CANADIANS FOR FAIR ACCESS
TO MEDICAL MARIJUANA

CANADIENS POUR L'ACCÈS ÉQUITABLE
À LA MARIJUANA MÉDICALE

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Members of the Standing Committee on Justice and Human Rights
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Subject: Bill C-46 and Medical Cannabis

Dear Honourable Members,

Canadians for Fair Access to Medical Marijuana (CFAMM) is a national non-profit organization focused on medical cannabis access, education, and research. CFAMM supports legislation that focuses on the safety of all Canadians on our roads and highways, including the creation of a robust public education campaign around driving and cannabis use. However, Bill C-46, in particular Part 1, must also consider the potential criminalization of responsible, non-impaired Canadians who use cannabis for medical reasons.

Although driving is a privilege, patients who use cannabis responsibly and are not impaired should still be able to drive without risk or fear of being criminally charged. While a strict precautionary approach may be appropriate in light of limited evidence, policymakers have a responsibility to both safeguard road safety and balance the rights of medical cannabis patients to ensure they are not unfairly criminalized by drugged driving laws that do not target impairment. It is necessary for the government to incentivize further research and include considerations for patients using cannabis.

For those who are prescribed medical cannabis, the purpose is not to 'get high', but rather to achieve effective symptom management. The testing of THC within a regular medical cannabis consumer's system is not a reliable or scientifically proven measure of impairment. As explored below, blood levels of THC can remain within a regular user/patient's system for days after last consumption – meaning patients may exceed the proposed *per se* limits even when not impaired and acting responsibly. **Special considerations for medical cannabis patients would not amount to a license to drive impaired, but would recognize the limited evidence related to the testing of cannabis-impaired driving.** Based on the evidence outlined below, we recommend these summarized considerations *(see pg. 8 for full recommendations):*

Recommendation 1: Protect Non-Impaired Medical Cannabis Patients

- **'Medical Defense' for *Per Se* Limits:** Recognizing there is inadequate evidence equating *per se* limits to impairment for medical cannabis use, legally authorized medical cannabis patients who follow safe-use guidelines and demonstrate no signs of impairment to their driving ability should receive a carve-out medical defense from *per se* related charges.
- **Reasonable Suspicion and Grounds:** A re-evaluation of what indicators establish reasonable suspicion and reasonable grounds for the collection of bodily fluids must be considered. Reasonable suspicion and grounds should be based on impairment - not previous use of cannabis or drugs in one's body.

Recommendation 2: Education Specific to Medical Cannabis

- **Patient Education:** It is vital to educate patients using medical cannabis on the potential dangers of drug-impaired driving and new laws as they are implemented. Preventing people from driving impaired in the first place is the safest and most effective approach to reducing risk to public safety. Patient organizations, such as CFAMM, should play key roles in delivering education.
- **Stakeholder Education:** Health care providers have an important role to play in educating patients about safe use of medical cannabis and driving. When prescribing cannabis, HCPs must discuss the risk of driving impaired and how to mitigate that risk by practicing safe-use guidelines. Police should be educated on the complexities of impairment and testing, specifically as it relates to medical cannabis use.

Recommendation 3: Fund Research Specific to Medical Use

- **Investment in research:** The federal government should dedicate funds towards impaired driving research including policy surveillance and monitoring. This research should follow national standards and must consider medical cannabis use.

EVIDENCE RELATED TO MEDICAL CANNABIS IMPAIRED DRIVING

In July 2017, CFAMM release a first-of-its kind preliminary research report on medical cannabis impaired driving. This evidence is an abridged version of the full report, which is available at cfamm.ca/impaired-driving-report-1/.

While CFAMM is fully against impaired driving and supports responsible driving legislation, the term "impairment" is widely used but is not always clearly defined. When speaking of impairment, critical to this dialogue is speaking to actual impairment of cognitive, psychomotor, and other functions necessary to safely drive – not simply a measure of previous use such as the presence of THC in blood. Unlike blood alcohol concentration, which is scientifically linked to levels of impairment, matching levels of impairment to levels of THC in one's system is still widely debated and has not been studied related to medical cannabis use.

