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WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2005-06
(session year)

Joint
(Assembly, Senate or Joint)

Committee on Audit...

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
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- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
  (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Stefanie Rose (LRB) (July 2012)

STATE OF WISCONSIN
BEFORE THE MEDICAL EXAMINING BOARD

IN THE MATTER OF THE DISCIPLINARY PROCEEDING AGAINST ELEAZAR M. KADILE, M.D. RESPONDENT.	)	CASE NO. LS0112061 MED **RESPONDENT'S MOTION IN LIMINE**

Now comes Respondent Eleazar M. Kadile, M.D. (hereinafter, "Respondent"), by and through undersigned counsel, and hereby moves *in limine* for an Order precluding Robert Baratz, D.D.S., Ph.D., M.D. (hereinafter, "Baratz") from testifying as an expert witness for the State of Wisconsin Medical Examining Board (hereinafter, the "State") in the within proceedings. As more fully set forth in the attached Memorandum, Baratz lacks the requisite qualifications to testify as an expert.

Respectfully submitted,

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Attorney for Respondent

Enclosure 3a

MEMORANDUM OF LAW

I. INTRODUCTION

Respondent respectfully moves for an Order from the Administrative Law Judge (hereinafter referred to as the "Court") precluding the State's witness, Baratz, from testifying as an expert in the within proceedings. As will be fully demonstrated herein, Baratz fails to qualify under the Wisconsin statute regulating the admissibility of expert testimony. The gist of the State's case against Respondent is that he fell below the standard of care required for medical doctors in Wisconsin when he administered EDTA chelation therapy on patients with coronary artery blockage. Although the defense will adduce evidence via expert testimony to controvert the State's assertions against EDTA chelation therapy, the fact is that Baratz has no qualifications or experience which would qualify him as an expert in EDTA chelation therapy.[1] Accordingly, Baratz should not be considered an expert witness in this case because he lacks any relevant knowledge or experience which would qualify him as having specialized knowledge which could assist the Court.

In addition, any testimony from Baratz should be excluded as prejudicial based on the fact that he has continually provided testimony in an assortment of cases brought against alternative medicine practitioners in states all across the country. Now it is the State of Wisconsin that has chosen to do business with Baratz, and has secured his mercenary-like services for its case against Respondent, who emphasizes alternative medicine in his general

[1] Baratz has testified that he once treated children who had lead toxicity with an I.V. treatment of calcium disodium EDTA sometime between 1985 and 1987. However, Baratz stated that this occurred when he was a medical student and was the only time he has ever used EDTA on a patient. He has never used EDTA as a licensed medical doctor, and his experience inserting IV's filled with EDTA into patients while a student does not qualify him as an expert on chelation therapy. See fn. 4.

family practice in Green Bay, Wisconsin.[2] However, Respondent will demonstrate that Baratz is not the expert the State purports him to be. Accordingly, it would be unconscionable for the State of Wisconsin to proceed to permanently revoke Respondent's license to practice medicine via Baratz's "expert" testimony. Therefore, Respondent is entitled to an Order which disallows Baratz from testifying as an expert on behalf of the State in the within matter.

II. THE WITHIN PROCEEDINGS ARE GOVERNED BY WISCONSIN STATUTORY RULES OF EVIDENCE

The instant matter against Respondent is a Class Two proceeding governed by ch. 227 of Wis. Stats. (Notice of Hearing, ¶ 1) Pursuant to Wis. Stats. §227.45(1), which provides in part:

> ***Except as provided in ss. 19.52(3)*** and 901.05, an agency or hearing examiner shall be bound by common law or statutory rules of evidence. The agency or hearing examiner shall admit all testimony having reasonable probative value, but ***shall exclude immaterial, irrelevant or unduly repetitious testimony***... (Emphasis added.)

Wis. Stats. §19.52(3) provides:

> ***Chapters 901 to 911 apply to the admission of evidence at the hearing***. The board shall not find a violation of this subchapter or subch. III of ch. 13 except upon clear and convincing evidence admitted at the hearing. (Emphasis added.)

Thus, the Wisconsin rules of evidence codified at Chapters 901 through 911 of Wis. Stats. apply to all Class Two proceedings, which necessarily includes those sections which govern the admissibility of certain evidence, including expert testimony. As discussed below, Wisconsin law requires that an expert must be duly qualified before he or she may testify. Pursuant to the above statutes, this requirement extends to administrative proceedings under ch. 227. Therefore, the rules regarding admissibility of evidence and expert witness testimony apply

[2] Indeed, it must have taken the State of Wisconsin a long time to find its hired gun. The investigation of Respondent was initiated over *EIGHT* years ago, and only this year (2002) was a complaint filed, presumably after the State finally found an "expert" willing to testify against Respondent.

in the instant proceedings against Respondent.

In addition, Wis. Stats. §227.45(1) requires the hearing examiner to exclude any testimony which it finds immaterial, irrelevant or unduly repetitious. As will be more fully demonstrated herein, any testimony from Baratz may be excluded as immaterial or irrelevant based on his failure to qualify as an expert under Wisconsin law. Accordingly, Baratz should be precluded from testifying as an expert witness for the State.

III. BARATZ DOES NOT QUALIFY AS AN EXPERT UNDER WIS. STATS. §907.02

A. Legal Standards for Qualification of Expert Witnesses In Wisconsin.

It is a matter of Wisconsin law that a witness qualified as an expert by knowledge, skill, experience, training or education may testify in the form of an opinion or otherwise, provided that the scientific, technical or other specialized knowledge of the witness will assist the trier of fact to understand the evidence or to determine a fact in issue. Wis. Stats. §907.02. The Supreme Court of Wisconsin, in interpreting this statute, has held that scientific evidence is admissible if (1) it is relevant; (2) the witness is qualified as an expert; and (3) the evidence will assist the trier of fact in determining an issue of fact. *State v. Walstad*, 192 Wis.2d 674 (1984). Only when these elements are met will the evidence be admitted. *State v. Peters*, 192 Wis.2d 674 (Ct. App. 1995).

Whether a witness is qualified as an expert is a preliminary question of fact for the court to decide under Wis. Stat. §907.04(1). *Martindale v. Ripp*, 246 Wis.2d 67 (2001). In *Martindale*, the Supreme Court of Wisconsin held:

> "***A witness must be qualified to answer the question put to him...*** a witness eminently capable on one subject may not be sufficiently qualified to give helpful testimony on another, albeit related, issue in a case. ***No expert has carte blanche.***" (Emphasis added.)
>
> *Id.* at 99.

