

80644-6

COURT OF APPEALS, DIVISION III
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

**WASHINGTON STATE HEALTH
DEPARTMENT MEDICAL QUALITY
HEALTH ASSURANCE COMMN.,**

Respondent.

ON APPEAL FROM THE SUPERIOR COURT OF
BENTON COUNTY, THE HON. CARRIE RUNGE PRESIDING

OPENING BRIEF OF PETITIONER

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PRELIMINARY STATEMENT

This appeal is about a device sometimes used by an alternative physician as part of his procedure for assessing patients with possible allergies. Although a medical commission panel did not find that the physician had deceived or injured anyone, that he had acted in bad faith, or that the device was unsafe, it did rule that using it with a patient was “unprofessional conduct” under RCW 18.130.180(4) and (16). The device, based on Asian and homeopathic medical theories, was, the panel asserted, “inefficacious.” Using it was, assertedly, negligence, and charging for the treatment to which it was related constituted “promotion for personal gain” of an “inefficacious” device. The panel suspended the physician’s license, stayed the suspension on condition that he refrain from using the device, pay the Commission a \$5,000 fine, and submit to regular practice reviews and reports to the Commission.

Petitioner contends that the Commission, believing but unable to prove, that the device could not work, lawlessly disregarded evidentiary norms, procedural safeguards and the language of the relevant statutory scheme in order to suppress its use. The evidence and the findings were not only insufficient, they were grossly insufficient and it is difficult not to conclude that the panel’s decision was a cynical manipulation of evidence, reasoning and statutory language to reach a result that could not be defended

even by conventional medicine's professional and scientific standards, let alone by those the law insists upon. The decision poses a severe threat to alternative medicine generally, because if the "method" of prosecuting and deciding this case were upheld it could be used by any panel of conventional practitioners to suppress any alternative approach that has not been expressly identified and protected by the legislature. It would effectively allow the Commission to make its own law in cases involving alternative physicians and disregard the legislative policy favoring choice and patient freedom in those areas where conventional medicine has failed to meet patient needs. Thus, it is imperative that this Court not only overturn the decision, but that it do so in language that notifies the Commission that it will not tolerate an agency's playing fast and loose with procedural due process, no matter how truly the agency believes that the ends justify the means.

ASSIGNMENTS OF ERROR

The Commission panel erred in entering the following findings of fact, because a reasonable fact-finder could not have found that they were supported by *clear and convincing* evidence (or even by a preponderance) and, as to many of them, they had not been pleaded as required by Department of Health ("DOH") regulations, the Administrative Procedure Act (34.05 RCW) and due process:

1. ¶ 1.7, first sentence.

2. ¶ 1.12 (to the extent that it finds that the device speeds up patient visits and implies use with all patients);

3. ¶ 1.13 (fourth sentence – that he described only the symptoms he felt on the day of the initial visit);

4. ¶ 1.15 (if it implies that there was not a specific finding of an egg allergy in the laboratory report);

5. ¶ 1.16 (last sentence - that he could cure the allergy);

6. ¶¶ 1.17, 1.18, 1.19, 1.20, 1.21, 1.22, 1.23 (to the extent an allergy other than hay fever is implied);

7. ¶ 1.24 (first sentence, to the extent it finds treatment actually occurred at second visit);

8. ¶¶ 1.25, 1.26, 1.27, 1.28, 1.29

The Commission panel erred in entering:

9. (a) the conclusion of law that expert testimony was not necessary to support its findings of facts supporting negligence;

10. (b) ¶¶ 2.3, 2.6, 2.7

11. The panel erred in suspending Petitioner, ordering the monitoring of his records and practice, and fining him (¶¶3.1-3.12).

12. The Superior Court erred in entering its Order of _____, upholding the Commission's Final Order.

**ISSUES PRESENTED
(WITH RELATED ASSIGNMENTS OF ERROR)**

1. Could a reasonable person find by clear and convincing evidence, and was it legal error to conclude, that a device was “inefficacious,” because on one occasion its use had allegedly led to an incorrect allergy diagnosis in one patient and there was no expert testimony, clinical or case studies, or other empirical, clinical or scientific documentation relating to the device’s use which even suggested that the device was not effective? (Assignment Nos. 3-10, especially, ¶¶1.23, 1.25: also, in part, *de novo*)

2. Could a reasonable person have found by clear and convincing evidence or legally conclude that the good faith use by an alternative physician of a noninvasive, harmless device as one of a number of techniques employed in assessing a patient for food allergies was negligence creating an unreasonable risk of harm solely because the panel found the device had indicated the patient had an allergy to eggs when, according to the panel, he did not? (Nos. 3-10, especially ¶¶ 1.20, 1.23, 1.25, 1.28, 1.29: also, *de novo*)

3. Could a reasonable person find by clear and convincing evidence that a test had incorrectly found a patient to have an allergy to eggs when the patient had been found to have such an allergy by a conventional blood test; there was no expert testimony or documentation of testing showing that the patient did not have the allergy; there was no evidence that the patient had ever been tested for food allergies or had ever been told by a health care

practitioner or anyone else that he did *not* have an allergy to eggs; there was no evidence that the test had been shown by scientific study or empirical experience to be inefficacious generally; and the only evidence offered in support of a finding that the test was incorrect was that (A) the patient had not been told by anyone else that he had a food allergy; (B) the patient had been diagnosed with and treated for allergies to dust and pollens twenty to twenty-five years earlier; and (C) the patient did not know of any reaction he had to eggs, although he also did not know the cause of the symptoms he reported to the physician? (Nos. 3, 4, 6, 8, 9, esp. ¶¶1.23, 1.25, 1.28, 1.29)

4. Did DOH¹ fail to provide necessary notice of facts central to the ultimate findings and conclusions in its Order? (Nos. 5, 6, 8, esp. ¶¶1.16, 1.18, 1.19, 1.20, 1.22, 1.23, 1.25, 1.27-1.29: *de novo*)

5. Is the use of a device used in assessing allergies treated by acupressure and based on Asian and homeopathic medicine part of “nontraditional treatment” under RCW 18.130.180(4)? (No. 8, ¶1.28: *de novo*)

6. Can a physician’s use of an assessment device for allergies, even though he does not advertise or commercially market it nor charge patients for using it, and its use does not affect the charge for allergy treatments,

¹ The prosecutorial wing of the Commission will be referred as “DOH.”

constitute “promotion” of the device “for personal gain” under RCW 18.130.180(16), because he encourages patients to be treated for allergies using his acupressure techniques? (Nos. 2, 7, 8, esp. ¶¶1.12, 1.24, 1.26: *de novo*)

7. Under RCW 18.130.180(4)’s declaration that nontraditional treatments are not unprofessional in the absence of harm or an unreasonable risk of harm, can a practitioner be held to have violated RCW 18.130.180(16) without evidence of such harm or risk/ (Nos. 8, 10, esp. ¶¶1.26, 1.29, 2.3, 2.6, 2.7: *de novo*)

8. Must an appellate court defer to the findings of an administrative panel and conclude that there is clear and convincing evidence of the truth of his account because the panel finds a witness credible as to certain testimony when, however much the witness may believe what he is saying, the patient admits to memory problems, gave demonstrative evidence of memory failures, and the documentary evidence in the case contradicted his memory? (Assignment Nos. 3-10: *de novo*)

9. In light of the findings of good faith, and the absence of harm, were the sanctions ordered an abuse of discretion? (No. 11, ¶¶3.1-3.12)

10. Did the Superior Court err? (All assignments of error: substantial evidence of high probability; *de novo*; abuse of discretion)

STATEMENT OF THE CASE

FACTS

1. Dr. Ames's Alternative Practice and Alternative Assessment Tools

Petitioner Geoffrey S. Ames, M.D., an alternative physician, board certified in holistic medicine, practices in Richland, Washington. CR 1854; App. 3, ¶1.1.² He specializes in chronic fatigue states and allergies, which are among the causes of fatigue. CR 3179, 3079, 3113; *e.g.*, DOH Ex. 2, pp. 10-13 (CR 1941-1944). One of the allergy modalities he uses is called "NAET," an acupressure treatment reported to be effective by many other alternative practitioners. CR 2158, 2695-2700, 2164, 2970-2972; 3042. There is no definitive food allergy test. CR 2973-2975; see also CR 2983-2984, 3037-3038, 3044-3045, 3047-3049. Thus, Dr. Ames considers many sources of information, including, most importantly, a detailed patient history, a physical examination, blood work, and hair analysis. CR 3079, 3080, 3085, 3177; CR 2151, 2171. In addition, he may use a muscle test employed by NAET practitioners, in which the strength of an arm muscle in the presence of a possible allergen is assessed. CR 2170; see generally CR 2976-2977, 3051. If the suspected allergen appears to weaken the arm, that is one indication for treatment – *i.e.*, non-invasive mild taps to acupuncture points on the back. CR 2968, 2970, 2151, 2153, 2158. And the acupressure

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Citation to the record in the Commission proceedings – *i.e.*, the "Certified Record on Review" – will be referred to as "CR." Citations to the Superior Court record as "CP."

in turn is itself used as a noninvasive assessment resource, in a tentative process of trial and error. CR 2152, 2176. If symptoms are not cleared up after the treatment, that suggests that the person did not have the suspected allergy. CR 2151-2152, 2175.

Often patients strongly suspect an allergen and report it to the physician. CR 2151. But often they have no idea: the actual cause of their symptoms, which may be any one of hundreds or thousands of substances. CR 3070. To reduce the time needed to find such an allergen, NAET employs a device based on both acupuncture and homeopathic theories of human health and functioning. CR 2165, 3061. This “galvanic skin response” (“GSR”) device emits by a signal generator the homeopathic electromagnetic signatures for hundreds or thousands of substances, thereby allowing many more suspects to be brought quickly in contact with a patient. CR 2155-2156, 3069, 3178. The conventional use for GSR devices is biofeedback or lie detection and the FDA has cleared them to be marketed for those purposes. CR 2104, 2165, 2318, 2854, 2899, 3000; CR 1919-1920. In their conventional, and one unconventional, use, they measure the conductivity between points on the skin when a tiny current is run between them. CR 2295, 2318. As DOH’s biofeedback expert testified repeatedly, such devices are completely safe. CR 2293, 2296, 2349; see also CR 2879-2881, 3000.

When practitioners use these devices – usually with additional

software – for purposes which cannot be stated on the labeling and for which the manufacturer may not promote them, this does not violate the Food, Drug and Cosmetic Act (“FDCA”). Buckman Company v. Plaintiff Legal Committee, 531 U.S. 341, 350, 121 S.Ct. 1012, 1019 (2001) (recognizing importance and widespread conventional use of devices and drugs “off label”). Nor does the fact that a drug, treatment or device has not been cleared for a particular use mean that it is either unsafe or inefficacious – only that it has not yet been cleared or approved by the FDA. CR 2412-2414 (DOH FDA expert: many devices may be safe and efficacious but not FDA approved, because of expense or time needed to satisfy FDA requirements).

The devices are often used for electrodermal screening (“EDS”) while NAET uses them to generate the homeopathic signals for muscle testing. CR 2875-2876. After researching them with NAET’s founder, other physicians, and vendors, Dr. Ames purchased one from a Utah company. CR 2157, 2839-2842. Called the LISTEN, it had been cleared by the FDA under the name “Digital Conductance Meter” (“DCM”) on the condition that the label state as its “intended use,” galvanic skin response measurement, biofeedback and muscle relaxation. CR 2843, 1919-1920. The clearance covered the device’s signal generator. CR 2873.

In about fifty percent of suspected allergy cases, Dr. Ames used the LISTEN for muscle testing. It was a preliminary, minor data source in the

comprehensive work-up for non-specific fatigue, distress and pain. CR 2084, 2100, 2151-2152, 3070, 3142, 3181. He did not charge for using the LISTEN; acupuncture patients were charged the same whether or not the LISTEN was employed; and Dr. Ames did not otherwise attempt to recoup the costs associated with the device. CR 2162, 3119, 2162.

2. Patient One's Two Visits and Concern About Dr. Ames's Alternative Medical Views

Patient One (also "P1") first saw Dr. Ames on June 6, 2001. CR 2188, 1933). Complaining of frequently suffering from severe fatigue and sluggishness, even after sleep, CR 1945, he also reported frequent, severe weakness or tiredness in joints and muscles; infrequent, but severe joint and muscle pain and aches; and infrequent but severe mood swings. *Ibid.*

P1 was an industrial hygienist at who had worked with conventional physicians throughout his career. CR 2186, 2189, 2197. He was taken aback by Dr. Ames's concern over mercury dental fillings, his criticisms of mainstream medicine and the American Medical Association, and what P1 felt was an obsession with alternative medicine. CR 2191, 2195, 2227-2228. He dismissed Dr. Ames's concern with symptoms like fatigue, lethargy, and apathy, because other physicians had shown no interest in them. CR 2233.

But P1 did submit samples for food allergy blood testing, and urine and hair testing, and returned for a second visit on July 10, 2001. CR 1932, 2170-2171, 2191, 2192, 2248, 2197. Most of this visit was spent discussing

the extensive laboratory results, Dr. Ames's concerns about metal poisoning from lead and mercury, and the advisability of chelation treatment. *Ibid*; CR 2197-2201. Dr. Ames noted that the RAST, a standard blood test, showed several food allergies, including egg and mustard. CR 2170-2171, 2203-2204, 2207. P2 also recalls a discussion of NAET, muscle testing with the LISTEN, energy and meridians, and not understanding much of it. CR 2207.

The testimony conflicted on what happened next. Dr. Ames testified that after describing NAET, the LISTEN and muscle testing, and the results his patients reported, CR 3091-3098, he then demonstrated the muscle-testing and acupressure by putting P1 through a simulation of the entire process. CR 3096-3097. Dr. Ames testified that his protocol with patients who might elect NAET for allergies was to begin a work-up at the first visit; discuss lab results, NAET and muscle testing at the second visit; and actually use the LISTEN, if he was going to use it, at the third visit. CR 3091-3092. Patient One, however, testified that he thought that Dr. Ames was doing actual muscle-testing using the LISTEN and actually did treat him with acupressure for his egg allergy, diagnosed, however, not with the muscle testing but the RAST blood testing. CR 2207-2209, 2220, 2223. He testified that Dr. Ames told him that, as long he did not eat eggs for a day or two after the treatment the allergy would be gone. *Ibid*. Dr. Ames agreed that most of this is what he did say and do, except that he was describing and demonstrating the

experience of other patients and what might happen with P1 if he elected to have NAET treatments. *E.g.*, CR 3098-3099. The panel found actual muscle testing with the LISTEN had occurred and that P1 had been treated for, and told he had been cured of, an egg allergy. CR 1859-1861; App. 3, ¶¶1.17-1.20, 1.22. Because courts usually defer to such findings, the text of this brief accepts them, *arguendo*, while assigning error for the reasons in the margin.³

Some weeks after P1's second visit, he contacted the Commission. He did not intend to make a complaint, or think that he had been hurt in any way, by Dr. Ames, by the LISTEN, the muscle-testing or the acupressure. CR 2227, 2228. He did not think Dr. Ames was trying to fool or mislead him. CR 2248. His emphasis was not primarily with the LISTEN, but with Dr. Ames's views on mercury, lead poisoning and chelation. CR 2221. But he wrote because he was disturbed by what he considered Dr. Ames's obsession with alternative modalities. CR 2228-2229. DOH then used his report to move

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Patient One's demeanor could only establish that he *believed* his account, not that his memory of the events was correct. His account could not be and was not established by clear and convincing evidence, because, *inter alia*, there is nothing in his medical records indicating that he was treated for the allergy (no chart note and no informed consent form – see DOH Ex. 2; CR 1932-1982) and DOH introduced no evidence that he was billed for such a treatment. In addition, P1 himself admitted to memory problems; demonstrated his faulty memory in his testimony; and had many conditions associated with faulty memory, which were uncontradicted and undisputed. For example, he testified that the LISTEN had dials when it did not and, at points, that it did not involve a computer or a keyboard, when it did. He admitted that his testimony that Dr. Ames had him hold the LISTEN's brass rod when it was covered with paper and not being used made no sense (as one panel member brought out in questioning him). See CR 2209-2210, 2217, 2225-2227, 2246-2247, 2249, 2270, 2271-2272, 3102-3107. In addition, P1's focus when he saw Dr. Ames was not on the LISTEN and he testified to not understanding what Dr. Ames was saying about it, all of which would account for a spotty, unreliable memory about it. See *infra*.

only against the LISTEN. CR 3.