There are no straightforward answers available in the scientific literature, yet it is crucial to identify at what point patients are impaired by their cannabis use - not simply if they have previously consumed cannabis or have presence of THC in their body. With an absence of reliable biological tests that can accurately determine impairment, it is likely that non-impaired regular medical cannabis users, in particular, will be unfairly criminalized.[1]

Medical Cannabis in Canada

Since 2001, the Canadian government has allowed patients to legally possess cannabis for medical purposes on the basis of a health care provider's authorization. The current medical access regime, known as the *Access to Cannabis for Medical Purposes Regulations* (ACMPR), supplies approximately 200,000 patients through over 50 licensed producers/'LPs'.[2] Based on Bill C-45, the medical cannabis system is expected to continue in parallel to the proposed non-medical cannabis market post-legalization.

Although the therapeutic benefits and safety of medical cannabis are outside the scope of this brief, it is worth noting that a 2013 survey found that 72% (n=439) of Canadian medical cannabis users self-report cannabis as "always helpful" in treating their symptoms, and an additional 24% (n=147) described it as "often helpful".[3] One of the most thorough analysis to date, conducted by the U.S. National Academies of Sciences, Engineering, and Medicine, reviewed over 10,000 articles and concluded strong evidence exists for medical cannabis/cannabinoid use in adult chronic pain, MS related-spasms, and chemotherapy-induced nausea and vomiting.[4] As the medical

cannabis program in Canada continues to grow at a rapid rate, so does the need to have impaired driving policy that considers the distinct, safe use of medical cannabis.

The *Cannabis sativa* plant contains over 100 active ingredients, known as cannabinoids, which vary in potency from strain to strain.[5] 'Cannabis impairment' generally refers to the impairment caused by THC, the cannabinoid responsible for the stereotypical 'high' or 'psychoactivity,' rather than cannabis as a whole. Patients using cannabis for medical purposes may use different types of cannabis (i.e. CBD strains) that are non-impairing or administer cannabis differently than a recreation user.[6]

Many patients use cannabis daily or near daily to manage symptoms associated with their illness and are expected to follow advice from health care providers, including safe-use guidelines to ensure impairment is minimized. Key differences between recreational and medical cannabis use include intent, tolerance, and how effects are experienced. **Failing to consider medical users as a distinct group in developing policy may lead to the unfair criminalization of this population or prejudicial restrictions on driving. It is essential to understand potential policy considerations for medical cannabis would not give patients a license to drive impaired, but rather, could recognize the distinct nature of responsible medical cannabis use.**

Administration of Medical Cannabis

As patients are generally suffering from chronic illnesses, the majority use cannabis at least once per day. The most prevalent and researched cannabinoids are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). While THC is responsible for some of the therapeutic effects, as well as the impairment or stereotypical "high", other cannabinoids, such as CBD, have gained much attention recently as a non-psychoactive component which can actually counter the effect of THC.[7] Research continues to build around CBD's analgesic, anti-oxidant, and anti-consultant effects and has, "modulatory effect on THC-associated adverse events such as anxiety, tachycardia, hunger, and sedation in rats and humans".[5,7] Although there are no specific studies measuring CBD related to driving, it is unlikely that that CBD dominant cannabis by itself would carry much, if any, MVA risk due to its non-impairing proprieties. Patients may also consume CBD alongside THC, which could reduce impairment, as demonstrated in the nabiximols study discussed below.

Driving Risks Related to THC

While the precise risk of cannabis-impaired driving remains a highly-debated issue, there is a consensus among scholars that acute consumption of THC likely causes an increased motor vehicle accident risk between 1-3x.[9-11] The vast majority of driving safety studies are not specific to the medical use of cannabis and often look at acute, recreational use of cannabis. This distinction is important as patterns of use differ for medical cannabis patients – again, the goal is symptom management, not getting high.