Thus, the Supreme Court of Wisconsin recognized that courts have a preliminary duty to ensure that a purported expert witness is properly qualified. The determination of whether a witness is so qualified is made under Wis. Stat. §907.04(1), which provides:

> Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the judge, subject to sub. (2) and ss. 971.31 (11) and 972.11 (2). ***In making the determination the judge is bound by the rules of evidence only with respect to privileges and as provided in s. 901.05.*** (Emphasis added.)

In citing s. 907.04 as the guide by which all courts must decide expert witness status, the Wisconsin Supreme Court has provided courts with almost unlimited discretion. The Supreme Court obviously believed that such discretion was necessary for courts to ensure that only reliable expert testimony is admitted as evidence. Indeed, this necessary court function has been recognized before. In *Peters, supra*, the court recognized that judges have a gate-keeping role in reviewing the admissibility of scientific evidence, and that expert testimony may be excluded via this gate-keeping function where such testimony is superfluous or a waste of the Court's time. *Id.* at 688-89.[3]

Finally, the Court should be aware that while education is part of the requisite factors which establish whether a witness is an expert, a qualified expert is most often established in Wisconsin by way of his or her relevant experience. Indeed, in Wisconsin, the qualification of an expert witness has historically been a matter of experience over licensure. See *State v. Robinson*, 146 Wis.2d 315 (1988); *State v. Hollingsworth*, 160 Wis.2d 883 (Ct. App.

[3] The gate-keeping function described by the court in *Peters* is a reference to the standards set forth by the U.S. Supreme Court for the admissibility of expert testimony. See *Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167 (1999); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In both *Kumho* and *Daubert*, the focus of the gate-keeper function is not on the relevancy of the expert testimony, but rather its reliability. Both cases stand for the proposition that a judge must have leeway in selecting a procedure by which he or she decides whether expert testimony is reliable in each case.

1991) (experience as well as technical and academic training is proper basis for giving expert opinion). It follows that an expert witness must be qualified by more than mere titles or affiliations; rather, the purported expert must demonstrate a specialized level of knowledge that is predicated upon actual experience as well.

B. Baratz Is Not A Qualified Expert Witness Under Wisconsin Law

Baratz fails to qualify as an expert pursuant to Wis. Stats. §907.02 because he is not an experienced medical doctor. As a result of Baratz's lack of experience, his testimony regarding the allegations in the Complaint against Respondent is irrelevant and prejudicial. Further, Baratz is clearly unreliable as an expert witness based on his reputation as a gun for hire by state boards and insurance companies, as well as his obvious prejudice against alternative medicine. Additional demonstrations of Baratz's unreliability may be found in his inconsistent testimony while under oath. Accordingly, Respondent's Motion to disqualify Baratz as an expert witness for the State should be granted by this Court.

(1) Baratz lacks experience as a medical doctor.

Baratz does not have sufficient practical work experience as a medical doctor to qualify him as an expert. He did not become an M.D. until later in his life. While he has been a dentist since 1972 (Transcript, p. 8), he did not complete medical school until 1987 (Transcript, p. 11), and did not finish his residency until 1991. (Transcript, p. 26) After completing his residency in 1991, his clinical experience has been limited to mostly urgent care centers and emergency rooms. (Transcript, pp. 53-55) Further, Baratz has testified that he has not practiced medicine in a clinical sense since 1999. At p. 17 of his deposition[4], Baratz stated:

Q. Were you disabled in 2001?

[4] Counsel for Respondent took Baratz's deposition on August 19, 2002. A Notice of Filing of Deposition Transcript has been filed simultaneously with Respondent's Motion *In Limine*. Counsel for Respondent also took Baratz's deposition on October 7, 2002. When the transcript from the second deposition is available, it will be filed.

A. For a good part of the year.

Q. But you had -- you were disabled for how many years?

A. From about the fall of 19 -- I'm sorry -- fall of 1999 to late in 2001, and unable to practice during that time on patients.

And at p. 59 of his deposition, Baratz stated:

Q. So from 1999 you have primarily -- you have been a consultant in the medical field and dentistry?

A. That's one of the things I've done.

Q. But you haven't been practicing dentistry or practicing medicine clinically?

A. I haven't been seeing patients.

Q. Since '99?

A. Correct.

Q. Up until?

A. This year.

Amazingly, Baratz has only begun a private practice of medicine this year:

Q. After your graduation from medical school, when did you set up your, or did you set up a private practice of medicine?

A. I haven't had a private practice of medicine until this year.

Q. That's 2002?

A. Yes.

According to Baratz, he practices medicine privately at South Shore Health Center, which he bought on January 1, 2002. (Transcript, p. 51) Even then, it does not appear that Baratz spends much time there practicing medicine by the standard of a regular work week. At pp. 124-25 of his deposition, Baratz provided:

Q. At South Shore how much time do you spend seeing patients?

A. Currently I'm scheduled for one session a week of regular patients, and then I see patients probably about three or four days a week when things get busy and the provider on duty can't keep up with patients who are there.

Q. What do you mean one session per week? What is a session?

A. Four-hour block.

Q. And then periodically other times?

A. Yes.

Q. Okay. You've been doing this one session a week since it opened?

A. No.

Q. You just started?

A. Just started a month or two ago.

By his own testimony, Baratz has seen patients in a private office setting *for only a few months* out of his entire career as a licensed physician, which spans little more than ten (10) years. (Transcript, p. 26) For most of the past three (3) years, he testified that he has seen no patients because of a disability. Yet the State offers Baratz as its sole expert witness against Respondent, who has been practicing in a private, clinical setting for decades.[5]

What then could possibly qualify Baratz as an expert to testify against Respondent? He has spent little time in the past several years actually treating patients. He has only begun seeing private patients recently, and sees them for only four (4) hours per week. If the State wishes to succeed in its case against Respondent, it should be required to present an expert that is an

[5] With the remainder of his time, it appears that Baratz does keep busy. In addition to his consulting services which vary in the amount of time he is required to spend week to week, Baratz also spends his time managing other projects and business he owns, including IMCSI, Inc., a consulting business of which he is the sole owner (Transcript, p. 72), and Skin Systems, Inc., a skin treatment and hair removal company for people with excess body hair, also of which he is the sole owner (Transcript, p. 73-74). Baratz testified that he spends several hours a week at IMCSI, Inc., and several days per week at Skin Systems, Inc. (Transcript, p. 125) *It is no wonder Baratz has so little time to devote to the actual treatment of patients.*

experienced physician. Was it that difficult for the State to find an expert who is actually a full-time practicing doctor? Is it fair or reasonable for doctor of Respondent's experience level to potentially suffer the permanent revocation of his license based on the testimony of an individual who has never had a full-time medical practice? Respondent submits that it would indeed be unfair and unreasonable to allow Baratz to testify in this matter. Accordingly, the within Motion should be granted by the Court.

