

RECEIVED
SUPREME COURT
STATE OF WASHINGTON

2008 OCT -6 P 4:01

NO. 80644-6Y RONALD R. CARPENTER

CLERK *b/h*

SUPREME COURT OF THE STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

v.

WASHINGTON STATE, DEPARTMENT OF HEALTH, MEDICAL
QUALITY ASSURANCE COMMISSION,

Respondent.

**SUPPLEMENTAL BRIEF OF RESPONDENT, DEPARTMENT OF
HEALTH, MEDICAL QUALITY ASSURANCE COMMISSION**

ROBERT M. MCKENNA
Attorney General

KIM O'NEAL, WSBA #12939
Senior Counsel
PO Box 40100
Olympia, WA 98504-0100
(360) 664-9006

ORIGINAL

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	COUNTERSTATEMENT OF THE CASE	1
	A. The LISTEN Device	1
	B. Dr. Ames' Treatment Of Patient One	3
	C. The Adjudicative Hearing.....	6
	D. Procedural History	8
III.	COUNTERSTATEMENT OF THE ISSUES	8
IV.	ARGUMENT	8
	A. The Standard Of Review Is Highly Deferential, Recognizing The Commission's Authority To Discipline Dr. Ames For Unprofessional Conduct.	8
	B. Due Process Is Satisfied When The Commission Uses Its Specialized Knowledge And Expertise To Evaluate The Evidence And To Draw Inferences From The Facts In Medical Disciplinary Proceedings.	9
	1. The Legislature Authorized The Commission To Adopt, Interpret, And Enforce The Standard Of Care For The Medical Profession.	10
	2. Expert Testimony Is Not Always Necessary In Medical Disciplinary Matters Because The Commission, As A Whole, Has The Specialized Knowledge, Expertise, And Experience To Evaluate The Evidence.	12

3.	Additional Expert Testimony Is Unnecessary When The Evidence Clearly Shows That A Doctor's Practice Fell Below The Standard Of Care.	16
C.	The Department's First Amended Statement Of Charges Provided Notice Of The Issues To Be Litigated.....	18
V.	CONCLUSION	20

TABLE OF AUTHORITIES

Cases

<i>Ancier v. Dep't of Health</i> , 140 Wn. App. 564, 166 P.3d 829 (2007).....	9
<i>Brown v. Dep't of Health</i> , 94 Wn. App. 7, 972 P.2d 101, <i>review denied</i> , 138 Wn.2d 1010 (1999).....	9, 14
<i>City of Marysville v. Puget Sound Air Pollution Control Agency</i> , 104 Wn.2d 115, 702 P.2d 469 (1985).....	18, 19
<i>Davidson v. State</i> , 33 Wn. App. 783, 657 P.2d 810, <i>review denied</i> , 99 Wn.2d 1011 (1983).....	14
<i>Eidson v. Dep't of Licensing</i> , 108 Wn. App. 712, 32 P.3d 1039 (2001).....	19
<i>Harris v. Robert C. Groth, M.D. Inc.</i> , 99 Wn.2d 438, 663 P.2d 113 (1983).....	13, 16
<i>Heinmiller v. Dep't of Health</i> , 127 Wn.2d 595, 903 P.2d 433 (1995).....	8
<i>In re Ruffalo</i> , 390 U.S. 544, 88 S. Ct. 1222, 20 L. Ed. 2d 117 (1968).....	18
<i>Motley-Motley, Inc. v. State</i> , 127 Wn. App. 62, 110 P.3d 812 (2005).....	9
<i>Nationscapital Mortg. Corp. v. Dep't of Fin. Insts.</i> , 133 Wn. App. 723, 137 P.3d 78 (2006).....	13
<i>Nisqually Delta Ass'n v. City of DuPont</i> , 103 Wn.2d. 720, 696 P.2d 1222 (1985).....	12

