

JUN 4 - 2014

IN THE OFFICE OF ADMINISTRATIVE HEARINGS

**ADHS/Clerk of the Department
Administrative Counsel**

In the Matter of:

No. 2014A-MMR-0254-DHS

Arizona Cannabis Nurses Association,

ADMINISTRATIVE LAW JUDGE

Appellant.

DECISION

HEARING: March 26, May 13, 14 and 15, 2014

APPEARANCES: Kenneth A. Sobel, Esq. for Appellant; Gregory W. Falls, Esq. and Matthew A. Hesketh, Esq. for the Department of Health Services

ADMINISTRATIVE LAW JUDGE: Thomas Shedden

FINDINGS OF FACT

1. On January 29, 2014, the Arizona Department of Health Services ("Department") issued a Notice of Hearing setting the above-captioned matter for hearing at 1:00 p.m. March 26, 2014, at the Office of Administrative Hearings in Phoenix, Arizona.

2. The Notice of Hearing provides that the hearing was set to consider the appeal of the Department's January 14, 2014 denial of the petition to add Post Traumatic Stress Disorder ("PTSD") to the list of debilitating medical conditions set forth in ARIZ. REV. STAT. section 36-2801(3).¹

¹ Ariz. Rev. Stat. section 36-2801.01 shows that the "denial of a petition is a final decision of the [D]epartment subject to judicial review pursuant to [ARIZ. REV STAT] title 12, chapter 7, article 6. Jurisdiction and venue are vested in the superior court." Consequently, the undersigned Administrative Law Judge issued an Order directing the parties to file memoranda addressing the Office of Administrative Hearings' ("OAH") jurisdiction to hear this appeal

The Department filed a memorandum asserting that the OAH has jurisdiction to hear the appeal. Appellant did not file a memorandum. In light of the Department's position, the matter was convened for hearing as scheduled.

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1 3. Appellant Arizona Cannabis Nurses Association presented the testimony
2 of its president Heather Manus, R.N., Richard Strand, M.D., Edith Lynn Edde, D.O.,
3 Gina Mecagni, M.D., Ricardo Pereyda, and Lezli Engelking

4 4 The Department presented the testimony of its Deputy Director Cara
5 Christ, M.D. and Doug Campos-Outcalt, M.D.

6 5. On July 25, 2013, the Department received Appellant's Petition to add
7 PTSD to the list of debilitating conditions for which medical marijuana may be
8 dispensed.

9 6. The Department determined that the Petition contained the information
10 required by ARIZ. ADMIN. CODE section 9-17-106(A).

11 7. The Department is required to hold a public hearing on petitions for which
12 the petitioner has provided evidence that: (1) the medical condition impairs a sufferer's
13 ability to accomplish the activities of daily living; and (2) marijuana usage provides a
14 palliative benefit to an individual suffering from the medical condition. For petitions that
15 do not meet these requirements, the Department is required to provide the petitioner
16 the specific reason for the Department's determination and to provide the petitioner
17 with information on obtaining judicial review of the Department's decision. ARIZ. ADMIN.
18 CODE § 9-17-106(B).

19 8. The Department's Medical Advisory Committee ("Committee") evaluated
20 the Petition and voted to set the Petition for a public hearing.

21 9. The Department notified Appellant that the Petition would be set for a
22 public hearing, which was conducted on October 29, 2013 ²

23 10. At the instant hearing, Dr. Christ testified that the Committee voted to hold
24 a public hearing on the Petition even though the Department had determined that
25 Appellant's Petition did not show that marijuana has a palliative effect on PTSD. At the
26 hearing, the Department acknowledged that by setting the Petition for public hearing it
27 had not properly followed the rules, but Appellant agreed to waive any objection.

28 11. At the public hearing, the Department accepted public comments and it
29 accepted additional scientific articles related to marijuana's effect on PTSD. The
30

1 Department also accepted written public comments, including comments through an
2 internet portal.

3 12. The Department received about 700 public comments supporting the effort
4 to add PTSD to the list of debilitating conditions, with only two comments opposing the
5 addition. Most of the comments were from PTSD sufferers or their family members who
6 have experienced or seen that marijuana alleviates the symptoms of PTSD.

7 13. After the public hearing, the Department had the University of Arizona's
8 College of Public Health (the "U of A") conduct an evidence review of the medical
9 literature regarding the benefits and harms of marijuana for treatment of PTSD. The U
10 of A had conducted a similar evidence review in 2012 and its 2013 review was
11 prepared as an update of the 2012 review.

