Comprehensive Overview of Contemporary Science

A White Paper on the Florida
medical marijuana consent form

Created by The Florida Cannabis Action Network

Acknowledgements

The Florida Cannabis Action Network is a 25 year old organization dedicated to educating the public about Cannabis. We represent people who have an interest in the many uses of the Cannabis plant.

This white paper was created by a team lead by Carla Ashburn, CEO of MMCare of Florida, a Cannabis support company offering consultation with a qualified physician who may recommend medical marijuana as a course of treatment.

Carla's team included Laramie Silber, former Chief Operating Officer of Patients Out of Time, a 501c(3) organization who delivered continuing medical education credits on Cannabis medicine and Science from 1999-2019.

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INTRODUCTION

Florida adopted legislation governing its Medical Marijuana Program in 2017. Currently over 800,000 people maintain an active authorization to purchase, transport, and consume products allowed under state laws.

The legislation put forth in FL Statute 381.986 the framework for the rules that govern the program. Section 381.986 (4) (a) (8) states "Obtains the voluntary and informed, written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient,"

The Board of Medicine operating under the authority of the Department of Health adopted Florida Emergency Rule No. 64B8-9.018 on April 30, 2018 creating the **Mandatory Standardized Informed Consent for Medical Marijuana.** In 2018, after the addition of smoking as a route of administration the form was revised again through Emergency Rulemaking. The form has been revised four times since 2017.

The voluntary Mandatory Medical Marijuana Consent Form provides the patient information used to make a course of treatment decision with the recommending physician.

Methodology - The team reviewed form DH-MQA-5026(Rev. 03/21) and did a comparative review of the contemporary data commonly used in states with mature Cannabis markets.

Cannabis has been legal in some form in the United States since Marinol, a synthetic THC formula received FDA approval in 1985.

US Department of HHS obtained patent # 6630507 in 1999 for Cannabinoids as antioxidants and neuroprotectants.

In 1996, California became the first state to allow the use of whole flower Cannabis as a medical treatment.

Key Recommendations

- The Board of Medicine should discontinue the use of form DH-MQA-5026 (Rev.03/21).
- The Board of Medicine should enter into Rulemaking to produce a new form.
- The Legislature should revise FL Statute 381.986 (4)(a)(8).
- In creating a new voluntary mandatory consent form the Board of Medicine should:
    - Remove vague/unsupported language ("some investigators argue" "one could hypothesize").
    - Remove points that are unsupported by current scientific research.
    - Re-focus language on peer-review/science based/backed data.
    - Bring the Medical Marijuana Consent Form into line with documentation regarding other therapeutic drugs/medicines.
    - Bring the Medical Marijuana Consent Form into line with the cautions taken regarding other Schedule I (Cannabis) or Schedule III (Marinol/Dronabinol).

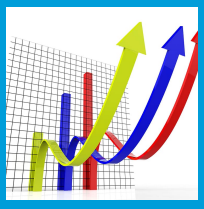
KEY FINDINGS

Key Findings #1

Information provided by the form is inaccurate on its face and the language is overly broad.

Key Findings #2

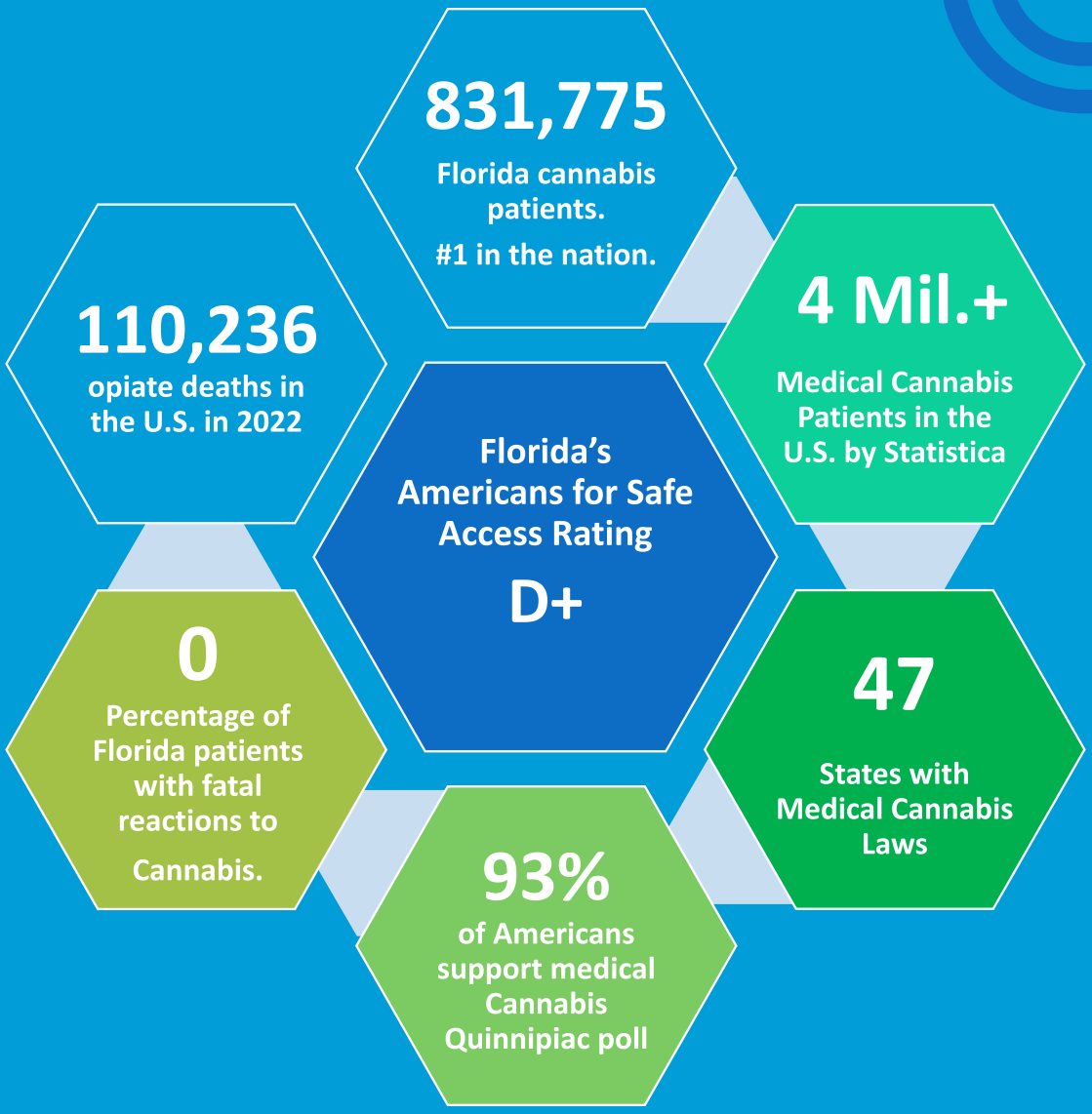
The form is prejudicial and strips patients of rights and privileges.



Key Findings #3

Contemporary research shows great potential for therapeutic use. The form appears to argue against the very uses for which Cannabis is allowed under law.

While popular support is no way to measure the therapeutic value of Cannabis, it is cause to use tax-dollars to fund quality studies of its potentials.



MEDICAL CONSENT FORM USES

A medical consent form is required when performing a medical procedure. The form explains the risks and benefits to the procedure and ensures the patient understands what is happening and what could happen.

A medical marijuana consent form is an instrument that provides information about the use of marijuana for medical use. It details the risks, benefits, and status of legal availability. Also known as informed consent, it requires that patients have the mental capacity to make their own decisions, as they must understand the treatment's procedure, benefits, and risks before consenting.

The FL Statute 381.986 (4) Physician Certification (8) states : Obtains the VOLUNTARY and informed, written consent of the patient for medical use of marijuana each time the patient is recertified. The Rule, 64B15-14.014, states that it is the Mandatory Standardized Informed Consent for Medical Marijuana; Required Documentation for Comparable Medical Conditions; Required documentation for Smokable Medical Marijuana. Form DH-MQA-5026 (rev. 03/21) entitled Medical Marijuana Consent Form is mandatory in that it is the only form that may be used.

We found no other mandatory consent forms used when prescribing pharmaceuticals. Pharmaceuticals with documented dangerous side effects and a high potential for abuse do not require a mandatory consent form. Patients are given a Drug Fact Sheet regarding the prescribed pharmaceutical that does not require a signature. There is no mandatory treatment plan document required between a doctor and patient which requires a signature at every renewal. A 90-day follow up is required for refills of Schedule II drugs.

Florida experienced nearly 8000 deaths attributed to opiates in 2022 according to the Florida Medical Examiners Annual Report. While the numbers continue to rise for opioid deaths, to date, less than .0048% of known Cannabis users had a fatal reaction. The opiate deaths equate to an average of 21a daily.

The NCBI (National Center for Biotechnical Information) maintains that:

'Informed consent remains valid for an indefinite period, allowing advance content to be sought, providing the patients' condition has not changed.'

www.ncbi.nlm.nih.gov

Key Finding 1

Information provided by the form is inaccurate on its face and the language is overly broad. See the *Rebuttals and References* section for the details of each statement included in the form. The form used does not provide the patient with up to date information in order to make an informed consent.

Key Finding 2

Florida's current Medical Marijuana program does not provide the state's patients and their physicians with protection of their civil rights. The form is prejudicial and is being used in Courts of Law against patients. Signing the form strips patients of rights and privileges. We have documented the use of this form to strip patients of the ability to drive a car during the course of treatment and the right to possess a firearm.

The patient cannot receive a certification without submitting their initials and signature that serves as their consent. **The patient has no alternative but to sign the form if they chose to participate in the program**.

In USCA11 Case: 22-13893 Cooper V Garland Document: 35 Filed: 03/15/2023 the Appellee states, **"The same statute that implements Florida's medical marijuana program also recognizes that marijuana can impair skills relevant to the safe handling of firearms.** In particular, the statute cautions that marijuana can impede "coordination, motor skills, and cognition." Fla. Stat. § 381.986(4)(a)(8)(e). Participants in Florida's medical marijuana program must therefore sign a consent form, see id. § 381.986(4)(a)(8), acknowledging that marijuana "can affect . . . the ability to think, judge and reason" and can produce side effects such as "dizziness, anxiety, confusion, . . . impaired motor skills, paranoia, [and] psychotic symptoms," Dkt. No. 14-1, at 2-3 (Florida Board of Medicine, Medical Marijuana Consent Form). **Florida accordingly makes it a crime to drive a motor vehicle while under the influence of marijuana.** See Fla. Stat. § 316.193(1); id. at § 381.986(14)(g) (explaining that participation in the medical marijuana program "does not exempt a person from prosecution for a criminal

offense related to impairment or intoxication resulting from the medical use of marijuana").

Key Finding 3

The form appears to argue against the very uses for which Cannabis is allowed under law. Contemporary research shows great potential for therapeutic use of Cannabis. **Adverse reactions to Cannabis are low compared to other commonly used products both prescribed and over-the-counter[1].** The data expressed in the form is detrimental to patients, as it appears to support the conclusion Cannabis is dangerous and the harms outweigh the potential benefits.

State of the States

States have been far more responsive to patient needs than the federal government. The most important markers of a well-designed state program are that all patients who would benefit from medical cannabis have safe and legal access to their medicine without fear of losing any of the civil rights and protections afforded to them as residents of that state.

Granting state-regulated access to medical cannabis does nothing to protect patients who require legal protections pertaining to employment, housing, education, and family legal matters. Without federal protection patients must give up many federal rights and protections in order to purchase, possess, and use medical cannabis without fear of monetary fine, arrests, prosecution, and imprisonment.

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[1] DEA Administrative Law Judge Francis Young concluded, "In strict medical terms marijuana is far safer than many foods we commonly consume. For example, eating ten raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death. Marijuana, in its natural form, is one of the safest therapeutically active substances known to man. By any measure of rational analysis marijuana can be safely used within a supervised routine of medical care." Source: US Department of Justice, Drug Enforcement Agency, "In the Matter of Marijuana Rescheduling Petition," [Docket #86-22], (September 6, 1988), pg. 58.

Conclusion

In its fourth draft, DH-MQA-5026 (Rev.03/21) ignores commonly accepted science related to the conditions set forth in Florida law.

The inconsistencies, inaccuracies and scare tactics used in this form have made it more difficult for physicians to feel comfortable recommending Cannabis, as well as hindering the patients' belief there is hope in introducing Cannabis into their health regimen.

As a result, Florida's medical marijuana program is failing to serve a large portion of people with disease sets that can benefit from the use of Cannabis, and failing to serve the interests of the voters or of the State. A new path to patient rights and their understanding of the medicine of their choice is needed.

The Board of Medicine should discontinue the use of form DH-MQA-5026 (Rev.03/21). The Board of Medicine should enter into Rulemaking to produce a new form.