(2) Baratz's obvious anti-alternative medicine animus should disqualify him as an expert.

The State's purported expert has a long history of providing testimony in various medical and dental malpractice, state licensure and workers' compensation cases. In fact, Baratz has been involved with matters in at least fourteen (14) different states, many of which are still current. (Transcript, pp. 63-67; 126-28) He has consulted for the states of Arizona, California, Colorado, Florida, Iowa, Kentucky, Maine, Massachusetts, Minnesota, New York, Ohio Rhode Island, Texas and Wisconsin. (Transcript, p. 63-67) In most of these respective states, Baratz provided his "expert" opinion on behalf of the state's medical or dental board against a licensed physician or dentist. (Transcript, p. 63-67) In several others, Baratz is or was a witness on behalf of plaintiffs in medical malpractice cases. (Transcript, p. 126-128)

At p. 69 of his deposition, Baratz was asked whether he had ever testified against any physician:

> Q. Have you been a witness providing testimony against any physicians?
>
> A. Not that I can recall.
>
> Q. So you've never testified for or against any medical physician in a court of law?
>
> A. Correct.

Q. Have you been a witness in any medical board proceeding against any medical doctor?

A. No, except for potentially the State of Wisconsin ...

Baratz's above testimony is inaccurate. As provided above, he testified to participating in a multitude of state board actions against licensed physicians and dentists. Yet he clearly stated that he has never been a witness against a physician, knowing full well that he had done so on many occasions. This apparent misstatement was most likely motivated by Baratz's desire to avoid any implication that he is a gun for hire for state prosecutors and plaintiffs. However, Baratz's actions speak much louder than his words. Indeed, he later revealed in his deposition that he has been hired to testify in several cases in Texas, one of which is for a plaintiff against a physician who uses chelation therapy. (Transcript, p. 128) The bottom line is that he testified that he has assisted states in every corner of the country in disciplinary actions by state boards against licensed professionals. He is without a doubt a gun for hire.

Further, Baratz has a clear anti-alternative medicine agenda. For example, most of the above-referenced matters involved alternative medicine practitioners similar to Respondent. He was more than willing to testify against them (for a fee of course). In fact, when asked if he has ever testified *on behalf of* a physician, Baratz quite predictably answered no. (Transcript, p. 69) Baratz has also published several articles on Quackwatch.com and Dentalwatch.com, two websites devoted to "policing" alternative medicine and dental practitioners. Incredibly, he does not view his participation with those websites as advertising his services as an anti-alternative medicine witness. At p. 217 of his deposition, Baratz states:

Q. When you voluntarily write those articles for Quackwatch or Dentalwatch, you don't think that that has any particular service in advertising you as a consultant?

A. No.

It appears that Baratz believes it is only coincidence that he has assisted in so many cases against alterative medicine and dentistry practitioners. To the contrary, it is his well-known anti-alternative medicine stance that makes him so appealing to prosecutors and plaintiffs. One must assume that Baratz was trying to protect his credibility as a witness by denying the existence of any agenda against alternative medicine. However, this Court cannot ignore the fact that Baratz has testified against alternative medicine practitioners for more than a quarter of the states in the U.S., and continues to do so. He has even admitted to his potential hiring in another matter against an alternative medicine practitioner currently under investigation by the State of Wisconsin. (Transcript, p. 132) He also continues to actively participate in anti-alternative medicine websites on the internet. As a result, Baratz cannot be relied upon to provide objective facts or relevant testimony. Accordingly, Respondent submits that sufficient grounds exist for this Court to disqualify Baratz as an expert witness based on his extreme bias against alternative medicine practitioners as demonstrated herein.

(3) Baratz has made several material misrepresentations about his practice and work experience.

Baratz has made several statements under oath that raise serious questions about his veracity as a witness in this or any other case. He has made several misleading statements about his current status as a practicing dentist, has continually misrepresented the nature and extent of his publication history, and has made inaccurate statements about his past experiences with the Food and Drug Administration (hereinafter, "FDA").

(i) Nature and extent of dental practice.

At first glance, it would appear that Baratz is more qualified as a dentist than as a medical doctor. He was licensed as a dentist in 1972. (Transcript, p. 8) In comparison, he only completed his medical residency just over ten years ago, in 1991. (Transcript, p. 26) Curiously,

upon graduating from medical school in 1987, he actually re-opened his practice of dentistry. (Transcript, p. 11) Currently, Baratz claims that he sees dental patients at his office in Newton, Massachusetts, which also happens to be his residence. (Transcript, pp. 11-12). Therefore, one may conclude that Baratz is currently a practicing dentist.

Or is he? At p. 11 of his deposition, Baratz stated:

Q. Do you have a patient base that you see on an annual basis?

A. I see some people on a regular basis.

Q. How large is that patient base?

A. It's relatively small, because it's mostly consults.

And on p. 12, Baratz provided:

Q. How many procedures have you performed on a patient in the year 2002?

A. On a single patient?

Q. On any patient.

A. As a physician or as a –

Q. As a dentist. We're only talking dentist.

A. I think on the order of five this year.

Yet on p. 20, Baratz answered the same question quite differently:

Q. So your regular practice of dentistry in the year 2002 has included how many patients?

A. More than 20 so far. Perhaps 30 or 40.

And what exactly do these dentistry "consults" performed by Baratz in 2002 include? We cannot be sure, but we do know what they did not include. At pp. 134-35, he states:

Q. So when is the last time you put a post in?

A. I believe it would have been in '86.

Q. When is the last time you fit a crown?

A. I really don't remember.

Q. When is the last time you did a root canal?

A. That would have been in '86.

Q. When is the last time you extracted a tooth?

A. I think it was '98. I may have done one in '99.

Q. On a private pay patient?

A. On a patient in the hospital.

Q. When is the last time you had a private pay patient have a tooth extracted?

A. It's generally not within the scope of what I do in my practice.

As the Court can see from the above testimony, Baratz was asked very simple questions, yet he somehow managed to provide confusing, contradictory responses. He testified he is a practicing dentist, yet later testified that its been years since he's performed those basic procedures which are performed by real dentists every day. He also testified that he has seen five (5) patients in 2002, and later testified that he has seen perhaps thirty (30) to forty (40) dental patients this year. If he cannot provide clear and accurate answers when testifying about his dental practice, one can only conclude that he cannot be trusted to accurately testify in regard to any other matter as well.