<i>Nguyen v. Medical Quality Assurance Comm'n</i> , 144 Wn.2d 516, 29 P.3d 689 (2001).....	9
<i>Sherman v. State</i> , 128 Wn.2d 164, 905 P.2d 355 (1995).....	10
<i>Skidmore v. Swift</i> , 323 U.S. 134, 65 S. Ct. 161, 89 L. Ed. 124 (1944).....	13
<i>Univ. of Wa. Med. Ctr. v. Dep't of Health</i> , No. 80264-5, 2008 WL 2686112 (July 10, 2008).....	9
<i>Wa. State Med. Disciplinary Bd. v. Johnston</i> , 99 Wn.2d 466, 663 P.2d 457 (1983).....	9, 14
<i>Wa. Water Power Co. v. Wa. State Human Rights Comm'n</i> , 91 Wn.2d 62, 586 P.2d 1149 (1978).....	13
<i>Wolff v. McDonnell</i> , 418 U.S. 539, 94 S. Ct. 2963 (1974).....	10
<i>Young v. Key Pharmaceuticals, Inc.</i> , 112 Wn.2d 216, 770 P.2d 182 (1989).....	16

Statutes

RCW 18.04.035	12
RCW 18.08.330	12
RCW 18.71.002	10, 11
RCW 18.71.003	10
RCW 18.71.015	11, 13, 14
RCW 18.71.017	14
RCW 18.96.040	12

RCW 18.130.010	11
RCW 18.130.020	11
RCW 18.130.050	14
RCW 18.130.050(8).....	6
RCW 18.130.080	14
RCW 18.130.090	6
RCW 18.130.095(3).....	6
RCW 18.130.180(1).....	6, 20
RCW 18.130.180(16).....	6, 20
RCW 18.130.180(4).....	6, 20
RCW 18.130.180(7).....	6, 20
RCW 18.220.030	12
RCW 19.16.280	12
RCW 28B.50.100.....	15
RCW 34.05.434	19
RCW 34.05.434(2)(f)-(h).....	19
RCW 34.05.452(5)(b).....	12
RCW 34.05.461(5).....	12
RCW 34.05.510	8
RCW 34.05.570(1)(a)	8
RCW 34.05.570(3)(d).....	9

RCW 43.101.380	16
RCW 43.21B.020.....	15
RCW 69.04.040(1).....	20
RCW 69.04.040(3).....	20
RCW 80.50.030	15
21 U.S.C. § 331(c)	6, 20

Other Authorities

<i>Webster's II New Riverside University Dictionary</i> (1994).....	2
---	---

Rules

RAP 13.7(d).....	1
------------------	---

Regulations

WAC 246-11.....	6
WAC 246-11-160(2).....	12
WAC 246-11-250.....	19
WAC 246-11-250(1)(b)	19
WAC 246-11-250(1)(c)	19

I. INTRODUCTION

This is Respondent's supplemental brief filed pursuant to RAP 13.7(d). The Court of Appeals affirmed, in an unpublished opinion, the Medical Quality Assurance Commission's Findings of Fact, Conclusions of Law, and Final Order (Final Order) determining that Dr. Ames' use of a Life Information System Ten (LISTEN) device violated the standard of care and created an unreasonable risk of harm to his patient. Expert testimony was unnecessary in this medical disciplinary proceeding. A layperson could evaluate the testimony and determine the impropriety of Dr. Ames' actions. Even so, there was expert testimony on the LISTEN device that did not substantiate Dr. Ames' claims regarding the device. Furthermore, the Commission could reach its conclusion by collectively drawing upon its specialized knowledge, expertise and experience to evaluate whether substantial evidence showed that Dr. Ames violated the acceptable standard of care. Dr. Ames received due process notice of the charges against him. For these reasons, the Commission requests that this Court affirm the Final Order of the Commission.

II. COUNTERSTATEMENT OF THE CASE

A. The LISTEN Device

Dr. Ames is a licensed physician who practices both traditional and alternative medicine. In approximately 1997, Dr. Ames purchased a

LISTEN device to assist him in his practice. Administrative Record (AR) 2088, 3065.¹ Per Dr. Ames, the LISTEN device is “nothing more than an ohmmeter² hooked up to a computer, and measures resistance at different acupuncture points.” AR 2086. Dr. Ames’ use of this machine was not based on actual knowledge, but on a general theory of how the machine should work. AR 2155-56, 2163. By his own admission, Dr. Ames was not familiar with the machine’s technology. AR 2102-03. Dr. Ames was also not aware of whether the LISTEN device was FDA approved. AR 2102-04, 2109.

