



August 17, 2023

Kentucky Cabinet for Health and Family Services  
Department for Public Health  
Division of Public Health Protection and Safety  
Office of Legislative and Regulatory Affairs  
275 East Main Street 5 W-A  
Frankfort, KY 40621

**Re: Emergency Regulation 902 KAR 45:190E**

Secretary Friedlander, Commissioner Stack, and Director Gillis:

The U.S. Hemp Roundtable appreciates the opportunity to submit comments to the Cabinet for Health and Family Services (“Cabinet”) regarding Emergency Regulation 902 KAR 45:190E (the “regulation”). The Roundtable, founded and partially headquartered in the Bluegrass State, is the hemp industry’s leading national advocacy organization. For nearly a decade, the Roundtable’s more-than-100 members have stood at the forefront of ensuring a fair regulatory environment for the safe and responsible manufacture and sale of hemp cannabinoid products.

The Roundtable recognizes the robust and comprehensive scope of the regulation, which amends 902 KAR 45:190 and establishes registration, processing, and manufacturing procedures for hemp-derived cannabinoid products in foods and cosmetics; creates a category of “adult-use cannabinoid” products; updates labeling and packaging requirements for products containing hemp-derived cannabinoids; and includes requirements for the sale of hemp-derived cannabinoid products, including age restrictions.

Unfortunately, we fear that under a literal reading of the regulation, its implementation would stray significantly from the key premise of the Kentucky General Assembly, which unanimously enacted HB 544 to authorize its promulgation. The intent of that statute – as well as the professed intent of the regulation – is to prohibit the sale of intoxicating products, such as delta-8 tetrahydrocannabinol (“THC”), to anyone under 21 years of age and address the proliferation of unsafe, unregulated intoxicating hemp products. We wholeheartedly embrace that mission.

However, the regulation’s definition of what is intoxicating, and therefore subject to strict scrutiny, would sweep in thousands of popular *non-intoxicating* hemp-derived products such as CBD. We are hopeful that was not your intent. Indeed, when we met with your office in April, we understood that you were planning to draw the line between intoxicating and non-intoxicating products at 0.3% total THC, such that products exceeding this amount of THC, including delta-8 THC, or any combination of THCs, would be classified as “adult-use”

products and subject to stricter regulation – which we fully support. This supposition is supported by the language in Section 6(3) which exempts “cannabidiol products” from the regulation’s age restrictions.

But as discussed in more detail below, a plain reading of the regulation’s definition of “adult-use cannabinoid” appears to include products with *any amount of THC*, regardless of whether the product is actually intoxicating. Such a reading would have a devastating impact on Kentucky’s hemp farmers and its non-intoxicating hemp product industry. Non-intoxicating broad-spectrum and full-spectrum hemp and CBD products are the lifeblood of the national and state hemp industry. Unlike CBD isolate, which has a strong but more limited popular market, broad- and full-spectrum products contain non-intoxicating traces of THC – often falling within the range of 1 mg to 3 mg per serving. Kentucky and American consumers find considerable value in the blend of CBD and traces of other cannabinoids like THC. We are also not aware of any real-world evidence of these products being misused or abused for the euphoric effect found in impairing compounds like delta-8 THC.

By lumping these non-intoxicating products into an adult-only framework aimed at regulating impairing products, the regulation will impose significant burdens on the state and domestic hemp industry. Some of our Kentucky-based members have indicated that they will need to relocate out of state to be able to compete in the national marketplace.

We know that such a blow to Kentucky’s hemp farmers and small businesses was not the intent of the legislature, nor of Governor Beshear when he took national leadership by signing his Executive Order several months ago on this subject matter. We are hopeful that this was an oversight, or that perhaps we are misinterpreting the regulation. In any case, we strongly urge you to amend the regulation to clarify that non-intoxicating cannabinoids and hemp products continue to be governed by the existing regulatory regime for CBD.

We have a number of other concerns, including about the regulation’s definitional changes and many of the regulation’s requirements for manufacturers, processors, and distributors, as well as the requirements for packaging and labeling, retailers, and food service establishments. However, we note that many of our concerns can at least be somewhat addressed by clarifying the status of non-intoxicating hemp products. Provided some of the more onerous labeling, testing, and purchase restrictions identified below are limited to impairing products, fewer revisions to the regulation would need to be made. Please see our section-by-section analysis below.

## **Section 1. Definitions.**

At Section 1(1), the regulation creates a category for *adult-use cannabinoid*, a new term that is defined as “tetrahydrocannabinols [THCs], tetrahydrocannabinolic acids that are artificially or naturally derived, delta-8 [THC], delta-9 [THC], the optical isomers of delta-8 [THC] or delta-9 [THC], and any artificially derived cannabinoid that is reasonably determined to have an intoxicating effect.” As written, the term would apply to a product with any amount of THC. The definition’s references to THCs and delta-9 THC may have been an unintended drafting error, as Section 6’s 21-or-older age restriction for adult-use cannabinoid products does not apply to CBD products. As you likely know, most—if not all—non-intoxicating hemp-derived CBD products, including full-spectrum and broad-spectrum hemp extract, contain delta-9 THC. KRS 218A.010 excludes hemp

and CBD products from the definition of marijuana and was intended to broadly protect the retail sale of such products.

If, however, the definition of *adult-use cannabinoid* is intended to apply to a product that contains any amount of any THC, it would be devastating for the industry. Non-intoxicating hemp products that pose no safety concerns or risk for abuse would be limited to persons 21 or older, akin to alcohol and intoxicating cannabis products in other states—even when the product satisfies the legal definition of *hemp* in Kentucky law and federal law.

However, if the Cabinet believes a THC limit is necessary for classifying a product as adult-use, the Roundtable urges the Cabinet to follow the science on intoxication instead of arbitrarily prohibiting THC. Based on ample scientific evidence, contained in our enclosed white paper (See **Appendix A**), we suggest modifying the definition of *adult-use cannabinoid product* to only include a product containing more than 5 mg per serving of an adult-use cannabinoid or combination of adult-use cannabinoids.

The Cabinet, of course, may look at the scientific evidence and determine that a lower milligram level is more appropriate. In any case, the final outcome should recognize the lack of real-world abuse of common full-spectrum hemp products that range from 1 mg to 3 mg of THC per serving.

