Recommended decision awaiting final administrative action as of 6/5/14 DATE

IN THE OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of: Arizona Cannabis Nurses Association, Appellant.	**No. 2014A-MMR-0254-DHS** **ADMINISTRATIVE LAW JUDGE 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]

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

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

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

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

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

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

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

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

11. At the public hearing, the Department accepted public comments and it accepted additional scientific articles related to marijuana's effect on PTSD. The Department also accepted written public comments, including comments through an internet portal.

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

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

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

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

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

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

17. Dr. Campos-Outcalt assessed the quality of the six studies that met all the search criteria. Dr. Campos-Outcalt's assessment was based on both the type of study (e.g., randomized controlled trial; case series) and by reference to generally accepted principles for the evaluation of scientific studies. *See* Exhibit C, Appendices 2 (Taxonomy of study designs) and 3 (GRADE Method to assess overall quality of evidence); and Exhibits L (Quality Rating Criteria for Case Control Studies) and M (Quality Rating Criteria for Cohort Studies).[4]

18. After receiving the 2013 Report, the Committee determined that because marijuana has not been subjected to any high quality, scientifically controlled testing in

[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.
[4] Similar Quality Rating Criteria exist for other types of studies.

humans, there was a lack of evidence to support adding PTSD to the list of debilitating conditions. Consequently, the Committee recommended that the Department's Director deny Appellant's Petition.

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

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

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

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

Dr. Christ's Testimony

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

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

25. The Committee was unanimous in its decision to recommend that Appellant's Petition be denied.

26. Dr. Christ testified that the six articles that Dr. Campos-Outcalt determined met the applicable search criteria were not persuasive because the articles were not of

sufficient quality or did not actually show that marijuana had a palliative benefit to PTSD sufferers.[5]

27. The Committee consists of eleven doctors (all M.D.s), with Dr. Christ serving as its chair. These doctors have diverse backgrounds covering many disciplines.

28. Many of the Department's decisions are based on scientific or medical evidence using the same method that was applied to Appellant's Petition. The Committee holds regular meetings and it provides advice to the Director on issues in addition to Petitions for the listing of debilitating conditions.

29. Dr. Christ testified that the Department errs on the side of holding a public hearing rather than rejecting petitions that may not meet the applicable rules because holding a public hearing allows more evidence to be considered.

30. The Department wants to be careful before adding any new debilitating conditions to the list because there is no method to take a condition off that list.

31. Dr. Christ was of the opinion that the Committee has a good balance of doctors, whereby some are pro-medical marijuana, some against it, and some who want to see the evidence.

Dr. Campos-Outcalt's Testimony

32. Dr. Campos-Outcalt testified as to the methods he used to locate and assess studies related to marijuana and PTSD and as to the strengths and weaknesses of various types of studies. Dr. Campos-Outcalt also provided his opinion as to the quality of each of the six studies that met all the search criteria.

33. Dr. Compos-Outcalt's role was limited to locating and assessing these studies and he did not participate in the Department's decision to deny Appellant's Petition.[6]

34. Dr. Campos-Outcalt did testify however, that the standards used in evidence based research were not necessarily those used to develop clinical guidelines for standard-of-care determinations. According to Dr. Compos-Outcalt, the preference

[5] Dr. Christ's opinion was that synthetic cannabinoids do not meet the definition of marijuana.
[6] Dr. Campos-Outcalt was present at the Committee meeting during which the Petition was considered, but solely to answer any questions the members may have had regarding his work.

is to have complete evidence, but there are times when standard-of-care determinations are made on incomplete evidence with those determinations subject to change as more evidence becomes available.

Ms. Manus's Testimony

35. About thirteen years ago, Ms. Manus was attacked and almost killed, resulting in her suffering from PTSD. For five years, Ms. Manus took a "cocktail" of prescription pharmaceuticals that had side effects including a loss of sex drive and leaving her in a "zombie-like" state. These side effects ruined her marriage and left her unable to properly care for her children. Ms. Manus cannot recall years of her children's lives from the time of her "zombie-like blackouts."

36. Ms. Manus made multiple suicide attempts, which would cause her doctor to increase her prescription-drug dosages.

37. Ms. Manus went online where she learned that one of these prescription drugs (Zoloft) carried a warning showing that it increased the risk of suicide. She then decided to get off the prescription drugs, which she did.

