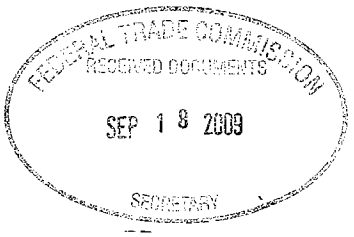
IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

Commissioners: Jon Leibowitz, Chairman
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch



In the Matter of	)	
DANIEL CHAPTER ONE,	)	**DOCKET NO. 9329**
a corporation, and	)	
	)	
	)	**PUBLIC DOCUMENT**
JAMES FEIJO,	)	
Individually, and as an officer of	)	
Daniel Chapter One.	)	
	)	

RESPONDENTS' APPEAL BRIEF

Respondents Daniel Chapter One, a corporation, and James Feijo, individually and as an officer of Daniel Chapter One, hereby submit the following Appeal Brief in the above-captioned action.

Dated: September 18, 2009

Respectfully Submitted,

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STATEMENT OF THE CASE

A. STATEMENT OF RELEVANT FACTS

The Federal Trade Commission ("FTC") issued the Complaint in this matter on September 16, 2008 against Daniel Chapter One ("DCO") and James Feijo ("Respondents"). The Complaint alleged that Respondents engaged in deceptive acts or practices in connection with the advertising, promotion, offering for sale, sale, and distribution of four products: BioShark, 7 Herb Formula, GDU, and BioMixx (collectively, the "Challenged Products"). The Complaint also alleged that Respondents operated linked web pages on the website, www.danielchapterone.com, through which they advertised and sold the Challenged Products.

The Complaint alleged that the Challenged Products are advertised to prevent, treat, or cure cancer or tumors, and specifically charged that the advertisements represent, expressly or impliedly, that:

> Bio*Shark inhibits tumor growth;
> Bio*Shark is effective in the treatment of cancer;
> 7 Herb Formula is effective in the treatment or cure of cancer;
> 7 Herb Formula inhibits tumor formation;
> GDU eliminates tumors;
> GDU is effective in the treatment of cancer;
> BioMixx is effective in the treatment of cancer; and
> BioMixx heals the destructive effects of radiation and chemotherapy.

The Complaint further alleged that Respondents represented, either expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the claims made, but that Respondents did not, in fact, possess and rely upon such reasonable basis. The Complaint charged Respondents with unfair or deceptive acts or practices, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act").

In their Answer, Respondents admitted that they operate a website that provides information on the Challenged Products in a religious and educational context, but otherwise denied allegations that they engaged in deceptive acts or practices in connection with the advertising or sale of the Challenged Products. Respondents averred that they did possess and rely upon a reasonable basis that substantiated the representations made about the Challenged Products at the time the representations were made. Respondents further asserted, and the record reflects, that Respondents did not expressly make any of the foregoing claims.

At the hearing before the Administrative Law Judge, Complaint Counsel provided one expert witness, Dr. Denis Miller, a research oncologist, who testified concerning the standard for chemotherapeutic agents used in the treatment of cancer. Respondents offered five, and were permitted two, expert witnesses, Dr. James Duke, a widely known ethnobotanist formerly with the U.S. Department of Agriculture, and Dr. Sally Lamont, a licensed naturopathic doctor, both of whom testified that in their opinions the statements made by Respondents on their website and in their materials were supported by competent and reliable scientific evidence concerning herbal dietary supplements. Respondent James Feijo and Patricia Feijo, his wife, testified that for over 26 years Daniel Chapter One had operated as a religious ministry and was organized as a religious corporation sole under the laws of Washington State. They further testified that James Feijo, as Overseer of Daniel Chapter One, held all assets in trust for its religious purposes, and that they took no salary.

B. SUMMARY OF THE ARGUMENT

In this brief Respondents argue that the FTC lacks jurisdiction over them on the grounds that Respondents are a religious ministry organized and operated for charitable purposes.

Respondents also argue that the Initial Decision violates the FTC Act and their right to due process of law by shifting the burden of proof from Complaint Counsel to Respondents, that their speech is protected by the First Amendment to the U.S. Constitution, that Complaint Counsel has the burden of proving that the information provided by Respondents is misleading and that its suppression is necessary to achieve a substantial government interest, and that Complaint Counsel failed to do so.