(ii) Past Publications.

In his *Curriculum Vitae*, Baratz states that he has published "more than 150 written papers, published abstracts, reviews, monographs and oral publications." A copy of Baratz's *Curriculum Vitae* is attached hereto as Exhibit "A". In addition, while a member of a panel discussing hair analysis, Baratz represented in a biographical profile contained in that panel's

summary report that he has published over 150 papers. A copy of the profile from the hair analysis panel's summary report is attached hereto as Exhibit "B". Baratz also represents that he has been published more than 150 times in the website of the State of Massachusetts Board of Registration in Medicine. A copy of the web-page providing Baratz's physician profile is attached hereto as Exhibit "C".

However, Baratz has provided testimony that directly contradicts his claim of having been published more than 150 times. At pp. 95-96 of his deposition, Baratz stated:

> Q. What studies have you published?
>
> A. I don't think there have been any clinical studies that were published in the general literature. Since I graduated from medical school most of my work has been private.
>
> Q. No clinical studies published?
>
> A. Correct.
>
> Q. What medical studies have you published?
>
> A. I'm not sure what you mean by medical study. We've talked about clinical studies. That would be a medical/clinical study. I think I've already answered your question.
>
> Q. Then have you published any type of study?
>
> A. By study you mean research study involving science and collecting data?
>
> Q. Uh-huh.
>
> A. The answer is no.

Based on his own testimony, Baratz's claim that he has been published more than 150 times is clearly overstated. He testified that he has never published a clinical or medical study involving research, science or data collection in any general literature. He further testified that most of his work since medical school has been private, yet he maintains that he has been

"published" more than 150 times! To reach this number, he has conveniently adopted an extremely loose interpretation of the term "published". Indeed, a review of Baratz's list of publications shows an attempt by him to give new meaning to this word. A copy of list of publications provided to Respondent by Baratz is attached hereto as Exhibit "D".[6] Apparently, Baratz counts internal corporate documents he has written in the past as "publications" (Transcript, p. 95). He even includes in his list of "publications" those times when he was interviewed off camera or quoted in an article.

Quite obviously, Baratz has misstated his past history as an author in an effort to bolster his credibility as an expert. He should not be permitted to manufacture credibility by falsely stating his publication track record. Accordingly, he should be disqualified as an expert witness in this matter.

(iii) FDA Experience.

At p. 113 of his deposition, Baratz states:

> "I've worked for the FDA in several capacities. ***I was invited as a consultant to product review panels of the FDA -- that was the dental products panel*** – on two occasions in '91 and '94."

Hence, Baratz has represented under oath that he was a consultant to the FDA Dental Products Panel on two (2) separate occasions. However, in a letter dated August 8, 2002, a copy of which is attached hereto as Exhibit "E", Sharon L. Blount, a Consumer Safety Officer for the FDA, states:

> "After contacting our Committee Management Office, I have been informed that ***we have had no consultant by the name of Dr. Robert S. Baratz on our FDA Dental Products Panel.***" (Emphasis added.)

[6] The Court should also note that almost every single entry on Baratz's list of "publications" is in regard to dentistry. Also, it appears that the most recent "publication" by Baratz on this list is from 1994, with the bulk of his "publications" dated in the 1970's and 1980's.

This letter serves as confirmation that Baratz has lied about his experience with the FDA. One can only assume that he misrepresented his level of involvement with the FDA Dental Products Panel in an effort to inflate his resume and bolster his credibility as a witness.

To summarize, Baratz has given inaccurate testimony about his past involvement as a witness in cases against physicians and doctors, the nature and extent of his current practice as a dentist, the number of times he's been published and his past involvement with the FDA. Therefore, it would be unconscionable to allow Baratz to testify in the instant matter. He cannot be relied upon to provide testimony that could assist the trier of fact. Accordingly, this Court should disqualify Baratz as an expert witness for the State.

(4) Conclusion.

It is undisputed that before Baratz may testify in this matter, this Court must determine whether Baratz's testimony is relevant and that Baratz is a qualified expert. *Walstad, supra;* Wis. Stats. §227.45(1). Pursuant to its gate-keeping role as provided in *Martindale, supra*, and *Peters, supra*, this Court may exclude Baratz's testimony on the grounds that it is irrelevant and a waste of the Court's time.

In the instant matter, there is no question that Baratz is not qualified to testify under Wis. Stats. §907.02. Baratz only finished his residency in 1991. Though a doctor by degree for just over ten (10) years, his clinical experience has been mostly limited to urgent care centers and emergency rooms. He became disabled in 1999, and has not practiced significantly since then. In 2002, he started his first private practice, and just recently began seeing patients for only four (4) hours *per week*. In addition, his business ventures involving laser hair removal equipment and other business matters take a significant amount of his time. Therefore, he lacks the requisite experience needed to qualify as a medical expert under Wisconsin law. Further, his

anti-alternative medicine agenda and inconsistent testimony render him suspect as an expert witness in this case. As a result, Baratz cannot assist this Court in determining any issue of fact via his testimony.

A purported expert who is in reality a businessman with an obvious bias who only dabbles in clinical medicine and who has shown to be less than candid under oath should be the poster boy for medical testimony that is irrelevant and a waste of court time. Accordingly, ample evidence exists which proves that Baratz is not an expert under Wisconsin law, and Respondent's Motion to disqualify him as an expert witness for the State should be granted.

IV. BARATZ DOES NOT QUALIFY AS AN EXPERT WITNESS UNDER THE STANDARDS PROMULGATED BY THE AMERICAN MEDICAL ASSOCIATION[7]

A. American Medical Association Standards for Expert Witnesses.

The American Medical Association ("AMA") has promulgated written guidelines for its member physicians on a variety of medical issues. One such AMA policy statement addresses expert testimony and the qualifications that the AMA expects of any member who wish to testify as an expert witness. In AMA Policy H-265.994(3)(a), it provides in part:

> The AMA believes that the minimum statutory requirements for qualification as an expert witness should reflect the following: (i) that ***the witness be required to have comparable education, training and occupational experience in the same field as the defendant***; (ii) ***that the occupational experience include active medical practice or teaching experience in the same field as the defendant***; and (iii) ***that the active medical practice or teaching experience must have been within five (5) years of the date of the occurrence giving rise to the claim***. (Emphasis added.)