Rebuttal and Research

Form DH-MQA-5026 (rev. 03/21)

PART A: a – Schedule 1

"*Classification of a Schedule 1 drug. Schedule 1 substances are defined, in part, as having a high potential for abuse, no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision.****"***

Rebuttal

Cannabis was used as a medicine for thousands of years until 1942 when it was removed from the official U.S. Pharmacopeia. The American Medical Association initially opposed prohibition. By 1970 a more comprehensive act was designed, the 'Controlled Substances Act of 1970'. Consequently, Marijuana was placed as a Schedule 1 provisionally, 'until the science could be assessed.'

The classification is outdated. The Drug Enforcement Association acting for the Federal Government has denied numerous petitions to evaluate and reschedule Cannabis. Despite the Federal Schedule Cannabis is 'treated as a medicine' in Florida and it has proven medical value. Cannabis was deemed essential during our recent pandemic as the need for this medicine was proven to be essential to patients' healthcare.

This continued unmerited Scheduling of Cannabis is tying our hands to complete viable Clinical Trials, cannabis being regulated by the FDA, and a patient's healthcare not being covered by health insurance. The Federal Scheduling of Cannabis is a barrier to safe, legal, and affordable access to our patients.

The U.S. Patent Office issued patent #6630507 to the Health and Human Services on 2/2/2001. This patent lists the use of certain cannabinoids found within the cannabis sativa plant as useful in certain degenerative diseases such as Alzheimer's, Parkinson's, and HIV dementia.

After reviewing World Health Organization (WHO) recommendations on cannabis and its derivatives, the United Nations Commission on Narcotic

Drugs (CND) voted in 2020 to remove cannabis from its most strictly controlled Schedule, recognizing the medicinal and therapeutic potential of the drug.[2]

The former Editor of the New England Journal of Medicine weighed in on the question of scheduling as well: "I believe that a federal policy that prohibits physicians from alleviating suffering by prescribing marijuana for seriously ill patients is **misguided, heavy-handed, and inhumane**….."[3]

PART A: b - The Approval & oversight status of marijuana by the FDA

"*Marijuana has not been approved by the FDA for marketing as a drug. Therefore the manufacturing of marijuana for medical use is not subject to any federal standards, quality control, or other federal oversight. Marijuana may contain unknown quantities of active ingredients of which may vary in potency, impurities, contaminants, and substances in addition to THC which is the primary psychoactive chemical component of marijuana.****"***

Rebuttal

This is misleading and is a scare tactic that alarms many patients. Clinics report patients have declined to continue the process believing there are no safety protocols in place at the state level. There are **very strict** guidelines, processes, and protocols in place to ensure safe plant medicine is dispensed.

FL St 381.986 Medical Use of Marijuana and FL St 581 Plant Nurseries govern the cultivation, processing, and distribution of products for the medical market. Cannabis medical distributors must:

- Consult with the Department of Agriculture & Consumer Services approval on pesticides.
- Food Establishment License from the Department of Agriculture
- Pass Food Safety Good Manufacturing inspections to be free from Contaminants.
- Package according to US Poison Prevention Packaging Act of 1970
- Assure every batch has a COA that coincides with what is dispensed.
- Utilize the Department of Environmental Protection assistance in implementing the rules for disposal of solid and liquid waste.

[2] https://news.un.org/en/story/2020/12/1079132
[3] Jerome P Kassirer, MD (Former) Editor, New England Journal of Medicine
"Federal Foolishness & Marijuana," Editorial of January 30th, 1997

Additionally:

- The FDA has approved two drugs, dronabinol (Marinol, Syndros) and nabilone (Cesamet), made from synthetic forms of THC, one active ingredient found in the Cannabis plant. They can be legally prescribed for the treatment of nausea and vomiting caused by chemotherapy. Dronabinol might also be used for the treatment of decreased appetite associated with weight loss in people with HIV and AIDS. These products are Schedule III.
- The FDA has also approved a liquid medication (Epidiolex) containing a purified form of cannabidiol (CBD), a chemical found in marijuana as a Schedule III drug. This was approved for use in the treatment of severe childhood epilepsy (Lennox-Gastaut syndrome and Dravet syndrome).
- The FDA did approve Dr. Sue Sisley, MD. to treat veterans with PTSD with Cannabis via smoking route. The first of those study results are listed with the NIH.[4]

PART A:c - The potential for addiction

"*Some studies suggest that the use of marijuana by individuals may lead to a tolerance to, dependence on, or addiction to marijuana. I understand that if I require increasingly high doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact my doctor.****"***

Rebuttal

According to research by Dr. Raphael Mechoulam[5]

"Despite the mild addiction to cannabis and the possible enhancement of addiction to other substances of abuse, when combined with cannabis, the therapeutic value of cannabinoids is too high to be put aside. Numerous diseases, such as anorexia, emesis, pain, inflammation, multiple sclerosis, neurodegenerative disorders (Parkinson's disease, Huntington's disease, Tourette's syndrome, Alzheimer's disease), epilepsy, glaucoma, osteoporosis, schizophrenia, cardiovascular disorders, cancer, obesity, and metabolic syndrome-related disorders, to name just a few, are being treated or have the potential to be treated by cannabinoid agonists/antagonists/or cannabinoid-related compounds. **In view of the very low toxicity and the generally benign side effects of this group of compounds, neglecting or denying their clinical potential is unacceptable."**

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7968689/
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3202504/

PART A:d - Driving

"*The potential effect may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.*

The use of marijuana can affect coordination, motor skills and cognition, i.e., the ability to think, judge and reason. Driving under the influence of cannabis can double the risk of vehicular accident, which escalates if alcohol is also influencing the driver. While using medical marijuana, I should not drive, operate heavy machinery or engage in any activities that require me to be alert and/or respond quickly and I should not participate in activities that may be dangerous to myself or others. ***I understand that if I drive while under the influence of marijuana, I can be arrested for "driving under the influence."***

Rebuttal

By initialing next to the statement and signing this form the patient declares that they understand that driving "under the influence" is a crime. Further, it could be construed to mean that by accepting a state medical marijuana patient status they are essentially giving up their right to drive since there is no way to determine impairment from a blood or saliva test.

"Driving under the influence of cannabis can double the risk of vehicular accident, which escalates if alcohol is also influencing the driver."

The form provided gives no data or references to corroborate the stated dangers. There is no reference provided that shows driving under the influence of Cannabis can double the risk of vehicular accidents.

- Any cautions given about cannabis use and motor skills should be given in accordance with label warnings given for medications that may cause drowsiness or dizziness in some patients: "do not operate a motor vehicle until you know how this medication will affect you."
- There has been no correlation established between elevated THC blood levels and impaired driving performance. [6]

[6] "Research studies have been unable to consistently correlate levels of marijuana consumption, or THC in a person's body, and levels of impairment. Thus some researchers, and the National Highway Traffic Safety Administration, have observed that using a measure of THC as evidence of a driver's impairment is not supported by scientific evidence to date." *Congressional Research Service, Marijuana Use and Highway Safety, 2019* <https://crsreports.congress.gov/product/pdf/R/R45719>

- There has been no correlation established between states having medical cannabis programs and an increase in traffic accidents.[7]
- Irvin Rosenfeld, who resides in Ft. Lauderdale, Florida, receives 300 joints a month for the past 32 years from the US government for a severe bone tumor disorder. To date, there have been no restrictions put on his driving privileges.
- Several robust analyses refute a correlation between driving under the influence of cannabis and increased risk of crash risk.[8] [9] [10]
- Studies have found statistically higher accident risk from driving under the legal limit of Blood Alcohol Concentration or from having multiple passengers in a vehicle than they have from cannabis use.[11] [12] [13]

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[7] "Instead of seeing an increase in fatalities, we saw a reduction." Deaths dropped 11 % on average in states that legalized medical marijuana. Research done on 1.2 million traffic fatalities nationwide from 1985 to 2014 found this as particularly striking. *U.S. Traffic Fatalities, 1985-2014, and Their Relationship to Medical Marijuana Laws, Journal of Public Health, 11/13/16*

[8] "Both Australian studies suggest cannabis may actually reduce the responsibility rate and lower crash risk. Put another way, cannabis consumption either increases driving ability or, more likely, drivers who use cannabis made adjustments in driving style to compensate for any loss of skill (Drummer 1995)" *Laberger, Jason C., Nicholar J. Ward, "Research Note: Cannabis and Driving -- Research Needs and Issues for Transportation Policy," Journal of Drug Issues, Dec 2003, pp 980.*

[9] The increased crash risk with pot alone "is so small you can compare it to driving in darkness compared to driving in daylight,". University of Oslo political scientist Rune Elvik, who conducted several major meta-analyses evaluating the risk of drugged driving. <https://pubmed.ncbi.nlm.nih.gov/22785089><https://pubmed.ncbi.nlm.nih.gov/26878835>

[10] https://www.sciencedirect.com/science/article/abs/pii/S0001457524000046

[11] "We undertook a systematic search of electronic databases, and identified 13 culpability studies and 4 case–control studies from which cannabis-crash odds ratios could be extracted. … Taking the role of study biases into account, we have shown that the best epidemiological evidence concerning the risk of crashing after using cannabis (as indicated by testing positive to THC) is compatible with the null hypothesis that the recent use of cannabis has no effect at all (such that the cannabis-crash OR = 1.0)." *The risk of being culpable for or involved in a road crash after using cannabis: A systematic review and meta-analyses, Drug Science, Policy and Law, 2021* <https://pubmed.ncbi.nlm.nih.gov/31106494/>

[12] "As noted above, even if cannabis impairment is present, it creates (unless combined with alcohol or other drugs) only a fraction of the risks associated with driving at the legal 0.08 BAC threshold, let alone the much higher risks associated with higher levels of alcohol. … The maximum risk for cannabis intoxication alone, unmixed with alcohol or other drugs, appears to be more comparable to risks such as talking on a hands-free cell phone (legal in all states) than to driving with a BAC above 0.08, let alone the rapidly-rising risks at higher BACs." <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3163816>

[13] Drivers with two or more passengers in the car possess a crash risk of more than two-fold (OR=2.2). "*The contribution of passengers versus mobile phone use to motor vehicle crashes resulting in hospital attendance by the driver, ScienceDirect, 2007.* <https://www.sciencedirect.com/science/article/abs/pii/S000145750700036X>

PART A: e- The potential side effects of marijuana use

"*Potential side effects from the use of marijuana include, but are not limited to, the following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of short term memory, euphoria, difficulty in completing complex tasks, suppression of the body's immune system,* ***may affect the production of sex hormones that lead to adverse effects****, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression and/or restlessness. Marijuana may exacerbate schizophrenia in persons predisposed to that disorder. In addition,* ***the use of medical marijuana may cause me to talk or eat in excess****, alter my perception of time and space and impair my judgment. Many medical authorities claim that use of medical marijuana, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, drug abuse, and schizophrenia.*

There is substantial evidence of a ***statistical association*** *between long-term cannabis smoking and worsening respiratory symptoms and more frequent chronic bronchitis episodes. Smoking marijuana is* ***associated with*** *large airway inflammation, increased airway resistance, and lung hyperinflation. Smoking cannabis, much like smoking tobacco,* ***can introduce levels of volatile chemicals and tar in the lungs that may raise concerns about the risk of cancer and lung disease."***

Rebuttal

Overstating the risks associated with an activity is counterproductive. The use of vague terms and statistical associations is not the basis of good science or good public education.

It is part of the healthcare professionals' job to familiarize their patients with the side effects of any medication, supplement, or OTC remedy they recommend. The healthcare professional will be familiar with the medical history of their patients and can, therefore, focus on side effects that that patient is most likely to experience. We trust our healthcare professionals to efficiently do this with substances, such as opioids (see appendix B), which carry potentially fatal side effects. It is important that this responsibility stay with the healthcare provider, to avoid outdated, incorrect information being foisted on patients.

