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January 23, 2019

Re: REVISED Final Agency Decision: Petitions to Establish Additional Debilitating Medical Conditions under the New Jersey Medicinal Marijuana Program

Dear Petitioners:

On March 22, 2018, I issued a final agency decision in the matter of the Department of Health's (Department) Request for Petitions to establish additional deliberating medical conditions under the New Jersey Medicinal Marijuana Program (MMP). In this final decision, I added chronic pain related to a musculoskeletal disorder as a debilitating medical condition to the MMP. Included in this chronic pain category was opioid use disorder, for which the Department received a petition, because the withdrawal symptoms for this disorder can cause severe and agonizing pain and research evidences that the use of medical marijuana was not only an effective alternative treatment to the opioids that are commonly used to treat this disorder but also reduces the likelihood of a patient developing opioid use disorder. As explained in detail below, after further review of this petition against the opioid crisis that is plaguing our State and research suggesting that the use of medical marijuana in conjunction with medication-assisted therapy to treat this disorder may aid in the reduction of relapses and assist with the prevention of opioid overdose deaths, I am issuing this revised final decision to include opioid use disorder as a standalone deliberating medical condition under the MMP. With this decision, opioid use disorder patients are eligible for medical marijuana if they suffer from chronic, painful withdrawal symptoms or as an adjunct treatment to their current medication-assisted treatment regimen. Accordingly, this Revised Final Agency Decision replaces my March 22nd final agency decision.

This letter sets forth the basis, rationale and final decision in the matter of the Department of Health's (Department) Request for Petitions to establish additional deliberating medical conditions under the New Jersey Medicinal Marijuana Program (MMP). As explained in detail below, I am granting the petitions seeking to add chronic pain conditions that are related to musculoskeletal disorders, chronic pain conditions that are of a visceral origin, as well as Tourette's Syndrome, migraine, and anxiety as debilitating medical conditions under the MMP. Additionally, I am granting the petition seeking to add opioid use disorder to the MMP, with the condition that medical marijuana be prescribed in conjunction with medication-assisted therapy for the treatment of the disorder. However, I am denying the petitions seeking to add asthma and chronic fatigue syndrome to the MMP.

In reaching this decision, I considered the Request for Petitions, the petitions submitted in response to the Request, the MMP panel's recommendations, written and oral public comments

received regarding various petitions, as well as the requirements of the New Jersey Compassionate Use Medical Marijuana Act (the Act), N.J.S.A. 24:6I-1 et seq., and the regulations promulgated thereunder. The referenced materials are incorporated herein and made a part of this final decision.

The Request for Petitions

On July 5, 2016, the Department published the Request for Petitions in the New Jersey Register advising that from August 1, 2016 to August 31, 2016, it was accepting petitions to establish additional medical conditions as “debilitating” under the MMP. 48 N.J.R. 1395(a). The Request for Petitions stated that the Department was seeking petitions in accordance with the Act, which authorizes the Department to include additional debilitating medical conditions under the MMP.

In the Request for Petitions, the public was advised that submitted petitions were required to include the following information, pursuant to N.J.A.C. 8:64-5.3:

- (1) The extent to which the condition is generally accepted by the medical community and other experts as a valid, existing medical condition;
- (2) If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;
- (3) The extent to which the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting, or otherwise severely impair the patient's ability to carry on activities of daily living;
- (4) The availability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition and/or the treatment thereof;
- (5) The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof; and
- (6) Letters of support from physicians or other licensed health care professional knowledgeable about the condition.

The Department also crafted a Petition Form that petitioners could use for their submissions. The form detailed the above-listed criteria, which each petitioner needed to provide in order for his or her submission to be accepted and considered.

In addition to publishing the request for petitions in the New Jersey Register, the Department also posted it on its website.

Completeness Review

At the close of the petition submission period, the Department received sixty-eight petitions. Thereafter, the Department reviewed each petition to determine whether it contained the information that was required for it to be accepted for consideration. From its review, the

Department determined that twenty-three petitions did not meet the criteria for consideration.¹ Accordingly, the Department denied these petitions under separate cover on December 7, 2016, pursuant to N.J.A.C. 8:64-5.3(b). The remaining forty-five petitions met the criteria for consideration and were accepted.

Statutory and Regulatory Criteria

The Act charges the Department with the responsibility of administering the State's MMP, including establishing a registry of qualifying patients and primary care givers. To qualify as a MMP patient, an individual must suffer from one of the debilitating medical conditions set forth in the Act. The Act defines a "debilitating medical condition" as:

- (1) one of the following conditions, if resistant to conventional medical therapy: seizure disorder, including epilepsy; intractable skeletal muscular spasticity; post-traumatic stress disorder; or glaucoma;
- (2) one of the following conditions, if severe or chronic pain, severe nausea or vomiting, cachexia, or wasting syndrome results from the condition or treatment thereof: positive status for human immunodeficiency virus; acquired immune deficiency syndrome; or cancer;
- (3) amyotrophic lateral sclerosis, multiple sclerosis, terminal cancer, muscular dystrophy, or inflammatory bowel disease, including Crohn's disease; [or]
- (4) terminal illness, if the physician has determined a prognosis of less than 12 months of life.

[N.J.S.A. 24:6I-3.]

In addition to the conditions listed in the Act, the Legislature authorized the Department to establish additional medical conditions as debilitating under the MMP. Ibid. Consistent with its statutory authority, the Department promulgated rules that outline the process for expanding the list of medical conditions that qualify as "debilitating" under the MMP. See N.J.A.C. 8:64-1.1 et seq. Pursuant to these rules, I am required to take into consideration the following factors in order to determine whether a condition should be added to the MMP as a "debilitating" medical condition that is likely to benefit from the use of medical marijuana to treat or alleviate the debilitating effect of the condition:

- (1) The extent to which the condition is generally accepted by the medical community and other experts as a valid, existing medical condition;
- (2) If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;
- (3) The extent to which the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or

¹ Legislation was enacted during the pendency of the petitions, which added post-traumatic stress disorder to the list of conditions that qualify as debilitating under the MMP. As a result, the petitions seeking to add this condition to the MMP were deemed moot and not forwarded to the Panel for consideration.

vomiting or otherwise severely impair the patient's ability to carry on activities of daily living;

(4) The availability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition and/or the treatment thereof;

(5) The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof; and

(6) Letters of support from physicians or other licensed health care professionals knowledgeable about the condition.

[N.J.A.C. 8:64-5.3]

The MMP Review Panel Meetings, Public Comments and Panel Recommendations

On May 11, 2017, the MMP Review Panel, which is a panel assembled by the Department to review and make recommendations on petitions seeking to add conditions to the MMP, met to review and hear public comments on the forty-five accepted petitions. At the meeting, the Panel acknowledged that they reviewed the material submitted with the petitions and that they also conducted their own independent analysis and research for each condition. During the meeting, the Panel also advised that it grouped the petitioned conditions into seven categories, namely chronic pain related to musculoskeletal disorders, chronic pain of a visceral origin, Tourette's Syndrome, migraine, anxiety, asthma and chronic fatigue. After offering a panel discussion on each condition and hearing public comments from two individuals, both of whom expressed support for the MMP, the Panel voted on each petition. Based upon a majority vote of the members who were present at the meeting, the Panel recommended that chronic pain related to musculoskeletal disorders, chronic pain of a visceral origin, Tourette's Syndrome, migraine, and anxiety be approved as debilitating conditions under the MMP and recommended denial of asthma and chronic fatigue.

After the meeting, the Chairman of the Panel reduced the Panel's initial recommendations to writing and submitted it to me for consideration. In the initial recommendation letter, the Panel advised that it was recommending that I add chronic pain related to musculoskeletal disorders, chronic pain of a visceral origin, Tourette's Syndrome, migraine, and anxiety to the MMP because these conditions are debilitating, and medicinal marijuana was more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with each condition.

As for asthma and chronic fatigue, the Panel recommended that these conditions not be added to the MMP because medical marijuana was not likely to have the potential to be beneficial to treat or alleviate the debilitation associated with the conditions.

After receiving the Panel's initial recommendation letter, it was posted on the Department's website for a 60-day public comment period to provide the public with an opportunity to submit written comments on the recommendations. At the time the comment period closed, the Department received approximately sixty comments, which were generally supportive of the MMP.

During the 60-day comment period, the Department's MMP Review Panel also convened a public hearing on September 18, 2017, which provided the public with an additional opportunity to comment on the recommendations. During this public hearing, the Panel heard from seven individuals. The comments provided by the commenters did not express any disagreement with the Panel's recommendations.