38. Ms. Manus uses medical marijuana for chronic pain and that usage effectively eliminates much of her anxiety and "releases [the] stresses" her attack left her with, including a fear of men and anxiety in social settings. The medical marijuana allows her to function, whereas on the prescription medications, she could not get out of bed.

39. Ms. Manus provided credible testimony that medical marijuana changed her life for the better and that it has relieved her PTSD symptoms.

40. Ms. Manus wants others who suffer from PTSD, especially veterans, to be able to receive the same benefit that she has received.

41. After learning about the side effects of the prescription drugs she was taking, Ms. Manus went to nursing school and in 2009 became a registered nurse.

42. Ms. Manus worked as a home-health nurse, where she had patients who used marijuana to treat their PTSD. Ms. Manus's clinical experience shows that marijuana helps with the symptoms of PTSD.

43. Ms. Manus's opinion was that the best way to determine whether a drug has a palliative effect is to hear from the patients who are using the drug. Ms. Manus

often hears from PTSD sufferers who have found that marijuana provides them a palliative benefit.

44. Ms. Manus's opinion was that the comments received by the Department are important in showing that marijuana provides a palliative benefit those suffering from PTSD.

45. Ms. Manus's opinion was that researchers accept that marijuana provides a benefit to PTSD sufferers and are focusing their studies on determining why it works, with a particular focus on the effect of marijuana on biochemical pathways.

46. Ms. Manus is the medical director for a dispensary in New Mexico, which requires her to stay informed about medical-marijuana issues and current research.

47. Since 2009, medical marijuana has been approved in New Mexico for patients with PTSD, and in 2013, by a unanimous vote New Mexico's medical advisory board denied a petition to remove PTSD from the approved list.

48. Through her work in New Mexico, Ms. Manus has spoken to members of the state's medical advisory board and other nurses, and she knew of no adverse outcomes from the use of medical marijuana in New Mexico.

49. Ms. Manus acknowledged that the sativa strain of marijuana might cause anxiety in a PTSD sufferer, whereas the indica strain does not have that affect.

Dr. Strand's Testimony

50. Dr. Strand completed medical school in 1969 and his residency in 1974. He was the Chairman of the United States Track & Field Substance Abuse, Education and Testing Committee from 1992 to 2000, and a member of the United States Olympic Team Medical Staff during the 2000 Olympics.

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

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

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

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

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

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

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

58. Dr. Strand's opinion was that medical marijuana is reasonably safe, especially when compared to the prescription drugs that are currently being used to treat PTSD.

59. Dr. Strand acknowledged that there are risks associated with marijuana use, but he added that over thousands of years, millions of people have used marijuana and these people are not "dropping dead," whereas the need of PTSD sufferers is great.

Dr. Edde's Testimony

60. Dr. Edde practiced in the area of neonatology and was an Assistant Professor of Pediatrics at the University of Arizona until 2011. While at the University, she conducted plant research, taught, and worked as a clinician.

61. Dr. Edde had reviewed the studies about which Dr. Campos-Outcalt testified and she has done additional research on PTSD.

62. Dr. Edde testified at the Department's public hearing, but was allotted only two minutes for her testimony.

63. Dr. Edde's opinion was that a palliative benefit may be seen by past experience, medical journals, and the patients' reports. For any medication, the doctor needs to listen to the patient and change what does not work, but keep doing what does work.

64. Dr. Edde's opinion was that the public comments received by the Department are evidence that marijuana provides a palliative benefit to those with PTSD and that these comments are of sufficient quality that a doctor would use them.

65. Dr. Edde's opinion was that marijuana provides a palliative benefit for PTSD and that it is safe and effective. But each person is unique, so it varies from patient to patient.

66. According to Dr. Edde, risk versus benefit is huge in medicine, which is especially true for an intensivist such as herself: either something works or it does not work. Neonatology is based on doing what works and there was not time to get studies done. A neonatologist cannot go to the lab first, because the baby will die while waiting for results – they see what works and the controlled studies come later.

67. Dr. Edde testified that generally the studies are showing that there is a benefit to the use of marijuana for PTSD and that the benefit outweighs the risks.

68. Dr. Edde was of the opinion that it is not known why marijuana is effective for PTSD sufferers. Most of the current research work is looking at bio-pathways and the trending information shows that this will explain why marijuana works.

69. Dr. Edde was of the opinion that the Committee should not have excluded studies conducted on animals because, although going from a mouse to man is a huge leap, essentially all medical research proceeds along this path and you will not get to man if you do not first look at the mouse.