PROCEEDINGS

This case was initiated by a Statement of Charges (“Statement”) alleging that Dr. Ames had tested P1 for a food allergy using the LISTEN. ; CR 3; App. 1. The LISTEN, it was alleged, had not been approved, exempted or cleared by the FDA, or, alternatively, if it had been cleared under another name, it had been used in a way not authorized by the FDA. *Id* at 3-4. Dr. Ames’s receipt and use of the LISTEN was alleged to violate the FD CA and the state food and drug act and therefore to violate RCW 18.130.180(7) (unprofessional to violate statute regulating the profession of medicine).

Dr. Ames challenged DOH’s good faith and initiated discovery of the FDA claim. CR 27-28, 46.⁴ In response, DOH issued an Amended

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Since the LISTEN had been cleared by the FDA under the DCM name, and “off-label” uses are not illegal, minimal investigation would have disclosed that Dr. Ames had done nothing illegal (indeed, the panel ultimately so found). Thus, the only reasonable inference was that the charges were brought in bad faith – *i.e.*, to use the expense and threat of a disciplinary proceeding against Dr. Ames to force him to cease using an alternative health care device which, however much DOH believed it to be ineffective, could not be proven to be either harmful (the FDA would not have cleared a device that was harmful) or ineffective. The animosity of state medical boards toward this device, especially as employed as an EDS device, was well known. See, *inter alia*, *Painter v. Abels*, 998 P.2d 931, 935, 939 (Wyo. 2000) where the Wyoming Supreme Court rebuffed an attempt by the Wyoming medical board, which also offered no evidence that the device was either harmful or ineffective, to stop a Wyoming physician from using an EDS device by making spurious, unsupported charges about her mental health and the alleged standards of the profession. For the use and acceptance of these devices among alternative practitioners, by some states in this country and by many major foreign countries, see CR 2850-2851, 2860-2861; see also CR 2970-

Statement of Charges (“Amended Statement”). CR 60, 141; App. 2.

The Amended Statement retained all of the factual allegations in the Statement, but added two new paragraphs. *Id* at 60-61. The first of these (¶1.13) alleged only that at the first of P1's two visits with Dr. Ames, the doctor had ordered blood, urine and hair testing. The second new paragraph (¶1.14) alleged that at the second visit Dr. Ames: discussed the test results, which showed several food allergies; muscle tested Patient One's arm in conjunction with using the LISTEN and stated that the testing showed that he was allergic to eggs; and later said that he “hardly needed the device anymore” because he could do what the device did “through telepathy.”⁵ *Ibid*. This was the extent of the new factual matter. *Id* at 60-61. Thus, there was no allegation that P1 did not have an egg allergy; that he had been treated, or charged for treating, an allergy; or that Dr. Ames had told him that he had been cured of one. Nor was there any allegation about the investigation Dr. Ames had or had not done about the device before beginning to use it with his patients. Nothing in these two new paragraphs stated that any of the facts alleged described or caused harm to the patient or constituted any form of immoral or negligent conduct by Dr. Ames.

2972 (David Martin, M.D.).

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This allegation was not confirmed in the panel's ultimate findings and the likelihood of this account was questioned by a panel member's examination of P1. CR 2271-2272

The “Alleged Violations” section of the Amended Statement, however, contained three new charges of unprofessional conduct in addition to the charge that Dr. Ames had violated the federal and state food and drug law. *Id* at 62. The new charges alleged that all facts pleaded constituted “an act involving moral turpitude, dishonesty, or corruption relating to the practice of the person’s profession” under RCW 18.130.180(1); negligence “which creates an unreasonable risk that a patient may be harmed” under RCW 18.130.180(4); and “promotion for personal gain of any . . . inefficacious . . . device” under RCW 18.130.180(16). *Ibid*. During discovery, DOH admitted that the new allegations were not based on new evidence or information, but on the same evidence it had when it issued the initial Statement. CR 110 ¶9; CR 140.

Dr. Ames’s motions for summary judgment, and inclusion of an alternative physician on the panel that would judge him, were denied. CR 1176, 1509. The panel chosen consisted of three Commission members, only one of which was a physician, Dr. Uberoi; one physician’s assistant, Ms. Paxton, a *pro tem*; and Mr. Tennis, a public member. CR 1850; App. 3, p.1.

The Evidence at the Hearing

The Department called four witnesses at the hearing – Dr. Ames, P1, Richard Sherman, Ph.D. and Neil Ogden, an FDA employee. CR 1851; App. 3, p. 2. No DOH witness, other than Dr. Ames, testified concerning the

The “Alleged Violations” section of the Amended Statement, however, contained three new charges of unprofessional conduct in addition to the charge that Dr. Ames had violated the federal and state food and drug law. *Id* at 62. The new charges alleged that all facts pleaded constituted “an act involving moral turpitude, dishonesty, or corruption relating to the practice of the person’s profession” under RCW 18.130.180(1); negligence “which creates an unreasonable risk that a patient may be harmed” under RCW 18.130.180(4); and “promotion for personal gain of any . . . inefficacious . . . device” under RCW 18.130.180(6). *Ibid*. During discovery, DOH admitted that the new allegations were not based on new evidence or information, but on the same evidence it had when it issued the initial Statement. CR 60, 141.

Dr. Ames’s motions for summary judgment, and inclusion of an alternative physician on the panel that would judge him, were denied. CR 1176, 1509. The panel chosen consisted of three Commission members, only one of which was a physician, Dr. Uberoi; one physician’s assistant, Ms. Paxton, a *pro tem*; and Mr. Tennis, a public member. CR 1850; App. 3, p.1.

The Evidence at the Hearing

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efficacy of the LISTEN or of NAET, and Dr. Ames did not support DOH. No DOH witness, other than Dr. Ames, testified about the field of allergy health care, and Dr. Ames did not criticize NAET and other alternative approaches. No DOH witness testified that Dr. Ames's LISTEN had been marketed in violation of federal or state laws; that the LISTEN created any risks of harm; that Dr. Ames had not sufficiently investigated its safety prior to allegedly using it with P1; that Dr. Ames's conduct or practices created any risks or was deficient in any respect.⁶

Dr. Ames called P2 and P3 (two of his patients); James Clark, the LISTEN's developer and a principal in the company that sold it; Dr. David Martin, a Harvard M.D. and acupuncturist; and Dr. Ames, himself. CR 1851.⁷

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References to the record for this testimony is set forth in the statement of facts and in the argument below and see footnote 7 *infra*. Dr. Sherman, an expert on biofeedback machines – into which class the LISTEN fell – described his conception of biofeedback and testified that such devices were completely safe. CR 2282-2353. He had no knowledge of the LISTEN and did not testify about the use of galvanic response devices for alternative purposes. *Ibid*. Mr. Ogden testified about FDA practices and procedures and the history of applications by the developer of the LISTEN for FDA permission to market his device, but he was not familiar with the device in this case and did not testify to its legal status. CR 2388-2434.

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The only expert evidence concerning acupuncture, acupressure, and allergies at the hearing came from Dr. Martin and Dr. Ames. CR 2958-2961, 2970-2975, 2983-2984, 3028-3032, 3036, 3038-3040, 3054-3057. Dr. Ames testified in his case in chief, *inter alia*, to basic facts about the allergy specialty, including the differences between conventional and alternative approaches. *Ibid*; CR 3179. Both Dr. Martin and Dr. Ames testified, *inter alia*, to the appropriateness of acupuncture and acupressure for treating allergies. See references cited above. Dr. Martin also testified to the differences between diagnosis under the Asian medical principles underlying acupuncture and acupressure and the efficacy of muscle testing and NAET, describing unusually positive results obtained by some of his patients who had seen an NAET practitioner for intractable allergies.

The Final Order Entered by the Panel

During the hearing the panel dismissed the charges under RCW 18.130.180(1) and (7), ruling that Dr. Ames had not been dishonest or immoral, and had not violated any food and drug law (the only basis of the original Statement of Charges). CR 1852-1853;App. 3. But the final order found Dr. Ames had violated RCW 18.130.180(4) and RCW 18.130.180(16). *Id* at 1863. It suspended his license for a minimum of five years, staying the suspension on condition that he refrain from using the LISTEN; and ordered him to pay a \$5,000 fine, submit to quarterly practice reviews, and appear before the Commission every six months. CR 1864-1865;App. 3, 3.1-3.12.

The primary finding and/or conclusion was that the LISTEN was “inefficacious,” based on the muscle testing’s asserted indication that P1 had an egg allergy that he did not have (an allegation not in the charges). *Id* at 1861. Negligence was found because an “inefficacious” device was assertedly used to assess and treat a patient (also not in the charges)⁸ and because Dr.

P2 and P3 testified about allergies that had been cleared up through the use of NAET by Dr. Ames and the use of the LISTEN to find allergens of which they were unaware. Mr. Clark testified, *inter alia*, about the acceptance of the device throughout the country and the world for alternative purposes, its safety and its FDA clearance.

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The finding that Dr. Ames used the LISTEN to treat, as opposed to “assess,” is directly contradicted by Findings of Fact ¶¶ 1.16, 1.18, 1.19, the panel’s own, earlier finding (see CR 1858, 1859; App. 3) as well as by P1’s own testimony, which expressly states that the “treatment” was acupuncture. CR 2224-2225. This is also an earlier Finding of Fact. *Id* at CR 1859, ¶1.19.

Ames had assertedly failed to adequately confirm the LISTEN's safety.⁹ *Id* at 1862 (also not in the chrges). "Promotion [of the device] for personal gain" was found, because, although Dr. Ames did not charge for its use, he did charge for and recommend NAET treatment. *Id* at 1861-1862.

The Order was upheld by the Benton County Superior Court. CP 31.

ARGUMENT

I. THE STANDARDS AND PROCEDURES GOVERNING REVIEW IN THIS CASE INCLUDE SOME THAT ARE SPECIFIC TO THIS TYPE OF CASE

A. The Standard of Review as to Findings of Fact – the Special Meaning of Substantial Evidence Here

On review of an agency final order, the Court reviews the administrative record directly, disregarding findings and conclusions of the superior court. *Tapper v. Employment Sec. Dept.*, 122 Wn.2d 397, 402-03, 858 P.2d 494 (1993). But here, the findings of fact must be supported by evidence that "could reasonably [be] found to be clear, cogent, and convincing." *Bay v. Estate of Bay*, 105 P.3d 434, 438 (Wn.App. Div. 1,2005); see *In re Sego*, 82 Wn.2d 736, 513 P.2d 831 (1973) (in a case that must be proved by clear and convincing evidence, "substantial evidence" has a special meaning – it is evidence that a rational fact finder would find to be "highly probable"). Thus to uphold the finding that the LISTEN was "inefficacious," a fair-minded, rational fact finder would have to be

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The panel did *not* find the LISTEN unsafe and *did* find that it could be marketed. CR 1857.

convinced that the LISTEN was clearly “inefficacious.”¹⁰

**B. The Standard for Reviewing the Meaning of the Statutes
And Regulations Relevant to this Cas Is *De Novo* and No
Weight is Given to Readings Contrary to the Statute’s Intent**

This Court reviews a statute’s interpretation and application to fact *de novo*. *Ted Rasmussen Farms, LLC v. State*, 127 Wn.App. 90, 94-95, 110 P.3d 823, 825 (Div. 3,2005); *Tapper v. State Employment Sec. Dept.*, 122 Wn.2d 397, 403, 858 P.2d 494, 498 (1993). If the meaning is “plain” – *i.e.*, not capable of more than one *reasonable* interpretation – no weight is given to an agency’s contrary interpretation. *Ted Rasmussen Farms, loc. cit. supra*; *Bauer v. State Employment Sec. Dept.*, 126 Wn.App. 468, 473-474, 108 P.3d 1240, 1243-1244 (Div. 3,2005). To determine if the meaning is plain, the *Court considers not only the words immediately in dispute, but the entire* statute and related statutes. It harmonizes all provisions “to effectuate a consistent statutory scheme,” attempts to give every word effect, and “avoid[s] unlikely, absurd, or strained consequences.” *Ibid.*

If, after this, there remains more than one reasonable reading, and the “statute falls within the agency’s expertise,” the court may give great weight to the agency interpretation. *City of Olympia v. Drebeck*, 156 Wn.2d 289, 295, 126 P.3d 802, 804 (2006) *Ted Rasmussen Farms, supra*, at 194-195. Yet

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This modification of the “substantial evidence” standard is derived from *Nguyen v. Medical Commission*, 144 Wn.2d 516, 534, 29 P.3d 689, 697 (2001) (finding of unprofessional conduct requires “clear and convincing proof”).

even where a court does so, the agency interpretation must be plausible and not “contrary to legislative intent.” Premera v. Kreidler, 131 P.3d 930, 938 (Div. 2,2006). “ Ultimately, it is for the court to determine the meaning and purpose of a statute.” Postema v. Pollution Control Hearings Bd., 142 Wn.2d 68, 77, 11 P.3d 726, 733 (2000). “[N]o deference is accorded if the agency interpretation conflicts with the statute.” Bauer, supra. City of Pasco v. Pub. Employment Relations Comm’n, 119 Wn.2d 504, 507, 833 P.2d 381 (1992).

C. Additional Requirements That the Panel’s Order Must Satisfy

In order to assure *meaningful* appellate review and to legitimize delegation of adjudicative and legislative power to an executive agency, the Administrative Procedure Act (“APA”), 34.05 RCW, makes special requirements of state agencies. *See e.g.*, RCW 34.05.461(3) and (4); *see United Chiropractors v. State*, 90 Wn.2d 1, 5, 578 P.2d 38, 39-40 (1978) (requiring adequate procedural safeguards to justify delegation of legislative, executive and judicial power to disciplinary board); *see generally Painter v. Abels, supra*, 998 P.2d at 939; Franz v. Board of Med. Quality Assrnce., 31 Cal.3d 124, 140, 181 Cal.Rptr. 732 (1982); Martin v. Sizemore, 78 S.W.3d 249 (Tenn.Ct.App. 2001).¹¹ Courts need only state their ultimate findings of

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MQAC is governed by all of these provisions. Nguyen v. Medical Assurance Commission, 144 Wn.2d 516, 520, 29 P.3d 689, 690 (2001); see RCW 18.130.100.

fact and conclusions of law, and nothing more.¹² But the Commission's final order must not only state findings and conclusions, but also "*the reasons and basis therefor*, on *all* the material issues of fact, law, or discretion presented on the record." *Ibid.* Emphasis added. For this requirement's importance, see *Drew v. Psychiatric Sec. Rev. Bd.*, 322 Or. 491, 498, 500, 909 P.2d 1211, 1214-1215 (1996).

In addition, unlike a court, under the APA, the agency must:

[1] [identify] *any findings based substantially on credibility* of evidence or demeanor of witnesses; [and]

[2] [provide] a concise and *explicit* statement of the underlying *evidence of record* to support the findings [when they are] set forth in language that is essentially a *repetition or paraphrase of the relevant provision of law*

RCW 34.05.461(3) (emphasis added). The findings must "be based *exclusively*" either

[1] on the evidence of record in the adjudicative proceeding [or]

[2] on matters officially noticed in that proceeding.

RCW 34.05.461(4) (emphasis added). Only the following may be noticed:

(a) any judicially cognizable facts, (b) *technical or scientific facts within the agency's specialized knowledge* and (c) codes or standards . . . of the United States, of this state or of another state, or

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The importance of holding an agency to these procedures is magnified here because the agency given judicial and legislative power is governed by professionals who are not compensated for their time, not full-time officials, and ordinarily free to pursue their private professional and economic interests, which can conflict with an accused's.

by a nationally recognized organization or association.

RCW 34.05.452(5) (emphasis added). However, the parties must be notified of any “material so noticed and the sources thereof” and “afforded an opportunity to contest” them. *Ibid.* In this case, there was no notification that any “technical or scientific fact[] within the agency’s specialized knowledge” (or any other fact) would be or had been officially noticed.

D. The *Johnston* Decision Cannot Pull the Panel’s Evidentiary Coals Out of the Fire

Defensiveness about the evidence and reasoning supporting the Order is betrayed by its invocation, even before it sets out its findings and conclusions, of *Johnston v. Medical Board*, 99 Wn.2d 466, 663 P.2d 457(1983) and *Brown v. Dental Board*, 94 Wn.App. 7, 972 P.2d 101 (Div. 3, 1998). CR 1852.¹³ *Johnston* found that where a disciplinary panel consists entirely of members of the regulated profession (not the case here, of course) and the charge is negligence, expert testimony as to the specific professional standard violated by the alleged conduct is unnecessary. This, *Davidson* says, is because the panel’s members will all know, and have the final word on, what the standard is. Applying *Johnston* and *Davidson* here raises several

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Brown cites *Johnston* and another 1983 decision, *Davidson v. Department of Licensing*, 33 Wn.App. 783, 657 P.2d 810 (Div. 1, 1983), in a general preamble, but its actual reasoning neither relies on or even mentions either case.

doctrinal and statutory difficulties.¹⁴ But they would have little bearing on this case, in any event, for two reasons. First, *Johnston* and the other cases do not purport to change the requirement that the decision must be based on evidence *exclusively* in the record and that the parties must be notified of any “technical or scientific facts” that the agency intends to notice. See *Franz v. Board of Medical Quality Assurance*, 31 Cal.3d 124, 140, 181 Cal.Rptr. 732 (1982) (“due process requires, when . . . an agency intends to rely on members’ expertise . . . that it notify the parties”).¹⁵ Thus, even if the panel can consult its experience about the conventional standard of care, its ultimate finding of negligence must still be based on clear and convincing evidence exclusively in the record.

