California Superior Court Judge Rules on Quackbuster "Credibility"

This is an html COPY of the original Court document signed by Judge Fromholz. The text in blue is for emphasis. None of the Judge's words have been anged. This was a case filed by the so-called National Council Against Health Fraud (NCAHF) a inst a manufacturer of Homeopathic products. The quackbusters were soundly, and publicly, beaten in this courtroom. The Judge's opinion about top quackbusters Stephen Barrett, and Wallace Sampson is classic...

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 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 th 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 gan with the testimony of two proffered experts, Wallace I. Sampson, M.D. and Stephe Barrett, M.D. Plaintiff also offered brief testimony by its counsel, Mr. Mehrban, and calle efendant 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 evid ce, 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 m tion 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 befo e Court. Having reviewed and considered all these matters, and having considered an 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 nd 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 provision f 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 misleadi g 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. Secti 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 Defendan 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 pl ntiff 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 supportin finding that Defendants' actions were unlawful, fraudulent or unfair within the meaning 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 tha 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 possib e 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 th fore 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 NCA F 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 Plai tiff'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 ele ent of its claims therefore lies with Plaintiff NCAHF. Cal. Evid. Code § 500.

In a subsequent, supplemental brief, the Plaintiff nex argued that even if the burden lies initially with the plaintiff in a false advertising ca , only slight evidence is required to then shift the burden to the defendant. This argument was b ed 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 decis ns 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 appr priate 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 evi nce.

IV. Analysis and evaluation of evidence

The Court now reviews the evidence presented by the pa ties.

A. Wallace I. Sampson, M.D.

Dr. Sampson was offered apparently to testify concerni g the scientific method generally, standards of clinical medical research the nature of h meopathic medical science, and the nature of the information upon which much of homeopath 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 testimo y 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 particul ding 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 littl xpertise in research methodology and does not instruct in that area. He is not an expert in armacology. He admitted to having had no experience with or training in homeopathic medicine rugs. He was unfamiliar with any professional organizations related to homeopathy, incl ding the Homeopathic Pharmacopeia Convention of the United States, which group is respon ble for designation and de-designation of such drugs as "official" drugs recogniz 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 h 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 desig ed to highlight the criticisms of such

alternative practices. Therefore, the Court finds that r. Sampson has relatively thin credentials to opine on the general questions of the p oper 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 absol tely 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 rior 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 Plain iff, but the Court found that there was substantial overlap on the issues that he and Dr. Samp n 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 o 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 h ve 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, is review of professional literature on the subject and certain continuing education activities.

As for his credential as an expert on FDA regulation o omeopathic drugs, the Court finds that Dr. Barrett lacks sufficient qualifications in th 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 appa t. 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 con ersations 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 i sues 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 ears. For these reasons, there is no sound basis on which to consider Dr. Barrett qualified 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 r. 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 s ed as its Chairman. Both participated in an application to the U.S. FDA du ng 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 futu ases if the Plaintiff prevails in the instant action and thereby wins funds to enrich the li ation 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, an therefore their testimony should be accorded little, if any, credibility on that basis as ll.

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 experi ced 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 comp ied 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 serv s on the faculty of the U.C. San Diego medical school. Dr. Wilson testified that she ha ned in homeopathic medicine and received certification to practice in the field from a ast 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. B tt 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 re ecting the effectiveness of homeopathic drugs, even when this evidence is evalu ted under the methodological standards testified to by Dr. Sampson. She also testif ed 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 n this area, the "indications" (i.e., drug effects) that must be placed on the label or pack e 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 th specific products in question.

V. Findings of fact/Conclusions of law

A. False advertising

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

§§ 17200 and 17508, a finding for Plaintiff under thes ctions 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 lse. 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 th any advertising or labeling of its products. Furthermore, the Plaintiff failed to show th ther of the Defendants knew or should have known that any of their statements were un e, 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 argumen es not aid the Plaintiff, since the Court finds that there is no showing of a false or misleadin tatement 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 tri there is no basis for a finding that Defendants violated the unlawful activity prong of B & ode § 17200.

C. "Unfair" business practice

The parties disputed the appropriate standard for dete ining whether Defendants' activities were "unfair" within the statute's meaning. It has been interpreted in a number of case e 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. Pla tiff 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 cause ubstantial 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 am rphous 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 find ng that Defendants violated the fraudulent activity prong of B & P Code § 17200. The Plaintiff fa led to show that any of the Defendants' labeling or advertising was likely to mislead a reason le person. *Committee On Children's Television v. General Foods Corp.* (1983) 35 Cal. 3d 197.

VI. Remaining issues raised by party requesting statem nt of decision

The foregoing resolves the majority of issues raised i the Defendants' Request for Statement of Decision, filed October 22, 2001. With respect to t e 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 und r 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 egulations constitutes a complete defense to Plaintiff's state law claims. Also, Defendants assert the doctri e of state court abstention. Federal preemption is asserted as Defendants' Tenth Affirmative Defense; presumably the other jurisdictional arguments are subc gories of this defense. In view of the findings above on the issues of liability, the Cou ds that it need not reach these jurisdictional questions, and therefore it makes no ru ing on those matters.

The Court notes, however, that the Plaintiff argued on e 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 crea ion of that evidence is costly and difficult. As noted above, Plaintiff has fa ed to support its argument on the burden of proof. In any event, however, its argument more log ally 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 requiremen s 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 fe walk into any court in any state in the Union and file a lawsuit against any business, casting he 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 clai s?

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 previou ly noted, the Court does not reach this issue.

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

Judge of the Superior Court