

80644-6

COURT OF APPEALS, DIVISION III  
STATE OF WASHINGTON

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**GEOFFREY S. AMES, M.D.,**

Appellant

vs.

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

Respondent.

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

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**REPLY BRIEF OF APPELLANT**

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*PRELIMINARY STATEMENT*

The Brief of Respondent Medical Commission (“DOH Brief” or “RB”), once fully analyzed and fully and properly cite-checked, may itself be the most telling evidence of the unlawfulness of its Order. To defend the Order, DOH relies not only on indefensible misrepresentations about relevant law and evidence, but on inexcusable misstatements of the Order’s own findings. Even where the DOH brief does not misrepresent the law and the record, its structure and content betray the poverty of support for the panel’s findings in this case. The most dramatic example is DOH’s manner of addressing the finding/conclusion that the LISTEN purchased by Dr. Ames was an inefficacious device. Although this finding/conclusion is essential both to the decision that Dr. Ames was negligent – because he assertedly used an inefficacious device in addressing P1’s complaints of fatigue, etc. – and that use assertedly constituted “promotion . . . for personal gain” of an “inefficacious” device, DOH defers addressing the finding/conclusion until the second half of its brief. One would expect that if it had the evidence necessary to support the finding, it would make the Court aware of it as quickly and vividly as possible. But it does not do that. And when it does finally address the issue, it does not actually defend the Order’s evidence and reasoning. Instead it attempts to present other grounds to persuade this Court of the device’s assumed inefficacy and to assert facts, law and legal

conclusions which the panel did not make or assert, some of which clearly and directly contradict the findings and conclusions that the panel did make. Indeed, the DOH brief, like the Order it defends is internally inconsistent at critical junctures – asserting facts and legal conclusions which support Dr. Ames at one place and then later asserting the very opposite of those facts and conclusions when its argument requires that.

Some of the assertions are so wild and puzzling that it suggests that they were thrown out in part to spread so much confusion, especially about the extremely complex federal Food Drug and Cosmetic Act and the FDA's function under it, that the Court would throw up its hands in bewilderment and simply defer to the panel's alleged expertise without attempting to see if the Order has a legal basis.

In this reply brief, Dr. Ames will attempt to address as many of the misstatements of the law, the facts and the record as he can in the space allotted without causing the Court to lose sight of the forest for the trees – the context surrounding and the consequences of this typical attempt by old-line, rearguard conventional medical regulators to suppress an alternative modality by whatever means are available.

**I. INSEEKING VIRTUALLY UNREVIEWABLE DEFERENCE TO ITS ALLEGED EXPERTISE, AND INSISTING THAT ONLY TOKEN NOTICE PLEADING IS NECESSARY, DOH IGNORES THE QUASI-CRIMINAL NATURE OF ITS SANCTIONS AND PROCEEDINGS**

The interest of the medical practitioner in a professional

disciplinary proceeding is obviously much greater than that which would be implicated by the mistaken rendition of a mere money judgment against him. It is much more than the loss of a specific job. It involves the professional's substantial interest to practice within his profession, his reputation, his livelihood, and his financial and emotional future.

Nguyen v. Medical Commission, 144 Wn.2d 516, 534, 29 P.3d 689, 697

(2001). Similarly, the interest affected by a medical disciplinary proceeding is far more profound and important than the interests ordinarily affected by the decisions of administrative agencies that regulate the economic behavior of corporate entities, where the sanction will ordinarily be against a business and will involve money or specific relief relating to a particular commercial or industrial practice or condition. There will be no necessary stigma; no individual's career and livelihood will be on the line; no major capital investment by an individual in education and training subject to forfeit or impairment. Decisions in such administrative proceedings are not, as they are in this one, "quasi-criminal." See Nguyen, supra, 144 Wn.2d at 529.

Dr. Ames's license was not revoked. But it was suspended, with the suspension stayed, a fine levied and an order entered requiring regular monitoring of his practice, the threat of revocation in the wings for any violation of the order. The monitoring placed an agency run by conventional physicians constantly looking over his shoulder as he attempted to conduct an alternative practice. The Order had to be reported not only to a national data bank and to the DOH website so that it would be available to any

prospective or current patient, colleague, or insurance carrier, but news releases were issued by DOH and local newspapers and the internet ran stories reporting that Dr. Ames had been disciplined for unprofessional conduct. See RCW 18.130.110(2).

Although they are not as severe, these sanctions are severe enough and have typical quasi-criminal effects. They stigmatize the respondent. They require him to forever disclose in all kinds of paperwork that he has been acted against by his medical board and to explain why – if people will listen – he was disciplined. The public does not make fine distinctions about professional discipline – what it knows is that the state has disciplined a physician for unprofessional conduct. For many, that is enough. Thus, these sanctions cause the loss of malpractice insurance; preclude the physician's membership on health insurance physician panels; undermine the ability to otherwise obtain patients; increase vulnerability to malpractice actions; affect the ability to testify as an expert witness and severely lower the practitioner's regard among his neighbors.

