2022 MEDICAL MARIJUANA STAKEHOLDER GROUP SUMMARY REPORT

JANUARY 2023





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2022 Medical Marijuana Stakeholder Group Summary Report

OVERVIEW

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Medical Marijuana Stakeholder Group

Meeting Dates

September 21, 2022 - 5:00 p.m. to 6:30 p.m.

November 16, 2022 – 5:00 p.m. to 6:30 p.m.

Sponsor

Delaware Department of Health and Social Services, Division of Public Health, Emergency Medical Services and Preparedness Section, Office of Medical Marijuana

Purpose

To provide a platform for communication and feedback to occur between the state entities, the organizations that work in the industry, and the patient and advocate groups associated with the Delaware Medical Marijuana Program.

Meeting Attendees

See Appendix A.

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SUMMARY

Needs Assessment

During August 2022, the Delaware Department of Health and Social Services, Division of Public Health, Office of Medical Marijuana (OMM) developed a survey which was distributed through an email push from their software to Medical Marijuana Program (MMP) participants. Its purpose was to gather feedback from patients and caregivers to increase understanding of their interaction with, and use of, the program, plus their level of satisfaction, and any concerns or issues.

Medical Marijuana Stakeholder Group Patient Selection

When forming the Medical Marijuana Stakeholder Group, OMM chose to incorporate an equal number of compassion center representatives and program patients or caregivers. The goal was to select two patients from each county, one newer to the program and another more experienced participant. By differentiating geographic location and time involved in the program, the varying viewpoints would provide the best overview of what is being done successfully in the program and any concerns or issues from the patient population. Delta Development Group, Inc. was contracted to assist in the facilitation of the project and stakeholder group meetings. Delta Development Group selected the program patient participants to avoid any potential selection bias.

Medical Marijuana Stakeholder Group Medical and Scientific Team

Paul Hyland, OMM Director, invited individuals from the scientific community and health professionals within the state who have worked with OMM to participate in the stakeholder group. The purpose of including this team was to provide medical and scientific information about cannabis and its use in medical treatment from the viewpoint of people who are not related to the cannabis industry.

September 21, 2022 Public Meeting

Medical Marijuana Program Discussion

During the meeting, the group was informed that the survey developed by OMM was designed to collect feedback from program participants about their experience and concerns. Key issues identified in the survey were concerns about product variety and availability. Most patients only visit one or two of the dispensaries located throughout the state, and patients were typically only willing to travel less than 10 miles or between 10 and 20 miles to purchase the desired product. One of the program's main objectives is to ensure that an adequate number of options are available to patients when choosing a dispensary and purchasing products.

As of the meeting date, the MMP had approximately 15,500 patients throughout the state, with 51% residing in New Castle County, 18% in Kent County, and 31% in Sussex County. To account

for the population size and to guarantee product availability, three new retail facilities opened since 2021, and two more were expected to open in the fall of 2022. CannTech Research, in conjunction with Best Buds, launched a new location in September 2022 in Dover and the group was told they expected to open a Georgetown location in October 2022. The Farm had recently opened a retail location in New Castle, and Fresh Delaware and Valor both have facilities that are beginning the process of developing retail locations, but opening dates are not yet established. Despite these newer retail locations opening across the state, their operators and owners struggle to advertise the new dispensary facilities. OMM maintains and updates the program's patient portal, webpage, and card correspondence that includes compassion center locations.

MMP continues to view Cannabidiol (CBD) as an important topic and would like to see additional one-to-one product availability, particularly for the 104 patients with CBD Rich patient cards and for the 19 pediatric patients. One-to-one refers to a product that is equal or near equal part CBD and Tetrahydrocannabinol (THC). The Farm offers the following one-to-one products: half gram and gram cartridges, tinctures, salve, gummies, and pediatric formulas. First State Compassion Center's available products include tinctures, waxes and salves, and half gram and gram cartridges; a new line of edibles and gummies will also be offered. Columbia Care's products include tinctures and are working towards releasing a press 2.0 tablet.

