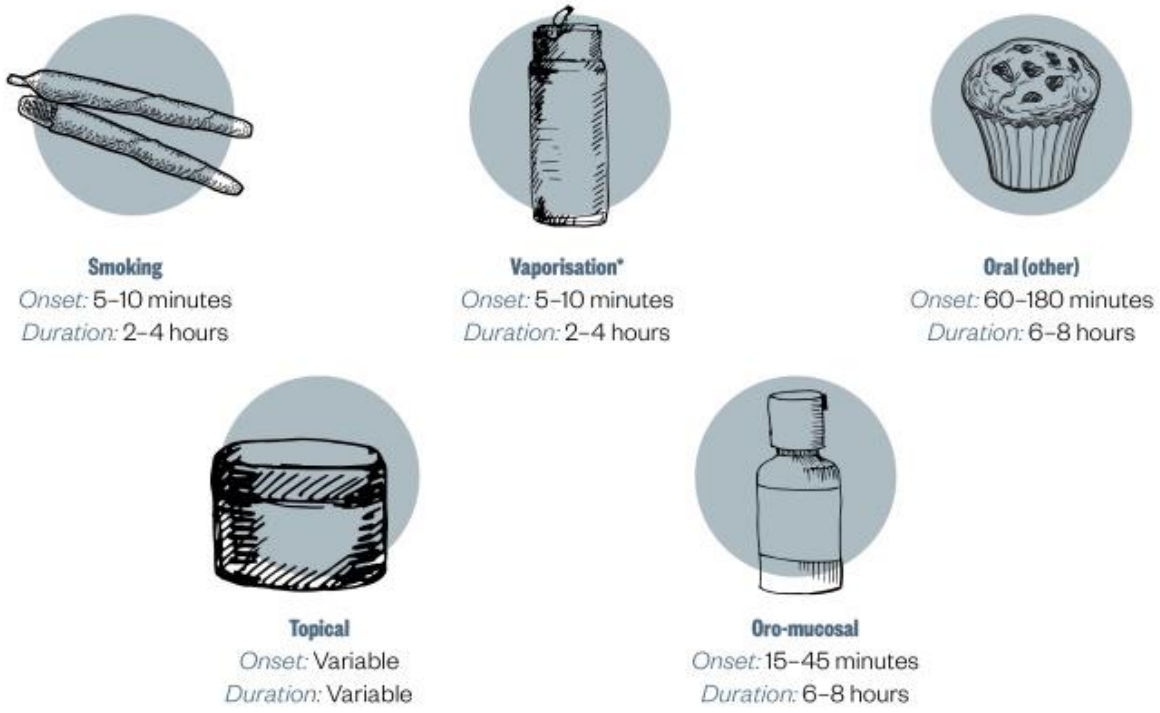
e.g. twice a day, once a day, etc.

Currie GM. J Nucl Med Technol. 2018, 46(3):221-230.



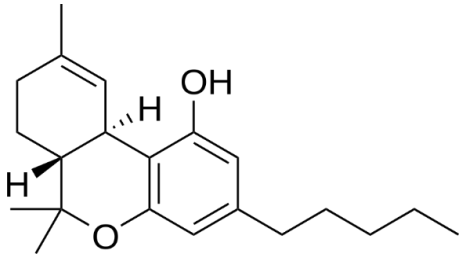
Route of administration matters!

- 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…

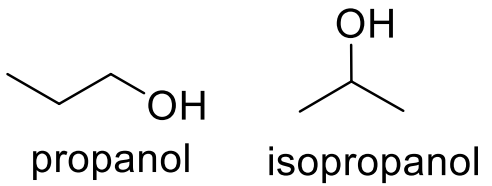


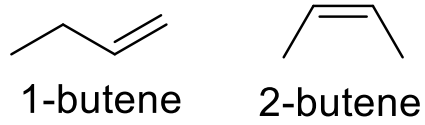
https://pharmaceutical-journal.com/article/infographics/a-quick-guide-to-medical-cannabis

“Isomers” and “Derivatives” of Δ9-THC



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





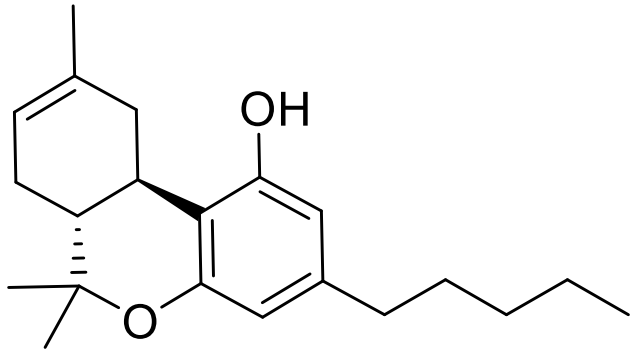
A **“derivative”** does NOT have the same chemical formula (but could have similar connectivity!).

