DRAFT SB 22-205 TASK FORCE REPORT
WORKING DOCUMENT - DELIBERATIVE

Senate Bill 22-205:

Intoxicating Hemp and Tetrahydrocannabinol Products

Concerning the regulation of cannabis-related products that may potentially cause a person to become intoxicated when used.

Task Force Report

Mark Ferrandino
Executive Director
State Licensing Authority
Colorado Department of Revenue

Task Force Members

Truman Bradley	Brian Higgins	Kyle Ray
Stephen Cobb	Wanda James	Jefferey Riester
Jeremy Epley	Sasha Kalcheff-Korn	Christian Sederberg
Garrett Graff	Alan Lewis	Bridget Seritt
James Granger	Dominique Mendiola	Priyanka Sharma
John Harloe	Bruce Nassau	Jared Stanley
Michael Hennesy	Erik Paulson	

January 1, 2023

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Commented [1]: Move to an appendix - proposed by TF members on 12/13 (agreement by TF members and confirmed by Alan)

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EXECUTIVE SUMMARY

It is the intent of this task force of hemp and marijuana industry representatives and government officials to study the topic of intoxicating compounds and propose legislative and rule recommendations, based on science. The task force includes broad representation from regulators, manufacturers, refiners, retailers, labs, consumer nonprofit organizations and patients, and is intended to ensure that all viewpoints are captured and incorporated in the following recommendations.

The recommendations presented are based on one or more of the following goals and guiding principles[1]: *[subject to ongoing TF member review/development]*

A. Ensure consumer protection and safety
B. Promote equitable participation by industry/market participants
C. Support opportunities for research
D. Ensure enforcement priorities are clear, consistently applied, and balanced with other compliance measures
E. Base recommendations on data and science
F. Develop clear recommendations and guidance that consider opportunities for alignment with other state, federal, and/or international standards where appropriate
G. [other]

The task force has developed purposeful recommendations regarding the sale of hemp-derived products which may intoxicate a consumer along with chemically-converted and synthetically-derived intoxicating THC isomers, which may potentially cause a person to become intoxicated when used.

Recommendations are conditional. It is recognized that additional research is necessary to sensibly propose recommendations based in science on intoxicating levels of specific cannabinoids.

DEFINITIONS

"**Adult Use**" is an alternate term for Retail Marijuana.

"**Department"** means the Colorado Department of Public Health and Environment.

"**Division**" means the Marijuana Enforcement Division.

"Industrial Hemp Product Regulations" means the Code of Colorado Regulations 6 CCR 1010-21, adopted by the State Board of Health

"**License**" means to grant a license, permit, or registration pursuant to the Marijuana Code.

"**Licensee**" means any Person licensed, registered, or permitted pursuant to the Marijuana Code

[1] *Task Force goals and guiding principles are based on feedback (previously referred to as "hopes and concerns") provided in the July 13, 2022 Task Force meeting and were further amended in the course of the Task Force's work.*

including an Owner Licensee and an Employee Licensee.

"**Local Jurisdiction**" means a locality as defined in Section 16 (2)(e) of Article XVIII of the State Constitution of Colorado.

"**Local Licensing Authority(ies)**" means an authority designated by municipal, county, or city and county charter, ordinance, or resolution; the governing body of a municipality or city and county; or the board of county commissioners of a county if no such authority is designated.

"**Marijuana Code**" means the Colorado Marijuana Code found at Sections 44-10-101 *et seq*., Colorado Revised Statutes (C.R.S.).

"**Marijuana Rules**" means the Code of Colorado Regulations 1 CCR 212-3.

"Registrant" means an industrial hemp product producer registered with the Department.

"**Regulated Marijuana**" means Medical Marijuana and Retail Marijuana. If the context requires, Regulated Marijuana includes Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana Concentrate, and Retail Marijuana Product.

"**Regulated Marijuana Business**" means Medical Marijuana Businesses and Retail Marijuana Businesses.

"**Regulated Marijuana Product**" means Medical Marijuana Product and Retail Marijuana Product.

"**Retail Marijuana**" means all parts of the plant of the genus Cannabis, whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including but not limited to Retail Marijuana Concentrate that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Business. "Retail Marijuana" does not include industrial hemp or fiber produced from stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant, which is incapable of germination, or the weight of any other Ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product. If the context requires, Retail Marijuana includes Retail Marijuana Concentrate and Retail Marijuana Product.

"**Retail Marijuana Business**" means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturer, a Marijuana Hospitality Business, a Retail Marijuana Hospitality and Sales Business, a Retail Marijuana Testing Facility, a Retail Marijuana Business Operator, and a Retail Marijuana Transporter.

"**Retail Marijuana Cultivation Facility**" or "**Retail Cultivation**" means an entity licensed to cultivate, prepare, and package Retail Marijuana and sell Retail Marijuana to Retail Marijuana Stores, to Retail Marijuana Products Manufacturers, and to other Retail Marijuana Cultivation Facilities, but not to consumers.

"**Retail Marijuana Product**" means a product that is composed of Retail Marijuana and other Ingredients and is intended for use or consumption, such as, but not limited to, edible product, ointments, and tinctures.

"**Retail Marijuana Products Manufacturer**" or "**Retail Manufacturer**" means an entity licensed to purchase Retail Marijuana; manufacture, prepare, and package Retail Marijuana Product; and Transfer Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product only to other Retail

Marijuana Products Manufacturers, Retail Marijuana Stores, Retail Marijuana Hospitality and Sales Businesses, and Pesticide Manufacturers.

"**State Licensing Authority**" or "**SLA**" means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacture, distribution, sale, and testing of Regulated Marijuana in Colorado, pursuant to Section 44-10-201, C.R.S.

"**Transfer(s)(ed)(ing)**" means to grant, convey, hand over, assign, sell, exchange, donate, or barter, in any manner or by any means, with or without consideration, any Regulated Marijuana from one Licensee to another Licensee, to a patient, or to a consumer. A Transfer includes the movement of Regulated Marijuana from one Licensed Premises to another, even if both premises are contiguous, and even if both premises are owned by a single entity or individual or group of individuals; a Transfer also includes a virtual Transfer that is reflected in the Inventory Tracking System, even if no physical movement of the Regulated Marijuana occurs.

BACKGROUND

Senate Bill 22-205 and Establishment of the Task Force

I. Bill Summary[2]

SB22-205, Intoxicating Hemp and Tetrahydrocannabinol Products, *Concerning the regulation of cannabis-related products that may potentially cause a person to become intoxicated when used.*

The act authorizes the department of public health and environment to promulgate rules to prohibit the chemical modification, conversion, or synthetic derivation of intoxicating tetrahydrocannabinol isomers that originate from industrial hemp or may be synthetically derived.

The act also creates a task force to study intoxicating hemp products and make legislative and rule recommendations. The task force will submit a report to the general assembly by January 1, 2023. The task force consists of 20 members including representatives of state government, experts in marijuana and industrial hemp regulation, persons licensed in the marijuana and medical marijuana fields, persons working with industrial hemp, testing laboratories, and a representative of a county or district public health agency.

For the 2022-23 state fiscal year, the act appropriates $587,347 from the marijuana tax cash fund to the department of law, $4,630 of which is reappropriated to the department of personnel.

II. Establishment of the Task Force

Senate Bill 22-205 directs the Colorado Department of Revenue's Executive Director to "*...create a Task Force to study intoxicating hemp products and make legislative and rule recommendations*." Senate Bill 22-205 directed the Task Force consist of the following representatives:[3]

A. One representative appointed by the Executive Director to represent the State Licensing Authority;
B. One representative appointed by the Executive Director of the Department of Public Health and Environment;
C. One representative appointed by the Attorney General;
D. One representative appointed by the Commissioner of Agriculture;
E. One representative appointed by the Executive Director who is an attorney with expertise in the regulation of marijuana;
F. Four representatives appointed by the Executive Director to represent persons licensed as a medical or retail marijuana cultivation or products manufacturer;
G. One representative appointed by the Executive Director of the Department of Public Health and Environment, in consultation with the Commissioner of Agriculture, who is an attorney with expertise in the regulation of Industrial Hemp;
H. One representative appointed by the Executive Director of the Department of Public Health and Environment, in consultation with the Commissioner of Agriculture, to represent hemp refiners;
I. One representative appointed by the Executive Director to represent a consumer nonprofit organization;

[2] Colorado General Assembly, SB22-205 Bill Summary
[3] *[Suggest adding link to Task Force Announcement with list of TF Members]*

J. One representative appointed by the Executive Director of the Department of Public Health and Environment, in consultation with the Commissioner of Agriculture, to represent full spectrum industrial hemp producers;

K. One representative appointed by the Executive Director to represent medical patients;

L. Two representatives appointed by the Executive Director of the Department of Public Health and Environment, in consultation with the Commissioner of Agriculture, to represent persons who sell hemp at retail;

M. Two representatives appointed by the Executive Director to represent persons licensed under Article 10 as a Medical or Retail Marijuana Store;

N. One representative appointed by the Executive Director of the Department of Public Health and Environment, in consultation with the Commissioner of Agriculture, to represent testing labs; and

O. One representative appointed by the Executive Director to represent a county or district public health agency established under section 25-1-506.

According to Senate Bill 22-205, the Task Force report must include any legislative recommendations concerning the regulation of industrial hemp, an analysis of the effectiveness of each recommendation, and rule recommendations concerning the regulation of intoxicating hemp products. See 44-10-206(2), C.R.S.

This report is founded on several core long-standing legal and policy principles that are fundamental to protecting public health and safety.

- 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 Food, Drug, and Cosmetics Act (FDCA), as well as other product safety laws and regulations.

- The Food and Drug Administration (FDA), the federal agency charged with implementing the FDCA 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 safety of hemp ingredients and establishing a regulatory pathway for hemp ingredients in consumer products, it has also failed to expand their authority on existing product safety regulations to encompass hemp products (except where products make egregious drug claims).

- Despite the FDA's failure to act, the legalization of hemp has allowed businesses to develop and innovate novel cannabinoids that are beneficial consumer products. States around the country are attempting to address regulation of these products to allow for a high standard of ~~balance~~ consumer safety while continuing to encourage development and innovation within an emerging industry.

- However, the absence of FDA enforcement also created an active market for THC-based intoxicating hemp products that may not be compliant with federal product safety standards nor are subject to state marijuana regulations. These products often have higher levels of THC than are permitted in marijuana 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 low THC cannabis plants 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 significant confusion by consumers, regulators, and enforcement agencies. 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 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.. To draw a comparison with another federally legal intoxicating substance, 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 product internally or through formal approach channels prior to a products introduction into the market and not the government's job to prove that something is unsafe unless it is challenging that company's determination.

Industrial Hemp Legal Authority

[Initial agency draft below - subject to ongoing review, discussion, and development]

I. Background and history of Industrial Hemp in Colorado

Colorado citizens voted to pass Amendment 64 in 2012 that made us the first state to legalize hemp and engrave it in our Constitution. The General Assembly enacted legislation in 2013 and delegated CDA with responsibility for most hemp-related registration and inspection oversight. Statutory authority for Colorado's Industrial Hemp Program appears in § 35 - 61 C.R.S.