In one of the only studies looking at a medical cannabis (a prescription form – Sativex/Nabiximols), researchers followed 33 multiple sclerosis (MS) patients and tracked various driving performance measures over a four to six-week course of nabiximols. The authors concluded nabiximols treatment possibly improved moderate to severe treatment-resistant MS spasticity, demonstrated drivers taking the drug remained fit to drive, and found improved driving performance in stress tolerance tests (a measure of reaction time and attention).[12] This was the only study exploring how the impairment of medical cannabis affects people with illness – and beyond demonstrating no impairment, it showed possible signs of *improved* driving. Although there is concern legalization will cause increased cannabis-impaired driving, it is worth considering US jurisdictions which have legalized medical cannabis have recorded an 8-11% drop in traffic fatalities one year following medical cannabis legislation.[13] Further research specific to medical cannabis use is needed.

Establishing THC *Per Se* Limits: Blood Testing

In the government's backgrounder on Bill C-46, they propose two different *per se* limits for blood levels of THC: 2ng/ml and 5ng/ml.[29] Although Bill C-46 contemplates a tough approach to driving under the influence of cannabis, there is ongoing debate within the scientific literature on the most effective and accurate ways to establish a level of impairment, similar to blood alcohol content (BAC). As it currently stands, cannabis detection devices or tests are only able to determine previous use of cannabis through presence of THC, which is not a test of impairment itself. This issue in detection is further complicated when assessing individuals who use cannabis for medical purposes, as authorized by their physician.

Per se limits refer to a specific concentration of a substance (i.e. THC in blood or blood alcohol concentration/'BAC') that trigger a criminal charge when the set limit/cut-off is exceeded (i.e. 0.05 Blood Alcohol Concentration or BAC). *Per se* limits, however, do not factor in impairment and may result in criminal charges for any user who exceeds the limit, even if no signs of impairment are demonstrated. Contrarily, if a user demonstrates impairment but remains below the cut-off, they will not be criminally charged under *per se* laws.

For police to be able to conduct THC tests as proposed in Bill C-46, officers must have reasonable suspicion that a person "has alcohol or drugs in their body" to submit drivers to oral fluid tests and reasonable grounds a crime has been committed to conduct blood tests. **A key consideration which addresses the intersection between enforcement and citizen rights includes transparency in how police officers will establish "reasonable suspicion" to initiate an assessment of impairment. Although the necessity to establish reasonable suspicion and grounds can act as a potential safeguard against random testing, these grounds, such as smell of cannabis, are not always indicative of impairment at the time of driving.** There are important concerns that what is considered 'reasonable' is up to the police officers discretion, which can lead to unequal targeting and application of these new laws, particularly for medical users.

The most problematic policy concern when it comes to medical cannabis-impaired driving is determining what specific *per se* limit could be set that would also factor in distinct medical use and high inter-individual variability. As one example, a study by Johnston et al. demonstrated that "permit holders" for medical cannabis use in California were significantly more likely than non-permit holders to test positive for THC – even among heavy or regular non-permit users, concluding that, "police officers may need to modify their enforcement effort to apprehend cannabis-impaired drivers based on medical cannabis legislation".[14]

An in-depth report by the American Automobile Association compared roadside testing and impairment to blood levels of THC and found that blood concentrations of THC did not accurately correlate to impairment or roadside evaluation measures (i.e. SFST and DRE).[15] The AAA report concluded *per se* limits of 5 ng/ml THC are not scientifically supported and would (a) criminalize drivers who exceed the limit but are not impaired and (b) would miss catching drivers who are impaired but are under the *per se* limit. Contrarily, other research has concluded *per se* limits between 2-10 ng/ml may be appropriate (mainly targeted at recreational use). In an epidemiological study, Ramaekers et al. found significant impairment correlated to THC blood concentrations between 2-5 ng/ml after acute use, recommending this as a lower and upper range of THC for impairment *per se* limits.[16] A meta-analysis of experiential studies by Grotenhermen et al. found that a higher level of THC in blood (7-10 ng/ml) correlated to impairment similar to a BAC of 0.05%, and concluded this range might represent a suitable *per se* limit.[17] Although a very limited amount of evidence exists related to driving impairment functions related in medical cannabis users, the authors concluded that a range of 7-10 ng/ml could reduce the chances of medical users being unfairly subject to *per se* limits.

