Final Decision Regarding Advisory Board Report and Recommendations from Meeting of April 7, 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 April 7, 2017.

The Department of Health is obligated by statute and by rule to determine the possible benefit of cannabis usage for specific conditions. The Lynn and Erin Compassionate Use Act requires the Department of Health to create and apply rules that implement the Act's purpose, which is to "allow the beneficial use of medical cannabis in a regulated system for alleviating symptoms caused by debilitating medical conditions and their medical treatments." NMSA 1978, §§ 26-2B-7, 2. The Advisory Board was created by statute for the purpose of recommending "additional debilitating medical conditions that would benefit from the medical use of cannabis" to the Department of Health. NMSA 1978, § 26-2B-6 A. In accordance with this, the written report of the Advisory Board must include a medical justification for the Board's recommendation that is based on the individual or collective expertise of the Advisory Board membership. 7.34.2.11(A) NMAC. Furthermore, a condition may not be added to the list of approved medical conditions unless it qualifies as a "debilitating medical condition" within the meaning of the medical cannabis rule. The definition of "debilitating medical condition" requires that there be credible medical evidence that the use of medical cannabis could alleviate the pain, suffering or debility stemming from the medical condition, medical treatment or disease. 7.34.2.7(J)(8) NMAC.

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 Autism

The Medical Cannabis Advisory Board considered a petition to add Autism to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 3-0, that Autism be recommended for inclusion in the list of conditions qualifying for enrollment.

I am declining to adopt the Advisory Board's recommendation to add Autism to the list of qualifying conditions. The articles that are cited in the petition were not included with the petition materials. However, it appears that, of the materials that suggest that endocannabinoids

have potential for therapeutic value for those persons diagnosed with Autism Spectrum Disorder (ASD), most if not all of them are based either on anecdotal reports, or limited studies not involving humans. The Advisory Board acknowledged this in part in its written report, in finding that much of the material referenced in the petition is speculative and relies upon anecdotal reports. I find that the information submitted is insufficient to reasonably conclude that the use of cannabis would be either safe or effective in alleviating symptoms of Autism.

B. Recommendation Regarding Attention Deficit Hyperactivity Disorder (ADHD)

The Medical Cannabis Advisory Board considered a petition to add Attention Deficit Hyperactivity Disorder (ADHD)/Attention Deficit Disorder (ADD) 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 ADHD be recommended for inclusion in the list of conditions qualifying for enrollment for persons over the age of 18.

ADHD/ADD was previously considered by the Department in 2015, at which time the previous Cabinet Secretary, Retta Ward, declined to approve them for inclusion in the list of conditions approved for participation in the Program. In her decision, Secretary Ward concluded that potential adverse consequences of approving ADHD/ADD as a qualifying condition "significantly outweigh[ed] the potential benefits", and noted the lack of clinical studies regarding its impact on persons with ADHD. Secretary Ward also noted her concerns regarding the impact that such a decision could have on minors, who are most commonly diagnosed with ADHD. The current recommendation alleviates that concern insofar as it would limit enrollment under ADHD to persons 18 and older.

However, I find that the instant petition to add ADHD as a qualifying condition suffers from the same deficits previously encountered. The petition includes considerable speculation regarding the cause(s) of ADHD, and primarily cites to anecdotal reports of physicians who have claimed to have observed a benefit to the use of cannabis by persons with ADHD/ADD. No studies regarding the effects of cannabis on persons with ADHD or ADD are noted. The petition states that the California Center for Medicinal Cannabis Research was funded to conduct one or two studies regarding ADHD or ADD, which is a positive development. However, I find that the information submitted is not sufficient to reasonably conclude at this time that the use of cannabis by persons with ADHD or ADD would be effective or safe.

C. Recommendation Regarding Anxiety

The Medical Cannabis Advisory Board considered a petition to add anxiety to the list of medical conditions qualifying for enrollment in the New Mexico Medical Cannabis Program. The Advisory Board recommended, by a vote of 3-1, that anxiety be recommended for inclusion in the list of conditions qualifying for enrollment.

The petition notes that much of the ongoing research regarding the effects of cannabis on anxiety disorders concern the non-psychoactive cannabinoid called cannabidiol (CBD). However, as members of the Advisory Board noted in their discussion, there is no system within

the Medical Cannabis Program to limit an enrolled patient's purchases to CBD products, rather than products containing THC.