The panel found that Dr. Ames did not act immorally or dishonestly and did find that he acted in good faith, which means that he believed that what he was doing could help his patients. *No* evidence was presented that conventional health care offered a different, let alone a superior, approach to the one he employed with P1. Did Dr. Ames's conduct justify stigmatizing

him and impairing his livelihood and career? When one steps back from the specific provisions of the Uniform Disciplinary Act, and considers the act as a whole, its purpose is to assure the “adequacy of professional competence and conduct.” RCW 18.130.010. Forgetting about the specific words of RCW 18.130.180(4) and 18.130.180(16), for a moment, and taking the statute as a whole in the context of a society with values like ours, does the conduct of which Dr. Ames has been found guilty *sound* like unprofessional conduct?

Taking the statute as a whole and considering its purpose in the light of this state’s needs and values and its commitments to freedom of choice in health care, common sense decrees that Dr. Ames did not deserve to be stigmatized. He did not deserve to have his career injured and his livelihood impaired. He did not deserve to be defamed to his friends and neighbors. The conduct sanctioned by the panel here was not unprofessional. Dr. Ames in good faith used a harmless device as part of his assessment process and allegedly came to an erroneous conclusion. That is not unprofessional conduct in any non-quixotic sense of the term. It is conduct based on the tenets of energy medicine, expressed in, for example, acupuncture and homeopathy, two modalities which Washington law expressly recognizes, even though their mechanisms are as mysterious as is the mechanism of the LISTEN signal generator. See RCW 18.06.010, 18.06.045(1), 18.36A.040,

18.36A.050(1) and (4).<sup>1</sup> Clearing away all of the verbal underbrush, this decision penalizes Dr. Ames for following a different medical paradigm – one that the legislature, however much the Commission may deplore it, has said may properly be the basis of a physician’s health care practice – from that of conventional medicine. But however fervently Commission members reject that paradigm, in the absence of scientific evidence for their position, it cannot properly be the basis of disciplinary action.

[I]mpressions or beliefs of physicians, no matter how fervently held, are treacherous.

Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 619, 93 S.Ct.

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NIH, National Ctr for Complementary and Alternative Medicine, *Background: Energy Medicine: An Overview*, <http://nccam.nih.gov/health/backgrounds/energymed.htm>: Therapies involving putative energy fields are based on the concept that human beings are infused with a subtle form of energy. This vital energy or life force is known under different names in different cultures . . . . Vital energy is believed to flow throughout the material human body, but it has not been unequivocally measured by means of conventional instrumentation. Nonetheless, therapists claim that they can work with this subtle energy, see it with their own eyes, and use it to . . . and influence health.

Practitioners of energy medicine believe that illness results from disturbances of these subtle energies (the biofield). For example, more than 2,000 years ago, Asian practitioners postulated that the flow and balance of life energies are necessary for maintaining health and described tools to restore them. Herbal medicine, acupuncture, acupressure, moxibustion, and cupping, for example, are all believed to act by correcting imbalances in the internal biofield, such as by restoring the flow of qi through meridians to reinstate health. Some therapists are believed to emit or transmit the vital energy (external qi) to a recipient to restore health. . . . One Western approach with implications for energy medicine is homeopathy. Homeopaths believe that their remedies mobilize the body's vital force to orchestrate coordinated healing responses throughout the organism. . . . Homeopathic medicine is based on the principle of similars, and remedies are often prescribed in high dilutions. In most cases, the dilution may not contain any molecules of the original agents at all. . . . Theories for a potential mechanism of action invoke the homeopathic solution, therefore, postulating that information is stored in the dilution process by physical means.

2469, 2478 (1973).

Upholding such a position sends a clear message to any physician that he or she had better not mess with any alternative device or treatment, no matter how good the empirical experience with it, no matter how noninvasive it may be, and no matter the policy of this state.

**II. DOH MISREPRESENTS THE STANDARD OF REVIEW AND ATTEMPTS TO GIVE *JOHNSTON'S* EVIDENTIARY HOLDING A SCOPE THAT CANNOT BE DEFENDED**

*A. Substantial Evidence When the Burden Below is Clear and Convincing Evidence.* Because the consequences of a medical disciplinary proceeding are so severe, the *Nguyen* court found that unprofessional conduct must be proved by clear and convincing evidence. For the same reasons, “substantial evidence” in such a case is evidence that a rational, fairminded person would consider to be *highly probable*. But this does not merely follow from the reasoning of *Nguyen*, it is the general law applicable to any fact to be proved by clear and convincing evidence. *Bay v. Estate of Bay*, 105 P.3d 434, 438 (Wn.App. Div. 1, 2005) (standard of review is evidence that “could reasonably [be] found to be clear, cogent, and convincing.”) ; 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” is what a rational fact finder would find to be “highly probable”) This is still a deferential standard, because express credibility determinations must be accepted and evidence contrary to the evidence supporting the decision below must be disregarded. But once the contrary evidence is cleared away, the evidence that remains and the reasonable inferences it supports, must still be evidence

that a rational, fair minded person would find clear and convincing. DOH's assertion to the contrary is supported by no cited authority and DOH makes no attempt to discuss the authority cited by Dr. Ames.