A sample of the side effects which the current Patient Consent Form, improperly and without scientific support, attributes to cannabis:

- **Suppression of the body's immune system**
  - "The short-term immunosuppressive effects are not well established but, if they exist, are not likely great enough to preclude a legitimate medical use." *Janet E Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Marijuana and Medicine: Assessing the Science Base. Division of Neuroscience and Behavioral Research, Institute of Medicine (Washington, DC: National Academy Press, 1999).*

  - "This study provides evidence that short-term use of cannabinoids, either oral or smoked, does not substantially elevate viral load in individuals with HIV infection…Because this study was randomized and analysis were controlled for all known potential confounders, it is very unlikely that chance imbalance on any known or unknown covariate masked a harmful effect of cannabinoids." *Abrams, Donald I., MD, et al. "Short-Term Effects of Cannabinoids in Patients with HIV-1 Infection - A Randomized, Placebo-Controlled Clinical Trial," Annals of Internal Medicine, Aug 19, 2003, Vol. 139, No. 4 (American College of Physicians) pg 264.*

- **Difficulty completing complex tasks & impaired motor skills**
  - "The result of our meta-analytical study failed to reveal a substantial, systematic effect of long-term, regular cannabis consumption on the neurocognitive functioning of users who were not acutely intoxicated. *Grant, Igor, et al., "Non-Acute (Residual) Neurocognitive Effects of Cannabis Use: A Meta Analytic Study," Journal of the International Neuropsychological Society (Cambridge University Press: July 2003), 9, p.685.*

  - "In conclusion, our meta-analysis of studies that have attempted to address the question of longer term neurocognitive disturbance in moderate and heavy cannabis users has failed to demonstrate a substantial systematic and detrimental effect of cannabis use on neuropsychological performance. It was surprising to find such few and small effects given that most of the potential biases inherent in our analyses actually increased the likelihood of finding a cannabis effect." (*ibid p. 687)*

  - A study by Johns Hopkins looked at 1,318 participants over a 15 year period, finding, "no significant differences in cognitive decline between

heavy users, light users, and nonusers of cannabis…These results…seem to provide strong evidence of the absence of a long-term residual effect of cannabis use on cognition" *Constantine G. Lyketsos, Elizabeth Garrett, King-Yee LIang, and James C. Anthony. (1999), "Cannabis Use and Cognitive Decline in Persons under 65 Years of Age," American Journal of Epidemiology, Vol. 149, No. 9.*

- **Psychotic symptoms & schizophrenia**
  - "These studies suggest, therefore, that CBD has an antipsychotic-like profile in healthy volunteers and may possess antipsychotic properties in schizophrenic patients, but not in the resistant ones. Confirming this suggestion, a preliminary report from a 4-week, double-blind controlled clinical trial, using an adequate number of patients and comparing the effects of CBD with amisulpride in acute schizophrenia and schizophreniform psychosis, showed that CBD significantly reduced acute psychotic symptoms after 2 and 4 weeks of treatment when compared to baseline. In this trial CBD did not differ from amisulpride except for a lower incidence of side effects (49). "In conclusion, results from pre- clinical and clinical studies suggest that CBD is an effective, safe and well-tolerated alternative treatment for schizophrenic patients. Future trials of this cannabinoid in other psychotic conditions such as bipolar disorder (50) and comparative studies of its antipsychotic effects with those produced by clozapine in schizophrenic patients are clearly needed."

    Zuardi, A.W.; Crippa, J.A.S.; Hallak, J.E.C.; Moreira, F.A.; and Guimarães, F.S., "Cannabidiol, a Cannabis sativa constituent, as an antipsychotic drug"; Brazilian Journal of Medical and Biological Research (Ribeirão Preto, Brazil: April 2006), Volume 39, Issue 4, p. 427-428. <http://www.scielo.br/pdf/bjmbr/v39n4/6164.pdf>

  - Having an increased familial morbid risk for schizophrenia may be the underlying basis for schizophrenia in cannabis users and not cannabis use by itself.
    Schizophr Res. 2014 Jan;152(1):283-8. doi: 10.1016/j.schres.2013.11.014. Epub 2013 Dec 2.,

  - A controlled family study of cannabis users with and without psychosis. Proal AC , Fleming J , Galvez- Buccollini JA , Delisi LE [Harvard Medical School, Boston MA] .
    <http://www.ncbi.nlm.nih.gov/pubmed/2430901>

  - "Our results provide evidence that the non-cannabimimetic constituent of marijuana, cannabidiol, exerts clinically relevant

antipsychotic effects that are associated with marked tolerability and safety, when compared with current medications." *Leweke, FM; Piomelli, D; Pahlisch, F; Muhl, D; Gerth, CW; Hoyer, C; Klosterkotter, J; Hellmich, M; and Koethe, D, "Cannabidiol enhances anandamide signaling and alleviates psychotic symptoms of schizophrenia"; Translational Psychiatry (New York, NY: Nature Publishing Company, March 2012), p. 6.*
<http://www.nature.com/tp/journal/v2/n3/pdf/tp201215a.pdf>

- "There was no significant association between any measure of cannabis use at baseline and either transition to psychosis, the persistence of symptoms, or functional outcome." Chester LA, Valmaggia LR, Kempton MJ, Chesney E, Oliver D, Hedges EP, Klatsa E, Stahl D, van der Gaag M, de Haan L, Nelson B, McGorry P, Amminger GP, Riecher-Rössler A, Studerus E, Bressan R, Barrantes-Vidal N, Krebs MO, Glenthøj B, Nordentoft M, Ruhrmann S, Sachs G, McGuire P; EU-GEI High Risk Study Group. *Influence of cannabis use on incidence of psychosis in people at clinical high risk. Psychiatry Clin Neurosci.* 2023 Sep;77(9):469-477. doi: 10.1111/pcn.13555. Epub 2023 May 13.
<https://pubmed.ncbi.nlm.nih.gov/37070555/>

PART A: f - The risks, benefits, and drug interactions of marijuana

"*Signs of withdrawal can include: feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances and unusual tiredness.*

Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks and incapacitation. If I experience these symptoms, I agree to contact Dr. immediately or go to the nearest emergency room.

Numerous drugs are known to interact with marijuana and not all drug interactions are known. Some mixtures of medications can lead to serious and even fatal consequences.

I agree to follow the directions of Dr. regarding the use of prescription and non-prescription medication. I will advise any other of my treating physician(s) of my use of medical marijuana.

Marijuana may increase the risk of bleeding, low blood pressure, elevated blood sugar, liver enzymes, and other bodily systems when taken with herbs and

supplements. I agree to contact Dr. immediately or go to the nearest emergency room if these symptoms occur.

*I understand that medical marijuana may have serious risks and may cause low birthweight or other abnormalities in babies. I will advise Dr. if I become pregnant, try to get pregnant, or will be breastfeeding.***"**

Rebuttal

Cannabinoids share metabolic pathways with other drugs – both use the cytochrome P450 enzymes in the liver. Stout, et al. concluded, "Studies of THC, CBD, and CBN inhibition and induction of major human CYP-450 isoforms generally reflect a low risk of clinically significant drug interactions with most use, but specific human data are lacking. In my clinical experience, drug interactions at low and moderate doses are uncommon."[14] In general, most interactions only occur in patients using high doses of cannabis.[15]

They recommend caution with certain classes of medication including:

- Warfarin (Coumadin)
- Statin cholesterol medications (especially at maximum dosages)
- Erythromycin
- Azole antifungals
- Stimulants (works well for some, can increase paranoia and psychiatric side effects in others)
- Anticholinergic drugs can worsen the adverse psychoactive effects.[16] Examples include Benadryl, Dramamine, Spiriva, Atrovent, Wellbutrin, Cogentin, and others.
- Alcohol:Marijuana can increase effects of alcohol
- CNS Depressants: May increase the sedation

Despite the implication of this Consent Form, Cannabis is not an outlier in terms of potential for interactions. The FDA already cautions patients to "Talk to your doctor or pharmacist about the drugs you take. When your doctor prescribes a new drug, discuss all OTC and prescription drugs, dietary supplements, vitamins, botanicals, minerals and herbals you take, as well as the foods you eat."[17] As with potential side effects, making patients aware of the interactions belongs firmly within the healthcare provider relationship.

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[14] Stout, Stephen M., and Nina M. Cimino. *"Exogenous cannabinoids as substrates, inhibitors, and inducers of human drug metabolizing enzymes: a systematic review."* Drug metabolism reviews 46.1 (2014): 86-95.

[15] https://reference.medscape.com/drug-interactionchecker

[16] McPartland, John M., Dan J. Blanchon, and Richard E. Musty. *"CLINICAL STUDY: Cannabimimetic effects modulated by cholinergic compounds."* Addiction biology 13.3-4 (2008): 411-415.

[17] https://www.fda.gov/drugs/resources-drugs/drug-interactions-what-you-should-know

Concerns Related to the Risk of Low Birth Weight Babies

Though some studies have claimed to show links between maternal cannabis use during pregnancy and adverse outcomes, those studies have not been robust in a variety of ways: conflating tobacco and cannabis use, over-interpreting data, or failing to correct for independent socio-demographic and parental variables in data sets.

- "Maternal marijuana use during pregnancy is not an independent risk factor for adverse neonatal outcomes after adjusting for confounding factors." Conner SN, Bedell V, Lipsey K, Macones GA, Cahill AG, Tuuli MG. Maternal Marijuana Use and Adverse Neonatal Outcomes: A Systematic Review and Meta-analysis. Obstet Gynecol. 2016 Oct;128(4):713-723. <https://pubmed.ncbi.nlm.nih.gov/27607879/>

- Torres CA, Hart CL. Marijuana and pregnancy: objective education is good, but biased education is not. Am J Obstet Gynecol. 2017 Aug;217(2):227. Epub 2017 Apr 8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5886302/>

- Torres CA, Medina-Kirchner C, O'Malley KY, Hart CL. Totality of the Evidence Suggests Prenatal Cannabis Exposure Does Not Lead to Cognitive Impairments: A Systematic and Critical Review. Front Psychol. 2020 May 8;11:816. <https://pubmed.ncbi.nlm.nih.gov/32457680/>

- "The results show no significant differences in developmental testing outcomes between children of marijuana-using and non-using mothers except at 30 days of age when the babies of users had more favourable scores on two clusters of the Brazelton Scales: autonomic stability and reflexes." Dreher MC, Nugent K, Hudgins R. Prenatal marijuana exposure and neonatal outcomes in Jamaica: an ethnographic study. Pediatrics. 1994 Feb;93(2):254-60.<https://pubmed.ncbi.nlm.nih.gov/8121737/> and Hayes JS, Lampart R, Dreher MC, Morgan L. Five-year follow-up of rural Jamaican children whose mothers used marijuana during pregnancy. West Indian Med J. 1991 Sep;40(3):120-3.<https://pubmed.ncbi.nlm.nih.gov/1957518/>

- "Reported cannabis use does not seem to be associated with low birth weight or preterm birth." van Gelder MM, Reefhuis J, Caton AR, Werler MM, Druschel CM, Roeleveld N; National Birth Defects Prevention Study. Characteristics of pregnant illicit drug users and associations between cannabis use and perinatal outcome in a population-based study. Drug Alcohol Depend. 2010 Jun 1;109(1-3):243-7. <https://pubmed.ncbi.nlm.nih.gov/20171023/>

PART A:g - The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

Condition: CANCER

"There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancers, including glioma.

> **There is evidence to suggest that cannabinoids (and the endocannabinoid system more generally) may play a role in the cancer regulation processes. Due to a lack of recent, high quality reviews, a research gap exists concerning the effectiveness of cannabis or cannabinoids in treating cancer in general.*

There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting. [18]

> **There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancer-associated anorexia-cachexia syndrome and anorexia nervosa."*

Contemporary Research

Cannabinoids were able to effectively modulate tumor growth in different in vitro and in vivo cancer models, however, these anticancer effects appear to be dependent on cancer type and drug dose. Understanding how cannabinoids are able to modulate essential cellular processes involved in tumorigenesis, such as the progression through the cell cycle, cell proliferation and cell death, as well as the interactions between cannabinoids and immune system are crucial for improving existing medications and developing new therapeutic approaches.[19]

"The antiproliferative action of cannabinoids on cancer cells was first noticed in the 1970s. Since then cannabinoids were found to act on various

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[18] Grimison P, Mersiades A, Kirby A, Lintzeris N, Morton R, Haber P, Olver I, Walsh A, McGregor I, Cheung Y, Tognela A, Hahn C, Briscoe K, Aghmesheh M, Fox P, Abdi E, Clarke S, Della-Fiorentina S, Shannon J, Gedye C, Begbie S, Simes J, Stockler M. *Oral THC:CBD cannabis extract for refractory chemotherapy-induced nausea and vomiting: a randomized, placebo-controlled, phase II crossover trial.* Ann Oncol. 2020 Nov;31(11):1553-1560.<https://pubmed.ncbi.nlm.nih.gov/32801017/>

[19] Dariš B, Tancer Verboten M, Knez Ž, Ferk P. *Cannabinoids in cancer treatment: Therapeutic potential and legislation.* Bosn J Basic Med Sci. 2019 Feb 12;19(1):14-23.<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6387667/>

cancer cell lines, through various mechanisms.Cannabinoids were also found to be suppressors of angiogenesis and tumor invasion. Our knowledge is expanding; hence only results of recent research on this topic are presented here. The cannabinoid agonists HU-210 and JWH-133 promoted glial differentiation in a CB receptor-dependent manner. Moreover, cannabinoid challenge decreased the efficiency of glioma stem-like cells to initiate glioma formation in vivo. The non psychoactive cannabidiol triggered caspase activation and oxidative stress in human glioma cells. Human melanomas express CB1 and CB2 cannabinoid receptors. Activation of these receptors decreased growth, proliferation, angiogenesis, and metastasis, and increased apoptosis, of melanomas in mice. THC, through activation of CB2 cannabinoid receptors, **reduced human breast cancer cell proliferation by blocking the progression of the cell cycle and by inducing apoptosis**. THC arrested cells in G2M via downregulation of Cdc2.258 Cannabinoids induced apoptosis of pancreatic tumor cells via stress protein p8 and endoplasmic reticulum stress-related genes. THC-induced apoptosis in Jurkat leukemia T cells was found to be regulated by translocation of Bad to mitochondria. Exposure of leukemia cells to CBD led to CB2-mediated reduction in cell viability and induction in apoptosis (although CBD is considered not to bind to either CB1 or CB2 receptors). Cannabinoid-induced apoptosis of human prostate cancer cells LNCaP proceeded through sustained activation of ERK1/2 leading to Gl cell cycle arrest. Rimonabant inhibited human breast cancer cell proliferation through a lipid raft-mediated mechanism. In a pilot phase I trial, nine patients with recurrent glioblastoma multiforme, that had previously failed standard therapy (surgery and radiotherapy) and had clear evidence of tumor progression, were administered THC intratumorally. THC inhibited tumor-cell proliferation in vitro, decreased tumor-cell Ki67 immunostaining and prolonged the survival time of two of the patients."[20]