If a THC milligram limit per serving is adopted, additional language should be added that still allows a manufacturer to manufacture products that exceed the limit provided the products are to be sold exclusively out of state. Many states have this protection, which is an acknowledgment of and consistent with the 2018 Farm Bill’s statutory protection of federally legal hemp and hemp products in interstate commerce.<sup>1</sup>

Section 1(2)’s definition of *artificially derived cannabinoid* also raises concerns. Unlike other states, the definition does not contain any exceptions. We request that the definition be modified to include exceptions for naturally occurring chemical substances separated by a chemical or mechanical extraction process, as well as cannabinoids produced by decarboxylation from naturally occurring cannabinoid acid without the use of a chemical catalyst.

Lastly, Sections 1(8) and 1(16) define the terms *cosmetic* and *topical* separately and differently. This is likely to cause confusion because topical products are generally considered to be cosmetics. We recommend that the definition of *topical* be deleted or, if a separate definition is deemed necessary, that the definition of *cosmetic* be modified as follows: “Cosmetic” is defined by KRS 217.015(7) and includes a topical hemp-derived cannabinoid product intended to be applied to the skin or hair.

## **Section 2. Processing, Manufacturing, Storage, or Distribution of Hemp-Derived Cannabinoid Products.**

We oppose Section 2(6), which prohibits an adult-use hemp-derived cannabinoid processing or manufacturing facility or distributor from employing anyone under 21 years of age. Kentucky law does not prohibit alcohol licensees from employing a person under 21 years of age, provided that the person is supervised by an

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<sup>1</sup> See Memorandum from Stephen Vaden, Office of General Counsel to Sonny Perdue, Secretary of Agriculture, Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Relating to Hemp (May 29, 2019), <https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf>.

employee 21 or older.<sup>2</sup> An adult-use hemp-derived cannabinoid processing or manufacturing facility or distributor should have the same privilege.

Section 2(7) prohibits manufacturers or processors from adding any of the following to hemp-cannabinoid products: (1) Any non-cannabinoid additive that increases toxicity or addictive potential; (2) Caffeine; (3) Nicotine; or (4) Other chemicals that may increase carcinogenicity or cardiac effects. This is a major policy change, as it significantly expands Kentucky’s existing list of prohibited hemp products.<sup>3</sup> In particular, subcategories (1) and (4) are broad and may unnecessarily encompass a wide range of substances, while the prohibition on caffeine will have a significant impact on the hemp industry in the state and the manufacturers that produce caffeine-containing hemp products. We are not aware of adverse events associated with such products, and we strongly urge the Cabinet to modify this language by deleting subsections (1), (2), and (4).

We also note this section introduces the term *edible* product, which is not defined within the regulation and is a term more closely associated with marijuana products. The term *ingestible* is more appropriate and would include products such as capsules and tinctures, which are ingestible but generally not considered “edible.”

Finally, the scope of the regulation for processing, manufacturing, storage, and distribution should not extend to products intended to be sold exclusively out of state. A patchwork of state-specific laws currently exists regarding hemp-derived cannabinoid products. The regulation as written is inconsistent with federal and other state laws with respect to fundamental product characteristics, including but not limited to ingredients, testing requirements, and product packaging and labeling. To mandate that any processor, manufacturer, or distributor with operations in the state of Kentucky deal in products exclusively fitting the definition of Kentucky law would unnecessarily and significantly handicap the hemp industry – effectively prohibiting any Kentucky-based firm from engaging in commerce in most other states. By limiting the scope to products to be sold in the state of Kentucky, the state will still achieve the stated intent to prohibit the sale of intoxicating products to anyone under 21 years of age and address the proliferation of unsafe, unregulated intoxicating hemp products, without running up against other state’s efforts to achieve these same objectives. And, as noted above, many states have this protection, which is consistent with the 2018 Farm Bill’s statutory protection of federally legal hemp and hemp products in interstate commerce.<sup>4</sup>

### **Section 3. Product Sample and Testing Requirements.**

We appreciate Section 3’s incorporation of comprehensive testing and contaminant limits. However, the testing requirements in this section use terms such as *infused hemp-derived cannabinoid product*, *hemp-derived cannabinoid concentrate*, and *cannabinoid extract* that are not defined. We request that these terms be deleted from the regulation or defined appropriately to avoid confusion.

In addition, the arsenic limit is extremely low and does not reflect industry practices, putting a strain on Kentucky hemp manufacturers. We recommend the arsenic limit for ingestible products be revised from 0.4

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<sup>2</sup> <https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=52573>

<sup>3</sup> See 302 KAR 50:070

<sup>4</sup> See Memorandum from Stephen Vaden, Office of General Counsel to Sonny Perdue, Secretary of Agriculture, Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Relating to Hemp (May 29, 2019), <https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf>.

ppm to 1.5 ppm, which is the limit in place in both Florida and New York for ingestible hemp-cannabinoid products.<sup>5</sup>

## Section 5. Product Packaging and Labeling.

Section 5(2) expands existing requirements to now require a tamper-evident seal and child-resistant packaging for all hemp-derived cannabinoid products, including cosmetics. However, child-resistant packaging is not warranted for cosmetic products, as we are not aware of accidental consumption or misuse of hemp-cannabinoid cosmetics (i.e., topical products) by children. And while we appreciate that the regulation's child-resistant packaging standard is more lenient than the Federal Poison Prevention Packaging Act's standard that we proposed, the requirement should only apply to ingestible hemp-derived cannabinoid products that are considered *adult-use cannabinoid products*—not all hemp-derived cannabinoid products.

In addition, we fully agree with the intent of the packaging restrictions in Section 5(3), especially the prohibitions on packaging that may be attractive to children. However, we recommend the regulation include explicit language clarifying that the use of seals associated with federal programs and used in accordance with federal law and regulations, such as the U.S. Department of Agriculture organic seal, is not prohibited. We also recommend the regulation include language indicating that the use of the Kentucky Proud® logo is not prohibited, if used in accordance with the program's requirements.

The label requirements in Section 5(4) relating to the total amount of hemp-derived cannabinoid per serving and total amount per container are unnecessarily confusing. For ingestible hemp-derived cannabinoid products, we urge the Cabinet to include a simple requirement to list the amount of (i) total THC in milligrams per serving, (ii) CBD in milligrams per serving, and (iii) any other marketed cannabinoids in milligrams per serving, if applicable. For cosmetics, we urge the Cabinet to restore the previous requirement that the label include the total amount of cannabinoids per container and a statement that the product is within the federal legal limit of 0.3% delta-9 THC.

