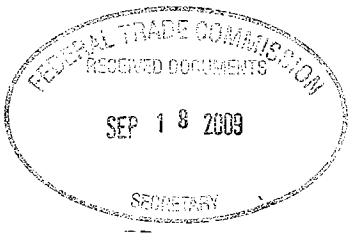
IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

the value of the information presented." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) [emphasis added]. Indeed, the ALJ's paternalistic insistence that DCO's claims be measured by current scientific orthodoxy directly contravenes the First Amendment's commitment to "the free flow of commercial information" which, to an individual consumer seeking a solution to a personal health need, "may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976).

The *Pearson* court recognized what the ALJ did not — the First Amendment protects the people from government suppression of commercial information if that suppression rests upon a paternalistic policy. Indeed, from the beginning of the development of its First Amendment commercial speech doctrine, the Supreme Court has consistently rejected paternalistic justifications for suppression of information, knowing "that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to **open** the channels of communication rather than to close them." *Thompson v. Western States Medical Center*, 535 U.S. 357, 375 (2002), quoting from *Virginia State Board of Pharmacy*, 425 U.S. at 769 [emphasis added].

This does not mean that the government may not protect the people from demonstrably fraudulent advertising. The complaint in this case, however, does not allege that DCO's health claims are false; rather, it rests upon the allegation that DCO did not have a "reasonable basis" of the sort that the FTC would accept for its health claims: double blind, placebo controlled, clinical trials. Initial Decision, pp. 67, 99. These two standards — falsity in fact and lack of a reasonable basis —are drastically different. The "falsity" theory **requires the government** to "carry the burden of proving that the

express or implied message conveyed by the ad is false." Initial Decision, p. 99, n.4. The "reasonable basis theory" **requires the marketer** to demonstrate that it relied upon "competent and reliable scientific evidence," in this instance defined as double-blind, placebo-controlled clinical trials, for its health claims. Initial Decision, p. 100.

Respondents argue, first, that it is the government's responsibility to show that Respondents did not have a "reasonable basis" for their claims. Complaint Counsel denied that the government has this responsibility and offered no evidence other than asserting that Respondents lacked double-blind, placebo-controlled, clinical studies. Second, Respondents argue, supported by their experts, that they did have competent and reliable scientific evidence, recognized in herbal medicine circles around the world, to support their claims.

According to the ALJ, since DCO did not meet the government's "reasonable basis" standard of double-blind, placebo-controlled, clinical studies, DCO was not entitled to the First Amendment protection afforded commercial speech. Initial Decision, pp. 115-16. By so ruling, the ALJ erroneously shifted to DCO the burden of proving that the First Amendment applied to its health claims and adopted the position that the Constitution permitted the FTC to prohibit Respondents from making truthful statements about the relationship between their herbal supplements and cancer.

The government has the burden of proof that DCO's marketing claims are misleading. *Ibanez*, 512 U.S. at 138-39; *Peel*, 496 U.S. at 100-01; *In re RMJ*, 455 U.S. at 202-03. As noted above, the ALJ brushed aside *Ibanez*, *Peel* and *In re RMJ* as inapplicable. Relying on all three cases, the *Pearson* court **rejected the FDA's effort to shift the burden** of proof to the marketers of dietary supplements that its claims were not

"unscientific," and thus, not "inherently misleading." *Pearson*, 164 F.3d at 655. By refusing to apply *Ibanez*, *Peel*, and *In re RMJ*, the ALJ committed reversible error by failing to apply to DCO's health claims the First Amendment test set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n. of New York*, 447 U.S. 557 (1980).

2. Respondents' Speech Deserves First Amendment Protection.

In *Thompson v. Western States Medical Center*, 535 U.S. 357, 367-377 (2002), addressing drug compounding, a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to an individual patient's needs, which is at least as, if not more, complex then choosing to use herbal supplements, the U.S. Supreme Court explicitly held that commercial speech receives First Amendment protection, and "explained the reasons for this protection" as follows:

> It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end the free flow of commercial information is indispensable.... Indeed, we recognized that a particular consumer's interest in the free flow of commercial information ... may be as keen, if not keener, by far, than his interest in the day's most urgent political debate. *Thompson*, pp. 366-67.

Additionally, the Court "emphasized":

> The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to coverage of the First Amendment. *Thompson*, p. 367.

The record shows that Respondents' statements concerning the Challenged Products fall squarely within the Supreme Court's First Amendment umbrella. The people seeking out Respondents' information are looking for natural and faith-based approaches to address their life situations.

In recognition of the First Amendment commitment to keep the channels of communication open, the Supreme Court has imposed strict rules designed to limit government efforts to close them off, insisting that any such regulation must "directly advance" a "substantial government interest" by a regulation that is "not more extensive than is necessary to serve that interest." *Thompson*, p. 367.

3. The FTC Has The Burden To Prove That The Information About The Challenged Products Shared By Respondents Is Misleading And That Its Suppression Of Such Information Is A Direct And Necessary Means To Achieve A Substantial Government Interest.

As did Complaint Counsel in its briefing, the ALJ misinterpreted and misapplied the U.S. Supreme Court holding in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980), concerning the regulation of commercial speech. To understand the ALJ's error, a review of constitutional analysis arising from *Central Hudson* is in order.

In 1995, the Supreme Court restated its *Central Hudson* formula, asserting that "the government may freely regulate commercial speech that ... is misleading." *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623-24 (1995). By means of this statement, the high court confirmed that the threshold burden for regulating commercial speech is the government's, to show that statements in question are misleading, rather than the semantic shift in burden that results from requiring a commercial statement to be non-misleading. Highlighting this clarification, the Court conformed its statement of the *Central Hudson* rule to the several court decisions that it had handed down in the 15 previous years since *Central Hudson* had been decided.

For instance, in 1982, the Supreme Court, applying *Central Hudson*, ruled that a particular attorney advertisement could not be "prohibited entirely," there being nothing

in the record to show that the ad was either "inherently likely to deceive" or that the ad "has in fact been deceptive." *In the Matter of R. M. J.,* 455 U.S. 191, 202 (1982).

Then, in 1990, the Supreme Court conferred First Amendment protection on another attorney promotional statement, on grounds that track almost exactly the basis of Complaint Counsel's case and the ALJ's Initial Decision:

(a) "[t]here is no contention that any client or person was actually misled or deceived by petitioner's stationery;" nor

(b) "any factual finding of actual deception or misunderstanding"; but only

(c) a "conclu[sion], as a matter of law, that petitioner's claims ... were necessarily misleading."

Peel, 496 U.S. 91 100-01 (1990). Thus, the *Peel* Court concluded that "[g]iven the complete absence of any evidence of deception in the present case, we must reject the contention that petitioner's letterhead is actually misleading." *Id.*, 496 U.S. at 106. What the court prohibited in *Peel* is exactly what the Initial Decision permits the FTC to do in this case.

Four years later, in 1994, the Supreme Court restated the *Central Hudson* rule and its rationale, as follows:

> Because 'disclosure of truthful, relevant information is more likely to make a positive contribution to decision making than its concealment of such information, *Peel* ..., **only false, deceptive, or misleading commercial speech may be banned** .... [*Ibanez*, 512 U.S. 136, 142 (emphasis added) (1994).]

Thus, the *Ibanez* Court ruled in favor of yet another attorney ad where "[t]he record reveals that the Board [of Accountancy] has not shouldered the burden that it must carry in matters of this order:"

> It has **not demonstrated** with sufficient specificity that any member of the public could have been misled by Ibanez' constitutionally protected speech or that any harm could have resulted from allowing that speech to reach the public's eyes. [*Ibanez*, 512 U.S. at 138-39 (emphasis added).]

Daniel Chapter One did not stand idly by in its relationship with the people who used its herbs. Rather it provided information to help its followers make better decisions. Complaint Counsel asserts, but offers no evidence, that since the information provided by Daniel Chapter One was not based on placebo-controlled double-blind clinical studies it was inherently misleading. Nor did Complaint Counsel offer, or the Initial Decision cite any evidence that suppressing Respondents' claims "directly advances" a "substantial government interest" by a regulation that is "not more extensive than is necessary to serve that interest." *Thompson*, 535 U.S. at 367.

Not only must the government agency that seeks to suppress commercial speech meet its burden to prove the commercial speech at issue to be false, misleading or deceptive, as a matter of fact, but it must also "show that the restriction directly and materially advances a substantial state interest in a manner no more extensive than necessary to serve that interest." *Ibanez*, 512 U.S. at 142. Again, as the *Ibanez* Court emphasized, "[t]he State's burden is not slight; the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Ibanez.*, 512 U.S. at 143.

In *Edenfield v. Fane*, 507 U.S. 761 (1995), the Court explained that the government's "burden is not satisfied by mere speculation or conjecture," but only by "demonstrat[ing] that the harms [the government] recites are real and that restriction will

in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. As addressed below this requires actual, extrinsic evidence – not presumption.

Later that same year, in *Rubin v. Coors Brewery Co.*, 514 U.S. 476, 487 (1995), the Court further stressed that unless this "critical" requirement is met, "a State could with ease restrict commercial speech in the service of ... objectives that could not themselves justify a burden on commercial speech." *Edenfield*, 507 U.S. at 771.