The 2018 Farm Bill legalized hemp to be produced in the U.S., amended the Controlled Substances Act (CSA) to remove hemp from the definition of marijuana. The legislation allowed commercial cultivation of hemp and effectively replaced the 2014 Farm Bill pilot projects. Under the 2018 Farm Bill, each state must submit a plan to the USDA for approval that includes a framework for regulation and monitoring of production. The USDA issued its Interim Final Rule in October of 2019 addressing hemp cultivation, harvest, and testing. The rule, however, puts lots of hardship on producers and states implementing the program. In January of 2021, the USDA published a Final Rule which has made several changes from the IFR where many of those changes aligned with the comments submitted by the State of Colorado.

Colorado has submitted its first State Plan based on the IFR on June 18, 2020 and later submitted the final State Plan on June 1, 2021. The State Plan was officially approved by USDA on July 15, 2021.

II. Hemp Advisory committee

The Industrial Hemp Advisory Committee was established in 2013 with § 35-61-103. The Industrial Hemp Act, specifically § 35-61-103 (Industrial hemp advisory committee- -appointments- -duties--coordination with commission) was amended on September 14, 2020, to include appointment of all 10 positions of the HAC by the Agricultural Commision ("Ag Commission") rather than the State Legislature. Members appointed to a position serve for a period of 3 years with appointments staggered to maintain continuity. Members of the Committee include representatives from hemp regulation, farmer from a cooperative, a commercial farmer, seed development and genetics, hemp manufacturing, hemp small business, citizen advocate for hemp, cannabinoid industry, certified seed growers, and research & development from an institution of higher learning. The Committee meets with CDA on a quarterly basis.

III. Rule making authority

CDA promulgated a comprehensive set of rules to administer and enforce the Colorado Industrial Hemp Regulatory Program Act § 35 - 61 C.R.S. which is enabled by the regulations in 8 CCR 1203-23 at the end of 2013. The rule was constantly revised a total of seven times prior to the 2018 Farm Bill showing the dynamic nature of the crop and the need to address several aspects of cultivation. CDA is the first agency in the state of Colorado to regulate Industrial Hemp and it is the second state to do so in the nation.

IV. Scope and focus of the CDA Hemp program

The Colorado Department of Agriculture's Hemp Program regulates only the cultivation of hemp. The Department also administers a certified seed program. CDA transitioned the certified seed program to CSU in 2021 while still retaining administrative oversight. Major components of the program include registration, reporting, inspection, sampling, testing, and enforcement. The Department issues commercial and research & development registrations for any individual or legal entity to grow Hemp on a Registered Land Area. Registrants are required to submit planting and harvest reports along with other documents in a timely manner. Inspections are conducted randomly and by risk with CDA inspectors to ensure

compliance with the rules and regulations. CDA's Biochemistry laboratory analyzes samples collected by CDA staff. All lots of hemp are sampled prior to harvest by CDA Authorized Samplers and tested by a Hemp Testing Lab certified by the Colorado Department of Public Health and Environment. Additionally, CDA enforces the Hemp Act and Rules including negligent and culpable violations.

Industrial Hemp Products Legal Authority

[Initial agency draft below - subject to ongoing review, discussion, and development]

I. Brief History of Hemp Products in Colorado

While the federal farm bill and Colorado legalized the cultivation of industrial hemp as a crop in 2014 and 2015 respectively, neither legislation legalized the production of industrial hemp products such as food and dietary supplements. In 2017, the Colorado Department of Public Health and Environment (CDPHE) implemented a policy allowing for the production of industrial hemp products with specific requirements for the sourcing of the industrial hemp and other ingredients, labeling, and potency testing, along with the requirements to register as a Wholesale Food Manufacturer under the provisions of § 25-5-426, C.R.S.

In 2018, the Colorado legislature modified the *Colorado Pure Food and Drug Law* by passing legislation (HB 18-1295) that allowed hemp as an ingredient in food, dietary supplements, and cosmetics. In 2019, legislation (SB 19-240) was passed, which standardized the fees paid by industrial hemp manufacturers to CDPHE to be one hundred dollars for an application fee and three hundred dollars as a registration fee, and clarified that counties or municipalities could not adopt additional or conflicting "food production" requirements for industrial hemp manufactures within their jurisdictions.

In 2019, CDPHE participated in the Colorado Hemp Advancement & Management Plan (CHAMP) initiative, specifically engaged in the manufacturing, processing, and testing stakeholder groups. An output of that initiative was to, through a stakeholder process, determine and adopt specific requirements for the hemp industry based on some of the industry uniqueness these products present.

In May of 2021, CDPHE issued a policy statement to the hemp industry prohibiting the chemical modification or conversion of any naturally occurring cannabinoids from industrial hemp. The policy considers such modification as non-compliant with the statutory definition of "industrial hemp product." This included any process that converts an industrial hemp cannabinoid, such as CBD isolate, into delta-9 THC, delta-8 THC, delta-10-THC, or other tetrahydrocannabinol isomers or functional analogs.

II. CDPHE Rulemaking Authority

CDPHE has been the long-standing agency with regulatory responsibility over the production of food, dietary supplements, and cosmetics under sections 25-5-401 *et.seq*., C.R.S. With the passing of HB 18-1295 and the allowance of hemp as an ingredient in a food, dietary supplements, or cosmetics, existing statute sections, 25-5-420(1) and 25-5-421(1)(a), C.R.S., respectively provide for the authority to both develop regulations for the enforcement of the *Colorado Pure Food and Drug Law* and for inspections of those facilities/operations subject to the statute and regulations, including operations engaged in the production of industrial hemp products. Additionally, SB 22-205 in section 25-5-426(4)(e), C. R.S., provided for:

"In addition to any powers listed in this section, the department may promulgate rules to prohibit, within final product made available for sale, the chemical modification, conversion, or synthetic derivation of intoxicating tetrahydrocannabinol isomers, including delta-8, delta-9, and delta-10, or other intoxicating tetrahydrocannabinol isomers that originate from industrial hemp or may be synthetically derived."

CDPHE has also been the long-standing agency with regulatory responsibility over chemical, bacteriological, and biological laboratories under section 25-1.5-1(f), C.R.S. Under this authority, the Department has established regulations for hemp testing laboratories, *Hemp Testing Laboratory Certification* 5 CCR, 1005-5.

III. Regulated Hemp Product Manufacturer Registration Structure

Hemp product manufacturers are required to obtain a *Colorado Wholesale Food Manufacturers Registration*, § 25-5-426(4)(a), 4(b)(IV), C.R.S. Registrations are renewed annually each July.

IV. Regulated Hemp Product Rules

In Colorado, all regulated hemp products are subject to the *Colorado Wholesale Food, Industrial Hemp and Shellfish Regulations* 6 CCR 1010-21 (Hemp Rules). These regulations are an incorporation by reference of the 21 Code of Federal Regulations (C.F.R.) parts 100-111, 113-170, and 172-190. Specifically, Part 111, *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements* and Part 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Prevention Controls for Human Food*. Additional specific requirements for testing, labeling, record keeping, waste management, and transportation were added for hemp product manufacturers to address the unique aspects associated with these products. Additional potentially relevant requirements and restrictions are summarized below.

- Tax Requirements: Industrial hemp products are subject to the general state sales tax of 2.9% plus applicable local sales taxes.
- Tracking Requirements: While tracking requirements of seed-to-sale are not applicable to hemp products, hemp manufacturers are required by 6 CCR 1010-21, section 21.7(G)(4) to use a code or numbering system for tracking, recalls and trace forward/trace back activities.
- Testing Requirements: The rules require hemp product manufacturers to comply with testing processes and standards including but not limited to required testing for all hemp products. All hemp products are subject to the following testing categories: microbials, mycotoxins, residual solvents, heavy metals, pesticides, and cannabinoid concentration. Test results must be documented via certificate of analysis and may be required on the label. Testing must be performed by a CDPHE-certified laboratory in accordance with 5 CCR 1005-5.
- Manufacturing and Processing Requirements: The Hemp Rules require hemp product manufacturers to follow all the requirements imposed on manufacturers of traditional foods or dietary supplements, along with additional testing, labeling, and waste management requirements. Operations manufacturing only "unfinished industrial hemp product" as defined by 6 CCR 1010-21 21.4(24) must be registered with the Department and can only transfer the product to another industrial hemp product manufacturer registrant.
- Packaging and Labeling Requirements: Hemp manufacturers are required by 6 CCR 1010-21, section 21.7(G)(2-6) to label products in accordance with the 21 CFR 101 "*Food Labeling*" subparts A-G and to ensure labels identify, in milligrams, the THC content or any isolated

Commented [3]: @CDPHE: Should we not also reference the Approved Source requirements -- that hemp manufacturers must obtain their input materials from lawful sources?

Commented [4R3]: @jeff.lawrence@state.co.us @heather.krug@state.co.us

cannabinoid content per serving and per container, or when using a broad of full spectrum product identify the total amount in milligrams. In addition, hemp manufacturers must also comply with a patchwork of state regulations, each with a wide-range of varying requirements for labeling, warnings, testing, registration, technical definitions, and product controls, among others. As with marijuana products, labeling or packaging cannot make any misleading or false statements, or make any claim about health, physical benefits, or that the product is intended to diagnose, cure, mitigate, treat, or prevent disease.

- Sales Requirements and Limitations: Not applicable to hemp products. Unlike marijuana which is sold on an intrastate basis, only in state-licensed dispensaries, hemp products are widely sold throughout the country, and are frequently found on the shelves of grocery stores, pharmacies, dietary supplement stores, gas stations as well as direct-to-consumer via the internet. There are also generally no age restriction requirements.

Regulated Marijuana Legal Authority

[Initial agency draft below - subject to ongoing review, discussion, and development]

I. Brief History Regulated Marijuana in Colorado

In 2000, Colorado voters passed Amendment 20 to the Colorado Constitution, creating an affirmative defense for the use of medical marijuana and thereby allowing the production, possession, and use of medical marijuana. *See* Colorado Const. Art. XVIII, sec. 14. Nearly a decade later, in 2010, the General Assembly adopted the Medical Marijuana Code, sections 12-43.3-101 *et seq.*, C.R.S., and charged the Department of Revenue Medical Marijuana Enforcement Division with regulation and enforcement. The Department of Revenue Medical Marijuana Enforcement Division, in response, adopted the initial Medical Marijuana Rules at 1 CCR 212-1.

In 2012, Colorado voters passed Amendment 64 to the Colorado Constitution, which legalized the possession of marijuana and created a commercial marijuana market. *See* Colorado Const. Art. XVIII, sec. 16. Amendment 64 also mandated that industrial hemp and marijuana be regulated separately. The following year, in 2013, the General Assembly adopted the Retail Marijuana Code, section 12-43.4-101 *et seq.*, C.R.S., and charged the Department of Revenue Marijuana Enforcement Division ("MED")[4] with the regulation, licensing, and enforcement of commercial marijuana businesses and the individuals working within those businesses. The MED, in response, adopted the initial Retail Marijuana Rules at 1 CCR 212-2. In 2014, the Department of Revenue MED began issuing commercial marijuana business licenses, owner licenses, and employee licenses.