Condition: EPILEPSY

"*There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy.*

> *Recent systematic reviews were unable to identify any randomized controlled trials evaluating the efficacy of cannabinoids for the treatment of epilepsy. Currently available clinical data therefore consist solely of uncontrolled case series, which do not provide high-quality evidence of efficacy. Randomized trials of the efficacy of cannabidiol for different forms of epilepsy have been completed and await publication.****"***

[20] Kogan NM, Mechoulam R. *Cannabinoids in health and disease*. Dialogues Clin Neurosci. 2007;9(4):413-30. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3202504/>

Contemporary Research

One role of the endocannabinoid system (ECS) is to dampen overactivity in the central nervous system, including preventing seizures. Activating those pathways, cannabis has been shown to have anticonvulsant properties. Cannabinoids have been especially critical in the treatment of pharmacoresistant seizures[21] [22] including Dravet syndrome and Lennox-Gastaut syndrome.[23]

Research show cannabis is well-tolerated in seizure patients[24] and also indicates the efficacy of whole plant medicines versus single molecule cannabinoids.[25] [26]

Condition: GLAUCOMA

"*There is little evidence that cannabinoids are an ineffective treatment for improving intraocular pressure associated with glaucoma.*

> *Lower intraocular pressure is a key target for glaucoma treatments. Nonrandomized studies in healthy volunteers and glaucoma patients have shown short-term reductions in intraocular pressure with oral, topical eye drops, and intravenous cannabinoids,suggesting the potential for therapeutic benefit. A good-quality systematic review identified a single small trial that found no effect of two cannabinoids, given as an oromucosal spray, on intraocular pressure. The quality of evidence for the finding of no effect is limited. However, to be effective, treatments targeting lower intraocular pressure must provide continual rather than transient reduction in intraocular pressure. To date, those studies showing positive*

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[21] Koubeissi M. Anticonvulsant *Effects of Cannabidiol in Dravet Syndrome.* Epilepsy Curr. 2017 Sep-Oct;17(5):281-282. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5716495/>

[22] Devinsky O, Cross JH, Laux L, Marsh E, Miller I, Nabbout R, Scheffer IE, Thiele EA, Wright S; *Cannabidiol in Dravet Syndrome Study Group.* N Engl J Med. 2017;376(21):2011–2020. <https://pubmed.ncbi.nlm.nih.gov/28538134/>

[23] Perucca E. *Cannabinoids in the Treatment of Epilepsy: Hard Evidence at Last?* J Epilepsy Res. 2017 Dec 31;7(2):61-76. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5767492/>

[24] "overall, adverse effects were mild and infrequent, and beneficial side effects such as increased alertness were reported" Sulak, D, Saneto R, Goldstein B. *The current status of artisanal cannabis for the treatment of epilepsy in the US.* Epilepsy Behav. 2017 May;70 (PtB):328-333. Epub2017 Feb 21. PMID: 2825350

[25] "The majority of patients used cannabidiol (CBD)-enriched artisanal formulas, some with the addition of delta-9-tetrahydrocannabinol (THC) and tetrahydrocannabinolic acid (THCA) the synergy of cannabinoids and terpenoids in artisanal preparations." *Ibid.*

[26] "The desire to isolate and treat with pharmaceutical grade compounds from cannabis (specifically CBD) may be inferior to therapy with whole plant extracts. Much more needs to be learned about the mechanisms of antiepileptic activity of the phytocannabinoids and other constituents of Cannabis sativa." Maa E, Figi P. *The case for medical marijuana in epilepsy.* Epilepsia. 2014 Jun;55(6):783-6. <https://pubmed.ncbi.nlm.nih.gov/24854149/>

*effects have shown only short-term benefit on intraocular pressure (hours), suggesting a limited potential for cannabinoids in the treatment of glaucoma.***"**

Contemporary Research

Glaucoma is a progressive eye disease that can lead to irreversible vision loss and blindness if left untreated. One of the primary causes of glaucoma is increased intraocular pressure (IOP), which can damage the optic nerve. Multiple studies have also shown Cannabis to be associated with lower IOP.[27] [28] [29]Critically, Cannabis has been found to have neuroprotective properties that can help preserve the function of the optic nerve and slow the progression of the disease.[30] [31] [32]

It has been shown by clinicians since the 1970s[33] that cannabis has the ability to lower IOP, and two of the patients given their cannabis by the federal government were Glaucoma patients.

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[27] THC (7.5 mg Dronabinol) orally, is shown to improve blood circulation in the retina and reduce intraocular pressure. (Plange N, et.al. Dronabinol and retinal hemodynamics in humans. Am J Ophthalmol. 2007 Jan;143(1):173-4. Bethesda: NEI/NIH, February 18, 1997)

[28] "Cannabinoids are a large class of chemical compounds that exploit their effects by interaction with cannabinoid receptors 1 and 2. These receptors are widely expressed in the human retina where they may influence important functions such as photo-transduction, amacrine cell network maintenance, and IOP regulation." *Passani A, Posarelli C, Sframeli AT, et al. Cannabinoids in Glaucoma Patients: The Never-Ending Story*. J Clin Med. 2020;9(12):3978. Published 2020 Dec 8. doi:10.3390/jcm9123978 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7763320/>

[29] "A number of drugs are available to lower intraocular pressure (IOP), but, occasionally, they are ineffective or have intolerable side-effects for some patients and can lose efficacy with chronic administration. The smoking of marijuana has decreased IOP in glaucoma patients." Jarvinen T, Pate DW, Laine K. *Cannabinoids in the treatment of glaucoma*. Pharmacol Ther. 2002 Apr-May;95(1):203-20. <https://pubmed.ncbi.nlm.nih.gov/12182967/>

[30] "Some cannabinoids otherwise present excellent neuroprotective effects without systemic or psychotropic involvement. These molecules may therefore be exploited in glaucoma treatment thanks to their neuroprotective, vasorelaxant, and antioxidant properties." *Passani* 2020 *Ibid.*

[31] The end point of glaucoma is the selective death of ganglion cells by apoptosis (Quigley, 1999) that may be caused by optic nerve injury following compression or ischemia. Activation of NMDA receptors by glutamate release during ischemia causes an increase in intracellular calcium that triggers a cascade leading to cell death (Osborne et al., 2004). Activation of CB1 receptors provides protection against neuron death." Yazulla S. *Endocannabinoids in the retina: from marijuana to neuroprotection.* Prog Retin Eye Res. 2008 Sep;27(5):501-26 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2584875/>

[32] " In glaucoma, the increased release of glutamate is the major cause of retinal ganglion cell death. Cannabinoids have been demonstrated to protect neuron cultures from glutamate-induced death." El-Remessy AB, Khalil IE, Matragoon S, Abou-Mohamed G, Tsai NJ, Roon P, Caldwell RB, Caldwell RW, Green K, Liou GI. Neuroprotective effect of (-)Delta9-tetrahydrocannabinol and cannabidiol in N-methyl-D-aspartate-induced retinal neurotoxicity: involvement of peroxynitrite. Am J Pathol. 2003 Nov;163(5)

[33] https://beyondthc.com/dr-john-merritts-call-to-reschedule-marijuana/

Additionally, Cannabis has other benefits for people with glaucoma. Studies have suggested that Cannabis can help alleviate symptoms such as eye pain and nausea associated with glaucoma medications[34], as well as help improve sleep quality, which is important for overall health and wellbeing.

Condition: HIV AIDS
POSITIVE STATUS FOR HUMAN IMMUNODEFICIENCY VIRUS as well as ACQUIRED IMMUNE DEFICIENCY SYNDROME

"*There is limited evidence that Cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.*

> *There does not appear to be good-quality primary literature that reported on Cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.****"***

Contemporary Research

"Cannabis as a clinical intervention in HIV disease would be a significant contribution to the field. When ingested, inhaled, or absorbed, THC and CBD, along with other exogenous Cannabis components, are anti-inflammatory and counter oxidative stress. Patients report that Cannabis has less harmful effects than other Medications.[35]**"**

"HIV-positive individuals attending a large clinic were recruited into an anonymous cross-sectional questionnaire study. Up to one-third (27%, 143/523) reported using Cannabis for treating symptoms. Patients reported improved appetite (97%), muscle pain (94%), nausea (93%), anxiety (93%), nerve pain (90%), depression (86%), and paresthesia (85%). Cannabis users reporting associated memory deterioration (47%). Symptom control using Cannabis is widespread in HIV outpatients. Many patients reported that Cannabis improved symptom control."[36]

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[34] Jarvin T, Pate DW, Line K. Cannabinoids in the treatment of glaucoma. Pharmacol Ther. 2002 Apr-May:95(1):203-20. doi:10.1016/sw0163-May:95(1):203-20. doi: 10.1016/s01637258)02)00252-x. PMID: 12182966

[35] Ellis RJ, Wilson N, Peterson S. *Cannabis and Inflammation in HIV: A Review of Human and Animal Studies.* Viruses. 2021 Aug 2;13(8):1521. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8402692/>

[36] Emily Woolridge, Simon Barton, Jonathon Samuel, Jess Osorio, Andrew Dougherty, Anita Holdcroft,*Cannabis Use in HIV for Pain and Other Medical Symptoms,* Journal of Pain and Symptom Management, Vol 29, Issue 4, 2005, p. 358-367 <https://doi.org/10.1016/j.jpainsymman.2004.07.011>

Condition: POST-TRAUMATIC STRESS DISORDER

"*There is limited evidence (a single, small fair-quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder.*

> *A single, small crossover trial suggests potential benefit from the pharmaceutical cannabinoid nabilone. This limited evidence is most applicable to male veterans and contrasts with non- randomized studies showing limited evidence of a statistical association between Cannabis use (plant derived forms) and increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder. There are other trials that are in the process of being conducted and if successfully completed, they will add substantially to the knowledge base.***"**

Contemporary Research

The Veterans Administration estimates that as many as one-third of all Veterans suffer from PTSD[37]. For many patients, the condition is not well controlled with currently available psychological and medication regimens[38] [39].

This makes the investigation of cannabis therapies all the most critical for both Veteran and non-Veteran PTSD patients.

Literature reviews, preclinical studies, and robust clinical trials support all that patients using cannabis can see a reduction in PTSD symptoms:

- "Cannabis may dampen the strength or emotional impact of traumatic memories through synergistic mechanisms that might make it easier for people with PTSD to rest or sleep and to feel less anxious and less involved with flashback memories."[40]

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[37]https://www.vfw.org/media-and-events/latest-releases/archives/2021/9/federal-study-finds-cannabis-beneficial-for-ptsd-treatment

[38] "However, a large proportion of patients avoid psychological treatment, and the dropout rate among veterans is high. Remission rates with medication are only around 20 to 30%, and their side effects cause low compliance resulting in poor efficacy. Considering the limitations of these treatments and the need for effective treatment for patients diagnosed with PTSD, an interest in medical cannabis for PTSD has risen in recent years." Nacasch, Nitsa; Avni, Chen; Toren, Paz. Medical cannabis for treatment-resistant combat PTSD. Frontiers in Psychiatry. Vol. 13, 2023.
<https://www.frontiersin.org/journals/psychiatry/articles/10.3389/fpsyt.2022.1014630>

[39] Bonn-Miller MO, Sisley S, Riggs P, Yazar-Klosinski B, Wang JB, Loflin MJE, Shechet B, Hennigan C, Matthews R, Emerson A, Doblin R. The short-term impact of 3 smoked cannabis preparations versus placebo on PTSD symptoms: A randomized cross-over clinical trial. PLoS One. 2021 Mar 17 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7968689/>

[40] Passie, T., Emrich, H.M., Karst, M., Brandt, S.D. and Halpern, J.H. (2012), *Mitigation of post-traumatic stress symptoms by Cannabis resin: A review of the clinical and neurobiological evidence*. Drug Test. Analysis, 4: 649-659.
<https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/10.1002/dta.1377>

- "There is also accumulating evidence from animal studies investigating the effects of cannabidiol on fear memory processing indicating that it reduces learned fear in paradigms that are translationally relevant to phobias and post-traumatic stress disorder."[41]
- "Over the course of 1 year, the cannabis users reported a greater decrease in PTSD symptom severity over time compared to controls. Participants who used cannabis were 2.57 times more likely to no longer meet DSM-5 criteria for PTSD at the end of the study observation period compared to participants who did not use cannabis"[42]
- "All symptoms were reduced by more than 50% immediately after cannabis use. Time predicted larger decreases in intrusions and irritability, with later cannabis use sessions predicting greater symptom relief than earlier sessions."[43]