Respondents also argue that the Administrative Law Judge (ALJ) improperly regulated their conduct by adjudication, that the Challenged Products are not drugs as found by the ALJ, that Respondents' claims were permitted structure/function claims for dietary supplements and that an incorrect standard was applied to those claims.

Finally, Respondents argue that adoption of the proposed order contained would violate their constitutional and statutory rights.

STATEMENT OF THE QUESTIONS PRESENTED

1 Should the Initial Decision of the Administrative Law Judge finding that the Federal Trade Commission has jurisdiction over respondents Daniel Chapter One, a non profit religious organization, and its single member and overseer James Feijo, be rejected as mistaken?

2. Did the Initial Decision of the Administrative Law Judge violate the FTC Act, the Due Process Clause and/or the First Amendment to the U.S. Constitution by:

(a) improperly shifting the burden of proof to Respondents on certain key Constitutional and statutory elements, including but not limited to (i) the governmental burdens associated with Free Speech under *Central Hudson*; (ii) the elements of allegedly

deceptive and misleading speech; and (iii) the required perceptions of consumers allegedly misled or harmed by Respondents' speech?

(b) permitting "evidence by presumption"?

(c) applying the incorrect standard of proof, to substantive elements of their charges against Respondents, including but not limited to the elements of alleged violations under 15 U.S.C. §§45 and 52?

(d) attempting to exercise FTC jurisdiction over Respondent Daniel Chapter One despite an express finding by the Administrative Law Judge that Respondent Daniel Chapter One is a religious organization?

(e) its overbroad ban on truthful statements about dietary supplements?

(f) engaging in illegal rule-making by adjudication, in that the Administrative Law Judge substituted his own presumptions for the evidence required for an "overall net impression" case?

(g) failing to consider the element of "intent" and arbitrarily rejecting Respondents' evidence while permitting presumptions to substitute for the evidence the statute requires Complaint Counsel to produce?

(h) improperly requiring double-blind, placebo-based clinical trials as the only acceptable substantiation for structure-function claims authorized by the Dietary Supplement Health and Education Act (DSHEA)?

(i) improperly accepting Complaint Counsel's testifying oncologist as an expert witness regarding the express structure/function claims authorized by DSHEA, despite that oncologist's admission that he did not know what a structure/function claim was?

(j) improperly rejecting Respondents' experts' bona fide qualifications to address structure/function claims?

(k) prohibiting truthful, authorized structure/function claims under the guise of an "overall net impression" analysis?

ARGUMENT

I. INTRODUCTION

A. Overview: Policy Considerations

The twelve years from 1969 to 1981 were tumultuous ones for the United States and for the FTC. During a period that included the presidential terms of Richard Nixon, Gerald Ford and Jimmy Carter, and the FTC Chairmanships from Paul Rand Dixon to Michael Pertschuk, both nation and agency went through major upheavals. The nation's trials and triumphs of the period are generally recalled. The agency's are not so well remembered.

For the agency, the period began with the 1969 Nader Report on the FTC, reinforced by an American Bar Association report requested by President Nixon, which brought it from obscurity to front page prominence. The period closed for the agency with near loss of its budget in 1980 for becoming seen, as the Washington Post editorialized, as the "nation's nanny." The Nader/ABA analysis found the FTC to be strikingly out of touch with the American Public.

1. FTC and the National Health Debate: Rodale Press

Part of the FTC's disorientation came from its effort to control the national health care discussion between buyers and sellers. In its 1967 Rodale Press, Inc. decision, 71 FTC 1184, overturned by a court the next year, the agency attempted, using a legal stratagem to get around the First Amendment, to assert authority over advertising of a book of health recommendations which it found to be unorthodox and therefore false or misleading. Concurring Commissioner

MacIntyer succinctly stated the theory of the complaint. The commission, he said, has "...valid power to regulate false representations in advertising [even] when integral to theories or views expressed in particular publications being advertised and sold." Rodale Press, Inc., at 1256. All but one of the other commissioners tried to get around the First Amendment by distinguishing the ads for the book in question from the content of the book itself.