In 2019, following an extensive sunset review, the General Assembly consolidated the Medical Marijuana Code and Retail Marijuana Code into a single Colorado Marijuana Code, sections 44-10-101 *et seq.*, C.R.S. ("Marijuana Code"), bringing the codes into as much alignment as possible between medical marijuana and retail marijuana. In response, the Department of Revenue MED consolidated the existing medical marijuana rules and retail marijuana rules into a single rule series - the Regulated Marijuana Rules at 1 CCR 212-3 ("Marijuana Rules").

In May of 2021, the MED issued Industry Bulletin 21-07 regarding the production/use of chemically modified or synthetically derived THC isomers from industrial hemp precursors. The bulletin responded to inquiries the MED received from stakeholders and licensees and clarified that industrial hemp

[4] The Medical Marijuana Enforcement Division was adapted into the Marijuana Enforcement Division.

product is not permitted to be further processed or extracted either before or after inclusion in a marijuana product, including processes to convert industrial hemp product, such as CBD isolate, into delta-9 THC, delta-8 THC, delta-10-THC, or other tetrahydrocannabinol isomers or functional analogs. The bulletin further reminded licensees that before taking possession of an industrial hemp product the licensee must verify the industrial hemp product passed all required tests.

II. State Licensing Authority Rulemaking Authority

The State Licensing Authority was created for the purpose of "regulating and controlling the licensing of the cultivation, manufacture, distribution, sale, and testing of regulated marijauna." § 44-10-201(1)(a), C.R.S. The legislature further delegated to the State Licensing Authority the power to promulgate rules for the proper regulation and control of the cultivation, manufacture, distribution, sale, and testing of regulated marjuana and regulated marijuana products and for the enforcement of the Marijuana Code. § 44-10-202(1)(c), C.R.S. This rulemaking authority is divided into permissible rulemaking, which may be undertaken, and mandatory rulemaking, which must be accomplished. § 44-10-203(1) and (2), C.R.S. The State Licensing Authority also has the discretion to make rules on "such other matters that are necessary for the fair, impartial, stringent, and comprehensive administration" of the Marijuana Code. § 44-10-203(k), C.R.S.

III. Regulated Marijuana Business Licensing Structure

Regulated marijuana businesses must obtain licenses from both the state and the local jurisdiction where the business intends to operate. § 44-10-313(2)(a) and (b), C.R.S. There are seven (7) types of medical marijuana business licenses: medical marijuana store, medical marijuana cultivation facility, medical marijuana product manufacturer, medical marijuana testing facility, medical marijuana transporter, medical marijuana business operator, and medical marijuana research and development. § 44-10-401(2)(a), C.R.S. Conversely, there are eleven (11) types of retail marijuana business licenses: retail marijuana store, retail marijuana cultivation facility, retail marijuana product manufacturer, retail marijuana testing facility, retail marijuana transporter, retail marijuana business operator, accelerator cultivator, accelerator manufacturer, marijuana hospitality business, retail marijuana hospitality and sales business, and accelerator store. § 44-10-401(2)(b), C.R.S. Owners and employees that work directly with marijuana or the inventory tracking system must also obtain an individual license. § 44-10-313(4), C.R.S.

IV. Regulated Marijuana Product Rules

In Colorado, all regulated marijuana is subject, under the Colorado Constitution, the Colorado Marijuana Code and the tax statutes in Title 39 to taxation, tracking, and testing, in addition to other requirements intended to protect the public health and safety and prevent diversion of marijuana. Colo. Const. Art. XVIII sec. 16(5)(a); § 44-10-203, C.R.S.; § 39-28.8-101, C.R.S., *et seq.*

- Tax Requirements

Medical Marijuana is subject to Colorado's standard 2.9% retail sales tax. Retail (adult use) Marijuana is subject to a retail marijuana special sales tax and a retail marijuana excise tax. §§ 39-28.8-202 and 39-28.8-302, C.R.S. Retail marijuana sales tax is imposed upon every sale of retail marijauna and retail marijuana products at a rate of fifteen percent. § 39-28.8-201, C.R.S. Retail marijuana excise tax is collected on the first sale or transfer of unprocessed retail marijuana from a retail marijuana cultivation facility to a retail marijuana products manufacturer to another retail marijuana business, such as a retail marijuana store

or retail marijuana hospitality and sales business, at the rate of fifteen percent of the average market rate[5] of unprocessed retail marijuana if the transfer is between affiliated retail marijuana business licensees. § 39-28.8-302(1)(a)(I), C.R.S. If the sale or transfer is between unaffiliated retail marijuana businesses then the rate is fifteen percent of the contract price for unprocessed retail marijuana. § 39-28.8-302(1)(a)(I), C.R.S.

- Tracking Requirements

The Marijuana Code and Marijuana Rules require that regulated marijuana be tracked from seed-to-sale, meaning marijuana must be tracked from either the seed or immature plant stage until the regulated marijuana is sold to a patient through a medical marijuana store, or to a customer through a retail marijuana store or a retail marijauna hospitality and sales business. The tracking of marijauna from seed-to-sale by use of an inventory tracking system is required to ensure that regulated marijauna is not sold or otherwise transferred outside of the regulated marijuana industry licensed in Colorado.

- Testing Requirements

The rules require regulated marijuana testing facilities to comply with testing processes and standards including but not limited to standards for testing category certification and required testing for all regulated marijuana. All regulated marijuana is subject to the following test categories: microbials, water activity, mycotoxins, residual solvents, elemental impurities, pesticides, and potency. Test results must be documented in the inventory tracking system and may be required on the label.

- Manufacturing and Processing Requirements

The Marijuana Rules impose restrictions on product manufacturers addressing permitted and prohibited manufacturing processes and testing requirements. In accordance with section 44-10-203, the Marijuana Rules prohibit certain solvents, ingredients and additives from being used in the manufacturing process. Further, the rules mandate how test samples are created and transferred to regulated marijuana testing facilities and how products are packaged and transferred to stores for sale.

- Packaging and Labeling Requirements

The Marijuana Rules have specific packaging and labeling requirements for transfers between Regulated Marijuana Businesses, transfers to marijuana testing facilities and transfers from a Regulated Marijuana Business to a consumer or patient. All transfers from a Regulated Marijuana Business to a consumer or patient must be in a child resistant container or exit package. All packages must comply with labeling requirements, which include that they may not make any misleading or false statements, or make any claim about health or physical benefits.

- Sales Requirements and Limitations

There are several requirements and limitations related to sales of regulated marijuana and which vary depending on whether the marijuana is medical or retail. Foremost, retail marijuana may only be sold to a customer who is 21 years of age or older and medical marijuana may only be sold to an individual registered with the Department of Public Health and Environment as a medical marijuana patient. Retail marijuana purchases are limited to 1 ounce of retail marijuana or 100 milligrams of THC for retail marijuana products. A single serving size of retail marijuana product may not exceed 10 milligrams of THC.

[5] The average market rate (AMR) is established by the Department of Revenue Taxation Division.

Task Force Recommendations

Definitions

Commented [5]: align with order of index of definitions

- Total THC
-
- Potentially Intoxicating Compound
- Synthetic cannabinoid
- Novel cannabinoid
- Serving size *CDPHE addressing/making this recommendation

Changes in terminology:

- Potentially Intoxicating Compound: We recommend defining the term "Potentially Intoxicating Compound." Such term should be defined to capture potentially intoxicating cannabinoids, as well as other potentially intoxicating constituents of hemp, when isolated and/or synthesized to create a distinct "article" with the intent to use such article as an ingredient. Certain cannabinoids are likely to be intoxicating at certain levels; similarly, research is scarce as to the intoxicating potential of other compounds derived from hemp, when isolated and/or synthesized and concentrated into a distinct "article." The law should direct the agencies [and standing scientific committee] to evaluate such Potentially Intoxicating Compounds as more scientific research and data becomes available. The law should define a standard for intoxication and that standard should be applied to isolated, synthesized cannabinoids or other compounds which are distinct "articles," and should specifically exclude (i) [Non-Intoxicating Cannabinoids] and (ii) cannabinoids or compounds when comprising a naturally derived full spectrum hemp extracts or broad spectrum hemp extracts.

- Total THC: We recommend the final definition of Total THC be left to regulation. As we have seen, the calculation for total THC will need to be adjusted as science evolves and amended more quickly than statutory changes allow. Further, federal legislation and/or regulation or enforcement guidance may impact this definition in the future. A regulatory definition will allow for more flexibility as we continue to learn about THC and as relevant federal regulation evolves.

- Serving size: CDPHE to address this recommendation for definition based on existing consumer protection laws and federal regulations

- Synthetic Cannabinoid means a cannabinoid like compound that was produced using chemical synthesis, chemical modification, or chemical conversion (including in-vitro biosynthesis and bioconversion) of any method or type except for those produced through the decarboxylation of natural occurring cannabinoids from their acidic form.

- Novel Cannabinoid means any cannabinoid that has not been assessed by MED/CDPHE, or CDPHE in coordination with MED for safety and intoxication profiles.

Commented [6]: DRAFTING NOTE (from Christian Sederberg during 12/7 TF meeting): I am wondering how this change in definition impacts the rest of the framework if we do a "find and replace"

Commented [7]: @jeff.lawrence@state.co.us _Assigned to Jeff Lawrence - CDPHE_

Classification of Cannabinoids:

The Task Force recommends that the legislature create classifications of cannabinoids (and other cannabis-derived compounds) to distinguish under what circumstances, if any, such cannabinoids and compounds may be used in manufacturing of Industrial Hemp Products.

Such classifications are recommended to include:

1. Non-Intoxicating Cannabinoids
2. Potentially Intoxicating Compounds
3. Intoxicating Cannabinoids

Non-Intoxicating Cannabinoids

The Task Force recommends these cannabinoids may be freely used as ingredients in the manufacture and sale of Industrial Hemp Products, in accordance with the potency and other requirements recommended herein and as required by CDPHE.