In fact, no FDA clearance was ever obtained for the LISTEN device for any purpose. AR 2872. According to its developer, James Clark, the FDA rejected his request to clear the LISTEN device in 1992 because he included claims that the device was useful for acupuncture or “electrodermal screening.”³ AR 2870-71. Dr. Ames justified the device’s use by claiming that the software in the LISTEN device could analyze the various electrical signals from the patient and match those signals to various potential allergies such as to foods. AR 2152. Mr. Clark,

¹ Any reference to the administrative record as certified to the Court is hereinafter referred to as “AR”. Any reference to the Clerk’s Papers in this matter will be referred to as “CP”.

² An ohmmeter is an instrument for measuring the resistance of a conductor directly in ohms. *Webster’s II New Riverside University Dictionary* 817 (1994).

³ Electrodermal screening is used in alternative health care to take galvanic skin response measurements. AR 2840.

however, testified that such data is part of electrodermal screening, and the device was not cleared for electrodermal screening. AR 2928. The LISTEN device as sold by Clark's company could not diagnose, cure, or prevent any disease. AR 2906-07.

Yet, without sufficient understanding of the machine or its purpose, Dr. Ames used the LISTEN device on approximately 50% of his patients to assist him in treating their allergies. AR 2100, 2162. Dr. Ames believed the machine created imbalances in patients' bodies by sending an electrical signal through their skin, which could be captured and analyzed by the device's software. AR 2152-56. Dr. Ames' belief was based on the word of others who had used similar devices, but not the actual LISTEN device. AR 2179. Dr. Ames believed and told patients that the machine helped speed up his assessment of patient allergies. AR 2162. Some of his patients believed that the LISTEN device was used to test for allergies. AR 2698-2700, 2705-08, 2751-63. At least one of these patients believed that the machine helped diagnose and treat her allergies. AR 2740.

B. Dr. Ames' Treatment Of Patient One

On June 6, 2001, Patient One came to Dr. Ames complaining of hormone issues and fatigue. AR 2081, 2190. Dr. Ames ordered extensive laboratory work. AR 2082, 2191. When Patient One returned for the

results, Dr. Ames told him that he had a mineral imbalance, that his testosterone level should be higher, and that he possibly had metal poisoning. AR 2197-98, 2200-01. Dr. Ames also told Patient One that foods like eggs and mustard could be weakening his body. AR 2203-04. Prior to Dr. Ames' statement, Patient One had never been diagnosed as allergic to eggs or any other food, and had never had a reaction to eating eggs. AR 2204, 2269.

Dr. Ames said he had a machine that could be used to find out what was going on with Patient One's body. AR 2209. He told Patient One that the LISTEN device helped him make a diagnosis and that he could cure the egg allergy. AR 2208, 2214. Dr. Ames told Patient One that when he walked out the door, he would be rid of the egg allergy. AR 2208. Dr. Ames had Patient One lie on his back, hold the probe attached to the LISTEN device in his right hand, and hold his right arm out at a 90-degree angle. AR 2209-10. Dr. Ames then told Patient One to resist, while Dr. Ames tried to pull on his arm. AR 2210. Dr. Ames was purportedly unable to pull Patient One's arm down. AR 2210. Dr. Ames then typed the word "eggs" into the LISTEN device using the keyboard. AR 2210. Dr. Ames again asked Patient One to resist and tried to pull his arm down. AR 2214. This time, Dr. Ames could pull Patient One's arm down. AR 2210.

Dr. Ames treated Patient One for the supposed egg allergy by rolling him onto his stomach and thumping on his back with an acupressure device that had rubber tips on it. AR 2211. Dr. Ames then rolled Patient One over onto his back again and used the probe and the LISTEN device as he had before. AR 2211. This time, Dr. Ames purportedly could not pull Patient One's arm down. AR 2211. Dr. Ames told Patient One, "See, it's gone." AR 2211. Dr. Ames then performed the test again wrapping the probe in tissue paper and having Patient One hold the probe. AR 2215-16. When Patient One asked why Dr. Ames was doing this, Dr. Ames answered that he had done it for so long that he could do what the machine could do, and he did not need the machine anymore. AR 2215.