While a lower *per se* limit has the potential to over-criminalize medical users, raising the limit higher than 2-5 ng/ml may not catch novice or infrequent cannabis users who are impaired.[16] An epidemiological study over ten years found that setting a *per se* limit at 5 ng/ml would result in a majority of recent cannabis users going undetected and recommended a zero-tolerance approach to *per se* limits.[18] However, the authors also noted a zero-tolerance approach might essentially ban regular users (i.e. legally authorized patients) from driving regardless of impairment.

Conversely, the reason why *per* se limits (0.05-0.08 BAC) for alcohol make sense is that they have well-established links to significantly increased MVA risk (OR 2.07-3.93 respectively) and impairment through extensive research and, "alcohol levels, which have linear pharmacokinetics, are easier to back-calculate to the time of the accident, and are consistently linked with increased culpability in crashes".[11,15,19]

It has been well established that regular cannabis users have different metabolism and distribution of THC than that in occasional users, leading to prolonged excretion of THC from lipid cells.[20-21] The current evidence base is cause for concern as the impaired driving literature has almost solely studied acute use, yet there are notable differences between acute and regular consumption. This has been illustrated in a few studies to date, including one that followed 12 heavy users and found that the THC concentrations in abstinence/sober phases matched that of occasional users after acute use.[22] This demonstrates that even though regular users may have THC in their blood that matches that of acute use, the impairment caused by their level of THC does not correlate to the same level of THC in acute users. Another study followed participants over seven days and exposed them to sustained doses of oral cannabis and found that 22.5 hours after the last dose administration, the mean blood concentration was 3.8 ng/ml THC.[23] These results suggest that even after 22.5 hours of consumption abstinence, many patients consuming oral cannabis would exceed a 2 ng/ml per se limit and some would exceed a 5 ng/ml limit. Finally, a similar study followed 18 participants over 7 days of monitored abstinence and found about 22% of participants would have exceeded the 2 ng/ml *per se* limit, and at least one would have exceeded the 5 ng/ml *per* se limit 7 days after consuming oral THC (see figure 2 below).[24]

Table II. Median (n = 18) and Range of Plasma Cannabinoid Concentrations During Seven Days of Continuous Monitored Abstinence, Number of Participants With Concentrations Above Common Analytical Cutoffs (1, 2, and 5 ng/mL) and LOQ of 0.25 ng/mL for THC and THCCOOH and 0.5 ng/mL for 11-OH-THC

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
THC (ng/mL)							
Median	1.9	1.6	1.4	1.3	1.2	1.0	1.1
Range	0.5–9.0	0.5–7.3	ND–6.7	ND–7.5	ND–4.0	ND–5.1	ND–5.5
$n \geq$ LOQ	18	18	17	17	14	13	16
$n \geq$ 1.0 ng/mL	15	14	13	11	12	9	9
$n \geq$ 2.0 ng/mL	9	6	5	6	5	4	4

Figure 2 **-** Reproduced with permission from Erin L. Karschner et al. Implications of Plasma Δ9-Tetrahydrocannabinol, 11-Hydroxy-THC, and 11-nor-9-Carboxy-THC Concentrations in Chronic Cannabis Smokers. Journal of Analytical Toxicology (2009) 33 (8): 469-477. Published by Oxford University Press on behalf of the Society of Forensic Toxicologists Inc. online at: https://academic.oup.com/jat/article/33/8/469/776927/Implications-of-Plasma-9-

Similar results were demonstrated in a different study, which found a portion of regular cannabis users would exceed the limit 1-2 days following inhaled cannabis use.[25] Based on these studies, regardless of actual impairment, long-term medical cannabis patients would have to wait at least a week after last orally consuming THC to ensure a *per se* limits would not be exceeded, and no criminal charges would result.