Here, as required by the APA, the panel stated the subordinate factual findings on which it based its finding of negligence. Dr. Ames contends that

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One reason *Johnston* and *Davidson* appear inapposite is that RCW 18.130.180(4), enacted eight years later, declares that “nontraditional treatment” is not in itself “unprofessional conduct.” Thus, alternative providers cannot be guilty of unprofessional conduct merely because they do not adhere to orthodox standards, making the panel’s expertise as to those standards largely irrelevant.

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Because, *Johnston* and *Davidson* were decided before enactment of the current APA, of RCW 18.130.180(4), and of other legislation protecting alternative health care, as well as almost twenty years before *Nguyen v. Medical Quality Assurance Commission*, *supra*, they could not have addressed any of the current evidentiary requirements – *e.g.*, of clear and convincing evidence – laid down by this authority or the new policies favoring alternative care that they reflect.

they are not only insufficient, but grossly so and so disingenuous as also to be arbitrary and capricious. See e.g., *Olmstead v. Department of Health*, 61 Wn.App. 888, 895, 812 P.2d 527 (Div. 1,1991). Similarly, but more obviously, although under *Johnston*, DOH need not, at least in cases like *Johnston*, introduce specific evidence of the assertedly applicable conventional standard of care, it is not relieved of the burden of introducing clear and convincing evidence of every other element constituting alleged unprofessional conduct. For example, *Johnston* does not relieve DOH of the need to establish that Dr. Ames's conduct created an "unreasonable risk" of harm to a patient, and that the device in this case was "inefficacious" and "promot[ed] for "personal gain."

Thus, *Johnston* and *Davidson* stand only for the proposition that the panel members in making a negligence determination may use the general, background knowledge that they have acquired through their training and experience to evaluate and draw inferences from the evidence that was introduced. E.g., *Brown* at 105 ("agency may use its experience and specialized knowledge to evaluate and draw inferences from the evidence"). There must still be clear and convincing evidence of record from which the rational, fair-minded fact-finder can infer the necessary ultimate fact. Compare, e.g., *Franz v. Board of Medical Quality Assurance*, *supra* at 142-

143 (record must disclose the basis of the panel’s expert opinion).¹⁶

II. THE EVIDENCE THAT DR. AMES WAS NEGLIGENT FOR USING THE LISTEN IS GROSSLY INSUFFICIENT, INDEED, DISINGENUOUS

A. Why There is a Special Need For Clear and Convincing Evidence in this Case

The Commission charged Dr. Ames with unprofessional conduct for using the LISTEN in assessing P1. It thus had the burden of production and persuasion as to each fact on which it based this quasi-criminal charge. WAC 246-11-520 (“the burden is on the department to prove the alleged factual basis of the initiating document”); *Nguyen v. Medical Quality Assurance Commission*, 144 Wn.2d 516, 29 P.3d 689 (2001). Because it is a quasi-criminal charge involving severe professional consequences, because the public invests in and needs the services of highly-trained health care practitioners, and because error is likelier on charges adjudicated by part-time agency members combining judicial, legislative and executive functions, and acting “as investigator, prosecutor, and decisionmaker” (*Painter v. Abels*, 998 P.2d 931 (Wyo. 2000), see footnote 3, *supra.*), Washington requires that DOH’s proof be “clear and convincing.” *Nguyen, supra.*

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Johnston’s holding about standard of care evidence – which was not the primary holding in that case – was cursory, incidental, almost casual, and the Court did not appear to be aware that its position was a minority one, raising serious due process and other problems. If Dr. Ames were forced to challenge it in the Supreme Court that it would not likely survive. See *Martin v. Sizemore*, 78 S.W.3d 249 (Tenn.Ct.App. 2001) for the reasons.

Where the respondent is an alternative physician – philosophically and professionally at odds with the medical establishment that necessarily controls the commission investigating, charging, and judging him – the chances of error are even greater. This is not merely common sense. It is a legislative finding. RCW 18.130.180(4) declares in pertinent part:

The use of a non-traditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed.

This language was enacted because of the perceived prejudice of conventional medicine against alternative practitioners. It was introduced in House Bill 1960. The legislative intent is expressed in the H.B. 1960 Bill Report:

The state Medical Disciplinary Board *has discriminated against physicians who practice alternative health care*, considered nontraditional medicine. Many patients who received no satisfaction with traditional medical care have gotten relief from physicians who practice under *other theories*, including *holistic medicine*. The board should not discriminate unreasonably against these physicians *as long as no harm is being done*. Their patients demand a *freedom to choose the health care that they believe is best for them, and this freedom is adversely affected by discrimination and harassment from state disciplinary authorities*.

Emphasis added. At a minimum, this prohibition against discrimination requires – what due process and equal protection should require in any event – that the standards of evidence, the modes of statutory interpretation and the

deference to the practitioner's professional judgment that would be applied to conventional physicians be applied to alternative physicians.

B. It Should Go Without Saying That One Anecdotal Case Cannot Establish a Device to be Inefficacious

The panel was required by RCW 34.05.461(3) to state the reasons for finding Dr. Ames negligent under RCW 18.130.180(4). It purported to comply. Negligence was predicated on a finding that the LISTEN was an inefficacious device, that using it as part of the assessment prevented Dr. Ames from making an appropriate diagnosis and treatment, and, apparently, that it led to mistakenly telling Patient One that he had been cured of an allergy he did not in fact have. ;CR 1861-62; App. 3 ¶¶1.25, 1.28.

Although the factual findings supporting the finding/conclusion of negligence are flawed in other ways, the finding of negligence (and of a violation under RCW 18.130.180(16)) fails without the finding that the LISTEN was inefficacious. But DOH called no expert or lay witness to testify that the device was inefficacious. It offered no testimony or studies – published or otherwise – showing that the device had been evaluated by competent researchers using competent research methods and found not to work. It did not even *claim* that the device had been shown scientifically to be of no value in the assessment of food allergies.

The sole basis of the finding/conclusion of inefficacy was the

assertion that Dr. Ames had used the device to diagnose P1 and that the device had erroneously found him to have an egg allergy. Passing for a moment the inadequacy of the evidence that Dr. Ames used the device to diagnose P1 and that his diagnosis was wrong, a rational judgment about the efficacy of a device, a remedy or anything else cannot be predicated on *one* use with *one* patient on *one* occasion. Speculation and conjecture are not evidence. Lamphiear v. Skagit Corp., 6 Wn.App. 350, 356, 493 P.2d 1018, 1022-1023 (Div. 3, 1972) (verdict may not be founded “on mere theory, speculation or conjecture”). A reasonable inference must logically follow from an established fact. *Id* at 356, at 1023. The panel is inferring from one assertedly false positive on one occasion that the device would yield false positives (or false negatives) on all other occasions, or (it would probably argue) that a false positive on one occasion means that any successes on other occasions would result from mere chance or, perhaps, the placebo effect. This, of course, is gross, preposterous speculation. An infinite number of explanations could account for a device’s failure on any one occasion. No evidence was presented to show that any of such explanations were not applicable here.

No device, remedy or procedure works all of the time. No rational person would conclude that a modality is ineffective just because it was incorrect on one occasion. No device would be efficacious by that standard.

Prescribing mammograms would be “unprofessional conduct,” because they are known to yield both false positives and false negatives. See Simmons v. East Nassau Medical Group, P.C., 260 A.D.2d 463, 464, 688 N.Y.S.2d 209, 210 (App.Div. 2d Dept., 1999). So, too, would be blood pressure and pap tests and CT scans, none of which have been scientifically established, even though they are widely used. Dr. Ames said that the device merely assisted him, did not claim it to be right every time and said it had to be confirmed by a successful acupuncture treatment. CR 2151-2152, 2175-2176.

That a panel of a medical board would decide that a device does not work – a decision that affects not only Dr. Ames, but the manufacturer, distributors and other users of the device, not to speak of the fully informed, competent patients who want it available to them – without any scientific studies, without any expert testimony and without any history of empirical evidence would probably be unbelievable to anyone who did not know the history of orthodox medicine’s attempts to suppress alternative modalities, irrespective of what the law might say. See, e.g., Wilk v. American Medical Association, 719 F.2d 207 (7th Cir. 1983) *cert denied* 467 U.S. 1210 (1984) (upholding antitrust judgment against organized medicine for attempting to destroy chiropractic profession); Andrews v. Ballard, 498 F.Supp. 1038 (D.Tex. 1980) (rejecting medical board ban on acupuncture); State Medical Board v. Rogers, 387 So.2d 937 (Fla. 1980) (medical board violated

constitutional right to provide chelation to fully-informed patients who wanted it); *Kurk v. Medical Society*, 46 Misc.2d 790, 260 N.Y.S.2d 520 (Sup.Ct. Queens 1965) (illegal exclusion of osteopaths from medical society and hospital privileges); *Painter v. Abels*, 99 8 P.2d 931 (Wyo. 2000) (medical board unconstitutionally acted against device like the LISTEN).

The record here demonstrates unequivocally that this case is part of the long history of orthodox medicine's attempts to suppress alternatives with which it disagrees, but which it cannot prove to be ineffective. Especially in light of this State's commitment to allowing patients freedom of choice in health care, this Court should perform its historic function of protecting individual liberty from official lawlessness and rule that no rational person could find the LISTEN inefficacious on the "evidence" invoked here.

**C. Even if Dr. Ames Had Made an Erroneous Diagnosis,
He Could Not Have Been Properly Found Negligent
Merely Because He Did So on One Occasion**

Just as the LISTEN could not be indicted as inefficacious based on one anecdote, Dr. Ames could not have been rationally found negligent based on one assertedly erroneous diagnosis, unless, again, the panel is applying a special discriminatory rule to alternative physicians. *Gerard v. Sacred Heart Medical Center*, 86 Wn.App. 387, 389, 937 P.2d 1104, 1105 (Div. 3, 1997) (error in judgment is not in itself negligence). Physicians and health care providers make errors all of the time. The panel found that Dr.

Ames used the LISTEN in good faith and was not guilty of acts of dishonesty or moral turpitude. CR 1863; App. 3, ¶2.5. This is a finding that when he used it, he thought it efficacious. The panel did not find that Dr. Ames had reason to know the device was inefficacious and that its empirical support was of no value – there was no evidence for such a finding. Thus, negligence could not properly be found for the one clinical error asserted.

D. The Finding Is Unsupported Because The Very Evidence Found Credible Was That the Diagnosis Asserted Was Based on Conventional Blood Testing

The Amended Statement alleged and the Order found that Dr. Ames ordered blood tests and discussed the findings with Patient One. CR 61, 1858; App. 2, ¶1.13; App. 3, ¶¶ 1.14, 1.15. One of those tests, the RAST test, as both P1 and Dr. Ames testified, showed that the patient had an egg allergy. CR 2082, 2170-2171. P1 testified that Dr. Ames's alleged diagnosis was based on this test. CR 2192, 2203-2204, 2206. The panel expressly found Patient One's accounts of his visits with Dr. Ames credible. CR 1854; App. 3, p. 5. There was no testimony that the alleged diagnosis of an egg allergy was based on the NAET muscle testing using the LISTEN.

The panel's finding of negligence rested not only on the finding that the LISTEN had been wrong on the one occasion involved in this proceeding, but also on a finding that Dr. Ames's alleged diagnosis of an egg allergy was based on his use of the LISTEN. Thus, just as a failure to establish that the

LISTEN was inefficacious would defeat the finding of negligence, so too would a failure to establish that Dr. Ames used the LISTEN to reach his alleged conclusion that there was such an allergy. But the evidence was that Dr. Ames relied not on the LISTEN, but on the blood test. Thus, the finding is unsupported by any evidence on this essential element and cannot stand.

E. The Finding That Patient One Did Not Have an Egg Allergy When He Saw Dr. Ames is Also Logically Fallacious, Speculative and Grossly Unsupported

The finding of inefficacy is based entirely on a finding that Patient 1 did not have an egg allergy when he came to see Dr. Ames. Thus, DOH had the burden of proving that P 1 did not have that allergy, by clear and convincing evidence. But DOH called no expert witness to so testify and introduced no medical records to this effect. There was no evidence that P1 had ever been tested for an egg or any other food allergy. There was no contention, let alone evidence, that anyone (with or without testing) – physician, other health care provider, or even layperson – had ever told him that he did *not* have such an allergy. Indeed, even P1 testified that he did not know if he had an egg allergy. CR 2269.

The only medical records introduced were in Dr. Ames's chart. CR 1851, 1932-1982. These contained P1's records from other physicians, but no reference to testing or diagnosis relating to allergies. *Ibid.* Nor did DOH call any medical or other experts on allergies – indeed, DOH called no physicians

for any purpose – and thus there was no evidence regarding the nature of food allergies, their symptoms, testing, or treatment that supported DOH. The reason there was no expert or documentary evidence that P1 did not have an egg allergy was that this proposition was not part of DOH's case when it filed either the original or the amended statement of charges; when it filed its pre-trial statement; or when it made its opening statement. See *infra*. Nor would essential testimony relating to the egg allergy have even been in the record when DOH rested had it not been elicited from P1 by Ms. Paxton, the *ad hoc* architect of this and another major theory reflected in the Order. (The illegality of relying on the testimony she elicited is discussed *infra*.)

Thus, the findings on which the panel found no egg allergy were solely as follows: (1) that no one other than Dr. Ames had diagnosed P1 with an egg allergy; (2) that P1 “had no reaction to eating eggs, except that he does not like to eat them;” and (3) “there was no clinical evidence to support” a finding of an egg allergy. CR 1861; App. 3, ¶ 1.25.

As to the Absence of an Earlier Diagnosis. That no one ever told P 1 he had an egg allergy does not even create a colorable inference.

where circumstantial evidence is relied on to prove negligence, the circumstances must, with reasonably certainty, lead to the conclusion for which they are adduced.

Sanchez v. Haddix, 95 Wn.2d 593, 627 P.2d 1312 (1981). For one thing, there was no evidence that P1 was ever *told* that he did *not* have an egg

allergy or ever tested for an egg or any other food allergy. There was evidence of a non-food allergy – i.e., to dust and pollens – and that he had hay fever. The panel may have assumed that if he was so diagnosed, he was tested or at least examined for food allergies as well. But that would be sheer, unsupported speculation. DOH called no witness to so testify. Not even a scintilla of evidence supports such an inference.

Even if it were admissible to infer that P1 had been tested for food allergies from the fact that he had been tested for dust and pollen allergies, there was no evidence to support a reasonable, non-speculative inference that P1 did not develop an egg allergy in the following 20 to 25 years.¹⁷

No Reaction (That he Knew Of). Nor can P1's testimony that he had no "reaction" to eggs establish that he did not have an allergy to them. First, when he gave the answer, it was in response to a question from Ms. Paxton, not a physician and obviously not an expert on allergies, who told him what she thought the symptoms of all allergies were ("congestion, hives, . . .

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Indeed, it would not even support a reasonable inference that he did not have an egg allergy 20 to 25 years ago. Since there was no evidence of any testing for food allergies, there was also no evidence that the testing that was hypothetically done was reliable. There was, of course, no evidence that this hypothetical testing was superior to Dr. Ames's testing, if the testing were different. The meaning of such testing – if it had occurred – could not be determined because there was no evidence about allergy testing, except testing from Dr. Ames's witnesses – i.e., himself and Dr. Martin – and that was to the effect that conventional allergy testing was not highly reliable – one of the reasons that alternative modalities were employed and why Dr. Ames did not rely on any one indicium in deciding whether to treat a patient for an allergy.

closing of the throat”) and her question, in effect, asked him if he had those symptoms. CR 2269. Thus, his statement that he had no “reaction” to eggs is ambiguous, not clear and convincing. It may only have meant that he did not have common pollen allergy symptoms. In legal terms, P1 was not competent to testify to the symptoms of food allergies; there was no evidence that he was; and he did not purport to so testify. See Ravsten v. Department of Labor and Industries, 108 Wn.2d 143, 736 P.2d 265 (1987) (diagnosis and prognosis are medical matters requiring medical testimony); McKee v. American Home Products Corp., 113 Wn.2d 701, 782 P.2d 1045 (1989) (“medical facts . . . must be proved by expert testimony”). No witness supporting DOH testified to the symptoms of food allergies. (Ms. Paxton’s assertion, of course, is not evidence.) P1, when asked if he was cured of his egg allergy, said “I don’t know,” CR 2269, suggesting his awareness of limited knowledge about his own allergies. Certainly, no one testified that P1’s symptoms were not the kinds that people with food allergies have. See CR 3079 (“allergies which cause fatigue”). P1 could only testify to reactions of which he was conscious and which he consciously connected to eating eggs. But the fact that he was not conscious of any effect on his body from eating a particular food would not support an inference that the food had no adverse effect on him. Allergy testing is common and necessary, because people commonly do not know if they are allergic, and if so, to what, but the

fact that they do not know, does not mean that they have no allergies. See CR 2975-2976. For a patient's dramatic discovery of a sugar allergy he did not know he had until muscle tested with the LISTEN, see CR 2697, 2699.