In addition, Section 5(4) requires product labels to include the total amount of hemp-derived cannabinoids per serving and per container "as reported by the testing facility." This language appears to be taken from medical cannabis regulations, whereby testing facilities perform onsite printing of the milligram amounts and/or percentages to be placed directly on the label. However, it is not appropriate for mass packaging where the concentration or amount of cannabinoids is already printed on the label or packaging, which takes into account a margin of error in formulations to account for the slight variations that occur with naturally occurring substances such as hemp extracts. We therefore request the deletion of "as reported by the testing facility," or clarify that including a web address, or QR code or other scannable code on the label or packing that provides access to Certificate of Analysis with testing results is also sufficient.

We also recommend the deletion of the requirement for a product modifier in Section 5(5). This requirement is unnecessary, given that the type of product is self-evident by the cannabinoid content that must appear on the labeling, as well as the product name or statement of identity. Additionally, we are not aware of any other

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<sup>5</sup> Florida, Section 5K-4.034 - Hemp Extract for Human Consumption, <https://ccmedia.fdacs.gov/content/download/89980/file/food-rule.pdf>; New York, Part 114 - Cannabinoid Hemp Regulations, [https://cannabis.ny.gov/system/files/documents/2021/11/part\\_114\\_cannabinoid\\_hemp\\_regulation\\_11-10-21.pdf](https://cannabis.ny.gov/system/files/documents/2021/11/part_114_cannabinoid_hemp_regulation_11-10-21.pdf).

state that requires hemp-derived cannabinoid products to include a modifier such as “Delta-8 THC” or “CBD” product.

Section 5(6) of the regulation includes label warnings that go well beyond what other states require for potentially impairing or intoxicating hemp products. For all ingestible *adult-use cannabinoid products*, we propose requiring the following statements:

- Warning: Contains THC.
- A statement indicating the product should be kept out of reach of children and animals.
- A statement indicating the product should not be used by individuals under 21, those who are pregnant, nursing, taking medication, or have a medical condition.
- A statement such as “May cause drowsiness or impairment. Do not drive or operate heavy machinery while taking this product.”

The statements proposed in the regulation, however, would be unique to Kentucky and would require unnecessary, burdensome, and costly label changes.

Finally, Section 5 uses undefined terms such as *hemp-derived cannabinoid infused edible product* and *hemp-derived cannabinoid concentrate* that are likely to cause confusion. The regulation should define the latter term, or it should be removed, and as noted above the term *edible* should be replaced with *ingestible*.

## **Section 6. Retail Sale of Hemp-Derived Cannabinoid Products.**

Section 6(2) requires that a retail establishment offering hemp-derived cannabinoid products of any kind register with the Cabinet. Most states that require retailer registration, however, require only sellers of ingestible or inhalable products to register. The Cabinet should do the same.

Section 6(3) raises yet another major concern. The regulation states that only CBD products may be sold to persons under 21 years of age, which is a significant limitation that would prohibit the sale of CBG, CBN, and other non-intoxicating cannabinoids to persons under 21. The age restriction should be limited to *adult-use cannabinoids* only, which also reflects the intent of the State Legislature in passing HB 544.

The special packaging and adult-signature requirements in Section 6(5)(b) would be highly disruptive to the industry and threaten e-commerce sales. We are not aware of any state that has such requirements, and coupled with the additional requirements noted above, would make Kentucky one of the strictest, if not the strictest, states in the country with respect to hemp-cannabinoid product requirements. If gatekeeping or age verification is the goal, we urge the Cabinet to include language mandating that online sellers require consumers to state affirmatively that they are at least 21 years of age, and then by January 1, 2024, require verification of age by either (i) using a reliable online age verification service, or (ii) obtaining and examining a copy of a government issued identification prior to completing a purchase, as outlined in our proposed regulatory framework.

## **Section 7. Ingestible Hemp-Derived Cannabinoid Products at Food Service Establishments.**

Similar to our concern in Section 6(3), Section 7(1) states, “Only [CBD] may be added to an ingestible product prior to retail sale at a food service establishment.” The prior language allowed all hemp-derived cannabinoids



to be added to products. The limitation to CBD will be unworkable for many Kentucky hemp businesses and will have a negative impact on the economy. We urge the Cabinet to remove this requirement and allow the addition of all hemp-derived cannabinoids to ingestible products sold at food service establishments, in accordance with the requirements for ingestible hemp-derived cannabinoid products sold at retail and comply with milligram limits as we have proposed above. In addition, food service establishments should be required to register with the Department for Public Health in the same manner as product manufacturers and be subject to audits to ensure compliance with Hazard Analysis and Critical Control Points (HACCP) and related food safety requirements.

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The Roundtable expresses its sincere gratitude to the Cabinet for its focus on the important topic of the safe and responsible manufacture and sale of delta-8 THC and other intoxicating hemp products in Kentucky. We respectfully urge you to include the suggested recommendations and modifications described above, and we look forward to participating in the public hearing on the regulation on September 25, 2023.

Thank you for your consideration.

Sincerely,



Jonathan Miller  
General Counsel  
U.S. Hemp Roundtable

Enclosures

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### Recommended Upper Limit THC Levels: Hemp-based Extract Products

#### INTRODUCTION

The hemp industry has experienced significant growth in recent years, driven by the increasing popularity of orally ingestible hemp-based products. However, with this growth comes the need for robust regulations to ensure consumer safety and protect public health. This white paper addresses the specific issue of impairment caused by ingestion of hemp-based cannabinoids, and specifically Tetrahydrocannabinol or THC, the main cannabinoid associated with impairment. There are several identified isomers of THC found in the hemp plant, with Delta 9 Tetrahydrocannabinol (Delta 9 THC) and Delta 8 Tetrahydrocannabinol (Delta 8 THC) being the most well-known. This paper will generically refer to THC throughout to refer to all *naturally occurring* isomers and variants of THC collectively.