After this treatment, Dr. Ames advised Patient One that he should not eat any eggs for 24 to 48 hours or the treatment would not take. AR 2211. Patient One understood that Dr. Ames had diagnosed him as allergic to eggs, had provided treatment, and had cured him of his egg allergy. AR 2211-12, 2215, 2255, 2268. Patient One understood that he would be able to eat eggs and would have no allergic reaction. AR 2205, 2211-13, 2220. Dr. Ames told Patient One that he could only cure one allergy at a time and that he would need to return for additional visits to treat each allergy. AR 2212-13.

C. The Adjudicative Hearing

On July 9, 2002, the Department of Health (Department), under authorization provided by members of the Commission, issued a Statement of Charges against Dr. Ames.⁴ AR 3-6. On February 5, 2003, the Department filed an Amended Statement of Charges. AR 60-64. Among other charges⁵, the Amended Statement of Charges alleged that Dr. Ames' treatment of Patient One violated the Uniform Disciplinary Act (UDA) RCW 18.130.180(1), (4), and (16). *Id.* Specifically, the Department asserted that Dr. Ames' use of the LISTEN device on Patient One was below the standard of care, constituted moral turpitude, and was inefficacious. *Id.*

The administrative hearing began on January 13, 2006, and lasted five days. AR 1850. During the hearing, a panel of three Commission members heard the evidence and made the decision in the case. AR 2048. The panel members included one licensed physician, one certified

⁴ The Commission has panels, authorized under RCW 18.71.015, to conduct reviews, investigate matters, approve charges, and hear disciplinary proceedings. RCW 18.130.050; RCW 18.130.080. If the Commission determines that unprofessional conduct occurred, then it directs the Department to prepare a statement of charges. RCW 18.130.090. A presiding officer issues rulings on evidentiary, procedural, and policy matters. RCW 18.130.095(3); *see also* WAC 246-11. The hearing panel of the Commission makes the final determinations of unprofessional conduct. RCW 18.130.050(8).

⁵ The Amended Statement of Charges also alleged violations of RCW 18.130.180(7), 21 U.S.C. § 331(c) and RCW 69.04.040(1) and (3). These charges were dismissed during the administrative hearing, and are not the subject of this appeal.

physician assistant, and one public member, who was also a licensed attorney. *Id.*

At the hearing, both Dr. Ames and Patient One testified. AR 2077-2183, 2184-2275, 3026-3189. The Department put forth one witness relevant to the FDA clearance of the LISTEN device and an expert in biofeedback and psychophysiology, Dr. Richard A. Sherman, Ph.D. AR 2388-2434, AR 2282-2353. Dr. Ames submitted the expert testimony of Dr. David R. Martin, M.D. and James Clark, creator of the LISTEN device and expert in galvanic skin response. AR 2937-2997, AR 2838-2933, AR 2997-3014. Dr. Ames also called two other patients as both fact and character witnesses to his use of the LISTEN device. AR 2694-2766.

On May 30, 2004, the Commission entered a Final Order determining that Dr. Ames' use of the LISTEN device to assess and treat Patient One violated the standard of care and constituted promotion of an inefficacious device in violation of RCW 18.130.180(4) and (16). AR 1850-69. The Commission, however, found that Dr. Ames' use of the LISTEN device did not constitute an act of moral turpitude, dishonesty or corruption. AR 1863. It, therefore, dismissed the charge under RCW 18.130.180(1). The only sanction was to direct Dr. Ames to stop using the LISTEN device.

D. Procedural History

On judicial review, the Benton County Superior Court affirmed the Commission's Final Order. The Court of Appeals also affirmed the Commission's Final Order, and denied Dr. Ames' motion for reconsideration.

III. COUNTERSTATEMENT OF THE ISSUES

1. Whether a medical disciplinary board can determine that the standard of care was not met in this case without specific expert testimony?
2. Whether notice pleadings in administrative hearings satisfy statutory and constitutional due process requirements?

IV. ARGUMENT

A. The Standard Of Review Is Highly Deferential, Recognizing The Commission's Authority To Discipline Dr. Ames For Unprofessional Conduct.