Δ8-THC, Δ9's "Legal" Younger Sibling…

- Δ8 can be produced from hemp (CBD)—hence was placed in a legal "gray" area

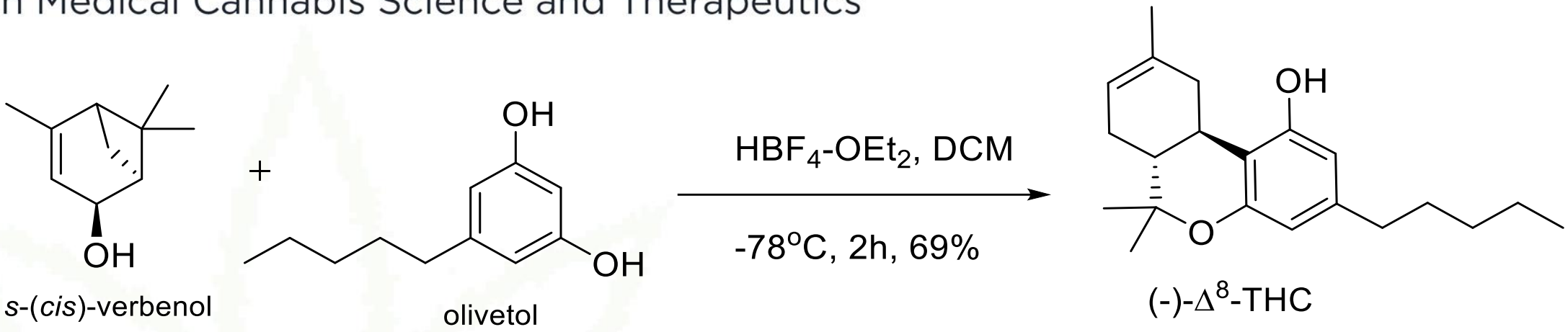
- Legalization of CBD led to overproduction of hemp (2018 Farm Bill…)

- What do growers do? Find a way to make their "hemp" more profitable.



Δ8, cont.

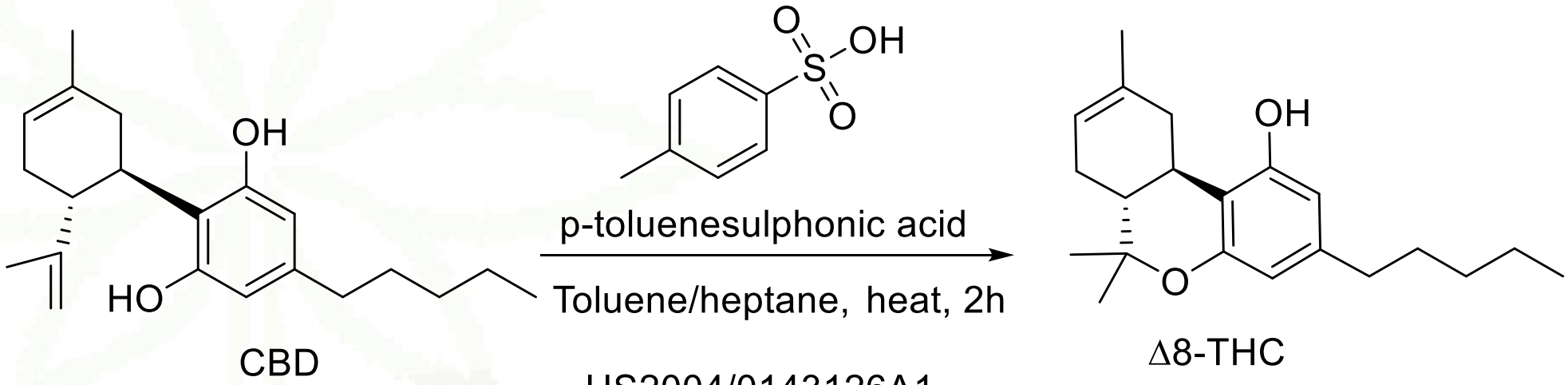
- Only occurs at minimal levels in the plant (≤1%)
- It has similar activity to Δ9-THC, but slightly less potent—yet it is marketed as hemp!
- Purification/QC issues
- *AK Futures LLC vs Boyd St Distro LLC* (early summer 2022)



s-(*cis*)-verbenol

olivetol

(-)-Δ^8-THC



CBD

US2004/0143126A1

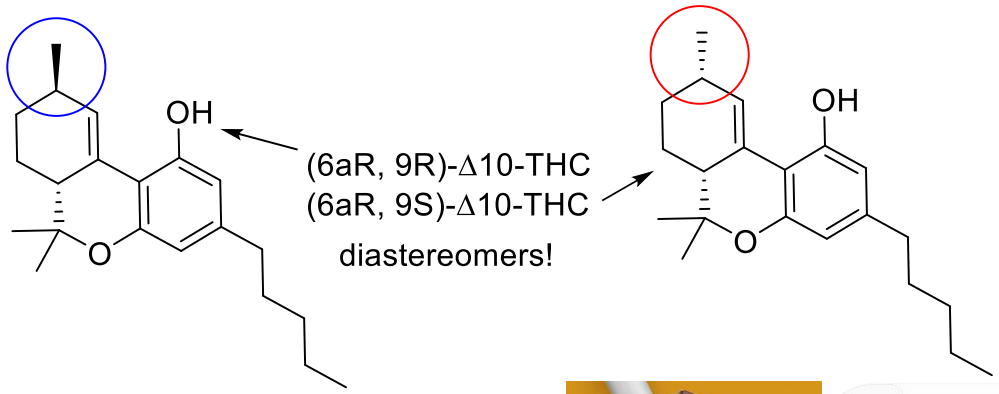
Δ8-THC

Abuse Liability of Δ8?