More generally, I am concerned about the potential effects of cannabis on persons with anxiety disorders. The consumption of cannabis is known to generate anxiety, and if cannabis is used by someone who already suffers from an anxiety disorder, it is possible that their condition will be exacerbated. The materials presented in the petition, while interesting, do not relieve me of this concern, and do not offer any assurance that this would not be the case.

A recent comprehensive review of human-based studies conducted by the National Academies of Sciences (NAS) observed that the NAS review committee did not identify any good-quality primary literature that reported on medical cannabis as an effective treatment for the improvement of anxiety symptoms. The report noted (with significant caveats) that there is limited evidence that CBD improves anxiety symptoms. It also stated that evidence from observational studies found moderate evidence that daily cannabis use is associated with increased anxiety symptoms and heavy cannabis use is associated with social phobia disorder.

I find that the petition does not provide information from which to conclude that the use of cannabis by persons with anxiety would be safe or effective in relieving their symptoms. Accordingly, I decline to adopt the Advisory Board's recommendation.

D. Recommendation Regarding Depression

The Medical Cannabis Advisory Board considered a petition to add depression 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 depression be recommended for inclusion in the list of conditions qualifying for enrollment.

The petition cites to limited studies on rodents that suggest a correlation between endocannabinoids activity and depression or the alleviation thereof. The petition acknowledges that there have been no clinical tests of human subjects concerning the impact of cannabis usage on depression. This is corroborated by the recent report of the National Academy of Sciences, which concluded that there was no good-quality primary literature identified that reported on medical cannabis as an effective treatment to reduce depressive symptoms.

I find that there is a dearth of evidence to demonstrate that the use of cannabis is either effective or safe for treatment of depression or its symptoms. Accordingly, I am declining to adopt the Advisory Board's recommendation concerning the addition of depression to the list of qualifying conditions.

E. Recommendation Regarding Diabetes

The Medical Cannabis Advisory Board considered a petition to add Diabetes 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 not be recommended for inclusion in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

Members of the Advisory Board commented that the use of cannabis does not appear to improve diabetes, and that the studies do not tend to indicate a benefit in diabetes control stemming from the use of cannabis. I agree with the conclusions stated, and I find, based on the petition submitted, that there is insufficient evidence from which to conclude that cannabis is either effective or safe for treating the symptoms of Diabetes. Accordingly, I am adopting the Advisory Board's recommendation to deny this petition.

F. Recommendation Regarding Dystonia

The Medical Cannabis Advisory Board considered a petition to add Dystonia 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 Dystonia not be recommended for inclusion in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

Spasmodic Torticollis, a.k.a. Cervical Dystonia, was approved for participation in the Medical Cannabis Program in 2012, and continues to be an approved condition for participation in the Program. In determining to include cervical dystonia in the list of approved conditions, then Interim Cabinet Secretary Brad McGrath found that there was support in the medical literature that cannabinoids may aid in alleviating symptoms of Cervical Dystonia; that the therapeutic options for the condition were limited and sometimes invasive; and that the potential for misuse within the program was limited, given the nature of the condition and the specificity of the diagnosis.

In contrast, the current petition does not offer the same assurances. The petition references a survey that was evidently mentioned in an amicus brief in a case captioned *Conant v. McCaffrey*, in which cannabis usage was found to result in improvements in controlling muscle spasticity and pain. A copy of the survey was not included with the petition materials. Further, no clinical studies of human subjects with Dystonia are referenced in the petition. The NAS report (previously referenced herein) noted that cannabis has not been studied in the treatment of Dystonia.

In consideration of the petition submitted, I find that there is insufficient evidence to conclude that the use of cannabis is either safe or effective for alleviating symptoms of Dystonia. For that reason, I am adopting the recommendation of the Medical Cannabis Advisory Board to deny this petition.

G. Recommendation Regarding Migraines

The Medical Cannabis Advisory Board considered a petition to add Migraine headaches 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 "Chronic Headaches to

include Migraines" be recommended for inclusion in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

The Advisory Board stated that there was a split vote to add Migraine headaches in the past, but that the Cabinet Secretary at that time decided not to add it to the list of qualifying conditions. The Advisory Board's report says little about why the Board recommends adding Chronic Headaches to the list of qualifying conditions, but mentions that the Medical Cannabis Program does currently receive applications from individuals who suffer from Chronic Headaches, who have applied under the qualifying condition "Chronic Pain".