P1 admitted that the fatigue, lethargy, aches and pains he reported were symptoms and he did not know what caused them. CR 2274-2275. Dr. Ames would not have ordered blood testing for food allergies – if he was acting in good faith, and the panel found him in good faith – unless he thought that these symptoms might be caused at least in part by a food allergy of some kind. There was no evidence of a motive to order unnecessary tests.

Clinical Evidence. The panel begs the question when it asserts that there was no clinical evidence of an egg allergy. It is assuming without proof that the RAST blood test showing of an egg allergy, P1's fatigue, lethargy, apathy, aches and pains, and the results of the muscle testing using the LISTEN were not even some evidence of such an allergy. Although none are conclusive, they are all some evidence of an egg allergy. Thus, the finding that there was *no* clinical evidence of such an allergy is unsupported and directly contradicts the record. That the muscle testing using the LISTEN produced evidence of an allergy is supported by the experience of the patients Dr. Ames was permitted to call and by Dr. Martin. *See, e.g.*, CR 2970-2972, 2696-2700, 2730, 2732. For Dr. Ames's testimony of efficacy, see CR 2164, 3037-3038, 3044-3048, 3051, 3061-3063, 3116. In the absence of clear and

convincing evidence that this testing was inefficacious – and at bottom the only evidence was the assertion of no egg allergy, based in part on the assumption that the testing indicating there was such an allergy did not work, *i.e.*, the proposition to be proved – it must be presumed to be efficacious.

F. The Finding of Negligent Use of the LISTEN Is Based on Uncharged Facts of Which Dr. Ames Was Not Given Notice And Thus Can Support No Finding or Conclusion Here

In the next section of this brief, Dr. Ames discusses the requirement of DOH regulations, the due process clause and the Administrative Procedure Act that the essential facts constituting a charge of unprofessional conduct must be pleaded in the statement of charges. That authority applies as well to the findings that P1 did not have an egg allergy, and that Dr. Ames treated him for one, and that told him that he had been cured. None of these facts were pleaded, set forth in the DOH pre-hearing statement or even mentioned in the DOH opening statement and they are the basis for a very different theory of the case than is expressed in the Amended Statement of Charges. See CR 3, 60; App. 1, 2; CR 898, 965, 2052-2058. Dr. Ames was not prepared to defend against that theory. The finding that P1 did not have an egg allergy, for example, is essential to the finding that the LISTEN was inefficacious and that there was an unreasonable risk of harm, but it was never claimed and the evidence relating to it came in casually and without indication that it was sought for more than background. Amendment of the

pleadings to conform to proof is not permitted under DOH regulations. WAC 246-11-260(2). And no such amendment was sought in any event. The discussion below shows why these central and other factual allegations had to be pleaded. The failure to plead them or otherwise give Dr. Ames notice in itself requires dismissal of this case.

III. THE FINDING OF NEGLIGENT FAILURE TO INVESTIGATE THE SAFETY OF AN FDA-CLEARED DEVICE IN WIDE USE WAS NOT ONLY NOT CHARGED, BUT IS SUPPORTED BY NOTHING OTHER THAN GROSS, *AD HOC* SPECULATION

The Commission apparently finds Dr. Ames additionally negligent, because, it asserts, he “failed to take the necessary safety measures to ensure that the LISTEN device would not be harmful.” CR 1862; App. 3, ¶1.27. There is no such charge in the statements of charges, or in the DOH pre-trial or opening statements. See CR 3, 60; App. 1, 2; CR 898, 965, 2052-2058. DOH could have amended when it filed its pre-hearing statement and at the outset of the hearing. See CR 898, 965; WAC 246-11-260(2). It did not do so. The presiding officer expressly rejected DOH’s belated attempt to make this an issue. CR 2677; see also CR 2168 (substance of statement of charges is that *use* of the LISTEN is unprofessional).¹⁸ The charges filed are based

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For an elaboration of what the law requires, see *Cooper v. Board of Professional Discipline of Idaho State Bd. of Medicine*, 134 Idaho 449, 454-455, 4 P.3d 561, 566-567 (2000) (emphasis added):

In order to satisfy due process, the complaint must specify the *particular acts* of unprofessional conduct alleged. [*citing authority*] The professional is not required to defend against or explain any matter not specified in the charges. . . . It is elementary that in any judicial or *quasi*-judicial proceeding, a pleading in

solely on P1's two visits with Dr. Ames and the spurious claim of an FDCA violation. Thus, to predicate a finding of unprofessional conduct under the UDA on other facts, plainly violates agency regulations, the APA and due process. WAC 246-11-250(1)(b) requires that a DOH statement of charges "include a *clear* and concise statement of the (b) *Factual* basis for the action or proposed action set forth in the document." Emphasis added. Due process entitles the licensee "to be notified of *clear* and *specific* charges and to be afforded an opportunity to anticipate, prepare, and present a defense." *In re Disciplinary Proceeding Against Romero*, 152 Wn.2d 124, 137, 94 P.3d 939, 945 (2004)(emphasis added.) See also RCW 34.05.434(2)(3).

No doubt because DOH had no complaint about Dr. Ames's investigation of the LISTEN, it offered no evidence on the subject in its case in chief. Nevertheless, the panel found that Dr. Ames "failed to

take the necessary safety measures to ensure that the LISTEN device would not be harmful to his patients. The Respondent obtained no literature or had no labeling on the LISTEN device, and he had not received any personal training on its use. The Respondent only listened to his colleagues and to a salesperson. The Respondent did not know the voltage or the amperage that the device produces.

Note: the panel does not find the LISTEN unsafe – as it could not, since the

the nature of an accusation or complaint must contain *positive statements of the essential facts, and that it is insufficient where it merely states conclusions....* [The defendant] was entitled ... to have the charges set out specifically, in order that he might have time and opportunity to prepare his defense."

FDA cleared it and the only testimony (including testimony from the DOH biofeedback expert, Dr. Sherman) was that it was safe. DOH introduced no evidence that Dr. Ames or anyone else – health care provider, patient, manufacturer, distributor, retailer – had ever had a safety problem with it or with any other similar device. Thus, the finding says in effect, that although the device was safe and was cleared by the FDA, it might have been unsafe and therefore Dr. Ames should not have relied “only” on his colleagues and a salesperson, but should have obtained literature or labeling about its safety and should have learned its exact voltage or amperage. .

First, there was no evidence that Dr. Ames relied “only” on consultations with his colleagues and the vendor. The only evidence relating to this was in Dr. Ames’s own testimony and Dr. Ames testified not only that he consulted colleagues and the vendor, but that he knew that the device and devices like it were being marketed freely without FDA interference; many other physicians and health care providers had told him that they were using them, and that they were quick, effective and safe; and that the device had been “registered” or “cleared” with the FDA. CR 2105, 2107-2108, 3037-3038, 3063-3065. Most importantly, Dr. Ames used it on himself and experienced no other problem with it. CR 3120. At the time he allegedly used it with P1 he had been using the device for four years and had never had any problem with it. CR 2102, 3119-3120. Second, there was no evidence

about the practices of physicians or features of the device which should have led Dr. Ames to do more than he did. That is, there was no evidence supporting a non-speculative inference that what he did was not sufficient in light of the risk. There was no evidence that physicians do not typically rely “only” on colleagues and vendors for this kind of information.

Third, the finding that literature, labeling or personal training was “necessary” was unsupported. There was no evidence that anything in the literature, labeling or a tutorial would not have been and was not learned from the consultations he had with colleagues and vendors and from his own personal use with it. *Who, after all, would have written the literature or the labeling if not colleagues and/or the vendor?* In this case, the “vendor” was the actual developer of the device. CR 2157, 2838-2839, 2841-2842, 3064-3066. The panel is speculating about what Dr. Ames learned from colleagues and Mr. Clark and about what could be learned from literature. These speculative inferences are not reasonable, not admissible and insufficient to support the finding. The fact that Dr. Ames could not recall the exact amperage or voltage – he correctly said there was a five ohm current – does not mean that he did not know that the energy involved was minuscule and insignificant, as it was. CR 2097-2098, 2177. That he was not sure of the specific number several years after purchasing, and after four years of using, the device supports no rational finding against him.

The evidence on which the Commission relies was developed primarily by Ms. Paxton. This questioning was one of a number of her attempts to save the case that DOH brought to the hearing (which plainly was not supported by relevant evidence) by raising unpleaded issues. CR 2167-2169, 2177, 2264-2268, 2349, 3155-3157, 3162-3164. Ms. Paxton apparently knew little about electricity (early on she asked Dr. Ames to tell her what “resistance” was: CR 2097). The findings express one layperson’s concern with an electronic device for which there was no evidence of any danger and one of her – and the panel’s ideologically-based attempts – to find a way to prevent the use of the LISTEN.¹⁹

IV. “PROMOTION FOR PERSONAL GAIN” WAS NOT SUPPORTED BY THE FINDINGS

The panel found that Dr. Ames violated RCW 18.130.180(16), which declares to be “unprofessional conduct”:

promotion for personal gain of any unnecessary or
inefficacious drug, device, treatment, procedure, or service

CR 1861; App. 3, ¶ 1.26. Since the evidence did not support a finding of

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The alleged requirement to take more steps to insure the safety of the device would never have been made of a conventional physician, many of whom it is certain know very little about the engineering of the devices they use or prescribe. And, although, in the Order and in its brief, the panel and DOH are dismissive of consultations with colleagues and vendors, the court can take as a legislative fact that they are a defining characteristic of medical and other health care practices. For example, conventional physicians rely – far too much – on drug and equipment salespersons for their knowledge of these items – and look to their colleagues in deciding what is acceptable practice.

inefficacy, the conclusion cannot stand. There are, however, additional grounds for overturning it.

Even if the LISTEN/NAET testing was inefficacious, the findings must still support the conclusion that Dr. Ames “promot[ed it] for personal gain.” But such a conclusion disregards fundamental principles of statutory interpretation and would never be invoked in a proceeding against a conventional physician. The panel finds that Dr. Ames “promot[ed]” the LISTEN “for personal gain,” because the device was used in his practice as “part of the whole picture of assessment and treatment,” helping in assessments and speeding up visits. CR 1857, 1861; App. 3, ¶1.12 and ¶1.26. It is conceded that the patient is not charged for using the device. But it is claimed that Dr. Ames bills “for visits that include the LISTEN device’s use,” and that he suggested that P1 return for additional food allergy treatments. *Ibid.* All of this, other than the statement about P1, is based on testimony of Dr. Ames, which the panel accepted. Dr. Ames also testified that patients are charged the same whether the device is used with them or not and that he did not recoup the cost of the LISTEN. CR 2162, 3119. The panel did not find otherwise and did find Dr. Ames acted in good faith. CR 1863; App. 3, ¶2.5.

The Panel’s finding means that the statute applies to any physician, conventional or alternative, who in good faith uses a device in his practice that is later determined to be inefficacious by a regulatory body, if the use of

the device is related to a service for which the physician charges and provides in good faith. This violates several fundamental principles of statutory interpretation set forth above. See generally Ted Rasmussen Farms, LLC v. State, *supra*, at 94-95; Bauer v. State Employment Sec. Dept., *supra*, at 473-474. Where possible every word in the statute must be given effect and the statute must be interpreted in the context of other related provisions – *e.g.*, RCW 18.130.180(1) and (4) – all of which must be given effect and harmonized. See also Mader v. Health Care Authority, 70 P.3d 931, 937 (Wa. 2003). Unlikely, strained or absurd interpretations should be avoided. Glaubach v. Regence BlueShield, 149 Wash.2d 827, 833-834, 74 P.3d 115, 118 (2003). The statute must be construed to effectuate, not defeat the legislature’s intent. Steele v. State, 85 Wash.2d 585, 590, 537 P.2d 782, 786 (1975) (statutes are construed to be purposeful and effective).

The panel’s interpretation disregards the literal language and defeats the purpose of RCW 18.130.180's provision that “The use of a non-traditional treatment by itself shall not constitute unprofessional conduct”; fails to give effect to the words “promotion” and “personal gain”; disregards the language of RCW 18.130.180(1), and yields absurd consequences, because if applied to conventional medicine, as it must be if the panel is not to be allowed to discriminate by *ad hoc* rulings against alternative medicine, it would indict all physicians for conduct that is clearly innocent and acceptable.

Although it appears in a section of the UDA which deals with incompetence, negligence and malpractice, the provision protecting alternative medicine in RCW 18.130.180(4) does not merely say that “use of a nontraditional treatment by itself” shall not constitute incompetence, negligence or malpractice. It says that it shall not constitute “*unprofessional conduct*,” which is another way of saying that it shall not constitute a violation of any subsection of RCW 18.130.180, the statute that defines unprofessional conduct. That in turn means that nontraditional treatment is not a violation of subsection 16 in the absence of unreasonable risk.

The literal interpretation is supported by considering the effect on alternative health care – and, therefore on the purpose of RCW 18.130.180(4) – if the use of what is later ruled to be an inefficacious device is held a violation of subsection 16. The reason various procedures and treatments are called alternative is that they are not accepted by orthodox physicians, who do not believe they work – *i.e.*, they believe (or profess to believe) that they are “inefficacious” or “unnecessary.” Thus, if subsection 16 were construed to permit a medical commission to find unprofessional the use in a typical alternative practice (*i.e.*, one in which the patient pays for the service) of any device or service that conventional physicians think to be inefficacious or unnecessary – the commission will inevitably represent conventional thinking, because the great majority of physicians are conventional and their

views dominate the mass media – it would make many if not most alternative physicians guilty of unprofessional conduct merely for being alternative. Thus, the protection provided by subsection 4 would have been largely read out of the statute by the interpretation given to subsection 16.

That the mere good faith use in an alternative practice of a device later determined to be inefficacious cannot be a violation of subsection 16 is also supported by other parts of RCW 18.130.180. Under subsections 1 and 4, the knowing use of an inefficacious device and the negligent use of such a device if the use creates an “unreasonable risk” of harm are prohibited. What would a prohibition of the use of such a device under subsection 16 add to these prohibitions? What it would add, if the panel’s interpretation is accepted, is strict liability. But strict liability for such a use would have two absurd consequences. The first we have already mentioned: it would severely deter the use of alternative modalities despite RCW 18.130.180(4). The second would potentially affect conventional medicine in ways it could not tolerate.

Suppose, for example, that a physician comes across a noninvasive remedy having anecdotal evidence of efficacy and, after fully informing them of the nature of the evidence, recommends it to patients who have no other treatment option. Later, after the remedy develops some popularity, it is subjected to rigorous clinical trials and found to be no better than a placebo. The physician then abandons it. But has he violated subsection 16 for trying

something out which seems to work for a condition that does not respond to any accepted treatment, and which seems to have little downside. Surely, the physician has not acted unprofessionally. But the panel's interpretation of subsection 16 would make his conduct "unprofessional," because he recommended and charged for the remedy. This is an absurd consequence.²⁰

The Meaning of "Promotion" and "Personal Gain." The section does not literally prohibit the "use" of an inefficacious device. It prohibits "promotion" of the device and only when "for personal gain" – which implies a commercial, not a professional act. Professional use of such devices can be handled under subsections 1 and 4. Physicians, as entrepreneurs, and consultants to and salespersons for drug, medical equipment and supplement companies, frequently promote medical products to the consuming public. Subsection 16 is confined to this kind of situation.

***Promotion and Personal Gain in this Case – Even
if the Subsection is Held to Apply to a Medical Practice***

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Nor is there a chance in a million that a medical board would prosecute – unless he were an alternative physician. The hypothesized situation is not materially different from the everyday practice of using devices and treatments "off label." These devices and treatments, although approved or cleared by the FDA for a different use, have not been determined to be effective for the "off label" use. In many cases, the "off label" use will eventually be shown to be inefficacious by rigorous studies. But will the thousands or hundreds of thousands of conventional physicians who have employed it for the inefficacious use be prosecuted under subsection 16? Not on your life. Such an interpretation would be recognized as inadmissible, unless, perhaps, the physician was an alternative physician.