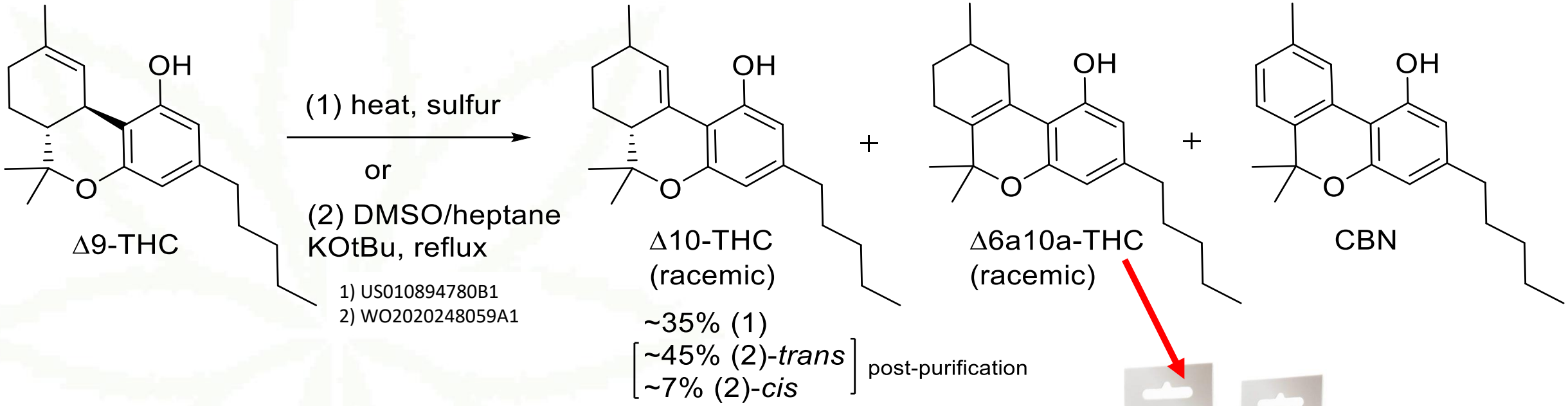
- Vanegas et al. Drug and Alcohol Dependence. 2022, 240, 109640

- They found that:
  - Acute and chronic effects of Δ8 resemble Δ9
  - “Classical” cannabinoid effects mediated by CB1 receptor
  - Tolerance (and cross tolerance) develops to WIN55,212
  - Δ8 substitutes for Δ9 in drug discrimination assays
  - Withdrawal symptoms develop from Δ8 (physical dependence)

Δ10-THC

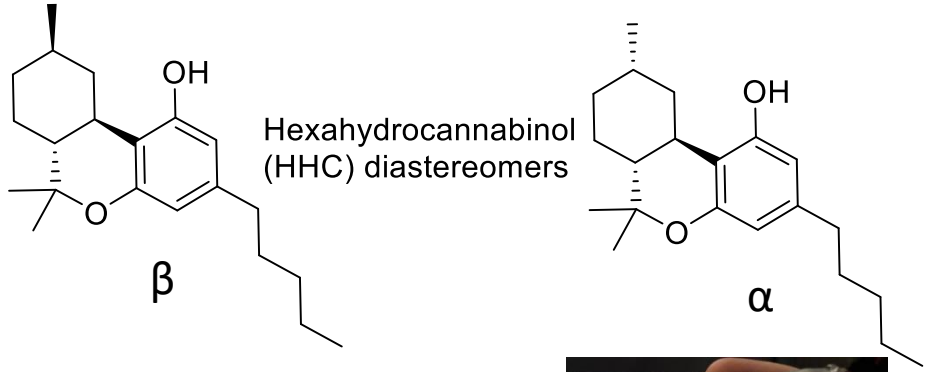


- **Not natural**
- Same legal issues as Δ8…
- 9R-isomer shows higher potency
- Both show much weaker (μM) potency than Δ9 (similar to Δ8)—very few studies done
- Purification/QC issues



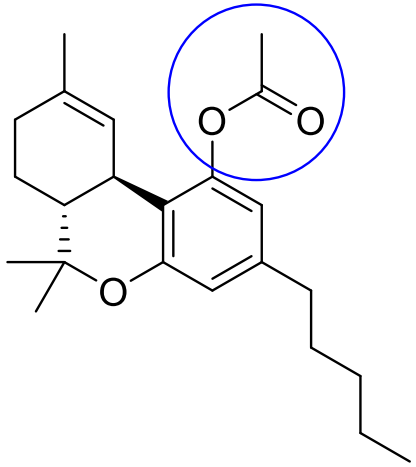
Conclusion: Purification is needed!

Hexahydrocannabinol (HHC)

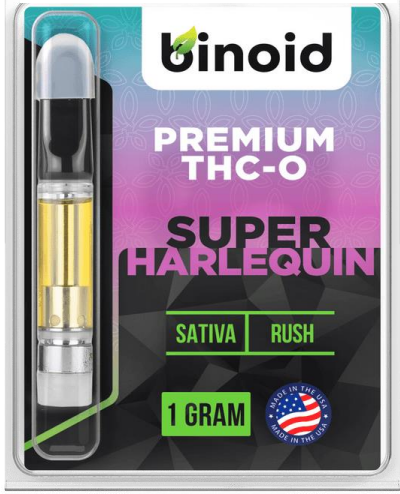


- Hydrogenated derivative of THC—only trace amounts from the plant
- Can be easily made from citronellal and olivetol
- Primarily sold in vape carts (not widely available…yet)
- Is legal to buy/sell/use for now—once again, a legal loophole
- 9β enantiomer=more active
- Purification/QC issues

THC-O-Acetate (THCO)

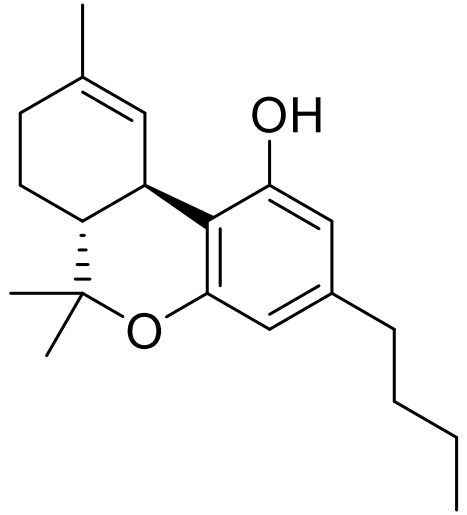


- Synthetic
- Still agonist at CB1/CB2, but increased potency (3-4x)
- Originally investigated as a possible non-lethal incapacitating agent (Edgewood Arsenal experiments) in mid-late 1900s (2x more likely at higher doses to produce ataxia)
- Not scheduled at the Federal level—legal loophole



