STATE OF MICHIGAN
RICK SNYDER
GOVERNOR
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING
MIKE ZIMMER
DIRECTOR

August 27, 2015

FINAL DETERMINATION OF DEPARTMENT

Procedural History

In accordance with the Michigan Medical Marihuana Act, Initiated Law 1 of 2008, MCL 333.26421 *et seq.* ("MMMA"), and the associated administrative rules, Mich Admin Code, R 333.101 et seq., a petition was filed with the Department of Licensing and Regulatory Affairs to consider adding autism as a qualifying disease or medical condition under R 333.131 and R 333.133.

After reviewing the record created pursuant to the May 27, 2015 public hearing, on July 31, 2015, the Michigan Medical Marihuana Review Panel discussed the petition and voted on a motion to add autism as a qualifying condition. The motion passed with a vote of 4 yes votes and 2 no votes. Pursuant to R 333.131(5) the majority vote to add autism as a qualifying condition became the official recommendation of the panel. As required by R 333.133(5), that recommendation now comes to the department for final action.

The Petition and its Scope

The petition under consideration lists "autism" without limitation as the medical condition proposed for inclusion as a qualifying condition under the MMMA. Although "severe autism" is referenced in the petition, the petition does not limit the proposed qualifying medical condition to "severe autism," nor is the term "severe autism" defined anywhere in the petition. Thus, the petition seeks to add autism without limitation as a qualifying medical condition under the MMMA.

In the justification section of the petition, the petitioner indicates that "medical marihuana has been used successfully in Michigan to treat the symptoms of *severe autism* in patients who also suffer from *epilepsy.*" (emphasis added) It is, therefore, important to examine the petition's illustrative linkage in the justification section to epilepsy. In fact, many of the parents who participated in the public hearing indicated that their severely autistic children experienced seizures as a result of that condition. An examination of the language in the MMMA, however, establishes that these children

may already be eligible. Under MCL 333.26423(b)(2), included within the definition of debilitating medical conditions for which a patient is eligible is the following:

> "(2) *A chronic or debilitating disease or medical condition or its treatment that produces 1 or more of the following:* cachexia or wasting syndrome; severe and chronic pain; severe nausea; *seizures, including but not limited to those characteristic of epilepsy;* or severe and persistent muscle spasms, including but not limited to those characteristic of multiple sclerosis (emphasis added)."

As a result, autistic individuals whose condition produces seizures may already be included within the category of individuals whose debilitating medical condition permits them access to medical marijuana. Therefore, our discussion on this petition is focused on autistic patients without associated seizure disorders.

Discussion

While the record is replete with sincere and well-articulated testimony on the potential benefits of medical marihuana to autism patients and, in particular, comments from parents of autistic children, several troubling concerns remain.

Initially, health professionals have expressed concern regarding the lack of clinical studies and evidence based practices relative to medical marihuana's use by autistic patients in general, and specifically by children. Indeed, at the July 31[51] panel meeting, the state's Chief Medical Executive, Dr. Eden Wells, noted that lack of studies regarding the epidemiology and biologic effects on children using medical marihuana and bemoaned that there were not more clinical trials to provide checks and balances on its benefits verses its possible ill-effects. Similarly, in her written statement, Dr. Colleen Allen, Chair of the Michigan Autism Council, while acknowledging the desperate plight of families seeking help for their affected child or siblings, complained of the lack of scientific research to justify this mode of treatment.

This lack of scientific evidence is more concerning when considering the broad scope of the petition, which does not limit medical marihuana treatment to only severe cases of autism. Even those cited as supporting the use of medical marihuana for autistic treatment raised this concern. Dr. Harry Chugani, Professor and Chief of the Division of Pediatric Neurology at Children's Hospital of Michigan, cited in public hearing testimony as a proponent, stated in a letter in the record that he "would not support a general recommendation for cannabis to treat all children with autism, as little scientific evidence exist to demonstrate gains in skill acquisition and research is still needed to assure children would not suffer short or long term psychotropic effects." Similarly, while generally supportive of the petition, Stephen D'Acry, Director and Co-Founder of the Autism Alliance of Michigan, noted in a letter that he does "not believe that a general recommendation for use with all children with autism is supported by existing evidentiary research."