Orally ingestible products containing a full suite of hemp-based cannabinoids, including THC, have been demonstrated to promote health and wellness. As discussed below, when an average healthy adult orally ingests THC in small servings below 5 mg, the THC does not exhibit a significant risk of impairment. Dietary supplements have a long history of providing consumers with nonpharmaceutical options to address health and wellness. There is a place for cannabinoid products in human health and wellness if they promote endpoints relevant to the structure or function of the body. Impairment does not promote health or wellness and is mentioned in the preamble of the applicable regulations as being a disease endpoint. Therefore, it is imperative any regulation of hemp-based dietary supplement products apply a sensible upper limit for THC/serving that allows consumers access to safe and efficacious health and wellness products containing THC while at the same time protecting public health and welfare.<sup>6</sup>

By establishing a clear and evidence-based upper THC limit, lawmakers can strike a balance between providing safe and efficacious dietary supplement products and safeguarding public health. Advocating for the implementation of an upper serving limit of 5 mg of orally ingested THC is analogous to the .5% Alcohol by Volume limit on food products before they are classified as alcohol and considered adulterated food. Due to the inherent differences between foods and dietary supplements, namely the significantly smaller serving sizes for dietary supplements, we recommend a discrete upper limit cap rather than a percentage by weight or volume.

#### THC: A NATURAL COMPONENT OF HEMP

THC is a naturally occurring component of hemp and the most well-known cannabinoid present in the plant. It is responsible for the psychoactive effects or “high” commonly associated with marijuana use. THC binds to cannabinoid receptors in the brain and central nervous system, leading to alterations in perception, mood, and cognition. The potency of THC can vary across different plant varieties and products, highlighting the

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<sup>6</sup> The upper limit described herein is intended to apply to healthy adults who are not pregnant or nursing.



importance of regulating its consumption with a discrete upper limit per serving to ensure consistent and predictable effects across all products.

THC is found in a variety of product formats in the market, including smokable, orally ingestible, and topically applied. Each form has its own onset time, duration of effects, and potential benefit and risks associated with consumption. Understanding the characteristics and variability of THC across different sources and forms is crucial for establishing appropriate safety limits that address potential health concerns while still allowing for the responsible use of hemp-based products.

Research has shown THC can have a range of effects on the body and mind depending on the amount orally ingested. Low doses of orally ingested THC are often associated with relaxation, mood regulation, improved sleep, and pain relief, which can be beneficial for overall health and wellness. However, higher doses of orally ingested THC can lead to increased likelihood of psychoactive effects, impaired cognitive function, and a heightened risk of adverse reactions.

The potential for negative effects, particularly at higher dosages, underscores the importance of establishing a safety limit to protect consumers from potential harm. This white paper will focus on the orally ingestible formats which would be classified as dietary supplements, including but not limited to gummies, soft gels, capsules, and tinctures. All following discussions and references will be in reference to orally ingestible formats.

## **EXISTING RESEARCH ON THC SAFETY LIMITS**

A comprehensive review of multiple scientific studies provides evidence in support of instituting an upper limit of 5 mg of THC per serving in an orally ingested product as the threshold limit to prevent impairment. These studies encompass diverse methodologies, including randomized controlled trials, observational studies, and meta-analyses, and have been conducted by reputable researchers and institutions. The findings indicate a 5 mg upper THC limit on an orally ingestible product strikes the proper balance between allowing for the potential therapeutic benefits of THC and minimizing the risk of adverse effects.

The selected studies have examined a wide range of health considerations related to THC ingestion. They have investigated the short-term cognitive impairments which can occur with higher THC doses, including impaired memory, attention, and decision-making abilities. Furthermore, these studies have explored the psychiatric effects of THC, such as increased anxiety and psychosis-like symptoms, particularly among individuals with a predisposition to mental health disorders. The collective evidence from these studies strongly supports the need for an upper limit at 5 mg per serving to mitigate potential health risks associated with excessive THC consumption.

## **THC LIMITS AND IMPAIRMENT**

To ensure a science-based approach was utilized to determine the proper reasonable upper limit for THC in hemp products, particularly considering the potential for impairment, the authors reviewed the literature for information pertaining to law enforcement and clinical research on levels of THC consumption and serum data to confirm impairment. The first step was to examine pharmacokinetics of oral ingestion of THC to understand what doses of orally ingested THC would equate to when serum levels were quantified.

Oral testing for cannabinoids offers an advantage over urine as presence of THC in oral fluid is indicative of recent cannabis use<sup>7</sup>. This is important when considering the effects of THC on performance as described above. Oral administration of a brownie laced with 25 mg of Delta 9 THC resulted in peak oral concentration of THC at 3.4 to 4.8 ng/mL within the first hour after consumption<sup>2</sup>. A separate study explored serum measures of THC following consumption of brownies laced with 10, 25 or 50 mg of Delta 9 THC. The peak concentration measured for each dose were 1.0, 3.5 and 3.3 ng/mL<sup>8,9</sup>. Another group found that oral doses of 8.4 and 16.9 mg Delta 9 THC in brownies resulted in peak serum concentrations of THC at 5 and 9 ng/mL THC<sup>10</sup>. Studies have shown that there is an initial and significant shift toward impairment when THC was measured in serum concentrations between 2 and 5 ng/ml. When concentrations are measured between 5 and 10 ng/ml, 75-90% of participants demonstrated symptoms of impairment in every performance test. Serum concentrations greater than 30 ng/ml demonstrated unequivocally that participants were 100% impaired on every performance test.<sup>11</sup>

Based on review of the literature, particularly data pertaining to the level of orally ingested THC that would lead to impairment for most consumers, an upper limit of 5 mg THC/serving is recommended. The information discussed above indicates limiting oral ingestion to 5 mg THC/serving or less would yield serum or oral THC levels lower than those indicated as causing impairment. Many states have passed legislation around serum limits for THC with a per se 5 ng/ml threshold which correlates with the recommended serving limit of THC at 5 mg/serving to remain below that per se impairment threshold. Therefore, in summary, the clinical data and state legislation around THC serum levels support a federal standard that delineates a per serving limit for THC at 5 mg.

