

# Final Decision Regarding Advisory Board Report and Recommendations from Meeting of November 3, 2017

#### I. Decision:

I have reviewed the recommendations of the Medical Cannabis Advisory Board contained in their report, which was based on the Advisory Board's findings at a public hearing held on November 3, 2017.

Having reviewed the Advisory Board's recommendations and the materials submitted, and in consideration of the purpose of the Lynn and Erin Compassionate Use Act to provide relief from pain and suffering associated with debilitating medical conditions, I am taking the following actions with regard to the petition and the recommendations submitted to the Department of Health ("Department").

#### A. Recommendation Regarding Opiate Use Disorder

The Medical Cannabis Advisory Board considered a petition to add Opiate Dependence to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program (Program). The Advisory Board recommended, by a vote of 5-1, that Opiate Use Disorder as defined in the DSM-V be recommended for inclusion in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am declining to adopt the Advisory Board's recommendation to add Opiate Use Disorder to the list of qualifying conditions. There have been various anecdotal reports of individuals who use cannabis experiencing a reduction in opiate usage, including individuals self-reporting to their doctor, as well as surveys and questionnaires of cannabis users. However, there is still very little medical literature that addresses the effect of cannabis usage on persons with Opiate Use Disorder. The Petition in this case includes abstracts from various medical journals, as well as from other articles discussing medical studies, and cites to various articles concerning the effect of cannabinoids on chronic pain. Chronic pain is currently an approved condition for enrollment in the Medical Cannabis Program. However, the fact that cannabis is approved for chronic pain does not demonstrate that cannabis is an effective treatment for Opiate Use Disorder or its symptoms.

The petition cites to articles that report that states with medical cannabis programs have been shown to have lower rates of opiate overdose. This finding identifies a correlation, but does not demonstrate causation. It is not established that the use of cannabis by persons who used opioids resulted in a decrease of opiate overdoses in those states, and other circumstances may be impacting this outcome. For example, states with medical cannabis programs may also have greater drug treatment resources to treat opiate addiction, or more aggressive outreach programs to combat opiate addiction. Other factors may also impact the rate of opiate overdose in a given area.

There has been very little human-based research conducted on the effect of cannabis usage on persons with opioid dependence or Opiate Use Disorder. Some animal-based studies have been conducted that indicate that cannabinoids may be useful in attenuating the reward effect of opioids and modulating opioid cravings. Those studies are by no means conclusive, and other studies have indicated that cannabis may be detrimental for persons who consume opiates. An article recently published in the American Journal of Psychiatry reported that cannabis use appears to increase rather than decrease the risk of developing nonmedical prescription opioid use and opioid use disorder. Olfson M. et al., *Cannabis Use and Risk of Prescription Opioid Use Disorder in the United States*, Am J Psychiatry 2018, Jan 1; 175 (1) 47-53. The authors observed that cannabis use appears to "substantially increase the risk of nonmedical opioid use", and that it was associated with "a substantially increased risk of nonmedical prescription opioid use at 3-year follow-up." Other data have indicated that there is an association between cannabis use and opioid misuse. Reisfield GM et al., *The Prevalence and Significance of Cannabis Use in Patients Prescribed Chronic Opioid Therapy: a Review of Extant Literature*, Pain Med 2009 Nov; 10(8): 1434-41.

In 2017, the National Academies of Sciences (NAS) conducted a comprehensive review of human-based studies regarding the health effects of marijuana. The NAS report cited a study (Whiteside, L. K. et al., Predictors of sustained prescription opioid use after admission for trauma in adolescents, Journal of Adolescent Health 2016, 58(1): 92–97) of 120 adolescents aged 12 to 18 years who were seen in a trauma center or an emergency department for injury, which found that preinjury cannabis use was an independent predictor of continued prescription opioid use up to 12 months after discharge. The report noted that the NAS committee did not identify a good-or fair-quality systematic review that reported on the association between cannabis use and the rates and use patterns of opioids.