The stakeholder group shifted the focus of discussion to gather opinions regarding the potential for MMP to offer a three-year program card to patients. By state law, a patient must visit a medical provider every year to be recertified for the program. Jason M. Silversteen, DO, Clinical Lead of Outpatient Neurology Specialists at ChristianaCare, cited that if implemented, the medical professional should have the opportunity to decide whether each patient medical card should be good for one year or three years. When evaluating a potential or returning patient and making that determination, providers could be given the option to state the desired or appropriate duration for usage of product while filling out the MMP application or recertification. When a medical professional approves a three-year period, the provider must keep track of and follow the patient. Most stakeholder group members representing the scientific and health professions expressed support for this idea. All favored the medical professional being able to initially approve someone for a one-year period, and with time spent successfully in the program, to extend it to three years. Having the option to select a one-year card in addition to selecting a three-year card allows providers to monitor the patient by observing how they respond to the treatment and any side effects that may occur. Although there have been no previous considerations for a three-year card and a similar process available for employees in the program, the idea does have merit and will be reviewed for requirements.

Members of the stakeholder group raised questions about patients' ability to get higher dose THC products (e.g., edibles in 20 mg) than the current 10 mg dose. Currently, this style of product is only available in pill form and some people have difficulty swallowing larger pills. OMM responded that it is unlikely those type of products, particularly edibles, would be made available at a higher dose. The reservation comes from a survey of product overconsumption

and emergency room visits that resulted from using higher dose products. Additionally, it is easy for the effects for products like higher potency edibles to overwhelm a patient who is a new user or to over-consume the product. For those patients, the program could possibly investigate alternative options and formulas for substitute products such as tinctures or chewable tablets.

Another discussion centered on medical marijuana prescriptions. MMP authorizes providers to write recommendations/prescriptions for medical marijuana patients and denote the prescriptive authority of medical professionals, such as a physician, advance practice nurse, or physician assistant. Dr. Silversteen informed the stakeholder group that Delaware is one of the most streamlined states for endorsing a patient for medical use, and does not require certain certifications, training, or classes. Dr. Andrew Willet, who operates a family practice in Kent County, commented that medical professionals, are not prescribing marijuana use as a treatment, but rather certify that a patient has a condition that might benefit from marijuana use.

Scientific and Health Care Related Medical Marijuana Subject Matter Discussion

Discussion was initiated among the stakeholder group members pertaining to Delta 8 THC products, which have been discovered in stores and are being frequently sold in Middletown and the surrounding areas of Delaware although they are illegal to sell in the state. The rise in Delta 8 THC products is believed to be a consequence of the Farm Bill that was passed, leading to an abundance of hemp which contains CBD. Through an unregulated process and use of basic chemistry and chemicals, the structure of CBD is altered into the Delta 8 THC, a "cousin" of the classic Delta 9 THC, which is a general form of THC that is present in marijuana products. The group commented on the importance of informing business owners that Delta 8 THC products are illegal to sell in the state and stressed the need for additional consumer education. Consumers should have the opportunity to become knowledgeable about the various cannabis products flooding the market so they will make properly informed purchasing decisions. The FDA noted in recent reports that there has been an uptick in the amount of Poison Control Center calls in response to Delta 8 THC, with 40% of those calls involving children.

Dr. Silversteen provided a presentation on cannabis drug interactions (Appendix B). He reviewed the current state of cannabis in the United States, explained how CBD and THC are broken down and metabolized, and shared the results of published drug interaction studies. He emphasized that use of certain prescription drugs in tandem with cannabis may result in an inhibiting or inducing impact on the effects of the cannabis products.

Public Comments

No questions or comments were provided by the members of the public present during the meeting.