Condition: AMYOTROPHIC LATERAL SCLEROSIS (ALS)

"*There is insufficient evidence that cannabinoids are an effective treatment for symptoms associated with amyotrophic lateral sclerosis.*

> *Two small studies investigated the effect of dronabinol on symptoms associated with ALS. Although there were no differences from placebo in either trial, the sample sizes were small, the duration of the studies was short, and the dose of dronabinol may have been too small to ascertain any activity. The effect of Cannabis was not investigated.****"***

[41] Lee, J. L. C., Bertoglio, L. J., Guimarães, F. S., and Stevenson, C. W. (2017) Cannabidiol regulation of emotion and emotional memory processing: relevance for treating anxiety-related and substance abuse disorders. *British Journal of Pharmacology*, 174: 3242–3256. <https://doi.org/10.1111/bph.13724>

[42] Bonn-Miller MO, Brunstetter M, Simonian A, Loflin MJ, Vandrey R, Babson KA, et al. The Long-Term, Prospective, Therapeutic Impact of Cannabis on Post-traumatic Stress Disorder. Cannabis Cannabinoid Res. 2020. <https://pubmed.ncbi.nlm.nih.gov/33998874/>

[43] LaFrance EM, Glodosky NC, Bonn-Miller M, Cuttler C. Short and Long-Term Effects of Cannabis on Symptoms of Post-Traumatic Stress Disorder. J Affect Disord. 2020;274: 298–304. 10.1016/j.jad.2020.05.132 <https://pubmed.ncbi.nlm.nih.gov/32469819/>

Contemporary Research

Preclinical models indicate that cannabinoids hold the potential to delay ALS progression[44] [45] [46]

- "..cannabis has powerful antioxidative, anti-inflammatory, and neuroprotective effects… translated to prolonged neuronal cell survival, delayed onset, and slower progression of the disease. Cannabis also has properties applicable to symptom management of ALS, including analgesia, muscle relaxation, bronchodilation, saliva reduction, appetite stimulation, and sleep induction. … Based on the currently available scientific data, it is reasonable to think that cannabis might significantly slow the progression of ALS, potentially extending life expectancy and substantially reducing the overall burden of the disease.[47]"
- "Cannabinoids exert anti-glutamatergic and anti-inflammatory actions through activation of the CB(1) and CB(2) receptors, respectively. Activation of CB(1) receptors may therefore inhibit glutamate release from presynaptic nerve terminals and reduce the postsynaptic calcium influx in response to glutamate receptor stimulation. Meanwhile, CB(2) receptors may influence inflammation, whereby receptor activation reduces microglial activation, resulting in a decrease in microglial secretion of neurotoxic mediators. Finally, cannabinoid agents may also exert antioxidant actions by a receptor-independent mechanism." [48]

These results are not just seen in mouse model studies or the lab, but in the lived experience of patients.

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[44] Raman et al. 2004. *Amyotrophic lateral sclerosis: delayed disease progression in mice by treatment with a cannabinoid. A*myotrophic Lateral Sclerosis & Other Motor Neuron Disorders 5: 33-39. <https://pubmed.ncbi.nlm.nih.gov/15204022/>

[45] Shoemaker et al., 2007. *The CB2 cannabinoid agonist AM-1241 prolongs survival in a transgenic mouse model of amyotrophic lateral sclerosis when initiated at symptom onset.* Journal of Neurochemistry 101: 87. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2819701/>

[46] Moreno-Martet et al. 2014. *Changes in endocannabinoid receptors and enzymes in the spinal cord of SOD1(G93A) transgenic mice and evaluation of Sativex-like combination of phytocannabinoids: Interest for future therapies in amyotrophic lateral sclerosis.* CNS Neuroscience and Therapeutics 20: 809-815. <https://www.ncbi.nlm.nih.gov/pubmed/24703394>

[47] Carter GT, Abood ME, Aggarwal SK, Weiss MD. *Cannabis and amyotrophic lateral sclerosis: hypothetical and practical applications, and a call for clinical trials.* Am J Hosp Palliat Care. 2010 Aug;27(5):347-56.

[48] Bilsland LG, Greensmith L. The endocannabinoid system in amyotrophic lateral sclerosis. Curr Pharm Des. 2008;14(23):2306-16 <https://pubmed.ncbi.nlm.nih.gov/18781981/>

Cannabis can act along a number of different pathways to improve quality of life for ALS patients - as a muscle relaxant, saliva reducer, bronchodilator, and analgesic.[49] [50] Furthermore, cannabis has been seen to slow progression of ALS in certain patients, and cannabinoids may prove be efficacious in moderating the disease's development.[51]

Many of the debilitating muscular symptoms of ALS can be lessened with Cannabis. Because it can be difficult for ALS patients to eat, the appetite-stimulant qualities of Cannabis are hugely beneficial. As many ALS patients suffer from depression because of their condition, medical marijuana can also greatly improve their mood and alleviate symptoms of depression. Depression can be debilitating for ALS patients and can make them completely lose faith in their future.

Condition: CROHN'S DISEASE

"*There is insufficient evidence to support or refute the conclusion that dronabinol is an effective treatment for the symptoms of irritable bowel syndrome.*

> *Some studies suggest that marijuana in the form of cannabidiol may be beneficial in the treatment of inflammatory bowel diseases, including Crohn's disease.****"***

Contemporary Research

"Inflammatory bowel disease (IBD) is an incurable disease which affects millions of people in industrialized countries. Anecdotal and scientific evidence suggests that Cannabis use may have a positive impact in IBD patients….In conclusion, CBG attenuated murine colitis and could be considered for clinical experimentation in IBD patients.[52] "

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[49]https://www.als.ca/wp-content/uploads/2020/12/Fact-Sheet-Cannabis-and-ALS_FINAL.pdf

[50] Amtmann et al. 2004. Survey of cannabis use in patients with amyotrophic lateral sclerosis. *The American Journal of Hospice and Palliative Care* 21: 95-104. <https://www.ncbi.nlm.nih.gov/pubmed/15055508>

[51] Urbi B, Broadley S, Bedlack R, et al *Study protocol for a randomized, double-blind, placebo-controlled study evaluating the Efficacy of cannabis-based Medicine Extract in slowing the disease progression of Amyotrophic Lateral sclerosis or motor neurone Disease*: the EMERALD trial BMJ Open 2019 <https://bmjopen.bmj.com/content/9/11/e029449>

[52] Borrelli F, Fasolino I, Romano B, Capasso R, Maiello F, Coppola D, Orlando P, Battista G, Pagano E, Di Marzo V, Izzo AA. *Beneficial effect of the non-psychotropic plant cannabinoid cannabigerol on experimental inflammatory bowel disease.* Biochem Pharmacol. 2013 May 1;85(9):1306-16. <https://pubmed.ncbi.nlm.nih.gov/23415610/>

"A significant number of patients with IBD currently use marijuana. Most patients find it very helpful for symptom control, including patients with ulcerative colitis, who are currently excluded from medical marijuana laws. Clinical trials are needed to determine marijuana's potential as an IBD therapy and to guide prescribing decisions." [53]

Condition: PARKINSON'S DISEASE

"*There is sufficient evidence that cannabinoids are an effective treatment for the motor system symptoms associated with Parkinson's disease or the levodopa induced dyskinesia.*

> *Evidence suggests that the endocannabinoid system plays a meaningful role in certain neurodegenerative processes; thus, it may be useful to determine the efficacy of cannabinoids in treating the symptoms of neurodegenerative diseases. Small trials of oral cannabinoid preparations have demonstrated no benefit compared to a placebo in ameliorating the side effects of Parkinson's disease. A seven-patient trial of nabilone suggested that it improved the dyskinesia associated with levodopa therapy, but the sample size limits the interpretation of the data. An observational study demonstrated improved outcomes, but the lack of a control group and the small sample size are limitations.****"***

Contemporary Research

"Medical marijuana has been observed to improve both motor and non-motor symptoms including bradykinesia, rigidity, tremor, sleep, and pain. A study demonstrated the effects of Cannabis on individuals with PD. Most of them consumed half a teaspoon of Cannabis leaves, along with their prescribed pharmacotherapy for PD. About 46% of these individuals reported relief of PD symptoms in general, occurring at an average of 1.7 months after beginning treatment." [54]

"The cannabinoids have a neuroprotective activity not only in vitro but also in vivo: HU-210, a potent synthetic analog of THC, increases survival of cerebellar granule cells exposed to 6-hydroxydopamine. In a model of experimental stroke, rimonabant reduced infarct volume by approximately 40 %. Rimonabant exerted neuroprotection independently of its cannabinoid

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[53] Ravikoff Allegretti J, Courtwright A, Lucci M, Korzenik JR, Levine J. *Marijuana use patterns among patients with inflammatory bowel disease*. Inflamm Bowel Dis. 2013 Dec;19(13):2809-14 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4126607/>

[54]Patel RS, Kamil S, Shah MR, Bhimanadham NN, Imran S. *Pros and Cons of Marijuana in Treatment of Parkinson's Disease.* Cureus. 2019 Jun 3; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6682376/>

receptor-blocking effect. In clinical trials, dexanabinol-treated patients achieved significantly better intracranial pressure/cerebral perfusion pressure control without jeopardizing blood pressure. A trend toward faster and better neurologic outcome was also observed. A wide range of cannabinoids has been shown to help in pathologies affecting the central nervous system (CNS) and other diseases that are accompanied by chronic inflammation." [55]

Condition: MULTIPLE SCLEROSIS

"*There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity.*

> *Based on evidence from randomized controlled trials included in systematic reviews, an oral cannabis extract, nabiximols, and orally administered THC are probably effective for reducing patient-reported spasticity scores in patients with MS. The effect appears to be modest. These agents have not consistently demonstrated a benefit on clinician-measured spasticity indices.****"***

Contemporary Research

"Inflammation, autoimmune response, demyelination, and axonal damage are thought to participate in the pathogenesis of MS. Evidence supports the idea of a beneficial effect of cannabinoid compounds for the treatment of this disease. In clinical trials, it has been shown that Cannabis derivatives are active on the pain related to MS. However, this is not the only positive effect of cannabinoids in this disease. In rat experimental autoimmune encephalomyelitis (EAE), a laboratory model of MS, THC, given once after disease onset, significantly reduced maximal EAE score. Reduction in the inflammatory response in the brain and spinal cord was also noted in animals These observations may explain the efficacy of cannabinoid agonists in improving motor symptoms (spasticity, tremor, ataxia) typical of MS in both humans and animal models.106 Spasticity is a common neurologic condition in patients with MS, stroke, cerebral palsy, or an injured spinal cord. Marijuana was suggested as treatment of muscle spasticity as early as the 1980s." [56]

In another case report, the chronic motor handicaps of an MS patient acutely improved while he smoked a marijuana cigarette. THC significantly reduced spasticity by clinical measurement. Responses varied, but benefit was seen in

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[55] Kogan NM, Mechoulam R. *Cannabinoids in health and disease.* Dialogues Clin Neurosci. 2007;9(4):413-30.<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3202504/>
[56] *Ibid.*

patients with tonic spasms. At a progressive stage of illness, oral and rectal THC reduced the spasticity, rigidity, and pain, resulting in improved active and passive mobility.

The objective was to determine whether a cannabis-based medicinal extract (CBME) benefits a range of symptoms due to multiple sclerosis (MS)[57]

Condition: CHRONIC NONMALIGNANT PAIN (CNMP)

"*There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.*

> *The majority of studies on pain evaluated nabiximols outside the United States. Only a handful of studies have evaluated the use of cannabis in the United States, and all of them evaluated cannabis in flower form provided by the National Institute on Drug Abuse. In contrast, many of the cannabis products that are sold in state-regulated markets bear little resemblance to the products that are available for research at the federal level in the United States. Pain patients also use topical forms.****"***

Contemporary Research

The definition of CNMP is 'pain is long lasting, probably neuropathic in nature and caused by injury or disease that persists longer than 3 to 6 months or longer than expected.' The majority of qualifying conditions in the state of Florida cause CNMP and/or are directly related to CNMP.

This study[58] agrees with the primary statement 'there is substantial evidence that Cannabis is an effective treatment for chronic pain in adults.' There are copious amounts of studies on pain, not just Nabiximols (Sativex).

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[57] Wade DT, Makela P, Robson P, House H, Bateman C. *Do cannabis-based medicinal extracts have general or specific effects on symptoms in multiple sclerosis? A double-blind, randomized, placebo-controlled study on 160 patients.* Multiple Sclerosis Journal. *2004;10(4):434-441.* <https://journals.sagepub.com/doi/10.1191/1352458504ms1082oa>

[58] "The results generally suggest increased THC exposure was related to pain-related improvement, while increased CBD exposure was related to improved mood. Cannabis expectancies were not related to observed improvements." Gruber SA, Smith RT, Dahlgren MK, Lambros AM, Sagar KA. *No pain, all gain? Interim analyses from a longitudinal, observational study examining the impact of medical cannabis treatment on chronic pain and related symptoms.* Exp Clin Psychopharmacol. 2021 Apr;29(2):147-156. doi: 10.1037/pha0000435. Epub 2021 Mar 25. PMID: 33764103.