Opiate abuse and dependence are serious issues in the United States, and they are of great concern in the state of New Mexico. While I share the Advisory Board's concern about opioid use and its costs, I cannot say with any degree of confidence that the use of cannabis for treatment of opioid dependence and its symptoms would be either safe or effective, and I therefore decline to adopt the Advisory Board's recommendation regarding Opiate Use Disorder.

#### B. Recommendation Regarding Substance Use Disorder

The Medical Cannabis Advisory Board reviewed a petition to add Substance Use Disorder to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 4-1, that Substance Use Disorder be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am declining to adopt the Advisory Board's recommendation to add Substance Use Disorder to the list of qualifying conditions. My concerns with this petition are essentially the same as those raised with respect to the petition to add Opiate Use Disorder. The literature regarding the use of medical cannabis to treat substance use disorders is generally poor in quality. As noted, studies have shown an association between cannabis usage and increased risk of opioid use. They have also indicated an association between cannabis usage and the misuse of other substances. For example, one recent report found that cannabis usage by persons undergoing treatment for alcohol use disorder was associated with reduced alcohol abstinence at the end of

treatment. Subbraman MS et al., Cannabis Use During Treatment for Alcohol Use Disorders Predicts Alcohol Treatment Outcomes, Addiction 2017 April; 112(4): 685-694.

In its 2017 report, the National Academy of Sciences concluded that its review committee "did not identify any good-quality primary literature that reported on medical cannabis as an effective treatment for the reduction in use of addictive substances", and that "[t]here is no evidence to support or refute the conclusion that cannabinoids are an effective treatment for achieving abstinence in the use of addictive substances." The report stated that the NAS committee "did not identify a good- or fair-quality systematic review that reported on the association between cannabis use and the rates and use patterns of substances other than cannabis." However, it noted that available literature indicated that "cannabis users were found to be at a higher risk than nonusers for heavy drinking"; that "cannabis use predicted continued opioid prescriptions 1 year after injury"; and that "cannabis use was associated with reduced odds of achieving abstinence from alcohol, cocaine, or polysubstance use after inpatient hospitalization and treatment for substance use disorders." The report further stated that "[t]here is moderate evidence of a statistical association between cannabis use and the development of substance dependence and/or a substance abuse disorder for substances including, alcohol, tobacco, and other illicit drugs", concluding that "[a]dditional studies are needed to determine whether cannabis use is an independent risk factor for, or causally contributes to, the initiation or use of and dependence on other drugs of abuse later in life."

For these reasons, I cannot say that the use of cannabis is safe or effective in addressing substance use disorders, and I am declining to add Substance Use Disorder to the list of qualifying conditions in the Program.

### C. Recommendation Regarding Eczema and Psoriasis

The Medical Cannabis Advisory Board considered a petition to add Eczema and Psoriasis to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 4-1, that these conditions be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am declining to adopt the Advisory Board's recommendation to add Eczema and Psoriasis to the list of qualifying conditions. While some articles have identified potential mechanisms for cannabis to have a beneficial effect on both conditions, there is very little good quality research on the subject. Of the articles cited, it appears that at most, cannabis is identified as having a potential role in treating the conditions, and that this is worthy of further research. They do not conclude that cannabis has in fact been found to benefit persons with these conditions. Accordingly, I am declining to add either Eczema or Psoriasis to the list of qualifying conditions in the Medical Cannabis Program.

#### D. Recommendation Regarding Muscular Dystrophy

The Medical Cannabis Advisory Board considered a petition to add Muscular Dystrophy to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis

Program. The Advisory Board recommended, by a vote of 3-2, that Muscular Dystrophy be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am declining to adopt the Advisory Board's recommendation to add Muscular Dystrophy to the list of qualifying conditions. There is not much data regarding the effect of cannabis on persons with Muscular Dystrophy, and indeed, the petition primarily focuses on studies that concern the effect of cannabis on pain, rather than Muscular Dystrophy itself. Muscular Dystrophy is a condition that causes muscle contractions that result in significant pain. Although there is very little literature regarding the effect of cannabis use on persons with Muscular Dystrophy, I find that persons with Muscular Dystrophy who experience pain from their condition can qualify under severe chronic pain, which is a qualifying medical condition in the Program. For these reasons, I am declining to add Muscular Dystrophy to the list of qualifying conditions.

