Petitions to Add Qualifying Medical Conditions to the Medical Cannabis Program

A REPORT TO THE COMMISSIONER OF HEALTH

DEPARTMENT OF HEALTH

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 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 three times in 2017 to consider 10 petitioned conditions. It received public testimony at two of the meetings and was given copies of written comments received by MDH. The Panel heard testimony about anxiety, dementia, endocannabinoid deficiency syndrome, liver disease, and obstructive sleep apnea at its September 26, 2017 meeting. It heard testimony about autism spectrum disorder, cortico-basal degeneration, nausea, Parkinson's disease, and peripheral neuropathy at its October 10, 2017 meeting.

In addition to the information submitted as part of the petitions, the Panel heard public testimony about the potential of cannabis to treat some of these conditions and received written comments from people who suffer from them. The Office of Medical Cannabis also produced a "research brief" reviewing scientific studies involving each petitioned medical condition.

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 last year, 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. Although there is an addictive potential for cannabis, the literature says only about 5% of chronic cannabis users become addicted.

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 addiction concerns. There are similar concerns with medications to treat the other diagnoses as well

One 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

Anxiety Disorders

Anxiety disorders include disorders with common features of excessive fear and anxiety and related behavioral disturbances. The DSM-5 defines several disorders under the broader definition of anxiety disorders. The Panel heard from four public testifiers regarding anxiety disorders at the public hearing held on September 26, 2017.

Arguments for adding:

- Medical cannabis might have fewer side effects than medications currently prescribed for anxiety.

- Effective treatment of anxiety would reduce social costs and trips to the emergency room, and result in fewer missed days of work, etc.

- Data from MN's medical cannabis program suggests medical cannabis could be effective for anxiety.

Arguments against adding:

- Medical cannabis could exacerbate depression and other dysphoric side effects.

Autism Spectrum Disorder (ASD)

Autism spectrum disorder (ASD) is a neurodevelopmental disorder that is characterized by sustained social impairments in reciprocal social communication and interactions; and repetitive behaviors, interests, or activities. These essential markers of autism spectrum disorder present in early childhood and limit everyday functioning. The word "spectrum" is used to define ASD since the disorder manifests itself in diverse ways, depending on varying symptom severity, the individual's development level, and chronological age. Fourteen people presented testimony at the October 10, 2017 public meeting.

Arguments for adding:

- Lack of effective current treatments/negative side effects of current (pharmaceutical) treatments.

- Severity of disabling effects, such as nonverbal, non-interactive, harm to self and others, rage, agitations, and difficulty/inability in attending school.

- Documented evidence of benefits for some children with autism certified for Minnesota's medical cannabis program for other reasons (e.g., Tourette syndrome and seizure disorders).

- Social costs/familial costs – cost of medical care, emergency room visits, lost work time, disruption of families, loss or reduction in social life and quality of life for entire family; and, risk of or actual physical harm to family members.

Arguments against adding:

- Autism is a broad spectrum of diseases, so there will be no panacea. The program would need to establish realistic expectations around medical cannabis.

- Autism can be misdiagnosed. Ideally, could treat as few people as need it and not more. You want to treat only those who need it, especially when it comes to children with developing brains. The way the program is set up makes that unlikely. Is this a health care practitioner education issue?

Cortico-basal Degeneration

Cortico-basal degeneration is a rare, progressive neurodegenerative condition due to pathological accumulation in brain neurons of tau protein. Clinical diagnosis of cortico-basal degeneration can be difficult. The Panel reviewed cortico-basal degeneration at the October 10, 2017 hearing; no one from the public requested to testify.

Arguments for adding:

- Current treatments are based on symptom control and do not try to cure the condition. Medical cannabis could be one more option for symptom control.

- Cortico-basal degeneration is a debilitating condition. Why not allow medical cannabis use if it could improve quality of life and present few side effects?

Arguments against adding:

- There are no clinical studies involving medical cannabis and cortico-basal degeneration.

- There are limited data supporting bio-mechanistic explanations why medical cannabis should work for neurocognitive disorders. More research and studies would be helpful.

- A more broadly defined condition that includes other progressive, neurodegenerative conditions or syndromes that could be symptomatically amendable to medical cannabis may be better than a condition-by-condition approach.

Dementia

Dementia is a general term to describe a decline in cognition (compared to a previously attained level of cognition) – to the point where it affects day-to-day life and social functioning. This decline can manifest as memory loss, diminished reasoning skills and executive functioning, and changes in personality and behavior. The Panel reviewed Dementia at the September 26, 2017 hearing. Two members of the public presented testimony.

Arguments for adding:

- Treatment alternatives are limited and only address further degradation. Medical cannabis could be another option, one with minimal risks.

- High costs to society – there would be social benefit and benefit to family if medical cannabis is able to lessen the severity of dementia and increase person's ability to manage their life.

Arguments against adding:

- Medical cannabis might aggravate confusion experienced by dementia patients.

- Limited evidence that medical cannabis may help with behavior/calming.

