

Medical Cannabis Program Decision Regarding Medical Cannabis Advisory Board Recommendations

I. Decision:

I have reviewed the recommendations of the Medical Cannabis Advisory Board to the Medical Cannabis Program contained in their report, submitted to me on April 9, 2010 based on their findings at a public hearing held on March 30, 2010.

Having reviewed the Advisory Board's recommendations and the available medical literature and materials, 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 petitions and recommendations submitted to the Department:

A. Conditions that were not recommended for addition to the list of eligible conditions:

- i. Autoimmune diseases (generally).

I am adopting the Advisory Board's recommendation to NOT add this diagnosis to the list of eligible conditions.

B. Conditions that were recommended for addition to the list of eligible conditions:

- i. Severe behavioral disturbances related to autism, dementia, traumatic brain injury, and mental retardation.

I am NOT adopting the recommendations of the Advisory Board to these conditions to the list of eligible conditions.

C. Recommendation for changes to enrollment criteria:

- i. The Advisory Board recommended that the Department revise its enrollment criteria for the category of severe chronic pain by removing the requirement that applicants provide written certification from a specialist with expertise in pain management or expertise in the disease or condition that is causing the pain.

I am NOT adopting the recommendation of the Advisory Board that the Department remove the requirement that persons applying under the eligible condition of "severe chronic pain" submit two written certifications, including a certification from a specialist with expertise in pain management.

II. Discussion:

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 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(E)(9) NMAC.

A. Autoimmune disease (in general).

I concur with the Advisory Board that "autoimmune disease in general" is too broad a category, and the supporting clinical data too scant, for the inclusion of this category in the list of conditions for which medical cannabis use is approved. The Department has included specific autoimmune medicated illnesses in the list of approved medical conditions, including multiple sclerosis, Crohn's disease, and autoimmune-mediated arthritis. However, those conditions were included in consideration of the debilitating nature of each, and in consideration of data specifically supporting the proposition that cannabinoids would likely alleviate symptoms caused by those debilitating medical conditions and/or their medical treatments. There are no such assurances with respect to the category of autoimmune disease in general, and I decline to add autoimmune disease in general to the list of approved medical conditions.

B. Severe behavioral disturbances related to autism, dementia, traumatic brain injury, and mental retardation.

In standard medical practice, medicines must be established through scientific studies before they can be marketed to the public. Clinical studies use established statistical methods to determine a drug's efficacy in treating patients who have the diagnosis under consideration. Scientific studies published in established medical literature, as well as consensus statements promulgated by established, recognized specialty organizations (e.g., American Academy of Family Physicians, etc.), offer several advantages in determining the efficacy of a drug,

including the presentation of results from a larger population of individuals under particular conditions, etc.

By contrast, the data regarding the effectiveness of cannabinoids in treating severe behavioral disturbances related to autism, dementia, traumatic brain injury, and mental retardation do not offer a reasonable assurance that cannabinoids would likely assist in alleviating symptoms caused by those debilitating medical conditions and/or their medical treatments. There is a need for additional scientific research to be conducted regarding the possible efficacy of using cannabis to treat numerous possible conditions. Without further research, and in the absence of any other evidence that could reliably establish the efficacy of medical cannabis usage for these medical conditions, I decline to add them to the list of approved medical conditions.

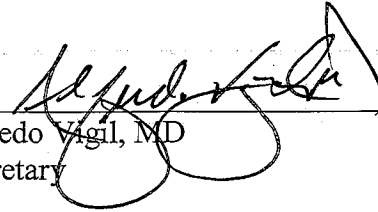
C. Recommendation for changes to severe chronic pain enrollment criteria

The Lynn and Erin Compassionate Use Act, at NMSA 1978, § 26-2B-3(B) identifies seven specific medical conditions, treatments and diseases for which the medical use of cannabis is approved. The Act also reserves to the Department the ability to add “any other medical condition... as approved by the department”. *Id.* When the Department added the condition “severe chronic pain” to the list of conditions for which the medical use of cannabis is approved, it identified certain requirements that must be met in order for an application submitted under that category to be approved. The Department imposed those requirements in order to recognize and address the debilitating nature of severe chronic pain, while also recognizing the subjective nature of pain and the need to limit the potential for abuse of this category, consistent with the purpose of the Lynn and Erin Compassionate Use Act.

A person applying under this category must present objective proof of the etiology of the severe chronic pain. The applicant must also submit at least two written certifications from clinicians, to include a certification from the applicant’s primary care physician, and a certification from a specialist with expertise in pain management or expertise in the disease or condition that is causing the pain, such as a neurologist, neurosurgeon, orthopedic surgeon, or rheumatologist. The two certifying clinicians must attest that *all other standard modalities for treating the pain have been tried and have failed to bring adequate relief for the patient’s pain and suffering.* Thus, the category “severe chronic pain” was included in the list of approved conditions with the intent that applications under this category only be approved in those limited circumstances in which the Department is reasonably assured that the use of medical cannabis will be a *treatment of last resort.* The requirement that certifications be submitted from both a primary clinician and a specialist provides that reasonable assurance. I do not believe that the Department could be reasonably assured of the same, however, if it removed the specialist certification requirement. I am also concerned that the removal of this requirement would significantly increase the potential for abuse of the category. For this reason, I decline to adopt the recommendation of the Advisory Board to remove the specialist certification requirement from the enrollment criteria for the category of severe chronic pain.

III. Closing

I want to thank the patients who submitted requests for consideration. I also want to thank the Advisory Board for their hard work and support of this program which has provided relief to hundreds of people suffering from debilitating conditions.



Alfredo Vigil, MD
Secretary

Date 5/3/10