Judicial review of an agency order is authorized under the Administrative Procedure Act (APA). RCW 34.05.510. Under the APA, a party challenging the validity of agency action bears the burden of demonstrating its invalidity. RCW 34.05.570(1)(a). The standard of review for an agency's factual findings is the "substantial evidence" test. Substantial evidence is evidence sufficient to persuade a fair-minded person of the truth of the finding. *Heinmiller v. Dep't of Health*, 127 Wn.2d 595, 607, 903 P.2d 433 (1995). This test is highly deferential to

the administrative fact-finder. *Motley-Motley, Inc. v. State*, 127 Wn. App. 62, 72, 110 P.3d 812 (2005). When reviewing an agency's factual findings, appellate courts do not reweigh the evidence; but instead are limited to assessing whether the evidence satisfies the applicable burden of proof. *Ancier v. Dep't of Health*, 140 Wn. App. 564, 574, 166 P.3d 829 (2007). Questions of law are reviewed under a *de novo* standard. RCW 34.05.570(3)(d); *Brown v. Dep't of Health*, 94 Wn. App. 7, 12, 972 P.2d 101, *review denied*, 138 Wn.2d 1010 (1999). Courts, however, defer to the agency's interpretation of its own laws and regulations, especially when the agency applies its experience, technical competency, and specialized knowledge to evaluate evidence. *Univ. of Wa. Med. Ctr. v. Dep't of Health*, No. 80264-5, 2008 WL 2686112, at *2 (July 10, 2008); *Wa. State Med. Disciplinary Bd. v. Johnston*, 99 Wn.2d 466, 482, 663 P.2d 457 (1983).

B. Due Process Is Satisfied When The Commission Uses Its Specialized Knowledge And Expertise To Evaluate The Evidence And To Draw Inferences From The Facts In Medical Disciplinary Proceedings.

Due process is met when adequate safeguards are provided to protect a health care professional from the erroneous deprivation of his license. *Nguyen v. Medical Quality Assurance Comm'n*, 144 Wn.2d 516, 524, 29 P.3d 689 (2001). It is a flexible concept, requiring such

procedural protections as the particular situation demands. *Sherman v. State*, 128 Wn.2d 164, 184, 905 P.2d 355 (1995); *Wolff v. McDonnell*, 418 U.S. 539, 556, 94 S. Ct. 2963 (1974). Nonetheless, the fundamental requirements of due process are notice and the opportunity to be heard. *Sherman*, 128 Wn.2d at 184. Due process is not violated when the Commission uses its statutory and legal authority to draw upon its expertise and experience to evaluate this evidence to determine whether a physician has committed unprofessional conduct. This point is especially true where, as in this case, a layperson could determine that the practitioner violated the acceptable standard of practice.

1. The Legislature Authorized The Commission To Adopt, Interpret, And Enforce The Standard Of Care For The Medical Profession.

To govern the competency and quality of all licensed physicians and physician assistants, the Legislature created the Medical Quality Assurance Commission. RCW 18.71.002. The Legislature created the Commission “to protect the public health, to promote the welfare of the state, and to provide an adequate public agency to act as a disciplinary body for the members of the medical profession licensed to practice medicine and surgery”. RCW 18.71.003. In order to achieve its stated purpose, the Legislature empowered the Commission with the authority to establish, monitor, and enforce “qualifications for licensing, consistent

standards of practice⁶, continuing competency mechanism, and discipline”. RCW 18.71.002.

The Commission consists of thirteen licensed physicians, two licensed physician assistants, and six public members. The Legislature specifically included public members on the Commission to ensure that patients are properly represented. Public members “give both the state and the public assurances of accountability and confidence in the various practices of health care”. RCW 18.130.010. They insert the patients’ perspective into disciplinary cases that an entire panel of practitioners could miss. Public members add an additional safeguard to ensure that healthcare professionals are accountable to both their peers and the public.

Each member of the Commission, including public members, has the same responsibilities of governing the profession. RCW 18.71.015. In order to act, the Legislature requires that the Commission, as a whole or in delegated panels of three, makes an affirmative majority decision. RCW 18.71.015. This ensures that no one member, be it a licensed physician or a public member, may make an individualized determination or import their personal opinion when disciplining the profession.

