

IN THE OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of:

Arizona Cannabis Nurses Association

No. 2016-MMR-0176-DHS

ADMINISTRATIVE LAW JUDGE

DECISION

HEARING: May 3 and 4, 2016. Held open to May 11, 2016

APPEARANCES: Ken Sobel for Petitioner; Greg Falls and Matthew Hesketh for
the Department of Health Services

Witnesses: Heather Manus, RN; Edith Lynn Edde, DO; Lezli Engelking; Tom Salow;
Cynthia Reed, MD; Lisa Villarroel, MD

ADMINISTRATIVE LAW JUDGE: Dorinda M. Lang

After appealing the refusal of the Arizona Department of Health Services to set its petition for public hearing, the Arizona Cannabis Nurses Association has established that the Department erred in issuing its denial. The applicable law does not allow the Department to consider safety of marijuana, nor does it require petitioners to prove its safety, and it does not allow the Department to apply any standard of proof other than to determine whether any evidence was provided to address whether the proposed condition is debilitating and whether marijuana treats the condition or provides a therapeutic or palliative benefit to them. Because the petition at issue contained the required type of evidence, the matter is appropriate to set for public hearing.

FINDINGS OF FACT

1. On or about July 30, 2015, Petitioner submitted a petition ("the Petition") to the Arizona Department of Health Services ("Department or ADHS") proposing to add Parkinson's Disease ("PD") to the list of debilitating medical conditions defined in Arizona Revised Statutes ("A.R.S.") § 36-2801(3) and Arizona

Administrative Code ("A.A.C.") R9-17-201.¹ If added, PD would be one of the conditions protected by the Arizona Medical Marijuana Act ("AMMA").²

2. On October 28, 2015, the Department issued a letter to Petitioner stating that the Department had found that the Petition did not meet the requirement of A.A.C. R9-17-106(B)(2)(b) in that it did not provide "sufficient evidence that the use of marijuana will provide therapeutic or palliative benefit for [PD] to be further considered at this time."³
3. Petitioner appealed and requested a hearing, arguing that the Department should have set the matter for a public hearing rather than deny it at this juncture.
4. The Department did not dispute that the Petition was complete in that it fulfilled the requirements of A.A.C. R9-17-106(A) by submitting all the paperwork and information required to be in a petition. The Department offered no objection to Petitioners' allegation that PD meets the definition of a debilitating medical condition as described in A.A.C. R9-17-106(B)(2)(a). The sole dispute in this matter concerned whether Petition met the requirement of A.A.C. R9-17-106(B)(2)(b), which requires the Department to review the Petition to determine whether it has "provided evidence" that use of marijuana offers PD sufferers "a therapeutic or palliative benefit" or "treatment of [PD]."
5. Petitioner did not argue that marijuana use offers any treatment of the illness itself but focused its case on the evidence that tended to show that marijuana offers PD sufferers a therapeutic or palliative benefit, which, it argued, can be as basic as simply making the patient feel good from the euphoric effects of its use.
6. Petitioner offered undisputed testimony that PD patients often suffer from psychosis from taking L-DOPA, one of the primary treatments for PD. Petitioner argued that the Petition seeks to allow PD patients the option to use marijuana for those who experience relief from the anxiety and depression that comes with PD, the decrease in tremors, improved sleep and improved mood that some

¹ Exhibit 1.

² A.R.S. § 36-2801 *et seq.*

³ Quoting the language used by ADHS in the denial letter. Exhibit 10.

1 users experience. Petitioner's evidence was clear that Petitioner is not arguing
2 that marijuana is a treatment for the cure of PD but that it helps with its
3 symptoms and the side effects of its medications.⁴

4 7. The Department argued that the information in the Petition did not establish that
5 marijuana is so effective for the treatment of PD that the Department can
6 recommend that patients use it.⁵ The Department also maintained that the
7 Petition did not establish that marijuana is safe enough for ADHS to recommend
8 its use for PD patients.⁶ The Department's evidence clearly established that its
9 decision to deny the Petition without allowing it to proceed to a public hearing
10 was based on what it deemed to be insufficient evidence that marijuana is safe
11 and effective. The Department deemed the articles provided with the Petition to
12 be inconclusive⁷ and did not find the other evidence in the Petition to be
13 sufficiently convincing.

14 8. The Petition⁸ included 4 points intended to summarize the evidence of
15 therapeutic benefit and 8 articles published in recognized peer-reviewed
16 scientific journals. The first point of general evidence and the first article are the
17 same, *Cannabis (Medical Marijuana) Treatment for Motor and Non-Motor*
18 *Symptoms of Parkinson Disease: An Open-Label Observational Study* ("The
19 Israeli Study").⁹ The Department did not rely on them because none of them
20 reached the quality of evidence that the Department sought. They either had too
21 small a sampling, they were studies on animals rather than humans, they studied
22 elements in the plant rather than the whole plant, or they were based on
23 scientific or medical theory rather than studies of actual patients.