Upon the conclusion of the public comment period, the Panel reconvened for a final meeting on the petitions. At the meeting, which was held on October 26, 2017, the Panel further deliberated its recommendations on the petitioned conditions, taking into consideration the petitions, information submitted with the petitions, public comments, the factors outlined in N.J.A.C. 8:64-5.3, each member's own research or that done by others, as well as each member's education and training, in order to determine whether any changes should be made to the Panel's initial recommendations. In so deliberating, the Panel discussed each condition in turn and permitted additional public comment on the conditions. Based upon the Panel's extensive and thorough discussions, the majority of the Panel members present at the meeting voted to uphold their initial recommendations on the conditions. As such, the Panel's initial recommendations converted to the Panel's final recommendations to the Commissioner, pursuant to N.J.A.C. 8:64-5.3(f).

Findings and Decisions on the Petitions

For the reasons that follow, I am granting the petitions seeking to add chronic pain that is related to musculoskeletal disorders, chronic pain conditions that are of a visceral origin, as well as Tourette's Syndrome, migraine, opioid use disorder and anxiety under the MMP and denying the petitions seeking to include asthma and chronic fatigue syndrome under the MMP. In reaching my decision, I considered the statutory and regulatory criteria articulated above, the Panel's recommendations and their supporting materials, the petitions with supporting information, public comments, emerging research on medical marijuana and the transcripts of the Panel's meetings, which provides the Panel members' detailed discussions on each condition.

Granted Petitions

Chronic Pain associated with a Musculoskeletal Disorder

Based upon my independent review of the petitions, I am granting those seeking to add chronic pain associated with a musculoskeletal disorder to the MMP.² In coming to this

² Thirty-five of the petitions received by the Department concern various forms of chronic pain. After reviewing these petitions, the Panel determined that they fell into two categories: chronic pain associated with a musculoskeletal disorder and chronic pain of a visceral origin. Based upon my review of this matter, I find that the Panel made the appropriate categorizations of these petitions. Thus, I agree with the Panel that the chronic pain conditions sought to be added to the MMP should be generally labeled as chronic pain associated with a musculoskeletal disorder and chronic pain of a visceral origin, rather than the unique, individual conditions set forth in each chronic pain petition. The list of petitions that fall into each category are set forth in the Panel's recommendation letter, which is incorporated herein by reference. The only exception I have to the bundling of these petitions into the two chronic pain categories is the petition seeking to add opioid use disorder to the MMP, which I find should be granted as both a standalone disorder and as a condition that falls under the category of chronic pain associated with a musculoskeletal disorder.

conclusion, I reviewed this condition against the six regulatory criteria cited above and found that it meets the requirements for inclusion in the MMP.

Regarding the first factor, which is whether the condition is generally accepted in the medical community as a valid medical condition, I find that chronic pain associated with a musculoskeletal disorder is a valid condition. According to the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention's National Center for Health Statistics (NCHS), chronic pain associated with a musculoskeletal disorder is pain that persists beyond the usual course of an acute condition, which is typically three months or more or past the time for normal healing, and includes injury and inflammatory conditions "that cause pain in the body's joints; ligaments; muscles; nerves; tendons; and structures that support the limbs, neck, and back."³ Moreover, as noted by the Panel, the World Health Organization's International Classification of Diseases, as clinically modified by the NCHS (ICD-10-CM), uses unique alphanumeric codes to identify known diseases and other health problems and lists multiple codes for chronic pain.⁴ Given the fact that chronic pain associated with a musculoskeletal disorder has a common medical definition and maintains several ICD-10-CM codes, which entities covered by the Health Insurance Portability and Accountability Act must use for processing claims pursuant to rules promulgated by the U.S. Department of Health and Human Services, I find that chronic pain associated with a musculoskeletal disorder is a valid condition recognized by the medical community. See 45 C.F.R. 162.

Under the second factor, I must consider whether the treatments for the condition, if the treatments are causing the patient suffering, are generally accepted by the medical community and other experts as valid treatments for the condition. As set forth in the petitions and acknowledged by the Panel, the generally accepted treatments for chronic pain associated with a musculoskeletal disorder are opioids and non-steroid anti-inflammatory drugs (NSAIDs), both of which can have significant side effects. I agree. According to the Centers for Disease Control and Prevention (CDC), NSAIDs, such as ibuprofen, are a common treatment for chronic pain associated with a musculoskeletal disorder.⁵ The CDC also recognizes opioids, such as oxycodone and hydrocodone, as a common and medically accepted treatment for chronic musculoskeletal pain.⁶ Thus, I find that the treatments for chronic pain, namely NSAIDs and opioids, are recognized and accepted by the medical community and relate to a patient's suffering.

As for the third factor, which is whether the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living, I find that chronic pain associated with a musculoskeletal disorder itself as well as the treatment for this condition cause severe suffering for patients inflicted with this condition. As the name suggests, a patient with chronic pain associated with a musculoskeletal disorder experiences just that - pain. Specifically, musculoskeletal chronic pain can cause widespread or localized pain that may worsen with movement, stiffness or achiness, fatigue, and/or muscle twitches.⁷ Thus, the condition itself is the main culprit for the suffering experienced by patients with this disorder. While

³See <https://www.cdc.gov/nchs/data/nhsr/nhsr098.pdf> (last visited March 13, 2018). See also <https://www.cdc.gov/drugoverdose/prescribing/guideline.html> (last visited March 13, 2018).

⁴ See ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2018/ (last visited March 13, 2018).

⁵ See https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf (last visited March 13, 2018).

⁶ See <https://www.cdc.gov/drugoverdose/opioids/index.html> (last visited March 13, 2018).

⁷ See <https://my.clevelandclinic.org/health/diseases/14526-musculoskeletal-pain> (last visited March 13, 2018).

chronic pain, in and of itself, causes extensive pain, the treatment for chronic pain associated with a musculoskeletal disorder can also cause significant suffering. Specifically, prolonged use of NSAIDs can cause gastritis, ulcerative disease, heartburn, nausea, vomiting and dizziness⁸. And, opioids can cause constipation, nausea, respiratory depression, dependency, opioid use disorder, sedation and dizziness.⁹ All of these side effects can prevent a patient from engaging in activities of daily living, thereby diminishing one's quality of life. Accordingly, I find that musculoskeletal chronic pain as well as the therapies to treat this condition cause severe suffering.

Under the fourth factor, I must evaluate the availability of conventional medical therapies, other than those that cause suffering, to alleviate the patient's suffering caused by the condition and/or the treatment thereof. Unfortunately, the treatments for chronic musculoskeletal pain that cause the patient suffering, namely NSAIDs and opioids, are essentially the most viable conventional medical therapies offered for this condition, which was noted by the Panel. As such, I find that there is an absence of effective alternative medical therapies to the conventional therapies currently prescribed for chronic musculoskeletal pain that cause patients to suffer.

Regarding the fifth factor, which is whether there is generally accepted evidence in the medical community that the use of marijuana alleviates suffering relating to the condition, I agree with the Panel's conclusion that there is extensive research establishing that the use of medical cannabis can relieve the chronic pain associated with a musculoskeletal disorder. Specifically, there are several peer-reviewed publications in leading medical journals, including a review published by the National Academies of Sciences, Engineering, and Medicine in 2017, as well as a significant number of clinical trials, which found that the use of medical marijuana was effective in relieving chronic pain.¹⁰ As such, I find that there is general acceptance in the medical community that medicinal cannabis can alleviate the suffering caused by chronic musculoskeletal pain.

As for the final factor, which is whether there were letters from physicians or other licensed health care professionals knowledgeable about the condition supporting the inclusion of chronic musculoskeletal pain under the MMP, I find that the petitions were submitted with support from medical professionals.

Based upon the above analysis, I find that the condition of chronic pain related to a musculoskeletal disorder is "debilitating" and that medical marijuana is more likely than not to be potentially beneficial to treat or alleviate the debilitating effect of this condition. As such, I find that chronic pain related to a musculoskeletal disorder should be added to the MMP.

Chronic Pain Conditions of a Visceral Origin

From my detailed review of the petitions, I am granting those seeking to add chronic pain conditions of a visceral origin to the MMP. In coming to this conclusion, I reviewed the petitions

⁸ See <https://my.clevelandclinic.org/health/drugs/11086-non-steroidal-anti-inflammatory-medicines-nsaids> (last visited March 13, 2018).