Even if merely recommending a treatment some times suggested by a test “promotes” a device used in the test, there was no evidence that Dr. Ames derived any personal gain from using the device with P1. Despite the finding to the contrary, there was no evidence that P1 was charged for the alleged egg allergy treatment. P1 did *not* so testify. Nor did DOH produce any statement, bill or other record reflecting such a charge. DOH made P1's chart an exhibit. See CR 1932-1982. But it shows no such a charge. Indeed, the chart notes for July 10, 2001, when P1 was allegedly treated for the egg allergy, report no such treatment. CR 1932.

The panel does not find that Dr. Ames charged patients for using the LISTEN device. Nor does it find noncredible his testimony that he charged patients the same fee whether he used it or not. There was no evidence or finding to the contrary. To be sure, use of the device did make it possible for Dr. Ames to speed up the testing of possible allergens. But that does not mean that he thereby made more money. That is wholly speculative.²¹

V. THE EVIDENCE WAS INSUFFICIENT TO SUPPORT THE FINDING OF AN UNREASONABLE RISK OF HARM

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There was no evidence that use of the device in any way increased his income, that he thought it did or that his purpose in using it was to do so. The fact that it speeded up the allergen checking process does not mean that Dr. Ames thereby saw more patients and thereby made more money because of the LISTEN. The sessions may have been just as long, more might have been covered and yet the charge would have been the same. In other words, the evidence did not support a finding of “promotion for personal gain” in P1's case, even if charging a professional fee for treatment qualifies as “personal gain.”

If Dr. Ames is correct, to find a violation of RCW 18.130.180(4) or (16), requires clear and convincing evidence that he either harmed, or created an unreasonable risk of harm to, P1. The panel first responds asserting that Dr. Ames's treatment is not "nontraditional," implying that, therefore, a showing of harm or unreasonable risk of harm is unnecessary. See CR 1862; ¶ 1.28. Second, it simply asserts an unreasonable risk to P1. CR 1862.

The finding that Dr. Ames's treatments are not "nontraditional" cannot be taken seriously. It is clear on its face that Dr. Ames's practice is an alternative, holistic, not a conventional, practice and that is all that is meant by "nontraditional." See the legislative history of RCW 18.130.180(4), *supra*, at p. 26. The panel's own findings recognize that Dr. Ames is a holistic physician and the legislative history describes this as "nontraditional." *Ibid*; CR 1854; App. 3, ¶1.1.

Nor is there sufficient evidence or appropriate factual findings to support a finding/conclusion that Dr. Ames by using the LISTEN created an unreasonable risk of harm to P1. The finding is that such a risk was created by relying on an inefficacious device, providing an ineffective treatment, and misinforming P1 that he had been cured. CR 1862, ¶1.29. But, first, the evidence was that Dr. Ames relied on the RAST blood test, not on the LISTEN. Second, two findings on which the ultimate finding of unreasonable risk is based – the finding that the *treatment* was ineffective and the finding

that P1 was told that he had been cured – were not in the statement of charges and therefore are invalid. See CR 2545. All that the relevant sections of the Amended Statement say is that Patient One had various lab tests, was muscle tested with the aid of the LISTEN and that he was told that Dr. Ames thought he could do what the device did. This gave notice that DOH was challenging the muscle testing with the LISTEN – a form of assessment, as ¶ 1.2 of the Amended Statement charged – but not the treatment, which was the acupuncture, or a prognosis of cure. Such allegations could have been added when the Amendment Statement or the pre-hearing statement was drafted, but they were not. Third, there is no evidence that the treatment itself was ineffective. Nor is that a reasonable inference from the finding that the patient did not have an egg allergy. If he did not have the allergy, there was nothing to treat, but that does not mean that if there had been an allergy, the treatment could not have been effective.

Fourth, there is no evidence of what the risk of harm is. There is only assertion of unreasonable risk. If the panel were right and P1 did not have an allergy, telling him after the treatment that he did not have an egg allergy was correct and reliance on the statement could cause no harm. If the claim is that a false positive from the muscle testing created an unreasonable risk of harm, there are two responses. First, false positives are common among even conventional assessment devices and procedures, and thus in themselves

could not be unreasonable risks. Second, by telling P1 that he had an egg allergy when, by hypothesis he did not, the only effect would be that he either would or would not continue to eat something he was already eating. Neither of these options created a new risk for him. That is a defining characteristic of alternative health care: it is noninvasive and so if it doesn't work there is little if any harm, unlike conventional medicine with its invasive drugs, surgery, radiation, etc.

If RCW 18.130.180(4) is to have any meaning, the courts – just as the legislature in RCW 18.120.010 – must insist on hard evidence of real, not manufactured or speculative risk of harm. See RCW 18.120.010 (health care should not be regulated unless “the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument”). It is always possible for an orthodox provider to say of a supposedly inefficacious or unnecessary (read: “alternative”) modality – as it has always been said of alternative health care – that it creates an unreasonable risk because patients may rely on the alternative and forego or delay a conventional modality that *might* have helped them (if there were a conventional treatment whose benefits clearly outweighed its side effects, it is unlikely that the patient would seek the alternative or that the alternative practitioner would recommend it). Thus, if the protection for alternatives is to be effective, a finding of harm or unreasonable risk of harm must be based on hard

evidence, not convenient, boilerplate speculation, that an inefficacious modality might cause harm because it is inefficacious. There was no such evidence of any risk of harm in this case.

**VI. THE SANCTIONS ORDERED BY THE PANEL
WERE A MANIFEST ABUSE OF DISCRETION**

The panel found that Dr. Ames purchased and used the LISTEN in good faith. It found that he had not acted fraudulently or immorally and that he had not violated the FDCA. There was substantial anecdotal evidence that the device worked. The evidence on negligence and inefficacy was essentially one anecdotal experience recounted by one patient who was not complaining about the use of the device. On these facts, the sanctions ordered were a manifest abuse of discretion. See *Olmstead v. Department of Health*, 61 Wn.App. 888, 812 P.2d 527 (1991) (“such order on these findings was arbitrary and capricious”)²²

CONCLUSION

From the beginning of this action through the entry of the final order, this has been an ideological, result-oriented attempt by rearguard elements in the Medical Commission to suppress an alternative modality irrespective of

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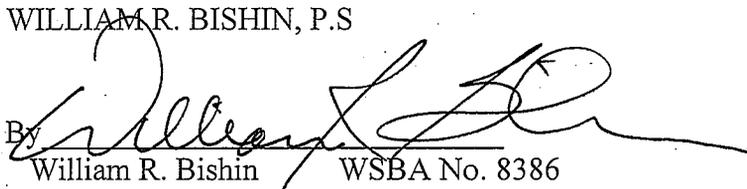
No suspension and no fine could be warranted. Nor could any monitoring of the sort ordered. This is especially so, because of the dangers of putting an alternative physician under the monitoring authority of a board comprised entirely of conventional practitioners and lay people who look to them for expertise. Such monitoring will inhibit the use of alternative modalities, contrary to state policy. See RCW 18.130.180(4) and 18.120.010.

evidence and procedure and the rules for construing statutes. The Court should reverse and vacate the Order and admonish the Commission that it will not be permitted to so grossly abuse the discretion entrusted to it.

Respectfully submitted this 5th day of July, 2006.

LAW OFFICES OF
WILLIAM R. BISHIN, P.S

By


William R. Bishin

WSBA No. 8386

COURT OF APPEALS, DIVISION III
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

**WASHINGTON STATE HEALTH
DEPARTMENT MEDICAL QUALITY
HEALTH ASSURANCE COMMN.,**

Respondent.

**ON APPEAL FROM THE SUPERIOR COURT OF
BENTON COUNTY, THE HON. CARRIE RUNGE PRESIDING**

APPENDIX

OPENING BRIEF OF PETITIONER

1. **Statement of Charges**
2. **First Amended Statement of Charges**
3. **Findings of Fact, Conclusions of Law and Final Order**
4. **Department of Health Regulations**
 - WAC 246-11-250
 - WAC 246-11-260
 - WAC 246-11-520
5. **RCW 18.130.180**
6. **Administrative Procedure Act (Excerpts)**
 - RCW 34.05.452
 - RCW 34.05.461
 - RCW 34.05.
7. **RCW 18.120.010**

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice)
As a Physician and Surgeon of:)

GEOFFREY S. AMES, MD)
License No. MD00026961)

Respondent.)
_____)

Docket No. 02-06-A-1012MD

STATEMENT OF CHARGES

FILED

JUL 10 2002

Adjudicative Clerk
Office

The Program Manager of the Medical Quality Assurance Commission, (Commission), on designation by the Commission, makes the allegations below, which are supported by evidence contained in program case file 2001-08-0007MD. Any patients referred to in this Statement of Charges are identified in an attached Confidential Schedule.

Section 1: ALLEGED FACTS

1.1 Geoffrey S. Ames, MD, Respondent, was issued a license to practice as a physician by the state of Washington in December 1989.

1.2 On or about July 10, 2001, Respondent tested Patient One for food allergies using an electro-diagnostic device called the Life Information System Ten device (LISTEN device). Respondent later admitted to a Department of Health representative that he uses the LISTEN device to detect food allergies in patients.

1.3 The LISTEN device uses low voltage to measure galvanic skin resistance.

1.4 The LISTEN device is a medical device under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h). A medical device may not be marketed until there is either an approved application for premarket approval, pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption, pursuant to 21 U.S.C. § 360j(g). There is no approved application for premarket approval or investigational device exemption for the LISTEN device.

1.5 A manufacturer is exempt from the requirements in the above paragraph if it files a pre-market notification under section 21 U.S.C. § 360(k), and the Food and Drug Administration (FDA) rules the device is "substantially equivalent" to a device already on the market. This is known as receiving "510(k) approval."

1.6 In 1996, the FDA granted "510(k) approval" for the Digital Conductance Meter to be used for relaxation training in the biofeedback process.

1.7 The FDA has not granted "510(k) approval" for the LISTEN device.

1.8 Although a component of the LISTEN device is a digital conductance meter, the LISTEN is different in several significant respects, including using different software, and is, therefore, a new device, which must meet the requirements listed in paragraph 1.4, above.

1.9 Commercial distribution of a device prior to obtaining an approved application for premarket approval or an investigational device exemption, or receiving "510(k) approval" results in the device being adulterated under 21 U.S.C. § 351(f)(1)(B).

1.10 By receiving an adulterated device in interstate commerce, Respondent has violated 21 U.S.C. § 331(c).

1.11 Even if the "510(k) approval" for the digital conductance meter applied to the LISTEN device, Respondent did not use the digital conductance meter for its approved purpose.

1.12 The LISTEN device is a medical device under RCW 69.04.010. The use of an adulterated or misbranded device is prohibited under RCW 69.04.040(1) and (3).

Section 2: ALLEGED VIOLATIONS

2.1 The violations alleged in this section constitute grounds for disciplinary action, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

2.2 The facts alleged in paragraphs 1.2 through 1.12 constitute unprofessional conduct in violation of RCW 18.130.180(7), which provides in part:

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice.

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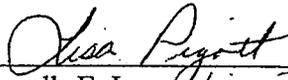
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Section 3: NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Program Manager of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

DATED this 9th day of July, 2002.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION



Maryella E. Jansen Lisa Pigott
Disciplinary Manager



Jim McLaughlin WSB# 27349
Assistant Attorney General Prosecutor

FOR INTERNAL USE ONLY. INTERNAL TRACKING NUMBERS: Program No. 2001-08-0007MD

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

FILED
FEB 05 2003
Adjudicative Clerk Office

In the Matter of the License to Practice)
As a Physician and Surgeon of:) Docket No. 02-06-A-1012MD
)
GEOFFREY S. AMES, MD) FIRST AMENDED STATEMENT
License No. MD00026961) OF CHARGES
)
Respondent.)
_____)

The Program Manager of the Medical Quality Assurance Commission, (Commission), on designation by the Commission, makes the allegations below, which are supported by evidence contained in program case file 2001-08-0007MD. Any patients referred to in this First Amended Statement of Charges are identified in an attached Confidential Schedule.

Section 1: ALLEGED FACTS

1.1 Geoffrey S. Ames, MD, Respondent, was issued a license to practice as a physician by the state of Washington in December 1989.

1.2 On or about July 10, 2001, Respondent tested Patient One for food allergies using an electro-diagnostic device called the Life Information System Ten device (LISTEN device). Respondent later admitted to a Department of Health representative that he uses the LISTEN device to detect food allergies in patients.

1.3 The LISTEN device uses low voltage to measure galvanic skin resistance.

1.4 The LISTEN device is a medical device under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h). A medical device may not be marketed until there is either an approved application for premarket approval, pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption, pursuant to 21 U.S.C. § 360j(g). There is no approved application for premarket approval or investigational device exemption for the LISTEN device.

1.5 A manufacturer is exempt from the requirements in the above paragraph if it files a pre-market notification under section 21 U.S.C. § 360(k), and the Food and Drug Administration (FDA) rules the device is "substantially equivalent" to a device already on the market. This is known as receiving "510(k) approval."

000060

ORIGINAL

ATT. 3

1.6 In 1996, the FDA granted "510(k) approval" for the Digital Conductance Meter to be used for relaxation training in the biofeedback process.

1.7 The FDA has not granted "510(k) approval" for the LISTEN device.

1.8 Although a component of the LISTEN device is a digital conductance meter, the LISTEN is different in several significant respects, including using different software, and is, therefore, a new device, which must meet the requirements listed in paragraph 1.4, above.

1.9 Commercial distribution of a device prior to obtaining an approved application for premarket approval or an investigational device exemption, or receiving "510(k) approval" results in the device being adulterated under 21 U.S.C. § 351(f)(1)(B).

1.10 By receiving an adulterated device in interstate commerce, Respondent has violated 21 U.S.C. § 331(c).

1.11 Even if the "510(k) approval" for the digital conductance meter applied to the LISTEN device, Respondent did not use the digital conductance meter for its approved purpose.

1.12 The LISTEN device is a medical device under RCW 69.04.010. The use of an adulterated or misbranded device is prohibited under RCW 69.04.040(1) and (3).

1.13 On or about June 6, 2001, Respondent saw Patient One complaining of chronic fatigue. Respondent ordered urine and blood tests and hair analysis.

1.14 On or about July 10, 2001, Patient One returned to see Respondent to discuss the test results. Respondent told Patient One that the blood tests showed a number of food allergies. Respondent then used the LISTEN device on Patient One. Respondent had Patient One lie down on a table and hold his left arm straight up in the air. Respondent then asked Patient One to try to resist when Respondent attempted to push his arm down. Respondent pushed on Patient One's arm but did not push it down. Respondent then had Patient One hold a brass rod in his hand, which was connected to the LISTEN device, and typed in "eggs" into the device. Respondent asked Patient One to hold his left arm up in the air and to try to resist when Respondent attempted to push his arm down. Respondent then pushed Patient One's arm down and told Patient One that this showed he was allergic to eggs. Respondent repeated the test, but placed a piece of paper over the brass rod. When Patient One asked Respondent why he placed a piece of paper over the brass rod, Respondent told him he could emit the EMF frequency for eggs and many other foods through telepathy, so he hardly needed the device anymore.

Section 2: ALLEGED VIOLATIONS

2.1 The violations alleged in this section constitute grounds for disciplinary action, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

2.2 The facts alleged in paragraphs 1.2 through 1.14 constitute unprofessional conduct in violation of RCW 18.130.180(1), (7), and (16) which provides in part:

(1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not.

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed.

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice.

The statutes Respondent violated are 21 U.S.C. § 331(c) and RCW 69.04.040(1) and (3), which provide as follows:

Sec. 331. - Prohibited acts

The following acts and the causing thereof are prohibited:

...

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

RCW 69.04.040 Prohibited acts.

The following acts and the causing thereof are hereby prohibited:

(1) The sale in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(2) The adulteration or misbranding of any food, drug, device, or cosmetic in intrastate commerce.

(3) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise.

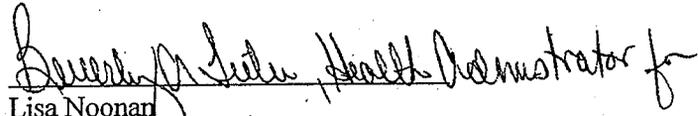
(16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure or service.