Dissenting Commissioner Elman argued that the Commission's theory violated the First Amendment, saying "It is not the function of the Federal Trade Commission or any other agency of government to sit as a board of review examining into the validity or worth of ideas, opinions, beliefs, and theories expressed in books and other publications offered for sale to the public. 'If there is any fixed star in our constitutional constellation, it is that no official high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion *** *West Virginia State Board of Education v. Barnette*, 319 U.S. 624, 642 (1943)."

"It is the glory of a free society that a man can write a book contending that the earth is flat, or that the moon is made of green cheese, or that God is dead, without having to 'substantiate' or 'prove' his claim to the satisfaction of some pubic official or agency. Such an inquisition, abridging the free expression of ideas, is intolerable. It is no less so because the inquisition is justified as an attempt to forbid deceptive advertising." In December of 1968, just as the Nader report was appearing, the Commission voted to dismiss rather than rehear the case.

In the case before the Commission today, the Federal Trade Commission brought a complaint against Daniel Chapter One, found by the Administrative Law Judge to be a religious ministry, for making claims such as saying that four herbal products available for money on its web site could help fight cancer. The publications of Daniel Chapter One—books, pamphlets, web site, radio broadcasts, etc; it had no advertising budget, placed no ads, and sought followers

only through its religious ministry—raise the same Constitutional questions for the FTC that the Rodale book raised for it in 1968. This action once again places the FTC at odds with the First Amendment of the Constitution. Once again, the FTC attempts to block certain information from the national health discourse.

2. FTC Tries to Ban the Words "Natural," "Organic," and "Health Food" from Commerce.

In 1974, six years after disposing of the Rodale case without banning the book in question or ads for it, the FTC made another effort to interfere in the unfolding national discourse between health orthodoxy and advocates for different approaches. The Commission proposed a Trade Regulation Rule for Food Advertising that included an effort to ban the words "natural," "organic," and "health food" from commerce. A perceptive Administrative Law Judge acting as Presiding Officer of the proceedings on the rule blocked the FTC action, writing:

"The fatal defect in its reasoning and the flaw in the argument of the proponents of a ban is that they have equated confusion with deception. It is true that some advertisers have exploited the confusion to create deception, but they are nonetheless not the same thing and it would be a legal, if not a linguistic error, to argue that they are....We should look also at where the arguments of the proponents would take us if followed to their logical end. If the Commission gets itself into the business of banning ambiguous words whenever there is no shared common meaning and some confusion exists, where would that lead us? The obvious result in the present context would be to put a ban on the word "energy." Proposed Trade Regulation Rule: Food Advertising [16 CFR Part 437] Report of the Presiding Officer Public Record Number 215-40, p. 239, February 21, 1978. If the FTC had been successful in banning the word "organic" from commerce it is unlikely that the current multibillion dollar organic food business would have come into existence.

The FTC case against Daniel Chapter One parallels the problem identified by the Presiding Officer in the 1978 word-banning exercise. The FTC allegations against Daniel Chapter One are grounded in the definition of a drug in the Food Drug and Cosmetic Act. That Act says "The term 'drug' means ...(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." Sec. 201. [21 U.S.C. 321] The FTC case against Daniel Chapter One embraces this definition, argues that the actual words used by Daniel Chapter One, such as "fight," implies that they intend to use the words in the definition of a drug, therefore they intend their herbs to be drugs, which requires them to conduct double-blind placebo-controlled studies to substantiate their claims that herbs could help the body fight cancer by strengthening its innate healing function such as its immune system.

This convoluted path of implication and presumption taken by Complaint Counsel and the ALJ reaches a conclusion that is the opposite of reality. Daniel Chapter One explicitly, clearly and insistently asserts in all the media it has access to that the herbal supplements they recommend are *not* drugs. The fact that they are not drugs is one of their main values to the people who seek them out. Because Daniel Chapter One explicitly asserts that their herbs are herbal supplements and not drugs, they avoid using the words that appear in the drug definition. Also because Daniel Chapter One intends the herbs to be supplements and not drugs it relies on herbal science—validated by the experts it presented at the hearing—to support their claims of enhancing the healing function of the body.