November 16, 2022 Public Meeting

MMP Program Discussion

One of the top survey responses from program participants centered on banking restrictions associated with the MMP. Currently, patients are allowed to purchase products either using cash or certain registered debit cards that have high interest rates and transaction fees. It would be more convenient for consumers to use a credit card for purchasing product. Furthermore, allowing credit card transactions could increase the number of options and make it easier for patients to purchase products. However, such permission would likely take some sort of federal legislation that lowered the drug scheduling of cannabis products or passage of a banking act. A stakeholder group member who travels observed that multiple U.S. states seem to accept credit cards. There may not be a federal legislation requirement but rather a case-bycase determination by different states to approve credit card use for purchase. This topic and the approval process could be explored further. It was acknowledged that some patients are using cannabis now to treat Workers Compensation injuries. There is at least some case law requiring employers or insurance companies to reimburse employees, and it is much easier to do that if a credit card receipt can be provided. Since a risk factor for workplace violence is having large sums of money on hand from cash transactions, cashless payment options may potentially increase worker safety. When a business makes cash transactions during its daily operations, it is at higher risk of workplace violence and theft.

In addition to impacting the patient population, banking restrictions affect the industry side of the program. Businesses face many challenges such as the inability to openly bank with any organizations in the state of Delaware, which creates additional expenses and generates fees when banking out of state. Compassion centers are unable to obtain a bank loan, so private investors are leveraged, and they often charge higher interest rates. The restrictions prevent the companies from being able to obtain and use company credit cards. Finding retail space is another barrier connected to banking restrictions, because shopping centers may have previous banking regulations that prevent them from allowing cannabis companies from owning space within their facilities. Group members agreed that these obstacles are being observed by the other businesses operating in the state, and if a solution can be reached to allow for some banks to accept businesses within the cannabis industry, it could help to control expenses, which in turn could trickle down some savings to MMP patients.

Paul Hyland informed the group that he previously attended the cannabis banking meeting in Washington, D.C., and while some of these difficulties were discussed, there did not appear to be any resulting actions to address these issues. From a review of some states that work with cashless transaction systems, it did not appear that those systems have worked very successfully. There is no indication of forthcoming changes regarding banking restrictions.

The current availability of flower products was another topic of concern observed from survey responses. In the dispensaries around the state, there are 442 pounds of flower product containing 102 different strains, with the calculated consumption rate of about six ounces per patient each year. The four compassion centers grow the yearly demand for flower product:

the patient demand runs about 81,000 ounces and the program capacity is at 118,000 ounces. Since the annual program population typically increases by approximately 15%, the current capacity levels are sufficient to support the program until the new growers start producing in 2024.

The feedback the organizations often hear from the customer base is that certain strains are not being made available. Many of the strains that consumers are requesting are often specific strains that individuals encountered or used while in other parts of the country. Growing operators face several limiting factors: capacity limitations on compassion centers; the time it takes for the product to grow from seed to flower which controls how often new strains can be introduced; and the extensive number of strains that exist. A few operators acknowledged and agreed with the feedback the compassion centers received from patient comments and limitations that were mentioned. Currently, the operators of Best Buds and Valor Cannabis obtain flower products from other operators who are growing, with the expectation to open their own growing operations in 2023. Best Buds and Valor Cannabis have been able to obtain an adequate amount of product and have 35 different strains available. The desire to offer a variety of product types, strains, and compositions is evident when looking at the assortment of products developed and generated by the Delaware's MMP industry members. Having a wideranging product line available to program participants will provide options and opportunities for individuals to discover the most effective products to treat their specific existing condition within the MMP qualifying debilitating medical conditions list. Often the strains that people request are additional products with high THC content. Delaware businesses do a good job producing a variety of terpene profiles in their varying strains, which provide a mix of THC and CBD levels.

The cost of the flower product was another concern that program participants cited in the survey results. It is important to find a balance between making flower product affordable to patients and for companies to cover their necessary expenses. Multiple industry members shared that they carefully consider whether patients can afford product. That is also an important consideration of the compassion centers. To avoid or combat the existing financial barriers to purchasing affordable product, the centers provide these opportunities through discounts, sales, or specials. Over time, some products, such as flower, have seen a slight decrease in cost. A straight large cut in cost of product would be difficult, factoring in production and operation expenses. A recommendation was made to write an article or develop information to share with the public that explains the cost components. This effort could focus on the legality of the industry product versus off the street, as well as product safety testing.