### E. Recommendation Regarding Polymyalgia Rheumatica

The Medical Cannabis Advisory Board considered a petition to add Polymyalgia Rheumatica to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 5-0 that Polymyalgia Rheumatica not be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am adopting the Advisory Board's recommendation to not include Polymyalgia Rheumatica in the list of qualifying conditions. Polymyalgia Rheumatica is an inflammatory disorder that causes muscle pain. For this reason, I concur with the Advisory Board that this condition is adequately covered by severe chronic pain and inflammatory autoimmune-mediated arthritis, both of which are qualifying conditions in the Program.

#### F. Recommendation Regarding Seizures

The Medical Cannabis Advisory Board, by a vote of 5-0, recommended that the Department clarify on the patient application that Seizure Disorder is included with Epilepsy. The Program has modified the application form to identify "Epilepsy/Seizure Disorder" as one of the qualifying conditions.

### G. Recommendation Regarding Dysmenorrhea

The Medical Cannabis Advisory Board considered a petition to add Dysmenorrhea to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 5-0, that Dysmenorrhea not be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program. I am adopting the recommendation of the Advisory Board to not approve Dysmenorrhea for inclusion on the list of qualifying conditions. I agree that Dysmenorrhea is adequately addressed by the qualifying condition severe chronic pain.

## H. Recommendation Regarding Sleep Disorders

The Medical Cannabis Advisory Board considered a petition to add "Sleep Disorders" to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 4-0, that Sleep Disorders be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am denying in-part and adopting in-part the Advisory Board's recommendation. Specifically, I am declining to add "Sleep Disorders" to the list of qualifying conditions in the Medical Cannabis Program, but I am approving Obstructive Sleep Apnea to be included as a qualifying condition.

Sleep disorders can be classified into groups that include insomnia, sleep-related breathing disorders, parasomnias, sleep-related movement disorders, and circadian rhythm sleep-wake disorders. While there is not good quality evidence to indicate that cannabis usage is safe and effective for treatment of all of these categories of sleep disorders, there have been good quality studies regarding Obstructive Sleep Apnea. One high-quality systematic review found moderate evidence indicating that cannabinoids improve short-term sleep outcomes in patients with sleep disturbance resulting from Obstructive Sleep Apnea. Whiting, P. F. et al., *Cannabinoids for medical use: A systematic review and meta-analysis*, JAMA 2015; 313(24):2456–2473. In its 2017 report, the National Academy of Sciences found that there is moderate evidence that cannabis or cannabinoids are effective for improving short-term sleep outcomes in individuals with sleep disturbance associated with Obstructive Sleep Apnea syndrome. For the reasons stated, I am approving Obstructive Sleep Apnea as a qualifying condition in the Program.

# I. Recommendation Regarding Cystic Fibrosis

The Medical Cannabis Advisory Board considered a petition to add Cystic Fibrosis to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 5-0, that Cystic Fibrosis not be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am adopting the recommendation of the Advisory Board. I concur that Cystic Fibrosis is sufficiently covered under severe chronic pain and intractable nausea/vomiting, both of which are currently qualifying conditions in the Program.