In reviewing these requirements, it is clear that the AMA's intention was to address the issue of "professional experts" who continually testify in medical malpractice cases. Thus, the AMA has singled out those professionals who, instead of making a living actively practicing

[7] According to Baratz's CV, he is a member of the American Medical Association.

Q. Was there any further review performed? Any other literature review performed for the State of Wisconsin other than the materials that they supplied to you?

A. Not as such. I think Mr. Thexton may have asked me to answer certain questions for him based on my knowledge that actually goes before this case on this topic.

MR. THEXTON: He may be asking did you find other materials in your--

THE WITNESS: He asked me if I reviewed it at your behest, and the answer to that was not specifically. You didn't ask me to go look at a particular paper. I have followed the literature.

Q. I asked you if you provided or if you did any other review, and you said not as such?

A. And not for this case. But my knowledge base extends to other areas and other cases in the same topical area perhaps.

Q. What were those topics?

A. Well, I have reviewed the chelation therapy literature involving other cases of chelation therapy that have been involved in litigation.

However, as of the date of filing of this Motion, Baratz has failed to identify or provide Respondent with any cites for the articles and cases he has reviewed, nor has he indicated the frequency with which he regularly reviews articles and cases regarding chelation therapy. The fact is that Baratz's only knowledge of chelation therapy comes from his reading about the topic, which most certainly does not make him an *expert*. Moreover, merely because he is a physician does not mean he can research a topic and thereafter become an expert on the subject. No purported expert has carte blanche. *Martindale, supra*. Therefore, any testimony from Baratz is clearly substandard with respect to expertise in the area of chelation therapy. Accordingly, Baratz is not an expert, and should be disqualified from testifying as such in the proceedings against Respondent.

medicine, make their living by testifying in medical litigation. By requiring that the witness actively practice in the same field as defendant within five (5) years of the occurrence giving rise to the claim, the AMA obviously intended to disqualify those witnesses who make their living as hired guns in lieu of the actual practice of medicine.

B. Baratz Fails To Satisfy AMA Expert Witness Qualifications.

It is undisputable that Baratz cannot meet any of the requirements of the AMA for expert witnesses. First of all, Baratz cannot demonstrate that he has comparable education, training and occupational experience in the same field as Respondent, who practices complementary and alternative medicine. He does not have a similar practice to Respondent in any manner whatsoever. In fact, Baratz testified that he has only been in the private practice of medicine since this year, and began seeing patients only a few months ago. On the other hand, Respondent has been in his own private family practice for decades.

Further, Baratz has no active medical practice or teaching experience in the same field as Respondent. Baratz has no experience in alternative medicine therapies and procedures, and he has never actively practiced or taught alternative medicine. Clearly then, there is great dissimilarity between Baratz's and Respondent's backgrounds. Accordingly, as Baratz cannot satisfy any of the requirements for qualification as an expert witness set forth by the AMA, an organization in which he claims membership, he should not be allowed to testify as an expert witness against Respondent.

Finally, Baratz may not claim he has a comparable background on chelation therapy based on his review of various articles on the subject. There is no question that any knowledge of chelation therapy which he may possess is based solely on his review of articles and recent cases. At pp. 83-84 of his deposition, Baratz provides:

V. CONCLUSION

If the State wishes to revoke Respondent's license to practice, it should be required to do so with a fair and unbiased expert who actually practices medicine. The public trust requires that the sovereign find experts who are capable of rendering opinions which are free of bias and personal agendas. Instead, the State has chosen as its expert Baratz, who spends more time testifying against physicians and dentists than actually practicing as either. Despite his attempts to minimize the amount of times he has testified against other licensed professionals, he is in reality a well-established anti-alternative medicine expert for hire.

In summary, Baratz clearly should not be qualified as an expert witness in this case because he cannot establish that he is an expert pursuant to the standards provided hereinabove. Further, Baratz is unreliable as an expert witness against Respondent based on his anti-alternative medicine agenda and inconsistent testimony under oath. Finally, there is no question that Baratz fails to meet the AMA standards for expert witness qualification, an organization to which he belongs. Therefore, Baratz should not be qualified as an expert witness in the proceedings against Respondent.

For the reasons set forth herein, Respondent's Motion should be granted by this Court.

Respectfully submitted,

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IN THE SUPERIOR COURT OF CALIFORNIA

IN AND FOR THE COUNTY OF LOS ANGELES

NATIONAL COUNCIL AGAINST HEALTH FRAUD, INC., Plaintiff v. KING BIO PHARMACEUTICALS, INC.; FRANK J. KING, JR.; and DOES 1-50, Defendants		CASE NO. BC 245271 Assigned for all purposes to Judge Haley J. Fromholz, Dept. 20 **REVISED STATEMENT OF DECISION**

Pursuant to the Court's order dated December 3, 2001 Defendants King Bio Pharmaceutical, Inc. and Dr. Frank J. King, Jr. hereby submit the following proposed revised statement of decision which incorporates the Court's revisions to that document.

I. Overview of Proceedings

The trial in this action was held commencing on October 22, 2001 in Dept. 20 of the above-entitled court, Hon. Haley J. Fromholz, Judge, presiding. Plaintiff National Council Against Health Fraud, Inc. ("Plaintiff" or "NCAHF") was represented by Morse Mehrban, Esq. Defendants King Bio Pharmaceutical, Inc. and Dr. Frank J. King, Jr. ("Defendants") were

Enclosure 3b

represented by Scott D. Pinsky, Esq.

Following opening statements by the parties, Defendants moved for a non-suit pursuant to Code of Civil Procedure § 631.8 on the grounds that the Plaintiff had not identified in its opening statement evidence sufficient to establish a prima facie case. The Court heard argument by counsel for the parties on Defendants' motion and denied the motion without prejudice. Thereafter, NCAHF presented its case, which began with the testimony of two proffered experts, Wallace I. Sampson, M.D. and Stephen Barrett, M.D. Plaintiff also offered brief testimony by its counsel, Mr. Mehrban, and called Defendant Frank J. King as a witness. By stipulation of the parties, the expert witness designated by Defendants, Jacquelyn J. Wilson, M.D., was called by Defendants to testify out of order and during the presentation of the Plaintiff's case due to scheduling reasons. Cross examination was permitted as to all of the above witnesses. In addition to the foregoing evidence, both sides filed extensive trial briefs and supplemental trial briefs both prior to and during the course of the trial, and also submitted further authorities during the course of the proceedings for the Court's consideration.