## HEALTH CONSIDERATIONS

Chronic excessive THC consumption has been associated with a range of adverse health effects, emphasizing the importance of establishing an upper limit per serving. Psychiatric effects are another crucial aspect to consider. Certain individuals may experience increased anxiety, paranoia, or psychosis-like symptoms with higher THC doses. Vulnerable populations, such as adolescents and individuals with a history of mental health disorders, may be more susceptible to these effects. By implementing an upper limit of 5 mg THC per serving,

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<sup>7</sup> Niedbala, R. S., Kardos, K. W., Fritch, D. F., Kardos, S., Fries, T., Waga, J., ... Cone, E. J. (2001). Detection of Marijuana Use by Oral Fluid and Urine Analysis Following Single-Dose Administration of Smoked and Oral Marijuana. *Journal of Analytical Toxicology*, 25(5), 289–303. doi:10.1093/jat/25.5.289

<sup>8</sup> Vandrey R, Herrmann ES, Mitchell JM, Bigelow GE, Flegel R, LoDico C, Cone EJ. Pharmacokinetic Profile of Oral Cannabis in Humans: Blood and Oral Fluid Disposition and Relation to Pharmacodynamic Outcomes. *J Anal Toxicol*. 2017 Mar 1;41(2):83-99. doi: 10.1093/jat/bkx012. PMID: 28158482; PMCID: PMC5890870.

<sup>9</sup> Swortwood MJ, Newmeyer MN, Andersson M, Abulseoud OA, Scheidweiler KB, Huestis MA. Cannabinoid disposition in oral fluid after controlled smoked, vaporized, and oral cannabis administration. *Drug Test Anal*. 2017 Jun;9(6):905-915. doi: 10.1002/dta.2092. Epub 2016 Oct 13. PMID: 27647820; PMCID: PMC5357602.

<sup>10</sup> Wachtel SR, ElSohly MA, Ross SA, Ambre J, de Wit H. Comparison of the subjective effects of Delta(9)-tetrahydrocannabinol and marijuana in humans. *Psychopharmacology (Berl)*. 2002 Jun;161(4):331-9. doi: 10.1007/s00213-002-1033-2. Epub 2002 Apr 19. PMID: 12073159.

<sup>11</sup> Ramaekers JG, Moeller MR, van Ruitenbeek P, Theunissen EL, Schneider E, Kauert G. Cognition and motor control as a function of Delta9-THC concentration in serum and oral fluid: limits of impairment. *Drug Alcohol Depend*. 2006 Nov 8;85(2):114-22. doi: 10.1016/j.drugalcdep.2006.03.015. Epub 2006 May 24. PMID: 16723194.

lawmakers can prioritize the mental well-being of individuals and mitigate potential risks associated with excessive THC consumption.

Long-term health considerations also warrant attention. Chronic, heavy THC use has been linked to an increased risk of cannabis dependence and addiction. By setting an upper limit, lawmakers can promote responsible use and minimize the likelihood of individuals developing problematic patterns of THC consumption. This is particularly relevant in regions where cannabis is legal for both recreational and medicinal purposes, as clear regulations help protect public health and reduce potential burdens on healthcare and law enforcement systems.

Establishing an upper limit of 5 mg of THC per serving accounts for various health considerations associated with THC consumption. By mitigating short-term cognitive impairments, psychiatric effects, and long-term risks of cannabis dependence, such a limit can promote public health and ensure responsible use of THC-containing products for health and wellness purposes. By combining scientific evidence and law enforcement limits which prioritize consumer safety, lawmakers can strike a balance that allows individuals to access the potential benefits of THC while minimizing the potential for impairment.

### **PUBLIC SAFETY AND RESPONSIBLE USE**

One crucial aspect of THC regulation in dietary supplements is ensuring public safety, particularly in relation to activities such as driving. Research consistently demonstrates THC impairs psychomotor skills, reaction time, and coordination. Implementing an upper per serving limit for THC helps establish clear guidelines and label warnings for individuals regarding safe timeframes between THC consumption and engaging in activities that require alertness, such as driving. By promoting responsible use through proper labelling with adequate warnings and educating consumers about the potential impairment effects of THC, lawmakers can minimize the risks to public safety.

Preventing unintentional overconsumption is a key component of responsible use. Without a sensible upper per serving THC limit establishing a national standard, accurate dosing of hemp products is challenging, leading to unintentional ingestion of higher THC levels than intended. By implementing an upper limit for THC per serving, lawmakers can encourage product manufacturers to provide accurate and standardized labeling, enabling consumers to make informed decisions about their consumption. This approach helps protect individuals from unintended overconsumption, reduces the likelihood of adverse effects, and promotes responsible use of hemp products.

A per serving, upper limit for THC not only addresses public safety concerns related to impaired driving but also fosters responsible use by preventing unintentional overconsumption. By providing clear guidelines for consumers, product manufacturers, and retailers, lawmakers can contribute to the overall well-being of individuals and society. Establishing a balance between access to THC-based dietary supplement products and public safety is paramount, and a 5 mg per serving upper limit aligns with these goals while allowing for responsible use and informed decision-making.

### **CONSIDERATIONS FOR REGULATING THC LEVELS**

When establishing THC limits for orally ingested hemp products, lawmakers must consider various factors to develop effective and feasible regulations. One crucial consideration is consumer demand and market dynamics. Understanding the preferences and patterns of hemp-based cannabinoid consumption among consumers is essential to ensure that regulations align with market realities. By engaging with industry stakeholders, lawmakers can gauge consumer expectations and tailor THC limits that strike a balance between meeting consumer needs and safeguarding public health.

Feasibility and enforceability are also vital aspects to address. Lawmakers should assess the practicality of implementing regulations around THC limits and the resources required for enforcement. Considerations include testing capabilities, labeling requirements, and monitoring compliance, all of which are currently authorized under the Dietary Supplement Health and Education Act and conducted by the FDA's Office of Dietary Supplement Programs, ensuring that the proposed limits can be effectively enforced and monitored.

The authors encourage lawmakers to take the guidance outlined in this white paper and further engage with a diverse range of stakeholders, including industry representatives, healthcare professionals, law enforcement and advocacy groups to consider different viewpoints and ensure the ultimate federally regulated per serving THC limit is informed by a broad range of expertise and science-based evidence. By incorporating stakeholder input, lawmakers can enhance the transparency, fairness, and legitimacy of the regulatory framework, fostering public trust and acceptance.

When regulating THC levels in products, lawmakers should consider consumer demand, market dynamics, feasibility, enforceability, and stakeholder perspectives. By taking a comprehensive approach that balances consumer needs, public health objectives, law enforcement/public safety concerns and practical implementation, policymakers can develop regulations that effectively manage THC consumption, promote responsible use, and protect public safety.