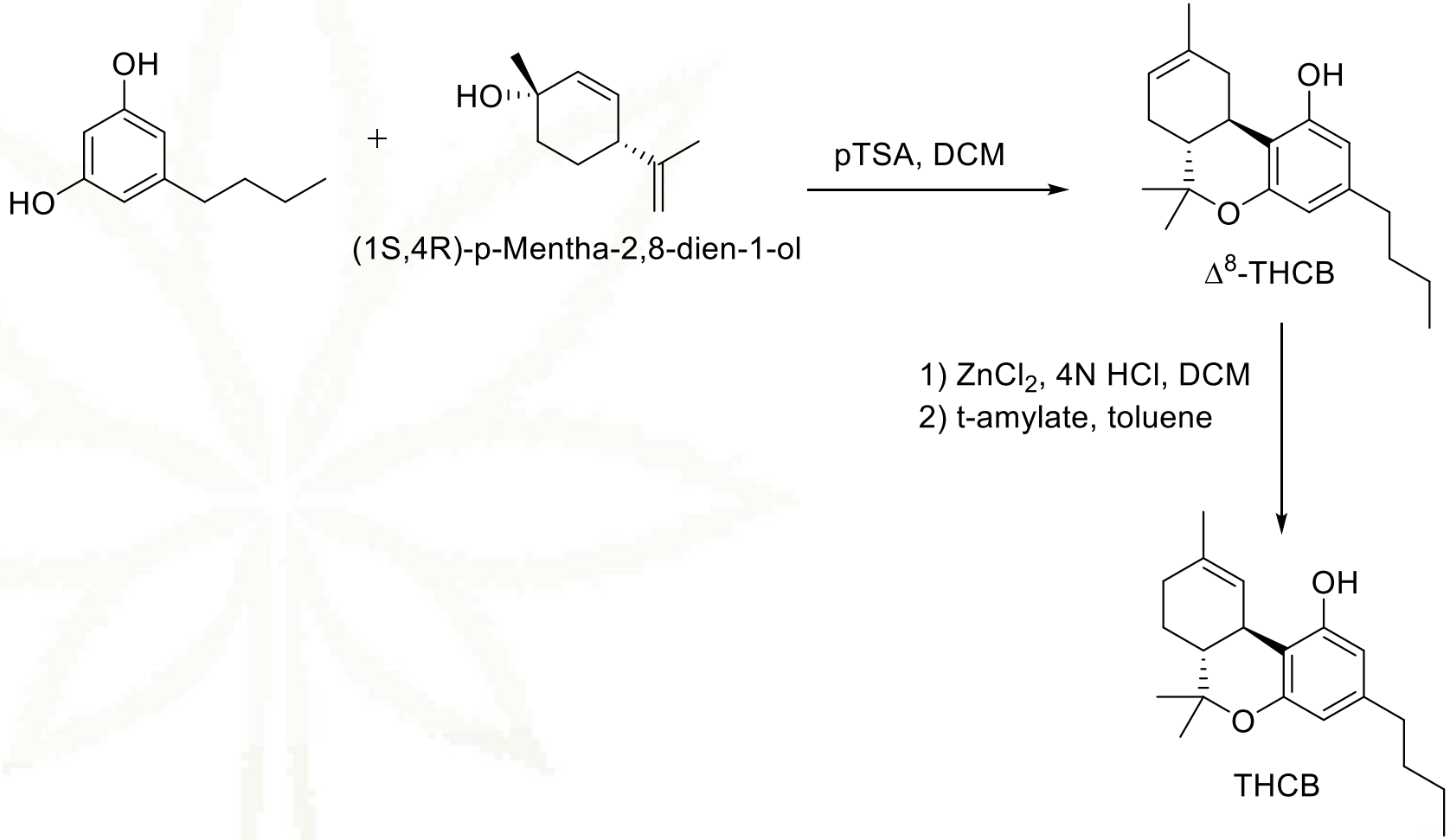
VERY FEW STUDIES DONE TO ESTABLISH SAFETY

Tetrahydrocannabibutol (THCB)

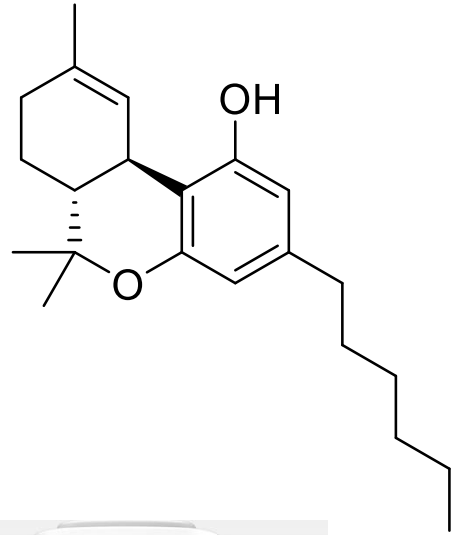


- Isolated from the plant, but in small quantities
- Similar binding affinity to CB1/CB2 (low nM range) as Δ9, moderate efficacy in mice (tetrad test: spontaneous activity [hyperlocomotion], analgesia, changes in body temp, and latency for moving)
- Δ8 version known as JWH-130

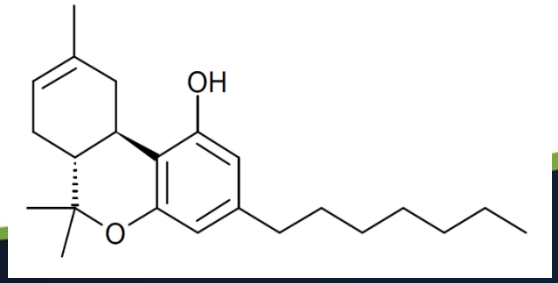
THCB synthesis



Tetrahydrocannabiphorol (THCP)



- Potent, synthetic derivative of Δ9—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 Δ8-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?