Endogenous Cannabinoid Deficiency Syndrome

Endocannabinoid Deficiency Syndrome has been proposed as a cause of several conditions, but at this point it remains a theory; no criteria have been proposed for making a diagnosis of Endocannabinoid Deficiency Syndrome. The Panel heard from one testifier at the hearing on September 26, 2017.

Arguments for adding:

- Testimony was presented about how the endocannabinoid system may be able to affect many conditions/symptoms, but the science is not there.

Arguments against adding:

- Endocannabinoid Deficiency Syndrome is a concept. There is no accepted clinical definition and there are no diagnostic measures. It would be difficult from a programmatic perspective to allow a qualifying condition that is not a defined medical condition.

Liver Disease

Liver disease refers to damage to the liver caused by hereditary factors or lifetime exposures, such as alcohol use, obesity or viruses, and the subsequent effects of such damage. There are a few common pathways in liver disease: alcohol-related fatty liver disease, nonalcoholic fatty liver disease, and viral hepatitis. These pathways have distinct causes but share features of disease progression. Other less common pathways in liver disease are immune system abnormalities, genetic conditions, and cancer or other growths. The Panel heard from one member of the public at the September 26 hearing.

Arguments for adding:

- Lack of other treatments.
- Severity of the disease, combined with lack of treatment options, causes hardships and diminishes quality of life.

Arguments against adding:

- There is limited documented evidence of potential benefit from medical cannabis.
- There is little evidence to suggest a biomechanistic reason that cannabis would be helpful in this setting.

Nausea

Nausea refers to a subjective, unpleasant feeling emerging from the stomach that individuals experience as an urge to vomit. Nausea may or may not be accompanied by vomiting (emesis). The panel heard from one testifier at the hearing on October 10, 2017.

Arguments for adding:

- There is ample evidence that cannabis is effective as a treatment for nausea. Cancer patients already qualify for medical cannabis to treat nausea; synthetic THC (Dronabinol) is approved by FDA to treat nausea.
- As we learn more about the endocannabinoid system, we are gaining a clearer bio-mechanistic explanation of how medical cannabis be effective to treat nausea.

Arguments against adding:

- As petitioned, it is a very broad diagnosis, without specific criteria; this vagueness could result in misuse or abuse. It would be more acceptable to the Panel if it was limited to “intractable nausea.”

- There are instances where medical cannabis is contra-indicated, such as cyclic hyperemesis syndrome (severe nausea and vomiting resulting from chronic cannabis use) or hyperemesis gravidarum (severe nausea and vomiting in pregnancy).

Obstructive Sleep Apnea

Obstructive sleep apnea is a sleep disorder characterized by repetitive episodes of complete or partial collapse of the upper airway during sleep, with a consequent cessation/reduction of the airflow. The obstructive events cause a progressive asphyxia, typically until the person is awakened. The Panel heard from two testifiers in support of adding obstructive sleep apnea as a qualifying condition at the September 26 hearing.

Arguments for adding:

- Obstructive sleep apnea leads to many downstream medical problems and costs.

- There is some scientific evidence of effectiveness; research indicating a bio-mechanistic explanation for how medical cannabis could be effective through increasing muscle tone of soft tissues and keeping airways open.

Arguments against adding:

- Small sample sizes of studies

- C-PAP can be effective, but is poorly tolerated by many.

Parkinson's Disease

Parkinson's disease is among the most common neurodegenerative conditions. It is a chronic, progressive disorder that involves malfunction and death of nerve cells in the brain. Each person with Parkinson's disease will experience symptoms differently. The disease progresses quickly in some people and not in others. Most people with Parkinson's disease also experience non-motor symptoms. The Panel heard from one testifier in support of adding Parkinson's disease as a qualifying condition at the October 10, 2017 hearing.

Arguments for adding:

- Current symptomatic treatments are only partially effective for many patients and often have very troublesome side effects. Medical cannabis could be one more option for symptom control.

- Parkinson's disease is a debilitating condition. Why not allow medical cannabis use if it could improve quality of life and present few side effects?

Arguments against adding:

- There are limited data supporting bio-mechanistic explanations why medical cannabis should work for neurocognitive disorders. More research and studies would be helpful.

- A clinical study focusing on tremor in Parkinson's started recruiting in July 2016. There are no data from it yet, but MDH should keep watch.

- A Colorado study mentioned in Research Brief suggests medical cannabis helps only a small number of patients with movement disorder symptoms (though is more helpful for sleep and quality of life).

Peripheral Neuropathy

Peripheral neuropathies are common neurological disorders resulting from damage to the peripheral nervous system – the nerves that communicate information to and from the central nervous system (brain and spinal cord). No one from the public testified at the public hearing on October 10, 2017.

Arguments for adding:

- Current treatments are often ineffective or only partially effective and they have negative side effects.

- Medical cannabis would be likely to have fewer significant side effects than current medications.

- Medical cannabis can be effective for pain, as evidenced by pain improvements seen in patients who enrolled in the program during the first year.

Arguments against adding:

- Significant, on-going pain symptoms are already covered under Intractable Pain.

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