## **CONCLUSION AND POLICY RECOMMENDATIONS**

In conclusion, the evidence presented in this white paper supports the implementation of a limit of 5 mg per serving of THC in all hemp-based products. The reviewed studies demonstrate a 5 mg per serving size limit on orally ingested THC is non-impairing. Review of scientific literature on levels of THC/serving and serum or oral THC measures that were associated with impairment also supports a 5 mg per serving limit on orally ingested THC as non-impairing. By establishing a reasonable hemp-based THC limit for orally ingested products, lawmakers can prioritize consumer well-being, public safety, and responsible use of hemp-based products.

Based on the findings and analysis, the following policy recommendations are proposed:

- Establish a statutory THC safety limit of 5 mg per serving for all THC-containing hemp products.
- Utilize the mechanism of the Farm Bill to establish a safe and reasonable federal standard for THC limits in orally ingestion hemp-based agricultural products without over-reaching into the mandates and authorities of the FDA. This would not legalize any hemp-based products without the input and oversight of the FDA, but it would address the proliferating conflicts in state laws authorizing the manufacture and sale of hemp-based cannabinoid products as foods, dietary supplements and food additives.
- Develop comprehensive education and awareness campaigns to inform the public about the potential health risks associated with excessive THC ingestion and the importance of adhering to the suggested serving size. These campaigns should focus on promoting responsible use, clear serving size guidelines, and the implications of impaired driving.
- Implement robust regulatory frameworks to enforce hemp-based THC limits, ensuring accurate product labeling, standardized testing protocols, and strict compliance measures. Collaboration with industry stakeholders, regulatory agencies, and law enforcement authorities is crucial to ensure effective enforcement and monitoring of THC levels in products.

By adopting these policy recommendations, lawmakers can strike a balance between facilitating access to the potential health benefits of hemp-based THC while protecting public health and promoting responsible use.

Implementing a 5 mg per serving size and per day THC safety limit is a proactive step toward ensuring consumer safety, mitigating health risks, and establishing a transparent and accountable hemp-based CBD and THC industry.

## REFERENCES – REVIEWED STUDIES

The reviewed studies provide substantial evidence to support the establishment of a per serving limit of 5 mg of THC. Studies have shown that doses as low as 2.5 to 3 mg of THC can provide therapeutic benefits without significant psychoactivity. Clinical trials involving various populations, such as individuals with PTSD, multiple sclerosis, anorexia, dementia, and cancer, have demonstrated the safety and efficacy of THC at doses ranging from 1.5 to 10 mg per day. These trials reported minimal adverse effects, with some studies highlighting the well-tolerated nature of THC even at higher doses.

Furthermore, research on driving impairment has shown that THC has a different impact compared to alcohol. THC-positive drivers are not necessarily impaired or meaningfully impaired, challenging the current approach of stand-alone cannabis-presence driving offenses. Studies comparing the effects of alcohol and cannabis on driving performance have consistently shown that alcohol has a more detrimental effect.

Overall, the evidence supports a 5 mg per serving size THC limit and strikes a balance between enabling therapeutic benefits and minimizing the risk of adverse effects. It aligns with the findings of numerous studies, clinical trials, and governmental guidelines, emphasizing the need to establish a clear and scientifically informed regulatory framework for THC ingestion.

## CLINICAL TRIALS

### **2022: Using brain imaging, the average THC dose to cause impairment was 35.6 ± 11.5 mg**

*Identification of  $\Delta 9$ -tetrahydrocannabinol (THC) impairment using functional brain imaging*

<https://pubmed.ncbi.nlm.nih.gov/34999737/>

“The mean THC dose for these 80 participants considered to be impaired was 35.6 ± 11.5 mg. Likewise, 57 participants had concordant ratings of not clearly impaired on the CCR and HR/self-rated high algorithm (Fig. 2A); the mean dose of THC for these 57 participants rated as not clearly impaired was 34.8 ± 16.1 mg.”

### **2022: In humans with PTSD, 7.5 mg THC helped with emotional processing during an emotional regulation task**

*Cannabinoid modulation of brain activation during volitional regulation of negative affect in trauma-exposed adults*

<https://pubmed.ncbi.nlm.nih.gov/35981598>

### **2021: A case series of patients with neuropathic itch using dronabinol (pharmaceutical THC) found low levels to only cause the transient side effect of lightheadedness**

*Neuropathic itch treated with oral cannabinoids: A case series*

<https://pubmed.ncbi.nlm.nih.gov/34692966/>

“All 3 patients reported improvement within their initial few doses and described a dose-dependent effect. Side effects included lightheadedness, which was mild and transient and resolved with persistent use. We found that initiating therapy at low doses divided throughout the day followed by gradual increases to be helpful in increasing tolerability.”

### **2020: In humans, 5 milligrams of dronabinol (synthetic THC) improved optic nerve had blood flow with no psychoactive or negative effects**

*The Effect of Orally Administered Dronabinol on Optic Nerve Head Blood Flow in Healthy Subjects-A Randomized Clinical Trial*

<https://pubmed.ncbi.nlm.nih.gov/31977076/>

### **2020: In multiple sclerosis patients, an average dose of 4 mg of THC caused no impairment**

*Safety and efficacy of low-dose medical cannabis oils in multiple sclerosis*

<https://pubmed.ncbi.nlm.nih.gov/33387864/>

“No impairment in disability, ambulation, dexterity or processing speed was observed.”

**2019: In humans, 5 to 10 mg of THC increased food consumption & altered hormones related to appetite & digestion**  
*Effect of acute Δ9-tetrahydrocannabinol administration on subjective and metabolic hormone responses to food stimuli and food intake in healthy humans: a randomized, placebo-controlled study*

<https://pubmed.ncbi.nlm.nih.gov/30949710/>

“Dronabinol capsules containing 2.5 mg of Δ9-THC were orally administered to the participants, depending on their body weight (0.1 mg/kg, titrated to the nearest 2.5 mg, with a minimum of 5 mg and maximum of 10 mg). This dose was chosen based on previous research demonstrating that a single dose of 10 mg is well-tolerated and does not induce any nausea or vomiting”

**2019: In humans with PTSD, 5 mg of dronabinol (pharmaceutical THC) caused no serious adverse effects & a similar level of nonserious adverse effects to the placebo**

*Effects of Delta-9 Tetrahydrocannabinol (THC) on Retention of Memory for Fear Extinction Learning in PTSD: R61 Study*