12 14. In December 2013, the U of A produced a report entitled "Medical
13 Marijuana for the Treatment of Post-Traumatic Stress Disorder" summarizing its
14 findings (the "2013 Report") Dr. Campos-Outcalt was the principal
15 investigator/reviewer and the author of both the 2012 Report and the 2013 Report.

16 15. Dr. Campos-Outcalt conducted his reviews by searching medical
17 databases for articles reporting on studies of adults with PTSD. The search was
18 restricted to English language studies only. A complete list of the search terms is
19 provided in Exhibits C (2013 Report) and D (2012 Report).

20 16. Dr. Campos-Outcalt determined that only six studies met all the required
21 search criteria, whereas eighty-eight did not.³

22 17. Dr. Campos-Outcalt assessed the quality of the six studies that met all the
23 search criteria. Dr. Campos-Outcalt's assessment was based on both the type of study
24 (e g., randomized controlled trial; case series) and by reference to generally accepted
25 principles for the evaluation of scientific studies. See Exhibit C, Appendices 2
26 (Taxonomy of study designs) and 3 (GRADE Method to assess overall quality of
27
28

29 ² Petitions to add two other conditions were considered at the same public hearing.

30 ³ Exhibit C at Tables 1 and 2 provide Dr. Campos-Outcalt's assessment of the six studies meeting the search criteria and a listing of the studies that did not meet those criteria.

1 evidence); and Exhibits L (Quality Rating Criteria for Case Control Studies) and M
2 (Quality Rating Criteria for Cohort Studies).⁴

3 18. After receiving the 2013 Report, the Committee determined that because
4 marijuana has not been subjected to any high quality, scientifically controlled testing in
5 humans, there was a lack of evidence to support adding PTSD to the list of debilitating
6 conditions. Consequently, the Committee recommended that the Department's Director
7 deny Appellant's Petition.

8 19. In its recommendation, the Committee also wrote that there was a growing
9 body of evidence concerning the potential effects of cannabinoids on PTSD that raised
10 valid clinical questions that need to be investigated. They went on to write that given
11 this evidence and that several states have approved medical marijuana for PTSD, the
12 Committee hoped that a randomized, controlled study might be conducted to further
13 investigate this question.

14 20. Dr. Christ testified that the Committee did not intend its comments to be
15 read as requiring that marijuana be tested in humans or that only randomized,
16 controlled trials would meet the applicable rule. Dr. Christ further explained that the
17 language regarding randomized, controlled studies was added to the Committee's
18 recommendation in an effort to support research being proposed by Dr. Sue Sisley.

19 21. Eleven states have approved medical marijuana for the treatment of
20 PTSD.

21 22. In a letter dated January 14, 2014, the Department's Director informed
22 Appellant that its Petition had been denied because there was insufficient evidence to
23 support adding PTSD to the list of debilitating medical conditions.

24 Dr. Christ's Testimony

25 23. The Director's decision to deny Appellant's Petition was based on the
26 Department's determination that Appellant had not demonstrated that marijuana
27 provides a palliative benefit to people suffering from PTSD.

28 24. The Committee agreed that PTSD is a condition that impairs the sufferer's
29 ability to accomplish the activities of daily living.

30 ⁴ Similar Quality Rating Criteria exist for other types of studies

1 and Testing Committee from 1992 to 2000, and a member of the United States Olympic
2 Team Medical Staff during the 2000 Olympics.

3 51. Dr. Strand's daughter is an anesthesiologist who recommends medical
4 marijuana for patients with chronic pain and it works for that condition.

5 52. Dr. Strand, with some other doctors, took part in Arizona's lottery for a
6 dispensary license, but they were not selected.

7 53. PTSD is common and any stressful event can cause it. Most people get
8 over the stressful event, which Dr. Strand characterized as extinguishing the "toxic"
9 memory. Those who do not extinguish these memories can suffer a physical or
10 emotional response to an inappropriate stimulus at a later time.

11 54. Dr. Strand's review of the medical literature shows that pharmacological
12 treatments for PTSD are not effective for everyone. Selective serotonin reuptake
13 inhibitors ("SSRI") such as Zoloft or Paxil can help, but these have side effects
14 including grogginess and effects on sexual performance. Anti-anxiety medications can
15 also be helpful. But these types of medications can lead to increased suicidal ideations,
16 and there is risk of overdosing.

17 55. There have been studies on the toxicity of marijuana, and there are no
18 reported cases of overdosing on marijuana, so it is safe from that stand point. And, in
19 New Mexico over 3000 PTSD sufferers have used medical marijuana without any
20 reported adverse effects.