⁶ HB 1103, which was signed into law on March 25, 2008, defines “standards of practice” as “the care, skill, and learning associated with the practice of a profession.” RCW 18.130.020.

Health professions boards are not the only professional regulatory bodies required by statute to include public members. The Washington State Board of Accountancy and the State Board of Registration for Architects also include public members. See RCW 18.04.035 and 18.08.330. The State Board of Registration for Landscape Architects, the State Geologist Licensing Board, and the Collection Agency Licensing Board are all mandated by statute to include public members. See RCW 18.96.040, 18.220.030, and 19.16.280. Neither statute nor case law contains any requirement that expert testimony be presented to support findings of a violation of the standard of care for these professions.

2. Expert Testimony Is Not Always Necessary In Medical Disciplinary Matters Because The Commission, As A Whole, Has The Specialized Knowledge, Expertise, And Experience To Evaluate The Evidence.

As a Washington State agency, the Commission is statutorily authorized by the APA to rely on its expertise when adjudicating matters within their statutory purview. RCW 34.05.461(5); *see also* RCW 34.05.452(5)(b); WAC 246-11-160(2).⁷ When the agency bases its determination on factual matters, especially factual matters that are

⁷ This statutory authorization is not limited to the professional members of the health disciplinary boards and commissions, but is accorded to all administrative agencies to make use of their expertise. *Nisqually Delta Ass'n v. City of DuPont*, 103 Wn.2d 720, 725-26, 696 P.2d 1222 (1985).

complex, technical, and close to the heart of the agency's expertise, the courts provide substantial deference. *Nationscapital Mortg. Corp. v. Dep't of Fin. Insts.*, 133 Wn. App. 723, 737, 137 P.3d 78 (2006). The Commission is given such broad authority to formulate policies and promulgate rules because the members are in a better position to apply their specialized knowledge and the expertise necessary to achieve their intended statutory purpose than the courts or legislature. *See Skidmore v. Swift*, 323 U.S. 134, 65 S. Ct. 161, 89 L. Ed. 124 (1944); *Wa. Water Power Co. v. Wa. State Human Rights Comm'n*, 91 Wn.2d 62, 69, 586 P.2d 1149 (1978).

Expert testimony is unnecessary in medical disciplinary proceedings, even when a Commission panel is not comprised solely of licensed physicians. Generally, expert testimony is required when an essential element in the case is best established by an opinion which is beyond the expertise of a layperson. *Harris v. Robert C. Groth, M.D. Inc.*, 99 Wn.2d 438, 449, 663 P.2d 113 (1983) (citing 5A Karl Tegland, *Washington Practice: Evidence* § 300 (1982)). However, as members of the Commission, with full responsibility for regulating and governing licensed physicians, public members are not laypersons. Public members have the same responsibilities as practitioners for governing the profession. RCW 18.71.015. They participate in rulemaking that governs

the profession. RCW 18.71.017. They attend Commission meetings, and have full voting rights. RCW 18.71.015. Public members also participate in panels to conduct case reviews, investigate matters, approve charges, and hear disciplinary proceedings. RCW 18.130.050; RCW 18.130.080. Based on these duties, public members of the Commission, unlike the average citizen, develop specialized knowledge and expertise of the proper standards of practices for these health care practitioners. It is their job to know and apply these standards in a medical discipline hearing.

Washington courts have already recognized that the Commission, comprised of medical practitioners and public members who are highly knowledgeable about the field, is competent to determine the propriety of medical conduct without additional expert testimony. *Johnston*, 99 Wn.2d at 483; *Brown*, 94 Wn. App. at 14.; *Davidson v. State*, 33 Wn. App. 783, 785, 657 P.2d 810, *review denied*, 99 Wn.2d 1011 (1983). The courts acknowledged that because the Commission has the authority to regulate the medical profession, the members of the Commission must be competent to know and apply the standards for proper medical conduct in the State of Washington. *See Davidson*, 33 Wn. App. at 783.

