

Petitions to Add Qualifying Medical Conditions to the Medical Cannabis Program

A REPORT TO THE COMMISSIONER OF HEALTH

2018

FOREWORD

This report was produced by the medical cannabis citizens' review panel established under Minnesota Rules part 4770.4003, subpart 3. The report was written by the panel members, with administrative support from the Minnesota Department of Health.

Members of the Review Panel participating in this report were:

Heather Tidd, chairperson (patient advocate)

Kerstin Lappen, CNS (health care practitioner)

Dr. Susan Sencer, MD (health care practitioner with pediatric expertise)

Elizabeth Melton, JD (member at large)

Dr. George Komaridis, Ph.D., LP (member at large)

Mikel Bofenkamp, Pharm.D. (member at large)

Dr. Andrea Hillerud, MD (member at large)

The Review Panel's report to the Commissioner of Health must include potential public health benefits and risks of adding or rejecting a medical condition petitioned for inclusion on the list of medical conditions that qualify a person's enrollment in the medical cannabis patient registry program. The Review Panel's report may review new medical and scientific evidence about current qualifying medical conditions and may also review any medical condition for which the commissioner's decision has been deferred.

The Commissioner of Health will consider this report, any available evidence-based, peer-reviewed research that medical cannabis will provide therapeutic benefit, and other potential therapeutic factors in reaching a decision regarding whether to add a qualifying medical condition petitioned for the medical cannabis patient registry program.

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Introduction

This Review Panel was appointed by the Minnesota Department of Health (MDH) to review petitions requesting the addition of qualifying medical conditions for the Minnesota medical cannabis program. The Panel's responsibility is to report on potential public health impacts, including therapeutic factors and known potential benefits and risks of using cannabis to treat the petitioned medical conditions.

The Panel met two times in 2018 to consider seven petitioned conditions. In addition to the information submitted in the petitions, the Panel heard testimony at public meetings about the potential of cannabis to treat some of these conditions and received written comments from interested parties. The Office of Medical Cannabis also produced an "issue brief" reviewing scientific studies involving each petitioned medical condition.

The Panel reviewed petitions for adding Hepatitis C, Juvenile Idiopathic Arthritis (also known as Juvenile Rheumatoid Arthritis), and Traumatic Brain Injury (TBI) at its October 10, 2018 meeting. It reviewed petitions for adding Alzheimer's Disease, Opioid Use Disorder, Panic Disorder, and Psoriasis at its October 24, 2018 meeting.

The Panel was asked to provide a review of factors that support adding the proposed medical condition and the factors that support not adding the proposed medical condition. After the conditions were discussed and testimony taken, Panel members were asked to supply the strongest arguments for and against adding the condition. This report collects those responses.

As the Panel stated in previous years, many of the potential harms of using cannabis to treat medical conditions are shared by all the petitioned conditions. These include concerns about negative effects on developing brains, use by pregnant or breastfeeding women, and use by those with a family history of psychosis. Other public health concerns include the potential increase in people driving while impaired by cannabis. There is an addictive potential for recreational marijuana - the literature says 5-10% of chronic marijuana users become addicted - but how applicable this is to the various cannabis products available through the Minnesota medical cannabis program is unclear.

These potential harms need to be weighed against the potential harms of treatments currently available to these patients. For example, many of the chronic drugs given to children with seizures or autism also have negative cognitive effects and other concerns. There are similar concerns with medications to treat the other diagnoses as well. In addition, overdoses of many prescription medications can be significantly more severe than overdoses of cannabis.

Another concern is over the unknown long-term effects of the cannabis extract products used in the Minnesota medical cannabis program, even the low-THC products. At this point, there is not sufficient data to say what these long-term effects could be. The concern is heightened when talking about children.

Review of the Petitioned Conditions

Alzheimer's Disease

Alzheimer's Disease is a neurodegenerative disorder that affects mainly elderly persons. It is the most common cause of dementia. Other symptoms include cognitive impairment, delusion, depression, and agitation. The Panel heard from two public testifiers regarding Alzheimer's disease at the public hearing held on October 24, 2018.

Arguments for adding:

- Alzheimer's Disease has a severe impact on the individual, families, and society.
- Medical cannabis may improve the quality of life for Alzheimer's Disease patients. It may decrease agitation, confusion, rage and other symptoms of Alzheimer's, and increase the appetite of those with the condition.
- The science suggests medical cannabis may have some neuroprotective value.
- Alzheimer's Disease has an older patient population so unknown risks of long-term cannabis use are mitigated.

Arguments against adding:

- There is limited scientific evidence that medical cannabis is effective for treating Alzheimer's Disease.

Hepatitis C (HepC)

Chronic Hepatitis C (HepC) (ICD-10-CM B18.2) is an inflammation of the liver caused by the Hepatitis C virus left untreated during the acute period, leading to a chronic and sometimes lifelong infection; it can lead to permanent liver damage and may, in some cases, require a liver transplant. People with HepC have an increased risk of developing liver cancer. One person presented testimony at the October 10, 2018 public meeting.

Arguments for adding:

- Medical cannabis may improve quality of life by reducing symptoms and side effects such as headache, nausea, tiredness, and pain.
- Anti-inflammatory benefits of cannabis could be effective symptom management. HepC is an inflammation from an infection and medical cannabis could reduce inflammation.
- 21 other states have adopted HepC as a qualifying medical condition.