Studies using cannabis-based sublingual oils show promising clinical outcomes.[59] [60] Clinical outcomes in fibromyalgia trials find medical Cannabis is both safe and effective.[61]

PART B: Certification for medical marijuana in a smokable marijuana for a patient under 18 with a diagnosed terminal condition

This portion of the form is only used for patients under 18 who have two physicians recommendations for Cannabis.

Part C: For certification of smoking marijuana as an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition

"*Acknowledgement of contaminant risks.*

> *Smokable marijuana has infectious risks that are not present in processed products. Certain molds and mildews can contaminate marijuana plants during growing, processing, storage in dispensaries and in patient homes. These contaminants can pose health risks, particularly to those who are immunosuppressed due to their disease state and treatments. While the State of Florida requires third party testing you should still inspect your product.*

Respiratory Health.

> *Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also*

[59] Michal Kawka, Simon Erridge, Carl Holvey, Ross Coomber, Azfer Usmani, Mohammad Sajad, Michael W Platt, James J Rucker, Mikael H Sodergren . Clinical outcome data of first cohort of chronic pain patients treated with cannabis-based sublingual oils in the United Kingdom – analysis from the UK Medical Cannabis Registry. *The Journal of Clinical Pharmacology*. 2021; 00: 1-10.< https://doi.org/10.1002/jcph.1961>

[60] "THC:CBD oromucosal spray proved to be an effective and well-tolerated add-on treatment for patients with elsewhere refractory chronic pain - especially of neuropathic origin." Ueberall MA, Essner U, Mueller-Schwefe GH. Effectiveness and tolerability of THC:CBD oromucosal spray as add-on measure in patients with severe chronic pain: analysis of 12-week open-label real-world data provided by the German Pain e-Registry. J Pain Res. 2019 May 20;12:1577-1604.<https://pubmed.ncbi.nlm.nih.gov/31190969/>

[61] Sagy I, Bar-Lev Schleider L, Abu-Shakra M, Novack V. Safety and Efficacy of Medical Cannabis in Fibromyalgia. *Journal of Clinical Medicine*. 2019; 8(6):807. https://doi.org/10.3390/jcm8060807 <https://www.mdpi.com/2077-0383/8/6/807 >

for the global burden of disease. Given the known relationships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term marijuana smoking leads to similar deleterious effects of respiratory health, and some investigators argue that marijuana smoking may be even more harmful that of tobacco smoking.

Information regarding health risks of 2nd and 3rd hand smoke to other household members.

> *You should never smoke medical marijuana around other family members, especially children and any household guests. You should smoke outside to allow adequate ventilation and to mitigate the dangers of secondhand and thirdhand smoke to others. Marijuana should never be smoked inside vehicles or other small spaces that children will occupy even if the children are not present at the time the product is consumed.**"***

Contemporary Research

Medical Cannabis has been demonstrated to alleviate inflammation and chronic pain caused by various conditions, as well as relieve pain. COPD is just one of almost 60 listed conditions medical Cannabis could continue to help treat, and that list keeps getting longer.

THC has been studied and found to be an effective bronchodilator as since 1976,[62] with even earlier cannabis-based medicines aimed at treating asthma.

One study that explored the trends in outcomes of Cannabis use among patients with COPD that were hospitalized found that "Among hospitalized patients with a diagnosis of COPD, Cannabis users had statistically significant lower odds of in-hospital mortality and pneumonia compared to non-Cannabis users. The association between Cannabis use and these favorable outcomes deserves further study to understand the interaction between Cannabis use and COPD"[63]

While tobacco smokers showed the expected drop in lung function over time, "habitual use of marijuana alone does not appear to lead to significant abnormalities in lung function when assessed either cross-sectionally or

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[62] Williams, S. J., Hartley, J. P., & Graham, J. D. (1976). Bronchodilator effect of delta1-tetrahydrocannabinol administered by aerosol of asthmatic patients. *Thorax*, *31*(6), 720–723. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC470501/

[63] Gunasekaran, K., Voruganti, D. C., Singh Rahi, M., Elango, K., Ramalingam, S., Geeti, A., & Kwon, J. (2021). Trends in prevalence and outcomes of cannabis use among chronic obstructive pulmonary disease hospitalizations: A nationwide population-based study 2005–2014. *Cannabis and Cannabinoid Research*, *6*(4), 340–348. https://pubmed.ncbi.nlm.nih.gov/33998884/>

longitudinally…findings from a limited number of well-designed epidemiological studies do not suggest an increased risk for the development of either lung or upper airway cancer from light or moderate use." [64]

APPENDIX

A. Medical Marijuana Consent Form DH-MQA-5026 (Rev.03/21)
B. Americans for Safe Access State Score Card
C. Potential Side Effect of Opiates

[64] Tashkin DP. Effects of marijuana smoking on the lung. Ann Am Thorac Soc. 2013 Jun;10(3):239-47. doi: 10.1513/AnnalsATS.201212-127FR. PMID: 23802821.

Medical Marijuana Consent Form

A qualified physician may not delegate the responsibility of obtaining written informed consent to another person. The qualified patient, or the patient's parent or legal guardian if the patient is a minor, must initial each section of this consent form to indicate that the physician explained the information and, along with the qualified physician, must sign and date the informed consent form.

This consent form contains three parts. Part A must be completed by all patients. Part B is only required for patients under the age of 18 with a diagnosed terminal condition who receive a certification for medical marijuana in a smokable form. Part C is the signature block and must be completed by all patients.

Part A: Must be completed for all medical marijuana patients

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

_____ The federal government has classified marijuana as a Schedule I controlled substance. Schedule I substances are defined, in part, as having (I) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use under medical supervision. Federal law prohibits the manufacture, distribution and possession of marijuana even in states, such as Florida, which have modified their state laws to treat marijuana as a medicine.

_____ When in the possession of medical marijuana, the patient or the patient's caregiver must have his or her medical marijuana use registry identification card in his or her possession at all times.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

_____ Marijuana has not been approved by the Food and Drug Administration for marketing as a drug. Therefore, the "manufacture" of marijuana for medical use is not subject to any federal standards, quality control, or other federal oversight. Marijuana may contain unknown quantities of active ingredients, which may vary in potency, impurities, contaminants, and substances in addition to THC, which is the primary psychoactive chemical component of marijuana.

c. The potential for addiction.

_____ Some studies suggest that the use of marijuana by individuals may lead to a tolerance to, dependence on, or addiction to marijuana. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact Dr._____(name of qualified physician).

d. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

_____ The use of marijuana can affect coordination, motor skills and cognition, i.e., the ability to think, judge and reason. Driving under the influence of cannabis can double the risk of vehicular accident, which escalates if alcohol is also influencing the driver. While using medical marijuana, I should not drive, operate heavy machinery or engage in any activities that require me to be alert and/or respond quickly and I should not participate in activities that may be dangerous to myself or others. I

understand that if I drive while under the influence of marijuana, I can be arrested for "driving under the influence."

e. The potential side effects of medical marijuana use.

_____ Potential side effects from the use of marijuana include, but are not limited to, the following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of short term memory, euphoria, difficulty in completing complex tasks, suppression of the body's immune system, may affect the production of sex hormones that lead to adverse effects, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression and/or restlessness. Marijuana may exacerbate schizophrenia in persons predisposed to that disorder. In addition, the use of medical marijuana may cause me to talk or eat in excess, alter my perception of time and space and impair my judgment. Many medical authorities claim that use of medical marijuana, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, drug abuse, and schizophrenia.

There is substantial evidence of a statistical association between long-term cannabis smoking and worsening respiratory symptoms and more frequent chronic bronchitis episodes. Smoking marijuana is associated with large airway inflammation, increased airway resistance, and lung hyperinflation. Smoking cannabis, much like smoking tobacco, can introduce levels of volatile chemicals and tar in the lungs that may raise concerns about the risk of cancer and lung disease.

_____ I understand that using marijuana while consuming alcohol is not recommended. Additional side effects may become present when using both alcohol and marijuana.

_____ I agree to contact Dr. _____ if I experience any of the side effects listed above, or if I become depressed or psychotic, have suicidal thoughts, or experience crying spells. I will also contact Dr._____if I experience respiratory problems, changes in my normal sleeping patterns, extreme fatigue, increased irritability, or begin to withdraw from my family and/or friends.

f. The risks, benefits, and drug interactions of marijuana.

_____ Signs of withdrawal can include: feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances and unusual tiredness.

_____ Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks and incapacitation. If I experience these symptoms, I agree to contact Dr. _____ immediately or go to the nearest emergency room.

_____ Numerous drugs are known to interact with marijuana and not all drug interactions are known. Some mixtures of medications can lead to serious and even fatal consequences.

I agree to follow the directions of Dr._____regarding the use of prescription and non-prescription medication. I will advise any other of my treating physician(s) of my use of medical marijuana.

_____ Marijuana may increase the risk of bleeding, low blood pressure, elevated blood sugar, liver enzymes, and other bodily systems when taken with herbs and supplements. I agree to contact Dr. _____ immediately or go to the nearest emergency room if these symptoms occur.

_____ I understand that medical marijuana may have serious risks and may cause low birthweight or other abnormalities in babies. I will advise Dr._____if I become pregnant, try to get pregnant, or will be breastfeeding.

g. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

___ Cancer

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancers, including glioma.

  There is evidence to suggest that cannabinoids (and the endocannabinoid system more generally) may play a role in the cancer regulation processes. Due to a lack of recent, high quality reviews, a research gap exists concerning the effectiveness of cannabis or cannabinoids in treating cancer in general.

- There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting.

  There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancer-associated anorexia-cachexia syndrome and anorexia nervosa.

___ Epilepsy

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy.

  Recent systematic reviews were unable to identify any randomized controlled trials evaluating the efficacy of cannabinoids for the treatment of epilepsy. Currently available clinical data therefore consist solely of uncontrolled case series, which do not provide high-quality evidence of efficacy. Randomized trials of the efficacy of cannabidiol for different forms of epilepsy have been completed and await publication.

___ Glaucoma

- There is limited evidence that cannabinoids are an ineffective treatment for improving intraocular pressure associated with glaucoma.

  Lower intraocular pressure is a key target for glaucoma treatments. Nonrandomized studies in healthy volunteers and glaucoma patients have shown short-term reductions in intraocular pressure with oral, topical eye drops, and intravenous cannabinoids, suggesting the potential for therapeutic benefit. A good-quality systemic review identified a single small trial that found no effect of two cannabinoids, given as an oromucosal spray, on intraocular pressure. The quality of evidence for the finding of no effect is limited. However, to be effective, treatments targeting lower intraocular pressure must provide continual rather than transient reductions in intraocular

pressure. To date, those studies showing positive effects have shown only short-term benefit on intraocular pressure (hours), suggesting a limited potential for cannabinoids in the treatment of glaucoma.

____ Positive status for human immunodeficiency virus

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

  There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

____ Acquired immune deficiency syndrome

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

  There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

____ Post-traumatic stress disorder

- There is limited evidence (a single, small fair-quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder

  A single, small crossover trial suggests potential benefit from the pharmaceutical cannabinoid nabilone. This limited evidence is most applicable to male veterans and contrasts with non-randomized studies showing limited evidence of a statistical association between cannabis use (plant derived forms) and increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder. There are other trials that are in the process of being conducted and if successfully completed, they will add substantially to the knowledge base.

____ Amyotrophic lateral sclerosis

- There is insufficient evidence that cannabinoids are an effective treatment for symptoms associated with amyotrophic lateral sclerosis.

  Two small studies investigated the effect of dronabinol on symptoms associated with ALS. Although there were no differences from placebo in either trial, the sample sizes were small, the duration of the studies was short, and the dose of dronabinol may have been too small to ascertain any activity. The effect of cannabis was not investigated.

____ Crohn's disease

- There is insufficient evidence to support or refute the conclusion that dronabinol is an effective treatment for the symptoms of irritable bowel syndrome.

  Some studies suggest that marijuana in the form of cannabidiol may be beneficial in the treatment of inflammatory bowel diseases, including Crohn's disease.

____ Parkinson's disease

- There is insufficient evidence that cannabinoids are an effective treatment for the motor system symptoms associated with Parkinson's disease or the levodopainduced dyskinesia.

  Evidence suggests that the endocannabinoid system plays a meaningful role in certain neurodegenerative processes; thus, it may be useful to determine the efficacy of cannabinoids in treating the symptoms of neurodegenerative diseases. Small trials of oral cannabinoid preparations have demonstrated no benefit compared to a placebo in ameliorating the side effects of Parkinson's disease. A seven-patient trial of nabilone suggested that it improved the dyskinesia associated with levodopa therapy, but the sample size limits the interpretation of the data. An observational study demonstrated improved outcomes, but the lack of a control group and the small sample size are limitations.

____ Multiple sclerosis

- There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity.

  Based on evidence from randomized controlled trials included in systematic reviews, an oral cannabis extract, nabiximols, and orally administered THC are probably effective for reducing patient-reported spasticity scores in patients with MS. The effect appears to be modest. These agents have not consistently demonstrated a benefit on clinician-measured spasticity indices.