⁹ See Footnote 6.

¹⁰ See, e.g., The Health Effects of Cannabis and Cannabinoids: the Current State of Evidence and Recommendations for Research, National Academies Press (2017) (<http://nationalacademies.org/hmd/Reports/2017/health-effects-of-cannabis-and-cannabinoids.aspx>) (last visited March 13, 2018); Cannabinoids for treatment of chronic non-cancer pain; a systematic review of randomized trials, British Journal of Clinical Pharmacology (2001) (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243008/>) (last visited March 13, 2018).

against the six regulatory criteria cited above and found that the condition meets the requirements for inclusion in the MMP.

For the first factor, which is whether the condition is generally accepted in the medical community as a valid medical condition, I find that chronic pain of a visceral origin is a valid condition. Chronic pain of a visceral origin is commonly defined by the medical community as pain that arises from the internal organs of the body and persists beyond the usual course of an acute condition, which is typically three months or more or past the time for normal healing.¹¹ Specifically, visceral pain is pain that results from the activation of nociceptors located in most viscera (internal organs of the body, specifically those within the chest (as the heart or lungs) or abdomen (as the liver, pancreas or intestines)) and the surrounding connective tissue.¹² Moreover, as noted by the Panel, there are multiple ICD-10-CM codes for chronic pain of a visceral origin, such as codes for pancreatitis, pain related to neurogenic bladder and bowel dysfunction, and irritable bowel syndrome. Because there is a common medical definition for chronic visceral pain as well as many ICD-10-CM codes for this condition, I find that chronic pain of a visceral origin is a valid and recognized medical condition.

As for the second factor, I must consider whether the treatments for the condition, if the treatments are causing the patient suffering, are generally accepted by the medical community and other experts as valid treatments for the condition. Like chronic musculoskeletal pain, chronic pain of a visceral origin is generally treated with opioids and NSAIDs, which, as I stated above, can have severe side effects. Indeed, the CDC advises that NSAIDs and opioids are the most common forms of treatment for chronic pain.¹³ Thus, I find that the treatments for chronic pain, namely NSAIDs and opioids, are recognized and accepted by the medical community as the treatments for chronic visceral pain and relate to a patient's suffering.

Regarding the third factor, which is whether the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living, I find that both the chronic pain condition itself as well as the treatments for this condition cause severe suffering for patients stuck with this disorder. Specifically, visceral pain due to an obstruction of a hollow organ is poorly localized, deep, and cramping and may be referred to remote cutaneous sites.¹⁴ Visceral pain that is caused by an injury of organ capsules or other deep connective tissues may be more localized and sharp.¹⁵ As such, the actual condition is the main cause for the suffering experienced by patients with this disorder. Although chronic pain itself causes severe pain, the treatment for this condition can also result in significant suffering. As I outlined above, prolonged use of NSAIDs can cause gastritis, ulcerative disease, heartburn, nausea, vomiting and dizziness. And, opioids can cause constipation, nausea, respiratory depression, dependency, opioid use disorder, sedation and dizziness. So, the condition itself as well as the side effects from the medications used to treat this condition can prevent a patient from engaging

¹¹ See <https://medical-dictionary.thefreedictionary.com/visceral+pain> (last visited March 13, 2018).

¹² See <https://www.merckmanuals.com/professional/neurologic-disorders/pain/overview-of-pain> (last visited March 13, 2018).

¹³ See footnotes 5 and 6.

¹⁴ See footnote 12.

¹⁵ *Ibid.*

in activities of daily living and eviscerate one's quality of life. Accordingly, I find that both the condition of chronic pain as well as the therapies to treat it cause severe suffering.

Under the fourth factor, I must evaluate the availability of conventional medical therapies, other than those that cause suffering, to alleviate the patient's suffering caused by the condition and/or the treatment thereof. Unfortunately, the treatments for chronic pain that cause the patient suffering, which are NSAIDs and opioids, are the only viable conventional medical therapies offered for this condition.¹⁶ Therefore, I find that there is a lack of medically-accepted, alternative medical treatments to the conventional therapies currently recommended for chronic pain of this nature.

As for the fifth factor, which is whether there is generally accepted evidence in the medical community that the use of marijuana alleviates suffering relating to the condition, the Panel concluded that there is comprehensive research demonstrating that the use of medicinal cannabis can alleviate the pain associated with chronic pain. As stated above, there are peer-reviewed publications in leading medical journals, including a review published by the National Academies of Sciences, Engineering, and Medicine in 2017, and a number of clinical trials that found that the use of medical marijuana was effective in relieving chronic pain. As such, I find that the medical community has generally accepted the use of medicinal marijuana as a likely effective treatment for alleviating the suffering caused by chronic pain.

As for the final factor, which is whether there were letters from physicians or other licensed health care professionals knowledgeable about the condition supporting the inclusion of chronic visceral pain under the MMP, I find that the petitions were submitted with support from medical professionals.

Based upon the above analysis, I find that the condition of chronic pain of a visceral origin is "debilitating" and that medical marijuana is more likely than not to be potentially beneficial to treat or alleviate the debilitating effect of this condition. As such, I find that chronic pain of a visceral origin should be added to the MMP.

Tourette's Syndrome

After a careful review of the petition seeking to add Tourette's Syndrome (TS) to the MMP, I have decided to grant this petition. In formulating this determination, I reviewed the condition against the six regulatory criteria cited above and found that it meets the requirements for inclusion in the MMP.

Under the first factor, I must determine whether the condition is generally accepted in the medical community as a valid medical condition. I find that TS meets this requirement. Specifically, TS is commonly defined by the medical community as a neurological disorder characterized by repeated involuntary movements (motor tics) and uncontrollable vocal sounds (vocal tics), with symptoms usually manifesting before the age of eighteen.¹⁷ Moreover, a CDC study found that "1 of every 360 (0.3%) children 6 – 17 years of age in the United States have been diagnosed with TS based on parent[al] report[s]," with boys being "three to five times more

¹⁶ Ibid.

¹⁷ See <http://www.merckmanuals.com/professional/pediatrics/neurologic-disorders-in-children/tic-disorders-and-tourette-syndrome-in-children-and-adolescents> (last visited March 13, 2018).

likely to have TS than girls.”¹⁸ Accordingly, I find that TS is a valid and recognized medical condition.

Regarding the second factor, I must consider whether the treatments for the condition, rather than the condition itself, are causing the patient's suffering and the extent to which the treatments causing the patient suffering are generally accepted by the medical community and other experts as valid treatments for the condition. According to the petition and as acknowledged by the Panel, the generally accepted treatments for TS are medication and behavioral treatments, which can help manage the tics.¹⁹ As noted by the Panel, there is no one primary medication to treat TS and, as a result, there is a varying approach to how it is addressed.²⁰ Most medications prescribed for TS have not been approved by the U.S. Food and Drug Administration (FDA) for treating tics and the medications that are approved fall into the category of anti-psychotics, which can have serious adverse side effects that include weight gain, stiff muscles, tiredness, restlessness, and social withdrawal.²¹ As such, I find that the treatments for the symptoms of TS are recognized and accepted by the medical community as the treatments for this condition and relate to a patient's suffering.

As for the third factor, which is whether the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living, I find that both TS itself as well as co-occurring conditions and the treatments for this condition cause severe suffering for patients inflicted with this condition. While the tics caused by TS clearly impair a patient's ability to carry on his or her activities of daily living, the co-occurring conditions that arise with this disorder can be equally if not more devastating to the patient. According to the National Institute of Neurological Disorders and Stroke, many individuals with TS experience additional neurobehavioral problems that often cause more impairment than the tics themselves. These include inattention, hyperactivity and impulsivity (attention deficit hyperactivity disorder — ADHD), problems with reading, writing, and arithmetic, and obsessive-compulsive symptoms such as intrusive thoughts/worries and repetitive behaviors.²² Thus, TS itself along with its co-occurring conditions negatively impact a patient's quality of life. Additionally, as I noted above, the pharmacological treatments for TS can cause serious side effects that negatively impact an individual's quality of life. As recognized by the Panel, TS is difficult to treat and very debilitating.²³ I concur. As such, I find that both the condition of TS as well as the therapies to treat it cause severe suffering.