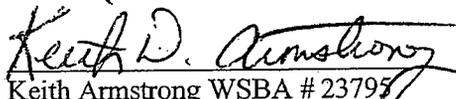
Section 3: NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Program Manager of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

DATED this 5th day of February, 2003.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION


Lisa Noonan
Disciplinary Manager


Keith Armstrong WSBA # 23795
Assistant Attorney General Prosecutor

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice)
as a Physician and Surgeon of:)

GEOFFREY S. AMES, M.D.)
License No. MD00026961,)

Respondent.)

) Docket No. 02-06-A-1012MD

) FINDINGS OF FACT,
) CONCLUSIONS OF LAW
) AND FINAL ORDER

APPEARANCES:

Respondent, Geoffrey S. Ames, M.D.
William Bishin, Attorney at Law

Department of Health, by
The Office of Attorney General, per
Keith D. Armstrong, Assistant Attorney General

COMMISSION PANEL: Cabell Tennis, J.D., Public Member, Panel Chair
Jan Paxton, PA-C, Pro Tem
Sunanda Uberoi, M.D.

PRESIDING OFFICER: Arthur E. DeBusschere, Health Law Judge

The Medical Quality Assurance Commission (the Commission) convened a hearing on January 13-16, 2004 and February 10, 2004. The Department's post-hearing brief was submitted to the Commission on February 25, 2004. The Commission deliberated on March 10, 2004.

The Department of Health issued First Amended Statement of Charges alleging that the Respondent had violated the Uniform Disciplinary Act. License Suspended. Stayed.

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

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ATT. 1

ISSUES

Whether the Respondent engaged in unprofessional conduct within the meaning of RCW 18.130.180(1), (4), (7) and (16).

If the Department proves unprofessional conduct, what are the appropriate sanctions under RCW 18.130.160?

SUMMARY OF EVIDENCE

In consideration of this matter, the Commission heard over thirty-three hours of testimony and oral argument. The Department presented testimony of the following witnesses: Geoffrey Ames, M.D. (the Respondent); Patient One; Richard Sherman, Ph.D.; and Neil Odgen. The Respondent testified on his behalf and presented testimony of the following witnesses: Donald Volkman; Joan McVey; James Clark; and David Martin, M.D. The Department's had two exhibits admitted, which were numbered as Department's Exhibit No. 2 and Department's Exhibit No. 3. The Respondent had eight exhibits admitted, Respondent's Exhibits Nos. 1-8.

ANALYSIS

The Uniform Disciplinary Act (the UDA) defines what conduct, acts, or conditions constitute unprofessional conduct. RCW 18.130.180. In this case, the Department alleged that the Respondent committed four violations under the UDA, specifically RCW 18.130.180(1), (4), (7) and (16).

First, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(1), unprofessional conduct is defined in part as:

The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the

FINDINGS OF FACT,
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act constitutes a crime or not.

RCW 18.130.180(1). During the hearing, the Commission granted the Respondent's motion to dismiss the alleged violation under RCW 18.130.180(1).

Second, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(4), which is defined as:

Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;

RCW 18.130.180(4).

Expert testimony is helpful, but not essential to the Department's case, nor would the lack of such testimony either support or require dismissal of the charges against Respondent. *Johnston v. Washington State Medical Disciplinary Board*, 99 Wn.2d 466, 663 P.2d 457 (1983); *Brown v. State Department of Health, Dental Disciplinary Board*, 94 Wn. App. 7, 972 P.2d 101 (1998). Based on the *Johnston* and *Brown* cases, the Commission can use its own expertise to evaluate the standard of care regarding the Respondent's actions with Patient One. No additional expert is necessary to resolve this case. RCW 34.05.461(5).

Third, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(7), which is defined as:

Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

RCW 18.130.180(7). Specifically, the Department charged the Respondent for violating a federal code, 21 U.S.C. § 331(c), which provides as follows:

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

Sec. 331. – Prohibited acts

The following acts and the causing thereof are hereby prohibited:

.....
(c) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

The Department also charged the Respondent for violating a state statute, RCW 69.04.040(1) and (3), which provides as follows:

The following acts and the causing thereof are hereby prohibited:

(1) The sale in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

.....
(3) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise.

This statute is similar to the above federal code, 21 U.S.C. § 331(c). The facts that would apply to the federal code would apply as well to the allegations under RCW 69.04.040, regarding the LISTEN device being adulterated or misbranded.

In this case, Mr. Ogden did not know about the LISTEN device that was purchased by the Respondent. Likewise, Dr. Sherman not only did not know about the LISTEN device, but also had not seen or evaluated it. In addition, there was no evidence that the manufacturer or the Respondent made significant changes to the LISTEN device that it thereby became adulterated. There was no evidence that the Respondent mislabeled the LISTEN device; thus, there was no evidence that it was misbranded. Finally, the Department failed to offer evidence that the Respondent delivered or offered it for delivery to someone else for pay. During the hearing, the Commission granted the Respondent's motion to dismiss the allegation of unprofessional conduct under RCW 18.130.180(7)

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Fourth, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(16), which is defined as:

Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service;

RCW 18.130.180(16).

During the hearing, the Commission heard and observed the testimony of Patient One and the Respondent. The Commission finds Patient One credible when he testified about his visits with and treatment by the Respondent on June 6, 2001 and July 11, 2001. The Commission did not find the Respondent credible when he testified about his treatment of Patient One on these dates. RCW 34.05.461.

I. FINDINGS OF FACT

1.1 Geoffrey S. Ames, M.D., the Respondent, was issued by the state of Washington in December 1989, a license to practice as a physician and surgeon. The Respondent completed a pathology residency. He completed a year of internal medicine training. He started a family practice in Gardnerville, Nevada. The Respondent is board-certified in holistic medicine. The Respondent took an acupuncture course at UCLA, San Francisco. Since 1995, he has been practicing as a physician in Richland, Washington. The Respondent's practice includes the following specialties: NAET¹ allergy therapy, JMT allergy therapy, neuromodulation technique allergy therapy, acupuncture, acupressure and dermatology.

¹ NAET stands for Nambudripad Allergy Elimination Technique. Devi S. Nambudripad developed the NAET, which is a technique that treats allergies using acupressure.

1.2 The Life Information System Tens device (the LISTEN device) is a galvanic skin response machine. The LISTEN device consists of a keyboard, monitor, a computer with hardware, foot mouse, black box used to create the circuit so an ohmmeter will work. The black box has a wire to a metal probe that is held by the patient in his/her hand. The LISTEN device is an electronic skin response device and it measures changes in resistance, which is the impediment of a flow of electrical current. The LISTEN device uses low voltage, a current of five ohms, to measure galvanic skin resistance.

1.3 James Clark developed the LISTEN device. On January 7, 1992, he submitted information on a LISTEN device to the United States Food and Drug Administration (FDA). The LISTEN system was described as having electrodermal screening techniques, alternative medicine techniques and bioenergetic techniques. The device was not cleared with that labeling. It did not receive pre-market approval since it was not substantially equivalent to predicate devices studied by the FDA.

1.4 In August 1992, James Clark made a submission for the Digital Conductance Meter (DCM) to clear the ohmmeter and the capability for the Listen System without the acupuncture claims and to market the LISTEN device. The FDA cleared the DCM as a biofeedback device for relaxation training. The DCM had been submitted for other uses, but those were removed from the FDA file.

1.5 James Clark has a number of upgraded models that are galvanic skin response devices. They are called the Orion, the Pegasus and the Mira. These upgraded devices have the same hardware as the LISTEN device; they both have the

ohmmeter, computer software and the signal generator. The only difference between the LISTEN device and the later devices was that the LISTEN device was a DOS-operated system while these upgraded devices were a WINDOWS based system.

1.6 In 1996, James Clark obtained clearance from the FDA for the Orion, the Pegasus and the Mira. In 1996, the FDA notified him that his devices (the Orion, the Pegasus and the Mira) were substantially equivalent to a predicate device, which permitted him to proceed to market the devices. James Clark received a pre-market "clearance," not a pre-market "approval." Nevertheless, he could not market the devices as being cleared, because the public might think that the FDA had approved them.

1.7 The Respondent does not know the physics behind the LISTEN device, nor did he know the voltage or amperage that the LISTEN device produces. The Respondent understands the LISTEN device functions like a biofeedback machine, but it is used in different ways. He used it in combination with kinesiology. Kinesiology is based on the theory that an imbalance in acupuncture meridians will make muscles weak. The Respondent learned kinesiology from a NAET course.

1.8 The Respondent heard about the LISTEN device from colleagues, from vendors and from attending conferences of the American Academy of Environmental Medicine. The Respondent has owned the LISTEN device since 1997, when he bought it from the company owned by James Clark. The LISTEN device was made in Utah.

1.9 The Respondent learned to operate the LISTEN device from his colleagues and from the manual, which told him how to operate it. The manual did not

make any claims on its use and provided basic instructions on how to turn it on and off. The LISTEN device had no labeling on it.

1.10 He also sent his office nurse to a course to learn about the LISTEN device. The nurse learned how to use it for Electrodermal Screening (EDS). On one hand, this was not helpful because he does not do EDS. On the other hand, it was helpful because it increased his understanding and knowledge about the device. The Respondent obtained information about the LISTEN device from others colleagues, including Dr. Nambudripad, who uses a machine similar to it, but who purchased it from a different manufacturer.

1.11 Before the Respondent purchased the LISTEN device, he talked with James Clark who informed him that it was registered with the FDA. The Respondent purchased a device that could be sold to him by the manufacturer. The Respondent purchased the LISTEN device in good faith.

1.12 Although the Respondent does not charge his patients specifically for its use, the Respondent bills his patients for visits that include the LISTEN device's use. The device helps in his assessment and speeds up his patient visits. When he sees a patient, the LISTEN device is part of the whole picture of assessment and treatment.

1.13 The Respondent saw Patient One on two occasions: June 6, 2001 and July 10, 2001. At the initial visit, Patient One informed the Respondent that he had been tired. Just before the initial visit, Patient One filled out a health history provided by the Respondent. Patient One described the symptoms that he felt the day of the initial visit. Patient One felt fatigue and experienced sluggishness and that these symptoms

were severe. Patient One frequently tired easily and felt weak. He experienced apathy and lethargy and the symptoms were severe.

1.14 At the initial visit, the Respondent discussed metal toxicity and metal poisoning with Patient One. The Respondent talked about his alternative medicine practice and informed Patient One that he would send him to the Tri-Cities laboratory for blood and urine testing. The Respondent took a hair sample. The first visit lasted about 30 to 45 minutes.

1.15 During the second visit on July 10, 2001, the Respondent reviewed Patient One's laboratory tests results. The Respondent reported to Patient One that he had a mineral imbalance, mineral deficiencies, and that his testosterone level should be higher. He reported that Patient One might have some metal poisoning which would contribute to the tiredness. He informed Patient One that he should undergo treatment for the metal poisoning. The Respondent also informed Patient One that foods like eggs and mustard could be weakening his body.

1.16 The Respondent informed Patient One that he had a machine that could be used to find out what was going on with his body. The machine that the Respondent was referring to was the LISTEN device. The Respondent informed Patient One that he would place a probe in his hand and the probe was connected to the LISTEN device. The Respondent informed Patient One that the LISTEN device helped him make a diagnosis. The Respondent informed Patient One that he could cure the egg allergy and that eggs would not bother him again.

1.17 Before using the LISTEN device, the Respondent assessed the strength of Patient One's deltoid muscle to obtain a baseline. The Respondent had Patient One lie on his back. The Respondent put the probe in Patient One's right hand and raised Patient One's right arm to a 90 degree point from his body. Patient One had a ring on his left-hand and on his right wrist he wore a watch. The Respondent asked Patient One to resist as hard as he could while the Respondent tried to pull his arm down next to Patient One's body. During this test, Patient One resisted pretty well and Patient One's resistance was strong.

1.18 The Respondent used the LISTEN device when he conducted the next muscle assessment. While Patient One was still lying on his back, the Respondent put the probe in Patient One's right hand and raised Patient One's right arm to a 90 degree point from his body. This time the Respondent had the LISTEN device operating and, using the keyboard, he typed in the word "eggs." The Respondent again asked Patient One to resist as hard as he could while the Respondent tried to pull Patient One's arm down. This time the Respondent was then able to easily pull Patient One's arm down. When this occurred, the Respondent informed Patient One that he could pull his arm down, because his body had been compromised due to the egg allergy.

1.19 Next, for the treatment, the Respondent had Patient One roll over on his stomach and the Respondent thumped Patient One on his back with an acupressure device. The device had rubber tips on it like a plunger. While the Respondent thumped Patient One on his back, he mentioned acupressure.

1.20 After the acupuncture treatment, the Respondent assessed whether it affected the muscles. The Respondent had Patient One roll over on his back again and the Respondent gave Patient One the probe that was connected to the LISTEN device. The Respondent had Patient One raised his arm to a 90 degree position and the procedure was repeated. The Respondent could not pull Patient One's arm down. The Respondent then said "See, it's gone."

1.21 After the Respondent used the LISTEN device, the Respondent performed a final assessment. The Respondent wrapped the probe in tissue paper and then had Patient One hold the probe with the tissue paper wrapped around it. Patient One asked him why he did this. The Respondent answered that he has done this so long, that he could do what the machine could do, and that he did not need the machine anymore.

1.22 After this series of assessments and treatment, the Respondent advised Patient One that he should not eat any eggs for 24 hours or perhaps 48 hours or the treatment would not take. Patient One understood that the Respondent had diagnosed that he was allergic to eggs, that the Respondent provided treatment, and that the Respondent cured him of his egg allergy. Patient One understood that he would be able to eat eggs and would have no allergic reaction.

1.23 In 1976-80, Patient One had been diagnosed by another health care practitioner that he was allergic to blowing dust and pollens for which Patient One took shots to help relieve the symptoms. He had also been diagnosed with hay fever, with

resulting symptoms of respiratory difficulties, feeling plugged-up, sinus drainage, and itching of eyes.

1.24 At the end of the second visit, the Respondent informed Patient One that he could only treat one allergy at a time and that he would need to come in for additional visits to treat each allergy. The Respondent wrote out some prescriptions and suggested that the Respondent sign up for additional treatments. The Respondent prescribed testosterone, DHEA, multi-mineral vitamins and a low glycemic index diet to be followed by a Metabolic typing diet.

1.25 As a physician, the Respondent used the LISTEN device to treat Patient One for an egg allergy. The LISTEN device was inefficacious and did not cure an egg allergy. The LISTEN device did not provide any manner of treatment or assessment. Before the Respondent's assessment and treatment for an egg allergy, Patient One had not been diagnosed to be allergic to eggs or mustard or any food allergies. There was no clinical evidence to support the Respondent's assessment and treatment that Patient One had an egg allergy. Before his visit with the Respondent, Patient One had not been advised that he was allergic to eggs and had no reaction to eating eggs, except that he does not like to eat them.

1.26 The Respondent promoted the use of the LISTEN device in his practice and for his own personal gain. He informed Patient One that he uses it for treatment. He billed Patient One for his treatment, which included using the LISTEN device. The Respondent was able to speed up his assessment and treatment by using it. He

suggested to Patient One to return for additional treatments so he can treat each individual allergy.

1.27 As a physician, the Respondent failed to take the necessary safety measures to ensure that the LISTEN device would not be harmful to his patients. The Respondent obtained no literature or had no labeling on the LISTEN device, and he did not receive any personal training on its use. The Respondent only listened to his colleagues and to a salesperson. The Respondent did not know the voltage or amperage that the LISTEN device produces.

1.28 The Respondent's use of the LISTEN device, an inefficacious device, precluded him from making as a physician an appropriate diagnosis and treatment. By using his credentials as physician, the Respondent took advantage of Patient One to use an inefficacious device to allegedly assess, treat and cure an egg allergy. By using the LISTEN device in his assessment and treatment of Patient One on July 10, 2001 for an egg allergy, the Respondent was negligent in his practice as a physician. The Respondent's use of the LISTEN device was not nontraditional treatment.

1.29 Making a false medical diagnosis through the use of an inefficacious device, providing an ineffective treatment, and misinforming Patient One that he had been cured, the Respondent subjected him to unreasonable risk of harm. The Respondent's reliance on the LISTEN device, an inefficacious device, created an unreasonable risk of harm to Patient One.

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FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

II. CONCLUSIONS OF LAW

2.1 The Commission has jurisdiction over the Respondent's license and over the subject matter of this proceeding. RCW 18.71; RCW 18.130.

2.2 The Washington Supreme Court has held that the standard of proof in disciplinary proceedings against physicians before the Washington State Medical Quality Assurance Commission is proof by clear and convincing evidence. *Nguyen v. Department of Health*, 144 Wn.2d 516, 534, cert. denied, 535 U.S. 904 (2002).