The compassion centers were provided an opportunity to share an overview of any new products coming to the market. Kristopher Kiely of Fresh Delaware stated that their business is working on new manufactured infused products and are also releasing their own line of concentrated products in early 2023. Products include cartridges, edibles, topicals, tinctures, capsules, hash, and rosin. Clayton Hewes of First State Compassion told the group about the availability of in-house rechargeable vape cartridges that include a disposable base with a oneto-one product line. Mr. Hewes mentioned that First State Compassion enhanced their edibles

by adding new fruit chews which have a little more flavor, with hopes of launching a hot chocolate in the libation's product line.

In October 2022 House Bill 276 passed through the Delaware House to authorize the ability for MMP participants to legally purchase and possess firearms, but Governor John Carney vetoed it. Federal laws exist prohibiting persons from using cannabis products in jobs that require carrying a firearm. For the average citizen, no federal law prohibits individuals who use cannabis from owning a firearm. However, on the federal form for purchasing a firearm, Form 4473, question 21g asks applicants about cannabis use and applicants who admit to cannabis use would not be cleared for purchase. Over the past couple of years, there have been instances where eligible patients turned down a marijuana card because they would not be able to work because their job required carrying a firearm, or because they had a personal reason and desire to own a firearm. Deciding between owning firearms and obtaining a medical card to treat eligible conditions is also seen with veterans who may benefit from cannabis treatment. If President Joseph Biden's call to remove cannabis from the controlled dangerous substance list is granted, this issue may be bypassed (Statement from President Biden on Marijuana Reform | The White House). Information was shared regarding efforts and decisions made by other states to circumvent the firearm possession laws for patients with cannabis medical use cards. For example, in Illinois the state grandfathers one's right to own firearms if their firearm permit precedes getting a medical card, and in Maryland the state police do not arrest or act against those who possess a firearm permit and medical card.

The meeting was then opened to the stakeholder group to ask questions or address other program-related topics of interest that were not on the agenda. A patient from New Castle County was interested in hearing from the scientific or health care professionals regarding cannabis use disorder or addiction from cannabis use. As research has found that 30% of cannabis users suffer from one of the disorders, the patient asked if there is a need to educate program participants on this information when initially being provider their medical card. When people are growing up and hear about cannabis, the substance can be portrayed as something that is not addictive, unlike alcohol or cigarettes. Brett Appelbaum of the Division of Public Health responded that when discussing or comparing addiction or substance use disorder of cannabis to another substance like alcohol or heroin, the cannabis substance is considered a more safe or less harmful substance in comparison. Dr. Jahan Marcu from the International Research Center on Cannabis and Health informed the group that cannabis use disorder is often measured on a spectrum that is determined through a patient's answers to a test that is completed with a questionnaire on use habits. Dr. Marcu noted that most medical use patients who use cannabis medication daily and follow medical guidelines and supervision are likely to score at the mild or moderate level on that spectrum. He stressed the importance of determining how cannabis use disorder or addiction is being defined when reviewing any study or discussing the topic. In addition to how a study defines an addiction, the individual should also determine if the study is referring to a physical or psychological addiction because they are quite different.

Scientific and Health Care Related Medical Marijuana Subject Matter Discussion

Dr. Marcu delivered a presentation on cannabis impairment and driving under the influence (DUI). The presentation defined cannabis impairment, laws prohibiting driving while impaired by cannabis, associated public health issues, and the challenges of determining thresholds of impairment for testing and determining DUI. He also shared information on scientific studies completed regarding THC levels and impairment durations. It was mentioned that patients from Delaware should be aware that currently, Pennsylvania is a zero-tolerance state. Dr. Marcu commented that he believes Pennsylvania is trying to pass legislation that would provide some protections to move the state from a zero-tolerance to more of a two-tier system. This would require more than just THC metabolites in the blood for a DUI conviction and may require a field sobriety test to charge for a DUI or driving while intoxicated (DWI).