70. Dr. Edde's opinion was that PTSD should be added to the list of debilitating conditions. The risk is rather low and marijuana is safe and effective when compared to the medications that are now being used to treat PTSD.

Dr. Mecagni's Testimony

71. Dr. Mecagni has been an emergency room doctor for the last ten years and she is also the Medical Director for a marijuana dispensary.

72. There is an epidemic of PTSD among veterans. PTSD is a "horrible" mental illness and the risk extends to the community because PTSD can lead to violence.

73. There are only two FDA approved treatments for PTSD, sertraline (Zoloft) and Paxil, all other treatments, including benzodiazepines, are off-label uses. All of these drugs have bad side effects including a risk of suicide, and Zoloft does not appear to work, especially with combat-related PTSD.

74. Marijuana is a safe plant that does not affect the brain stem so the respiratory system is not affected. There are no reported marijuana overdoses leading to death and there is nothing showing that the risk of suicide goes up. Marijuana's side effects are benign, but the sativa strain is not a good choice for PTSD sufferers.

75. Dr. Mecagni has done research on the cellular biology of the endocannabinoid system (how it works) and on the experiential, observational studies of marijuana in the general population.

76. There are receptors in the hippocampus that control, or are related to, the fight-or-flight response. PTSD comes about from maladaptive responses to the flight-or-fight stimuli and with memory retrieval and dealing with stressful situations. The endocannabinoid system is connected to this part of the brain's neurochemistry and is active in memory retrieval and retention.

77. Dr. Mecagni agreed that whether marijuana works for those with PTSD is not in question and that how it works is the focus of research. Her opinion was that the current research shows that the endocannabinoid system is involved with the aberrant pathways that develop with PTSD in response to stress and that exogenous cannabinoid mitigates that effect.

78. Dr. Mecagni's opinion is that marijuana is safe and that, to a reasonable degree of scientific and medical certainty, observational studies show it is effective for the treatment of PTSD.

79. As a clinician Dr. Mecagni agrees that double blind studies are the best evidence, but there are none for marijuana. Moreover, off-label drug uses are not based on double blind studies, but rather are based on observations showing that the drug is effective for the off-label condition.

Mr. Pereyda's Testimony

80. Mr. Pereyda is a combat veteran of the United States Army, having served as a military policeman in Iraq.

81. Mr. Pereyda suffers from PTSD and other maladies including chronic pain. Mr. Pereyda holds a patient's qualifying card that was issued based on his chronic pain.

82. Mr. Pereyda had used medical marijuana every day in the four years prior to the hearing and found that using medical marijuana alleviated his PTSD and that it "helped tremendously."

83. Prior to his use of medical marijuana, Mr. Pereyda used prescription medications for his PTSD, including valium, Xanax, and Paxil. These prescription drugs did not alleviate his symptoms and they had side effects that he found to be unpleasant, including lethargy and reduced libido.

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

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

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

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

Ms. Engelking's Testimony

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

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

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

CONCLUSIONS OF LAW

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

2. A preponderance of the evidence is:

> The greater weight of the evidence, not necessarily established by the greater number of witnesses testifying to a fact but by evidence that has the most convincing force; superior evidentiary weight that, though not sufficient to free the mind wholly from all reasonable doubt, is still sufficient to incline a fair and impartial mind to one side of the issue rather than the other.
>
> BLACK'S LAW DICTIONARY 1301 (9th ed. 2009).

3. "A [rule] is to be given such an effect that no clause, sentence or word is 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 Arizona*, 226 Ariz. 395, 249 P.3d 1095 (2011)(statutes and rules are construed using the same principles).

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

> 6. A summary of the evidence that the use of marijuana will provide therapeutic or palliative benefit for the medical condition or a treatment of the medical condition; and
> 7. 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.
>
> ARIZ. ADMIN. CODE § 9-17-106 (A).

5. The Department's determination that Appellant did not show that marijuana usage provides a palliative benefit to those who suffer from PTSD was based on its review of peer-reviewed articles. By limiting its evaluation to those articles, the Department has interpreted the applicable rules in a manner that leaves ARIZ. ADMIN.

CODE section 9-17-106(A)(6) with no significance. Consequently, the Department's interpretation of the rule is not valid.

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

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

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

ORDER

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

Done this day, June 4, 2014.

/s/ Thomas Shedden
Thomas Shedden
Administrative Law Judge

Transmitted electronically to:

William Humble, Director
Arizona Department of Health Services

[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.