MS in Medical Cannabis Science and Therapeutics




UNIVERSITY of MARYLAND
SCHOOL OF PHARMACY

Regulation of Hemp Derived THC Products

Mathew Swinburne, J.D.

Associate Director

The Network for Public Health Law-Eastern Region

The Network for Public Health Law

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

The Network for Public Health Law

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.

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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)*

The Network for Public Health Law

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 1639o)*

50 grams x 0.3%=150mg

The Network for Public Health Law

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

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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.

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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.

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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.

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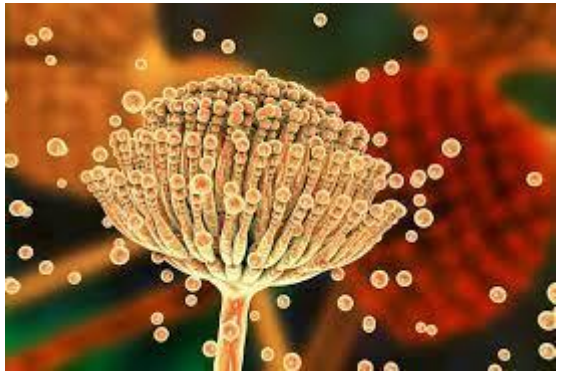
New York- Separate Licensing System

- **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



The Network for Public Health Law

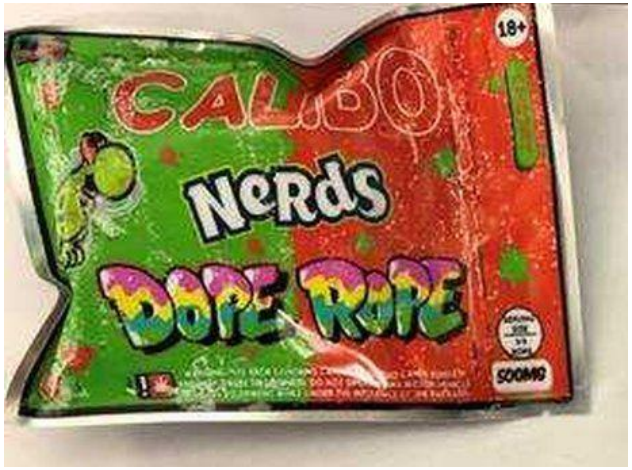
Minnesota-Unlicensed Adult-Use Market

- 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

The Network for Public Health Law

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.



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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.

The Network for Public Health Law

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.

The Network for Public Health Law

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.

The Network for Public Health Law

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).

The Network for Public Health Law

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.

The Network for Public Health Law

Ideas. Experience. Practical answers.

Thank you for you time.

Mathew Swinburne
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The Network for Public Health Law-Eastern Region

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mswinburne@networkforphl.org

MMCC
MARYLAND
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COMMISSION

Chapter 511/512 Report on Regulation of Non-Delta-9 THC Products
Meeting #2
Thursday, November 17th – 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

MMCC
MARYLAND
MEDICAL
CANNABIS
COMMISSION

Ch. 511/512 Mandated Report Meeting #2

Thursday, November 17th

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 derivates 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.