***B. Overstating the Scope of Johnston, Brown and Davidson.*** DOH, relying on the Johnston, Brown, and Davidson cases<sup>2</sup>, claims that when negligence is the charge, no evidence in support of a negligence finding need be introduced (other than, one supposes, the specific conduct claimed to be negligent), and that all other evidentiary requirements can be provided by the panel from its putative expertise. See RB 15 ("separate testimony is not necessary when determining standard of care *cases*") (emphasis added). Thus, on this interpretation, if DOH charged that Dr. Ames had taken pulses – a standard acupuncture diagnostic technique – when performing acupressure, it need introduce no other evidence to establish that this is negligence, and a panel of three commission members could decide, based on its "expertise," that this mode of diagnosis is ineffective and therefore negligent. The DOH brief does not address Dr. Ames's position that Johnston only applies to the inference of negligence that a panel consisting entirely or almost entirely of members of the relevant profession may draw from the evidence, does not relieve DOH of the requirement that the decision must be based exclusively on record evidence, and that there must be reasons and evidence adequate to support every dispositive factual finding.

Arizona has adopted the Johnston view, but it has made it clear that

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Johnston v. Medical Board, 99 Wn.2d 466, 663 P.2d 457(1983); Brown v. Dental Board, 94 Wn.App. 7, 972 P.2d 101 (Div. 3, 1998); Davidson v. Department of Licensing, 33 Wn. App. 783, 657 P.2d 810 (Div. 1, 1983)

that doctrine does not approach the scope DOH claims for it, as the evidence introduced in *Johnston*, *Brown* and *Davidson* would make clear in any event.

¶ 19 At the underlying interview, Board members Zonis and Keen and Board consultant Saba identified mistakes that they felt Webb had made and rendered opinions about what they thought he should have done, but they did not articulate a standard of requisite professional care under the circumstances and in the relevant community. "[A] doctor is not liable in negligence for mere mistakes in judgment in treating a patient, but is only liable where the treatment falls below the recognized standard of good medical practice. [citing authority]

....

¶ 20 Although the Board may establish the standard of professional care based upon its members' experience and expertise, the Board "cannot base its findings ... upon either undisclosed evidence or personal knowledge of the facts." *Croft*, 157 Ariz. at 209, 755 P.2d at 1197 (quoting *Davidson v. State*, 33 Wash.App. 783, 657 P.2d 810, 812 (1983)). ***Nor in our judgment can the Board provide a fair hearing on an issue of negligence without identifying the standard of care and articulating the alleged deviation. Not only must the Board identify the standard and articulate the alleged deviation in order to provide the physician under investigation a fair opportunity to respond to a charge of negligence; it must do so in order to provide a reviewing court an opportunity for meaningful review.*** "Without clearly articulated standards as a backdrop against which the court can review discipline, the judicial function is reduced to serving as a rubber-stamp for the Board's action." [citing authority].

....

¶ 22 In summary, if the Board undertakes to establish upon remand that Webb's conduct was negligent and thus unprofessional under A.R.S. § 32- 1401(25)(11), ***it must establish a deviation from an articulated standard of professional care***, establish that the deviation resulted in actual harm, and ***provide reviewable findings on both points***.

*Webb v. Arizona Bd. of Med. Exmnrs*, 202 Ariz. 555, 560, 48 P.3d 505, 510 (App.Div.1, 2002) (emphasis added).

Note the Arizona court's emphasis on meaningful review and its refusal to be "a rubber stamp for the Board's action." DOH is asking the Court to be precisely that – a rubber stamp, which is even less appropriate in

Washington, because of its commitment to health care freedom and because the legal standard of care here is not merely the recognized standard of practice in the profession – what conventional physicians would normally do in the situation. There is a public interest element in the Washington formula that trumps the professional “standard of care” when they conflict.<sup>3</sup>

Nor do the facts of *Johnston*, *Brown* or *Davidson* suggest that Washington does not require adequate evidence in the record and adequate reasons in the Order before a reviewing Court will uphold a medical board decision. In this case DOH called no physicians or other health care providers – other than Dr. Ames himself – and there was not expert or other witness to testify to medical facts from which a reasonable inference of negligence or inefficacy could be drawn. In both *Johnston* and *Brown* there was ample expert testimony from practitioners in the field which cast clear doubt on the propriety of the respondent’s conduct and identified the nature of his derelictions. Counsel for the Department in those cases had merely neglected to elicit a formal statement from one of those witnesses expressly intoning what was obvious on the facts – that the conduct departed from the standard of care expected by society. In *Davidson*, there was no expert

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*Harris v. Robert C. Groth, M.D., Inc.*, 99 Wn.2d 438, 445, 663 P.2d 113, 117 (1983) (“It is society and their patients to whom physicians are responsible, not solely their fellow practitioners.”); *Bauer v. White*, 95 Wn.App. 663, 668, 976 P.2d 664, 667 (Div. 3, 1999) (“The standard of care . . . is not limited to the standard practiced by those in the profession.”); *Adair v. Weinberg*, 79 Wn.App. 197, 202-203, 901 P.2d 340, 343 (Div. 1, 1995) (“Conformance to the standard of the medical profession no longer unilaterally defines the standard of care in a medical negligence action. . . . the Legislature had changed the standard from ““expected by the medical profession”” to that ““expected by society.”””)

testimony. But the facts spoke for themselves. The chiropractor there had sexually molested two patients claiming that this was part of his chiropractic treatment. No expert evidence of the standard of care would have been necessary even if the case had been brought in a civil court for malpractice, because any layperson could know this was inappropriate. In this case, on the other hand, there are technical questions in bioengineering and alternative health care that can only be resolved by expert evidence, but DOH provided no witness or document to establish the proper resolution.