Arguing that by using the word "fight" in its broadcasts, publications and web site (DCO neither purchased or placed any "advertisements") DCO turned its dietary supplements into drugs, and therefore it is required to substantiate any statements it makeswith double-blind, placebo-controlled clinical trials is exactly the slippery slope that the Presiding Officer in the

1978 Food Advertising Trade Regulations proceedings warned against. If the FTC adopts the Initial Decision in this case, it will be attempting to set itself up as the decider in the struggle between prevailing health orthodoxies and emerging knowledge that even its own guidelines recognize as important, and it will be setting itself up not as a neutral arbiter but as the advocate of orthodoxy. If successful, it is unlikely that we will ever know what important innovations, such as the organic food market, the FTC will have eliminated.

3. United States v. Johnson: Constitutional Logic to Decide this Case

In *United States v. Johnson*, 221 U.S. 488 (1911), Justices Oliver Wendell Holmes and Charles Evans Hughes offers a clear way to think about the issues presented, and a Constitutional context to guide action, in the Daniel Chapter One case. Mr. Johnson shipped his drug from Missouri to Washington, DC, claiming on the label that it would cure cancer when he knew it would not cure cancer. *Johnson*, p. 488.

Mr. Justice Holmes, writing for the court majority, said, "It is a postulate, as the case comes before us, that in a certain sense the statement on the label was false, or, at least, misleading. What we have to decide is whether such misleading statements are aimed at and hit by the words of the act. It seems to us that the words used convey to an ear trained to the usages of English speech a different aim; and although the meaning of a sentence is to be felt rather than to be proved, generally, here, the impression may be strengthened by argument, as we shall try to show." *Johnson*, p. 488.

Justice Holmes's argument concluded that Congress intended the Pure Food and Drug Act of 1906 to restrict false or misleading claims about the content, ingredients, origin, etc., of a product, "matters of fact" he called them, and did not intend to restrict claims about what a product might do, which he considered "matters of opinion." Congress, he said, "was much more

likely to regulate commerce in food and drugs with reference to plain matter of fact, so that food and drugs should be what they professed to be, when the kind was stated, than to distort the uses of its constitutional power to establishing criteria in regions where opinions are far apart. See *American School v. McAnnulty*, 187 U. S. 94, 47 L. ed. 90, 23 Sup. Ct. Rep. 33." *Johnson*, p. 488.

Mr. Justice Hughes, writing the dissent, said, "The question, then, is whether, if an article is shipped in interstate commerce, bearing on its label a representation that it is a cure for a given disease, when, on a showing of the facts, there would be a unanimous agreement that it was absolutely worthless and an out-and-out cheat, the act of Congress can be said to apply to it. To my mind the answer appears clear." *Johnson*, p. 489. To Justice Hughes the clear answer was "yes," the statutes applied. In a case where the authorities proved by a "showing of the facts, there would be a unanimous agreement that it was absolutely worthless and an out-and-out cheat" the statue applied. The matter that these two giants of the law struggled over in *Johnson* is the matter which the presiding officer in the FTC "ban the word 'organic'" case called "a legal, if not a linguistic error..." That matter is how should regulators deal with differences of opinion that cannot easily be disposed of as matters of fact. While they disagreed over the interpretation of the 1906 Act, Holmes and Hughes agreed that in order to act the authorities need to rely on fact not opinion. Thus Justice Hughes argued that, in a case where it was established as a matter of fact that a claim for a product was "absolutely worthless and an out-and-out cheat," Congress could act against it. The failure of Complaint Counsel and the ALJ to even attempt to establish that Respondents' claims were misleading as to facts, rather than the expression of opinions, renders any action against Respondents fatally flawed under both the statute and the Constitution.

The *Johnson* case did not reach the constitutional question because the majority disposed of it as a legislative interpretation case. If the FTC is not able to follow the lead of these two justices and find, as set out in the argument that follows, that the FTC Act does not authorize the action proposed by the Initial Decision it must then explain how those actions pass Constitutional scrutiny.