Public Comments

An individual from the public audience raised a question to the stakeholder group about what compassion centers, which are "not for profit" organizations, do if or when their profit margins exceed their profit thresholds. A stakeholder confirmed that compassion centers are "not for profit" and when their permits are being renewed, they are required to submit financial documents to validate that their profit margins remain at the proper levels. Clarification was made that the term "not for profit" represents the legal structure of a business in which the business does not disburse profits to owners, more so than referring to a company that makes money. In Delaware, if a program organization or business generates revenue that exceeds their expenses, the money is reinvested into the business versus dispersed among the ownership members. Under existing laws, cannabis organizations operate as "not for profit" businesses and are taxed as corporations. "Not for profit" businesses must follow the 280E Tax Code Assistance rule, which sets the federal standard for taxing corporations or companies that are involved in the trafficking or selling of Schedule I substances. The 280E rule prohibits these companies from claiming the same standard business deductions that other companies are allowed. Because of this rule, cannabis companies are not allowed to claim tax deductions for equipment that other businesses may deduct; therefore, cannabis businesses' excess profits are often reinvested in equipment.

Another question was posed to the stakeholder group as to whether Delaware has any current case studies on the success of medical marijuana use or if any of the compassion centers are conducting such research. OMM conducts biennial surveys to gather data on the topic by having program participants answer questions on how well the products address the qualifying conditions provided by their medical card. Of the nearly 1,400 responses received from August 2022, 73% of the respondents said that it was very helpful and 21% said it was fairly helpful. Based on comments from both patients and prescribing medical professionals, compassion center representatives suggest that anecdotal evidence results support the success of using medical marijuana to treat qualifying conditions. Dr. Marcu mentioned that successful use of medical marijuana is a significant topic that can be interpreted multiple ways. He stressed the importance of epidemiology, physician case reports, and using surveys as being on the forefront of public health research on the subject. Dr. Marcu shared results from a study conducted in

Delaware where results indicated that first-time cannabis patients showed a decrease in the use of legally prescribed opioids during a six-month period as the study was being conducted.

Points of Consensus

During two public meetings mentioned in this report, members of the Medical Marijuana Stakeholder Group shared equivalent opinions on the following aspects regarding the MMP.

- It would be beneficial to the program if OMM could implement an option for medical professionals to offer a three-year program card when evaluating a potential patient or recertifying an existing medical card.
- The current banking restrictions associated with the program creates barriers and obstacles for both businesses and patients involved in the MMP and continued research into opportunities to reduce or work around those restrictions should continue.
- Businesses in the industry have displayed an appropriate level of focus on selecting and generating a variety of strains, compositions, and product options for patients to find suitable products to treat their medical conditions.

Next Steps

As the Medical Marijuana Stakeholder Group completed the two meetings in 2022 required by the Concurrent Resolution (CR), now OMM needs to determine the group's next steps. The goal of OMM is to ensure that proper efforts and focus on building and improving the MMP are maintained, while recognizing and acknowledging the concerns of program participants. The 151st Legislative Session is no longer open, and the CR expired on December 31, 2022. OMM will consult with the stakeholder group to determine if quarterly meetings should be held in 2023, and whether the meetings offer an effective platform to allow for open conversation avenues between representatives of the industry and the patient population to identify, discuss, and devise solutions to existing program issues and concerns. Another option for OMM to ensure the office receives feedback from program participants on the MMP, if the stakeholder group were not to continue, would be to continue using the office's biennial surveys in an attempt to reach a larger percentage of program participants to increase the opportunity for feedback.

APPENDIX A: MEDICAL MARIJUANA STAKEHOLDER GROUP PUBLIC MEETING ATTENDEES

A1. Number of Medical Marijuana Stakeholder Group Public Meeting Attendees, Delaware, 2022.

ORGANIZATION/TITLE	# OF ATTENDEES 9/21/22	# OF ATTENDEES 11/16/22
Patient/Caregiver	4	4
Compassion Centers Representatives	8	6
Scientific/Health Professional	3	2
State Representatives	3	4
Public Attendees	5	7

Source: Delaware Department of Health and Social Services, Division of Public Health, Office of Medical Marijuana, 2022.

APPENDIX B: MEDICAL MARIJUANA STAKEHOLDER GROUP PUBLIC MEETING PRESENTATIONS

B2. Cannabis Drug Interactions by Dr. Jason Silversteen, Delaware, Presented September 21, 2022.