**III. DOH'S DEFENSE OF THE FINDING OF INEFFICACY BETRAYS THAT FINDING'S WEAKNESS, BECAUSE DOH RELIES NOT ON THE REASONS AND EVIDENCE CITED BY THE PANEL, AND EVEN ITS NEW GROUNDS ARE INDEFENSIBLE**

The first of numerous objections to DOH's defense of the finding/conclusion that the LISTEN was, in the words of the Order, "an inefficacious device," is that it makes barely any attempt to defend the reasons given and the evidence cited by the Order. If the panel stated what its reasons and evidence were – as it was required to by RCW 34.05.461(3) – and did not rely on or even mention the reasons and "evidence" which the DOH brief asserts, how can this Court presume that the panel's decision was based on those other reasons and other evidence. This Court can have no way of knowing whether the panel subscribed to those reasons or believed the "evidence" invoked by the DOH brief. Indeed, the very fact that the Order does not mention these reasons and asserted "evidence," suggests that they did not subscribe to them. And it would violate the APA requirement that the panels' reasons must be given and, where a finding is in the words of the statute, the evidence relied upon must be cited, if the Commission could

abandon the reasons its panel did give and the evidence it did cite and attempt to scavenge through the record and the law for fragments which it thinks might provide more defensible support. See RCW 34.05.461(3).

The panel's grounds for finding Dr. Ames's LISTEN inefficacious were that when it was used with Patient One it caused an allegedly inaccurate conclusion that on that particular occasion the patient had an egg allergy.<sup>4</sup> The Order's reason for concluding that the muscle testing with the device was inaccurate was that P1 had not been told that he had a food allergy by anyone else, that he did not have the same reaction to eggs that he had to pollen, that he was unaware of any other reaction he had to eggs and that, assertedly, there was no "clinical evidence" of an egg allergy. Dr. Ames responds to these assertions – their illogic, speculativeness and evidentiary baselessness – in his opening brief, but the DOH brief essentially ignores the assertions and Dr. Ames's response and attempts to defend the finding on the grounds discussed below. What could be stronger evidence of DOH's own lack of

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It is possible to read ¶1.28 which purports to state the reasons why Dr. Ames was negligent as stating that Dr. Ames's LISTEN was also inefficacious, because it was used to treat as well as assess and it was ineffective as treatment as well as assessment. CR 1862. This is flatly contradicted by the panel's own finding that the "treatment" was the acupuncture. ¶1.19; CR 1859. It is also contradicted by the amended statement of charges which refers to the device only in the context of the muscle testing assessment, which specifically describes it as testing, not treatment, and the absence of any statement regarding treatment, cure or statement of cure anywhere in the statement. Nor is there any indication in the Order – or in the evidence – of how the LISTEN might have been used for treatment. The only description of the LISTEN's use in the Order or in the evidence was as a mechanism to see if an arm muscle would be weakened by the device's generation of the electromagnetic signature of eggs. Be that as it may, even if the Order were viewed as finding that the device was ineffective as both assessment and treatment, the only basis for that finding given by the Order is that its use with a particular patient on one occasion yielded an incorrect result.

confidence in the legal basis of this Order?

Of the new arguments to defend the finding/conclusion that Dr. Ames's device was "inefficacious," the one which DOH emphasizes and which spreads most confusion is that the device was never cleared by the FDA for any purpose and thus could not properly be used with Patient One even as part of a larger assessment process. RB 25-26. Even if any of this were true – and *none* of it is – it would not establish that the device was inefficacious. For example, every device that is ultimately cleared or approved by the FDA was necessarily effective before the FDA said so: it did not magically become effective only when the FDA agreed that it was. FDA approval only signifies that the FDA now is willing to certify that the device is efficacious. It may take years before such an approval may be secured, but the device necessarily was effective when created and for all of the time prior to the FDA's recognition of the fact. See Opening Brief ("OB"), p. 9

*A. Dr. Ames's Device Was Cleared.* The device, however, was cleared. DOH simply disregards and contradicts the panel's own findings:

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*. . . .

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.*

.....  
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. . . .*

Emphasis added. Thus, the LISTEN was cleared under the name Digital Conductance Meter and then marketed under the name LISTEN. See CR 2843-44. Indeed, the DOH brief itself states – in one of several examples of the incoherency of its and the panel’s positions – that “the Commission concluded” that the charges that “the device had not been cleared or approved by the Food and Drug Administration . . . were unproven.” RB 11 n.4.