In sum, a long line of Supreme Court cases has demonstrated the requirement that "the Government bears the burden of **identifying** a substantial interest and **justifying** the challenged restriction." *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173, 183 (1999) (emphasis added). *Thompson v. Western States Medical Center*, 535 U.S. 357, 367-377 (2002). The Initial Decision is wrong in concluding that Complaint Counsel has met this burden.

4. The FTC Has Not Met Its Burden to Prove that Respondents' Statements Are Misleading.

As noted throughout this case, despite the justifications asserted in the Initial Decision, Complaint Counsel has produced absolutely no evidence that Respondents' statements concerning the Challenged Products have in fact actually misled anyone. Rather, Complaint Counsel and the ALJ maintain that Respondents' statements are deceptive under the FTC Act if they are likely to mislead consumers, acting reasonably under the circumstances. Implementing this "'likely to mislead' standard, the ALJ examined the "overall net impression" of Respondents' communications, coupled with its own reasoned analysis to determine what claims an advertisement conveys.

Thus, the ALJ excused Complaint Counsel from having to produce any actual consumer to determine how 'reasonable consumers' interpret a claim. Indeed, efforts by

Respondents to introduce consumer testimony were opposed by Complaint Counsel and its opposition was upheld by the ALJ. The cumulative effect of the ALJ's rulings was to place himself in the shoes of "'desperate consumers with terminal illnesses'" in order to determine whether Respondents' statements concerning the Challenged Products are "likely to mislead."

In one of its earliest opinions applying its First Amendment commercial speech doctrine, the Supreme Court warned against this kind of "paternalistic approach" to protect "unwitting customers." *Virginia State Board of Pharmacy*, 425 U.S. 748, 769-770 (1976). In that case, the Court stated:

> There is ... an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed that the best means to that end is to open the channels of communication rather than to close them... It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us. *Virginia State Board of Pharmacy,* 425 U.S. at 770.

This First Amendment principle is especially applicable to efforts by government agencies to suppress commercial speech by labeling it to be misleading on "the paternalistic assumption that the recipients of [an advertisement] are no more discriminating than the audience for children's television." *Peel*, 496 U.S. at 105.

In short, there is no First Amendment short-cut for the FTC. It may not by-pass the consumers of the Challenged Products, actual or potential, by using its own views of the allegedly "misleading impression" in lieu of actual testimony from people to whom the information is directed or valid studies of such persons' responses to the statements. *Ibanez*, 512 U.S. at 148. *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (striking down Florida ban on CPA solicitation where Board "presents no studies that suggest personal

solicitation ... creates the dangers ... the Board claims to fear," nor even "anecdotal evidence ... that validates the Board's suppositions."). Nor can the FTC justify its failure to produce such testimony or such studies on the ground that, because of its expertise, it "is in a far better position than is [a court] to determine which statements are misleading or likely to mislead." *Peel*, 496 U.S. at 108.

The reason the ALJ cites for allowing Complaint Counsel to avoid its First Amendment burden of proving that people are actually misled by Respondents' statements is that Respondents' statements are not supported by "competent and reliable scientific" evidence, which Complaint Counsel defined as double-blind, placebo-controlled studies. But Respondents have not made statements claiming to be based on evidence of that type; nor could anyone reasonably infer from Respondents' statements that their claims were based on double-blind, placebo-controlled studies. Consistent with its nature as a religious ministry, Respondents did present first-person testimonies from people actually using its products. But whether Respondents' products actually helped individuals improve their health is deemed irrelevant, since it does not fall within the confines of Complaint Counsel's narrow view of "scientific evidence."

The ALJ assumes that Respondents' statements concerning the Challenged Products are "inherently misleading" without double-blind, placebo-controlled, clinical studies in evidence to support them. Yet, the United States Court of Appeals for the District of Columbia rejected a strikingly similar claim by the federal Food and Drug Administration ("FDA"). In *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the FDA asserted "that health claims lacking 'significant scientific agreement' are *inherently* misleading and thus entirely outside the protection of the First Amendment." *Pearson*,

164 F.3d at 655 (italics in original). The court of appeals dismissed the government's claim as "almost frivolous," having no basis other than in an impermissible "paternalistic assumption" that any such health claim would have such an "awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of the sale.*" *Pearson*, 164 F.3d at 655 (italics in original). The ALJ erred as a matter of law in disregarding the requirement that the government prove that the claims it attacks are misleading.

B. The Initial Decision Violates Due Process by Replacing Evidence with Presumptions.

Three cases establish an important start on this subject: *Stanley v. Illinois*[1], *Mathews v. Eldridge*[2] and *Addington v Texas*[3]. The importance of these cases lies in their explanation of the process by which courts evaluate the procedures and burden of proof due from the government in special circumstances.

The *Stanley* case concerned the due process requirements involved in parentage cases. The Court there addressed the specific question of whether the State could forego due process requirements by **allowing presumptions to supplant evidence** in the interest of efficiency. In a quote that seems to have anticipated the instant case, the *Stanley* court said:

> The establishment of prompt efficacious procedures to achieve legitimate state ends is a proper state interest worthy of cognizance in constitutional adjudication. But the Constitution recognizes higher values than speed and efficiency. Indeed, one might fairly say of the Bill of Rights in general, and the Due Process Clause in particular, that they were designed to protect the fragile values of a vulnerable citizenry from the overbearing

[1] 405 U.S. 645 (1972).

[2] 424 U.S. 319 (1976).

[3] 441 U.S. 418 (1979).

> concern for efficiency and efficacy that may characterize praiseworthy government officials no less, and perhaps more, than mediocre ones.

And then, in a quote that gets to the heart of the adjudicative presumptions applied by the ALJ in this present case, the *Stanley* court stated:

> Procedure by presumption is always cheaper and easier than individualized determination. But when, as here, the procedure forecloses the determinative issues . . . when it explicitly disdains present realities in deference to past formalities, it needlessly risks running roughshod over the important interests . . . [Such a procedure] therefore cannot stand. *Stanley,* at 656-657.

Stanley foreshadowed *Mathews*, which explained four years later the three-part test used to examine the minimum constitutional process due in a variety of procedural situations. In *Mathews*, 424 U.S. at 335, the Court considered whether a hearing prior to administrative termination of social security benefits was constitutionally required. The Court stated the three-part test for evaluating due process procedures as follows: (1) the private interest that will be affected by the official action; (2) the risk of erroneous deprivation of such interest through the procedures used; and (3) the governmental interest in the added fiscal and administrative burden that additional process would entail.

The importance of these decisions lies not in comparing the authority of the Social Security Administration with that of the FTC. Rather, the importance lies in understanding the importance of the First Amendment interest affected here; the risk of an erroneous ban of truthful claims; and the minimal additional burden that would be placed on the FTC by requiring it to prove its case with actual extrinsic evidence under a "clear, cogent and convincing" standard, rather than presuming evidence under a "preponderance" standard.

C. The "Preponderance" Standard Violates Due Process.

The U.S. Supreme Court's next decision along this line came in *Addington*. With *Mathews* as foundation, the Court addressed the standard of proof required in a civil commitment proceeding. As the Court stated at 423,

> The function of a standard of proof, as that concept is embodied in the Due Process Clause and in the realm of fact-finding, is to "instruct the fact-finder concerning the degree of confidence our society thinks he should have in the correctness of factual conclusions for a particular type of adjudication." - (Harlan, J., concurring). The standard serves to allocate the risk of error between the litigants and to indicate the relative importance attached to the ultimate decision.

In regard to the "clear, cogent and convincing" standard, the Court said this at 424-425:

> One typical use of the standard is in civil cases involving allegations of fraud or some other quasi-criminal wrongdoing by the defendant. **The interests at stake in those cases are deemed to be more substantial than mere loss of money and some jurisdictions accordingly reduce the risk to the defendant of having his reputation tarnished erroneously by increasing the plaintiff's burden of proof**. Similarly, this Court has used the "clear, unequivocal and convincing" standard of proof to protect particularly important individual interests in various civil cases. . . . [quoting *Tippett v. Maryland*[4]] a "standard of proof is more than an empty semantic exercise." In cases involving individual rights, whether criminal or civil, "[the] standard of proof [at a minimum] reflects the value society places on individual liberty."(Emphasis added.)

The cases cited within the Initial Decision to support application of the "preponderance" standard pertain to proof of the FTC's jurisdiction only. Those cases do not concern Due Process owed to the fundamental constitutional issues involved here. Indeed, this case does not involve "mere loss of money."

> [I]n certain limited circumstances, the heightened burden of clear and convincing evidence is required "when the government seeks to take unusual coercive action - action more dramatic than entering an award of

[4] 436 F. 2d 1153, 1166 (CA 4, 1971).

money damages or other conventional relief - against an individual." [citing *Price Waterhouse v. Hopkins*[5]; other citations omitted.][6]

Here, Respondents are faced with the following:

- Disregard for their religious ministry by unprecedented extension of FTC authority into their religious domain;
- Regulation by adjudication on their authorized use of truthful claims abut herbs;
- Adjudication by presumption in lieu of actual evidence on issues of harm and consumer perception;
- Adjudication by presumption in lieu of actual evidence on the truthfulness of the claims Respondents made;
- The stigma of commercial fraud allegations based on government presumptions;
- A remedy that prohibits Respondents' truthful speech; and
- An unprecedented remedy that compels Respondents to speak against their religious faith.