Such hemp derivatives and cannabinoids, including their acid forms and varin analogs, include:

- Full spectrum hemp extract
- Broad spectrum hemp extract
- Cannabidiol (CBD)
- Tetrahydrocannabivarin (THCV)
- Cannabichromene (CBC)
- Cannabicitran (CBT)
- Cannabicyclol (CBL)
- Cannabielsoin (CBE)
- Cannabigerol (CBG)
- Cannabidivarin (CBDV)
- Cannabinol (CBN)

Potentially Intoxicating Compounds:

The Task Force recommends these cannabinoids shall not be allowed to be manufactured within Colorado or incorporated into Industrial Hemp Products for sale within Colorado, except as provided for in the Safe Harbor provisions hereof (if at all), unless and until these cannabinoids are further assessed by the MED/CDPHE [and a standing scientific committee]:

- Novel Cannabinoids which are not already deemed Non-Intoxicating Cannabinoids
- Non-phytocannabinoids

Intoxicating Cannabinoids:

The Task Force recommends these cannabinoids shall not be allowed to be manufactured within Colorado or incorporated into Industrial Hemp Products for sale within Colorado, except as provided for in the Safe Harbor provisions hereof (if at all), unless and until these cannabinoids are further assessed by the MED/CDPHE [and a standing scientific committee]:

- Delta-10 tetrahydrocannabinol and isomers;
- Delta-9 tetrahydrocannabinol and isomers;
- Delta-8 tetrahydrocannabinol and isomers;
- Delta-7 tetrahydrocannabinol and isomers;
- Delta-6a, 10a tetrahydrocannabinol and isomers; and
- Exo-tetrahydrocannabinol
- Metabolites of THC including but not limited to:
    - 11-hydroxy-THC
    - 3-hydroxy-THC
    - 7-hydroxycannabidiol
- Hydrogenated forms of THC including but not limited to:
    - HHC
    - HHCP
    - THCH
    - HHCH
    - H4CBD
- Synthetic forms of THC including but not limited to:
    - Dronabinol
- Ester forms of THC including but not limited to:
    - Delta-8 THCO-acetate
    - Delta-9 THCO-acetate
    - HHC-O-acetate
- Varin forms of THC including but not limited to: (Excluding Delta-9-THCV)
    - Delta-8-THCV
- Alkyl analogues C4 or higher including but not limited to:
    - Delta- 8 THCP,
    - Delta-9 THCP,
    - Delta-8 THCJD,
    - Delta-9 THCJD,

- Delta-8 THCH,
- Delta-8 THCB
- Delta-9 THCB

Please note, there are dissenting opinions to this Task Force recommendation, available in the Dissenting Opinion Index.

Dissent of Kyle Ray (pg. XX)

THC in Hemp Products

Colorado should enact limits on the milligrams of THC that are permissible for hemp products based on existing safety data. These limits should be low enough to effectively prohibit the sale of intoxicating products to the public to address the public safety issues that they present. Potential limits to be established in two phases:

- Initially, THC limits should be set high enough to avoid unintentionally capturing non-intoxicating hemp products and provide producers of non-intoxicating products with sufficient notice to comply with approvals for THC levels after those regulations have been finalized.

- Subsequently, the limits should be more conservative and prohibit products that would reasonably be assumed to be intoxicating. These new limits should only be imposed after the MED/CDPHE, or CDPHE in coordination with MED, finalize regulations that create approvals and a reasonable transition period. MED and CDPHEshould have rulemaking authority to ~~i~~amend~~impose~~ the proposed limits to serving size and containers ~~and containers~~ as well as ratios of Non-intoxicating Cannabinoids to Intoxicating Cannabinoids (i.e. CBD:THC)~~.~~ ~~allowing~~ ~~legislators~~~~them~~ along with making~~to~~ other timely changes to regulations based on evolving science to be protective of public health.

- Those initial limits would be included in statute, with a regulatory authority for MED/CDPHE, or CDPHE in coordination with MED to adjust~~lower~~ those limits based on scientific findings on intoxication levels of intoxicating cannabinoids.

- Notably, full spectrum hemp products will often contain at least 1.0 - 2.0 mg THC per serving, but are rendered non-intoxicating given the ratio considerations noted below.

- Dietary supplements – including tinctures, capsules and other similar product types – are normally and conventionally sold across the country in volumes exceeding 30-60 servings per container. Restricting non-intoxicating hemp products to container limits comparable to marijuana products (i.e. 10 servings per container) would adversely impact hemp companies in

Commented [8]: Please link to dissent at end of document.

Commented [9]: 12/14 TF Meeting Note - Agencies agreed to review this section to inform further refining of this language to ensure appropriate guardrails and authority + overall transparency and expectations on approach. @jeff.lawrence@state.co.us @heather.krug@state.co.us @allison.robinette@state.co.us @dominique.mendiola@state.co.us

Commented [10]: I do not believe this was the consensus of the task force. I believe the conclusions related to serving size limits and ratios, but not container limits.

Commented [11R10]: Container limits need to be in there. Serving size alone doesn't do much.

Commented [12R10]: We should work to separate task force recommendations from a broader understanding of the bill that will be introduced. Once legislation or proposed bills are introduced, we recognize further discussion on this point can arise. Truman, we can work to understand where this statement can be made either in this section or elsewhere in the report.

Commented [13R10]: I'm striking this for the same reasons as my prior comments.

Commented [14]: Suggest agencies instead of legislators- see previous comment

Commented [15R14]: Agree. With standing scientific committee?

Commented [16]: Adjustments should be based on science, and legislators/regulators should have the ability to make those adjustments, not be constrained to a specific outcome.

Commented [17R16]: We would like to see the language stay the same at lower.

Commented [18]: Suggest replacing are with "may be"

reconfiguring packaging and being unable to create universal packaging and labeling for products sold throughout the country. Given there are not purchase limits on hemp products, any container limits would also be easily circumvented by consumers simply purchasing additional units.

- There has been initial scientific evidence presented to the task force indicating that the intoxicating effect of THC is mitigated and counteracted when combined with substantial potencies of CBD – such evidence indicates a ratio of 15:1 CBD:THC may be an appropriate standard to guard against intoxication. This ratio requirement would prevent the ability for manufacturers to incorporate isolated and highly potent THC, with little to no CBD, to create a product intended to intoxicate consumers.

- Given the foregoing considerations concerning potency limits of THC per serving when coupled with the foregoing ratio considerations, and the foregoing considerations concerning potential container limits, the Task Force recommends that a milligram potency limit *per serving* coupled with a CBD:THC ratio is currently sufficient to guard against intoxicating hemp products from being sold within Colorado and no container limit is recommended at this time. Moreover, the task force recommendations give the agencies the tools necessary to adapt and change regulations, if needed.

- With respect to initial limits, the Task Force recommends that the legislature adopt the following standard for finished hemp products to be sold in Colorado:
  - No greater than 2.5 mg THC per serving; *AND*
  - The formulation shall contain a ratio of CBD:THC of greater than or equal to 15:1 CBD:THC;
  - The foregoing limitations do not apply when a finished hemp product exclusively contains one or more Non-Intoxicating Compounds~~annabinoids~~ (i.e. CBD isolate; CBG isolate; CBN isolate); provided, however, that CBN shall be restricted to no more than 25 milligrams per serving;
  - No container limits; ~~with regulatory authority to CDPHE on the issue.~~
  - Non-intoxicating compounds do not need to meet these requirements. Hemp products that contain only non-intoxicating compounds are not subject to these limitations. It is also important to note that the definition of THC includes all of its isomers. Hemp companies will also be able to use other potentially intoxicating compounds if they can prove that those products are considered non-intoxicating by review of the standing scientific committee.

Note:

- All these limits would be applicable to finished products in addition to the federally established 0.3% standard applicable to hemp's exemption from the controlled substances act (or hemp's status as a legal agricultural crop and not a controlled substance).

- Additionally, the state should clarify and promote awareness of the existing state and local laws and requirements for businesses in general. There are requirements already in place today that apply to different businesses, regardless of any recommendations made by this Task Force or other legislative or regulatory actions that, if enforced, would help address many of the active public safety issues.

Commented [19]: Perhaps we can note a dissenting opinion here?

Commented [20]: Easiest way to do this is probably just make it comply with the definition of broad spectrum, i.e. under 0.01% THC.

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Commented [21]: May already be in here somewhere else, but we should have a recommendation for a scientific committee to assist regulators

Commented [22R21]: John: see Action Item 6 below. Does still need resolution.

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- For example, companies that work with solvents currently must undergo a construction permit and an air permit process. Existing divisions of CDPHE, such as the air pollution control division (APCD – link here) are already responsible for making those assessments and have processes in place, including exemptions for small businesses. It is pertaining to public health that vapors from solvents are addressed to ensure employee safety, which is why these rules are in place.

Please note, there are dissenting opinions to this Task Force recommendation, available in the Dissenting Opinion Index.

Dissent of Truman Bradley (pg. XX)

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Labeling and Marketing Recommendations

The Task Force recommends that the legislature should direct CDPHE, in coordination with MED, to promulgate regulations for labeling Industrial Hemp Products which distinguish those products which contain synthetic/synthesized cannabinoids from those which only contain naturally occurring cannabinoids.

The Task Force further recommends that Industrial Hemp Products shall not be marketed as, or promoting, containing THC or other Potentially Intoxicating Cannabinoids. Notwithstanding the foregoing, the Task Force recommends that CDPHE promulgate regulations requiring a notice statement (versus a warning statement) that such product includes THC and other Potentially Intoxicating Compounds. Nothing herein shall preclude manufacturers from including potency and other required disclosures of content of THC and Potentially Intoxicating Cannabinoids.

Approval of Certain Non-Intoxicating Hemp Products

The MED/CDPHE, or CDPHE in coordination with MED shall create a process whereby manufacturers of Industrial Hemp Products that exceed permissible levels of THC or other intoxicating compounds can obtain approval for sale in Colorado, based upon a reasonable determination that the product is safe and non-intoxicating. This process should be based upon FDA standards, prioritizing those most important aspects to protect public health and safety, including information such as:

- Product form and method of consumption/delivery;
- A description of the manufacturing process;
- Whether the product's manufacturing process alters the cannabinoid profile from the natural plant;

- Evidence demonstrating that the product will not cause intoxication~~, including for minors,~~ based upon legitimate scientific evidence about the products method of consumption and cannabinoid profile;

- Whether the product has a GRAS or self-GRAS determination or similar safety studies that would be deemed by public health experts as sufficient to demonstrate that a product is safe for consumption; and

- Marketing, testing, and labeling information relating to the product.

Additionally, the producers would be able to provide information for the MED/CDPHE's~~Division's~~ consideration outside the narrow scope of requirements. The MED/CDPHE ~~Division~~ would also consider information submitted by other applicants, creating efficiency and increased opportunity. Finally, statute should expressly exempt the information submitted pursuant to this process from CORA requests and should be further subject to C.R.S. 6-1-111(2).

Note: There are many existing state and local laws and regulations specific to hemp products and applicable to all foods and dietary supplements that would help mitigate existing risks to public safety if enforced appropriately. Compliance with these laws and regulations to the extent possible should be expected until more narrowly tailored processes are developed, including compliance with process safety, product safety standards like cGMP and other consumer protection laws.

Standing Scientific Committee

The Task Force recommends that the legislature consider (i) a newly established standing scientific committee or (ii) an expansion of scope of an~~the~~ existing committee, such as the Retail Marijuana Public Health Advisory Committee, where such committee is enabled to assist the agencies in the ongoing evaluation of scientific data and research related to cannabinoid research and the evaluation of cannabinoids for their safety profiles and intoxicating potential of cannabinoids, including the appropriate classification of cannabinoids (based on the classifications recommended herein). Such standing scientific committee should be primarily comprised of representatives of academia stakeholders as well as representatives of industry stakeholders and applicable regulatory agencies.