Following the close of Plaintiff's presentation of evidence, Defendants renewed their motion for judgment pursuant to Code of Civil Procedure § 631.8. The Court again heard argument by counsel for the parties on Defendants' motion. The Court also considered and weighed the evidence presented by the above-stated witnesses for the parties. Moreover, the Court considered the various trial briefs and supplemental trial briefs and supporting authorities submitted and argued by the parties on the issues before the Court. Having reviewed and considered all these matters, and having considered and weighed the evidence presented by the Plaintiff in its case in-chief, as well as the evidence adduced through cross-examination of the Plaintiff's witnesses, the Court hereby grants Defendants motion and directs that judgment shall be entered in favor of the Defendant, and against Plaintiff, as set forth below. The reasons for the Court's ruling are as follows.

II. Plaintiff's claims and elements thereof

Plaintiffs' claims are brought principally under certain provisions of the Cal. Business and Professions ("B & P") Code, specifically B & P Code §§ 17200, 17500 and 17508. Sections 17500 and 17508 of the Code prohibit false or misleading advertising. A violation of these false advertising prohibitions may also constitute a separate, parallel violation of the unfair business practices bar under B & P Code § 17200. Section 17200 also permits an action based on any business practice that is unlawful, fraudulent or unfair. The principal allegations in the Complaint and the focus of the Plaintiff's evidence at trial indicate that the primary violation of law alleged by NCAHF against the Defendants is false advertising, i.e. some form of false, deceptive or misleading statements or representations in the labeling or advertising used by Defendants in marketing their products. The plaintiff did not strongly assert that the Defendants have violated the other prongs of B & P Code § 17200, which prohibit business practices that are unlawful, fraudulent or unfair. Plaintiff did make an attempt to argue that the evidence adduced at trial could be viewed as supporting a finding that Defendants' actions were unlawful, fraudulent or unfair within the meaning of § 17200. But the only evidence offered by Plaintiff concerned the alleged falsity of Defendant's advertising.

Although Plaintiff did not present evidence specifically pertaining to the labeling of Defendants' products, there was no dispute between the parties that the labels affixed to Defendants' products contained substantively the same information as was contained in the advertising which formed the basis for the Plaintiff's claims. The parties further agreed that

the products in question are homeopathic drugs regulated under numerous provisions of federal and state law. *See* 21 U.S.C. §§ 321 *et seq.*; B & P Code §§ 13 and 4025; Cal. Health & Safety Code §§ 11014, 109985, 111225 and 111235. Plaintiff also admitted that there is no evidence of a violation of such state or federal drug laws by Defendants; Plaintiff offered no evidence or legal authority respecting any such possible violation. Plaintiff further did not dispute that Defendants' products fall squarely within the definition of legal, non-prescription homeopathic "drugs" under both federal and state laws. *Id.*

Nonetheless, Plaintiff argued and attempted to offer testimony to the effect that the claims stated in Defendants' advertising are scientifically unsupportable and is therefore allegedly false.

III. Burden of proof

The Plaintiff's initial trial brief argued that the burden of proof in this action should be shifted to the Defendants, citing several California and federal administrative cases. The Plaintiff's trial brief seemed implicitly to concede that the Plaintiff could not meet its burden of proof--i.e. the establishment of Defendants' liability by a preponderance of the evidence-if the burden were not so shifted to Defendants. The Defendants filed a supplemental brief responding to the Plaintiff's arguments and asserted that the burden lies with NCAHF and that the cases it cited to the contrary are inapposite or do not govern in California. The Court finds that the authorities cited by the Plaintiff do not support Plaintiff's position on this issue. There appears to be no case in California to support the shifting of the burden of proof to the Defendant in a case of this type. The burden of establishing each element of its claims therefore lies with Plaintiff NCAHF. Cal. Evid. Code § 500.

In a subsequent, supplemental brief, the Plaintiff next argued that even if the burden lies initially with the plaintiff in a false advertising case, only slight evidence is required to then shift the burden to the defendant. This argument was based on several federal appellate opinions from appeals of administrative hearings before the U.S. Federal Trade Commission. No authority was presented to suggest that these decisions are applicable to the issues at bar, namely who has the burden of proof and to what degree in a civil action brought in state Court. Since Plaintiff has failed to demonstrate through appropriate authorities that the burden of proof is in any way transferred or modified by any of the authorities it cited, the Court finds that the burden is on the Plaintiff NCAHF to prove its case by establishing each element of its various causes of action by a preponderance of the evidence.

IV. Analysis and evaluation of evidence

The Court now reviews the evidence presented by the parties.

A. Wallace I. Sampson, M.D.

Dr. Sampson was offered apparently to testify concerning the scientific method generally, standards of clinical medical research the nature of homeopathic medical science, and the nature of the information upon which much of homeopathic science may be said to rest. The

thrust of his testimony appeared directed to the conclusion that the evidence supporting claims of efficacy for homeopathic drugs does not meet the standard that he believes applies to valid clinical studies. In this regard, his testimony was largely an attempt to discredit the group of reference sources known as *"Materia Medica,"* which resources the U.S. FDA recognizes as a significant source of information concerning homeopathic drugs.

All of Dr. Sampson's testimony was quite general in nature and he did not provide any specific facts that would tend to support any particular finding as to Defendants' products. Dr. Sampson, a retired medical doctor with an oncology specialty, has had only limited involvement in clinical research studies. He has little expertise in research methodology and does not instruct in that area. He is not an expert in pharmacology. He admitted to having had no experience with or training in homeopathic medicine or drugs. He was unfamiliar with any professional organizations related to homeopathy, including the Homeopathic Pharmacopeia Convention of the United States, which group is responsible for designation and de-designation of such drugs as "official" drugs recognized by the U.S. Food and Drug Administration. He thus does not have expertise as to the drug products that are the sole products at issue in this case. While he stated that he teaches a university course on "alternative medicine," Dr. Sampson admitted that the course does not instruct on how such methods may be practiced, but rather is a course designed to highlight the criticisms of such alternative practices. Therefore, the Court finds that Dr. Sampson has relatively thin credentials to opine on the general questions of the proper standards for clinical or scientific research or other methods of obtaining valid evidence about the efficacy of drugs. The Court further finds that Dr. Sampson lacks experience in the field of homeopathic drugs, which renders his testimony of little or no weight in this case.