2.3 Based upon Findings of Fact, Paragraphs 1.1, 1.2 and Paragraphs 1.7 through 1.30 above, along with the above Analysis, the Commission concludes that the Department proved by clear and convincing evidence that Respondent violated RCW 18.130.180(4) and (16).

2.4 Based upon Findings of Fact, Paragraphs 1.1 through 1.6 above, along with the above Analysis, the Commission concludes that the Department failed to prove by clear and convincing evidence that Respondent violated RCW 18.130.180(7). This charge under RCW 18.130.180(7) shall be dismissed.

2.5 Based upon Findings of Fact, along with the above Analysis, the Commission concludes that the Department failed to prove by clear and convincing evidence that Respondent violated RCW 18.130.180(1). The Respondent purchased the LISTEN device in good faith. The decision to use an inefficacious device, even though its use resulted in unprofessional conduct, did not constitute an act of moral turpitude, dishonesty, or corruption. This charge under RCW 18.130.180(1) should be dismissed.

2.6 As a result of the unprofessional conduct found under RCW 18.130.180(4) and (16), the Commission may impose sanctions. The first consideration is the protection of the public. RCW 18.130.160.

2.7 Based upon the above Findings of Fact, Analysis and Conclusions of Law, the Commission concludes that the Respondent's license should be suspended, but the suspension should be stayed provided that he complies with the conditions ordered below. The Respondent should not be permitted to use the LISTEN device with patients. The Respondent should pay a fine for his conduct and he should be monitored during this period of stayed suspension, including a regular review of his patient records. The Commission concludes that these conditions are necessary to ensure that sufficient safeguards are in place to protect the public.

III. ORDER

Based on the foregoing, the Commission hereby issues in this case the following ORDERS:

3.1 Stayed Suspension. The license to practice as a physician and surgeon in the state of Washington held by the Respondent, Geoffrey S. Ames, M.D., is SUSPENDED for a period of at least five (5) years from the date of service of this Order. The suspension of the Respondent's license is hereby STAYED, PROVIDED that the Respondent complies with the following terms and conditions in this Order.

3.2. Limitation on Practice. The Respondent shall not use the LISTEN device to assess for or to treat allergies. Further, the Respondent shall not have the LISTEN device in his medical office(s) where he sees and/or treats patients.

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

3.3 Record Reviews. Within thirty (30) days from the effective date of this Order, or as soon thereafter as deemed by the Commission or its designee, the Department shall conduct a review of 10 to 15 patient records, randomly selected, on a quarterly basis. After a compliance hearing in review of this condition, the Commission at its discretion may order the record reviews to continue this quarterly review of the Respondent's records for an additional period as long as the Commission deems it necessary.

3.4 Quarterly Declaration. The Respondent shall submit a quarterly declaration under penalty of perjury stating whether there has been compliance with all conditions of the Order. The quarterly declarations shall be submitted to the Commission on the first day of the following months: September, December, March and June, unless ordered otherwise by the Commission.

3.5 Compliance with Laws and Rules. The Respondent shall obey all federal, state, and local laws and all rules governing the practice of medicine and surgery in the state of Washington.

3.6 Fine. The Respondent shall pay an administrative fine to the Commission in the amount of \$5,000 (five thousand dollars) within 180 days of the entry of the effective date of this Order. The payment shall be made payable to the Washington State Treasurer and sent to the following address:

Medical Quality Assurance Commission
P.O. Box 1099
Olympia, WA 98507-1099

3.7 Appearance at Compliance Hearings. The Respondent shall appear before the Commission six months from the effective date of this Order, or as soon thereafter as the Commission's schedule permits, and shall present proof that he is complying with this Order. He shall continue to make such compliance appearances every six months, or as frequently as the Commission otherwise requires, until the period of stayed suspension, is terminated by the Commission. The Respondent shall be given notice of the compliance hearing, and if he fails to comply with this Order, the Commission may impose other sanctions as appropriate under RCW 18.130.160 to protect the public. Further, after a compliance hearing, the Commission may determine that the Respondent is in compliance and that he need not personally appear for a six-month compliance hearing.

3.8 Costs. The Respondent shall be responsible and shall pay for any and all costs involved in his compliance with any and all conditions in this Order.

3.9 Responsibility for Providing Current Address. The Respondent shall ensure that the Commission has his current practice and residence addresses and telephone numbers. The Respondent shall notify the Commission in writing of any address change within twenty (20) days after the change.

3.10 Placed on Notice. The Respondent is hereby placed on notice that it is his responsibility to ensure that all required reports are submitted to the Commission on time and in the manner specified in this Order.

3.11 Periods of Out of State Practice. In the event the Respondent should leave Washington State to practice or reside outside the state, the Respondent shall

notify the Commission, in writing, of the date of departure and return. Periods of residency or practice outside Washington State will not apply to the reduction of this five (5) year period of suspension.

3.12 Modification of Order. Except as provided above, the Respondent may petition the Commission for modification of this Order no sooner than five (5) years from the date this Order is signed. Upon notice duly given by the Commission, the Respondent shall appear personally before the Commission to present evidence in support of the petition. Evidence in opposition to the petition may also be presented for the Commission's consideration. The Commission has sole discretion to grant or deny the Respondent's petition for modification and has the authority to impose restrictions and/or conditions on the Respondent's license to practice as long as the Commission's jurisdiction over the Respondent, pursuant to this Order, continues.

3.13 Termination of this Order. After the Respondent completes the conditions of the stayed suspension and after five (5) years from the effective date of this Order, the Respondent may file a petition for termination of the stayed suspension and for a license to practice medicine and surgery in the state of Washington without restrictions and conditions. At a hearing on the petition, the Department may present evidence in opposition to be considered by the Commission. After considering the petition and the evidence presented, the Commission has the sole discretion to grant or deny the Respondent's petition and has the authority to remove or to impose restrictions and/or conditions on the Respondent's license to practice as long as the jurisdiction remains over the Respondent, pursuant to this Order.

3.14 Violation of Order. If the Respondent violates any provision of this order, the Commission, after giving the Respondent notice and the opportunity to be heard, may set aside the stay order and impose the suspension, or may impose any sanction as it finds appropriate under RCW 18.130.160, or may take emergency action ordering summary suspension restriction or limitation of the Respondent's practice as authorized by RCW 18.130.150.

3.15 The charges in this matter that the Respondent's conduct violated RCW 18.130.180(1) and (7) are DISMISSED.

Dated this 30th day of May, 2004.

Medical Quality Assurance Commission



CABELL TENNIS, J.D.
Panel Chair

FOR INTERNAL USE ONLY: (Internal tracking numbers)
Program No. 2001-08-0007

CLERK'S SUMMARY

Charges	Action
RCW 18.130.180(1)	Dismissed
RCW 18.130.180(4)	Violated
RCW 18.130.180(7)	Dismissed
RCW 18.130.180(16)	Violated

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

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Docket No. 02-06-A-1012MD

NOTICE TO PARTIES

This order is subject to the reporting requirements of RCW 18.130.110, Section 1128E of the Social Security Act, and any other applicable interstate/national reporting requirements. If adverse action is taken, it must be reported to the Healthcare Integrity Protection Data Bank.

Either party may file a **petition for reconsideration**. RCW 34.05.461(3); RCW 34.05.470. The petition must be filed within 10 days of service of this Order with:

The Adjudicative Clerk Office
P.O. Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Medical Quality Assurance Commission
PO Box 47866
Olympia, WA 98504-7866

The petition must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration is considered denied 20 days after the petition is filed if the Adjudicative Clerk Office has not responded to the petition or served written notice of the date by which action will be taken on the petition.

A **petition for judicial review** must be filed and served within 30 days after service of this order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed, however, the 30-day period will begin to run upon the resolution of that petition. RCW 34.05.470(3).

The order remains in effect even if a petition for reconsideration or petition for review is filed. "Filing" means actual receipt of the document by the Adjudicative Clerk Office. RCW 34.05.010(6). This Order was "served" upon you on the day it was deposited in the United States mail. RCW 34.05.010(19).

FINDINGS OF FACT,
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AND FINAL ORDER

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Docket No. 02-06-A-1012MD

(6) A subpoena may be served by any suitable person 18 years of age or older by:

(a) Giving a copy to the person to whom the subpoena is directed;

(b) Leaving a copy at the residence of the person to whom the subpoena is addressed with a person of suitable age and discretion;

(c) Sending a copy by mail to the current address on file with the program if the person is licensed by the board or has an application for a license with the board; or

(d) Sending a copy by certified mail with proof of receipt if the person is neither licensed by nor has applied for a license with the board.

(7) Proof of service may be made by:

(a) Affidavit of personal service;

(b) Certification by the person mailing the subpoena to a licensed holder or applicant; or

(c) Return or acknowledgment showing receipt by the person subpoenaed or his/her representative. Any person receiving certified or registered mail at the last known address of the person subpoenaed shall be considered an authorized representative.

(8) The presiding officer, upon motion made promptly before the time specified for compliance in the subpoena,

(a) Quash or modify the subpoena if the subpoena is unreasonable or requires evidence not relevant to any matter in issue; or

(b) Condition denial of the motion upon just and reasonable conditions, including advancement of the reasonable costs by the person on whose behalf the subpoena is issued of copying the books, documents, or tangible things; or

(c) Issue a protective order under RCW 34.05.446.

(9) The board may seek enforcement of a subpoena under RCW 34.05.588(1) or proceed in default pursuant to RCW 246-11-280.

(10) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(11) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(12) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(13) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(14) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(15) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(16) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(17) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(18) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(19) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(20) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(21) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(22) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

(23) Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 4.24.240, 4.24.250 and 4.24.260, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

SECTION II
INITIATING ACTIONS

WAC 246-11-250 Form and content of initiating documents. (1) Initiating documents shall include a clear and concise statement of the:

(a) Identity and authority of the person issuing the document;

(b) Factual basis for the action or proposed action set forth in the document;

(c) Statutes and rules alleged to be at issue;

(d) Identity of the party against whom the action is taken or proposed to be taken;

(e) Action or proposed action or penalties, including the statutory or rule authority for those actions or penalties;

(f) Signature of the person issuing the document and the date signed; and

(g) Method by which an adjudicative proceeding may be requested.

(2) Initiating documents shall be accompanied by the following documents:

(a) Notice that the respondent may defend against the action or proposed action; and

(b) Form for requesting adjudicative proceeding.

(3) Initiating documents shall be served as described in WAC 246-11-080.

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-250, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1) and 34.05.220, 93-08-003 (Order 347), § 246-11-250, filed 3/24/93, effective 4/24/93.]

WAC 246-11-260 Amendment of initiating documents. (1) Prior to the hearing date, initiating documents may be amended subject to the following conditions:

(a) Amended initiating documents shall meet the requirements of WAC 246-11-250(1);

(b) Amended initiating documents shall be accompanied by the documents described in WAC 246-11-250(2);

(c) Whenever amended initiating documents are issued, a new interval for response will begin, as described in WAC 246-11-270, unless the respondent requests the time periods set by the original initiating document; and

(d) Issuance of amended initiating documents ends all obligations of the parties under the prior initiating documents.

(2) On the hearing date, the initiating documents may be amended subject to the following conditions:

(a) The documents may be amended upon motion of the state;

(b) The documents may not be amended without the approval of the presiding officer; and

(c) Upon motion of a party or upon his/her own initiative, the presiding officer may grant a continuance on all or part of the matter if necessary to afford the respondent an opportunity to prepare a defense to the amended documents.

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-260, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1) and 34.05.220, 93-08-003 (Order 347), § 246-11-260, filed 3/24/93, effective 4/24/93.]

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-260, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1) and 34.05.220, 93-08-003 (Order 347), § 246-11-260, filed 3/24/93, effective 4/24/93.]

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-260, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1) and 34.05.220, 93-08-003 (Order 347), § 246-11-260, filed 3/24/93, effective 4/24/93.]

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-260, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1) and 34.05.220, 93-08-003 (Order 347), § 246-11-260, filed 3/24/93, effective 4/24/93.]

presiding officer proposed findings of fact and conclusions of law and a proposed order.

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-500, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 93-08-003 (Order 347), § 246-11-500, filed 3/24/93; effective 4/24/93.]

WAC 246-11-510 Issuance of final order. If the adjudicative proceeding is heard by the board or a panel of the board the presiding officer and board or panel of the board shall:

(1) Issue a final order containing findings of fact and conclusions of law and an order; and

(2) Cause the adjudicative clerk office to serve a copy of the order on each party and any designated representative of the party.

[Statutory Authority: RCW 18.155.040, 97-13-015, § 246-11-510, filed 6/6/97, effective 7/7/97; Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-510, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 93-08-003 (Order 347), § 246-11-510, filed 3/24/93, effective 4/24/93.]

WAC 246-11-520 Standard of proof. The order shall be based on the kind of evidence upon which reasonably prudent persons are accustomed to rely in the conduct of their affairs. In all cases involving an application for license the burden shall be on the applicant to establish that the application meets all applicable criteria. In all other cases the burden is on the department to prove the alleged factual basis set forth in the initiating document. Except as otherwise provided by statute, the burden in all cases is a preponderance of the evidence.

[Statutory Authority: RCW 18.130.050(1), 93-08-003 (Order 347), § 246-11-520, filed 3/24/93, effective 4/24/93.]

WAC 246-11-530 Consolidated proceedings. (1) When two or more applications for adjudicative proceeding involve a similar issue, the applications may be consolidated by the presiding officer and the hearings conducted together. The presiding officer or hearings officer may consolidate on his/her own motion or upon the request of a party.

(2) A party scheduled for a consolidated proceeding may request to withdraw from the consolidated proceeding in favor of an individual proceeding. The presiding officer may grant a motion to withdraw from a consolidated proceeding at any time when good cause is shown.

(3) Each respondent in a consolidated proceeding shall retain the right to representation.

[Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-530, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1) and 34.05.220, 93-08-003 (Order 347), § 246-11-530, filed 3/24/93, effective 4/24/93.]

WAC 246-11-540 Initial order. (1) If the adjudicative proceeding is not heard by the board or panel of the board the presiding officer shall:

(a) Issue an initial order containing proposed findings of fact, conclusions of law, and a proposed order.

(b) Cause the adjudicative clerk office to serve a copy of the initial order on each party and any designated representative of a party; and

(c) Forward the initial order and record of the adjudicative proceeding to the adjudicative clerk office.

(2) Initial orders on brief adjudicative proceedings shall become final orders as provided in WAC 246-11-540.

(3) Following receipt of initial orders in matters other than brief adjudicative proceedings, the board shall review the initial order and the record as provided in RCW 34.05.464, and issue a final order as provided in WAC 246-11-560.

[Statutory Authority: RCW 18.155.040, 97-13-015, § 246-11-540, filed 6/6/97, effective 7/7/97; Statutory Authority: RCW 18.130.050(1) and 18.130.060(3), 94-04-078, § 246-11-540, filed 1/31/94, effective 3/3/94; Statutory Authority: RCW 18.130.050(1), 93-08-003 (Order 347), § 246-11-540, filed 3/24/93, effective 4/24/93.]

SECTION VII POST HEARING PROCESS

WAC 246-11-550 Appeal from initial order. (1) Any party may file a written petition for administrative review of an initial order issued under WAC 246-11-430 or 246-11-540 stating the specific grounds upon which exception is taken and the relief requested.

(2) Petitions for administrative review must be served upon the opposing party and filed with the adjudicative clerk office within twenty-one days of service of the initial order.

(3) The opposing party may file a response to a petition for administrative review as provided in this section. The response shall be filed at the place specified in subsection (2) of this section. The party filing the response shall serve a copy of the response upon the party requesting administrative review. If the initial order was entered pursuant to WAC 246-11-430, the response will be filed within ten days of service of the petition. In all other matters, the response will be filed within twenty days of service of the petition.

[Statutory Authority: RCW 18.155.040, 97-13-015, § 246-11-550, filed 6/6/97, effective 7/7/97; Statutory Authority: RCW 18.130.050 and 43.70.040, 96-21-027, § 246-11-550, filed 10/7/96, effective 11/7/96; Statutory Authority: RCW 18.130.050(1) and 34.05.464, 93-08-003 (Order 347), § 246-11-550, filed 3/24/93, effective 4/24/93.]

WAC 246-11-560 Final orders. (1) The form and content of final orders shall be as follows:

(a) Final orders shall contain findings of fact, conclusions of law, and an order. All final orders shall be signed by a member of the panel of board members who heard the matter.

(b) Final orders may adopt by reference the initial order in whole or in part.

(c) Final orders may modify or revise the initial order in whole or in part.

(2) Final orders shall be served upon the parties and their representatives as provided in WAC 246-11-080.