Assessment of Novel Cannabinoids

The MED/CDPHE, or CDPHE in coordination with MED will establish a process for the assessment of ~~n~~Novel Ceannabinoids to determine whether they are non-intoxicating when consumed~~safe for consumption or cause intoxication~~. Novel Ceannabinoids determined to be:

- N~~Safe and~~ non-intoxicating shall be considered a permitted ingredient in food, dietary supplements, and other hemp products in Colorado.

- Potentially ~~unsafe or~~ intoxicating compounds (at certain~~)~~ dosages) will be treated similarly to THC and may be used as a permitted ingredient provided it falls below established levels or meets the standards set forth in the approval process.

Commented [24]: Ethically this seems impossible, no one is going to OK studies to see if/when children get high, particularly since they're still developing. Moreover the other proposed controls on retail sales should ultimately fix this issue

Commented [25]: Suggest striking this. Otherwise we may need to vote on which regulatory body should run point.

- Intoxicating compounds: ~~Unsafe~~ at any level will be prohibited entirely as ingredients, unless otherwise approved in individual instances by companies. Through the approval process, companies can show that a product is not intoxicating in its totality.

In complementing the policy recommendations, the T~~t~~ask F~~f~~orce recommends that the legislature give authority to the agencies [and standing scientific committee] to establish an assessment process for individual products, I~~i~~ntoxicating C~~c~~ompounds and N~~n~~ovel C~~c~~annabinoids. ~~Policy framework:~~

- The process here should follow standards for ingredients in food and dietary supplements established by the FDA, which are consistent with the topics outlined in the approval process outlined above. This should include consideration of any determination of whether that cannabinoid has been approved as GRASs, self-GRAS, or NDIN. In addition, materials prepared in anticipation of a submission should be given due consideration because the implications of the drug preclusion act have prevented many submissions that would likely be approved from moving forward.
    - Notwithstanding the foregoing, because FDA will not presently recognize the permissibility of any cannabinoids, the agencies and standing scientific committee shall not be strictly bound to FDA standards in evaluating such compounds, although the integrity of such standards should certainly be maintained as best as possible without FDA's direct involvement.

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- The law should commence with the initial position that those compounds deemed by the Task Force as Non-Intoxicating Cannabinoids (see Definitions section) ~~CBD, CBG, and CBC and CBNN (currently under debate)~~ should be considered ~~safe and~~ non-intoxicating under the safeguards and limitations established in this report~~.~~
    - MED/CDPHE, or CDPHE in coordination with MED, is authorized to reconsider the classification for these cannabinoids and/or ~~and~~ establish amount limitations ~~therefor~~ to ensure products containing such cannabinoids are ~~safe or~~ non-intoxicating.
    - Any reconsideration should not begin until after the establishment of regulations governing THC and the approval process outlined below.

Commented [26]: Adjust per above list/discussion.

- No N~~n~~ovel ~~c~~Cannabinoid~~,~~ ~~restrictions or~~ approvals until after the process for assessment is created.
- The division should consider relevant information from previous submissions or publicly available information that meets scientific thresholds.
- Information submitted pursuant to this section by companies should be protected from CORA

Synthetic Cannabinoids

The Task Force recommends that statutory changes should be made to ensure ~~Statute should give~~ MED/CDPHE, or CDPHE in coordination with MED, have sufficient authority to create approval processes on the production and sale of synthetic cannabinoids in Colorado. All natural and synthetic cannabinoids should be subject to the N~~n~~ovel C~~c~~annabinoids process outlined above to be assessed for safety and intoxication. Those cannabinoids determined to be ~~safe and~~ non-intoxicating should be permitted ingredients in Industrial H~~h~~emp P~~p~~roducts.

Timeline of Implementation of Framework

The Task Force recommends the following timeline would allow for both the state and companies to have enough time to build a framework, and comply with future legislation and regulations:

- Statute with initial limits and is signed by Governor by (estimated May 2023)
  - Statute mandates MED/CDPHE, or CDPHE in coordination with MED to create regulatory limits, prohibitions, and authorizations related to the recommendations in this report for THC by January 1, 2024
  - Statute mandates the MED/CDPHE, or CDPHE in coordination with MED create an approval process for ingestibleconsumable Industrial hHemp Pproducts that fall outside of those limits by January 1, 2024.
  - Statute mandates the MED/CDPHE, or CDPHE in coordination with MED create a process to assess Novel Cannabinoids, Potentially Intoxicating Compounds and Intoxicating Cannabinoids by July 1, 2024.
- MED/CDPHE, or CDPHE in coordination with MED adopts regulations for THC compound limits, other recommendations, and approval processes by January 1, 2024, but products are not required to comply with these two standards until July 1, 2024.
  - Similarly, the MED/CDPHE, or CDPHE in coordination with MED will adopt regulations for novel cannabinoids and intoxicating compounds assessment by July 1, 2024, but products would not be required to comply until January 1, 2025.

Enforcement and Education; Appropriations

Without active enforcement, the policies outlined above will not address the active and ongoing public safety issue. The Task Force recommends t~~T~~he state needs to allocate sufficient funding to enforce against in-state and out-of-state actors violating the law and placing public safety at risk. A system must be established for members of the public to report unsafe or intoxicating products, such as adverse reactions and false or misleading labeling claims. The initial funding provided to the AG's Office must be maintained and expanded upon to ensure there are staff to conduct the necessary enforcement to protect public safety. Should the AG Office recommend in the future that it needs additional funding in the

Commented [27]: Made this comment earlier, but I think we should add a sentence about non-phytocannabinoids being banned.

Commented [28]: Let's discuss this phrase?

Commented [29]: @Dominique.mendiola@state.co.us and Jeff, how do these dates look to both agencies regarding feasibility, staffing needs, etc? _Assigned to Dominique Mendiola - DOR_

Commented [30]: One staff member is hired and working on these issues. Remaining staff are being on boarded in early December.

future, the legislature should take appropriate steps to ensure such funding is allocated to continue to protect public safety.

Additionally, funding should be provided to CDPHE and MED primarily for the enforcement of these proposed regulations, as well as existing regulations, and secondarily to develop and create resources to educate Coloradans about the health risks posed by intoxicating hemp products and specific messaging for parents about the ability for youth to purchase these products online. Just like marijuana products, public messaging is essential to educate youth about the dangers posed by intoxicating hemp products and ensure they are kept away from children.

Commented [31]: I added this b/c the biggest issue is resources to increase enforcement, so I wanted to make it clear that funds should be diverted to that first, while also underscoring the importance of education and that it should not be lost or ignored in favor of diverting all resources to enforcement.

Furthermore, the Task Force believes that compliance inspections, technical assistance and when necessary enforcement are appropriate elements of this regulated industry. Current registration fees are not adequate to support the necessary compliance activities, enforcement provisions are outdated and the penalty provisions are limited and do not function as an adequate deterrent to willful non-compliance.

Though the Task Force is not equipped to determine specific penalties or funding appropriations, the Task Force supports a modernization of the enforcement provisions that align with other environmental health programs at CDPHE. Correspondingly, the Task Force recommends that CDPHE make recommendations to the legislature of the additional funding and penalties necessary to support the necessary inspections, compliance and related support, as determined by CDPHE.

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Manufacturing Safe Harbor

1. The Task Force recommends that the legislature establish a "safe harbor" for manufacturers to manufacture finished industrial hemp products which do not meet the finished product requirements required to be sold in Colorado, but which may be lawfully sold in another state. The Task Force recommends that manufacturers maintain recordkeeping in accordance with CDPHE regulations sufficient to distinguish between batches of products intended for sale in Colorado versus those intended for sale in other states.

   E.g. The Task Force recommends that a finished full spectrum hemp product sold in Colorado contain no more than 2.5 Total THC and have a ratio of greater than or equal to 15:1 CBD:THC. Conversely, the State of Minnesota allows for the sale of finished hemp products up to 5 mg THC. This safe harbor would allow for finished product manufacturers in Colorado to manufacture 5 mg THC products, which are to be sold in Minnesota, but not in Colorado.

   This safe harbor is not intended to allow for the bulk manufacturing of [Intoxicating Cannabinoids] for export to other states, except for the exception noted below. Colorado-based manufacturers may freely export approved Novel Cannabinoids, in bulk or in finished products, which Colorado deems lawful to be sold within the state.

2. As an exception to the foregoing prohibition on manufacturing Intoxicating Cannabinoids, the Task Force recommends that Colorado-based manufacturers shall be permitted to manufacture delta-8 THC and hexahydrocannabinol strictly as an in-process material for use in the process of

making a ~~Novel Cannabinoid~~Non-Intoxicating Cannabinoid (*e.g.* CBN). Such in-process material may be transferred between CDPHE-registered facilities.

a. The Task Force recommends that the legislature consider implementing requirements such as inventory tracking, surveillance, and/or recordkeeping requirements, as necessary, which exceed normal recordkeeping requirements in accordance with good manufacturing practices (GMPs) and existing CDPHE regulations, to apply to the foregoing in-process materials which exceed WIP (5% THC, as presently defined by CDPHE regulation).

3. Notwithstanding the inclusion of delta-9 THC in the classification of "Intoxicating Cannabinoids," manufacturers shall be able to manufacture hemp products which contain THC, subject to the finished products requirements (potency and ratio) set forth herein.

Please note, there are dissenting opinions to this Task Force recommendation, available in the Dissenting Opinion Index.

Dissent of Kyle Ray, pg. [x]
Dissent of Garrett Graff, pg. [X]

Commented [32]: I replaced the term here, wanted to call it out in case i'm missing some negative potential outcome

Commented [33]: @stephenmcobb@gmail.com When I went to strike the language, it struck your comment too. Adding new comment to flag newly added (a), which reflects the language that Allison Robinette had included as part of meeting minutes -- my recollection is that additional security measures were recommended, but that no one specific measure was mandated.

Commented [34]: Please link to dissents.

CONCLUSION

DISSENTING OPINIONS

DISSENT OF ALAN LEWIS

The Intoxicating Hemp Task Force has presented its consensus vision for regulation of cannabis compounds in the near term. The specific product safety and public health issues raised by synthetic and novel intoxicants have largely been settled in a way that allows Colorado entities to remain competitive within the national hemp and cannabis economy and continue to invest in innovation.

What follows is not necessarily a dissenting opinion; it lists a number of large issues that are outside the scope of the Task Force's mandate or, although discussed, were outside the capacity of an industry stakeholder group to address comprehensively.

Nevertheless, the Colorado Legislature may need to take a wider view of hemp and cannabis regulation in light of the following:

1. Federal agencies are tolerating hemp and cannabis products as long as they do not cause adverse health events. However, supportive regulation of hemp and cannabis is not forthcoming.

2. The hemp and cannabis industry must harmonize manufacturing and marketing practices with federal regulations for food and dietary supplements to avoid antagonizing federal regulators.

3. Federal regulations allow for the use of specific chemicals and chemical process to produce food ingredients. The maximum allowed residues of the allowed chemicals is often measured in parts per billion, and those ingredients usually comprise less than one percent of the finished product.