Under the fourth factor, I must analyze the availability of conventional medical therapies, other than those that cause suffering, to alleviate the patient's suffering caused by the condition and/or the treatment thereof. Unfortunately, the only FDA-approved therapies for TS are anti-psychotic medications. While these medications have an 80% rate of tic suppression, which was noted by the Panel, the medications have serious side effects that can include weight gain and social withdraw. And, although behavioral therapy is a treatment that teaches people with TS

¹⁸See <https://www.cdc.gov/ncbddd/tourette/data.html> (last visited March 13, 2018).

¹⁹ See <https://www.cdc.gov/ncbddd/tourette/treatments.html> (last visited March 13, 2018).

²⁰ In Re: Medicinal Marijuana Review Panel Transcript. 55: 4 -6. October 25, 2017.

²¹ See footnote 19.

²² <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Tourette-Syndrome-Fact-Sheet> (last visited March 13, 2018).

²³ In Re: Medicinal Marijuana Review Panel Transcript. 54:11. October 25, 2017.

ways to manage their tics, it is not a cure for tics. As such, the conventional therapies for TS, which are pharmaceutical and behavioral treatment, may not fully suppress or manage tics and the presence of TS may severely impair the patient's ability to carry on activities of daily living. Accordingly, I find that there is a lack of medically-accepted, alternative medical therapies to the conventional therapies currently prescribed for TS that cause suffering for some patients.

Regarding the fifth factor, which is whether there is generally accepted evidence in the medical community that the use of marijuana alleviates suffering relating to the condition, I agree with the Panel's conclusion that there is research establishing that the use of medical cannabis can relieve the symptoms associated with TS. Evidence on the use of cannabis for effective symptomatic treatment of movement disorders, including TS, dates to the late 1990s with the work of Dr. Kirsten Müller-Vahl of the Hannover Medical School in Hannover, Germany.²⁴ Dr. Müller-Vahl's studies demonstrated improvements in global functioning and tic severity scores with cannabis use. Specifically, Dr. Müller-Vahl conducted a clinical survey among sixty-four TS patients of whom seventeen had reportedly consumed cannabis and approximately 82% of these patients reported a reduction in symptoms.²⁵ Subsequent studies of single cases confirmed that administration of 10mg of tetrahydrocannabinol (THC), which is one of the active chemical compounds in cannabis, led to an 80% reduction in tics and a simultaneous increase in the attention of patients.²⁶ And, a randomized, placebo-controlled six-week trial of up to 10mg THC per day confirmed the previous findings.²⁷ Furthermore, case reports have suggested that cannabis can reduce tics and that the therapeutic effects of cannabis might be due to the anxiety-reducing properties of marijuana rather than to a specific anti-tic effect.²⁸ Moreover, several states, such as Minnesota and Illinois, have approved medical marijuana specifically for the treatment of TS. Even more, a recent systematic review and meta-analysis published in the Journal of the American Medical Association (JAMA) in 2015 suggests there is some evidence that cannabinoids may improve symptoms of TS.²⁹ While the 2015 JAMA review suggests that marijuana may only have a minimal effect on relieving the symptoms of TS, the fact that the study evidenced some relief, even with the limited number of clinical trials available on the medical benefits of marijuana due to the legal restrictions surrounding cannabis, shows promise that marijuana is effective for this condition. As such, I find that the totality of the above research exhibits a general consensus in the medical community that marijuana is likely to alleviate some of the suffering caused by TS.

As for the final factor, which is whether there were letters from physicians or other licensed health care professionals knowledgeable about the condition supporting the inclusion of TS under the MMP, I find that the petition was submitted with support from medical professionals.

Based upon the above analysis, I find that the condition of TS is "debilitating" and that medical marijuana is more likely than not to be potentially beneficial to treat or alleviate the

²⁴ Müller-Vahl, K R., et al. "Treatment of Tourette's syndrome with delta-9-tetrahydrocannabinol." *American Journal of Psychiatry* 156.3 (1999): 495-495 .

²⁵ See <http://researchfeatures.com/2017/06/01/cannabis-based-medication-tourettes-syndrome/> (last visited March 13, 2018).

²⁶ *Ibid.*

²⁷ *Ibid.*

²⁸ See <https://www.nap.edu/read/24625/chapter/6?term=tourette#104> (last visited March 13, 2018).

²⁹ See <https://media.jamanetwork.com/news-item/mixed-findings-regarding-quality-of-evidence-supporting-benefit-of-medical-marijuana/> (last visited March 13, 2018).

debilitating effect of this condition. As such, I find that Tourette's Syndrome should be added to the MMP.

Migraine

After a thorough review of the petitions, I am granting those seeking to add migraine to the MMP. In coming to this conclusion, I reviewed these petitions against the six regulatory criteria cited above and found that the condition meets the requirements for inclusion in the MMP.

Regarding the first factor, which is whether the condition is generally accepted in the medical community as a valid medical condition, I find that migraine meets this criterion. According to the Merck Manual, migraine is an episodic primary headache disorder.³⁰ Symptoms typically last four to seventy-two hours and may be severe.³¹ Pain is often unilateral, throbbing, worsen with exertion, and accompanied by symptoms such as nausea and sensitivity to light, sound, or odors. Auras occur in about 25% of patients, usually just before but sometimes after the headache.³² And, there are approximately 28 million individuals living with migraines in the United States.³³ As such, I find that migraine is a valid and recognized medical condition.

Under the second factor, I must consider whether the treatments for the condition, rather than the condition itself, are causing the patient's suffering and the extent to which the treatments causing the patient suffering are generally accepted by the medical community and other experts as valid treatments for the condition. As stated in the petitions and recognized by the Panel, the generally accepted treatments for migraines are NSAIDs, triptans, opioids and/or ergots (ergot alkaloids), all of which can have significant side effects.³⁴ Specifically, prolonged use of NSAIDs can cause gastritis, ulcerative disease, heartburn, nausea, vomiting and dizziness.³⁵ Side effects of triptans include nausea, dizziness, drowsiness and muscle weakness.³⁶ Furthermore, triptans should not be used by those who have a past history of, or risk factors, for heart disease, high blood pressure, high cholesterol, angina, peripheral vascular disease, impaired liver function, stroke or diabetes.³⁷ Ergots may worsen nausea and vomiting related to migraines, and it may also lead to medication-overuse headaches.³⁸ And, as outlined above, opioids have serious side effects including addiction and nausea.³⁹ Thus, I find that the treatments for migraine, namely NSAIDs, triptans, opioids and ergots, can cause a patient to suffer and are accepted by the medical community as the treatments for this condition.

³⁰ See <http://www.merckmanuals.com/professional/neurologic-disorders/headache/migraine> (last visited March 13, 2018).

³¹ *Ibid.*

³² *Ibid.*

³³ <https://www.hopkinsmedicine.org/otolaryngology/docs/Migraine%20patient%20handout.pdf> (last visited March 13, 2018).

³⁴ <https://www.hopkinsmedicine.org/otolaryngology/docs/Migraine%20patient%20handout.pdf> (last visited March 13, 2018). See also <https://www.mayoclinic.org/diseases-conditions/migraine-headache/diagnosis-treatment/drc-20360207> (last visited March 13, 2018).

³⁵ See <https://my.clevelandclinic.org/health/drugs/11086-non-steroidal-anti-inflammatory-medicines-nsaids> (last visited March 13, 2018).

³⁶ See <http://www.headaches.org/2007/10/25/triptans/> (last visited March 13, 2018).

³⁷ *Ibid.*

³⁸ See <https://www.drugs.com/mcd/migraine> (last visited March 13, 2018).

³⁹ See footnote 6.

As for the third factor, which is whether the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living, I find that both the migraine condition itself as well as the treatments for this condition cause severe suffering for patients. As stated above, the condition itself causes intense pain, nausea and sensitivity to light, sound, or odors. In fact, the pain and sensitivity may become so intense that the patient may have no other option than to rest in a dark, quiet room until the migraine passes.⁴⁰ Thus, the migraine condition causes severe suffering.

The same holds true for migraine treatments. The side effects caused by the treatments for migraines can be equally if not worse than the symptoms produced by this condition. Specifically, the treatments, which include opioids and triptans, can cause nausea, dizziness, and muscle weakness and may even cause rebound symptoms that are more intense than the original onset of the migraine.⁴¹ Thus, the migraine condition as well as side effects accompanying the treatment for this condition impair or even prevent a patient from engaging in activities of daily living, thereby diminishing one's quality of life. With this, I find not only that the migraine condition in and of itself causes a patient severe suffering but that the therapies to treat it also cause significant suffering.