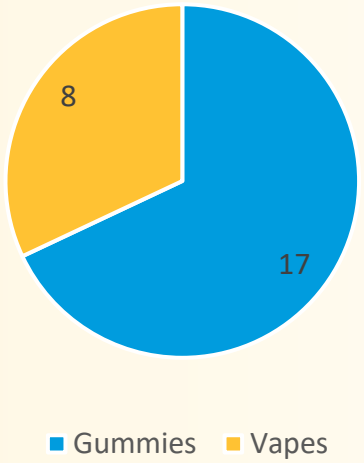
Open Questions

- 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

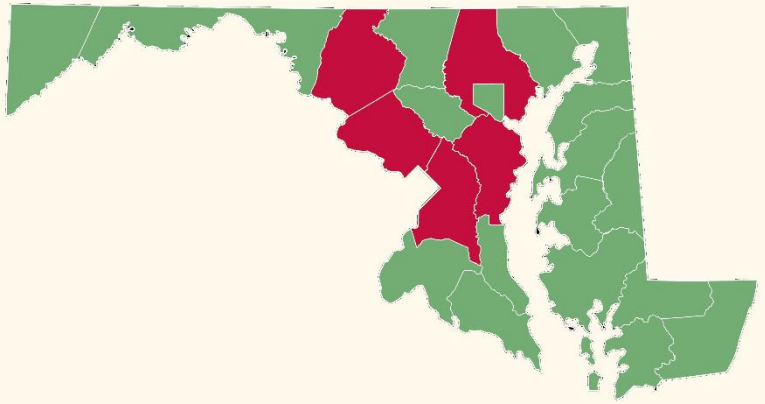
Lori Dodson, MMCC Senior Advisor

Delta-8 Study Demographics



IDs Checked on **50%** of Purchases

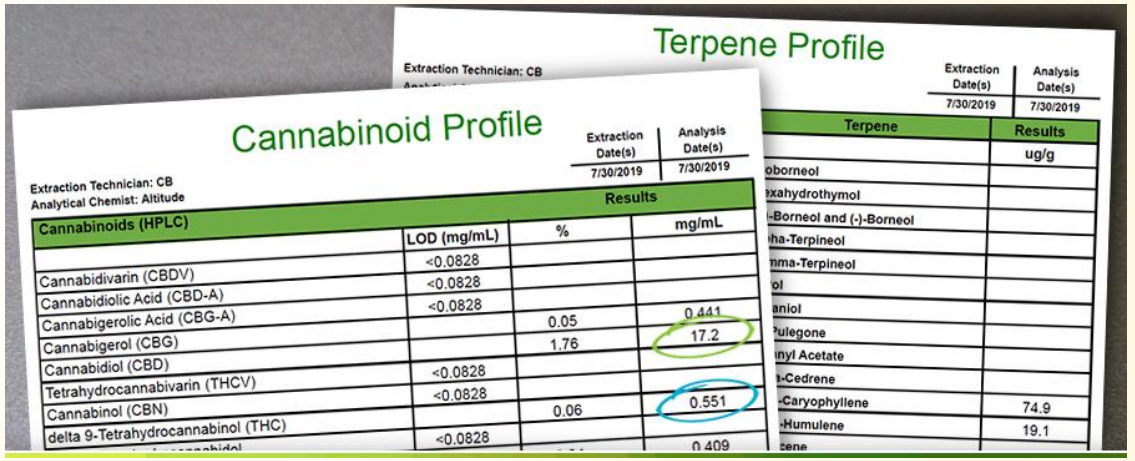
Products Purchased Across 5 MD Counties



Packaging and Labeling

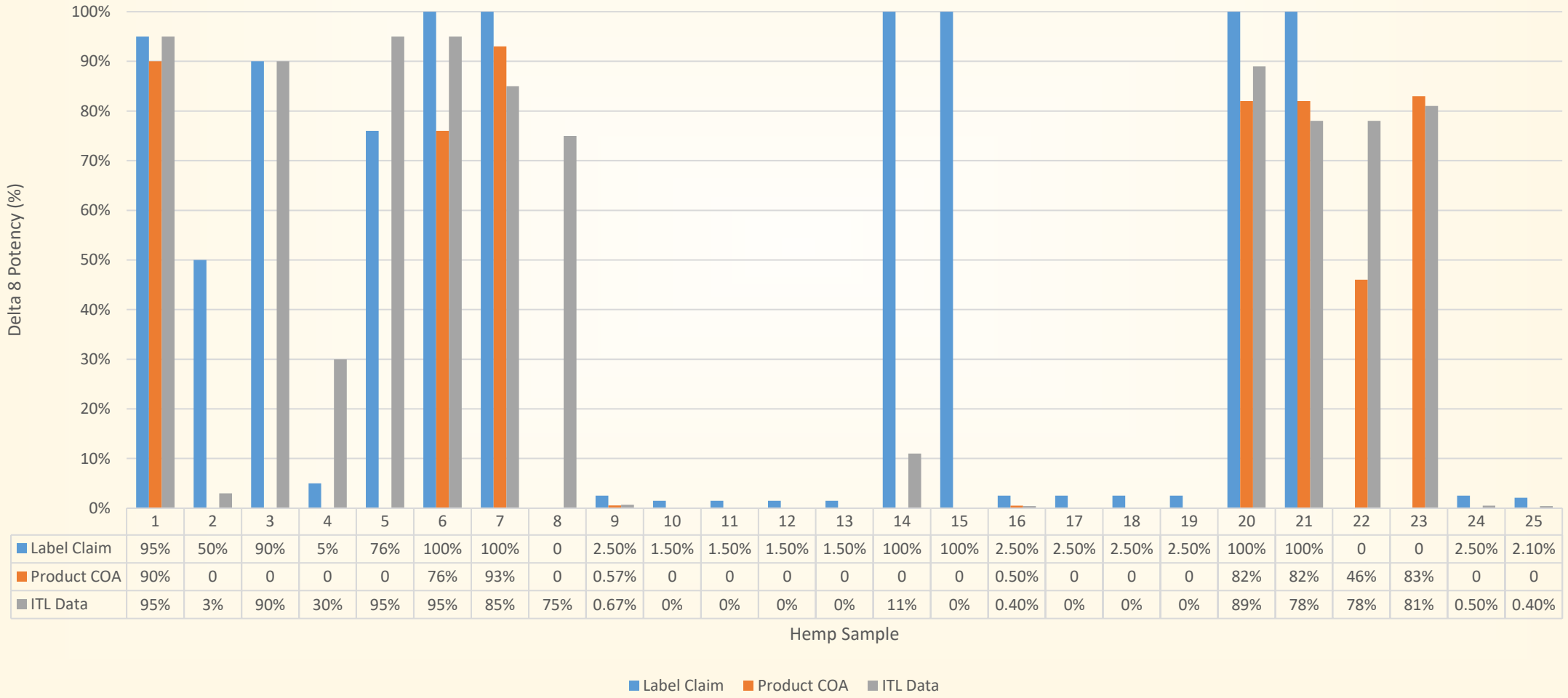
44% Included Expiration Dates

60% Included Warning Statements



44% Included Certificates of Analysis

Potency of Delta-8 Comparisons – Preliminary Data



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Label Claim	95%	50%	90%	5%	76%	100%	100%	0	2.50%	1.50%	1.50%	1.50%	1.50%	100%	100%	2.50%	2.50%	2.50%	2.50%	100%	100%	0	0	2.50%	2.10%
Product COA	90%	0	0	0	0	76%	93%	0	0.57%	0	0	0	0	0	0	0.50%	0	0	0	82%	82%	46%	83%	0	0
ITL Data	95%	3%	90%	30%	95%	95%	85%	75%	0.67%	0%	0%	0%	0%	11%	0%	0.40%	0%	0%	0%	89%	78%	78%	81%	0.50%	0.40%

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

Jordan Wellington, Vicente Sederberg

Jen Flanagan, Vicente Sederberg

Next Steps:
Report due to MDGA by January 1, 2023

Regulatory Framework

SB22-205 Intoxicating Hemp Task Force

VS STRATEGIES

VS Strategies Policy Priorities

- **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: <u>Potentially</u> 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