4. It will fall to individual states, in collaboration with each other, to establish a common national regulatory framework to promote interstate trade in safe products that protects public health. Colorado should lead this effort by seeking trade compacts with other states and harmonizing regulatory frameworks.

5. Previously unknown sources of cannabinoids, created using technologies such as gene editing of seeds, crops, soil, and microorganisms, are already changing the regulatory landscape and economics of hemp and cannabis. Most of what the current Task Force is solving for will have to be addressed again in the future.

DISSENT OF KYLE RAY

Summary:

1. Legislators should classify all cannabinoids as potentially intoxicating

a. Exemptions should be made for CBD, CBDA, CBG, CBGA, CBDV, CBDVA

b. Intoxication is based on dosage not specific cannabinoids

c. Recommendations must stay consistent for Delta-9 THC and other associated isomers

2. Legislators should expand the temporary manufacturing safe harbor status to include allowances for out-of-state sales for potentially intoxicating THC isomers for labs that meet the criteria outlined by the Taskforce

a. Allowances for export of potentially intoxicating THC isomers will protect public health, promote scientific research, and protect the hemp industry in the state of Colorado

b. A ban on export of potentially intoxicating THC isomers while allowances for the manufacture of these cannabinoids is tantamount to a total prohibition for the hemp industry and will result in many companies leaving the state of Colorado

Technical Analysis:

This dissenting opinion focuses on two primary points proposed by the taskforce. The first point is regarding the section titled, "Approaches to Defining and Determining Intoxication". This section states that synthetic THC isomers such as Delta 8 THC are inherently psychoactive regardless of their dose in a finished product. The taskforce recommends classifying these isomers as "intoxicating cannabinoids" when in fact intoxication is the result of dosage and I would argue that a cannabinoid cannot be "inherently intoxicating". The second point is with regards to the section titled, "Temporary Manufacturing Safe Harbor". I am in full agreeance with the requirements needed to achieve and maintain a temporary safe harbor status. I am also in full agreeance with the taskforce in that there should be allowances for the manufacture and storage of synthetic THC isomers. However, where my opinion differs is regarding the out of state sale of these synthetic THC isomers. I will argue in this opinion that creating an allowance for the export of synthetic THC isomers out of the state of Colorado will protect public health in both the short and long term while also minimizing the economic impact that these rules will have on the Colorado hemp industry.

The notion that any specific cannabinoid is inherently intoxicating is an untrue statement. Take D9 THC as an example molecule. Delta-9 THC is used in the recreational marijuana market for the purposes of creating euphoria. However, Delta-9 THC is also allowed to be sold in hemp products at lower levels than recreational marijuana products. This is because Delta-9 THC is not inherently intoxicating, it is the dosage of Delta-9 THC in the finished product that determines whether that is an intoxicating product, or a wellness product. There are many examples of hemp products that contain Delta-9 THC and are not intoxicating. Intoxication is not based on specific molecules; it is based on the dosage of specific molecules in a finished product. This is very similar to the Kombucha Market and ethanol. Ethanol is the active ingredient in beer, wine and spirits and can cause intoxication. However, kombucha contains ethanol in lower doses and is not considered to be intoxicating.

The framework proposed by the task force create serious inconsistencies that will cause significant issues if made into law. For example, with this proposed framework, a product containing 2.5mg of Delta 9 THC would be considered lawful, whereas in this same framework, a product containing 1mg of the less psychoactive cannabinoid Delta 8 THC would be considered unlawful. Even though the former product clearly contains a higher content of a more psychoactive cannabinoid than the latter example, the latter is prohibited while the former would be allowed.

Additionally, the taskforce has scrutinized the synthetically derived THC isomers for their potential for dangerous impurities. Despite the taskforce's scrutiny regarding synthetic THC isomers, they recommend an allowance of non-intoxicating synthetic cannabinoids for production and sale. The taskforce came to this conclusion because the majority of the taskforce agreed that synthesis can be done safely in a regulated environment. This proposed framework creates a path forward for synthetic cannabinoid production if it is done in a regulated environment with safety studies done on the finished ingredients. This is a tremendous step forward and I am in full support of this stance, however, there are a few issues that exist with the framework as proposed by the taskforce. Primarily, the task force recommends creating a very generous 2.5mg limit for Delta 9 THC in finished hemp products, while also prohibiting the sale of other, less psychoactive THC isomers. Where the inconsistencies get even more burdensome is the fact that the task force also recommends allowances for the manufacture, storage, and transfer of synthetic THC isomers, but would prohibit the sale of these isomers, even for export out of the state.

Finally, I want to point out that the taskforce's recommended prohibition regarding out of state sales for synthetic THC isomers will harm public health. The fact of the matter is, Delta 8 THC and its associated isomers represent a huge marketplace in the United States; the genie is out of the bottle, so to speak. As much as we would like to believe that prohibition will solve the problem, we have seen that prohibition does not work. Colorado residents and lawmakers understand that prohibition does not work, that is why we legalized marijuana in the first place and have recently legalized certain psychedelics. If we

prohibit the out of state sale of Delta 8 THC and its associated isomers, other states will continue to consume Delta 8 THC; they just will not be buying it from Colorado companies. These policy recommendations put forth by the task force do not differentiate between good actors and bad actors and as a result these policies will end up harming good actors and empowering bad actors.

For reference imagine a bad actor; this "company" makes Delta 8 THC in a garage, it does not fully remove all residual byproducts of the synthesis, it does not get third party test results to ensure purity and they have no batch records or traceability program. Now compare the bad actor to a good actor; a good actor has a fully built out GMP laboratory, has invested in equipment and infrastructure to properly purify the cannabinoid ingredient, always gets 3rd party testing results prior to shipment, and has a full traceability program with regular mock recalls. The taskforce recommendation would not make a distinction between these companies; because there is no distinction, the good actor is punished for investing into doing business the correct way and is forced to decide between shutting down their business and losing their investment or moving out of the state. The bad actor is not afraid of CDPHE enforcement because they were never registered, they do not care about new safety frameworks for synthesis proposed by the taskforce because they were never going to follow them anyways. However, because other states, such as Florida, Kentucky and Tennessee have created allowances for Delta-8 THC and its associated isomers, the demand will not decrease because the good actors are forced to shut down. Instead, the demand will remain the same and the bad actors who operate from the shadows will instead take a greater portion of the market share. This means that the potentially dangerous products being manufactured and sold by bad actors will represent a greater proportion of the Delta 8 THC products being consumed.

Instead of taking a huge step backward for the cannabis industry by recommending prohibition of certain phytocannabinoids, I advocate for a modern approach in harm reduction. Using a harm reduction model, we will empower good actors to work with regulatory agencies to create the safest possible ingredients and products for export to other states. A harm reduction approach would also place a significant emphasis on promoting safety studies and additional research on these cannabinoids. While manufacturers that meet a certain criteria to be considered "good actors" are allowed to export these synthetic THC isomers out of the state, much of the profits from this endeavor would be required to be funneled into safety studies, toxicology studies and other important scientific studies. The taskforce has recommended that companies that wish to manufacture synthetic cannabinoids in Colorado would be required to conduct safety studies on their ingredients prior to allowance for in state sales. This is very close to alignment with my proposal, however the key difference is my proposal advocates allowances for Delta 8 THC manufacturing and export out of the state. An important distinction here is that without the ability to export Delta 8 THC and its associated isomers to states that have already legalized its sale, companies in Colorado will be unable to fund these studies. All of the regulatory burdens put forth by the task force are comprehensive,

but achievable; however, the only way that a good actor in the state of Colorado will choose to stay in the state and adhere to these comprehensive regulatory burdens, is if they have the economic means to do so. Without the ability for good actors to export THC isomers out of state there will be no funds to conduct these safety studies in the first place.

If we take the prohibition approach, we will empower a black market, destroy the Colorado hemp industry, and endanger public health. If we instead decide to take a bold approach and embrace harm reduction, the good actors in Colorado's hemp industry will become nationwide leaders in the manufacture of safe synthetic cannabinoids. No approach is perfect, however, when taking into consideration public health and the economic impact this will have on Colorado; I must advocate against prohibition.

This framework in its proposed state will have the following effects:

1. Endangering public health by allowing bad actors to have greater proportion of the synthetic THC isomer market

a. Good actors will be forced to choose between losing the majority of their income and staying in Colorado or keeping the majority of their income and moving out of state

i. Good actors may also opt to shut their doors permanently

b. Bad actors will not worry about new regulations and will happily fill the void created by the exodus of good actors

c. When the good actors are destroyed by the taskforces proposed policies, there will be no scientific advancement

i. There will be no funding for these studies

ii. Bad actors will not conduct these studies

d. Ingredients that are produced by bad actors and sold out of state will be manufactured into finished products and sent back to Colorado consumers, creating public health concern at home as well as out of state

2. Mass exodus of Colorado Hemp companies resulting in a significant loss of jobs and tax income

a. The overly burdensome and inconsistent recommendations outlined by the taskforce will force hemp companies out of Colorado if they wish to stay in business

b. The synthetic cannabinoid market in Colorado represents approximately $700,000,000 worth of revenue in the state of Colorado and has created 3000 well-paying jobs for Colorado citizens according to a 3rd party economic report created by Whitney Economics

c. Much of this market share is from wholesale ingredient manufacturers exporting these cannabinoids out of the state

d. The vast majority of synthetic cannabinoids that are currently being exported out of state are synthetic THC isomers such as Delta 8 THC

3. Enforcement Nightmare created by allowances for manufacture, storage, and transfer but a prohibition on sales

a. Regulatory agencies would require significant resources to be able to create and implement a monitoring program that oversees manufacture, storage, and transfer of this material while also ensuring none is sold

My Recommended Changes and rationale:

1. Do not lump cannabinoids into three categories, non-intoxicating, potentially intoxicating and intoxicating. Instead create two categories, non-intoxicating and potentially intoxicating.

a. Intoxication is based on dosage of a cannabinoid in a finished product

i. For example, a 25mg CBN gummy is likely to be more intoxicating than a 2mg D9 THC gummy

ii. Almost all cannabinoids have the potential to be intoxicating some have a higher potential some have a lower potential

1. Create limits for all potentially intoxicating cannabinoids in the state of Colorado

a. This will allow for low dose therapeutic products that contain different THC isomers to be allowed in the wellness market, once the ingredients have been proven safe

b. Category 1: Non-intoxicating cannabinoids

i. CBD

ii. CBDV

iii. CBDA

iv. CBG

v. CBGV

vi. CBGA

c. Category 2: Potentially intoxicating cannabinoids

i. All other cannabinoids: For example,

1. THC isomers

2. CBN

3. CBT

4. CBC

ii. There are already recommended limits for Delta 9 THC, implement these limits for other THC isomers as well

2. Change the Temporary manufacturing safe harbor status to allow for the export of THC isomers

a. The Temporary manufacturing safe harbor status has robust requirements for both attaining and maintaining the status, these should remain unchanged

b. The Temporary manufacturing safe harbor status also allows for the manufacture, storage and transfer of the synthetic THC isomers

i. I propose we also allow for the sale outside of the state of these THC isomers in addition to the recommended allowance for manufacture, storage, and transfer of these THC isomers

c. As described in the above opinion, allowing for the export of these synthetic THC isomers will protect public health nationally as well as in the state of Colorado, while also protecting Colorado businesses and jobs

3. Enforcement in the current proposal will be bogged down trying to ensure that companies are not exporting ingredients out of the state. Instead, I propose that enforcement is focused on finished products coming into the state. These products are what kids can get high on, these products undermine the legal marijuana industry and promote black market businesses.

