



Division of Public Health Licensing Services
Medical Marijuana Program

P.O. Box 19000
Phoenix, Arizona 85005

DOUGLAS A. DUCEY, GOVERNOR
CARA M. CHRIST, M.D., DIRECTOR

October 28, 2015

Arizona Cannabis Nurses Association
Attn: Heather Manus, RN, President
c/o Ken Sobel, Attorney
5346 Soledad Rancho Court
San Diego, CA 92106

Dear Ms. Manus:

Thank you for submitting a petition to add Huntington's Disease to the list of Medical Marijuana debilitating medical conditions defined in Arizona Revised Statutes (A.R.S.) § 36-2801(3) and Arizona Administrative Code (A.A.C.) R9-17-201.

Pursuant to A.R.S. §§ 36-2801.01 and 36-2803, the Arizona Department of Health Services (ADHS) adopted rules governing the manner in which ADHS shall consider petitions from the public to add debilitating medical conditions. According to A.A.C. R9-17-106(B)(2), in order for ADHS to consider a petition for review, the requestor is required to submit *each* of the elements listed in the rule.

ADHS has determined that the petition does not meet the requirements in A.A.C. R9-17-106(B)(2). Specifically, the petition failed to satisfy the following elements, as required in A.A.C. R9-17-106(B)(2)(b):

- b. Marijuana usage provides a therapeutic or palliative benefit to an individual suffering from the medical condition or treatment of the medical condition;

The petition does not provide sufficient evidence that the use of **marijuana** will provide therapeutic or palliative benefit for the medical condition or a treatment of the medical condition to be further considered at this time. A summary of the reasons for this conclusion follows:

The petition identifies five "articles published in peer-reviewed, scientific journals" which are cited in support of the petition.

Two of the articles involve a very thorough discussion of molecular or neurologic theory on the potential effects of specific individual marijuana compounds, such as cannabidiol (CBD) or tetrahydrocannabinol (THC), on processes within the body. Cell research and mouse models may be a necessary precursor to studies on humans, but they are not sufficient evidence that the use of **marijuana** will provide therapeutic or palliative benefit for the medical condition or a treatment of the medical condition that is the subject of the petition. These limitations are expressly recognized in the authors' comments, such as "most of the studies that have examined the therapeutic potential of cannabinoids in these disorders have been conducted in animal or cellular models, whereas the number of clinical trials is still very

limited” and “this type of compounds may be considered a novel disease-modifying therapy susceptible to be evaluated at the clinical level.”

One of the articles was a study on the treatment of rats with combinations of CBD and THC mixed in varying ratios. Marijuana was not used at all. Another article was limited to a review of the molecular theory and other articles involving the neuroprotective properties of CBD alone. It also did not consider the use of marijuana. The authors concluded “from a pharmaceutical point of view, CBD is an unusually interesting molecule” and “CBD has tremendous potential as new medicine.” Separate approval of individual molecules found in marijuana is not contemplated in the program rules.

One of the articles appears to have actually involved an open-label observational study regarding the use of marijuana by patients with Huntington’s disease. The study was conducted on two men who reported that they had been using marijuana to treat their symptoms. The two subjects’ responses to treatment were inconsistent: one improved with treatment, but the other worsened. The authors reported: “Subject two had less depression . . . subject one had slightly worse depression . . . subject one had minor improvement in his motor exam . . . subject two had insignificant worsening. There was no change in cognitive performance for either subject.” A single study comprised of only two subjects that exhibited mixed results is insufficient evidence.

The authors reported briefly on two studies of CBD use in humans conducted by others and noted that one found mild improvement on chorea severity, where the other, a placebo-controlled, double-blind, randomized, cross-over design found no significant effect. The authors stated: “Marijuana is from the cannabis plant and it may contain over 60 cannabinoid compounds. The role of each of these compounds in the behavioral response to the drug is unknown.”

If one of the stated goals of AMMA is to facilitate the medical use of marijuana then the well-established and accepted standards used in approving all other medications in the United States should be followed. The petition submitted for Parkinson’s Disease contained low quality scientific evidence, anecdotal reports, individual testimonials, legislative and voter initiatives, or administrative approvals in other states, and the personal opinion, of the public in general or a medical professional specifically. None of which meet the well-established and accepted standards.

The petition does not provide sufficient evidence of articles, published in peer-reviewed scientific journals, reporting the results of research on the effects of **marijuana** on the medical condition or a treatment of the medical condition supporting why the medical condition should be added to be further considered at this time.

Due to its failure to satisfy the requirements set forth in A.A.C. R9-17-106(B)(2)(b), ADHS will not consider the petition for review.

You are advised that an administrative hearing (Hearing) may be requested¹ to have this Denial reviewed by submitting a request for a Hearing. A Hearing shall be held only if you submit your written request for a Hearing to the Clerk, ADHS, 1740 W. Adams St., Room 203, Phoenix, AZ 85007 within **30**

¹ If you timely request a Hearing, you may also request that the ADHS hold an informal settlement conference by submitting a written request to the ADHS no later than 20 calendar days before the Hearing scheduled in the matter.

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calendar days after this Denial is received. The Hearing will be conducted under the authority of, and in accordance with A.R.S. Title 36, Chapter 28.1 and Title 41 Chapter 6, Article 10.

If you request a Hearing and a Hearing is conducted, in accordance with A.R.S. § 41-1092.08, the administrative law judge of the Office of Administrative Hearings shall submit to the Director of the ADHS (Director) a written decision, including proposed findings of fact, conclusions of law and a recommended decision regarding the disposition of the matter. The Director's decision to accept, reject or modify the written decision becomes the Final Decision of the ADHS.

You are advised that pursuant to A.R.S. §§ 36-2801.01 and 41-1092.08(H), the ADHS's Final Decision is subject to judicial review pursuant to A.R.S. Title 12, Chapter 7, Article 6. Jurisdiction and venue are vested in the Superior Court.

ADHS will be accepting petitions to add to the list of debilitating medical conditions again in January 2016. Please visit our website at <http://www.azdhs.gov/medicalmarijuana/debilitating/> for the most current information and updates about this process.

Sincerely,



Colby Bower
Assistant Director