



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 Parkinson'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 eight "articles published in peer-reviewed, scientific journals" which are cited in support of the petition. Five of the articles involve a very thorough discussion of molecular or neurologic theory on the potential effects of specific individual marijuana compounds, such as cannabinoids or 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. One of the "articles" is not an article published in a peer-reviewed journal, rather it is a copy of a patent.

The remaining two articles appear to have actually involved low level studies, a survey and an observational study, regarding the use of marijuana on patients with Parkinson's disease.

In the survey, participation and reporting were voluntary and anonymous, and consumption of marijuana was almost exclusively in the form of a teaspoon of fresh or dried leaves taken orally. The response rate was only slightly greater than fifty percent (50%), and of those responding, less than fifty percent (50%) reported mild or substantial alleviation of their symptoms in general. Twenty five percent (25%) of those who responded reported the use of cannabis. Reducing the patient sample from 339 to 85. A survey conducted in this manner cannot prove causality, in fact the authors themselves concluded that "results from this type of study cannot be conclusive and should rather serve as a baseline for future research."

The open-label observational study sought to evaluate the efficacy of cannabis treatment in alleviating symptoms. The study started with twenty-eight participants. Almost immediately, six of them were dismissed from the study because they "could not tolerate the drug and discontinued treatment after a short period because of severe adverse effects (inability to smoke, vomiting, dizziness, and psychosis)." Out of the remaining twenty-two, it appears that marijuana improved patient motor symptoms on a rating scale while non-motor symptoms, including quality of sleep, improved for the majority. The authors reported: "Although promising, our results should be interpreted with caution and confirmed in larger double-blind, placebo-controlled studies conducted over a longer term, with specific attention to the possible addictive potential of the drug."

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 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.

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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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