The Legislature empowered the Commission, including public members, with the authority and ability to use its specialized knowledge and expertise to determine whether a healthcare practitioner violated the

appropriate standard of practice. Requiring separate expert testimony as to the standard of care in each and every case would take away from the Commission's authority to set the appropriate standards and defeat the Commission's primary purpose of protecting the public and the standing of the profession in the eyes of the public.

Further, in all disciplinary cases, including standard of care matters, the Commission panel does not sit as a jury, rather it is the decision-making body on both the law and facts. It is the Commission panel's role to hear the evidence, deliberate and rule on the case. While members of the Commission, regardless of whether they are a licensed physician or a public member, are presumed to know and apply the relevant standards of care, they do not substitute their own knowledge for that of the evidence presented during hearing. Instead, they collectively apply the knowledge, expertise, and experience, acquired in their professional lives and as members of the regulatory authority, to the evidence presented at hearing in order to determine whether, clearly and convincingly, the licensee committed unprofessional conduct.⁸

⁸ Many state regulatory boards are required by statute to have some members with particular expertise not shared by all members. For example, the boards of trustees of technical colleges must have at least one member from business and one member from labor. RCW 28B.50.100. The Pollution Control Hearings Board must have one member who is an attorney licensed to practice and engaged in practice at the time of appointment. RCW 43.21B.020. The Energy Facility Site Evaluation Council is required to be made up of representatives of various agencies with different areas of expertise. RCW 80.50.030. The Criminal Justice Training Commission hearing panels for

3. Additional Expert Testimony Is Unnecessary When The Evidence Clearly Shows That A Doctor's Practice Fell Below The Standard Of Care.

In this matter, the Commission was entitled to apply its expertise and specialized knowledge from governing the profession to determine that Dr. Ames' violated the standard of care. Even without expert testimony that explicitly stated that Dr. Ames' use of the LISTEN device fell below the standard of care, the administrative record clearly shows Dr. Ames' use of the LISTEN device was inefficacious and negligent. As Dr. Ames acknowledges, even in medical malpractice cases, no expert testimony is necessary when substandard practice is readily observable by the mere facts in the case. *Harris*, 99 Wn.2d at 449. "[W]here the want of skill or lack of care is so apparent as to be within the comprehension of laymen and requires only common knowledge and experience to understand and judge it, expert evidence is not essential." *Young v. Key Pharmaceuticals, Inc.*, 112 Wn.2d 216, 228-29, 770 P.2d 182 (1989) (quoting *Hart v. Steele*, 416 S.W.2d 927, 37 A.L.R.3d 456, 462 (Mo. 1967)). Thus, as in this case, when the essential facts are observable by a

certification of law enforcement officers each contain a professor as well as members with law enforcement expertise. RCW 43.101.380. There is no requirement for expert testimony to be presented in any of the hearings held by these bodies even though their members use varying, individual expertise not necessarily shared by all members to decide the issues before them.

layperson's senses and describable without medical training, it would be superfluous to require additional expert testimony.

The record is clear that the LISTEN device, as created by James Clark, could not diagnose, treat or cure any medical condition. *See, e.g.*, AR 2165, 2906-07. Mr. Clark specifically testified as to the machine's FDA-cleared capabilities. AR 2870-71, 2928. Further, Dr. Sherman, the Department's expert, provided testimony on the use and purpose of biofeedback devices. AR 2289-2296. Dr. Sherman testified that these machines cannot treat or cure allergies. AR 2318-2320. Dr. Ames, however, used the LISTEN device to assist him in the medical treatment of his patients' allergies. AR 2162-63. He further unmistakably led his patients to believe that the LISTEN device did in fact help him diagnose, treat, and cure their allergies. *See generally* Testimony Patient One, Patient Two, and Patient Three, AR 2184-2239, 2246-75, 2694-2718, 2719-66.