Under the fourth factor, I must evaluate the availability of conventional medical therapies, other than those that cause suffering, to alleviate the patient's suffering caused by the condition and/or the treatment thereof. The treatments for migraine that cause the patient suffering, namely NSAIDs, triptans, opioids and ergots, are the conventional medical therapies offered for this condition. Furthermore, as noted by the Panel, the conventional therapies are ineffective for some patients, leaving them with a decreased ability to function and a decreased quality of life. Alternatives such as biofeedback, ice packs, acupuncture, aromatherapy, adequate sleep, smoking cessation, avoiding any food and environmental triggers are available and may alleviate migraine symptoms.⁴² However, these alternative treatments usually do not treat all of the symptoms associated with a migraine and do not necessarily alleviate the patient's suffering caused by the migraine. Therefore, patients that are not responsive to conventional or alternative therapies may suffer constant unrelenting pain, which produces mental and physical debilitation. As such, I find that there are serious limitations with the medically-accepted, alternative medical therapies and the conventional therapies currently prescribed for migraine.

Regarding the fifth factor, which is whether there is generally accepted evidence in the medical community that the use of marijuana alleviates suffering relating to the condition, I agree with the Panel's conclusion that there is extensive research establishing that the use of medical cannabis can relieve the pain associated with migraine. There are studies which found that the use of medical marijuana was effective in decreasing the frequency of migraine headaches and relieving migraine pain.⁴³ Most notably, a recent study recommended that prospective studies

⁴⁰ <https://www.hopkinsmedicine.org/otolaryngology/docs/Migraine%20patient%20handout.pdf> (last visited March 13, 2018).

⁴¹ *Ibid.*

⁴² *Ibid.* See also <https://migraine.com/complimentary-and-alternative-therapies/> (last visited March 13, 2018).

⁴³ Ethan B. Russo, Clinical Endocannabinoid Deficiency Reconsidered: Current Research Supports the Theory in Migraine, Fibromyalgia, Irritable Bowel, and Other Treatment-Resistant Syndromes, *Cannabis and Cannabinoid Research*, 20a6, 1,1, 154. See <https://www.liebertpub.com/doi/10.1089/can.2016.0009> (last visited March 13, 2018).

should be conducted to explore a cause-and-effect relationship and the use of different strains, formulations, and doses of marijuana to better understand the effects of medical marijuana on migraine headache treatment and prophylaxis.⁴⁴ A majority of the Panel agreed that a review of the literature suggests that marijuana might alleviate some of the symptoms caused by a migraine with less side effects than commonly accepted medical treatment. Based upon this research, I find that there is generally accepted evidence in the medical community that medicinal cannabis can alleviate the suffering caused by migraine.

As for the final factor, which is whether there were letters from physicians or other licensed health care professionals knowledgeable about the condition supporting the inclusion of migraine under the MMP, I find that the petitions were submitted with support from physicians and an advanced practice nurse. Indeed, one petition was submitted by a board certified anesthesiologist. Thus, I find that this requirement is met.

Based upon the above analysis, I find that the condition of migraine is “debilitating” and that medical marijuana is more likely than not to be potentially beneficial to treat or alleviate the debilitating effect of this condition. As such, I find that migraine should be added to the MMP.

Anxiety

Based upon my independent review of the petitions, I am granting those seeking to add anxiety to the MMP. In coming to this conclusion, I reviewed these petitions against the six regulatory criteria cited above and found that the condition meets the requirements for inclusion in the MMP.

Regarding the first factor, which is whether the condition is generally accepted in the medical community as a valid medical condition, I find that anxiety satisfies this criteria. Specifically, the American Psychiatric Association defines anxiety and anxiety disorders as conditions characterized by excessive fear and behavioral disturbances.⁴⁵ Anxiety results from anticipation of a future threat and may be associated with symptoms of muscle tension, vigilance in preparation for future danger, and overly cautious or avoidant behaviors.⁴⁶ Additionally, there are multiple ICD-10-CM codes for anxiety disorders.⁴⁷ Because anxiety maintains a common definition in the medical community and has ICD-10-CM codes, I find that anxiety is a valid and recognized medical condition.

Under the second factor, I must consider whether the treatments for the condition, rather than the condition itself, are causing the patient’s suffering and the extent to which the treatments causing the patient suffering are generally accepted by the medical community and other experts as valid treatments for the condition. From my review of this condition, the generally accepted treatments for anxiety are dependent on the symptoms and the severity of the particular disorder. Mild and moderate forms of anxiety may not require a pharmacologic intervention, but may necessitate other forms of treatment, such as meditation, mindfulness, breathing techniques as well as psychotherapy (counseling) or cognitive therapy.⁴⁸ The most common classes of

⁴⁴ See <https://www.ncbi.nlm.nih.gov/pubmed/26749285> (last visited March 13, 2018).

⁴⁵ See <https://dsm.psychiatryonline.org/doi/abs/10.1176/appi.books.9780890425596.dsm05> (last visited March 13, 2018).

⁴⁶ *Ibid.*

⁴⁷ See ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2018/ (last visited March 13, 2018).

⁴⁸ See <https://adaa.org/finding-help/treatment#> (last visited March 14, 2018).

medications used to combat anxiety disorders are antidepressants, anti-anxiety drugs, and beta-blockers.⁴⁹ Antidepressants are safe and effective but they may be risky for children, teens, and young adults.⁵⁰ Antidepressants also come with a “black box” warning – the FDA’s strongest warning - advising that some people may have suicidal thoughts or make suicide attempts while taking the medication.⁵¹ The most common anti-anxiety medications are called benzodiazepines. As noted by the Panel, the common side effects of benzodiazepines include headache, confusion, tiredness, and in some cases nightmares and memory impairments.⁵² And, benzodiazepines carry a risk of dependence and addiction.⁵³ Furthermore, the FDA notes that the number of patients who were prescribed both an opioid analgesic and benzodiazepine increased by 41% between 2002 and 2014.⁵⁴ As a result, the FDA requires black box warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines to inform the patient about the serious risks associated with using these medications at the same time.⁵⁵ Thus, I find that the treatments for anxiety are recognized and accepted by the medical community as the treatments for this condition and relate to the suffering of the patient.

As for the third factor, which is whether the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living, I find that both the anxiety condition itself as well as the treatments for this condition cause severe suffering for patients. Specifically, anxiety may lead to problems that negatively impact an individual's activities of daily living and quality of life and may lead to suicide and depression. Anxiety disorders can also cause significant distress or interfere with social, occupational, and other areas of functioning. In fact, an estimated 31.1% of U.S. adults experience an anxiety disorder at some time in their lives.⁵⁶ Medications, in some instances, may exacerbate the symptoms and are associated with debilitating side effects that can prevent a patient from engaging in activities of daily living, thereby diminishing one's quality of life. Accordingly, I find that both the condition of anxiety as well as the therapies to treat it cause severe suffering.

Under the fourth factor, I must evaluate the availability of conventional medical therapies, other than those that cause suffering, to alleviate the patient's suffering caused by the condition and/or the treatment thereof. As discussed above, mild and moderate forms of anxiety may be treated with meditation, mindfulness, breathing techniques as well as counseling or cognitive therapy that can be effective. Progression to medication therapy may be initiated; however, in both instances, one must consider the therapeutic response. Failure to respond to therapies or side effects associated with treatments may result in significant impacts on quality of life. As such,

⁴⁹ *Ibid.*

⁵⁰ See <https://www.mayoclinic.org/diseases-conditions/teen-depression/in-depth/antidepressants/art-20047502> (last visited March 14, 2018).

⁵¹ *Ibid.*

⁵² See <https://www.nimh.nih.gov/health/topics/mental-health-medications/index.shtml> (March 14, 2018).

⁵³ *Ibid.*

⁵⁴ See <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm> (last visited March 14, 2018).

⁵⁵ *Ibid.*

⁵⁶ See <https://www.nimh.nih.gov/health/statistics/any-anxiety-disorder.shtml> (last visited March 13, 2018).

I find that there is an absence of medically-accepted, alternative medical therapies to the conventional therapies currently prescribed for migraine that cause suffering.