24 CONCLUSIONS OF LAW

25 ⁴ Hearing Record of 5/3/16 from 42:00 to 57:12.

26 ⁵ Hearing Record of 5/3/16 from 8:50 to 9:50.

27 ⁶ Testimony of Dr. Villaroel, Hearing Record of 5/4/16 from 2:44:50 to 2:50:32.

28 ⁷ In addition to Dr. Villaroel's testimony, Tom Salow, another member of the group that made the decision,
29 testified that it would be irresponsible for ADHS to add PD without more conclusive evidence and because
30 the only 2 articles about studies done on humans stated that their results required more study. Hearing
Record 5/4/16 from 4:16:00 to 4:39:00.

⁸ Exhibit 1.

⁹ Exhibit 2. Lotan, I., Treves, T., Roditi, Y, Djaldetti, R., *Cannabis (Medical Marijuana) Treatment for Motor
and Non-Motor Symptoms of Parkinson Disease: An Open-Label Observational Study*, Clin Neuropharm
2014:37:41.

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1. Petitioner has the burden of proof and the standard of proof on all issues is by a preponderance of the evidence. See A.A.C. R2-19-119. A preponderance of the evidence is “such proof as convinces the trier of fact that the contention is more probably true than not.” Morris K. Udall, Arizona Law of Evidence, § 5 (1960). Proof by preponderance of the evidence “is evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole shows that the fact sought to be proved is more probable than not.” Black’s Law Dictionary 1182 (rev. 6th ed. 1990).
 2. Arizona law provides for the addition of debilitating medical conditions for which medical marijuana is included in the AMMA. It provides as follows:

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Addition of debilitating medical conditions

The public may petition the department to add debilitating medical conditions or treatments to the list of debilitating medical conditions set forth in section 36-2801, paragraph 3. The department shall consider petitions in the manner required by department rule, including public notice and hearing. The department shall approve or deny a petition within one-hundred-eighty days of its submission. The approval or denial of a petition is a final decision of the department subject to judicial review pursuant to title 12, chapter 7, article 6. Jurisdiction and venue are vested in the superior court.

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A.R.S. § 36-2801.01.

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3. A.A.C. R9-17-106 sets forth the requirements for adding a new debilitating condition to the AMMA. It provides as follows:

A. An entity may request the addition of a medical condition to the list of debilitating medical conditions in R9-17-201 by submitting to the Department, at the times specified in subsection (C), the following in writing:

1. The entity’s name;
2. The entity’s mailing address, name of contact individual, telephone number, and, if applicable, e-mail address;
3. The name of the medical condition the entity is requesting be added;
4. A description of the symptoms and other physiological effects experienced by an individual suffering from the medical condition or a treatment of the medical condition that may impair the ability of the individual to accomplish activities of daily living;

1 5. The availability of conventional medical treatments to provide
2 therapeutic or palliative benefit for the medical condition or a treatment of
3 the medical condition;

4 6. A summary of the evidence that the use of marijuana will provide
5 therapeutic or palliative benefit for the medical condition or a treatment of
6 the medical condition; and

7 7. Articles, published in peer-reviewed scientific journals, reporting the
8 results of research on the effects of marijuana on the medical condition or
9 a treatment of the medical condition supporting why the medical condition
10 should be added.

11 B. The Department shall:

12 1. Acknowledge in writing the Department's receipt of a request for the
13 addition of a medical condition to the list of debilitating medical conditions
14 listed in R9-17-201 within 30 calendar days after receiving the request;

15 2. Review the request to determine if the requester has provided evidence
16 that:

17 a. The specified medical condition or treatment of the medical condition
18 impairs the ability of the individual to accomplish activities of daily living,
19 and

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

23 3. Within 90 calendar days after receiving the request, notify the requester
24 that the Department has determined that the information provided by the
25 requester:

26 a. Meets the requirements in subsection (B)(2) and the date the
27 Department will conduct a public hearing to discuss the request; or
28 b. Does not meet the requirements in subsection (B)(2), the specific
29 reason for the determination, and the process for requesting judicial
30 review of the Department's determination pursuant to A.R.S. Title
12, Chapter 7, Article 6;

4. If applicable:

a. Schedule a public hearing to discuss the request;

b. Provide public notice of the public hearing by submitting
a Notice of Public Information to the Office of the Secretary of State, for
publication in the *Arizona Administrative Register* at least 30 calendar
days before the date of the public hearing;

c. Post a copy of the request on the Department's web site for public
comment at least 30 calendar days before the date of the public hearing;
and

d. Hold the public hearing no more than 150 calendar days after receiving
the request; and

5. Within 180 calendar days after receiving the request:

a. Add the medical condition to the list of debilitating medical conditions,
or

1 b. Provide written notice to the requester of the Department's decision to
2 deny the request that includes:

- 3 i. The specific reasons for the Department's decision; and
4 ii. The process for requesting judicial review of the Department's decision
5 pursuant to A.R.S. Title 12, Chapter 7, Article 6.