The Findings, Conclusions and Remedy on which these points are based cannot stand. The U.S. Constitution, the Administrative Procedures Act and the FTC enabling statutes require a result far different from the Initial Decision in this case.

III. THE FTC LACKS JURISDICTION

A. The Initial Decision's Extension of Authority over Respondents' Religious Ministry is Improper and Unprecedented.

The ALJ determined that Respondent Daniel Chapter One (DCO) is a religious ministry, properly organized as a Corporation Sole under the laws of the State of Washington as of October 30, 2002, and that Respondent James Feijo is the Overseer of DCO as called for in the statute. Revised Code of Washington (RCW) §24.12. Nonetheless, the ALJ thereafter came to conclusions about FTC jurisdiction over the

[5] 490 U.S. 228, 253 (1989)

[6] *Coleman v. Anne Arundel Cty. Police Dept.*, 797 A. 2d 770, 791 (Md. 2002).

Respondents' religious ministry that are unprecedented, legally incorrect and unsupported by the facts.

Under the Washington statute, DCO is a non-profit religious organization, notwithstanding the ALJ's unfounded legal conclusion to the contrary. The evidence showed that, beginning in 1983, operating as an unincorporated religious association,[7] Respondents traveled on missions to home churches (places of worship used by followers of the worldwide home church movement) bringing Bibles to Christian worshipers in then-Communist countries such as Poland, East Germany, and China, including being present during the demonstrations in Tienamen Square. Respondents have established missionary relationships with Christian individuals organized into worshiping communities in Holland and Israel. Respondents have worked with individuals in nursing homes and with the handicapped and youth since 1983.

As part of their missionary work, Respondents addressed the health concerns of their followers. They worked with people as diverse as the elderly in nursing homes, with the physically and mentally challenged, and with high performance athletes. As they worked with these individuals, guided by their Biblical studies they began creating dietary guidelines drawn from the Bible. This work ultimately led to their developing the DCO products.

Consistent with their status as a Corporation Sole, Respondents do not make a profit. The evidence showed that their newsletters and handbooks are provided for free or small donations. Respondents maintain a non-profit charitable program that allows anyone to obtain products for free. The Corporation Sole's Overseer, Respondent James

Feijo, holds in trust all the property belonging to Respondent DCO. Respondent James Feijo and his wife, Patricia Feijo, have taken an effective vow of poverty.

In its organization and operation, DCO is a not for profit religious organization and as such is not subject to the jurisdiction of the Federal Trade Commission. The ALJ's finding of FTC jurisdiction over Respondents is based on the above-referenced Due Process errors and misapplication of the law.

1. The FTC Has No Jurisdiction Over Non-Profit Businesses Or Associations Except Those Associations That Engage In Anti-Competitive Practices That Provide Substantial Benefits To Their For-Profit Members.

In *California Dental Association v. Federal Trade Commission*[8], the US Supreme Court addressed FTC's jurisdiction over non-profit organizations, holding that, "The FTC Act gives the Commission authority over *persons, partnerships, or corporations*." *Corporation* is defined to include "any company . . . or association, incorporated or unincorporated, without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members." The *California Dental* Court went on to adopt a standard, proposed by the FTC itself, that "the Commission has jurisdiction 'over anticompetitive practices by nonprofit associations whose activities provid[e] **substantial** economic benefits to their for-profit members' businesses.'" (Emphasis added.)

The court expanded its reasoning as follows:

> To be sure, proximate relation to ***lucre*** must appear; the FTC Act does not cover all membership organizations of profit-making corporations without more and an organization devoted solely to professional education may lie outside the FTC Act's jurisdictional reach, even though the quality of professional services ultimately affects the profits of those who deliver them. (Emphasis added.)

[8] 526 U.S. 756 (1999).

The evidence showed that Respondents have no for-profit members and only one non-profit member. Lucre (i.e., profit) must flow to members of the non-profit in order for the FTC to exercise jurisdiction. In the *California Dental* case, the profit was evident and thus standards for evaluating "profit" were born.

> Through for-profit subsidiaries, the CDA provides advantageous insurance and preferential financing arrangements for its members, and it engages in lobbying, litigation, marketing, and public relations for the benefit of its members' interests. This congeries of activities confers far more than *de minimis* or merely presumed economic benefits on CDA members; the economic benefits conferred upon the CDA's profit-seeking professionals plainly fall within the object of enhancing its members' 'profit,' which the FTC Act makes the jurisdictional touchstone.

DCO engages in none of these activities and has no for-profit subsidiaries.

The ALJ here did exactly what the *CDA* Court forbade. He presumed economic benefit to DCO's Overseer. With this in mind, the CDA Court's analysis deserves a deeper look, because the court spelled out in more detail what it meant by "profit." The CDA court said, "according to a generally accepted definition profit 'means gain from business or investment over and above expenditures, or gain made on business or investment where both receipts and payments are taken into account...,'" quoting *American Medical Assn. v. Federal Trade Commission*[9].

2. <u>As a Corporation Sole, Respondent DCO Exists As A Legitimate Entity Outside The Jurisdiction Of The FTC</u>.

Respondent DCO operates as a church and "Churches ... may be legally organized in a variety of ways under state law, such as unincorporated associations, nonprofit

[9] 455 U.S. 676 (1982).

corporations, **corporations *sole, and charitable trusts.*"** IRS Tax Guide for Churches and Religious Organizations, p. 2 (italics original; bold added).

A corporation sole is composed of a series of natural persons who hold the office of religious leader of the particular religious organization. *In re the Catholic Bishop of Spokane.*[10] "The corporate sole statute specifically authorizes the Bishop, who is deemed to be the body corporate, to hold the property in trust.... The trustee holds only 'bare legal title'..." *In re Catholic Bishop*, p. 325. While the Washington statutes do not establish a trust, they do require that the Articles of Incorporation of a corporate sole provide that all property of the corporation must be held in trust "for the use, purpose, benefit and behoof of [the overseer's] religious denomination, society or church." *In re Catholic Bishop*, p. 326 and Revised Code of Washington, Chapter 24.

The evidence showed that Respondents met all of these qualifications.

a. A Corporate Sole May Engage in Commerce to Further its Charitable Purpose

The modern corporate sole statutes "are meant to provide a framework for the operation of a continuing concern. They are also both meant to provide a structure for the planning, financing, direction and management necessary for an organization existing and working in a sophisticated business environment." O'Hara, *The Modern Corporate Sole*, 93 Dickinson L. Rev. 23, 35 (1988). According to Washington State law, "a corporate sole ... is a legal entity with powers to sue and be sued, hold and manage property, enter into binding contracts and generally take other actions and engage in other activities common to legal entities ...." *In re Catholic Bishop*, p. 325.

b. Respondents' Articles of Incorporation established a Religious Trust.

[10] 329 Bankruptcy Rep. 304, 326 (U.S. Bank. Ct., E.D. Wash. 2005).

As with the Roman Catholic Church in *In re Catholic Bishop*, the evidence established that Articles 3 and 4 of the Articles of Incorporation of Daniel Chapter One established a religious trust, having designated Daniel Chapter One as the beneficiary of the trust required by law of all corporate soles. As a corporate sole engaged in the work of an apostle (health care ministry proselytizer) and evangelist (health care ministry preacher), the property of which is held in trust for that apostolic and evangelistic ministry, such property cannot legally, and does not, in fact, inure to the private benefit of the Feijos.

3. It Is The FTC's Burden Of Proof To Show That Respondent DCO Is Organized To Carry On Business For Its Own Profit Or That Of Its Members.

In order for the FTC to have jurisdiction over DCO, Complaint Counsel would need to prove that DCO is a "corporation ... which is organized to carry on business for its own profit or that of its members." 15 U.S.C. sections 44 and 45(a)(2). The Initial Decision failed to require such proof.

In *Community Blood Bank of the Kansas City Area, Inc. v. FTC*[11], the court rejected the FTC claim that it has jurisdiction over "any corporation engaged in business only for charitable purposes and which is forbidden by law to carry on business for profit ...." *Community Blood Bank*, at 1016.

Congress "did not intend to bring within the reach of the Commission any and all nonprofit corporations regardless of their purposes and activities." *Community Blood Bank,*, at p. 1018. Thus, "even though a corporation's income exceeds its disbursements, its non-profit character is not necessarily destroyed." *Community Blood Bank,*, at 1017.

[11] 405 F.2d 1011 (8th Cir. 1969).

The evidence showed that DCO operates at a breakeven point or less. Complaint Counsel provided no evidence that DCO's income from the sale of its products exceeds the cost of goods sold and overhead expenses. That alone should be fatal to the FTC's position. However, even had Complaint Counsel provided such evidence, it still would not support FTC jurisdiction.

Rather, the FTC must show more, namely, that "making profits [from the sales of its products] is more than a subordinate ...characteristic of [DCO's] existence for it to be considered one operated for profit." *Community Blood Bank of the Kansas City Area.* In order for the FTC to satisfy its burden of proof, it must show that DCO and the Feijos are engaged in business for profit for themselves, not for the purposes stated in the DCO Corporate Sole Articles of Incorporation and reflected in their actual operations.