At public hearing, several suggested that the lack of scientific supportive research could be offset by strict certification practices by a patient's physician. Mr. Michael Komorn, an attorney for the petitioner and an ardent advocate, stated that under current law, two doctors must sign off on approval for the use of medical marihuana by minors and that "obviously, in the case of minors these doctors will likely be their doctors, their autism specialist (5/27/15 Hrg. Tr., p 17)." Similarly, Dr. Harry Chugani, in his letter to the panel, stated that "I also highly recommend that determinations of which patients may be appropriate should be made strictly by a highly skilled, experienced medical doctor, with significant experience in treating autism." Unfortunately, there is no such requirement in the MMMA. MCL 333.26426(b)(2) simply requires written certifications from two physicians and does not contain any requirement that those physicians be expert, comply with specific certification practices, or even be trained in the treatment of autism.

Finally, the petition fails to acknowledge the direct impact on children. Indeed, the petition avers that there are only 55 minors currently in the Michigan Medical Marijuana Program and "approval of autism will not cause a radical increase in participation . . ." That assumption fails to recognize the prevalence of autism diagnosed in Michigan's children. In his letter to the panel, Dr. Christian Bogner points out that 1 in 68 children are diagnosed with Autism in the United States with the incidence rising by 10% each year. Further, according to a study included in the hearing packet entitled "Targeting alterations in the endocannabinoid system of rodents and non-human primates in the study of autism," the symptoms of autism are typically present in children before age 3. In addition, testimony at the public hearing indicated that children were currently being given forms of medical marihuana at very young ages. As a result, autism likely impacts more children than other qualifying medical conditions – effectively rebutting any claim that any increase in MMMA participation by minors would be minimal.

While not determinative of the department's decision on the petition itself, I would be remiss if I did not acknowledge serious concerns with the form of use by children described at public hearing. While the testimony varied in terms of specificity on how medical marihuana was administered to autistic children, most indicated it was given through oil or juice including several references to "Rick Simpson Oil." The voter initiated MMMA contains a very precise definition what qualifying patients and authorized caregivers are able to possess.

1) MCL 333.26424(a) generally permits a qualifying patient who has been issued and possesses a registry identification card to possess an amount not exceeding 2.5 ounces of "useable medical marihuana." Similarly, MCL 333.26424(b) permits a primary caregiver to possess an amount to not exceed 2.5 ounces of usable marihuana for each qualifying patient.
2) MCL 333.26423(k) defines usable marihuana as "the dried leaves and flowers of the marihuana plant, and any mixture or preparation thereof, but does not include the seeds, stalks, and roots of the plant."

Michigan courts have narrowly construed the definition of "usable marihuana." In *People v Carruthers*, 301 Mich. App. 590, 600 (2013), for example, the Court of Appeals determined that brownies containing marihuana were not usable marihuana within the meaning of the Act. The court determined that resin extracted from the plants does not fall within that definition (*Id.* at 601). The Court concluded that "an edible product made with THC extracted from resin is excluded from the definition of 'usable marihuana.'"(*Id* at 604).

Significantly, the Court in *Carruthers* explicitly addressed edibles as follows:

> "Our interpretation does not preclude the medical use of marijuana by ingestion of edible products; to the contrary, the use is authorized by the MMMA, within the statutory limitations, provided that the edible product is a 'mixture or preparation' of 'the dried leaves and flowers of the marihuana plant,' rather than of the more potent THC that is extracted from marijuana resin." *Id.* At 607.

By specifically outlining what preparations are permissible and focusing on the statutory definition that includes preparations made from dried leaves and flowers of the plant itself, the Court appears to be excluding other forms and products. As a result, I would note that even if the petition were approved, some of the forms of delivery of medical marijuana advocated by those appearing at public hearing would not appear to be authorized under the MMMA.

Decision

For the reasons stated above, under the authority granted me pursuant to R 333.133(5), the recommendation of the Michigan Medical Marihuana Review Panel for inclusion of "autism" in the list of qualifying conditions is DENIED.

Mike Zimmer, Director