"The State of Cannabis"

- Growing acceptance of cannabis for medical use
- ♦ 39 states approved for medical use; 19 have legalization for recreational use
- ♦ At least 2/3rds of Americans support legalization
- Opiate epidemic continues and dissuades providers from utilizing opiates
- * Growing utilization and endorsement of cannabis by medical providers
- ♦ Limited knowledge of and "not top of mind" for drug-cannabis interactions

Drug Interactions Cytochrome P450 Enzymes

- ♦ THC and CBD are metabolized by CYP3A4 and CYP2C9 (Yamaori et al 2012, Watanabe et al 2007).
 - ♦ CYP3A4 inhibitors may increase THC and CBD levels.
 - ♦ CYP3A4 inducers may decrease THC and CBD levels
- ♦ CBD, but not THC, is metabolized by CYP2C19 (Stout and Cimino 2014)
- ♦ CBD also inhibits CYP2C19 and CYP3A4

Inhibiting Effects

- ♦ CYP3A4 inhibitors
 - ♦ Ketoconozole
 - ♦ Erythromycin
 - ♦ Carbamazepine
 - ♦ Verapamil/Diltiazem
 - ♦ Amiodarone

- ♦ CYP2C9 inhibitors
 - ♦ Omeprazole
 - ♦ Clopidogrel
 - ♦ Fluoxetine
 - ♦ Leflunomide
 - ♦ Dilantin

Inhibiting effects augment psychoactive effects of THC and dose related effects of CBD(somnolence, transaminase elevation)

Inducing Effects

- ♦ CYP3A4 inducers
 - ♦ Cyclosporin
 - ♦ Carbamazepine
 - ♦ Barbiturates
 - ♦ St Johns Wort

- ♦ CYP2C9 inducers
 - ♦ Rifampicin
 - ♦ Phenobarbital(weak)
 - ♦ St Johns Wort(weak)

Inducing effects lead to a greater metabolism of the substrate and could result in higher doses of cannabis required

Drug Interactions Cytochrome P450 Enzymes

- ♦ THC is a CYP1A2 inducer.
 - Theoretically, THC can decrease serum concentrations of clozapine, duloxetine, naproxen, cyclobenzaprine, olanzapine, haloperidol, and chlorpromazine (Flockhart 2007, Watanabe et al 2007).
- ♦ CBD is a potent inhibitor of CYP3A4 and CYP2D6.
 - As CYP3A4 metabolizes about a quarter of all drugs, CBD may increase serum concentrations of macrolides, calcium channel blockers, benzodiazepines, cyclosporine, sildenafil (and other PDE5 inhibitors), antihistamines, haloperidol, antiretrovirals, and some statins (atorvastatin and simvastatin, but not pravastatin or rosuvastatin).
 - CYP2D6 metabolizes many antidepressants, so CBD may increase serum concentrations of SSRIs, tricyclic antidepressants, antipsychotics, beta blockers and opioids (including codeine and oxycodone).

Drug Interaction Studies

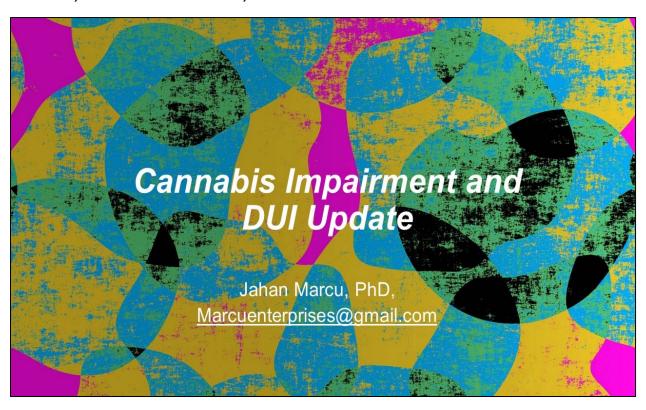
- ♦ Warfarin
 - ♦ THC and CBD increase warfarin levels(inhibits CYP3A4 and CYP2C19) (Yamaori et al 2012).
 - ♦ Frequent cannabis use has been associated with increased INR.
- ♦ Alcohol
 - ♦ Alcohol may increase THC levels (Hartman 2015).
- ♦ Theophylline
 - ♦ Smoked cannabis can decrease theophylline levels (Stout and Cimino 2014)
- ♦ Clobazam
 - In children and adults treated with CBD for epilepsy, CBD increased clobazam levels (CBD inhibits CYP2C19) (Geffrey et al 2015).