Arguments against adding:

- HepC lasts for relatively short interval of time for some people.
- There is a lack of extensive experience and research specific to HepC.

Juvenile Idiopathic Arthritis

Juvenile Idiopathic Arthritis (JIA), formerly known as Juvenile Rheumatoid Arthritis, encompasses a diverse group of immune-mediated medical disorders affecting children under 16 years of age which share as a common feature arthritis lasting more than six weeks. It can cause persistent joint pain, swelling, and stiffness. In some children the symptoms last for only a few months; others have symptoms for the rest of their lives. Some types of JIA can result in serious complications, such as growth problems, joint damage, and eye inflammation. The Panel reviewed JIA during its October 10, 2018 hearing; two people offered testimony about how JIA and its treatment affect their minor daughter.

Arguments for adding:

- Known side effects of available treatments are significant and severe (liver damage, infections, cancer)
- Keeping JIA separate from Intractable Pain would encourage pediatricians and rheumatologists to register to certify patients for the medical cannabis program

Arguments against adding:

- There is concern about long-term developmental, cognition, and mental health effects of cannabis use by children.
- There is very limited evidence directly related to medical cannabis' effectiveness treating JIA.

Opioid Use Disorder (OUD)

Opioid Use Disorder (OUD) is a problematic pattern of opioid use that results in significant impairment or distress on a clinical level. The clinical course of OUD involves periods of exacerbation and remission, but the underlying vulnerability never disappears and increases the risk of early death. The Panel reviewed Opioid Use Disorder at the October 24, 2018 meeting. Four members of the public presented testimony.

Arguments for adding:

- Medical cannabis can be a beneficial adjuvant to existing treatments. Physicians who have used medical cannabis as another medication-assisted treatment tool presented anecdotal evidence to the Panel as to its usefulness.
- Opioid addiction is an epidemic. High social costs. Many lives lost. Risks of cannabis are much smaller.
- Some form of opioid prescription or use disorder is a recognized qualifying condition in at least three states.
- There is evidence that in states with recreational use of cannabis, there has been a decrease in opioid deaths.

Arguments against adding:

- Minnesota's medical cannabis program is unable to require patient be seen by addiction medicine specialist with expertise in concurrent use of medical cannabis with opioid use disorder treatments (e.g., suboxone or methadone). Without the support of an addiction specialist, people with opioid use disorder may not get the full support needed for recovery (e.g., CBT, support groups, etc.). Written comments from Dr. Reznikoff are worth taking into account.

However, some panelist believe a requirement that patients be seen by an addiction specialist would be based on the historic belief that marijuana is a Schedule I drug, which is a politically-based rather than a scientifically-based premise.

- Preclinical data are conflicting as to benefit of cannabis for opioid withdrawal symptoms.
- Small clinical trials suggest current treatments are more effective at decreasing opioid withdrawal symptoms than cannabis.

Panic Disorder

Panic Disorder is an anxiety disorder characterized by episode of intense anxiety, increased heart rate, fear, palpitations, and shortness of breath lasting between five to ten minutes. The Panel heard from two testifiers during the October 24, 2018 meeting.

Arguments for adding:

- Medical cannabis can be effective reducing anxiety. Many in Minnesota that use medical cannabis for other qualifying conditions have reported an anxiety reducing effect. Anecdotal stories about benefit and relative lack of adverse effects from medical professionals and public.
- Safer management of CBD/THC levels are possible if patients are getting medical cannabis through the program and working with a pharmacist rather than if they are getting street marijuana.
- Vaporized cannabis, because it is inhaled, works quicker than current medications used to treat panic attacks. Patients have reported that they can medicate when they feel an attack coming on and prevent it. They also report that using medical cannabis reduces how often they feel they are going to have a panic attack.

Arguments against adding:

- THC, if too high a dose, can exacerbate anxiety symptoms.
- There is limited research specific to panic disorder and medical cannabis. There is limited clinical data on the effects of cannabis on anxiety-related symptoms. There is limited evidence that cannabidiol (CBD) may improve anxiety symptoms. One on-going clinical study of daily CBD oral capsules to treat anxiety disorders may provide additional information in the future.

Psoriasis

Psoriasis is a chronic, inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. No one testified for or against the petition at the Panel's October 24, 2018 meeting.

Arguments for adding:

- Studies show cannabis has anti-inflammatory effects. There is potentially a relationship to other immune-system conditions for which there is more evidence.
- Cannabis can help with symptom control (pain, itching).

Arguments against adding:

- There is very limited evidence (close to none) directly related to medical cannabis' effectiveness treating psoriasis.
- Potential effects on pediatrics is unknown.

Traumatic Brain Injury (TBI)

Traumatic Brain Injury (TBI) results from an external force causing an alteration in brain function, or other evidence of brain pathology, with primary (direct tissue damage) and secondary effects (a cascade of effects that occur in the injured brain over a variable, undefined amount of time). The panel heard from one testifier at the hearing on October 10, 2018.

Arguments for adding:

- TBI can have debilitating effects of the conditions on daily life.
- Cannabis can decrease anxiety and increase positive mood/feeling of well-being; may moderate intensity of emotions, such as agitation, rage, and aggression.

Arguments against adding:

- There is a general lack of evidence (research) to support benefits of using cannabis to treat TBI.

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