Patients regularly using medical cannabis may have different tolerance, strains, and methods of administration than recreational users – a key area yet to be well explored. Raising the limit to the point that would allow non-

impaired, daily medical cannabis users to drive would also likely result in riskier, occasional users being able to drive without being caught.

The Canadian Association of Chiefs of Police has been advocating for changes to the Canadian impaired-driving landscape.[26-27] Especially considering the government's proposal to establish *per se* limits for THC, it is significant to note that the Chiefs of Police also expressed concerns on the use of *per se* limits, stating:

> *Evidence-based permissible limits are not defined and supported by science. There is no evidence that "per se" limits adequately quantify impairment and therefore we are concerned with regards to potential challenges within our judicial system. We know with cannabis that people react differently to its effects. Per se limits must be research-based and the science must catch up to strengthen their credibility.*[26 (p.4)]

A 2006 study demonstrated the importance of considering regular use, such as how patients consume cannabis, and found drivers who claimed to be regular users of cannabis were less often judged as impaired, but there was no difference in THC concentration between regular users and non-regular users.[28] These results demonstrate the possible effects of regular use as both regular and inexperienced users had equal THC concentrations, but the regular user group demonstrated decreased frequency and levels of impairment. Again, this is important because regular users of medical cannabis may have THC concentrations that do not correlate to impairment caused by occasional or acute use, which ultimately leads to problems when setting a specific level of THC-related to *per se* charges.

Put simply, there is no scientific basis for any *per se* limit that would accurately relate to impairment in all populations, leaving *per se* limits as primarily arbitrary decisions that likely will leave a portion of the population unfairly criminalized – most likely patients. The proposed THC limits of 2 ng/ml and 5ng/ml would essentially bar daily users of medical cannabis from driving without prolonged periods of abstinence (1+ week for oral use, 3+ days for inhaled). Even a responsible patient who never drives while impaired and follows safe-use guidelines to mitigate risk would be left with the decision to either (a) continue driving and risk exceeding the *per se* limit, (b) never drive, (c) or stop using cannabis. Although driving is a privilege, people with medical conditions that include mobility challenges, such as severe arthritis, have a genuine need for vehicles to go about their daily activities. It is necessary to develop policy that will protect non-impaired patients from the proposed *per* se limits.

Establishing THC *Per Se* Limits: Oral Fluid (OF) Testing

In addition to establishing *per se* limits and charges, Bill C-46 would also enable police officers to use roadside oral fluid (OF) testing device where reasonable cause is established for impairment. The OF test would help police establish recent use and a positive THC test would help them to more easily obtain blood samples and/or Drug Recognition Expert (DRE) evaluations that, if failed, would allow charges to be laid.[29]

At time of this brief, the government has yet to announce what specific cut-off level of THC in oral fluids would yield a pass/fail on the roadside test or if they would be the same as blood *per se* levels. One difficulty in setting an OF cut-off is how to extrapolate THC presence in OF to blood, and although some calculations do exist, there is significant inter-individual variability.[30-31] A randomized cross-over, double-blind placebo-controlled study of occasional cannabis users also found that smoked cannabis had a high degree of inter-individual variability between the relationship of THC detected in blood and THC detected in OF, meaning different people had wide-ranging levels of THC in their system from similar doses of cannabis.[32] Additionally, currently available OF testing devices have a false positive rate of 3-7%, so charges should not be directly applied due to their potential for error.[33]

Mitigation of Risk

The mantra of medical cannabis dosing is "start low, go slow" to obtain maximum clinical benefit with the smallest dose possible. Health Canada's dosage fact sheet states that, "doses of THC as low as 2.5–3 mg of THC (and even lower) are associated with a therapeutic benefit and minimal psychoactivity" and that "acute effects generally peak between 3 and 4 hours after dosing and can last up to 8 hours or longer (e.g. 12–24 hours)."[34] Again, the goal of medical cannabis use is not to experience its psychoactive effects, but rather the treat symptoms and is related to specific health outcomes.