The only difference between the LISTEN as first submitted and as later cleared was in the labeling. The original labeling stated “intended uses” for the device – *i.e.*, uses for which the manufacturer intended to *market* the device – which the FDA would not clear. See 21 U.S.C. §360c(i)(E)(i). The LISTEN submitted under the DCM application did not state such uses on the labeling. This procedure was followed at the suggestion of the FDA personnel with whom Mr. Clark was interacting so that he could get the LISTEN on the market. CR 2870-2873. Of course, the FDA knew that when the device was cleared for one purpose it could be used by a practitioner – but not marketed – for any other purpose (an “off-label use”) as far as the FDA was concerned. *See infra*. Indeed, contrary to DOH is unsupported assertion there is no statute or doctrine – and DOH despite its assertion to the contrary cites none – holding that a device cannot be used by a health care professional for any purpose if it has not been cleared by the FDA.<sup>5</sup> The statute cited – 21

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DOH’s resurrects the frivolous claims of the initial statement of charges that the FDA has the power to regulate the use of devices by physicians. Although the FDA has

U.S.C. §396 – simply states that the FDA cannot use its authority over a device it may have cleared to invade the practice of health care.

***B. The Absurdity of Arguing That Not the Device, But Its Use on One Occasion Was Inefficacious.*** The second new major argument that the DOH brief advances as to efficacy seems to be that the panel did not actually find that the LISTEN was inefficacious generally, but only that it was inefficacious in its use with Patient One on that one occasion. A look at ¶¶ 1.28, 1.29, and 2.5 of the Order – especially ¶ 1.28, which states the conduct which is alleged to be negligent – shows this to be another misrepresentation of the findings. CR 1862-63. But if it were a supportable reading of the Order, it would mean that the panel ruled that use of any device that does not work correctly on one occasion – although the device is efficacious on more occasions than could be explained by chance – is negligence, and recommendation of such a device or an associated treatment is promotion for personal gain of such a device within the meaning of the relevant statutes.<sup>6</sup> These are patently absurd interpretations of the statute. See authority at OB 19, 44. Any “efficacious” device can fail to function properly on a given

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occasionally made noises as if it was thinking of empire-building in this way with respect to devices it had cleared or approved – that is why 21 U.S.C. §396 was enacted – the idea has been rejected by the courts, by Congress and, usually, by the FDA itself. The FDA’s function is to regulate the *marketing* in interstate commerce of drugs, devices and cosmetics and although its activities will indirectly affected health care practice it has no authority *per se* over the practice of medicine or other modalities. See *Buckman Company v. Plaintiffs Legal Committee*, 531 U.S. 341, 350, 121 S.Ct. 1012, 1018 (2001); see *Ibid* cite to Beck and Azari, *FDA, Off-Label Use and Informed Consent*, 53 Food and Drug Law Journal 71 (1998)); see Beck and Azari at 72, 76-78; see FDA written policy positions quoted *id* at 77-78.

<sup>6</sup> Note that the DOH brief expressly states that the finding was that the *device* – not the treatment, or the use of the device – was inefficacious. RB 27-28

occasion. Yet surely that failure cannot support an after-the-fact indictment of a health care professional for using or recommending the device on that occasion.

*C. The Impermissibility of Placing the Burden on Dr. Ames.* The remaining arguments regarding efficacy advanced by the DOH brief amount in sum to the contention that Dr. Ames's evidence for the efficacy of the device was inadequate and therefore the panel was entitled to rule that the device was inefficacious. DOH argues that Dr. Ames's evidence – *i.e.*, the experience he had with his clients – as exemplified by the testimony of the two patients the presiding officer would allow Dr. Ames to call – Dr. Ames had listed ten patients as a sample, but this was rejected by the PO –, by that of his colleagues who use NAET treatment and by Dr. Martin's experience with NAET were anecdotal and unscientific. See CR 904, 1495-96; OB 36. This, of course, is to switch the burden of proof of inefficacy onto the respondent, when it is squarely on DOH to prove its allegations. DOH had the burden of proving the “factual basis” of its charges. That means it was DOH's burden to prove the device was *not* efficacious, not Dr. Ames's burden to prove that it *was*.<sup>7</sup> For another attempt by quackbusters to improperly shift the burden of proof to alternative health care, see National Council Against Health Fraud v. King Bio Pharmaceuticals, 107 Cal.App.4th 1336, 133 Cal.Rptr.2d 207 (2d Dist., Div. 5, 2003).

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<sup>7</sup> DOH would not have given such an argument a second thought if the respondent were a conventional physician making an off-label use – *i.e.*, a use that the FDA has not approved, because it is not yet scientifically established – of a device cleared or approved for another purpose. Because off-label use is so common, if such an argument were accepted it would render literally hundreds of thousands of physicians guilty of unprofessional conduct.

It should be noted that Dr. Ames's empirical evidence is very strong and that it is the panel's one piece of spurious "evidence" that is worthless. It bases its conclusion on the speculative assertion that Patient One did not have an egg allergy, which itself is trumped solely by the far more credible anecdotal experience of Patient Two, who described how the LISTEN was used to help Dr. Ames discover – what neither of them knew – that P2's mysterious symptoms were caused by sugar. CR 2697, 2699.