The petition acknowledges that there are no clinical studies examining the impact of cannabis usage on Migraine headaches. The petition references a survey from 2016, the results of which suggested that cannabis usage could result in decreased Migraines. A copy of the report from that survey was not included with the petition materials, although it appears that the sample population and findings were fairly limited. No other studies directly concerning the impact of cannabis on Migraine headaches were cited in the petition.

I find the information presented insufficient to conclude that cannabis is effective or safe in addressing Migraines or their symptoms. Accordingly, I am declining to add Migraines to the list of approved conditions.

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 recommended for inclusion in the list of conditions qualifying for enrollment in the Medical Cannabis Program.

The petition proposes that cannabis use could be of benefit for persons with Insomnia or Sleep Apnea. It references (but does not include within the materials) one study involving the testing on rodents, which reportedly suggested a potential benefit in alleviating symptoms of Sleep Apnea. No other studies regarding the impact of cannabis usage on sleep disorders are referenced, and no human-based clinical studies are described.

Based on the petition submitted, I find that there is insufficient information from which to conclude that cannabis usage is either safe or effective for alleviating symptoms of sleep disorders, and for that reason, I am declining to add sleep disorders to the list of qualifying conditions.

I. Request for the Department to Allow Patient Collectives to Grow Cannabis

The Medical Cannabis Advisory Board was created by statute at NMSA 1978, § 26-2B-6. The stated role of the Advisory Board is to:

A. review and recommend to the department for approval additional debilitating medical conditions that would benefit from the medical use of cannabis;

B. accept and review petitions to add medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the medical use of cannabis;

C. convene at least twice per year to conduct public hearings and to evaluate petitions, which shall be maintained as confidential personal health information, to add medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the medical use of cannabis;

D. issue recommendations concerning rules to be promulgated for the issuance of the registry identification cards; and

E. recommend quantities of cannabis that are necessary to constitute an adequate supply for qualified patients and primary caregivers.

Department rule 7.34.2.9 NMAC states that "the advisory board may accept and review petitions from any individual or association of individuals requesting the addition of a new medical condition, medical treatment or disease for the purpose of participating in the medical cannabis program and all lawful privileges under the act." "Petitioner" is defined at 7.34.2.7(II) NMAC as "any New Mexico resident or association of New Mexico residents petitioning the advisory board for the inclusion of a new medical condition, medical treatment, or disease to be added to the list of debilitating medical conditions that qualify for the use of cannabis".

The request to allow the production of cannabis via patient collectives is not a petition within the terms of the statute or the rule, and also does not fall within the stated responsibilities of the Advisory Board. Accordingly, I am declining to address the request or the Advisory Board's recommendation concerning it. As always, members of the public are welcome and encouraged to suggest rule changes to the Department outside of the petition process, by submitting comment to the Program, or by offering public comment during rule hearings.

J. Request for the Department to Increase Adequate Supply Possession Limit

The Medical Cannabis Advisory Board recommended, by a vote of 4-0, that the Department increase the "adequate supply" three-month possession limit from the current 8 ounce standard to 16 ounces, with the current medical exception also doubled from the current 12 ounce total to 24 ounces. Members of the Advisory Board expressed that the basis for this recommendation is their belief that the current medical exception to the limit creates too great an obstacle for qualified patients. Members also expressed that the current limit creates a challenge for persons who would otherwise seek to harvest a year's worth of cannabis from the summer harvest of their personal production license (PPL) grow. Significantly, in rendering this recommendation the Advisory Board did not rely upon or reference any identified standard regarding clinically appropriate dosage of cannabis, and I am not aware that any such standard exists or has been adopted within the medical community.

In 2015, the Department increased the adequate supply possession & usage limit from the previous 6-ounce limit to the current 8-ounce standard, together with the new medical exception standard, which did not exist previously. In adopting the adequate supply limit, the Department of Health sought to fulfill the goal of the Compassionate Use Act of ensuring that patients are able to possess and use a quantity of cannabis sufficient to meet their medical needs. Simultaneously, the Department sought to ensure that the adopted limit was not so high as to create an unnecessary risk of diversion of cannabis.