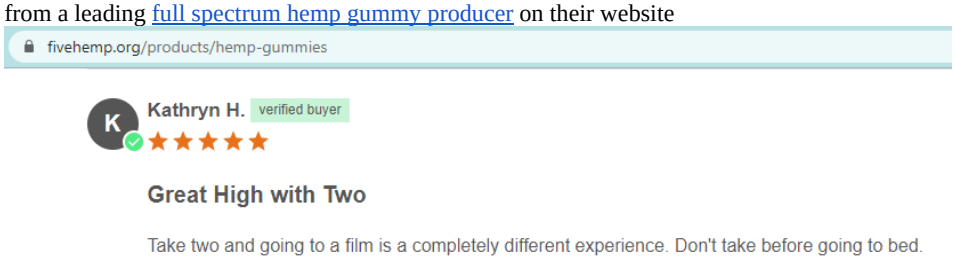
a. With an enforcement strategy that focuses on safe manufacturing of ingredients and also focuses on preventing intoxicating products to come into the state we will be protecting public health, protect marijuana business interests while also accepting the reality that prohibition does not work.

DISSENT OF TRUMAN BRADLEY

While I stand in support of virtually all of the recommendations from the SB22-205 Work Group, **I strongly oppose the work group recommendation that a maximum dosage *per unit* of up to 2.5 mg of THC be the legal limit for "non-intoxicating" THC products.** A serving size at 2.5mg threatens public safety unless sold within the regulated marijuana space, which has developed robust public safety regulations and protocols in regulating the sale of THC to the public. (See full Dissent at the end of the report)

- Public safety concerns:
  - Serving size of 2.5 mg of THC is too high to be considered "non-intoxicating"
  - There is no recommendation for prevention of sales to minors
  - There is no limit of servings per container (a 90 serving container could contain up to 225 mgs of THC, which exceeds the per container limit in retail marijuana)
  - Task force recommended "safeguards" to justify the 2.5mg are inadequate to overcome the first three points
- The sale of these products in Colorado should be regulated by MED
  - Full spectrum hemp derived THC can be produced by hemp manufacturers but should be sold through the current Colorado regulated marijuana system.
    - There is already a system in place to track potentially intoxicating cannabinoids (METRC)
  - Sales outside of Colorado should be outside the scope of this task group.
  - Products containing as much as 225 mg of THC should not be for sale to anyone without restrictions either online or in general retail outlets (e.g. convenience stores).

Public Safety: 2.5 mg of THC may be intoxicating. 10 mg certainly is.
Due to differences in enzymes present in one's liver and one's ability to process THC, some people are more sensitive to THC levels than others. *Simply put, 2.5 mg will be intoxicating for some people.* Furthermore, calling products that contain 2.5mg to be "non-intoxicating" may lead purchasers to consume more than one serving. For example, the serving size for most packaged goods is far lower than people typically consume in one sitting (e.g. Doritos). Here is a review from a leading full spectrum hemp gummy producer on their website



Further studies for intoxication need to be conducted before permitting a number as high as 2.5 mg *per piece*. In the absence of reliable data, the task group and any legislation should err on the side of caution, which 2.5 mgs greatly exceeds.

As an aside, if the task group determines that these products are "non-intoxicating" and hence safe for all, the regulations surrounding identical products from the marijuana industry should be abolished.

Public Safety: The report fails to recommend restricting sales to minors.

At 2.5mg per serving, it is absolutely critical to restrict minors from accessing these products. Even if one accepts that 2.5 mg is not intoxicating, there is broad consensus that at a minimum, 10 mg of THC is. With no limit to the number of servings per container, minors will simply be able to take a few servings to achieve an intoxicating dose. If the total container size can enable a minor to achieve intoxication, the sale of those products needs to be restricted to the regulated marijuana space.

Public Safety: A lack of recommendation for total servings per container opens a gigantic loophole to youth intoxication

Allowing minors unfettered access packages containing up to 60 servings totalling up to 150 mg of THC to be sold online, in a retail store, or worse handed to them by a FedEx delivery driver should not be acceptable in Colorado. These are available for sale now and represent a clear danger to our youth.

Public Safety: The 15:1 CBD to THC ratio is not a proven safeguard to outweigh the risks to public safety.

I have heard two arguments for the ratio: financial and "scientific." Both lack merit today.

Financial

The argument that these products are too expensive for minors to purchase them does compute. For example, a 60 count container of "Daily Buzz" gummies on fivecbd.com (12/14/22) is being sold for $53.19 (if one subscribes for monthly delivery) on their website . Under the proposed legal limit, this container could have up to 100 mg of THC, which could get 10 teenagers high at 10 mg per teenager at a cost of only $5.31 per teenager. That's already cheaper than a six pack of beer today. Furthermore, these products will get much cheaper in the years to come. The cost of producing CBD has been declining for years and will continue to become cheaper as businesses scale up and achieve common production efficiencies. *Given the costs coupled with ease of access, it is likely that hemp derived THC products will become the cheapest as well as the easiest intoxicating products for Colorado youth to obtain.*

Scientific

The studies that show that CBD has a lessening impact on THC need further research. There are no solid, independent, peer reviewed, longitudinal studies supporting the statement that a 15:1 CBD to THC ratio is not intoxicating. The reality is, we do not today have sufficient evidence to

Commented [35]: @jared.stanley2010@gmail.com I updated the example.
Assigned to Jared Stanley

Commented [36R35]: I changed the 150 mg to 100. At 25 mg of CBD/gummy under the 15:1 ratio, each gummy can have 1.66 mg of THC per gummy. 1.66 * 60 = 100. I then changed the math throughout. Please fact check. This puts the price per mg at $.53 and $5.31 per 10 mg of THC.

Commented [37R35]: Mind as well, this product would be illegal because they are marketing THC on label pack should that position hold.

Commented [38R35]: Agree that this product would be illegal for both labeling and ratio. Would changing the ratio impact the price? I guess my thought is that any legal product under the proposed ratio could have a much higher total THC per container than 100 mg. Isn't the math just # of gummies x max THC of 2.5 each? So: 30 *2.5 = 75 mg of THC, 60 = 150, and 90 = 225?

Commented [39R35]: No,
It is based on the amount of CBD mg's in the gummy at a 15:1 ratio. In this case, 25 mg of CBD per gummy can only have 1.66 mg of THC. Also keep in mind, gummy is very difficult to formulate with. As a full spectrum ingredient, CW cannot make full spectrum cbd gummies in greater than 25 mg per two gummy's. If we do, the gummies taste terrible. That is why CW formulates full spectrum at 10 mg per 2 gummy to mask the full spectrum flavor.

Commented [40R35]: What about other forms (gel tabs, etc)? What I'm trying to understand is what is the worst case scenario from a total THC perspective per container? Do we expect manufacturers to put a product out there that's 37.5mg CBD & 2.5mg THC in large quantity containers? I think it's important to be eyes wide open on this.

Commented [41R35]: I get the argument, but at the same time how many products can we name that can be abused by ignoring the instructions for use? Some aspects of individual freedoms can cut both ways. I can take a serving of benadryl for a cold, or drink the whole bottle and hallucinate. Same for Vanilla extract, or mouthwash. End of the day this is your dissent so I get it, and to be fair, if we were discussing the same argument but for MJ, I'd be arguing against container limits in that industry as well.

declare that any ratio of CBD to THC will render THC not intoxicating for all people. We certainly should not be betting our children's future on it. Internal studies are not sufficient for something this important.

The Medical Marijuana Space, not the Hemp Space is the Correct Space for the Treatment of Medical Conditions with products containing THC.

It is well known that some individuals require extremely high doses of THC to feel its effects, even as high as 500 mg, whereas others can become intoxicated at a dose of 5 mg or less THC. This is a result of the enzymes present in one's liver and their ability to process THC.

In order to receive THC in any dosage under the marijuana industry, a minor must be recommended to do so by a doctor, and they must receive the products from a caregiver or strictly licensed medical dispensary. They must see at least one medical doctor each year to renew their medical card. Doctors, under Colorado law, must include in their recommendations a recommended dosage amount of THC. The use of THC should remain in the medical marijuana space where a doctor's recommendation and continuing care is necessary to obtain this product.

THC at 2.5 MG per Serving Belongs in the Marijuana Space.

If the SB22-205 Work Group's recommendation of 2.5 mg per serving becomes Colorado law, the hemp industry will be allowed to sell containers of products containing THC at levels far greater than those allowed in a single container of any regulated marijuana infused product, which is limited to 100 mg per container. THC has always been regulated in Colorado by the Marijuana Enforcement Division through its oversight and licensing of production and sale of marijuana and its key active ingredient, THC. The recommendations by this SB22-205 Work Group to allow a maximum dose per serving size of 2.5 mg of THC provides an effective "end run" around this system, avoiding sales limitations, comprehensive testing, taxes, licensing, and oversight of the MED.

This creates an unequal market where one industry is allowed to sell unregulated THC without taxation through the mail or through convenience stores while the other industry must pay licensing fees, comply with package and purchase limits, pass burdensome testing, and remit exponentially higher taxes for the sale of the same product containing the same THC levels. If these recommendations go forward and become law, the marijuana space should also be deregulated for the same products.

Conclusion and Recommendations.

In truth, I do not believe there is an appetite to deregulate the current system, which is why there should not be an alternative, largely unregulated system for the sale of the same products solely because they are hemp derived. Accordingly, the sale of THC products over .5 mg per container should not be permitted outside of the marijuana dispensary system that has been designed to prevent the sale of THC products to minors. This aligns with what Oregon did. If the hemp industry wants to continue to produce these full spectrum products containing hemp derived THC above the recommended levels, then the state should legislate a system allowing the hemp industry

to produce these products and only sell them in Colorado within the marijuana industry for distribution through dispensaries. Let the other states figure out how they want to regulate it if at all and permit the sale of these products to other states or countries and the Colorado hemp producer can comply with those laws.

There is already a system to move product from the hemp space into the marijuana space through METRC and all of the safeguards that have been carefully legislated and regulated in Colorado can be deployed for the sale of these beneficial products. Allowing the sale of these products online or through convenience stores puts Colorado youth at risk and runs counter to over a decade of Colorado's national and international leadership in the THC space.

Furthermore, we recommend the creation of a task force within the attorney general's office of 5-10 staff members to monitor online sales of intoxicating products from outside of Colorado to individuals within Colorado. Again, we support the work of the SB22-205 work group with the exception of this ill-conceived plan to produce unregulated hemp-derived products with intoxicating levels of THC for unfettered sale in the Colorado marketplace.