**IV. DOH'S ATTACK ON THE RAST TEST IS DIVERSIONARY AND IT DOES NOT EVEN EXPLAIN WHY ONE DIAGNOSTIC ERROR IN THE ABSENCE OF EVIDENCE THAT THE PROCEDURE FOLLOWED WAS DEFICIENT CAN RATIONALLY BE HELD TO CONSTITUTE NEGLIGENCE**

Another of DOH's gross misstatements of the record – a statement which is not adopted, and is implicitly rejected by, the panel (see ¶ 1.15-16; CR 1858)<sup>8</sup> – is that Dr. Martin testified that the RAST test is worthless. What Dr. Martin said – in response to general questions from Dr. Ames's counsel and from a member of the panel, not in response to questions about the facts of Patient One's case – was that the RAST test was a conventional food allergy test which was not reliable enough to establish a diagnosis by itself and that he would not treat a person who had a positive RAST in the absence of symptoms. CR 2976, 2993. The implication is that he would if

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The panel's treatment of the RAST blood test for food allergies is another example of the incoherence of its decision, recognizing at the beginning of the findings that it was the blood test and its finding of mustard and egg allergies that prompted the muscle testing and the treatment, ¶¶ 1.14-1.16; CR 1858, and then finding as if it was only the LISTEN – it was never the LISTEN by itself, but the muscle testing using the LISTEN rather than a sample of egg – that accounted for Dr. Ames's "negligent" diagnosis. ¶1.28; CR 1862.

there were symptoms. In this case, of course, there were symptoms. But the point here is that the evidence was that the decision to treat, according to P1, was based not on the muscle testing, but on the RAST test, and that P1 did have symptoms, and DOH's argument does not controvert this.

*The Failure To Show Why One Error in Testing Can Support a Finding of Negligence.* All professionals make mistakes, but that a decision turns out to be the wrong decision cannot in itself be negligence. Accordingly, there must be some evidence other than the error itself to support a rational finding that the conduct fell below the standard of a reasonably prudent physician and created an unreasonable risk of harm. Webb v. Arizona Bd. of Med. Examiners, *supra*. Yet upon analysis it appears that the only evidence of negligence is that the alleged conclusion and report that P1 had an egg allergy was incorrect – nothing more.

**V. THE CASES AND ARGUMENTS CITED BY DOH TO ESTABLISH ADEQUATE NOTICE DO NOT ARISE UNDER THE CONTROLLING REGULATION IN THIS CASE, ARE NOT APPLICABLE TO A QUASI-CRIMINAL ADMINISTRATIVE PROCEEDING IN ANY EVENT AND IN FACT SUPPORT DR. AMES'S CONTENTION THAT THERE WAS NO NOTICE OF THE "FACTUAL BASIS" OF THE CHARGES**

From the very beginning of this case, with the initial statement of charges and its spurious assertions of an FDCA violation by Dr. Ames, this has been a case in search of a theory the Commission's quackbusters could use to suppress the use of the LISTEN. The facts and the theories under which the panel ultimately found unprofessional conduct are not in either the first or second statements of charges, the DOH pre-hearing statements or even in the DOH opening statement. Neither the statement of issues nor the description of the testimony of the witnesses DOH proposed to call suggested

that this case was about more than the validity of the LISTEN as a testing device or, possibly, about muscle testing. The factual theories on which the panel ultimately decided against Dr. Ames only began to emerge during the hearing itself and then, not straightforwardly, but as questions posed primarily by the physician assistant and pro tem panel member, Ms. Paxton. Only when the panel issued its Order did those theories finally present themselves as a purported basis for a finding of quasi-criminal conduct.

Because medical disciplinary cases are “quasi-criminal” cases, the rules governing notice for such cases are not the same as those for a civil lawsuit or for a proceeding initiated by an agency regulating businesses or governmental bodies. For example, CR 8 states:

A pleading which sets forth a claim for relief . . . shall contain (1) a short and plain *statement of the claim* showing that the pleader is entitled to relief and (2) a demand for judgment for the relief to which he deems himself entitled.

This is so-called notice pleading and it does not require a pleading of the key facts on which the theory of liability is predicated. On the other hand, WAC 246-11-250(1)(b) requires that a statement of charges

shall include a *clear* and concise statement of the . . .

*Factual basis* for the action or proposed action set forth in the document [and] the statutes and rules alleged to be at issue .

Emphasis added. Note that the term “factual basis” occurs again in WAC 246-11-520 which declares that

[T]he burden is on the department to prove the alleged *factual basis* set forth in the initiating document [i.e., the statement of charges].

Emphasis added. It is clear from this that by “factual basis” the WACs mean the facts that must be established in order for there to be liability. But most of the facts which the panel found necessary to establish liability here were not set forth in the statement of charges, the prehearing statement or in DOH’s opening statement.

As for other types of administrative proceedings, in each of the cases cited by DOH to establish that Dr. Ames was given adequate notice here – although the language and principles of none of them would be adverse to Dr. Ames in any event – none of these cases involved quasi-criminal conduct and none were governed by WAC 246-11-250 and 260. See *City of Marysville v. Puget Sound Air Poll. Control Agcy*, 104 Wn.2d 115, 702 P.2d 469 (1985); *Inland Foundry Co. v. Dept. of Labor and Industries*, 106 Wn.App. 333, 24 P.3d 424 (Div. 3, 2001); *Natl. Realty & Const. Co. v. Occup. Safety and Health Rev. Commn.*, 489 F.2d 1287 (D.C. Cir. 1973). One involved air quality and two involved employee safety on the job. The respondents were two businesses and a municipality. The sanctions involved were no more than penalties and an order to remedy a condition or practice.