In addition, Dr. Sampson admitted to having done absolutely no investigation concerning Defendants' specific products. He admitted to no real knowledge as to their ingredients and acknowledged that he had not seen any of the products prior to the trial. He admitted that he was aware of no tests ever performed on Defendants' products by anyone. In view of the foregoing, Dr. Sampson did not show that the evidence in the *Materia Medica* as it relates to the ingredients in Defendants' products is invalid. Accordingly, the Court finds that the testimony of Dr. Sampson did not show that there is no valid scientific or medical evidence to support the claims associated with Defendants' products, even according to his own standards.

B. Stephen Barrett, M.D.

Dr. Barrett was offered on several issues by the Plaintiff, but the Court found that there was substantial overlap on the issues that he and Dr. Sampson were asked to address. Thus, in order to avoid duplicative or cumulative evidence (*see* Cal. Evidence Code §§ 352, 411, 723), Dr. Barrett's testimony was limited by the Court to the sole issue of FDA treatment of homeopathic drugs. The relevancy of this issue was questionable at best, since the Plaintiff had previously asserted that its case did not depend on or seek to establish any violation of federal food and drug laws or regulations. Nevertheless, Plaintiff elicited testimony from Dr. Barrett on his experience with the FDA as it relates to regulation of homeopathic drugs.

Dr. Barrett was a psychiatrist who retired in or about 1993, at which point he contends he allowed his medical license to lapse. Like Dr. Sampson, he has no formal training in homeopathic medicine or drugs, although he claims to have read and written extensively on homeopathy and other forms of alternative medicine. Dr. Barrett's claim to expertise on FDA issues arises from his conversations with FDA agents, his review of professional literature on

the subject and certain continuing education activities.

As for his credential as an expert on FDA regulation of homeopathic drugs, the Court finds that Dr. Barrett lacks sufficient qualifications in this area. Expertise in FDA regulation suggests a knowledge of how the agency enforces federal statutes and the agency's own regulations. Dr. Barrett's purported legal and regulatory knowledge is not apparent. He is not a lawyer, although he claims he attended several semesters of correspondence law school. While Dr. Barrett appears to have had several past conversations with FDA representatives, these appear to have been sporadic, mainly at his own instigation, and principally for the purpose of gathering information for his various articles and Internet web-sites. He has never testified before any governmental panel or agency on issues relating to FDA regulation of drugs. Presumably his professional continuing education experiences are outdated given that he has not had a current medical licence in over seven years. For these reasons, there is no sound basis on which to consider Dr. Barrett qualified as an expert on the issues he was offered to address. Moreover, there was no real focus to his testimony with respect to any of the issues in this case associated with Defendants' products.

C. Credibility of Plaintiff's experts

Furthermore, the Court finds that both Dr. Sampson and Dr. Barrett are biased heavily in favor of the Plaintiff and thus the weight to be accorded their testimony is slight in any event. Both are long-time board members of the Plaintiff; Dr. Barrett has served as its Chairman. Both participated in an application to the U.S. FDA during the early 1990s designed to restrict the sale of most homeopathic drugs. Dr. Sampson's university course presents what is effectively a one-sided, critical view of alternative medicine. Dr. Barrett's heavy activities in lecturing and writing about alternative medicine similarly are focused on the eradication of the practices about which he opines. Both witnesses' fees, as Dr. Barrett testified, are paid from a fund established by Plaintiff NCAHF from the proceeds of suits such as the case at bar. Based on this fact alone, the Court may infer that Dr. Barrett and Sampson are more likely to receive fees for testifying on behalf of NCAHF in future cases if the Plaintiff prevails in the instant action and thereby wins funds to enrich the litigation fund described by Dr. Barrett. It is apparent, therefore, that both men have a direct, personal financial interest in the outcome of this litigation. Based on all of these factors, Dr. Sampson and Dr. Barrett can be described as zealous advocates of the Plaintiff's position, and therefore not neutral or dispassionate witnesses or experts. In light of these affiliations and their orientation, it can fairly be said that Drs. Barrett and Sampson are themselves the client, and therefore their testimony should be accorded little, if any, credibility on that basis as well.

D. Dr. Frank J. King, Jr.

Plaintiff called Defendant King, who is also president of Defendant King Bio Pharmaceuticals, Inc., pursuant to Evidence Code § 776. Dr. King testified to the actions he took to assure his and his company's compliance with all applicable laws, state and federal. These actions included the retention of and consultation with experienced regulatory counsel practicing in the area of FDA compliance. He also testified that he and his company hired a medical doctor to consult on FDA compliance issues. These and others steps were taken by the Defendants to be sure that their products and their labeling complied with federal and other laws and regulations. Dr. King's testimony, therefore, did nothing to support Plaintiff's case against him

and his company.

E. Jacquelyn J. Wilson, M.D.

Dr. Wilson testified for the Defendants. She is a board certified medical practitioner with particular experience in homeopathic medicine and serves on the faculty of the U.C. San Diego medical school. Dr. Wilson testified that she has trained in homeopathic medicine and received certification to practice in the field from at least one state agency. She lectures and consults on the subject of homeopathy and is a member of the Homeopathic Pharmacopeia Convention of the United States, in which capacity she helps designate official homeopathic drugs recognized by the U.S. FDA. She has treated many patients using homeopathic drugs. Based on this background, Dr. Wilson is, unlike Drs. Barrett and Sampson, qualified as an expert on issues relating to homeopathy generally. On these issues, she testified that the *Materia Medica* contain several types of valid scientific evidence respecting the effectiveness of homeopathic drugs, even when this evidence is evaluated under the methodological standards testified to by Dr. Sampson. She also testified about the general manner in which homeopathic drugs are recognized and regulated by the FDA. Dr. Wilson further explained through her testimony that, according to FDA guidance in this area, the "indications" (i.e., drug effects) that must be placed on the label or package of any homeopathic drug may be taken from the *Materia Medica*.