Regarding the fifth factor, which is whether there is generally accepted evidence in the medical community that the use of marijuana alleviates suffering relating to the condition, I find that cannabis is generally accepted as an effective treatment for anxiety. The Panel discussed medical evidence that cannabis may exacerbate anxiety symptoms or that an effect related to cannabis may be associated with anxiety, such as dependence and cravings. Literature suggests that individuals with anxiety sensitivity may be more likely to turn to cannabis as a mechanism for coping with stress, which may in turn lead to problematic use behaviors.⁵⁷ However, the Panel further discussed a review published by the National Academies of Sciences, Engineering, and Medicine in 2017, which found that there is limited evidence that cannabidiol is an effective treatment for the improvement of anxiety symptoms, which was assessed by a public speaking test utilizing individuals with social anxiety disorders.⁵⁸ On balance, the Panel recommended adding anxiety as an allowable condition under the MMP as research suggests that it could be helpful to some patients with this condition. I agree. While marijuana may not be effective for all anxiety sufferers, there is research evidencing that it may be helpful to some, especially those with social anxiety disorders. Thus, I find that there is acceptance in the medical community that marijuana is likely to relieve the suffering associated with some anxiety conditions. However, like any medical condition, the use of medical marijuana to treat anxiety must be explored by the medical professional treating the patient to determine whether it is the best and most appropriate course of treatment for the patient.

As for the final factor, which is whether there were letters from physicians or other licensed health care professionals knowledgeable about the condition supporting the inclusion of anxiety under the MMP, I find that the petitions were submitted with support from medical professionals.

Based upon the above analysis, I find that the condition of anxiety is “debilitating” and that medical marijuana is more likely than not to be potentially beneficial to treat or alleviate the debilitating effect of this condition. As such, I find that anxiety should be added to the MMP.

Opioid Use Disorder

From my independent review of the petitions, I am granting the petition that seeks to add opioid use disorder to the MMP. In coming to this conclusion, I reviewed this condition against the six regulatory criteria cited above and find that it meets the requirements for inclusion in the MMP, with the condition that physicians prescribing medical marijuana for this disorder do so in conjunction with their patient’s medication-assisted treatment, instead of as a singular treatment for the disorder.

Regarding the first factor, which is whether the condition is generally accepted in the medical community as a valid medical condition, I find that opioid use disorder is a valid condition. According to the U.S. Department of Health and Human Services, Centers for Disease Control

⁵⁷ Anxiety Sensitivity and Distress Intolerance as Predictors of Cannabis Dependence Symptoms, Problems, and Craving: The Mediating Role of Coping Motives. Farris SG, Metrik J, Bonn-Miller MO, Kahler CW, Zvolensky MJ. *J Stud Alcohol Drugs*. 2016 Nov;77(6):889-897.

⁵⁸ The Health Effects of Cannabis and Cannabinoids: the Current State of Evidence and Recommendations for Research, National Academies Press (2017); Cannabinoids for treatment of chronic non-cancer pain; a systematic review of randomized trials, *British Journal of Clinical Pharmacology* (2001).

and Prevention, opioid use disorder is “[a] problematic pattern of opioid use that causes significant impairment or distress.”⁵⁹ Additionally, there are multiple ICD-10-CM codes for opioid use disorder.⁶⁰ Because opioid use disorder has a common medical definition and maintains several ICD-10-CM codes, I find that opioid use disorder is a valid condition recognized by the medical community.

Under the second factor, I must consider whether the treatments for the condition, if the treatments are causing the patient suffering, are generally accepted by the medical community and other experts as valid treatments for the condition. As noted in the petition, the generally accepted treatment for opioid use disorder is medication-assisted treatment (MAT), which includes methadone, naltrexone, and buprenorphine (suboxone). I agree. As stated by the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), MAT is the “gold standard” for treatment of opioid use disorder.⁶¹ According to SAMHSA, MAT consists of FDA-approved medications, namely methadone, buprenorphine or naltrexone, in combination with behavioral therapies, “to provide a whole-patient approach to the treatment of substance use disorders.”⁶² Side effects from MAT medications include insomnia, headaches, abdominal pain, body aches and vomiting, to name a few.⁶³ Thus, I find that the treatment for opioid use disorder, specifically MAT medications, is recognized and accepted by the medical community. And, while I agree that MAT medications are an effective treatment for opioid use disorder, there are serious side effects that come with this treatment. Accordingly, I also find that MAT medications can cause a patient’s suffering.

As for the third factor, which is whether the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient’s ability to carry on activities of daily living, I find that opioid use disorder itself as well as the treatment for this condition cause severe suffering for patients inflicted with this condition. It is without question that opioid use disorder causes severe suffering for an individual stricken with this condition. According to the U.S. Department of Health and Human Services, Office of the Surgeon General, “[o]pioid addiction typically involves a pattern of: (1) intense intoxication, (2) the development of tolerance, (3) escalation in use, and (4) withdrawal signs that include profound negative emotions and physical symptoms, such as bodily discomfort, pain, sweating, and intestinal distress.”⁶⁴ With increased use, the individual not only must take the opioid to avoid the severe withdrawal side effects, but the individual will also experience intense cravings for the opioid and preoccupation with using the opioid.⁶⁵ As such, an individual living with opioid use disorder can experience suffering that ranges from severe psychosocial impairment to overdosing and even death.⁶⁶ With these side effects, a patient is unable to engage

⁵⁹See <https://www.cdc.gov/drugoverdose/opioids/terms.html> (last visited January 17, 2019).

⁶⁰ See ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2018/ (last visited January 17, 2019).

⁶¹ See https://addiction.surgeongeneral.gov/sites/default/files/Spotlight-on-Opioids_09192018.pdf (last visited January 17, 2019).

⁶² See *Ibid.*

⁶³ See <https://medlineplus.gov/druginformation.html> (last visited January 17, 2019).

⁶⁴ See https://addiction.surgeongeneral.gov/sites/default/files/Spotlight-on-Opioids_09192018.pdf (last visited January 17, 2019).

⁶⁵ *Ibid.*

⁶⁶ *Ibid.*

in activities of daily living, thereby diminishing his or her quality of life. Thus, the condition itself causes the patients with this disorder to suffer immensely.

While opioid use disorder, in and of itself, causes extensive suffering, the treatment for the disorder can also cause significant suffering. Specifically, MAT medications can cause headaches, vomiting, body aches and insomnia.⁶⁷ All of these side effects can prevent a patient from engaging in activities of daily living, thereby diminishing one's quality of life. Accordingly, I find that opioid use disorder as well as the medications used to treat this condition cause severe suffering.

Under the fourth factor, I must evaluate the availability of conventional medical therapies, other than those that cause suffering, to alleviate the patient's suffering caused by the condition and/or the treatment thereof. Unfortunately, the treatment for opioid use disorder that causes the patient suffering, specifically MAT medications, is the most effective and viable conventional medical therapy offered for this condition. As such, I find that there is an absence of effective alternative medical therapies to the conventional therapies currently prescribed for opioid use disorder that cause patients to suffer.

Regarding the fifth factor, which is whether there is generally accepted evidence in the medical community that the use of marijuana alleviates suffering relating to the condition, I find that there is sufficient evidence that the use of medical marijuana may relieve the suffering related to opioid use disorder when it is used in conjunction with MAT. There is a recent publication by the Cannabis and Cannabinoid Research Journal that sets forth emerging evidence that the use of medical cannabis in conjunction with MAT has the potential to "ease opioid withdrawal symptoms, reduce opioid consumption, ameliorate opioid cravings, prevent opioid relapse, improve [opioid use disorder] treatment retention, and reduce overdose deaths."⁶⁸ However, the publication notes that these findings are preliminary and that additional research, which is hampered by the federal government's designation of marijuana as a Schedule I drug, should be conducted on this promising form of treatment for opioid use disorder.⁶⁹ While I acknowledge that there is little research on the effectiveness of medical marijuana, either alone or in conjunction with MAT, as a treatment for opioid use disorder, given the current opioid epidemic consuming our great State, the citizens of New Jersey suffering from this horrible disorder simply cannot wait for the removal of the political barriers that are preventing research on this promising treatment in order to receive a medication that may ultimately save their lives.

Moreover, as declared under Executive Order No. 219 (2017), "[t]he abuse of and addiction to opioid drugs is a public health crisis in New Jersey, necessitating the marshalling of all appropriate resources to combat its harmful effects on the citizens of our State." This crisis is further evidenced by the staggering number of deaths resulting from opioid overdoses that occur each year in New Jersey. In fact, overdose deaths have more than doubled since 2013. In 2013, there were 1,336 drug-related deaths; in 2016, that number increased to 2,221.⁷⁰ For 2018, the

⁶⁷ See Footnote 6.