<https://clinicaltrials.gov/study/NCT03008005>

**2018: In healthy humans, 10 mg of THC caused no changes to the brain’s fronto-striatal resting-state connectivity while CBD increased it**

*Probing the endocannabinoid system in healthy volunteers: Cannabidiol alters fronto-striatal resting-state connectivity*

<https://pubmed.ncbi.nlm.nih.gov/29887287/>

**2018: In a test of THC on ocular dynamics, 5 mg of THC caused no serious adverse events & only one non-serious adverse event (skin rash)**

*The effect of Tetrahydrocannabinol on ocular hemodynamics in healthy subjects*

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-004852-52/results>

**2017: In humans with chest pain, 10 mg of dronabinol (pharmaceutical THC) increased pain thresholds & caused no significant adverse events**

*Dronabinol increases pain threshold in patients with functional chest pain: a pilot double-blind placebo-controlled trial*

<https://pubmed.ncbi.nlm.nih.gov/26822791/>

**2017: A study of the pharmacokinetics of THC in healthy humans finds a single dose of 5 mg to be well-tolerated**

*Effect of food on the pharmacokinetics of dronabinol oral solution versus dronabinol capsules in healthy volunteers*

<https://pubmed.ncbi.nlm.nih.gov/28138268/>

**2017: In humans with dementia, 3 mg of THC per day had “a benign adverse event profile regarding mobility and was well tolerated by community-dwelling dementia patients”**

*Effects of tetrahydrocannabinol on balance and gait in patients with dementia: A randomised controlled crossover trial*

<https://www.ncbi.nlm.nih.gov/pubmed/27624148>

**2017: In healthy humans given 10 mg of THC orally, they showed no impairment & a third of them did not even test positive for cannabinoids in their blood**

*Pharmacokinetic Profile of Oral Cannabis in Humans: Blood and Oral Fluid Disposition and Relation to Pharmacodynamic Outcomes*

<https://pubmed.ncbi.nlm.nih.gov/28158482/>

“Also, for two participants, no blood cannabinoids were detected after administration of the 10 mg THC dose....

Significant correlations were also observed between psychoactive blood cannabinoids and DSST percent correct, but these correlations were highest at the 10 mg THC dose when there was no impairment relative to baseline task performance.”



**2015: In humans with anorexia, 5 mg of dronabinol (pharmaceutical THC) per day did not change their insulin levels but did help with HPA axis activity with no mention of negative side effects**

*Changes in IGF-I, urinary free cortisol and adipokines during dronabinol therapy in anorexia nervosa: Results from a randomised, controlled trial*

<https://pubmed.ncbi.nlm.nih.gov/26248813/>

**2015: In humans, a month of 5 mg of dronabinol (pharmaceutical THC) twice per day did not alter metabolic parameters & mentions no negative side effects**

*A 4-week pilot study with the cannabinoid receptor agonist dronabinol and its effect on metabolic parameters in a randomized trial*

<https://pubmed.ncbi.nlm.nih.gov/26283236/>

**2015: In surgical patients, 5 mg before the surgery was well tolerated & helped with nausea**

*Prevention of Postoperative Nausea and Vomiting (PONV) in Surgical Patients (PONV)*

<https://clinicaltrials.gov/study/NCT00757822?intr=THC%20&aggFilters=status:com&page=4&rank=40&tab=results>

**2015: In humans with dementia, up to 3 mg THC was safe & well tolerated but did not reduce symptoms**

*Tetrahydrocannabinol in Behavioral Disturbances in Dementia: A Crossover Randomized Controlled Trial*

<https://www.ncbi.nlm.nih.gov/pubmed/26560511>

**2015: In humans with dementia, 4.5 mg of THC caused a similar number of adverse events in the placebo group as the active ingredient group**

*Tetrahydrocannabinol for neuropsychiatric symptoms in dementia: A randomized controlled trial*

<https://pubmed.ncbi.nlm.nih.gov/25972490/>

“The number of patients experiencing mild or moderate adverse events was similar (THC, n = 16; placebo, n = 14, p = 0.36). No effects on vital signs, weight, or episodic memory were observed.”

**2015: In older humans with dementia, 1.5 mg of THC for 2 months caused no significant impairment & more adverse events were reported for the placebo group than the active ingredient group**

*Safety, pharmacodynamics, and pharmacokinetics of multiple oral doses of delta-9-tetrahydrocannabinol in older persons with dementia*

<https://pubmed.ncbi.nlm.nih.gov/25752889/>

“All participants completed the study as scheduled. In general, THC was safe and well tolerated by these older individuals with dementia. In total, 98 adverse events were reported during the study period. More adverse events were reported with placebo (55 adverse events) than with THC (43 adverse events) (period A, 0.75 mg THC 21 adverse events and placebo 30 adverse events, P = 0.290; period B, 1.5 mg THC 22 adverse events and placebo 25 adverse events, P = 0.435).

Thirteen (13 %) of the reported adverse events were considered to be possibly (n = 12) or probably (n = 1) related to study drugs (THC and placebo). Of these, only six adverse events (6 % of total adverse events) were considered to be (possibly) related to THC, two with 0.75 mg (dizziness and fatigue in one patient each), and four with 1.5 mg (agitation in three patients and fatigue in one patient). All were mild and transitory in nature. There were no THC-related serious adverse events. THC treatment was not associated with changes in the patients’ physical state, laboratory test results (hematology and clinical chemistry), or ECG parameters (e.g., QT and RR intervals).”

**2014: In older adults, 5 mg THC safe & well tolerated**

*Safety and pharmacokinetics of oral delta-9-tetrahydrocannabinol in healthy older subjects: a randomized controlled trial*

<https://pubmed.ncbi.nlm.nih.gov/25035121/>

**2013: In multiple sclerosis patients, 1.5 or 5 mg caused no significant deleterious effects**

*A two-phased, randomized, double blind, placebo-controlled study of ECP002A ( $\Delta$ 9-THC) to determine safety, tolerability and efficacy in Multiple Sclerosis patients suffering from spasticity and pain*

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-022033-28/results>

**2012: In cancer patients, those using Sativex at the 2.5 mg to 25 mg THC dosage range showed little difference in adverse effects or patient discontinuation from the placebo**

*Nabiximols for opioid-treated cancer patients with poorly-controlled chronic pain: a randomized, placebo-controlled, graded-dose trial*

<https://pubmed.ncbi.nlm.nih.gov/22483680/>

“There was a dose related incidence of AEs, with the high-dose group comparing unfavorably with placebo and the 2 lower dose groups showing little difference from placebo.”