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

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

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

VS STRATEGIES

Appendix D – Review of Online Retailers

	Product Category*	Maryland Online Retailer 1		Maryland Online Retailer 2	
		Number of Products	Share of Total Products	Number of Products	Share of Total Products
Potentially Intoxicating Products	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%
All THC/Potentially Intoxicating Products		***646***	***64%***	***169***	***57%***
Non-Intoxicating Products	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%
All CBD Products		***371***	***36%***	***130***	***43%***
All Products Available		**1017**	**100%**	**299**	**100%**

***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

Residual Solvents (Limits in parts per million, or ppm)			
Contaminant	**Florida Restrictions for Hemp Products**	**New York Restrictions for Hemp Products**	**MMCC Product Restrictions***
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

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

Biological Impurities (CFU = Colony Forming Unit)			
Contaminant	**Florida Restrictions**	**New York Restrictions**	**MMCC Product Restrictions**
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 *Ingestion* or *Inhalation.*	<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.
Mycotoxins (Limits in parts per billion, or ppb)			
Contaminant	**Florida Restrictions**	**New York Restrictions**	**MMCC Product Restrictions†**
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.

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CANNABIS

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

Regulation off 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."[1] 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, the it explicitly preserved the authority of the Food and Drug Administration (FDA) over products derived from hemp.[2] 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.[3] 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.[4] The manufacturing, packaging, and distribution of Industrial Hemp Products is regulated by Colorado Department of Public Health and Environment.[5] Industrial Hemp Products distributed through the licensed marijuana industry are also subject to regulation by the Marijuana Enforcement Division.[6] 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.[7]

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.[8]

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%.[9] While this is the statutory definition, the product testing standards look at maximum total THC concentration of 0.3%.[10] Total THC incorporates tetrahydrocannabinolic acid (THCA) and various THC isomers.[11]

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).[12]

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.[13]

Packaging Requirements: Product packaging must be food-grade or Generally Regarded as Safe (GRAS).[14]

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.[15] 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.[16]

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).[17]

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.[18]

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.[19]

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.[20]

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.[21] Also, the CRA has developed extensive labeling and packing requirements for marijuana products that could serve as a basis for future regulations.[22]

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.[23]

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.[24]

Product Testing: Hemp products are not subject to product testing. However, Michigan requires preharvest testing to measure THC concentration.[25]

Minnesota

Regulatory Agency: The Minnesota Board of Pharmacy has been granted regulatory authority.[26]

Licensing: Minnesota does not require licensing of hemp derived product manufacturers, distributors, or retailers.[27]

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.[28]

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

THC Profile: When evaluating the THC potency of a hemp derived product, Minnesota includes all forms of THC.[32]

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.[33] 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.[34]

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.[35]

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."[36] 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.[37]

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.[38]

New York

Regulatory Agency: The New York Cannabis Control Board and the Office of Cannabis Management tasked with regulating cannabinoid hemp products.[39]

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. [40] While cannabinoid hemp product processors and retailers are licensed through the Office of Cannabis Management.[41]

Age Restriction: Retailers may not sell inhalable cannabinoid hemp products or flower products to anyone under 21.[42]

Potency Restrictions: Products are limited to 0.3% of delta-9 THC.[43] 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.[44] 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.[45]

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.[46]

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 hemps country of origin; and
9. A means for reporting serious adverse events.[47]

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.[48] 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.[49] In addition, products must have clear serving and use instructions.[50] 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.[51]

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.[52] Next, all cannabinoid hemp products must have tamper-evident packaging that minimizes exposure to oxygen and light.[53]

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.[54] 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).[55] Inhalable cannabinoid hemp products are subject to special requirements pertaining to prohibited ingredients and safety measures for electronic vaporization devices.[56] Finally, cannabinoid hemp products cannot be made into cosmetics.[57]

Product Testing: Cannabinoid hemp processors must contract with an independent commercial laboratory to test their hemp extract and products.[58] 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.[59] In addition, New York set product limits on a broad spectrum of pesticides, residual solvents, heavy metals, biologicals, and mycotoxins.[60]

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.[61] Hemp handlers are the licensed parties that are permitted to process hemp into various products.[62] However, no specific license is required to sell cannabinoid hemp products.[63] 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.[64] In addition, a marijuana processor can obtain an endorsement that allows them to also function as hemp handlers.[65]

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.[66]

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.[67]

THC Profile: Oregon evaluates product potency based on total delta-9 THC.[68] This number is calculated by adding the mass of delta-9 THC to 0.877 times the mass of delta-9 tetrahydrocannabinolic acid (THCA).[69] Cannabinoid hemp products may not contain any artificially derived cannabinoids.[70] 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. [71] 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.[72]

Packaging: Consumable hemp products are subject to the same packaging requirements as marijuana products in the licensed cannabis market.[73] 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.[74] 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.[75]

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.[76] Hemp handlers with a certificate to sell their products to OLCC licensed business are required to comply with the same standards.[77] 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.[78] Starting in March of 2023, these products will also be tested for heavy metals and microbiological contaminants.[79] However, certain hemp concentrates made only using food grade animal fat or food grade plant-based oil are subject to less stringent testing protocol.[80] 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.[81] Industrial hemp derived vapor products are currently tested for solvents, pesticides, select cannabinoids, and mycotoxins. [82] Starting in March of 2023, these products will also be tested for heavy metals and microbiological contaminants. [83]

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

[1] 7 U.S.C. § 1639o.

[2] 7 U.S.C. § 1639r.

[3] 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* .

[4] COLO. REV. STAT. § 35-61-113.

[5] 6 COLO. CODE REGS. § 1010-21:7.

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

[7] COLO. REV. STAT. § 44-10-201

[8] *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/1gayiLhfxLI7K2HQX15bRcZYYGlqFC8bD/view.