B. The Initial Decision is in Error and Violates Respondents' Statutory and Constitutional Rights

Respondents Daniel Chapter One ("DCO") and James Feijo (hereinafter collectively, "Respondents") ask the Commission to review *de novo* the ALJ's Initial Decision, and reject it for the following reasons:

- The Initial Decision violates Due Process and the First Amendment. To begin with, the ALJ's analysis improperly shifts the burdens of proof to Respondents on several key Constitutional and statutory elements. The ALJ also permits "evidence by presumption" and applies the incorrect standard of proof.
- Although expressly finding Respondent DCO to be a religious organization, the ALJ exercised jurisdiction over that religious organization's activities. In so doing, the ALJ extended FTC jurisdiction in an unprecedented way that violates the FTC statutes and the U.S. Constitution.
- The over-breadth of the Initial Decision bans truthful statements about dietary supplements, by virtue of the following improper tactics:
    - The ALJ improperly supplanted required evidence with his own presumptions in an "overall net impression" case, the effect of which is to illegally rule-make by adjudication.

- The ALJ ignored the element of "intent" required by statute. In so doing, he arbitrarily rejected Respondents' evidence while again using his own presumptions in lieu of the required evidence that Complaint Counsel failed to produce.
- The Initial Decision improperly mandates double-blind, placebo-based clinical trials as substantiation for structure-function claims authorized by the Dietary Supplement Health and Education Act (DSHEA).
- The Initial Decision improperly cloaks Complaint Counsel's testifying oncologist with expertise over the express structure/function claims authorized by DSHEA, despite that oncologist's admission that he does not know what a structure/function claim is.
- The ALJ achieved this result with Complaint Counsel's expert by improperly stripping Respondents' experts of their bona fide qualifications to address structure/function claims.
- The Findings and Conclusions prohibit truthful, authorized structure/function claims under the guise of an "overall net impression" analysis.

- In an unprecedented Constitutional violation, the Remedy not only prohibits truthful speech, but also compels Respondents to conduct government-mandated speech as a condition precedent to continuing their religious ministry.

Any one of these points is an independently sufficient basis on which to reject the Initial Decision and find in favor of Respondents. Cumulatively, the Commission is urged to look long and hard at the Constitutional abuses that have been perpetrated here in the name of consumer protection.

II. THE INITIAL DECISION VIOLATES PROCEDURAL DUE PROCESS IN SEVERAL FUNDAMENTAL WAYS.

Due process required Complaint Counsel to meet its burden of proof with clear, cogent and convincing extrinsic evidence on each and every required element of its case. That standard was not met. Instead, the ALJ allowed Complaint Counsel to shift the burden to the Respondents with respect to some key elements of its case. With respect to other key elements, the ALJ determined that Complaint Counsel had met its burden of proof where Complaint Counsel had provided no extrinsic evidence but relied solely on presumptions. Both of these departures from the requirements of the FTC Act deprived Respondents of due process.

The due process considerations addressed here are important threshold issues. Numerous decisions from higher courts set forth the criteria for determining the proper due process procedures when administrative agencies attempt to carve new paths into constitutionally protected territory, as the Initial Decision does here.

A. The Initial Decision Violates Due Process by Ignoring the Fact that the Government has the Burden of Proof when Regulating Protected Speech.

According to the ALJ, Respondents' "representations have been found to lack adequate substantiation and therefore have been determined to be deceptive or misleading." Initial Decision, p. 115. "Accordingly," the ALJ concluded, "the deceptive commercial speech at issue in this case is not protected by the First Amendment." Id. The threshold issue in First Amendment commercial speech cases, however, is not whether "[Respondents'] representations . . . lack adequate substantiation," but whether the FTC has attempted to shift the burden of proof to the Respondent. The Initial Decision improperly shifts the burden to Respondents.

If the commercial speech doctrine applies, the FTC must show that its effort to restrict Respondents' promotional activities "directly and materially advances a substantial government

interest and in a manner that is no more extensive than necessary to serve that interest." *Ibanez v. Florida Dept. of Business and Professional Regulation Board of Accountancy*, 512 U.S. 136, 142 (1994).

The ALJ adopted Complaint Counsel's proposed Findings, Conclusions and legal analysis in this regard without justification. By doing so, he shifted to Respondents the burden of proving that their speech was not misleading, rather than requiring Complaint Counsel to meet its burden of proving actual deception. The ALJ shifted the burden of proof to Respondents by requiring them to come forward with "competent and reliable scientific" evidence consisting of double-blind, placebo-controlled clinical drug trials, even though Respondents have never represented that their promotional information was based on such evidence. In his Initial Decision, the ALJ punished Respondents for lacking what Respondents never claimed to have and improperly disparaged the scientific evidence that Respondents did have, without explaining how this shift in burden meets the Constitutional requirement of directly and materially advancing a substantial government interest in a manner that is no more extensive than necessary to serve that interest.