____ Medical conditions of same kind or class as or comparable to the above qualifying medical conditions

- The qualifying physician has provided the patient or the patient's parent or legal guardian a summary of the current research on the efficacy of marijuana to treat the patient's medical condition.
- The summary is attached to this informed consent as Addendum_____

____ Terminal conditions diagnosed by a physician other than the qualified physician issuing the physician certification

- The qualifying physician has provided the patient or the patient's caregiver a summary of the current research on the efficacy of marijuana to treat the patient's terminal condition.
- The summary is attached to this informed consent as Addendum_____

____ Chronic nonmalignant pain

- There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.

  The majority of studies on pain evaluated nabiximols outside the United States. Only a handful of studies have evaluated the use of cannabis in the United
  States. and all of them evaluated cannabis in flower form provided by the National Institute on Drug Abuse. In contrast, many of the cannabis products that are sold in state-regulated markets bear little resemblance to the products that are available for research at the federal level in the United States. Pain patients also use topical forms.

While the use of cannabis for the treatment of pain is supported by well controlled clinical trials, very little is known about the efficacy, dose, routes of administration, or side effects of commonly used and commercially available cannabis products in the United States.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

_____ The Department of Health submits a data set to the Consortium for Medical Marijuana Clinical Outcomes Research for each patient registered in the medical marijuana use registry that includes the patient's qualifying medical condition and the daily dose amount and forms of marijuana certified for the patient.

PART B: Certification for medical marijuana in a smokable marijuana for a patient under 18 with a diagnosed terminal condition.

____ Initial here if you are not a patient under 18 with a diagnosed terminal condition who will be receiving medical marijuana in a smokable form. After initialing here, complete part C.

If the patient is under 18, has a diagnosed terminal condition, and will be receiving medical marijuana in a smokable form, please review and initial the remainder of Part B before completing Part C.

Respiratory Health

____ Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relations ships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term cannabis smoking leads to similar deleterious effects of respiratory health, and some investigators ague that cannabis smoking may be even more harmful that of tobacco smoking. Data collected from 15 volunteers suggest that smoking one cannabis joint can lead to four times the exposure to carbon monoxide and three to five times more tar deposition than smoking a single cigarette.

Cognitive and Psychosocial Development

____ Researchers are still studying the long-term health effects of marijuana. Most people agree that marijuana use hurts adolescents more than adults. It is during the period of adolescence and young adulthood that the neural substrates that underlie the development of cognition are most active. Adolescence marks one of the most impressive stretches of neural and behavioral change with substantial a protracted development in terms of both brain structure and function. As a result, cannabis and other substance use during this period may incur relatively greater interference in neural, social, and academic functioning compared to late developmental periods.

- There is moderate evidence of a statistical association between acute cannabis use and impairment in the cognitive domains of learning, memory, and attention.
- There is limited evidence of a statistical association between sustain abstinence form cannabis use and impairments in the cognitive domains of learning, memory, and attention.

- There is limited evidence of a statistical association between cannabis use and impaired academic achievement and education outcomes.
- There is limited evidence of a statistical association between cannabis use and increased rates of unemployment and/or low income.
- There is limited evidence of a statistical association between cannabis use and impaired social functioning or engagement in developmentally appropriate social roles.

Addiction

Marijuana, like some other brain-altering substances, can be addictive. Nearly one in 10 marijuana users will become addicted. Starting to use marijuana at a younger age can lead to a greater risk of developing a substance use disorder later in life. Adolescents who begin using marijuana before age 18 are four to seven times more likely than adults to develop a marijuana use disorder.

Part C: For certification of smoking marijuana as an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition

____ **Acknowledgement of contaminant risks.**

Smokable marijuana has infectious risks that are not present in processed products. Certain molds and mildews can contaminate marijuana plants during growing, processing, storage in dispensaries and in patient homes. These contaminates can pose health risks, particularly to those who are immunosuppressed due to their disease state and treatments. While the State of Florida requires third party testing you should still inspect your product.

____ **Respiratory Health.**

Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relations ships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term marijuana smoking leads to similar deleterious effects of respiratory health, and some investigators ague that marijuana smoking may be even more harmful that of tobacco smoking.

_____ **Information regarding health risks of 2nd and 3rd hand smoke to other household members.**

You should never smoke medical marijuana around other family members, especially children and any household guests. You should smoke outside to allow adequate ventilation and to mitigate the dangers of secondhand and thirdhand smoke to others. Marijuana should never be smoked inside vehicles or other small spaces that children will occupy even if the children are not present at the time the product is consumed.

____ **Dangers of smoking marijuana in households where oxygen is in use.**

If you use oxygen or have others in your household who use oxygen you should not smoke marijuana or any other combustible material in the vicinity of where the oxygen is in use due to the risk of fire and explosion.

____ **Self-dosing, if permitted.**

I have been given instructions or discussed guidance on self- dosing with my qualified physician if permitted to do so.

Part D: Must be completed for all medical marijuana patients

_____ I have had the opportunity to discuss these matters with the physician and to ask questions regarding anything I may not understand or that I believe needed to be clarified. I acknowledge that Dr._____has informed me of the nature of a recommended treatment, including but not limited to, any recommendation regarding medical marijuana.

Dr._____also informed me of the risks, complications, and expected benefits of any recommended treatment, including its likelihood of success and failure. I acknowledge that Dr. _____informed me of any alternatives to the recommended treatment, including the alternative of no treatment, and the risks and benefits. Dr. _____ has explained the information in this consent form about the medical use of marijuana.

Patient (print name) _____

Patient signature or signature of the parent or legal guardian if the patient is a minor:

_____ Date _____

I have explained the information in this consent form about the medical use of marijuana to _____ (Print patient name).

Qualified physician signature:

_____ Date _____

Witness:

_____ Date_____

64B8-9.018, F.A.C.
64815-14.013, F.A.C.
DH-MQA-5026 (Rev. 03/21)

MEDICAL CANNABIS ACCESS STATE REPORT CARD **2022**

Americans for Safe Access

FLORIDA

Improvements and Recommendations

The Florida medical cannabis program has seen tremendous growth over the past few years. In 2021, the state added almost 260,000 patients to the registry, and in 2022 another 170,000 new patients enrolled. The state is fast approaching one million registered medical cannabis patients, but has a long way to go in ensuring the medical cannabis law protects and serves patients in the state. At the end of 2022, the state opened the door to adding more cannabis retailers and facilities, which will eventually ease access restrictions. At the same time, the state also substantially raised licensing fees and requirements for cannabis businesses; only time will tell just how that impacts patient access and affordability.

In 2023, ASA recommends that legislators make improvements, particularly when it comes to patients rights. These include, addressing discriminatory roadside sobriety testing, and provisions that protect medical cannabis patients from discrimination in their employment; something that must be corrected immediately. While the current law prohibits landlords from discriminating against someone based on their status as a medical cannabis patient, landlords are permitted to prohibit specific behaviors within the lease, which harms patients. ASA also recommends that Florida do away with requiring patients to register every 7 months; administrative costs of running the medical cannabis program should not fall on the shoulders of patients, and patients should not be required to pay a fee just to have access to a treatment option.

BASE CATEGORIES POINTS: 341
PENALTIES: 0
POINT TOTAL: 341/700
SCORE PERCENTAGE: 48.71%

778,781	3.53%	571	1,506 : 1
Registered Patient Population	of Total Population Represented by Patients	Retail Locations Currently in Operation	Patients : Retail Locations

CATEGORY	POINTS
PATIENT RIGHTS AND CIVIL PROTECTIONS	**50/100**
Arrest Protection	25/25
Affirmative Defense	20/20
Parental Rights Protections	0/20
Employment Protections	0/20
DUI Protections	0/10
Explicit Privacy Standards	5/5
ACCESS TO MEDICINE	**65/100**
Authorizes Retail Access	10/10
Alternative Accessibility Methods	20/20
– Authorizes Delivery	10/10
– Authorizes Curbside Pickup	10/10
Personal Cultivation	0/15
Collective Gardening	0/5
Sufficient Number of Licensed Retailers	30/30
Reciprocity	5/20
AFFORDABILITY	**30/100**
Sales Tax Break for Patients and Caregivers	20/20
Covered by State Insurance or Health Aid	0/20
Reasonable Registration Fees	10/20
Financial Hardship Waivers or Discounts	0/20
Donation Program	0/10
Allows Multi-year Registrations	0/10

CATEGORY	POINTS
PROGRAM FUNCTIONALITY	**80/100**
Legal Protections Within Reasonable Time Frame	20/20
Reasonable Possession Limits	10/10
Reasonable Purchase Limits	10/10
Telemedicine for Physician Certification	0/15
Patient and Physician Representation in Program Decision Making	20/20
Reasonable Caregiver Standards	2/5
– Background Checks	2/2
– Number of Caregivers	0/3
Reasonable Physician Standards	5/5
Access to Administration Methods	10/10
– Allows Dried Flower	5/5
– Allows Edibles, Concentrates, and Other Forms	5/5
Provides Access to Minors on School Grounds	3/5
HEALTH AND SOCIAL EQUITY	**32/100**
State Program Protections	10/25
Housing Protections	10/25
Access for Minors	5/10
Access in Underserved Areas	2/10
List of Qualifying Conditions is Exhaustive or All Inclusive	5/10
Allows Patients to Medicate Where They Choose	0/10
Organ Transplants	0/5
Ownership or Employment Restrictions	0/5

CATEGORY	POINTS
CONSUMER PROTECTION AND PRODUCT SAFETY	**84/200**
Cultivation Operations	**12/50**
Quality Management Systems	0/10
Staff Training	0/10
Standard Operating Procedures	0/8
– Facility and Equipment Sanitation	0/1
– Workplace Safety	0/1
– Storage	0/1
– Batch and Lot Tracking	0/1
– Security	0/1
– Waste Disposal	0/1
– Water Management	0/1
– Records Management	0/1
Pesticide Usage Limitations	2/2
Environmental Impact Regulations	0/2
Required Testing	7/8
– Cannabinoids	1/1
– Terpenes	0/1
– Microbials	1/1
– Aflatoxins	1/1
– Pesticides	1/1
– Heavy Metals	1/1
– Foreign Matter	1/1
– Moisture Content	1/1
Packaging and Labeling	1/3
– Cannabinoids	1/1
– Terpenes	0/1
– Pesticides	0/1
Complaints, Adverse Event Reporting and Recall Protocol	2/7
Manufacturing Operations	**17/50**
Quality Management Systems	5/10
Staff Training	0/10
Standard Operating Procedures	0/7
– Facility and Equipment Sanitation	0/1
– Workplace Safety	0/1
– Storage	0/1
– Batch and Lot Tracking	0/1
– Security	0/1
– Waste Disposal	0/1
– Records Management	0/1
Environmental Impact Regulations	0/3
Required Testing	8/10
– Cannabinoids	1/1
– Terpenes	0/1
– Microbials	1/1
– Aflatoxins	1/1
– Pesticides	1/1
– Heavy Metals	1/1
– Residual Solvents	1/1
– Homogeneity	0/1
– Foreign Matter	1/1
– Water Activity	1/1
Packaging and Product Labeling	3/5
– Cannabinoids	1/1
– Terpenes	0/1
– Ingredients	1/1
– Allergens	1/1
– Nutritional Content	0/1
Complaints, Adverse Event Reporting and Recall Protocol	1/5
Dispensary Operations	**15/50**
Staff Training	5/20
Standard Operating Procedures	0/7
– Facility Sanitation	0/1
– Workplace Safety	0/1
– Storage	0/1
– Batch and Lot Tracking	0/1
– Security	0/1
– Waste Disposal	0/1
– Records Management	0/1
Product Testing	0/10
– Product Meets Requirements Before Sale	0/5
– COA Disclosure	0/5
Complaints, Adverse Event Reporting and Recall Protocol	10/13

CATEGORY	POINTS
Laboratory Operations	**40/50**
Independent or Third-Party	5/5
Laboratory Sampling	5/5
Method Validation	4/4
Quality Management Systems	5/5
Staff Training	10/20
Standard Operating Procedures	7/7
– Facility and Equipment Sanitation	1/1
– Equipment and Instrument Calibration	1/1
– Workplace Safety	1/1
– Sample Tracking	1/1
– Security	1/1
– Waste Disposal	1/1
– Records Management	1/1
Result Reporting	4/4
SCORE PENALTIES	**0/100**
Gives Regulatory Preference to Adult Use	0/20
Classifies Cannabis as a Medicine of Last Resort	0/15
Administrative or Supply Problems	0/15
Requires Vertical Integration	0/10
Creates New Criminal Penalties for Patients	0/10
Limits Patients to a Single Retailer	0/10
No System for Adding Qualifying Conditions	0/10
Imposes Bans or Limits on THC	0/5
Imposes Bans or Limits on CBD	0/5

Patient Feedback

Patients surveyed in Florida had varying opinions on the state's medical cannabis program, with most believing access to medical cannabis has decreased. While many surveyed patients believe that there are an adequate amount of dispensaries to purchase products from, patients reported that products are expensive, there are harsh regulations on the quantity of cannabis one can purchase, and the new limits on THC content prevent patients from receiving therapeutic benefits. One survey response noted that Florida's requirement to renew certifications every 7 months creates financial stress for patients, preventing many from having consistent access to cannabis and receiving its subsequent benefits.