B. The FTC Has Not Met its Burden of Showing that DCO is Not a Non-profit Corporation Organized and Operated for Charitable Purposes as a Corporate Sole Under Washington State Law.

As the ALJ points out on page 69 of his opinion, the FTC does not have jurisdiction over a corporation solely because it engages in business. To exercise jurisdiction over Respondents, the FTC must show not only the "source" of DCO's income, but also its "destination." That is, the FTC must prove that the corporation or its members derived a profit from DCO's activities. Initial Decision, p. 69. The burden is on the FTC, not on Respondents.

With respect to the **source** of DCO's income, the ALJ found that the FTC sustained the entirety of its burden by showing that the products at issue were sold at a profit. Findings of Fact Nos. 8, 9, 10, 80-84, Initial Decision, pp. 6-7, 14. His findings did not establish that the products were sold at a net profit—that is the reasonable cost of

goods, overhead, and general operations were exceeded by income. But, even if true, the ALJ's findings do not support the next required step in the FTC's burden: the ALJ's conclusion that the **destination** of DCO's income was for the profit of either DCO or its sole member, James Feijo. Rather, the ALJ shifted the burden of proof from the FTC to Respondents to show that the income did not profit either DCO or its member, contrary to the ruling in *Community Blood Bank of the Kansas City Area, Inc.* v. *FTC*.[12]

1. The Evidence Does Not Prove That DCO Is Organized And Operated For Its Own Profit.

The ALJ acknowledged that there was uncontested testimony that DCO began as a "house (sic) church." Finding of Fact No. 11, Initial Decision, p. 7. He also acknowledged that there was uncontested testimony that DCO was "created for the purpose of healing based on ... biblical verses, including Daniel Chapter One, and that DCO engaged in "ministry activities includ[ing] helping house (sic) churches in other countries, holding religious meetings, performing baptisms, ... performing healings, and reaching out to interested persons to inform them about ... the integration of spiritual and physical well being." Findings of Fact Nos. 16, 17, and 18, Initial Decision, p. 7. Additionally, the ALJ found as a matter of fact that DCO was engaged in "nutritional counseling," housing the homeless, supporting an athletic team, and in giving away DCO products. Findings of Fact Nos. 19-21, Initial Decision, p. 8.

Thus, the ALJ concluded that "it is not disputed that DCO has engaged in **some** charitable activities." Initial Decision, p. 73. Yet, it faulted DCO for not "provid[ing] documents to indicate how much of DCO's products they have given away or how much financial support they have dedicated to its charitable activities, and the testimony on this

[12] 405 F.2d 1011, 1015 (8th Cir. 1969).

point was **inconclusive."** Initial Decision, p. 73 (emphasis added). If inconclusive, then the FTC has failed to sustain its burden of proof that DCO's income did not go to charitable purposes, especially considering that DCO was organized as a corporate sole under the statutes of Washington State and that DCO was:

- duty bound by its Articles of Incorporation and by state law to engage only in charitable activities. Articles 1, 2, and 3 and RCW 24.12.010 and 24.12.030; and
- duty bound by Article 4 and RCW 24.12.030 that all properties in which DCO acquires any interest, including real and personal property, "shall be held in trust for the use, purpose, benefit, and behalf of [DCO]."

To rule to the contrary without sufficient evidence, as the ALJ has done, is to disregard the DCO Articles of Incorporation, the relevant Washington statutes, and the undisputed evidence in this case. Initial Decision, pp. 71-73 and Findings of Fact Nos. 22-36.

2. The ALJ Did Not Require The FTC To Meet Its Burden Of Showing That DCO Was Operated For The Profit Of Its Member, James Feijo.

The ALJ has also disregarded the evidence in this case that DCO's sole member, James Feijo, does not profit from the DCO's activities. The ALJ summarily concluded that since "DCO distributes funds to support all of the living expenses of both James and Patricia Feijo" DCO operates in such a way as to "profit" the Feijos. Initial Decision, p. 73 and Findings of Fact Nos. 55-70. Payment of expenses, however, is not evidence that the income received by DCO from its sales of products is destined to profit the Feijos.

Rather, payment of their expenses enables the Feijos to carry out the charitable and religious ministry of DCO. It is commonly understood business practice to recognize such expenses as a cost to, rather than a profit for, a business.

Just as was the case in *Community Blood Bank*, payments received by the Feijos enabled the Feijos to promote the religious and healing ministry of DCO, which they do full-time. Absent evidence to the contrary, these efforts are not infected by commercial intent. Nevertheless, the ALJ determined that the expenses paid to the Feijos enabled them to "live lavishly." Initial Decision, p. 75. In order to sustain this finding, however, the ALJ made findings about expense reimbursements. A far less arbitrary and capricious method would have been to break the expenses down in monthly reimbursement amounts. Viewed in this context, such monthly amounts are not lavish, and thus should not be considered "profit" to the Feijos, but reasonable and necessary in the carrying out of DCO's mission. Findings of Fact Nos. 67-70, Initial Decision, pp. 12-13 and 75.

The fact is that the ALJ made no finding whatsoever about the relationship of the expenses paid, the checks cut, the credit cards used, etc. on the one hand, and the charitable and religious purposes of DCO on the other hand. Instead, he presumed. And in so doing, he shifted the burden of proof to Mr. Feijo to prove otherwise. In contrast to *Ohio Christian College*, upon which the ALJ relies, there is no evidence here, nor even an assertion by Complaint Counsel, that DCO was a sham operation, operating solely as a cover to profit the Feijos.

3. The ALJ Failed To Consider Evidence Bearing On James Feijo's Status.

a. Exempt Business Activities

Churches may carry on ordinarily non-exempt "business" activities. If these "business" activities are church-related (such as publication of religious books and periodicals) they are also exempt from federal income taxes. Additionally, certain types of "passive" income of churches are also exempt (this category includes dividends, interest, royalties and capital gains).

b. Religious Workers' Special Exemptions

Individual Ministers and members of religious orders have special tax law provisions that apply to them. Insofar as religious workers receive secular income, it will be reportable and taxable as any other person's income. Church-related income, however, is treated differently.

First, church-related income is exempt from withholding under IRS Code Section 3401(A)(9).

Second, the income is exempt from the Social Security Tax, Section 3306(c)(8), if the proper form is filed (No. 4361 for Ministers, 4029 for members of religious orders).

Third, a Minister's Parsonage Allowance, under Section 107, is "excluded from gross income" and is not taxed or reportable as income at all. This includes rental or mortgage and realty tax costs, repairs, utilities and other expenses necessary to provide a parsonage. The Law permits the payment of these expenses directly by the Church, by donors or even by the Minister.

Regulation 1.107.1 provides that the Parsonage Allowance includes expenses that are directly related to providing a home (including maintenance, repairs and enhancements) except expenses for food and servants. In the case of a home owned by the church or minister, the expenses may also include real estate taxes and mortgage

payments. The Parsonage Allowance does not include the Minister's Professional Expenses (which are paid or reimbursed separately from the Allowance) nor any personal Stipend, Reimbursement, Gratuity or Gift received by the Minister.

Fourth, as noted above, all of a Minister's Professional Expenses (office, educational, ministerial travel, entertainment, etc.) may be paid as an ordinary business expense of the Church. Again, this is not personal income to James Feijo.

Very clearly, the ALJ did not consider these provisions to any extent whatsoever. Pursuant to the Parsonage Allowance, DCO funds used for James Feijo's home and other incidentals are not income to him. As a matter of law, those funds do not inure to his benefit and thus under no circumstances could be considered profit.

IV. THE ALJ'S FINDINGS AND CONCLUSIONS IN REGARD TO 15 USC §§ 45 AND 52 WERE UNCONSTITUTIONAL, INCLUDED ERRORS OF LAW AND LACKED SUBSTANTIAL EVIDENCE

A. The ALJ Has Improperly Regulated By Adjudication.

There are two exceptions to the general principle that the choice between rulemaking and adjudication lies within an agency's discretion. First, an agency may not articulate new principles through adjudication if doing so would disadvantage those who had relied on existing law. *Weight Watchers v. FTC*, 830 F. Supp. 539, 542 (W.D. WA 1993); 1993 U.S. Dist. LEXIS 12555. Second, "the agency may not use adjudication to circumvent the APA's rulemaking procedures by . . . amending . . . or bypassing a pending rulemaking proceeding." *Id.* Accord, *Montgomery Ward v. FTC*, 691 F. 2d 1322 ((9th Cir. 1982); 1982 U.S. App. LEXIS 24194.

Here, the FTC's violation of these exceptions is a violation that has been perpetrated in concert with the FTC's sibling agency, the FDA. Consider the following:

- On or about April 29, 1998, the FDA issued a proposed rule titled *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body.*
- On or about August 27, 1998, the FTC issued its comments in response to this proposed rule. These comments included the following:
    - "The FTC and FDA have complementary jurisdiction to address the marketing of dietary supplements. . . Their shared jurisdiction means that the two agencies coordinate closely to ensure that their actions are consistent to the fullest extent feasible given the statutory authority of each.
    - "The newly proposed amendment to this rule defining permitted structure/function claims does not . . . explicitly restate that such claim be substantiated."
    - *FTC staff recommend that any final rule reiterate explicitly the requirement that structure/function claims be adequately substantiated.* (Italics supplied in original.)
    - *[FTC] Staff also recommends that FDA include guidance in the final rule as to what constitutes adequate substantiation of a structure/function claim.* (Italics supplied in original.) This would help address uncertainty within the dietary supplement industry about how FDA applies the DSHEA substantiation requirement. It would also clarify how the FDA's approach to substantiation relates to FTC's substantiation standard.