The College of Family Physicians of Canada's evidence-based recommendations/safe-use guidelines on cannabis prescribing advises that patients wait, "four hours after inhalation, six hours after oral ingestion, and eight hours after inhalation or oral ingestion if the patient experiences euphoria" (p. 13) to reduce risk of impairment.[35] **Safe-use guidelines are essential to ensuring patients can balance their medical cannabis consumption and the ability to safely drive when not impaired, however, they would not ensure patients remain below the proposed *per se* limits.** If Bill C-46 were to be adopted as proposed, patients and physicians will need to be re-educated on *per se* limit guidelines.

RECCOMENDATIONS

1. Protect Non-Impaired, Responsible Medical Cannabis Patients

Medical Defense: Patients following safe-use guidelines, which ensure chance of impairment is eliminated, may still be targeted under the proposed *per se* limits. Given the paucity of research, policy must consider the limitations of tests in measuring cannabis impairment, particularly when it comes to medical cannabis.

We recommend Canada consider the United Kingdom model of *per se* limits and 'medical defenses'. The UK's laws allow for a 'medical defense' if people are taking drugs for medical reasons and are not impaired.[36] According to the medical defense, drivers are not guilty of *per se* offenses if they are not impaired and the following conditions are met:

- "the medicine was prescribed, supplied, or sold to treat a medical or dental problem, and
- it was taken according to the instructions given by the prescriber or the information provided with the medicine" [36-37]

A medical defense for *per se* limits ensures that other evidence of impaired driving, rather than indicators of previous use, must be established to ensure patients are not criminalized for simply exceeding a *per se* limit. In regard to Canadian laws around impaired driving, a medical defense will be not only essential to patients, but the Canadian justice system as a whole. As impaired driving is currently the number one offence heard by Canadian criminal courts, in addition to the serious problem with court delays, an arbitrary *per se* limit applied to patients could further clog courts with cases that never posed risk to public safety.[38-39]

Reasonable Suspicion and Grounds: A re-evaluation of what indicators establish reasonable suspicion and reasonable grounds for the collection of bodily fluids must be considered. Reasonable suspicion and grounds should be based on impairment - not previous use of cannabis or drugs in one's body. Some indicators, such smell of cannabis, are not signs of impairment and may lead to the criminalization of non-impaired patients.

2. Education Specific to Medical Cannabis Impairment

Given the technology to identify cannabis-impaired driving is not backed by sufficient research, laws must be coupled with evidence-based education around the risks of driving while impaired, information on how *per se* limits effect patients, and encourage safe-use guidelines and responsible use for medical cannabis patients.

As individuals using cannabis medically must be authorized through a health care provider, this interaction provides an ideal avenue of education to ensure patients know and follow safe-use guidelines to eliminate risk of impairment. When prescribing cannabis, HCPs must discuss the risk of driving impaired and how to mitigate that risk by practicing safe-use guidelines. By having an informed conversation, HCPs will play an essential role in lowering risk of medical cannabis patients driving impaired. Law enforcement should be educated on the complexities of impairment and testing, particularly as it concerns medical cannabis use.

Preventing people from driving impaired in the first place is the safest and most effective approach to reducing risk to public safety. It is vital to educate patients using medical cannabis on the potential dangers of drug-impaired driving and new laws as they are implemented. Patient organizations, including CFAMM, must be supported by government to play key roles in delivering education.

3. Fund Research Specific to Medical Use

The federal government should dedicate funds towards impaired driving research including policy surveillance and monitoring. This research should follow national standards and must consider medical cannabis use. Further areas of study that should be prioritized include the determination of the correlation between levels of THC and impairment for regular medical cannabis users and an evaluation of impairment-based testing (including DRE and SFST).

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ABOUT CFAMM

Canadians for Fair Access to Medical Marijuana (CFAMM) is a national, non-profit, patient-run organization dedicated to protecting and improving the rights of medical cannabis patients. Founded in 2014, CFAMM's goal is to enable patients to obtain fair and safe access to medical cannabis with a special focus on affordability, including private and public insurance coverage.