[9] COLO. REV. STAT. § 25-5-426, *see also* 1 COLO. CODE REGS. § 212-3:1-115.

[10] 6 COLO. CODE REGS. § 1010-21:7.

[11] *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).

[12] 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.

[13] 6 COLO. CODE REGS. § 1010-21:7.

[14] *Id.*

[15] *See* 6 COLO. CODE REGS. § 1010-21:7 (providing testing standards for industrial hemp products).

[16] *See* 1 COLO. CODE REGS. § 212-3:6-105 (retail cannabis), *see also* 1 COLO. CODE REGS. § 212-3:5-105 (medical cannabis).

[17] MICH. COMP. LAW § 333.27002.

[18] 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.

[19] MICH. COMP. LAW § 333.27953.

[20] *Id.*

[21] MICH. COMP. LAW § 333.27958.

[22] *See* MICH. ADMIN. CODE R 420.504 (providing labeling and packing restrictions for marijuana products).

[23] MICH. COMP. LAW § 333.27958.

[24] *Id.*

[25] MICH. COMP. LAW § 286.854.

[26] MINN. STAT. § 151.72
[27] 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.
[28] MINN. STAT § 151.72 subdiv. 3(c).
[29] 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.*
[30] *Id.*
[31] MINN. STAT § 151.72 subdiv. 5.
[32] 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.
[32] MINN. STAT § 151.72 subdiv. 3(c).
[33] MINN. STAT. § 151.72 subdiv. 5.
[34] MINN. STAT. § 151.72 subdiv. 5(e).
[35] MINN. STAT. § 151.72 subdiv (5)(c)
[36] MINN. STAT. § 151.72 subdiv. 4(a).
[37] *Id.*
[38] *Id.*
[39] 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).

[40] N.Y. AGRIC. AND MKTS. LAW § 509.

[41] N.Y. CANNABIS LAW § 92(Processor), N.Y. CANNABIS LAW § 93 (Retailer).

[42] N.Y. COMP. R. & REGS. TIT. 9, § 114.16.

[43] 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

[44] N.Y. COMP. R. & REGS. TIT. 9, § 114.1(c).

[45] N.Y. COMP. R. & REGS. TIT. 9, § 114.8(10)(b).

[46] N.Y. COMP. R. & REGS. TIT. 9, § 114.8(a)(11).

[47] N.Y. COMP. R. & REGS. TIT. 9, § 114.9(a).

[48] *Id.*

[49] N.Y. COMP. R. & REGS. TIT. 9, § 114.9(f).

[50] N.Y. COMP. R. & REGS. TIT. 9, § 114.9(d).

[51] N.Y. COMP. R. & REGS. TIT. 9, § 114.9(g).

[52] N.Y. COMP. R. & REGS. TIT. 9, § 114.9(b).

[53] N.Y. COMP. R. & REGS. TIT. 9, § 114.9(c).

[54] N.Y. COMP. R. & REGS. TIT. 9, § 114.8.

[55] N.Y. COMP. R. & REGS. TIT. 9, § 114.8.(c)

[56] N.Y. COMP. R. & REGS. TIT. 9, § 114.8.(d)

[57] N.Y. COMP. R. & REGS. TIT. 9, § 114.1(d).

[58] N.Y. CANNABIS LAW § 105.

[59] N.Y. COMP. R. & REGS. TIT. 9, § 114.10(b)

[60] N.Y. COMP. R. & REGS. TIT. 9, § §114.10(f-j)

[61] *See* OR. ADMIN. R. 603-048-0125 (hemp growers), *see also* OR. ADMIN. R. 603-048-0150 (hemp handlers).

[62] OR. ADMIN. R. 603-048-0150.

[63] 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.

[64] *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).

[65] OR. ADMIN. R. 603-048-0150.

[66] OR. ADMIN. R. 845-026-0300.

[67] OR. ADMIN. R. 845-026-0400 Table 3.

[68] *Id.*

[69] OR. ADMIN. R. 333-064-0100(4).

[70] OR. ADMIN. R. 845-026-0400.

[71] OR. ADMIN. R. 333-064-0100(3).

[72] OR. ADMIN. R. 845-025-7140.

[73] OR. ADMIN. R. 845-025-7020.

[74] *Id.*

[75] OR. ADMIN. R. 845-025-1015.

[76] See OR. ADMIN. R. 845-025-3220 (providing product restrictions).

[77] OR. ADMIN. R. 845-025-2755.

[78] *See* OR. ADMIN. R. 603-048-2330 (referencing existing testing protocol); see also OR. ADMIN. R. 333-007-0330 (providing testing protocol).

[79] OR. ADMIN. R. 333-007-0330.

[80] OR. ADMIN. R. 603-048-2330.

[81] OR. ADMIN. R. 603-048-2340.

[82] OR. ADMIN. R. 333-007-0342.

[83] *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

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. 1639*o*(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:

- 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.
- 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

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,

Maryland Hemp Coalition

Matthew “Levi” Sellers

MARYLAND HEALTHY ALTERNATIVES ASSOCIATION

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,

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.

MARYLAND HEALTHY ALTERNATIVES ASSOCIATION

MARYLAND HEMP COALITION

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,

Matthew “Levi” Sellers, Daniel Simmonds, & Nicholas Patrick

Maryland Hemp Coalition & Maryland Healthy Alternatives Association

CANMD
Maryland Wholesale Medical Cannabis Trade 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 CANMDs 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.

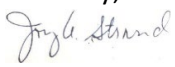
   CANMD agrees with the MMCC recommendation that the certified good manufacturing practices (cGMP) standard be extended to include the manufacture, storage and distribution of consumable hemp-derived products to ensure product quality and consumer safety. Before requiring all ingredients for consumable 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,



Executive Director
CANMD

cc: CANMD Executive Committee