⁶⁸ See Wiese B, Wilson-Poe AR (2018) Emerging evidence for cannabis' role in opioid use disorder, Cannabis and Cannabinoid Research 3:1, 179–189, DOI: 10.1089/can.2018.0022.

⁶⁹ *Ibid.*

⁷⁰ See <https://www.njcares.gov/>

number of deaths is projected to jump to a staggering 3,163.⁷¹ With opioid overdose deaths climbing at such an alarming rate, I am compelled to find that the research to date on the beneficial use of medical cannabis as an adjunct to MAT for the treatment of opioid use disorder is sufficient evidence that this form of treatment may alleviate the suffering relating to the disorder and prevent overdose deaths. Indeed, I cannot ignore these disturbing numbers and allow more of our citizens to succumb to this disorder when there is at least some research suggesting that the use of medical marijuana in conjunction with MAT may be an effective treatment for opioid use disorder and ultimately prevent a patient's demise. As such, in giving effect to Executive Order 219's call to garner all possible resources to combat the opioid crisis, I find that the available research I have reviewed establishes sufficient evidence that the use of medical marijuana may relieve the suffering related to opioid use disorder when it is used in conjunction with MAT.

As for the final factor, which is whether there were letters from physicians or other licensed health care professionals knowledgeable about the condition supporting the inclusion of opioid use disorder under the MMP, I find that the petitions were submitted with support from medical professionals.

Based upon the above analysis, I find that the condition of opioid use disorder is "debilitating" and that medical marijuana is more likely than not to be potentially beneficial to treat or alleviate the debilitating effect of this condition when it is used in conjunction with MAT. As such, I find that opioid use disorder, as a standalone condition, should be added to the MMP.

Denied Petitions

Asthma

After carefully reviewing the petition seeking to include asthma as a debilitating condition under the MMP, and in accordance with the Panel's recommendation, I am denying the request. In coming to this conclusion, I reviewed the petition against the six regulatory factors cited above and found that the condition fails to meet the requirements for inclusion in the MMP.

Regarding the first factor, which is whether the condition is generally accepted in the medical community as a valid medical condition, I find that asthma meets this requirement. The CDC defines asthma as a chronic lung disease⁷² that "causes repeated episodes of wheezing, breathlessness, chest tightness, and nighttime or early morning coughing."⁷³ Moreover, the Department recognizes asthma as a chronic medical condition with approximately 600,000 adults and 167,000 children suffering from this condition in New Jersey.⁷⁴ Thus, I find that asthma is generally accepted by the medical community as a valid medical condition.

Under the second factor, I must consider whether the treatments for the condition, if the treatments are causing the patient suffering, are generally accepted by the medical community and other experts as valid treatments for the condition. In the petition, the petitioner asserts that the use of albuterol to treat asthma causes an individual to experience an increased heart rate and shakiness and that the use of corticosteroids to treat asthma can cause the patient to become

⁷¹ *Ibid.*

⁷² See https://www.cdc.gov/asthma/stateprofiles/asthma_in_nj.pdf (last visited March 13, 2018).

⁷³ See <https://www.cdc.gov/asthma/default.htm> (last visited March 13, 2018).

⁷⁴ See <http://www.nj.gov/health/fhs/chronic/asthma/in-nj/> (last visited March 13, 2018).

addicted to the drug. While corticosteroids and bronchodilators, such as albuterol, are generally accepted treatments for asthma, I do not find that the average patient suffers from the use of these medications. As stated by the Panel, there are several treatments for asthma that are not only effective but also provide minimal side effects. Specifically, asthma is generally treated with inhaled, oral and intravenous corticosteroids and bronchodilators.⁷⁵ Common side effects associated with the use of corticosteroids include acne, weight gain and upset stomach.⁷⁶ However, these side effects rarely occur with the short-term use of these medications, such as when they are used for acute asthma episodes.⁷⁷ While the use of corticosteroids is accepted by the medical community as valid treatments for asthma, I do not find that these treatments cause the vast majority of patients to experience suffering from their use.

The same holds true for bronchodilators. While bronchodilators can cause nervousness or shakiness, headache, throat or nasal irritation, muscle aches and, in rare instances, a rapid heart rate or heart palpitations, these side effects can be greatly reduced and even eliminated by changing the delivery method of the medication and/or reducing the dosage.⁷⁸ Although these side effects could potentially cause a patient to suffer, they can be effectively decreased and even eliminated through medication management. As such, I find that the treatments for asthma do not cause an average asthma patient to experience suffering.

As for the third factor, which is whether the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living, I find that asthma can cause severe suffering. Specifically, when asthma is not well-controlled, it can severely impair a patient's ability to engage in his or her activities of daily living, such as limiting the patient's physical activity, cause sleep disturbances and can even result in death. Accordingly, I find that asthma can cause a patient to experience severe suffering.

Under the fourth factor, I must evaluate the availability of conventional medical therapies, other than those that cause suffering, to alleviate the patient's suffering caused by the condition and/or the treatment thereof. While asthma cannot be cured, it can be well-controlled with self-management education, adequate pharmacological management, and avoidance of exposure to environmental triggers.⁷⁹ Specifically, asthma is commonly and effectively treated with bronchodilators and corticosteroids, which are widely available to patients and have little side effects.⁸⁰ Thus, I find that the conventional medical treatments for asthma are effective and easily attainable by patients.

Regarding the fifth factor, which whether there is generally accepted evidence in the medical community that the use of marijuana alleviates suffering relating to the condition, I agree with the Panel's conclusion that there are no reliable clinical trials or research supporting the proposition that medical cannabis is an effective treatment for asthma. While the petitioner points

⁷⁵ See <https://www.mayoclinic.org/diseases-conditions/asthma/diagnosis-treatment/drc-20369660> (last visited March 13, 2018).

⁷⁶ See <https://my.clevelandclinic.org/health/diseases/16864-treating-the-inflammation-of-asthma> (last visited March 13, 2018).

⁷⁷ *Ibid.*

⁷⁸ See <https://www.mayoclinic.org/diseases-conditions/asthma-attack/expert-answers/albuterol-side-effects/faq-20058088> (last visited March 13, 2018).

⁷⁹ See <https://www26.state.nj.us/doh-shad/topic/Asthma.html> (last visited March 13, 2018).

⁸⁰ See Footnote 62.

to a study published in the New England Journal of Medicine in 1973, which suggests that marijuana dilates the airway for a short period of time, the study did not evaluate the effect marijuana has on patients suffering from asthma. In fact, the study utilized thirty-two male subjects with no serious medical conditions and advised that “further investigation is required to determine . . . the effects of marijuana smoking and oral THC on the airway of asthmatic subjects.” As such, I find that this study does not support the proposition that marijuana is an effective treatment for asthma.

Even more, physicians with the American Thoracic Society recently published an article in the American Journal of Respiratory and Critical Care Medicine advising that marijuana can worsen existing lung conditions and specifically noted that “marijuana smoke can cause an asthma attack leading to hospitalization and even death.”⁸¹ Thus, the medical community appears to be opposed to the use of marijuana as a treatment for asthma. Because the petitioner failed to point to any evidence demonstrating that the medical community accepts medical marijuana as a treatment for asthma, and neither I nor the Panel found any reliable trials or research in support of this, I find that the medical community is not in favor of using medicinal cannabis to alleviate the suffering associated with asthma.

As for the final factor, which is whether there are letters from physicians or other licensed health care professionals knowledgeable about the condition supporting the inclusion of asthma under the MMP, I find that the petition only referenced the 1973 New England Journal of Medicine article and did not include any letters of support from healthcare professionals. While the journal article was authored by three physicians, I do not find that this lone article from 1973 on the general effects of marijuana on the airway constitutes support from a medical professional for the inclusion of asthma to the MMP. Additionally, there were no public comments from medical professionals supporting the inclusion of asthma under the MMP. Thus, I find that there is a lack of support from physicians or other health care professionals for this condition to be added to the MMP.

Based upon the foregoing, I find that asthma can be debilitating if uncontrolled, but that marijuana is not likely to be a beneficial treatment for this condition or alleviate the debilitating effect of this condition. Indeed, as noted by the Panel, inhalation of smoke is a known trigger for asthma exacerbation and, as a result, smoking marijuana may actually increase the suffering of asthma patients rather than alleviate the suffering associated with this condition⁸². And, while I acknowledge that medicinal marijuana is available in non-smokable forms, I am not convinced that there is credible support for its use in treating asthma. Unless and until there is sufficient research and evidence demonstrating that the use of marijuana can be beneficial for an asthma patient, I find that asthma should not be added to the MMP.