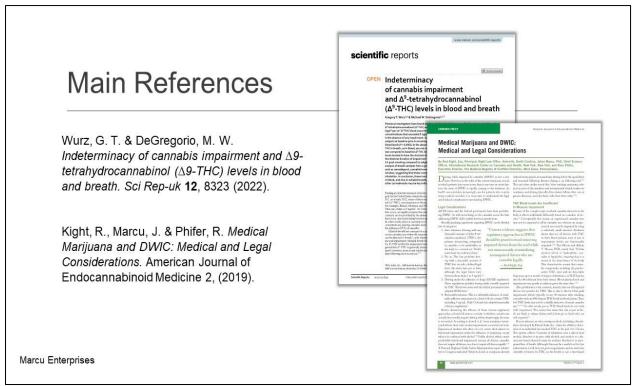
Take Home Message

- Cannabis, both CBD and THC, have proven and theoretically impact on drug-drug interactions(potentiate effect or inhibit effect of other prescription drugs)
 - ♦ May lead to reduce effect of a prescription drug
 - ♦ May also lead to reduced effect of cannabis or increase psychoactive effects of cannabis
- Unknown what dose or frequency of THC/CBD use leads to drug-drug interactions
- Must maintain vigilance prior to and subsequent to endorsing Medical cannabis to assure no signs of drug-drug interactions

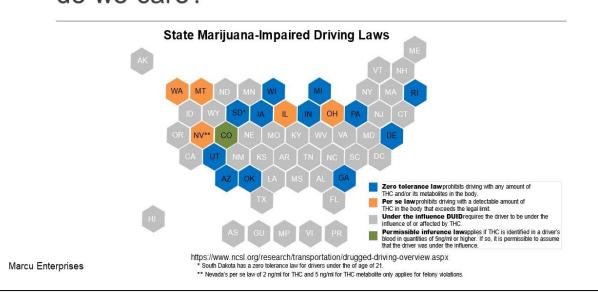
Source: Dr. Jason Silversteen, Neurology Specialist, Christiana Care, September 21, 2022.

B3. Cannabis Impairment and Driving Under the Influence Update by Dr. Jahan Marcu, Delaware, Presented November 16, 2022.





What is cannabis impairment? And why do we care?



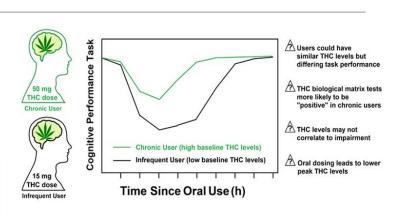
Public Health Issue of Cannabis & DUI/DWIC

- Harm to the individual
- Harm to the public
- Regulation
- Enforcement
- Cost

States with employment protections for medical cannabis patients: AZ, AR, CT, DE, DC*, FL, GA, HI, ME, MI*, MN, NY, OH, PA,

States with **DUI** protections: AZ, MI*, MN, RI

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Johnson, O. E., Miskelly, G. M. & Rindelaub, J. D. Testing for cannabis intoxication: Current issues and latest advancements. Wiley Interdiscip Rev Forensic Sci 4, (2022).

Pitfalls of DUI and Thresholds

- Ability to monitor DUI of cannabis
- Identifying cannabinoids at autopsy
- Delays in blood testing
- ☐ Various exposure levels (Edibles vs inhalation)
- ☐ Peak effects of THC do not coincide with per se limits (i.e., 5ng/ml)

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Science

- Variable experiences and blood levels
- □ THC Brain concentrations
- Breath and blood correlate
- Product formulation

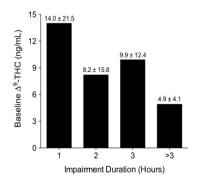


Figure 3. Post-smoking duration of impairment compared to baseline Δ^9 -THC blood concentration in 64 subjects. As determined by self-assessment, subjects were stratified by duration of impairment [l h (N=19), 2 h (N=4), 3 h (N=41), 3 h (N=4)] after smoking a 500-mg cannabis cigarette. Mean Δ^9 -THC concentration $(\pm SD)$ is shown above each bar.

