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.[1]

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,

[1] The upper limit described herein is intended to apply to healthy adults who are not pregnant or nursing.

and cognition. The potency of THC can vary across different plant varieties and products, highlighting the 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[2]. 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[2]. 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[3,4]. 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[5]. 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.[6]

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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[2] 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

[3] 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.

[4] 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.

[5] 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.

[6] 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 Δ9-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 heathy 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%205&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 (Δ9-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 × 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 Δ(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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MEDTERRA

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