Chronic Fatigue Syndrome

From my detailed review of the petition seeking to include chronic fatigue syndrome as a debilitating condition under the MMP, and in accordance with the Panel’s recommendation, I have concluded that the petition should be denied. In coming to this conclusion, I reviewed the petition

⁸¹ Drake MD, Matthew G. and Slatore MD, Christopher G. “Smoking Marijuana and the Lungs.” Am. J. Respir. Crit. Care Med., Vol. 195, P5-6 (2017).

⁸² Ibid.

against the six regulatory factors cited above and found that the condition fails to meet the requirements for inclusion in the MMP.

Regarding the first factor, which is whether the condition is generally accepted in the medical community as a valid medical condition, I find that chronic fatigue syndrome meets this criteria. According to the CDC, chronic fatigue syndrome, also known as myalgic encephalomyelitis, is a “long-term illness that affects many body systems.”⁸³ In addition to extreme fatigue, which may worsen with physical or mental activity, but does not improve with rest, an individual with this condition may experience insomnia, depression, joint and muscle pain and memory impairments.⁸⁴ In fact, there is an estimated 836,000 to 2.5 million individuals affected with this condition in the United States.⁸⁵ Thus, I find that chronic fatigue syndrome is a valid medical condition.

Under the second factor, I must consider whether the treatments for the condition, if the treatments are causing the patient suffering, are generally accepted by the medical community and other experts as valid treatments for the condition. Unfortunately, there is neither a cure nor an FDA-approved treatment for chronic fatigue syndrome.⁸⁶ As a result, treatment is largely palliative as the treatment is tailored to relieve the symptoms experienced by each individual patient. For example, a patient experiencing depression as a result of chronic fatigue syndrome could be treated with an anti-depressant and a patient experiencing muscle and joint pain could be prescribed an NSAID to relieve the pain.⁸⁷ Moreover, the symptoms of chronic fatigue are oftentimes treated with nutritional supplements and complementary therapies, such as massage, meditation, tai chi and acupuncture, which may be helpful in increasing the patient’s energy level and decreasing his or her pain.⁸⁸ But, these are not treatments for the actual condition but rather treatments for the symptoms associated with the condition. As such, I find that there is no treatment generally accepted in the medical community for this disease that causes suffering.

However, I do find that the above therapies prescribed by healthcare professionals to treat the **symptoms** associated with chronic fatigue syndrome are accepted by the medical community. While I find that the treatments for chronic fatigue symptoms are medically acceptable, the specific treatment prescribed depends on the type and severity of the symptoms presented and can range from anti-depressants and NSAIDs, which can have severe side effects for some patients and thereby cause suffering, to massage therapy and acupuncture, which have little to no side effects. Because there is a vast array of treatment options for chronic fatigue symptoms and no two patients are treated the same, I am unable to conclude that chronic fatigue patients generally suffer from the treatments they receive for their symptoms. However, individuals with severe forms of chronic fatigue syndrome may suffer from the treatments used to alleviate their symptoms.

⁸³ <https://www.cdc.gov/me-cfs/index.html> (last visited March 13, 2018).

⁸⁴ <https://www.mayoclinic.org/diseases-conditions/chronic-fatigue-syndrome/symptoms-causes/syc-20360490> (last visited March 13, 2018).

⁸⁵ Wright Clayton, MD, Ellen, “Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome An IOM Report on Redefining an Illness.” JAMA (2015).

⁸⁶ <https://www.cdc.gov/me-cfs/treatment/index.html> (last visited March 13, 2018).

⁸⁷ <https://www.cdc.gov/me-cfs/index.html> (last visited March 13, 2018).

⁸⁸ *Ibid.*

As for the third factor, which is whether the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living, I find that chronic fatigue syndrome can cause severe suffering. Specifically, some individuals suffering from chronic fatigue syndrome can experience severe pain, gross memory loss and even such extreme fatigue that the patient is house-bound or even bed-bound, all of which greatly impacts a patient's ability to engage in activities of daily living and maintain a quality life. Accordingly, I find that chronic fatigue syndrome can cause a patient to experience severe suffering.

Under the fourth factor, I must evaluate the availability of conventional medical therapies, other than those that cause suffering, to alleviate the patient's suffering caused by the condition and/or the treatment thereof. While chronic fatigue cannot be cured and there is no approved treatment for the condition, there is a wide array of pharmacological therapies available for alleviating the symptoms associated with this condition. Specifically, chronic fatigue symptoms can be effectively managed for some patients with NSAIDs, anti-depressants and sleep-aids, depending on the severity and type of symptoms presented. However, depending upon the patient, the pharmacological treatments for chronic pain symptoms may be effective but may also cause the patient to suffer from side effects. Thus, I find that there are available conventional medical therapies to alleviate a chronic fatigue patient's suffering, but those treatments may cause suffering for some patients.

Regarding the fifth factor, whether there is generally accepted evidence in the medical community that the use of marijuana alleviates suffering relating to the condition, I agree with the Panel's conclusion that there are no reliable clinical trials or research supporting the proposition that medical cannabis is an effective treatment for chronic fatigue syndrome. While the petitioner points to studies suggesting that medical marijuana can alleviate an individual's pain, which is potentially one symptom a patient inflicted with chronic fatigue syndrome may experience, the studies fail to articulate that marijuana is an effective treatment for the condition of chronic fatigue syndrome as a whole. Because the petitioner failed to point to any evidence demonstrating that the medical community accepts medical marijuana as a treatment for the actual condition of chronic fatigue syndrome, and neither I nor the Panel found any credible clinical evidence in support of this, I find that there is a lack of support in the medical community for the use of medicinal cannabis to alleviate the suffering associated with chronic fatigue syndrome.

As for the final factor, which is whether there are letters from physicians or other licensed health care professionals knowledgeable about the condition supporting the inclusion of chronic fatigue under the MMP, I find that the petition only referenced the above-mentioned studies reflecting on the effectiveness of medical marijuana to treatment pain and did not include any letters of support from healthcare professionals to have chronic fatigue added to the MMP. Additionally, there was an absence of public comments from medical professionals supporting the inclusion of chronic fatigue under the MMP. Thus, I find that there is a lack of support from physicians or other health care professionals for this condition to be added to the MMP.

Based upon the above analysis, I find that chronic fatigue syndrome can be debilitating for some patients, but that medical marijuana is not likely to be a potentially beneficial treatment for the debilitating effect of this condition or the alleviation of the symptoms associated with this condition. Indeed, as noted by the Panel, this condition has been researched for years and there is yet to be found a solid elucidation of the etiology of this condition or the treatments that are

effective for it.⁸⁹ Because there are still so many unknowns with this condition and there is no clinical evidence suggesting that marijuana would be beneficial as a treatment, I find that chronic fatigue syndrome should not be added to the MMP at this time.

Conclusion

Based upon the foregoing, I am adding chronic pain associated with musculoskeletal disorders, chronic pain of a visceral origin, as well as Tourette's Syndrome, migraine, anxiety and opioid use disorder (with the condition that medical marijuana be prescribed in conjunction with medication-assisted therapy for the treatment of the disorder) to the MMP. However, asthma and chronic fatigue syndrome will not be added to the MMP.

In order to provide patients with relief as soon as possible from the suffering they are experiencing from these debilitating conditions, I am immediately adding chronic pain associated with musculoskeletal disorders, chronic pain of a visceral origin, Tourette's Syndrome, migraine, anxiety and opioid use disorder to the MMP in advance of rule promulgation. While I am including these conditions under the MMP, please note that this decision is not intended to be a blanket endorsement for every patient inflicted with a condition falling under the MMP to utilize medicinal marijuana as a treatment. As with any condition, the course of treatment must be determined by a medical professional after a thorough evaluation and discussion with the patient regarding the benefits and possible negative effects of the recommended therapy. Accordingly, I encourage patients to discuss the possibility of utilizing medical marijuana as a treatment for their debilitating conditions with the medical professionals treating them. I hope that this decision brings needed relief to those suffering with these conditions.

This is a final agency decision. You have the right to appeal this final agency decision within 45 days to the New Jersey Superior Court, Appellate Division, Richard J. Hughes Justice Complex, P.O. Box 006, Trenton, New Jersey 08625-0006.



Shereef M. Elnahal, MD, MBA
Commissioner

⁸⁹ <https://www.ncbi.nlm.nih.gov/books/NBK293931/> (last visited March 13, 2018).