**2011: In 2 patients with dementia, 2.5 mg of dronabinol before bed helped with nighttime agitation & was well tolerated**

*Randomized, controlled crossover trial of dronabinol, 2.5 mg, for agitation in 2 patients with dementia*

<https://pubmed.ncbi.nlm.nih.gov/21364345/>

**2011: Double-blind placebo trial finds 2.5 mg THC to be a threshold dose**

*Combined effects of acute, very-low-dose ethanol and delta(9)-tetrahydrocannabinol in healthy human volunteers*

<https://pubmed.ncbi.nlm.nih.gov/21110996/>

“When given alone, 2.5mg THC produced modest effects on subjective ratings, measures of cognitive performance, and physiological measures. Although participants did not report feeling any drug effects, THC significantly reduced POMS ‘vigor’ scale scores (Table 3) and increased sedation as measured by the ARCI PCAG scale. THC altered POMS ‘friendliness’ scale scores (THC  $\times$  Time:  $F[2,9] = 4.99$ ;  $p = 0.035$ ) but none of the individual time points differed significantly in post hoc tests. Additionally, THC slightly impaired performance on the DSST overall ( $F[1,10] = 4.60$ ;  $p = 0.058$ ), and visual inspection and a follow-up post hoc test indicated that THC significantly impaired performance on this task at 100 min (Table 3). THC also significantly reduced diastolic blood pressure overall (Table 3). No other significant effects were seen on behavioral or physiological measures.”

**2010: In patients with ALS, 2.5 to 10 mg of THC did not help their cramps but it was well tolerated**

*Tetrahydrocannabinol (THC) for cramps in amyotrophic lateral sclerosis: a randomised, double-blind crossover trial*

<https://pubmed.ncbi.nlm.nih.gov/20498181/>

“Oral doses from 2.5 to 10 mg were well tolerated... Two serious adverse events occurred. Both patients were admitted to hospital. One patient developed pneumonia during the wash-out period (after THC period) and later died; the other developed deep venous thrombosis before the THC period. These adverse events were felt not to be study-related. None of the remaining patients withdrew from the study. One patient experienced mild dizziness while on THC (sequence 0/1). The patient continued the study with half the dosage. Otherwise, none of the patients reported any side effects.”

**2009: In patients with schizophrenia, 5 to 10 mg a day of THC improved symptoms & “all subjects made the point that the medication did not feel like real marijuana and did not give them a high”**

*Synthetic delta-9-tetrahydrocannabinol (dronabinol) can improve the symptoms of schizophrenia*

<https://pubmed.ncbi.nlm.nih.gov/19440079/>

**2006: In humans with severe dementia, 2.5 mg dronabinol helped for agitation at night with no negative side effects (6 patients in an open-label pilot study)**

*Delta-9-tetrahydrocannabinol for nighttime agitation in severe dementia*

<https://www.ncbi.nlm.nih.gov/pubmed/16521031>

**2006: In patients with cancer, 2.5 mg twice daily for two weeks was well tolerated**

*Comparison of orally administered cannabis extract and delta-9-tetrahydrocannabinol in treating patients with cancer-related anorexia-cachexia syndrome: a multicenter, phase III, randomized, double-blind, placebo-controlled clinical trial from the Cannabis-In-Cachexia-Study-Group*

<https://pubmed.ncbi.nlm.nih.gov/16849753/>

**2003: In women who underwent a hysterectomy, 5 mg of oral THC caused no significant adverse effects compared to the placebo besides an increased awareness of surroundings**

*Lack of analgesic efficacy of oral delta-9-tetrahydrocannabinol in postoperative pain*

<https://pubmed.ncbi.nlm.nih.gov/14581124/>

“Increased awareness of surroundings was reported more frequently in patients receiving delta-9-THC (40 vs 5%, P=0.04). There were no other significant differences with respect to adverse events.”

**1995: Patients with anorexia receiving 5 mg of dronabinol (pharmaceutical THC) per day caused no serious side effects**

*Dronabinol as a treatment for anorexia associated with weight loss in patients with AIDS*

<https://pubmed.ncbi.nlm.nih.gov/7730690/>

“Dronabinol was well tolerated. The majority of side effects reported were central nervous system disturbances that are commonly associated with cannabinoids. In most cases, they were not severe enough to warrant intervention. There was no significant difference between both treatment groups in the patient dropout rates due to adverse reactions. Six dronabinol versus three placebo recipients discontinued therapy due to any adverse effect thought to be possibly or probably related to treatment. These numbers are small and attest to the safety and tolerance of treatment.”

**DRIVING**

**2022: A deep dive into the uneven science of cannabis & impaired driving: a call for a new paradigm**

*How to read a paper on the short-term impairing effects of cannabis: A selective and critical review of the literature*

<https://journals.sagepub.com/doi/pdf/10.1177/20503245221119046>

“The recent use of cannabis is indicated toxicologically by the presence of delta-9-tetrahydrocannabinol (THC) in blood or oral fluid. Evidence is provided that most THC-positive drivers are not impaired, and certainly not meaningfully impaired. It follows that the justice of stand-alone cannabis-presence driving offences must be questioned.”

**2022: In a review about policy guidelines, they recommend a "per se limit" with a quantitative THC cut-off between 3.5 and 5 ng/ml in the bloodstream to “currently be considered the most balanced [policy] choice”**

*Cannabis and Driving: Developing Guidelines for Safety Policies*

<https://pubmed.ncbi.nlm.nih.gov/35713145>

**2022: In a comparison of alcohol & cannabis for driving, only alcohol caused worse driving**

*Comparison of the effects of alcohol and cannabis on visual function and driving performance. Does the visual impairment affect driving?*

<https://pubmed.ncbi.nlm.nih.gov/35717788>

**2012: 10 mg of dronabinol (pharmaceutical THC) caused only moderate changes to driving performance in occasional users & no change in habitual users**

*Medicinal  $\Delta(9)$ -tetrahydrocannabinol (dronabinol) impairs on-the-road driving performance of occasional and heavy cannabis users but is not detected in Standard Field Sobriety Tests*

<https://pubmed.ncbi.nlm.nih.gov/22553980/>

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