[Note that at no time has the FTC ever had any rule or regulation pertaining to dietary supplements specifically, least of all regulations covering the standards for substantiation. Clearly, the FTC has deferred – then and now – to the FDA on this area of law.]

- On January 15, 1999, the D.C. Circuit Court of Appeals issued its decision in *Pearson v. Shalala*, wherein the Court expressed concerns nearly identical to

the FTC's concern expressed just months earlier about the lack of clear standards for adequate substantiation.[13]

- The FDA's final rule was issued on or about January 6, 2000.[14] That rule includes nothing that addresses the FTC's concerns, nor the *Pearson* Court's directions.

The matter of what constitutes adequate substantiation for dietary supplement health claims remains one of guesswork on the part of the regulated classes. And as stated by the *Pearson* Court at 660, the omission continues to be arbitrary and capricious on the part of the regulating agencies.

The effect is especially egregious here, where the ALJ has adjudicated the elements of the government's case under 15 U.S.C. §§45 and 52 by presumption, rather than with required extrinsic evidence, and where he has allowed the burden of proof to shift to Respondents. Before this approach can be sanctioned, it must be the subject of proper rulemaking, not regulation by adjudication.

B. The ALJ Erred As A Matter Of Law In Finding That Respondents' Products Are Drugs.

The ALJ concluded that Respondents' statements were misleading, not because they were false, but because Respondents lacked substantiation. That is, Respondents' speech did not constitute "establishment claims" because Respondents did not express a specific level of substantiation. Instead, the ALJ evaluated Respondents' speech as "non-establishment" claims. Furthermore, he did so not on the basis of Respondents' express

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[14] Federal Register: January 6, 2000; Vol. 65, No. 4.

structure/function claims, but on the basis of the purported "overall net impression" of Respondents' speech. This approach is rife with error.

1. The ALJ Erroneously Shifted The Burden Of Proof On The Elements Of Deception.

First, the Initial Decision on these points gives a specific example of how the ALJ shifted the burden of proof to the Respondents. Had Complaint Counsel charged that Respondents' speech was outright false, then without question, it would have the burden of so proving. By adopting by judicial fiat that there was no reasonable basis for Respondents' claims (the purported implied claims, no less – not express claims), the ALJ shifted the burden of proof to Respondents to show that their claims were **not** misleading or deceptive. As the ALJ plainly stated it, under the FTC's "reasonable basis theory," Respondents have "the burden of establishing what substantiation they relied on for their product and Complaint Counsel has the burden of proving that [Respondents'] purported substantiation is inadequate." Initial Decision, p. 100.

To close the loop on his error, the ALJ stated that, as matter of law, the only way that Respondents could meet this substantiation burden was to demonstrate that they had "competent and reliable scientific evidence" consisting of placebo-controlled double-blind clinical drug trials for its claims. This burden was imposed on Respondents, notwithstanding the fact that they had made absolutely no representations that their claims were based on such evidence, and thus, that no consumer could have been affirmatively misled to believe that they were making any such scientific claim. In fact, Respondents based all their claims on "competent and reliable scientific evidence" that is recognized by herbal science, and presented expert witnesses to verify that fact.

Complaint Counsel presented no evidence, and none was cited in the Initial Decision , that the statements about herbs presented by Respondents misled anyone.

This approach violates Due Process.

2. The ALJ Misapplied The Element Of Intention.

The ALJ held that Respondents' subjective intent had no bearing on the overall net impression of their representations. This finding was essential to reach the outcome of the Initial Decision, since authentic examination of Respondents' intent, as shown by the evidence, would establish that Respondents did not intend for their products to be considered drugs at all. On the contrary, Respondents' claims were that their Biblically-based approach to health care – including the Challenged Products – could reinforce the naturally healing capability of the body, including the immune system, and thereby provide adjunct support for whatever path—drugs, radiation, surgery or other--an individual freely chose to take for their cancer care regimen. Respondents took considerable steps to express their intent that their approach was not based on drug tests, and was not to replace the advice of a medical doctor or other health professional.[15]

By ignoring the element of Respondents' intent, the ALJ committed another error of law. Subjective intent is not an element unless the statute requires it. In the case of DSHEA and 15 U.S.C. §55(c), intent is expressly an element of the government's burden of proof. *NNFA v. FDA*[16] and *NNFA v. Mathews, et. al.*[17] In fact, Respondents' intent is a key element in one of the threshold findings that Complaint Counsel was required to prove. *NNFA v. Mathews*. The ALJ ignored Respondents' intent and the substantial

[15] Respondents' disclaimer included not only the required language, it also included substantial spiritually-based qualifications which were virtually ignored by the ALJ.

[16] 504 F. 2d 761 (2nd Cir. 1975).

[17] 557 F. 2d 325 (2nd Cir. 1977).

evidence that Respondents assiduously avoided any possible confusion between their products and pharmaceutical drugs.

3. The ALJ Ignored Respondents' Structure/Function Claims.

As discussed in greater detail below, the government's expert did not know what a structure/function claim was, despite the fact that the authorization provided by DSHEA for such claims was central to the case. The ALJ's dismissal of the significance of this lack was based on the same impermissible presumptions, shifts of the burden of proof, and errors of law as were used to justify ignoring Respondents' express claims. At no time has Complaint Counsel or the ALJ ever raised a real challenge to Respondents' express claims, which were structure/function claims. Yet, the ALJ's remedy would apply to those structure/function claims all the same.

C. The Initial Decision Improperly Requires Double-Blind, Placebo-Controlled Clinical Trials As Substantiation For Structure-Function Claims.

As discussed above, the Initial Decision turns entirely on the ALJ's improper presumptions, accepted in lieu of extrinsic evidence, and on the burdens of proof he improperly shifted to Respondents. It is on the basis of these that he was able to ignore Respondents' express claims, Respondents' entire religious context, and Respondents' specific and clearly expressed intent to avoid association with pharmaceutical medicine. From there is was a short step to requiring Respondents to conduct double-blind, placebo-controlled trials for substantiation, contrary to law.

The testimony of Dr. Denis Miller, the only substantive witness offered by Complaint Counsel, was narrowly focused. Cancer drugs, he testified, must be tested by double-blind, placebo-controlled clinical trials to receive approval by the US Food and

Drug Administration. Complaint Counsel rested its case on the presumption that only substantiation by double-blind, placebo-controlled clinical trials, as required by the Food and Drug Administration under the US Food Drug and Cosmetic Act for approval of drugs, qualifies as competent and reliable scientific evidence to substantiate the claims made by Respondents.

However, the FTC Act does not require double blind, placebo-controlled trials as the basis for reasonable substantiation. In fact, as described above, the FTC could not create such a standard, without APA rulemaking, if it could at all, since such a standard is so far afield from established practice.

The Food Drug and Cosmetic Act (FDCA) itself does not require such studies for structure or function claims for dietary supplements which are allowed by the Dietary Supplement Health and Education Act (DSHEA), a 1994 amendment to the FDCA.[18] "*Placebo-controlled, double-blind testing is not a legal requirement for consumer products.*" *FTC v. QT*, 512 F. 3d 858, 861 (7th Cir. 2008). In the *FTC v. QT* case, the U. S. Court of Appeals for the Seventh Circuit spelled out the argument graphically, saying:

> Defendants maintain that the magistrate judge subjected their statements to an excessively rigorous standard of proof. Some passages in the opinion could be read to imply that any statement about a product's therapeutic effects must be deemed false unless the claim has been verified in a placebo-controlled, double-blind study: that is, a study in which some persons are given the product whose effects are being investigated while others are given a placebo (with the allocation made at random), and neither the person who distributes the product nor the person who measures the effects knows which received the real product. Such studies are expensive, not only because of the need for placebos and keeping the experimenters in the dark, but also because they require large numbers of participants to achieve statistically significant results. Defendants observe that

[18] The Dietary Supplement Health and Education Act of 1994 (DSHEA) added section 403(r)(6) to the Federal Food, Drug, and Cosmetic Act.

> requiring vendors to bear such heavy costs may keep useful products off the market (this has been a problem for drugs that are subject to the FDA's testing protocols) and prevent vendors from making truthful statements that will help consumers locate products that will do them good.
>
> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. The burden is on the Commission to prove that the statements are false. (This is one way in which the Federal Trade Commission Act differs from the Food and Drug Act.) Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable how much the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. Placebo-controlled, double-blind testing is not a legal requirement for consumer products.

Dr. Miller could not testify about the meaning of a "structure or function" claim, the distinction between health claims and structure or function claims, or any other aspects of DSHEA. The phrase "structure or function" in the context of dietary supplement claims refers to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 26, fn. 2. The permission granted by DSHEA for Dietary Supplement Structure or Function claims is consistent with FTC standards. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10 and fn. 3.