### J. Recommendation Regarding Tourette's Syndrome

The Medical Cannabis Advisory Board considered a petition to add Tourette's Syndrome to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 5-0, that Tourette's Syndrome be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am declining to adopt the recommendation of the Advisory Board to add Tourette's Syndrome to the list of qualifying conditions. There have been systematic reviews concerning the effects of cannabinoids (primarily THC) on Tourette's syndrome that indicate low quality evidence to support the use of those substances to treat Tourette's Syndrome. In terms of actual studies, it appears that there have been only a few small studies regarding the impact of THC on persons with

Tourette's Syndrome, which suggested that consumption of THC could reduce vocal tics. However, methodological problems with those studies have been identified in some of the reviews. There have been no controlled studies on the effectiveness of medical cannabis itself in alleviating symptoms of Tourette's syndrome. There are anecdotal reports that cannabis use may be of benefit. The evidence supporting the use of cannabis to address symptoms of Tourette's syndrome generally appears to be of low quality. This is reflected, for example, in the finding of the National Academy of Sciences in its 2017 report, in which it concluded that there is only "limited evidence that THC capsules are an effective treatment for improving symptoms of Tourette syndrome." For the reasons stated, I am declining to add Tourette's Syndrome to the list of qualifying conditions.

## K. Recommendation Regarding Post-Concussion Syndrome and TBI

The Medical Cannabis Advisory Board considered a petition to add "Post-Concussion Syndrome" and Traumatic Brain Injury (TBI) to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 5-0, that these conditions not be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am adopting the recommendation of the Advisory Board to not approve Post-Concussion Syndrome and TBI for inclusion in the list of qualifying conditions. I agree that the research regarding acute brain trauma is not substantial, and that the Medical Cannabis Program, with its associated timelines for obtaining certification and applying for enrollment, is an ill fit for addressing acute injuries of this kind.

## L. Recommendation Regarding Diabetes Mellitus

The Medical Cannabis Advisory Board considered a petition to add Diabetes Mellitus to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 4-0, that Diabetes Mellitus not be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am adopting the recommendation of the Advisory Board to not add Diabetes Mellitus to the list of qualifying conditions. To the extent that the inclusion of Diabetes Mellitus is sought to address peripheral neuropathic pain that results from the condition, I find that the currently qualifying condition severe chronic pain sufficiently addresses this condition. The petition emphasizes certain findings that persons who used cannabis had a lower incidence of the disease, and that they possessed a lower body mass index. These findings identify a correlation between cannabis usage and lower risk of Diabetes, but do not identify a causative effect. There have been some animal studies that indicated that consumption of cannabis (and particularly, cannabidiol) could potentially decrease susceptibility to developing Diabetes, but these studies are not conclusive. Of the few human-based studies that have been conducted, it appears that none have identified a causal connection between consumption of cannabis and decreased susceptibility to Diabetes. Further, certain preclinical animal studies have identified a correlation between smoking cannabis and hyperphagia, obesity, and insulin resistance. Silvestri C, Di Marzo V., *The endocannabinoid system in energy homeostasis and the etiopathology of metabolic disorders*, Cell Metab. 2013;17(4):475–90; Osei-Hyiaman D et al., *Endocannabinoid activation at hepatic CB1* 

receptors stimulates fatty acid synthesis and contributes to diet-induced obesity, J Clin Invest. 2005;115(5):1298–305. In its 2017 report, the National Academy of Sciences concluded that there was only "limited evidence" demonstrating a statistical association between cannabis use and decreased risk or increased risk of diabetes.

For the reasons stated, I find that the medical literature is not adequate to conclude that the use of cannabis would be beneficial in treating Diabetes or the effects of Diabetes, apart from chronic pain, which (as noted) is already a qualifying condition in the Program. Accordingly, I decline to add Diabetes Mellitus to the list of qualifying conditions in the Program.

## M. Recommendation Regarding "All Forms of Arthritis"

The Medical Cannabis Advisory Board considered a petition to add "All Forms of Arthritis" to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 4-0, that this condition not be included in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

I am adopting the recommendation of the Advisory Board to not add "All Forms of Arthritis" to the list of qualifying conditions. I agree that Arthritis is already addressed by the qualifying conditions severe chronic pain and Inflammatory Immune-Mediated Arthritis.

## II. Closing

In closing, I would like to thank the individuals who submitted petitions for consideration. I would also once again like to thank the Advisory Board for its work and support of this program, which has provided relief to thousands of people suffering from debilitating medical conditions.

Lynn Gallagher Cabinet Secretary

Date