With respect to the products at issue in this case, Dr. Wilson is the only expert who investigated and evaluated any of the Defendants' products and their ingredients. Based on her review and general knowledge of the field, she offered her opinion that all of the ingredients in Defendants' products are listed in the *Homeopathic Pharmacopeia of the United States*, which is the federally approved reference guide for all officially recognized homeopathic drugs. She also testified that all of Defendants' labeling was consistent with the information respecting drug indications found in the *Materia Medica*. Based thereon, Dr. Wilson concluded, the Defendants' products complied with all applicable FDA laws and regulations.

F. Documentary and physical evidence

Apart from testimonial evidence, Plaintiff offered no documentary or other evidence to support its claims. The principal exhibit offered by NCAHF was a collection of Internet web-page downloads from the Defendants' web-site, admitted in evidence without objection. These documents established only what Defendants' claims were, not the alleged falsity of those claims. Plaintiff offered no evidence pertaining to the specific products in question.

V. Findings of fact/Conclusions of law

A. False advertising

With respect to the false advertising claims brought under B & P Code

§§ 17200 and 17508, a finding for Plaintiff under these sections requires that the Plaintiff show by a preponderance of the evidence that each of the Defendants made false or misleading statements in advertising or labeling as to one or more of their products. Moreover, it must be shown that the defendants knew, or through the exercise of reasonable diligence should have known, that the statements were false. With respect to these claims, the Court finds that the Plaintiff has failed to prove that Defendants made any false or misleading statements or representations in connection with any advertising or labeling of its products. Furthermore, the Plaintiff failed to show that either of the Defendants knew or should have known that any of their statements were untrue, false or misleading.

Because the Court has found that there was no false statement or representation shown, it follows that Plaintiff has also failed to establish a claim under

B & P Code § 17200. The necessity of a false or misleading statement is no different under these two provisions. The Plaintiff argues that a different scienter standard applies under § 17200, and that strict liability applies. This argument does not aid the Plaintiff, since the Court finds that there is no showing of a false or misleading statement in the first place, thus the Court need not reach the issue of knowledge or intent.

B. "Unlawful" business practice

The Court finds that under the evidence adduced at trial there is no basis for a finding that Defendants violated the unlawful activity prong of B & P Code § 17200.

C. "Unfair" business practice

The parties disputed the appropriate standard for determining whether Defendants' activities were "unfair" within the statute's meaning. It has been interpreted in a number of cases. The case offered by Defendants, *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.* (1999) 20 Cal.4th 163, 187, appears to apply more to actions involving alleged competitive injury, rather than harm to consumers. Plaintiff asserts that the correct standard should be taken from *People v. Casa Blanca Convalescent Homes, Inc.* (1984) 159 Cal.App.3d 509, 530. Under *Casablanca*, unfairness may exist if it is shown that a practice offends public policy established by statute, common law or otherwise, or is shown to be immoral, unethical, oppressive, unscrupulous, or causes substantial injury to consumers.

There is uncertainty as to the continued validity of the opinion in *Casa Blanca* in light of the *Cell-Tech* decision. *Cel-Tech* was the Supreme Court's first case directly addressing the definition of "unfair" in the context of B & P Code § 17200, (20 Cal.4th at 184), and it analyzed and apparently rejected the definitions arrived at in prior decisions by several intermediate appellate rulings, including *Casa Blanca*. 20 Cal.4th at 184-85. As to these earlier decisions, the *Cel-Tech* court wrote: "We believe these definitions are too amorphous and provide too little guidance to courts and businesses." *Id.* at 185. In light of this decisions, this Court may be unable to rely on the test advanced by Plaintiff from *Casa Blanca*. But even under the standard articulated in that case-which Plaintiff advances-none of the above offenses were proved by Plaintiff's evidence.

D. "Fraudulent" business practice

The Court also finds that there is no basis for a finding that Defendants violated the fraudulent activity prong of B & P Code § 17200. The Plaintiff failed to show that any of the Defendants' labeling or advertising was likely to mislead a reasonable person. *Committee On Children's*

Television v. General Foods Corp. (1983) 35 Cal. 3d 197.

VI. Remaining issues raised by party requesting statement of decision

The foregoing resolves the majority of issues raised in the Defendants' Request for Statement of Decision, filed October 22, 2001. With respect to the remaining issues, the Court holds:

A. Federal preemption/state court jurisdiction

Defendants asserted in their trial brief and argument that the fact of U.S. FDA regulation requires dismissal of the Plaintiff's claims insofar as federal law preempts an action under state law, particularly where the result of the state court action could impose requirements on Defendants' labeling practices that might vary from federal requirements. Defendants also argue that their compliance with federal drug laws and regulations constitutes a complete defense to Plaintiff's state law claims. Also, Defendants assert the doctrine of state court abstention. Federal preemption is asserted as Defendants' Tenth Affirmative Defense; presumably the other jurisdictional arguments are subcategories of this defense. In view of the findings above on the issues of liability, the Court finds that it need not reach these jurisdictional questions, and therefore it makes no ruling on those matters.

The Court notes, however, that the Plaintiff argued on the question of burden that it is placed in an unreasonable position by being forced to assemble proof of the alleged falsity of a drug manufacturer's advertisements, since (as Plaintiff argues) the creation of that evidence is costly and difficult. As noted above, Plaintiff has failed to support its argument on the burden of proof. In any event, however, its argument more logically leads to the conclusion of state court abstention. The complexity necessarily involved in the development and interpretation of clinical tests and trials of drug products suggest strongly that questions of enforcement and regulation of drug advertising and labeling requirements should be brought before the agency possessing the expertise and experience most needed to resolve medical and scientific issues involved in drug regulation. That agency, obviously, is the U.S. FDA.

Furthermore, the Court notes that the logical end-point of Plaintiff's burden-shifting argument would be to permit anyone with the requisite filing fee to walk into any court in any state in the Union and file a lawsuit against any business, casting the burden on that defendant to prove that it was not violating the law. Such an approach, this Court finds, would itself be unfair.

B. Is Plaintiff is a proper party to assert these claims?

Defendants sought a determination as to whether Plaintiff adequately represented the interests of the People of California. As no liability was found and therefore no relief is to be awarded, the Court need not reach this issue.

C. Is equitable relief is warranted where there is a remedy at law?

Defendants sought a determination as to whether Plaintiff is entitled to equitable relief where there is an adequate remedy at law. For reason previously noted, the Court does not reach this issue.

Dated: December 17, 2001 /s/ Judge Haley J. Fromholz

Judge of the Superior Court