Though he summarily dismissed the FTC Guideline by ignoring Respondents' express structure/function claims, the ALJ did not adequately explain away the following express FTC policies and Guidelines for dietary supplements, nor why these standards do not apply to Respondents' express claims:

- "The FTC's standard for evaluating substantiation [for dietary supplement claims] must be sufficiently flexible to ensure that consumers have access to information about emerging areas of science." *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 8.
- There is no requirement that a dietary supplement claim be supported by a specific number of studies. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.
- Research concerning the biological mechanism underlying the claimed action is acceptable as reasonable substantiation for claims about dietary supplements. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.

D. The ALJ Erred As A Matter Of Law Concerning The Elements Of 15 USC §§45 And 52.

1. The FTC's Case Failed To Establish Necessary Elements Of Proof.

The shortcomings in the Initial Decision extend to several elements of required proof.

a. General Elements of Proof.

i. The Elements of Proof under 15 USC § 45(n).

To prove unfairness, Complaint Counsel must prove that:

> the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination. 15 U.S.C. §45(n)

The ALJ disagrees, but the relevant case law and FTC policy show that these same standards apply to deceptive and misleading charges under 15 U.S.C. §45(a) and 52. First, this standard of proof is a clear statutory expression that extrinsic evidence is required, and that policy considerations alone (e.g., presumption) will not suffice. Second, this standard of proof tracks the standards that have been set forth by past adjudications.

b. The Elements of Proof under the Reasonable Basis Test.

For non-establishment claims, the FTC employs a reasonable basis test for determining whether an alleged advertisement is deceptive. *Pfizer, Inc.* 81 FTC 23, 62 (1972); *FTC v. Pharmatec*, 576 F. Supp. 294, 302 (DDC, 1983). The reasonable basis for a product claim differs with the particular product at issue, and depends on factors that include the degree to which consumers will rely on the claim (i.e., whether alleged harm is reasonably avoidable by consumers). *Pfizer*, at 64 and *Pharmatec*, at 302. This element alone was never proved by Complaint Counsel, nor considered by the ALJ.

As a general rule, extrinsic evidence is required to prove the inference of deceptive advertising. *FTC Policy Statement on Deception*, appended *to Cliffdale Associates*, 103 FC 110, 174 (1984), hereinafter "*Cliffdale* Statement." This is particularly true on the issue of consumer perceptions or expectations, where extrinsic evidence or expert testimony is necessary to prove consumer perceptions of an advertising message. *Thompson Medical v. FTC*, 791 F.2d 189, 197 (D.C.Cir. 1986), and *FTC Policy Statement Regarding Advertising Substantiation*, appended *to Thompson Medical v. FTC*, 104 FTC 648, 839, aff'd 791 F.2d 189 (D.C.Cir. 1986), hereinafter "*Thompson* Policy Statement." The reasonableness of a representation or practice that affects or is directed primarily to a particular group is evaluated from the perspective of a member of that group. *Cliffdale* Statement.

Again, Complaint Counsel produced no evidence at the hearing to meet its requirements under the "reasonable basis" test. And the Initial Decision did not address this requirement in any proper fashion.

c. The Elements of Proof for an Overall Net Impression Case.

When the charges against a Respondent are based on the "overall net impression" rather than on express claims, as is the case here, those charges must be proved by substantial evidence of consumer expectations in order for Complaint Counsel to prevail. *Thompson*[19], 791 F. 2d at 197. Accord, *Thompson* Policy Statement at p. 2. Nevertheless, the ALJ allowed Complaint Counsel to skip this requirement in favor of a presumption.

Absent actual evidence of consumer expectations, according to the *Thompson* Policy Statement, the FTC's substantial evidence must address the following 6 factors:

- The type of claim;
- The Products;
- The consequences of a false claim;
- The benefits of a truthful claim;
- The cost of developing substantiation for the claim;[20] and
- The amount of substantiation experts in the field believe is reasonable.

Thompson Policy Statement at p. 2.

These factors are virtually identical to the standards of proof of §45(n), and underscore the statutory mandate requiring the FTC to prove its case with extrinsic evidence. Indeed, the *Thompson* Policy Statement states clearly that these factors apply to charges of false/misleading advertising, deception and unfairness. "The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include [the 6-point list described above.]"

The Commission must also examine the allegedly deceptive practice from the perspective of a reasonable consumer. If the representation is directed *primarily* to a

[19] *Thompson Medical*, 104 FTC 648 (1984), aff'd 791 F. 2d 189 (D.C Cir 1986).

particular group, the FTC is required to examine reasonableness from the perspective of that group.[21] *Cliffdale* Statement. That is, the FTC must determine the effect of the challenged claims on a reasonable member of the target group. In this case, that group consists of individuals devoted to natural health in general and the constituents of Respondents' religious ministry in particular.[22]

When such a specific group of recipients is involved, extrinsic evidence about that group's reasonable perceptions is necessary. *Cliffdale* Statement. In *Thompson*, 791 F. 2d at 197, the Circuit Court made special note that "The issue of [consumer perception of the claims] was extensively addressed by expert testimony."

Nothing of the sort was offered here, nor considered by the ALJ.

d. Specific Elements of Proof for Dietary Supplement Claims.

The ALJ never considered the extent to which Respondents' express claims were permissible structure/function claim under DSHEA. It dodged that question by means of presumptions purportedly allowed by the "overall net impression" analysis. Nevertheless, Respondents' express statements are permitted by DSHEA.

The Dietary Supplement Health and Education Act (DSHEA) allows dietary supplement manufacturers to make "structure or function" claims about their products:

> [A] statement for a dietary supplement may be made if:
>
> > (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, **describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,** characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or

[21] Note that the representation need not be directed *exclusively* to a particular group.

[22] *Cliffdale* Statement at footnotes 13 and 29.

> describes general well-being from consumption of a nutrient or dietary ingredient,
> (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and
> (C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
> A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

21 USC §343(r)(6). [Bold emphasis added.]

The meaning of this statute is well settled: a natural supplement provider is lawfully allowed to make structure or function claims describing how a particular nutrient or dietary supplement may affect a structure or function of the human body. *Pearson v. Shalala*, 164 F. 3d 650 (1999); and *U.S. v. Lane Labs*, 324 F. Supp. 2d 547, 565 (D.N.J., 2004).

Furthermore, as previously stated, the FTC's position with regard to dietary supplement claims is clear:

- "The FTC's standard for evaluating substantiation [for dietary supplement claims] must be sufficiently flexible to ensure that consumers have access to information about emerging areas of science." *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 8.
- There is no requirement that a dietary supplement claim be supported by a specific number of studies. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.
- Research concerning the biological mechanism underlying the claimed action is acceptable as reasonable substantiation for claims about dietary supplements. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.

The ALJ's analysis rationalized away DSHEA and the FTC's own guidelines for dietary supplement claims. Complaint Counsel's expert's testimony concerned only the reasonable basis for he Approval by the FD of claims about chemotherapeutic agents. He made no reference to, or claimed any expertise about, the standards that govern claims

made for dietary supplements. As described more fully below, Complaint Counsel's expert testimony was not relevant under, and did not take into consideration, either DSHEA or the FTC's Official Guidance to the Dietary Supplement Industry, which says that the amount and type of substantiation required for dietary supplements is determined by what experts *in the relevant field* would consider to be adequate.[23]

What the FTC's Dietary Supplement Guide requires from experts is consistent with the qualifications required of an expert under the relevancy prong of the *Daubert* standard.[24] Complaint Counsel's expert did not even know what a structure or function claim was! Miller, Tr. 173-174.

In contrast, Respondents' experts Dr. Duke and Dr. LaMont testified competently about dietary supplements. The FTC's need for qualified expert testimony from the field of dietary supplements is drawn from the sharp distinction drawn by Congress between the regulation of dietary supplement claims on the one hand, and the regulation of drugs on the other hand.

Dr. LaMont's testimony in particular demonstrated that Respondents' claims are proper structure or function claims. Nowhere on the face of the actual, express statements by Respondents do Respondents state that their products "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," which are the claims prohibited by DSHEA. Each of the Respondents' statements on their face describe how the products and/or their constituent ingredients support the structure or function of the human body, e.g., as "adjuncts" to – not in lieu of - cancer or other health treatment.

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[23] *Dietary Supplements: An Advertising Guide for the Industry*, produced by Complaint Counsel as evidence of policy in this case. A copy is provided at Appendix 2, Bates no. FTC-Respondents 1041 to 1070, p. 1052, specifically.

[24] *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

Dr. LaMont's testimony was largely unchallenged. Yet, the ALJ choose to disregard it.

E. The ALJ Improperly Perpetuated Adjudication By Presumption In The Way He Weighed Expert Testimony On Structure/Function Claims.

1. The ALJ Ignored Obvious Shortcomings In The Testimony Of The Government's Expert.

The testimony of Complaint Counsel's expert should have been rejected. That testimony consisted almost entirely of how inherently dangerous single entity chemicals, proposed for use as pharmaceutical drugs, are to be tested and approved. Once again, in order to treat this testimony as relevant, the ALJ employed the presumptions of his "overall net impression" analysis, and allowed Complaint Counsel's expert to do the same.