A key legal fact in this case is that although DOH is free prior to the prehearing conference to amend at will – which makes its failure to plead the missing facts here even more censurable – WAC 246-11-260(2) by necessary implication does not permit amendments to conform to proof, nor amendments on the first day of the hearing without motion and approval of the presiding officer. For the unfairness of allowing such amendments after the hearing in a professional discipline case, cf. *Disciplinary Proceedings*

Against Bonet, 144 Wn.2d 502, 510, 29 P.3d 1242, 1246 (2001)<sup>9</sup> No motion was in fact ever made, but the panel here by its decision in effect amended the pleadings. See National Realty, *supra*, at 1267 (Even where amendment to conform is allowed, “An employer is unfairly deprived of an opportunity to cross-examine or to present rebuttal evidence and testimony when it learns the exact nature of its alleged violation only after the hearing.”)<sup>10</sup>

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9 (“considerations of procedural due process dictate that [board] . . . *sua sponte* cannot amend the charges in the Formal Complaint to conform to the evidence.”)

10 City of Marysville involved a \$500 fine and yet the Court held that although “strict rules of pleading do not apply,” the proceeding was not under WAC 246-11-250, and even though it was clear what conduct the agency was complaining about, nevertheless the pleadings had *not* given adequate notice of the violation ultimately found. In the Inland Foundry case, this Court ruled that the citations in question “specifically stated what the employer had failed to do.” 106 Wn.App. at 337. In addition, the employer had participated in opening and closing investigations “that explained the nature of the investigation and the violations discovered.” *Id* at 338. The statements of charges, the pre-hearing statement, and DOH’s opening statement here did not “specifically state” what Dr. Ames had done or failed to do. It told him only a part of what the panel ultimately found the negligence to consist – about one third of *one* of the two negligence theories – and of the conduct that allegedly created the “unreasonable risk” of harm the panel ultimately found.

The National Realty case was cited by DOH primarily for its quotation of Professor Davis about the “unimportance” of administrative pleadings. But that quotation – which clearly was not referring to professional disciplinary proceedings – was not addressing the one important function such pleadings do have – *i.e.*, notice. See 3K.Davis, Administrative Law Treatise §14.11 at 46 (2d ed. 1980) (Agencies still use pleadings, “but only for notice purposes”) (as quoted in City of Marysville, *supra*, at 119). After quoting this language from Professor Davis, this Court immediately stated that the citation in suit “must give reasonably particular notice so that the cited employer will understand the charge.” National Realty was a case where the respondent employer was fined \$300 for permitting an employee to ride on a piece of equipment. There was ambiguity as to whether this meant the employer specifically consented to a particular instance of such riding or had a practice of not acting sufficiently to prevent it. The factual *basis* of the charge could hardly have been clearer, however, and the alternative meanings were clear on the face of the charges.

DOH attempts to repair the deficiency in the pleading by one of its more egregious misstatements of the record – it says that the Statement of Charges mentions treatment. RB 3, 20, 22 The Court will see, however, that both statements speak only about testing for and detecting food allergies. *E.g.*:

“On or about July 10, 2001, respondent tested Patient One for food allergies

**VI. DOH FAILS TO EVEN ADDRESS THE LEGISLATURE'S USE OF THE WORDS "PROMOTION FOR PERSONAL GAIN"**

DOH makes no attempt to respond to Dr. Ames's argument that RCW 18.130.180(16) can only fairly be read to prohibit commercial exploitation

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using an electrodiagnostic device called the Life Information System Ten device (LISTEN). Respondent later admitted to a Department of Health Representative that he uses the LISTEN device to detect food allergies in patients."

¶1.2; CR 60. The other paragraphs of the Amended Statement that alleged facts about the interactions between P1 and Dr. Ames were 1.13 and 1.14 and they refer only ordering laboratory tests, discussion of the test results, and the muscle testing. CR 61. Note the allegations in ¶1.14 that Dr. Ames told P1 that the muscle testing "showed he was allergic to eggs" and "Respondent repeated the test."

These paragraphs say nothing about treatment, nor about curing the patient, nor about telling the patient that he was cured. Nor does DOH contend in its brief that such charges could be inferred from such allegations. No reasonable person could infer from its total focus on testing that anything other than the use of Dr. Ames's device for testing for allergies was the conduct of which DOH was complaining. Dr. Ames did try to learn more about the Statement of Charges by noting the depositions of the Reviewing Board Member in charge of the case and the investigator referred to ¶1.2. DOH opposed these depositions and the presiding officer quashed them. CR 280. If DOH had intended to raise these issues it was free to amend its complaint prior to hearing or, at least, it could have alerted Dr. Ames by setting them forth in their statement of issues or designating expert witnesses who would have been identified as addressing treatment, cure and statements to patients. The only witnesses identified, however, as their testimony at the hearing showed, were not represented as, and in fact did not, testify about any of these matters. There was no hint from the prehearing statement or from their depositions that they would address any of these issues. Nor was there such a hint even in DOH's opening statement