Further, the record is clear that Dr. Ames used the LISTEN device without sufficient knowledge or understanding of how it worked or whether it created any danger to his patients. *See, e.g.*, AR 2102-04, 2109, 2177-80. He instead operated the device based on a general theory of how homeopathic signals *should* work without any basis for believing the device could work in that way. AR 2102-04, 2109, 2155-56, 2163, 2177-

80. Therefore, even without independent expertise about the standard of care of using such a machine, the Commission appropriately applied its expertise and knowledge to the facts to conclude that Dr. Ames' use of the LISTEN device was inefficacious, negligent, and created an unreasonable risk of harm to his patients.⁹

C. The Department's First Amended Statement Of Charges Provided Notice Of The Issues To Be Litigated.

The Department's First Amended Statement of Charges complied with due process by providing adequate notice of the violations charged. Due process requires notice of the issues to be raised at a disciplinary hearing. *In re Ruffalo*, 390 U.S. 544, 88 S. Ct. 1222, 20 L. Ed. 2d 117 (1968). To meet the requirements of due process, the charging document must be reasonably calculated to inform the affected party of the action and afford him an opportunity to defend against those charges. *City of Marysville v. Puget Sound Air Pollution Control Agency*, 104 Wn.2d 115, 119, 702 P.2d 469 (1985). As long as the notice is specific enough to inform the respondent with reasonable certainty of the nature of the charges before the proceedings commenced, then due process is met. *In re Ruffalo*, 390 U.S. at 551. The purpose served by the administrative

⁹ Practically, there could be no testimony as to the standard of care for use of the LISTEN device to diagnose and treat allergies, because, according to its creator, the device was never intended for that purpose and had no capability to do it. There was no expert testimony that the LISTEN device could do what Dr. Ames claimed it could do.

complaint is to give the responding party notice of the charges against that party and provide a fair opportunity to prepare and present a defense. *City of Marysville*, 104 Wn.2d at 119 (1985) (strict rules of pleading do not apply to administrative matters). Parties must be put on notice of the issues to be litigated, not the facts underlying the issues. *Eidson v. Dep't of Licensing*, 108 Wn. App. 712, 727, 32 P.3d 1039 (2001).

The APA outlines the requirements for notice in an administrative setting. RCW 34.05.434. The statute requires that the charging document notice the legal authority and jurisdiction under which the hearing will be held; reference the particular sections of the statutes and rules involved; and provide a short and plain statement of the matters asserted by the agency. RCW 34.05.434(2)(f)-(h). In health professional disciplinary matters, the Commission's Model Rules governs the content of notices. WAC 246-11-250. The rule provides that an initiating document shall contain a clear and concise statement of the factual basis for the action or proposed action, and the statutes and rules alleged to be at issue. WAC 246-11-250(1)(b),(c).

The Amended Statement of Charges provided Dr. Ames with adequate notice of the issues to be litigated with a concise factual statement sufficient for Dr. Ames to prepare and present a defense. In the charging document, the Department specifically described the LISTEN

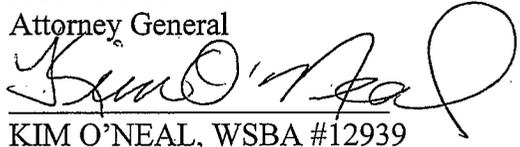
device as an electro-diagnostic device which uses low voltage to measure galvanic skin resistance. AR 60-61 at ¶ 1.2-1.3. It specifically alleged that, on July 10, 2001, Dr. Ames used the LISTEN device to test Patient One for food allergies. *Id.* at ¶ 1.2 and 1.14. It also described, in detail, the specific manner in which Dr. Ames used the device on Patient One. *Id.* at ¶ 1.14. The Department further stated in the charging document that these alleged facts constituted unprofessional conduct in violation of RCW 18.130.180(1), (4), (7), and (16), as well as 21 U.S.C. § 331(c) and RCW 69.04.040(1) and (3). AR 62 at ¶ 2.2. At all times, Dr. Ames was on notice that his use of the LISTEN device on Patient One was alleged to be inefficacious and below the standard of care.

V. CONCLUSION

For the foregoing reasons, the Medical Quality Assurance Commission's Final Order determining that Dr. Ames' use of the LISTEN device was negligent and created an unreasonable risk of harm to his patients should be affirmed.

RESPECTFULLY SUBMITTED this 6th day of October, 2008.

ROBERT M. MCKENNA
Attorney General



KIM O'NEAL, WSBA #12939
Senior Counsel
Attorneys for Respondent