Complaint Counsel's expert concluded, contrary to law, that only double-blind, placebo-based clinical trials can be used to substantiate claims about dietary supplements. The ALJ allowed the FTC expert to buy into the "overall net impression" approach, while simultaneously allowing him to avoid consideration of the Respondents' express claims themselves. In fact, though the FTC expert disavowed any expertise in consumer perceptions, the ALJ allowed him to speculate about how people will perceive and respond to Respondents' purported implied statements.

Not only should Complaint Counsel's expert's testimony been given little or no weight, the Respondents' Motion in Limine concerning the FTC expert's testimony should have been granted at the outset.

2. The ALJ Improperly Perpetuated Adjudication By Presumption By Ignoring The Qualifications Of Respondents' Experts On Structure/Function Claims.

In contrast, the Respondents' experts hit the mark. Respondents' expert Dr. James Duke is a renowned botanist who, for thirty years, worked for the U.S. Department of Agriculture and the National Institutes of Health on the creation of natural products of various kinds from herbs. He is widely published and recognized as one of the most knowledgeable individuals in the world on the nature of herbs.

Similarly, Respondents' expert Dr. Sally LaMont is a licensed naturopath, trained and practiced in the treatment of patients with herbs. She has acted as policy advisor on herbal laws in California. She is versed in the herbal science literature.

In both cases, Drs. Duke and LaMont qualified and testified consistent with the FTC's own guidelines for dietary supplements.[25]

Both Drs. Duke and LaMont testified about Respondents' express statements. They found that those express statements were (a) truthful; and (b) supported by adequate substantiation. Their credibility, authenticity and accuracy were unchallenged. Their testimony deserved greater weight than afforded to them by the ALJ, and certainly greater weight concerning Respondents' truthful express statements than that afforded to Complaint Counsel's expert.

V. THE PROPOSED REMEDY IS ILLEGAL

The remedy fashioned by the ALJ in his Initial Decision is arbitrary and capricious. It is grounded in the constitutional and statutory violations discussed above. As a result, the Commission should reject it entirely.

[25] The FTC's Dietary Supplement Guidelines to Industry state that in making the determination about the amount of substantiation necessary for structure/function claims, the FTC "consults with experts from a wide variety of disciplines, including those with experience in botanicals and traditional medicines."

A. Recent Developments in the Law Require the Commission to Take a Close and Critical Look at the Remedy Here.

The very recent decision issued by Judge Cavanaugh of the U.S. District Court for New Jersey in *FTC v. Lane Labs*[26] should be instructive and considered here. Judge Cavanaugh's opinion addressed the FTC's efforts to enforce overly broad remedies against a dietary supplement manufacturer. His rejection of the FTC's improper tactics included comments that bear on the ALJ's remedy in this case.

For example, Judge Cavanaugh considered the substantiation relied upon by the manufacturer – substantiation that was considerably less than double-blind clinical trials. He credited the manufacturer with the following comment by stating, "This is not a case of a company making claims out of thin air." Drs. Duke and LaMont testimony proved that Respondents' claims were also not made from thin air.[27]

Judge Cavanaugh also credited the dietary supplement manufacturer for adequate substantiation for their express claims when he stated that, "[the manufacturer] provided credible medical testimony that the products in question are good products and could have the results advertised . . ." This is exactly the proof and testimony provided by Drs. Duke and LaMont on behalf of Respondents here.

Finally, in a statement that speaks for itself and also has direct application here, Judge Cavanaugh said this:

> [T]he Court notes that there has been no physical harm to the public. The FTC seeks to [enforce the remedy] to cure consumer injury . . . Despite the FTC's claims, the FTC provides no evidence that consumers have complained that they were physically harmed by the use of [the]

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[26] Civil Action no. 00-cv-3174 (DMC), unpublished decision issued August 10, 2009.

[27] In this regard, the current case is dramatically distinguishable from the QT case and the Direct Marketing case on which Complaint Counsel and the ALJ so inappositely rely.

supplements. This compounds the fundamental fairness issues in this case.

Since its formation in 1980 and expanding into its herbal ministry in 1986 Daniel Chapter One has received no complaints from people who use its herbs. Indeed, it has received hundreds of positive testimonials.

B. The Proposed Remedy Would Constitute An Arbitrary, Capricious And Retaliatory Attack On Respondents' Constitutional Rights.

In the Initial Decision, the ALJ omitted any evidence and legal analysis of the Respondents' political, religious and educational efforts. These efforts, when properly included in the "mosaic" purportedly considered by the ALJ, show that Respondents' representations about their products are part and parcel of their deeply and authentically held religious beliefs. In contrast, the ALJ did focus on the content of Respondents' speech in crafting the proposed remedy. Specifically, the ALJ both criticized and used as justification for his overbroad Initial Decision the Respondents' political commentary about the FTC, broadcast during Respondents' radio show.

In other words, the ALJ apparently considered all evidence and legal analysis of Respondents' political and religious speech and activities irrelevant when portraying Respondents as being engaged purely in commerce. When, however, crafting a remedy containing an unconstitutional prior restraint Respondents' political and religious speech and activity became relevant as justification. On this grounds if no other the Initial Decision stands revealed as arbitrary and capricious.

C. The Proposed Remedy Would Violate The Religious Freedom Restoration Act

The Supreme Court, in 2006, under the leadership of Chief Justice Roberts, reaffirmed the efficacy of the Religious Freedom Restoration Act of 1993 (RFRA), 107

Stat. 1488, as amended, 42 U. S. C. §2000bb et seq., stating that the law, applied to Federal agencies and programs,

"... adopts a statutory rule .... Under RFRA, the ...Government may not, as a statutory matter, substantially burden a person's exercise of religion, "even if the burden results from a rule of general applicability." §2000bb–1(a). The only exception recognized by the statute requires the Government to satisfy the compelling interest test—to "demonstrat[e] that application of the burden to the person—(1) is in furtherance of a compelling government interest; and (2) is the least restrictive means of furthering that compelling governmental interest." §2000bb–1(b). A person whose religious practices are burdened in violation of RFRA "may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief." §2000bb–1(c)." *Gonzales v. O Centro*, No. 04–1084. Argued November 1, 2005—Decided February 21, 2006.

The most important recent Supreme Court development in the area of First Amendment religious freedom is the well-known New Jersey Boy Scout case, *Boy Scouts v. Dale*, 530 U.S. 640 (2000). The Court reiterated that freedom of speech and freedom of association together give rise to what the Court calls "expressive association" which is the expression of the association's beliefs through its internal decisions and activities. These are protected by constitutional rights, "While the law may promote all sorts of conduct in place of harmful behavior, it may not interfere with speech for no better reason than promoting an approved message or discouraging a disfavored one, however enlightened either purpose may seem... The record reveals... the Boy Scouts is a private association..."

Regarding the health-related aspects of religious thought, the North Carolina Supreme Court concluded, a century ago, that

> The state has not restricted the cure of the body to the practice of medicine and surgery -- allopathy, as it is termed, -- nor required that, before anyone can be treated for any bodily ill, the physician must have acquired a competent knowledge of allopathy and be licensed by those skilled therein. To do that would be to limit progress by establishing allopathy as the state system of healing, and forbidding all others. This would be as foreign to our system as a state church for the cure of souls. All the state has done has been to enact that, when one wished to practice medicine or surgery, he must, as a protection to the public [not to the doctor], be examined and licensed by those skilled in surgery and medicine. To restrict all healing to that one kind -- to allopathy, excluding homeopathy, osteopathy, and all other treatments -- might be a protection to doctors in surgery and medicine; but that is not the object of the act, and might make it unconstitutional, because creating a monopoly. *State v. MacKinght*, 42 S.E. 580, 1902 at p 582.

Further that court held that there could be no "state system of healing" and while:

> Those who wish to be treated by practitioners of medicine and surgery had the
> guaranty that such practitioners had been duly examined...those who had faith in treatment by methods not included in the 'practice of medicine and surgery' as usually understood, had reserved to them the right to practice their faith and be treated, if they chose, by those who openly and avowedly did not use either surgery or drugs in the treatment of diseases... *State v. Biggs*, 46 SE Reporter 401, 1903 at p.402

> Medicine is an experimental, not an exact science. All the law can do is to regulate and safeguard the use of powerful and dangerous remedies, like the knife and drugs, but it cannot forbid dispensing with them. When the Master, who was himself called the Good Physician, was told that other than his followers were casting out devils and curing diseases, he said, 'Forbid them not.' *Biggs,* p. 405.

As a private religious association, the expressive association activities of which are protected under the First Amendment as exemplified in the *Boy Scouts* case, any church or ministry has the right to the exemptions and prerogatives provided by law.

Daniel Chapter One expresses its First Amendment speech, association and religious rights through its activities in expressing its strong views on health and wellness practices and providing herbs and nutrients that may be legally sold.

As the Court stated in *Thompson,* 535 U.S. 357

> If the First Amendment means anything, it means that regulating speech must be a last - not first - resort. . . We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.
>
> Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.