As for the findings in the panel's Order that Dr. Ames did not adequately investigate the safety of his LISTEN, there is, of course, nothing in the amended statement of charges, the pre-hearing statement or DOH's opening statement which remotely suggests that this was an issue in the case. See CR \_\_. Indeed, there is not even an allegation that the LISTEN used by Dr. Ames raised any safety concerns whatsoever (as it certainly did not). DOH did give Dr. Ames notice that there would be testimony about the device by identifying Dr. Sherman – an expert on biofeedback devices – and Mr. Ogden, who at the time of hearing was an official at the FDA who dealt with clearing or approving such devices. But there was no suggestion in the statement of issues or the description of the proposed testimony of Sherman or Ogden that there was a contention in the case that Dr. Ames had not adequately investigated the safety of the LISTEN prior to using it with P1. These witnesses – Dr. Sherman and Mr. Ogden – might have been able to testify to the safety of devices like the LISTEN and what precautions practitioners normally take with respect to them. But only Dr. Sherman testified on any of this, and his only related testimony was that the devices were safe.

of inefficacious devices for commercial profit and not the recommendation and use of a device in a medical practice to assess for conditions which he might treat for a fee. The relevant definition of “promotion” in Webster’s Third New International Dictionary 1815 (1986) is: “active furtherance of sale of merchandise through advertising or other publicity.” No other definition comes closer than that one.

RCW 18.130.180(16) does not prohibit the “use,” or the “recommendation,” or the “prescription” of inefficacious modalities and devices. It could easily have done so and thereby have swept in “promotion” as well. But it did not. It is also important to explain why the legislature did not simply prohibit promotion of inefficacious modalities whatever the motive – why add “*for personal gain,*” since in an ideal world the inefficacious should not be promoted at all. The only explanation, especially when considering that RCW 18.130.180(1) and (4) would cover all non-innocent promotions of inefficacious modalities in medical practice, is that the legislature had in mind a non-practice setting, one in which the promotion is not part of service to patients, is not for the benefit of the patients, but solely for the personal gain of the professional – that is, commercial.

**VII. TAKEN AS A WHOLE THIS IS AN UNLAWFUL PROCEEDING  
WHICH THIS COURT SHOULD NOT TOLERATE**

From the beginning of this case, this has been an attempt to suppress a particular device, not to discipline unprofessional conduct. Consider the patently spurious and frivolous initial statement of charges. It was directed solely at the LISTEN and pleaded only a violation of RCW 18.130.180(7), an asserted violation based solely on an asserted violation of food and drug

laws. If DOH thought it had a basis for charging some other kind of unprofessional conduct, surely it would have done so. It obviously thought at the time that its best shot was the FDCA violation. But it should have known – and probably strongly suspected – that its best shot was no shot. As became clear beyond peradventure when it identified its experts on this subject, neither of them knew anything about Dr. Ames's LISTEN and none could testify that it did not have a clearance. In other words DOH never had colorable evidence that there was no clearance. DOH knew that Jim Clark had sold the device to Dr. Ames, but it made no attempt to contact him to determine if he had a clearance. CR 2883-84. It attempted to maintain plausible deniability, by not doing what was necessary under CR 11 to determine if it had a colorable basis for accusing a physician of unprofessional conduct and violation of a federal criminal statute.

It was always clear, without waiting to see its supposed evidence, that DOH's alternative theory of FDCA violation – that if there was a clearance, Dr. Ames was using the device for a purpose the FDA had not cleared – was frivolous and that DOH knew or should - if it had done requisite legal research – have known this. This is because off-label uses are not illegal under the FDCA. Only after the presiding officer allowed Dr. Ames to propound some interrogatories about the factual basis for the FDCA claims did DOH realize the game was up and then file a new statement of charges cynically claiming moral turpitude, negligence and promotion for personal gain. At that time it had no choice, if it did not want to slink away with its tail between its legs, but to add those charges, even though it must have

thought they were weaker than the FDCA charges they first pleaded . Note that it admitted in discovery that the new charges were not based on new investigation or discovery, but on the exact same investigative file which had been the basis of the initial charges. CR 110.

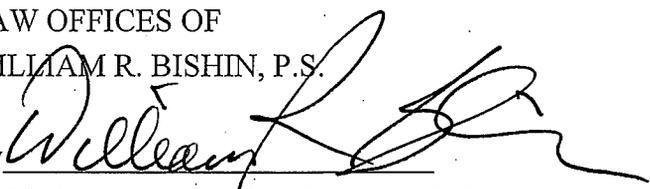
DOH showed up at the hearing without a scintilla of evidence to establish any of its theories, but the panel – all of whose members had to have been involved in the decision to file the charges against Dr. Ames – attempted to bail it out by pursuing lines of panel questioning on which the ultimate decision was based. This case is a classic example of what can go wrong when legislative, judicial and executive functions are combined in an agency run by one school of professional thought and procedural safeguards are disregarded. Only this Court can prevent the resulting abuse of power.

### CONCLUSION

The Court should reverse this gross miscarriage of justice and direct the Commission to vacate the Order, dismiss the charges and return the monetary penalty it exacted from Dr. Ames.

Respectfully submitted this 2d day of October 2006.

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By 

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