Signed Task Members: Truman Bradley

DISSENT OF GARRETT GRAFF

This dissenting opinion relates to: (i) the scope of the proposed safe harbors; and (ii) the negative impacts of designating certain cannabinoids as, *per se*, intoxicating, at both the manufacturing and finished product level.

To be clear, this dissent agrees with the Task Force's decision to recommend certain potency and ratio limitations on the sale of finished intoxicating hemp products within the State of Colorado. It is the broader conclusions of the Task Force associated with these recommendations, along with their failure to provide freedom to operate outside Colorado's borders, with which this dissent takes issue.

As the Task Force is well aware, the legal and regulatory framework governing hemp and cannabinoid products in the United States is fractured, inconsistent, and ever-changing. In a word, it is a "patchwork." Colorado companies that participate in our nationwide hemp economy reside in this State, but they cultivate, manufacture, and sell hemp, hemp ingredients, and finished products everywhere—in Colorado, every other State, and internationally. The ability to participate in this broader market is critical, as hemp companies face high costs of compliance, varied regulatory requirements, low margins, and a relatively small marketplace in Colorado for their products and services. That is why, as far as this dissent is aware, every State thus far has limited their hemp laws and regulations to intrastate activities, thereby preserving in-state "hemp business's ability to compete in the hemp market in other states." *Considerations in Establishing Cannabinoid Limits for Hemp Products,* Rationale for Rulemaking, Oregon Liquor & Cannabis Commission.

Nonetheless, the Task Force has concluded that the in-state potency and ratio limitations it recommends will generally apply even if a Colorado company is manufacturing bulk ingredients or finished products solely for sale or distribution outside Colorado's borders—e.g., in a State where those bulk ingredients and finished products are completely legal. Although the Task Force recommends a narrow set of "safe harbors"—exceptions to these in-state limits—those safe harbors only allow Colorado companies to export to other states *a narrow and specific set of ingredients and/or finished hemp products*. In other words, the Task Force has chosen to disregard Colorado's geographic boundaries. This is bad policy and unlikely to survive one of many credible legal challenges.

Although Colorado is certainly free to impose limitations, in the interest of public health and safety of its citizens, on what kind of finished products can lawfully be sold in this State, it simply has no authority to speak for and override or police the laws and regulations of other States. Colorado cannot apply its own legislative determinations extraterritorially.

Specific examples of how the Task Force's approach will prohibit Colorado companies from participating in the legal hemp marketplace of other States include:

- Many States do not impose restrictions on manufacturers beyond general compliance with food manufacturing requirements and sourcing compliant hemp derivatives (by contrast, the Task Force would dictate what cannabinoids a Colorado manufacturer could manufacture and/or transfer to an out-of-state facility, even though an out-of-state facility would not be subject to the same restrictions, yet transfer some of those very same cannabinoids into Colorado without consequence);

- The State of Minnesota explicitly allows for hemp-derived products up to 5 mg THC per serving to be sold (by contrast, it is unclear whether the Task Force would prohibit a Colorado-based company from manufacturing these products in-state and selling them in Minnesota, as the Task Force proposes to limit products to 2.5 mg per serving, plus a 15:1 CBD:THC ratio);

- The States of Florida and Kentucky have determined that cannabinoids, such as delta-8 THC, are lawful within their states (where the Task Force proposes to entirely prohibit delta-8 THC from manufacture or sale (even, for instance, a company wanted to sell a .1 mg delta-8 THC product), except for use to make CBN);

- Many States freely authorize the manufacture and sale of CBN and other novel cannabinoid products (where the Task Force proposes to restrict potency to 2.5 mg);

As a general principle in any industry (particularly in the manufacture of foods, supplements and cosmetics generally), ingredient and product manufacturers require freedom to operate in order to handle a number of different ingredients to serve different customers, even if the finished products may be regulated differently by industry or in different states or jurisdictions. However, in this case, Colorado seeks to restrict: (i) which cannabinoids manufacturers may possess in the State; (ii) how manufacturers can use those cannabinoids; (iii) and to whom and to where manufacturers may sell those cannabinoids—here, in all 50 states, and even abroad. Not only is this facially unreasonable and impractical to actually enforce, but it will lead to one of two outcomes, all of which are bad policy. First, Colorado-based manufacturers who value compliance will simply choose to leave the State, as they cannot justify continuing to operate in Colorado when doing so cuts them off from participation in the legal, nationwide hemp marketplace. Second, so-called "bad actors" will continue to act with impunity in violation of these requirements, pushing more activity underground and increasing risks to consumers. In short, the Task Force fails to recognize a fundamental reality: Hemp is not an *intra*state industry, it is an interstate industry.

Perhaps more importantly, such restrictions are likely unconstitutional by discriminating against Colorado manufacturers in a disproportionate manner relative to out-of-state manufacturers, thereby violating constitutional protections for interstate commerce. Any rules implementing these regulations are similarly vulnerable to challenge on administrative grounds as lacking any rational basis, as arbitrary and capricious, or otherwise violative of applicable law. This means any legislation (including implementing regulations) arising out of this Task Force report will certainly be challenged on constitutional grounds, may well be enjoined from enforcement, and could otherwise be subject to protracted litigation.

This dissent proposes that the legislature implement a modified safe harbor protection:

- Allowing for Colorado-based ingredient manufacturers to freely handle and export bulk hemp-derived cannabinoids for use in products to be sold in Colorado or in other states;
- Allowing for Colorado-based product manufacturers to freely manufacture finished products for sale in Colorado or in other states, so long as measures (i.e. batch tracking) are taken to ensure that only products which comply with Colorado requirements for finished products are sold within Colorado;
- All manufacturers shall generally comply with CDPHE regulations applicable to food manufacturers

APPENDICES

IMPACT ON FUTURE FEDERAL REGULATORY LANDSCAPE

(Note-Original language from Alan Lewis)

The stakeholder task force would like to highlight the consensus thought that is developing in the national arena, where longtime marijuana and hemp advocates are carefully examining the following approaches:

1. *Emphasize the need for federal decriminalization of adult-use marijuana. This will free many incarcerated people who would not have been convicted under current laws. Decriminalization includes expungement of related court records of arrests and convictions.*
2. *At the federal level, remove marijuana from the controlled substances list to facilitate interstate trade. This will allow individual companies to consolidate operations in the state(s) whose regulations best suited their needs, and from there distribute across state lines legally and efficiently.*
3. *Establish a deadline for compliance with FDA rules for production of food and dietary supplement ingredients and products, including labeling and marketing. This will forestall risk-based enforcement actions against Colorado companies, and prevent product seizure due to misbranding and safety concerns.*
4. *At the state level, regulate all intoxicating cannabis derivatives under marijuana laws. This will capture potentially dangerous compounds in a licensed, regulated, taxed economy to improve public safety and economic viability.*
5. *Unstudied potentially intoxicating cannabinoids should be limited to de minimis amounts in finished products until their characteristics and safety are understood.*
6. *Immediate funding should be allocated to undertake baseline safety studies of D8 and D10 to determine if they can be marketed like D9 THC and in what amounts and combinations.*
7. *Immediate funding should be allocated to undertake baseline studies of chemically synthesized cannabinoids, with special attention to unknown, unexpected, and potentially dangerous entourage chemicals resulting from these materials, methods, and processes.*
8. *Require lot-level lab analysis of all potentially intoxicating cannabinoids sold through dispensaries to ensure purity and safety.*
9. *Prevent the introduction of intoxicating cannabinoids, including compounds like D8 and D10, into any retail channel except licensed marijuana dispensaries.*
10. *Recognize that unregulated production presents a threat to both marijuana and hemp markets, since uncontrolled safety, potency, identity and adulteration may cause significant adverse effects that may taint the reputation of compliant businesses and products.*
11. *Recognize that the underground economy for these compounds now comprises over half of sales, so it is imperative that a legal path to market exists for properly produced, formulated, and marketed products.*
12. *Increase surveillance testing of suspect products sold in other retail stores and online.*

Commented [42]: While I agree with at least 95+% of what's written here, I'm not sure that this is appropriate. This is a state task force, dealing with state issues, which was not directed to opine on federal matters. The more extraneous information we include in this report, the more open it is to being undermined. Is this worth it? As presented, an objective reader would likely conclude this was voted on and adopted, so we're also playing fast and loose with the bar at which information is included in the report.

Commented [43R42]: I second what John has said. I like what's here but I'm not sure it fits in the report here

Commented [44R42]: Agree.

Commented [45]: This is, practically speaking, impossible. Hemp naturally contains D9. If the goal is to capture intoxicating cannabis *products* under marijuana laws, that could make sense here. But, consistent with our comment around defining PICs, it is the finished product, not the cannabinoid, that renders something intoxicating.

Commented [46]: Again, practically speaking, impossible and arbitrary. No cannabinoid has been accepted as safe by FDA, so the task force is capable of approving the grandfathering of certain cannabinoids, but not others? Yes, we need to protect consumer safety in the meantime, but this argument could be easily applied to virtually all cannabinoids (since none have FDA approval) and impede the entirety of the marijuana/hemp industries.

Commented [47]: I'm not sure how to reconcile this with states that don't have dispensaries. KY for example has legalized D8 (via judiciary/executive) but they don't have dispensaries. So, maybe this can just be rewritten as products need to go through some sort of regulated purchasing scheme much like alcohol, be it dispensaries or a similar storefront.

Commented [48R47]: Again, per discussion last week, D8 is used to make CBN.So, even within CO, this is an impossible standard.

And, I agree with John Harloe's comment -- states like KY or FL that have authorized D8, I'm not sure how we can reconcile this statement with other states that have decided to allow products that CO may not agree with.

I also note, what's the purpose of a "Total THC" definition relative to a statement such as this? I'm not sure how to reconcile the two.

Commented [49]: Not sure what this statement means. Please clarify.

13. Recognize the harm potentially caused by the proliferation of unregulated synthesized and/or intoxicating products as compared to beneficial cannabis products which are produced in accordance conventional food manufacturing regulationsat the halo of efficacy and safety of marijuana, especially compared to alcohol, is being destroyed by the negative consequences of gray market D8 and D10 derivatives.

14. Provide public education about the potential dangers of:

– cannabinoids which are not produced in accordance with conventional food manufacturing safety regulations and which illegally produced intoxicating cannabinoids that may contain chemical residues, impurities, and adulterants that can cause sever harm including death;

– intoxicating cannabinoids.

15. Maintain a firewall between dietary supplement products containing full spectrum hemp extract and other non-intoxicating hemp products, compliant with the Farm Bill, and intoxicating cannabis marijuana products, includingespecially D8 and D10. Dietary supplements are under attack by powerful forces in Washington, and we must take care to ensure that the integrity of safety studies on certain non-intoxicating hemp products – such as dietary supplements containing full spectrum hemp products – are maintained, upheld and observedso we can provide them no reason to suspect the safety of CBD dietary supplement products.

16. Share the economic opportunity with minority, marginalized, and formerly incarcerated communities, including access to capital and equal treatment under the law.

Commented [50]: This seems duplicative of 10.