Currently, there are more than 48,000 patients enrolled in the Medical Cannabis Program. Sales figures from quarterly reports collected by the Program indicate that, on average, patients purchase a total of about 40-45 units of cannabis and cannabis-derived products in a 90-day time period, a figure well below the 230-unit limit. Also, despite the increased enrollment figures, the Program receives relatively few requests for medical exceptions. When it does receive such requests, the Program typically grants them, based upon a simple certification of a medical practitioner attesting that a greater number of units is medically necessary for the patient. I find that this process does not impose a significant obstacle for enrolled patients, and that the current limit is appropriate.

While I understand the issue raised regarding summer harvesting by personal production license holders, I have concerns about patients warehousing large quantities of cannabis for the entire year, including but not limited to concern regarding the safety and security of patients growing the cannabis, and the increased potential for diversion resulting from an over-supply. Also, PPL holders are not restricted to growing cannabis outdoors during the summer months, but can (and commonly do) grow cannabis indoors throughout the year. One commenter stated that a greater quantity of cannabis is necessary for creating cannabis concentrates. By adopting personal production licenses in its rules, the Department did not seek to encourage individual patients to engage in the practice of creating cannabis concentrates. Creating cannabis concentrates typically involves complex, dangerous processes, including primarily the use of compressed natural gases to generate extracts. Such processes require not only specialized knowledge, but sophisticated equipment, as well as permits and approvals from state and local authorities for their use. Licensed nonprofit producers carry a wide variety of concentrated cannabis products, and patients who wish to obtain concentrated products may obtain them from LNPPs.

For each of the reasons stated, I am declining to adopt the recommendation regarding the proposed increase of the adequate supply limit and the associated medical exception.

K. <u>Request for the Department to Remove the Upper THC Limit of 70%</u>

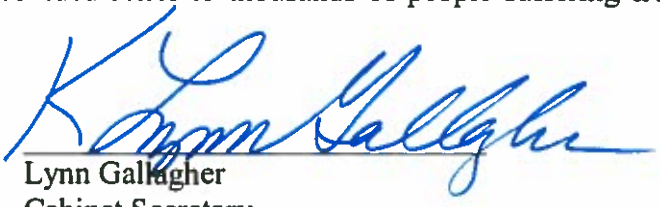
The Medical Cannabis Advisory Board recommended, by a vote of 4-0, that the Department remove the 70% THC concentration limit for cannabis-derived product from its rules. The Advisory Board did not explain its recommendation, but stated that it had made the same recommendation previously.

The 70% THC limit was adopted in Department rules in 2015, based on concern that extremely high concentrations of THC in cannabis-derived products may lead to negative outcomes for consumers. In adopting the provision, the Department sought to establish a reasonable limit on THC concentration that would not impose an undue burden on qualified patients. High concentrations of THC have not been well studied, and by applying this standard, the Department hopes to ensure the health and safety of qualified patients, while not unduly impacting the availability of cannabis-derived products for qualified patients. High concentrations of THC may involve a higher risk of negative health consequences for patients, particularly given that many patients experience compromised immunities as a result of their medical condition. Consuming extremely high concentrations of THC may also negatively impact patients' tolerances. Currently, there are many available forms of concentrated cannabis-derived products available in the medical cannabis marketplace, and the Department is not aware of the 70% THC limit having negatively impacted anyone within the Program. For these reasons, at this time I am declining to adopt the proposal to remove the 70% THC concentration limit from Department rules.

II. Closing

The Department has continued to receive more petitions for the addition of medical conditions and medical treatments for enrollment in the Medical Cannabis Program. In reviewing the petitions, it is the agency's goal to evaluate the medical efficacy of cannabis based on the medical and scientific information presented, with an emphasis placed on credible medical evidence. The Medical Cannabis Advisory Board reviews each petition and makes recommendations to the Department. The Advisory Board is comprised of several board-certified medical specialists who bring with them a wealth of knowledge and expertise regarding medical conditions and their treatments. However, in some instances, the Advisory Board's written reports have recommended in favor of or in opposition to a given petition without providing any detail as to why the Advisory Board reached their conclusion. In future reports, it would be helpful for the Advisory Board to emphasize the strengths and weaknesses of a petition, and to highlight whatever information (clinical studies, etc.) they consider to be the most salient.

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 continued work and support of this program, which has provided relief to thousands of people suffering from debilitating medical conditions.



Lynn Gallagher
Cabinet Secretary

10/26/17
Date