6 C. The Department shall accept requests for the addition of a medical
7 condition to the list of debilitating medical conditions in R9-17-201 in
8 January and July of each calendar year starting in January 2012.

- 9 4. A.A.C. R9-17-106(B)(3) provides that the Department's duty in reviewing a
10 petition is to determine whether the petition **has provided evidence** that the
11 requirements of A.A.C. R9-17-106(B)(2) have been met. That is, whether the
12 Petition has provided evidence that PD is a debilitating condition, which is not
13 disputed, and whether the Petition has provided evidence that marijuana
14 provides treatment or a therapeutic or palliative benefit for suffers of the disease.
15 5. In passionately carrying out its duties, the Department has gone beyond what
16 was required of it. It was clear at the hearing that the Department's witnesses
17 are genuinely concerned for the well-being of Arizona citizens and that they took
18 their responsibility to review petitions extremely seriously. However, in doing so,
19 they considered factors that are not part of the rule and therefore cannot be
20 relied upon by a government agency.
21 6. In its desire for professionalism, the Department has utilized a standard of proof
22 that is higher than the rules provide for. The Department argued that as a
23 medical agency, it has a duty to use the standards that doctors would use in
24 ethically treating their patients. The Department requires a standard akin to
25 practicing "evidence-based medicine," which does not rely on studies until a
26 certain degree of reliability has been reached that physicians generally accept as
27 useful to their level of responsibility.
28 7. However, the rule does not require any degree of reliability of the evidence.¹⁰
29 A.A.C. R9-17-106(B)(3) requires only that the Department determine whether
30 "evidence" was provided to establish therapeutic or palliative benefit or treatment

¹⁰ The one evidentiary standard that one might read into this rule is the requirement in A.A.C. R9-17-106(A)(7) that peer-reviewed articles must be included in a petition. This does offer one aspect of reliability and requires that it be included in all petitions.

1 of the illness. By failing or refusing to include any qualifiers on the word, the rule
2 must be interpreted to require only that evidence, any evidence, be provided with
3 the Petition.

- 4 8. The other factor considered by the Department that is not a requirement in the
5 rule is the Department's need for marijuana to be proven safe. As conscientious
6 professionals, the Department's witnesses openly discussed their safety
7 concerns at the hearing. However, A.A.C. R9-17-106 does not require an
8 applicant to offer any evidence of safety. Therefore, to the extent that the
9 Department's decision was based on safety, it went beyond the requirements of
10 the rule. Unfortunately, because a complete petition under A.A.C. R9-17-106(A)
11 does not even require the Petitioner to include any information on the safety of
12 marijuana use, much less for the targeted patients, the Department has
13 effectively denied Petitioner due process by denying the application on a basis
14 that Petitioner had no opportunity to address.
- 15 9. A.A.C. R9-17-106(B)(3)(a) requires the Department to set a public hearing if it
16 determines that the requirements of subsection (B)(2) were met by the Petition.
17 Therefore, the only question at issue in determining whether a public hearing is
18 appropriate is whether the requirements of subsection (B)(2) have been met.
- 19 10. The Department does not dispute that the requirement of subsection (B)(2)(a)
20 was met. The only remaining question, then, is whether any evidence was
21 provided with the Petition that would go to establish that marijuana use either
22 treats the illness (which was not argued) or offers a therapeutic or palliative
23 benefit for PD sufferers. This evidence is not required to be of the kind a
24 physician would rely on or the kind that the FDA would rely on. It is only required
25 to be evidence. To establish this, one only need to review one of the articles, the
26 Israeli Study in Exhibit 2. Although a limited study that not all of the patients
27 could tolerate, it concluded, in part, that PD patients who could tolerate it
28 experiences "significant" motor improvement, "significant" improvement of their
29 sleep problems and pain, and, as a sop to those who balk at the lack of safety
30 requirements, observed no significant adverse effects. This is more than a
scintilla of evidence. It was conducted by medical professionals and published in

1 a peer-reviewed journal and its results are, as the article states, "significant." It
2 more than fulfills the requirement of A.A.C. R9-17-106(B)(2)(b). Therefore,
3 A.A.C. R9-17-106(B)(3) requires that the Petition be set for public hearing.

4 **ORDER**

5 **IT IS ORDERED** that Petitioner's appeal is granted and that a public hearing be
6 held on the issue of whether Parkinson's Disease should be added to the list of
7 debilitating conditions for which marijuana may be dispensed under the AMMA.

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9 *In the event of certification of the Administrative Law Judge Decision by the Director of the*
10 *Office of Administrative Hearings, the effective date of the Order will be the date of certification.*

11 Done this day, May 24, 2016.

12 /s/ Dorinda M. Lang
13 Administrative Law Judge

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15 Transmitted electronically to:

16 Dr. Cara Christ, Director
17 Arizona Department of Health Services