21 56. Dr. Strand's opinion was that medical marijuana "definitely" has a
22 palliative benefit for PTSD sufferers, which is supported by his review of the recent
23 medical literature on this issue. Dr. Strand acknowledged however that marijuana may
24 not have a palliative benefit for all PTSD sufferers and that "conventional" medicine
25 may work for some PTSD sufferers.

26 57. Dr. Strand also testified that marijuana also may have a therapeutic effect
27 by helping to extinguishing "toxic" memories and that recent research is showing that
28 the endocannabinoid system may have an important role in the extinction of toxic
29 memories.

1 84. Mr. Pereyda had been “hooked” on these pills, but since he started using
2 medical marijuana he no longer uses the prescription drugs.

3 85. Mr. Pereyda acknowledged that he still has some issues related to his
4 PTSD and that he has suffered panic attacks since he started using medical marijuana,
5 but these attacks are less frequent and less severe than those that he previously
6 experienced

7 86. Mr. Pereyda has not suffered any side effects from his medical marijuana
8 use

9 87. Mr. Pereyda knows other veterans with PTSD for whom medical marijuana
10 has been a tremendous help.

11 Ms. Engelking’s Testimony

12 88. Ms. Engelking is the executive director of the Bloom Dispensary.

13 89. Ms. Engelking was a pharmaceutical sales rep for about thirteen years,
14 during which time she interacted with over 600 doctors’ offices.

15 90. Ms. Engelking testified as to the dangers of prescription medications and
16 the operations at Bloom Dispensary.

17 CONCLUSIONS OF LAW

18 1 Appellant bears the burden of proof and the standard of proof on all
19 issues in this matter is that of a preponderance of the evidence. ARIZ. ADMIN. CODE § 2-
20 19-119.

21 2 A preponderance of the evidence is:

22 The greater weight of the evidence, not necessarily established by the
23 greater number of witnesses testifying to a fact but by evidence that
24 has the most convincing force; superior evidentiary weight that, though
25 not sufficient to free the mind wholly from all reasonable doubt, is still
26 sufficient to incline a fair and impartial mind to one side of the issue
27 rather than the other.

28 BLACK’S LAW DICTIONARY 1301 (9th ed. 2009).

29 3 “A [rule] is to be given such an effect that no clause, sentence or word is
30 rendered superfluous, void, contradictory or insignificant.” *Guzman v. Guzman*, 175
Ariz. 183, 187, 854 P.2d 1169,1173 (App. 1993); *Gutierrez v. Industrial Commission of*

1 *Arizona*, 226 Ariz 395, 249 P.3d 1095 (2011)(statutes and rules are construed using
2 the same principles)

3 4. Among other things, a petitioner to add a new condition must provide the
4 Department with:

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

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

12 ARIZ. ADMIN. CODE § 9-17-106 (A).

13 5. The Department's determination that Appellant did not show that
14 marijuana usage provides a palliative benefit to those who suffer from PTSD was based
15 on its review of peer-reviewed articles. By limiting its evaluation to those articles, the
16 Department has interpreted the applicable rules in a manner that leaves ARIZ. ADMIN.
17 CODE section 9-17-106(A)(6) with no significance. Consequently, the Department's
18 interpretation of the rule is not valid.

19 6. At the hearing, there was substantial evidence showing that PTSD
20 sufferers receive a palliative benefit from marijuana use. There was also substantial
21 evidence showing that medical professionals rely on patients' feedback when
22 determining the appropriate treatments and that the practice of off-label prescribing is
23 predicated on such feedback. In addition, Drs. Strand, Edde and Mecegni, and Ms.
24 Manus all provided credible testimony showing medical marijuana provides a palliative
25 benefit to PTSD sufferers.⁷

26 7. The preponderance of the evidence shows that marijuana use provides a
27 palliative benefit to those suffering from PTSD.

28 8. Consequently, Appellant's appeal should be granted and PTSD should be
29 added to the list of debilitating conditions for which marijuana may be dispensed.

30 ⁷ Although Dr. Sisley did not testify, in a video clip admitted into evidence, she expressed her opinion
that marijuana has a palliative benefit for PTSD sufferers.

ORDER

1
2 **IT IS ORDERED** that Appellant's appeal is granted and that PTSD is added to
3 the list of debilitating conditions for which marijuana may be dispensed
4 *In the event of certification of the Administrative Law Judge Decision by the Director of*
5 *the Office of Administrative Hearings, the effective date of the Order will be five days*
6 *after the date of that certification.*

7 Done this day, June 4, 2014.

8 /s/ Thomas Shedden
9 Thomas Shedden
10 Administrative Law Judge

11 Transmitted electronically to:

12 William Humble, Director
13 Arizona Department of Health Services
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