To meet its burden of proof, Complaint Counsel should have been required to produce evidence that consumers were actually misled by Respondents' promotional efforts and representations. Respondents did have "competent and reliable scientific" evidence supporting their actual claims provided by experts on the relationship between health, health claims and the herbal supplements that are the subject of this case.

To summarize the analysis that follows in the next several subsections of this Brief, the constitutional challenge addressed here under the commercial speech doctrine is comparable to the challenge waged and won against the federal government in *Pearson v. Shalala*, 164 F.3d

650 (D.C. Cir. 1999). There, the D.C. Circuit Court found that the FDA's use of the standard of proof called "significant scientific agreement" was too vague to support the FDA's contention that a health claim for a dietary supplement was "inherently misleading" unless that claim had significant scientific agreement. *Pearson* at 655. Significantly, the Initial Decision makes no mention of *Pearson*, despite Respondents' efforts to bring to the ALJ's attention *Pearson* and three U.S. Supreme Court cases relied upon by the *Pearson* Court.

1. The Federal Trade Commission Cannot Ignore the Pearson Case

After concluding that Respondent DCO's claims for its dietary supplements are "commercial speech," the ALJ found those claims outside the protection of the First Amendment on the grounds that he found DCO's claims to be "misleading." Initial Decision, pp.113-15. The ALJ found the claims to be "misleading" based not on competent medical evidence introduced by the government, but solely on the ground that DCO had not demonstrated that they were based on what the ALJ would permit into evidence as "competent and reliable scientific evidence." Initial Decision, p. 100. The case rests on the government's assertion that only double-blind, placebo-controlled clinical studies, comparable to those used to support new drug approvals by the FDA, qualify as "competent and reliable scientific" evidence.

However, in *Pearson,* a strikingly similar case involving comparable marketing claims for dietary supplements, the U.S. Court of Appeals for the District of Columbia rejected the very position taken by the ALJ in the Initial Decision. The *Pearson* court applied the First Amendment commercial speech doctrine to claims that did not meet an FDA "scientific" standard—"significant scientific agreement"—similar to the standard relied on by Complaint Counsel and the ALJ in this case.

In *Pearson*, as here, marketers of dietary supplements made claims that their products would help people in the battle against cancer. *Compare Pearson*, 164 F.3d at 652 *with* Initial Decision, pp. 83-95. In *Pearson*, as here, the government agencies found these claims misleading because they did not meet the agencies' "scientific" standards. *Compare Pearson*, 164 F.3d at 652-55 *with* Initial Decision, pp. 99- 106. Thus, in *Pearson*, as here, the government agencies asserted that the health claims were "entirely outside the protection of the First Amendment." *Compare Pearson*, 164 F.3d at 655 *with* Initial Decision, pp. 115-16. In *Pearson*, however, the Court of Appeals rejected the agency's claim (calling it "almost frivolous"), whereas in this case, the ALJ embraced it.

The *Pearson* decision relied on three prior cases applying First Amendment commercial speech doctrine — *In re R.M.J.*, 455 U.S. 191 (1982), *Ibanez*, 512 U.S. 136 (1990), and *Peel v. Attorney Registration and Disciplinary Comm'n. of Illinois*, 496 U.S. 91 (1990). The Court in *Pearson* rejected the FDA's contention that health claims, unless consistent with the then-prevailing scientific consensus, were inherently misleading and thus not protected free speech. It found the FDA's argument unpersuasive because it was based upon the unconstitutional "paternalistic assumption" that the ordinary consumer was unable to make an informed and independent judgment on the truthfulness of health claims for vitamins and other dietary supplements. *Pearson*, 164 F.3d at 655.

In this case the ALJ dismissed *RMJ*, *Ibanez*, and *Peel*, as "inapposite." Initial Decision, p. 116. In fact, the ALJ embraced the "paternalistic assumption" that health claims must meet a "high level of substantiation, such as scientific tests" because it is "difficult or impossible for consumers to evaluate [health claims] for themselves." Initial Decision, p. 102. In so ruling, the ALJ violated the "general rule ... that the speaker and the audience, **not** the government, assess