(3) Final orders shall be issued following:

(a) A review of the record;

(b) A review of the initial order, if any;

(c) A review of any request for review of the initial order and any response thereto; and

(d) Consideration of protection of the public health and welfare.

(4) Unless a later date is stated in the final order, final orders shall be effective when entered but a party shall not be

RCW 18.130.180

→18.130.180. Unprofessional conduct

The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:

- (1) **The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not. If the act constitutes a crime, conviction in a criminal proceeding is not a condition precedent to disciplinary action. Upon such a conviction, however, the judgment and sentence is conclusive evidence at the ensuing disciplinary hearing of the guilt of the license holder or applicant of the crime described in the indictment or information, and of the person's violation of the statute on which it is based. For the purposes of this section, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for the conviction and all proceedings in which the sentence has been deferred or suspended. Nothing in this section abrogates rights guaranteed under chapter 9.96A RCW;**
- (2) Misrepresentation or concealment of a material fact in obtaining a license or in reinstatement thereof;
- (3) All advertising which is false, fraudulent, or misleading;
- (4) **Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;**
- (5) Suspension, revocation, or restriction of the individual's license to practice any health care profession by competent authority in any state, federal, or foreign jurisdiction, a certified copy of the order, stipulation, or agreement being conclusive evidence of the revocation, suspension, or restriction;
- (6) The possession, use, prescription for use, or distribution of controlled substances or legend drugs in any way other than for legitimate or therapeutic purposes, diversion of controlled substances or legend drugs, the violation of any drug law, or prescribing controlled substances for oneself;
- (7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;
- (8) Failure to cooperate with the disciplining authority by:

- (a) Not furnishing any papers or documents;
- (b) Not furnishing in writing a full and complete explanation covering the matter contained in the complaint filed with the disciplining authority;
- (c) Not responding to subpoenas issued by the disciplining authority, whether or not the recipient of the subpoena is the accused in the proceeding; or
- (d) Not providing reasonable and timely access for authorized representatives of the disciplining authority seeking to perform practice reviews at facilities utilized by the license holder;
- (9) Failure to comply with an order issued by the disciplining authority or a stipulation for informal disposition entered into with the disciplining authority;
- (10) Aiding or abetting an unlicensed person to practice when a license is required;
- (11) Violations of rules established by any health agency;
- (12) Practice beyond the scope of practice as defined by law or rule;
- (13) Misrepresentation or fraud in any aspect of the conduct of the business or profession;
- (14) Failure to adequately supervise auxiliary staff to the extent that the consumer's health or safety is at risk;
- (15) Engaging in a profession involving contact with the public while suffering from a contagious or infectious disease involving serious risk to public health;
- (16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service;**
- (17) Conviction of any gross misdemeanor or felony relating to the practice of the person's profession. For the purposes of this subsection, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for conviction and all proceedings in which the sentence has been deferred or suspended. Nothing in this section abrogates rights guaranteed under chapter 9.96A RCW;
- (18) The procuring, or aiding or abetting in procuring, a criminal abortion;
- (19) The offering, undertaking, or agreeing to cure or treat disease by a secret method, procedure, treatment, or medicine, or the treating, operating, or prescribing for any health condition by a method, means, or procedure which the licensee refuses to divulge upon demand of the disciplining authority;
- (20) The willful betrayal of a practitioner-patient privilege as recognized by law;

(21) Violation of chapter 19.68 RCW;

(22) Interference with an investigation or disciplinary proceeding by willful misrepresentation of facts before the disciplining authority or its authorized representative, or by the use of threats or harassment against any patient or witness to prevent them from providing evidence in a disciplinary proceeding or any other legal action, or by the use of financial inducements to any patient or witness to prevent or attempt to prevent him or her from providing evidence in a disciplinary proceeding;

(23) Current misuse of:

(a) Alcohol;

(b) Controlled substances; or

(c) Legend drugs;

(24) Abuse of a client or patient or sexual contact with a client or patient;

(25) Acceptance of more than a nominal gratuity, hospitality, or subsidy offered by a representative or vendor of medical or health-related products or services intended for patients, in contemplation of a sale or for use in research publishable in professional journals, where a conflict of interest is presented, as defined by rules of the disciplining authority, in consultation with the department, based on recognized professional ethical standards.

RCW 34.05.452

➔34.05.452. Rules of evidence--Cross-examination

(1) Evidence, including hearsay evidence, is admissible if in the judgment of the presiding officer it is the kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs. The presiding officer shall exclude evidence that is excludable on constitutional or statutory grounds or on the basis of evidentiary privilege recognized in the courts of this state. The presiding officer may exclude evidence that is irrelevant, immaterial, or unduly repetitious.

(2) If not inconsistent with subsection (1) of this section, the presiding officer shall refer to the Washington Rules of Evidence as guidelines for evidentiary rulings.

(3) All testimony of parties and witnesses shall be made under oath or affirmation.

(4) Documentary evidence may be received in the form of copies or excerpts, or by incorporation by reference.

(5) Official notice may be taken of (a) any judicially cognizable facts, (b) technical or scientific facts within the agency's specialized knowledge, and (c) codes or standards that have been adopted by an agency of the United States, of this state or of another state, or by a nationally recognized organization or association. Parties shall be notified either before or during hearing, or by reference in preliminary reports or otherwise, of the material so noticed and the sources thereof, including any staff memoranda and data, and they shall be afforded an opportunity to contest the facts and material so noticed. A party proposing that official notice be taken may be required to produce a copy of the material to be noticed.

RCW 34.05.461

→34.05.461. Entry of orders

(1) Except as provided in subsection (2) of this section:

(a) If the presiding officer is the agency head or one or more members of the agency head, the presiding officer may enter an initial order if further review is available within the agency, or a final order if further review is not available;

(b) If the presiding officer is a person designated by the agency to make the final decision and enter the final order, the presiding officer shall enter a final order; and

(c) If the presiding officer is one or more administrative law judges, the presiding officer shall enter an initial order.

(2) With respect to agencies exempt from chapter 34.12 RCW or an institution of higher education, the presiding officer shall transmit a full and complete record of the proceedings, including such comments upon demeanor of witnesses as the presiding officer deems relevant, to each agency official who is to enter a final or initial order after considering the record and evidence so transmitted.

(3) Initial and final orders shall include a statement of findings and conclusions, and the reasons and basis therefor, on all the material issues of fact, law, or discretion presented on the record, including the remedy or sanction and, if applicable, the action taken on a petition for a stay of effectiveness. Any findings based substantially on credibility of evidence or demeanor of witnesses shall be so identified. Findings set forth in language that is essentially a repetition or paraphrase of the relevant provision of law shall be accompanied by a concise and explicit statement of the underlying evidence of record to support the findings. The order shall also include a statement of the available procedures and time limits for seeking reconsideration or other administrative relief. An initial order shall include a statement of any circumstances under which the initial order, without further notice, may become a final order.

(4) Findings of fact shall be based exclusively on the evidence of record in the adjudicative proceeding and on matters officially noticed in that proceeding. Findings shall be based on the kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs. Findings may be based on such evidence even if it would be inadmissible in a civil trial. However, the presiding officer shall not base a finding exclusively on such inadmissible evidence unless the presiding officer determines that doing so would not unduly abridge the parties' opportunities to confront witnesses and rebut evidence. The basis for this determination shall appear in the order.

(5) Where it bears on the issues presented, the agency's experience, technical competency, and specialized knowledge may be used in the evaluation of evidence.

(6) If a person serving or designated to serve as presiding officer becomes unavailable for any reason before entry of the order, a substitute presiding officer shall be appointed as provided in RCW 34.05.425. The substitute presiding officer shall use any existing record and may conduct any further proceedings appropriate in the interests of justice.

(7) The presiding officer may allow the parties a designated time after conclusion of the hearing for the submission of memos, briefs, or proposed findings.

(8)(a) Except as otherwise provided in (b) of this subsection, initial or final orders shall be served in writing within ninety days after conclusion of the hearing or after submission of memos, briefs, or proposed findings in accordance with subsection (7) of this section unless this period is waived or extended for good cause shown.

(b) This subsection does not apply to the final order of the shorelines hearings board on appeal under RCW 90.58.180(3).

(9) The presiding officer shall cause copies of the order to be served on each party and the agency.

RCW 18.120.010

►18.120.010. Purpose--Criteria (*Effective until January 1, 2006*)

(1) **The purpose of this chapter is to establish guidelines for the regulation of health professions not licensed or regulated prior to July 24, 1983, and those licensed or regulated health professions which seek to substantially increase their scope of practice: PROVIDED, That the provisions of this chapter are not intended and shall not be construed to: (a) Apply to any regulatory entity created prior to July 24, 1983, except as provided in this chapter; (b) affect the powers and responsibilities of the superintendent of public instruction or state board of education under RCW 28A.305.130 and 28A.410.010; (c) apply to or interfere in any way with the practice of religion or to any kind of treatment by prayer; and (d) apply to any remedial or technical amendments to any statutes which licensed or regulated activity before July 24, 1983. The legislature believes that all individuals should be permitted to enter into a health profession unless there is an overwhelming need for the state to protect the interests of the public by restricting entry into the profession. Where such a need is identified, the regulation adopted by the state should be set at the least restrictive level consistent with the public interest to be protected.**

(2) It is the intent of this chapter that no regulation shall, after July 24, 1983, be imposed upon any health profession except for the exclusive purpose of protecting the public interest. All bills introduced in the legislature to regulate a health profession for the first time should be reviewed according to the following criteria. **A health profession should be regulated by the state only when:**

(a) Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public, and **the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;**

(b) The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and

(c) The public cannot be effectively protected by other means in a more cost-beneficial manner.

(3) After evaluating the criteria in subsection (2) of this section and considering governmental and societal costs and benefits, if the legislature finds that it is necessary to regulate a health profession not previously regulated by law, the least restrictive alternative method of regulation should be implemented, consistent with the public interest and this section:

(a) Where existing common law and statutory civil actions and criminal prohibitions are not sufficient to eradicate existing harm, the regulation should provide for stricter civil actions and criminal prosecutions;

(b) Where a service is being performed for individuals involving a hazard to the public health, safety, or welfare, the regulation should impose inspection requirements and enable an appropriate state agency to enforce violations by injunctive relief in court, including, but not limited to, regulation of the business activity providing the service rather than the employees of the business;

(c) Where the threat to the public health, safety, or economic well-being is relatively small as a result of the operation of the health profession, the regulation should implement a system of registration;

(d) Where the consumer may have a substantial basis for relying on the services of a practitioner, the regulation should implement a system of certification; or

(e) Where apparent that adequate regulation cannot be achieved by means other than licensing, the regulation should implement a system of licensing.

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**COURT OF APPEALS, DIVISION III
STATE OF WASHINGTON**

In the Office of the Clerk of Court
Washington Court of Appeals, Division Three

By _____

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

**WASHINGTON STATE HEALTH DEPARTMENT
MEDICAL QUALITY ASSURANCE COMMN.,**

Respondent.

ON APPEAL FROM THE SUPERIOR COURT OF
BENTON COUNTY, THE HON. CARRIE RUNGE PRESIDING

**STATEMENT OF ADDITIONAL AUTHORITIES
(RAP 10.8)**

WILLIAM R. BISHIN, P.S.

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Attorneys for Geoffrey S. Ames, M.D.

CERTIFICATE OF SERVICE

This Statement of Additional Authorities was filed by mail with the Court on this date and served on respondent herein by depositing a copy in the United States mail first class postage pre-paid on this date and addressed as follows:

Kim O'Neal, Esq.
Assistant Attorney General
Office of Attorney General
1125 Washington S.E.
Olympia, WA 98504

October 24, 2006


WILLIAM R. BISHIN

ORIGINAL

STATEMENT OF ADDITIONAL AUTHORITIES

Pursuant to RAP 10.8, which permits the parties to state additional authorities without argument, Petitioner calls the Court's attention to the cases cited below. The relevant language of those authorities is set forth thereafter.

ISSUES

Whether the use of modalities that are not popular with conventional physicians are by virtue of that fact "unprofessional" and/or instances of negligence.

State v. McDonagh, 123 S.W.3d 146, 159 (Mo. 2003)

Id at 164-165 (Wolfe, J. concurring and dissenting)

Whether actual harm or serious danger of serious harm is required before use of unconventional modalities can be found to be negligence.

State v. McDonagh, 123 S.W.3d 146, 164 (Mo. 2003) (Wolfe, J. concurring and dissenting)

Id at 164-165

Whether the use of unconventional modalities can constitute negligence in the absence of substantial scientific evidence that the modality is ineffective.

Kirschner v. Mills, 711 NYS2d 65, 69, 274 A.D. 786, 791 (2000)

LANGUAGE TO WHICH PETITIONER REFERS

***State v. McDonagh*, 123 S.W.3d 146, 159 (Mo. 2003):**

Application of this standard does not merely require a determination of what treatment is most popular. Were that the only determinant of skill and learning, any physician who used a medicine for off-label purposes, or who pursued unconventional courses of treatment, could be found to have engaged in repeated negligence and be subject to discipline. . . .

Rather the statute requires only what it says--that Dr. McDonagh use that degree of skill and learning used by members of the profession in similar circumstances. By analogy, one doctor may use medicine to treat heart problems while another might chose to perform a by-pass and a third to perform angioplasty, yet all three may be applying the requisite degree of skill and learning. That they came to differing conclusions by applying that skill and learning does not make one negligent and one non-negligent.

So too, here, if Dr. McDonagh's treatment, including his use of a diet and exercise regimen, and the lack of evidence of harm from his approach, demonstrates the application of the degree of skill and learning ordinarily used by members of his profession, then it is not a basis for discipline under the statute, even if other doctors would apply these facts to reach a different result.

***State v. McDonagh*, 123 S.W.3d 146, 164-165 (Mo. 2003)
(Wolfe concurring and dissenting):**

So is this off-label use of chelation therapy negligence? The real question-- the answer to which is fatal to the board's position--is whether acts of negligence, as defined by this statute, can be cause for discipline if there is no showing that the physician's conduct "is or might be harmful or dangerous." If there is no harm or danger, there is no cause for discipline under this section. Section 334.100.2(5) is a catchall provision; read in the

context of the entire statute, it does not make negligent acts actionable unless there is harm or danger. [footnote omitted] This subdivision cannot be read to make acts subject to discipline where there is no prospect of harm. . . .

Physicians are afforded considerable leeway in the use of professional judgment to decide on appropriate treatments, especially when applying the negligence standard. For instance, *Haase v. Garfinkel*, 418 S.W.2d 108, 114 (Mo.1967), a medical negligence case, holds that "as long as there is room for an honest difference of opinion among competent physicians, a physician who uses his own best judgment cannot be convicted of negligence, even though it may afterward develop that he was mistaken." "Negligence" does not seem an appropriate concept where the physician has studied the problem and has made a treatment recommendation, even though that is not the prevailing view of the majority of the profession. The lack of general acceptance of a treatment does not *165 necessarily constitute a breach of the standard of care. The use of negligence in licensing situations, in the absence of harm or danger, is particularly inappropriate.

One could argue that because chelation therapy is not accepted by mainstream medicine and is an off-label practice not approved by the FDA, it is therefore harmful and dangerous. If that were the board's position, the licensing statute would thwart advances in medical science. A dramatic example is the treatment of stomach ulcers, which were long thought to be caused by stress. In 1982, two Australians found the bacterium *helicobacter pylori* in the stomach linings of ulcer victims. Because *helicobacter pylori* is a bacterium, some physicians--a minority to be sure--began prescribing antibiotics to treat stomach ulcers as an infectious disease. The National Institutes of Health did not recognize antibiotic therapy until 1994; the FDA approved the first antibiotic for use in treating stomach ulcers in 1996; and the Centers for

Disease Control began publicizing the treatment in 1997. Today's physicians accept as fact that most stomach ulcers are primarily caused by helicobacter pylori bacteria infection and not by stress. [footnote omitted] But, by the chronology of this discovery, if a physician in the late 1980s or early 1990s had treated ulcers with antibiotics, that treatment would have been "negligent" as the board in this case interprets that term because inappropriate use of antibiotics can be dangerous.

Kirschner v. Mills, 711 NYS2d 65, 69, 274 A.D. 786, 791 (2000) (emphasis added).

The record also reflects sharp disagreement of the parties' experts as to the professional competence of each of petitioner's opinions. We find that such dichotomy of opinion, in the context of this case, establishes the existence of a bona fide dispute or controversy within the profession unresolved by the proof in this record. In the absence of substantial proof that petitioner's statements of opinion are without sound scientific basis this court rejects respondent's determinations of guilt. . . .

Respectfully submitted this 24th day of October 2006.

LAW OFFICES OF
WILLIAM R. BISHIN, P.S.

By 
William R. Bishin, WSBA No. 8386