Background

For background information regarding this state, please visit www.safeaccessnow.org/states and click on the state.

Scoring Information

For information on how each section was scored, please check out the full scoring rubric at www.safeaccessnow.org/sos22rubric

Recommendations for Regulators

To aid government agencies in establishing sound rulemaking policies, ASA created the Patient Focused Certification (PFC) program. PFC is a third party certification and training program for the cannabis industry. PFC utilizes the American Herbal Products Association (AHPA) recommendations for botanical products, good agricultural (collection) practices (GAP), good manufacturing practices (GMP), and good laboratory practices (GLP) to thoroughly evaluate a business for compliance. PFC was the first and only first cannabis compliance organization to attain ISO/IEC 17065 accreditation in the U.S. cannabis market. PFC is available to companies cultivating, manufacturing, or distributing cannabis and hemp products, as well as to laboratories providing cannabis analytic services.

The PFC training program prepares individuals to understand state and local regulations and to learn required safety and operational protocols, while teaching them the basics of cannabis as medicine and common therapeutic uses of cannabis. PFC trainings are available online to anyone interested in learning more about medical cannabis. Trainings are available in Cultivation, Manufacturing, Distribution, and Laboratory. A full training course guide can be found at www.PatientFocusedCertification.org/training.

Learn more about PFC at www.PatientFocusedCertification.org.

Appendix C: Potential side effect of opiates

AMERICAN ADDICTION CENTERS . When used improperly, these legal opioid drugs can present some of the same risks as illicit heroin sold on the street.

Abuse of opiates, whether prescription painkillers or heroin, can have a serious impact on your health. In addition to the hazards of overusing opioid painkillers, sharing needles for the injection of heroin or injecting crushed pills poses its own dangers. These substances and practices can affect almost every part of your body, potentially leading to permanent damage to your health.

A multitude of health consequences can accompany long-term opiate abuse, but many of the dangers are seen more acutely. Even a first-time user can experience respiratory arrest, for example.

The Effects of Opiates on the Brain: Opiate painkillers are known to have side effects such as daytime sleepiness, which could consequently require additional stimulant medication to counteract. The long-term use of painkillers was also found to be associated with a heightened risk of developing major depression: Patients using painkillers in excess of six months had more than a 50 percent greater chance of developing a depressive episode.

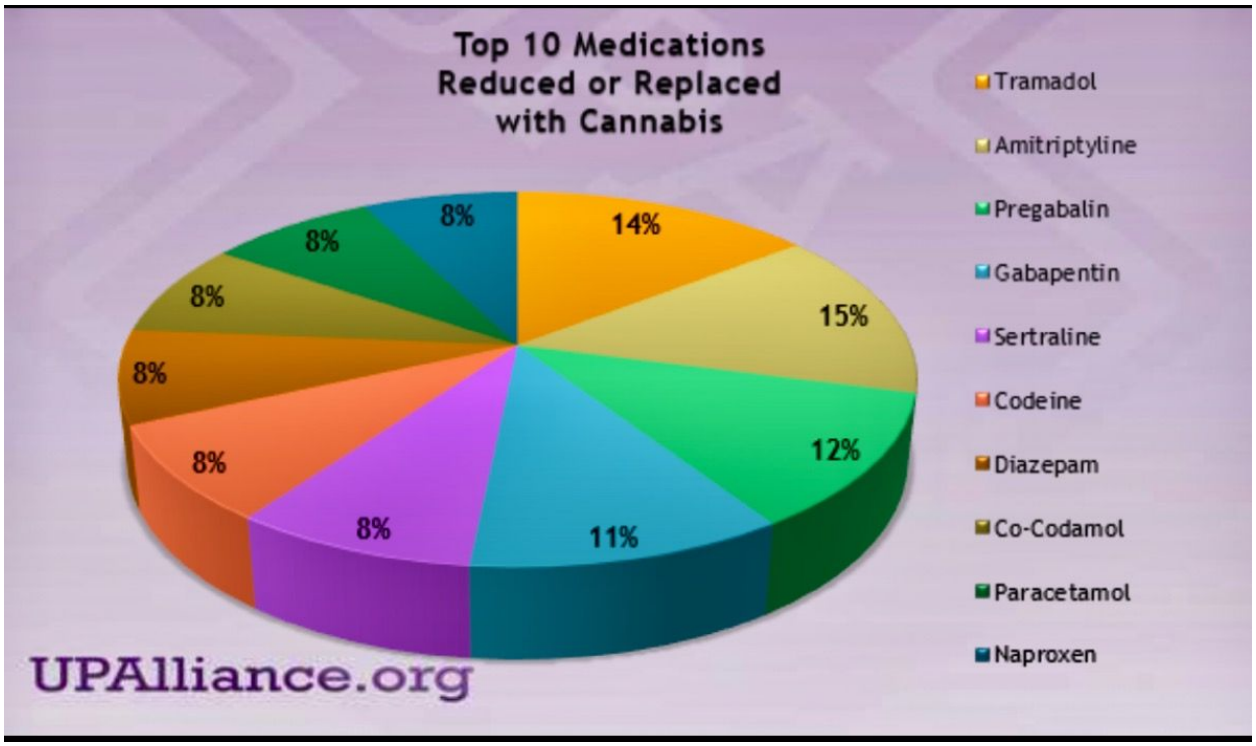
The Effects of Opiates on the Respiratory System: Overdosing on opioid painkillers or heroin can lead to respiratory depression, a slowing of breathing. At sufficient doses, respiratory arrest can deprive the brain and body tissues of oxygen. This can easily prove fatal or result in debilitating organ system injury.

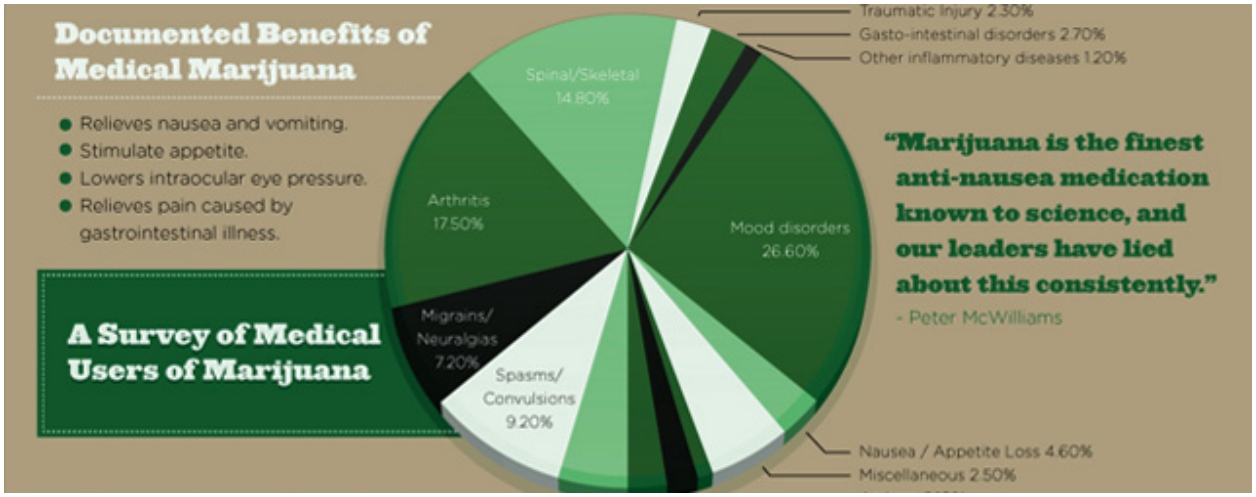
The Effects of Opiates on the Digestive System: Opiates affect the muscles of the digestive system, leading to constipation due to a slowing of digestive transit. The slowed gastrointestinal motility and chronic constipation can also place users at heightened risk for more serious conditions, such as small bowel obstruction, perforation and resultant peritonitis. Nausea also occurs frequently in many users of opioids, along with sudden, uncontrollable vomiting; antiemetic medication may be required in order to treat this.

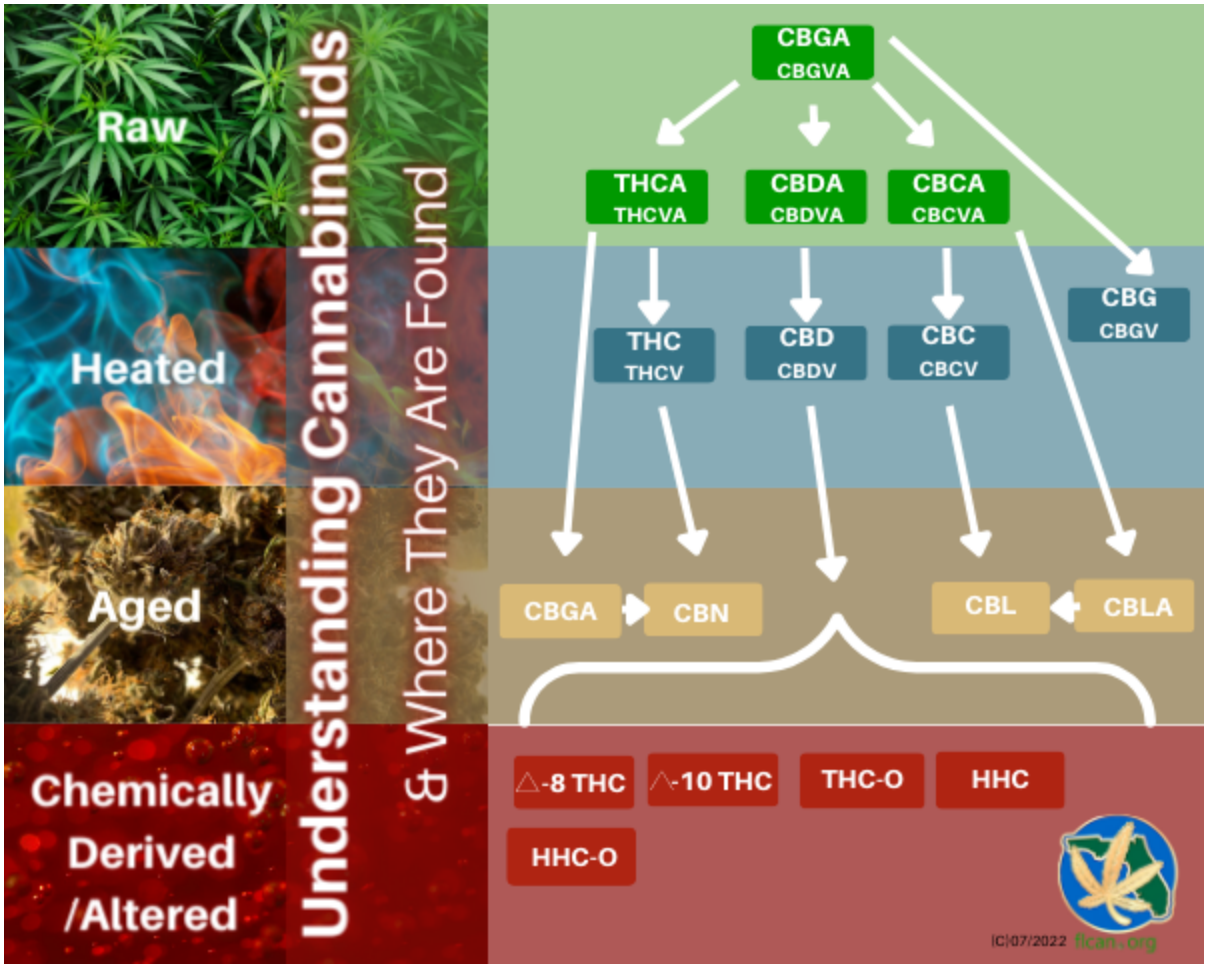
The Effects of Opiates on the Nervous System: Chronic use of opioid painkillers can lead to the development of hyperalgesia, a syndrome of increased sensitivity to pain. Opioid use is also associated with psychomotor impairment, an overall slowing of a person's physical movements and loss of coordination.

The Effects of Opiates on the Immune System: Opioid painkillers are known to be associated with suppression of the immune system, as opioid receptors are involved with regulation of immunity.

The Effects of Opiates on the Liver: Opioid painkillers, combined with acetaminophen, can cause liver damage from acetaminophen toxicity. Damage to the liver from acetaminophen toxicity is an undeniable risk of taking excessive doses of many prescription painkillers. Adding alcohol to the mix further decreases the liver's ability to process the toxic combination of ethanol and acetaminophen.






Raw
Heated
Aged
Chemically Derived /Altered
Understanding Cannabinoids & Where They Are Found
CBGA
CBGVA
THCA
THCVA
CBDA
CBDVA
CBCA
CBCVA
CBG
CBGV
THC
THCV
CBD
CBDV
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CBGA
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CBL
CBLA
△-8 THC
△-10 THC
THC-O
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