Wurz, G. T. & DeGregorio, M. W. Indeterminacy of cannabis impairment and Δ9-tetrahydrocannabinol (Δ9-THC) levels in blood and breath. Sci Rep-uk 12, 8323 (2022).

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More Science

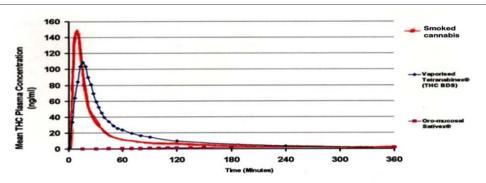


Figure 2: Comparison of pharmacokinetic peaks of Sativex® oromucosal spray containing 10.8 mg THC and 10 mg CBD (purple trace), vaporized Tetranabinex® with 6.65 mg THC (GWPK0114, data on file, GW Pharmaceuticals, blue trace), and smoked cannabis from a cigarette containing an estimated 34 mg THC^{76,77} (red trace). Note that the mean THC plasma concentration with Sativex never exceeds 2 ng/ml.

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From: Russo EB. 2007. The solution to the medicinal cannabis problem. In: Schatman ME (ed.). Ethical issues in chronic pain management. Boca Raton, FL: Taylor & Francis.

Scientific Consensus

"In conclusion, we present further evidence that single measurements of $\Delta 9$ -THC in blood cannot establish impairment, that single measurements of $\Delta 9$ -THC in exhaled breath likewise do not correlate with impairment, and that $\Delta 9$ -THCV and CBC may be key indicators of recent cannabis use through inhalation within the impairment window."

Several years of studies strongly suggests that there is currently no scientific justification for the use of per se legal limits for D9-THC.

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Standard Field Sobriety Testing (SFST aka FST) for Impairment

Impaired performance on the SFSTs is positively related to the dose of THC administered

Designed for both alcohol and drug impairment

Horizontal Gaze Nystagmus (HGN)

SFST Manual – detailed training for administration of tests

Walk-and-Turn (WAT)



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	Legislation format	Strengths	Limitations	Examples
Summary	Zero-tolerance	Can definitively identify exposure to cannabis	Requires chemical analysis Cannot differentiate intoxication from either current use, historical use, or passive exposure	Arizona (1990) ^a , Sweden (1999) ^b
	Behavioral — impairment	Can be conducted onsite Does not require chemical analysis Can potentially identify intoxication from cannabis inhalation Non-invasive	Not a definitive test for cannabis use Analysis is subjective May not be able to detect intoxication from oral use Limited types of FSTs are useful	Canada (1925) ^e , Australia (2000) ^d
	Per se/nonzero	Objective measurement of cannabis-related chemicals within the body May be useful in identifying intoxication in occasional users	Requires chemical analysis Current analysis methods deployed are not feasible for rapid on-site testing Per se limits may not represent intoxication in heavy users Impairment may occur at less than per se limits in infrequent users or from oral use	Norway (1959) (1.3 ng/ml in blood (2012)°); Canada (2008) ^f (2.0 ng/ml in blood); Denmark (2007) ^g (1.0 ng/ml in blood); Washington (2010) ^h (5.0 ng/ml in blood)
	Two-tier approach	Combines two methods to identify intoxication May be useful in identifying intoxication in occasional users	Requires chemical analysis Oral fluid screening techniques do not have high sensitivity or selectivity Per se limits may not represent intoxication in heavy users Impairment may occur at less than per se limits in infrequent users or from oral	Belgium (1999) ⁱ , Australia (2004) ^d

Thanks!

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Source: Jahan Marcu PhD, Chief Operations Officer, Director of Experimental Pharmacology and Behavioral Research at International Research Center on Cannabis and Health, November 16, 2022.



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