The basic rule, announced by the case, to determine constitutionally permitted government restrictions on commercial speech (speech that makes or is about an offer for a transaction) is a two prong test: the first prong is to ask two questions: (1) is the speech in question about unlawful activity and (2) is the speech misleading. If "no" to both, the speech is entitled to protection unless the government can carry its burden and prove (1) the governmental interest involved is "substantial", (2) the regulation must "directly advance" the governmental interest and (3) the regulation of commercial speech cannot be "more extensive than is necessary to serve that interest" (quoting *Central Hudson v. Public Service*, 447 US 557, at 566).

> ...[N]either this court nor any branch of this government will consider the merits or fallacies of a religion. Nor will the court compare the beliefs, dogmas, and practices of a newly organized religion with those of an older, more established religion. Nor will the court praise or condemn a religion, however excellent or fanatical or preposterous it may seem. Were the court to do so, it would impinge upon the guarantee of the First Amendment. Judge Brattin, Eastern District of California, in *Universal Life Church, Inc. v. United States*, 372 F. Supp. 770, 776 (E.D. Cal 1974).

D. The Remedy Imposes An Unconstitutional Prior Restraint On Truthful Speech.

The ALJ ignores DCO's claim that its promotional activities concerning the Challenged Products are an integral part of an educational, charitable and religious mission, and thus, protected by the First Amendment religion, speech and press guarantees. As noted in Part I above, the ALJ diminishes the unrebutted testimony of the Feijos that DCO is engaged in a nonprofit educational, charitable and religious mission, belittling its corporate sole status and its substantial religious ministry. Instead, the ALJ presents DCO as an exclusively commercial enterprise, downplaying at every opportunity the nonprofit charitable and religious aspects of the ministry.

In this case, the ALJ has found that the "overall net impression" created by DCO with respect to the cancer affecting properties of its products is misleading, but it made no finding that DCO or James Feijo knew the representations were false, or recklessly disregarded the truth or falsity of those representations. Indeed, there is not even a finding of negligence or other individual fault. While the FTC Act does not require such a "fault" finding, the charitable solicitation cases do. The question in DCO's case is whether its solicitations to sell the products at issue were an integral part of an educational, charitable, and religious mission.

E. The Proposed Remedy Would Unconstitutionally Establish Government Religious Speech By Coercing Respondents To Disseminate Government-Sanctioned Speech That Is Expressly Contrary To Their Religious Beliefs and Ministry.

In his proposed order requiring DCO and Jim Feijo to send a letter to the purchasers of the Challenged Products, the ALJ has acknowledged that "the proposed letter attached to the Complaint could be seen as requiring Respondents to adopt as their

own statements and opinions that are contrary to the beliefs to which Respondents testified at trial." Initial Decision, p. 121. "Therefore," the ALJ states, "the letter is modified to make it clear that the information contained in the letter is information that the FTC has required Respondents to transmit to consumers." *Id.*

Not only is the proposed modification wholly inadequate to remedy the defect that the ALJ has identified in his opinion, but it fails completely to remedy the proposed unconstitutional encroachment upon DCO's rights under the religion guarantees of the First Amendment.

1. The Modification is Inadequate to Protect Religious Free Exercise.

The ALJ proposes that the consumer letter be modified by separating the last sentence from the first paragraph, as it appeared in the letter attached to the Complaint, and making that sentence the first sentence of the second paragraph followed by a colon. The ALJ further proposes that the rest of the original letter be indented on the left side on the assumption that, by a simple grammatical change, the letter recipient will understand that the information contained in the two indented paragraphs is not being "adopted" by DCO and Mr. Feijo, but only "required" by the FTC Order. Little more than this convoluted twisting and turning is needed to establish how far, how unconstitutionally far, the ALJ is leading the FTC into the treacherous area of compromising the religious freedom of Respondents.

Only the most sophisticated grammarian would so read the proposed modified letter. Most readers would miss the colon altogether, and not even notice the left-side indentation. Even if the rest of the original letter were placed in block quotes, it strains the imagination to believe that the ordinary reader of a letter signed by Mr. Feijo as

Overseer of DCO would understand that it is the FTC, and not Mr. Feijo, who is acknowledging that "very little scientific research has been done" and that "BioShark, 7 Herb Formula, GDU, and BioMixx are [in]effective." (There is no evidence in the record establishing that the DCO herbal products are "ineffective." There is in fact evidence that herbal doctors believe them to be effective for what was claimed for them.) Nor would the typical reader come away from the letter believing that the FTC, and not Mr. Feijo, was urging the reader to "talk to your doctor or health care provider before using any alternative or herbal product." Nor would that reader believe that it is the FTC, and not Mr. Feijo, who is recommending that the reader turn to the National Cancer Institute or the National Center for Complementary and Alternative Medicine for "further information."

The proposed modified letter, like the original one, is designed to be confessional, an admission that DCO's claims were "false or unsubstantiated," even though the ALJ has conceded that the FTC did not proceed against DCO and Jim Feijo under a "falsity theory." *Compare* Initial Decision, p. 99, n.4 *with* Initial Decision, p. 121. Moreover, the only conceivable reason for DCO and Mr. Feijo to send such a letter over Mr. Feijo's signature would be to give the reader the distinct impression that, as Overseer, Mr. Feijo has repented of having made "false and unsubstantiated" claims, an impression that would be totally contrary to Mr. Feijo's deeply held religious beliefs and contrary to his right of free exercise of religion. *West Virginia State Board of Education*, 319 U.S. 624 (1943). Further, it is contrary to Mr. Feijo's right "to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705 (1977). Compelled speech is anathema to a free society.

Complaint Counsel's insistence that DCO's product marketing statements be isolated from DCO's overall religious and political mission as unprotected commercial speech is comparable to the efforts by other government agencies to isolate an organization's charitable solicitations which are integral to that organization's political mission. The Supreme Court has resoundingly rejected that approach:

> Soliciting financial support is undoubtedly subject to reasonable regulation but the latter must be undertaken with due regard for the reality that solicitation is characteristically intertwined with informative and perhaps persuasive speech seeking support for particular causes or for particular views on economic, political or social issues, and for the reality that without solicitation the flow of such information and advocacy would likely cease. *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620, 632 (1980).

That same standard has been embraced by the Supreme Court in its latest charitable solicitation case in order to "provide sufficient breathing room for protected speech." *Illinois ex rel Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600, 620-21 (2003).

That heavy presumption of unconstitutionality applies equally to the FTC and any other administrative agency empowered by Congress to enjoin the future publication of allegedly "deceptive" statements. Indeed, if a State and Defense Department appeal to "national security" was found constitutionally insufficient — as the Court did in the Pentagon Papers case — the FTC's appeal to the need for "competent and reliable scientific evidence" in this case is clearly insufficient. As Justice Brennan observed in the Pentagon Papers case, the First Amendment prohibits a court injunction based upon "surmise or conjecture that untoward consequences may result." *New York Times,* 403 U.S. at 725-26. The First Amendment doctrine of prior restraint would also prohibit an FTC order enjoining Respondents when that order is based upon the FTC's "overall net

impression" that Respondents' promotional statements are misleading without any concrete evidence that anyone was misled by such statements or physically harmed.

IV. CONCLUSION

Based on the foregoing argument, applicable statutory and constitution law, and the record in this case, Respondents request the Commission to reject the Proposed Order contained in the Initial Decision, adopt Respondent's proposed Order attached hereto, and dismiss the Complaint against Respondents Daniel Chapter One and James Feijo.

IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	**Docket No.: 9329**
DANIEL CHAPTER ONE,	)	
a corporation, and	)	
JAMES FEIJO,	)	**PUBLIC DOCUMENT**
individually, and as an officer of	)	
Daniel Chapter One	)	
	)	
	)	
	)	
	)	

[PROPOSED] ORDER DISMISSING COMPLAINT

The hearing in the administrative action *In the Matter of Daniel Chapter One*, Docket No. 9329 having concluded, the record being closed, counsel for both parties having briefed the relevant issues, and the Commission being fully advised,

THE COMMISSION FINDS:

1. Respondents Daniel Chapter One and James Feijo have not violated Sections 5 and 12 of the FTC Act;
2. Respondents' statements concerning the Challenged Products are not untruthful or misleading and are substantiated by competent and reliable scientific evidence; and
3. Respondents' statements concerning the Challenged Products are protected speech under the First Amendment to the United States Constitution.

THEREFORE, IT IS ORDERED that the Complaint *In the Matter of Daniel Chapter One*, Docket No. 9329, be, and is hereby DISMISSED WITH PREJUDICE against all Respondents.

Dated this___ day of _____, 2009.

_____

CERTIFICATE OF SERVICE

I certify that on September 18, 2009, pursuant to Federal Trade Commission Rules of Practice 4.2(c) and 4.4(b), I caused the foregoing Respondents' Appeal Brief and Proposed Order Dismissing Complaint to be served and filed, as follows:

The original and twelve paper copies via hand delivery and one electronic copy via email to:

Donald S. Clark
Office of the Secretary
Federal Trade Commission
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Washington, DC 20580
Email: secretary@ftc.gov

One paper copy via hand delivery and one electronic copy to:

Hon. D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Avenue, NW, Room H-106
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I further certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original, and that a paper copy with an original signature is being filed with the Secretary of the Commission on the same day by other means.

Martin R. Yerick