

**ORIGINAL**



**IN THE UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION  
OFFICE OF THE ADMINISTRATIVE LAW JUDGES**

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

**PUBLIC DOCUMENT**

**RESPONDENTS' PROPOSED FINDINGS OF FACT,  
CONCLUSIONS OF LAW AND ORDER,  
AND BRIEF IN SUPPORT THEREOF**

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## **Table of Contents**

- 1.) Respondents' Post-Hearing Brief
- 2.) Respondents' Proposed Findings of Fact
- 3.) Respondents' Proposed Conclusions of Law
- 4.) Respondents' Proposed Order
- 5.) Index of Respondents' Exhibits
- 6.) Index of Respondents' Witnesses
- 7.) Certificate of Service

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**RESPONDENTS' POST-HEARING BRIEF**

As directed by this Court's Order on Post-hearing Briefs, Respondents supply the attached Findings of Fact and Conclusions of Law, which are supported by the legal analysis that appears below. Further, as directed by the Court's Order, only Findings of Fact are provided on the issue of the Commission's jurisdiction over Respondents' religious ministry. The jurisdiction issue is not addressed below or in Respondents' proposed Conclusions of Law.

For the reasons set forth below, Respondents contend that Complaint Counsel has not proven that Respondents violated 15 U.S.C. §§45 and 52 and has not established a constitutionally-valid predicate for action against Respondents. Therefore, Complaint should be dismissed with prejudice, and Complaint Counsel's proposed Order should be rejected in its entirety.

**I. Complaint Counsel Has Not Shown That Respondents Violated 15 U.S.C. §§45 and 52.**

This case can be summarized as follows: Complaint Counsel has presumed much and proven little of what is required of the Commission.

**A. Complaint Counsel's focus on double-blind, placebo-based studies as the only basis for substantiation of dietary supplements is incorrect.**

Dr. Denis Miller MD, a well known cancer research administrator, was the only substantive witness offered by Complaint Counsel. The scope of his testimony was narrow and specific. Cancer drugs, he testified, must be tested by double-blind, placebo-based clinical trials to receive approval by the US Food and Drug Administration. Complaint Counsel rests its case on the presumption that only substantiation by double-blind, placebo-controlled clinical trials, as required by the US Food Drug and Cosmetic Act for approval of drugs, qualifies as reasonable substantiation for claims made by Respondents.. Essentially, Complaint Counsel places all its eggs in this double-blind basket. It chose, contrary to law, to meet all the other required elements of proof based on presumptions. Presumptions, as set out below, fail to make the FTC case.

Even the double-blind element of proof about the purported requirement of placebo controlled, clinical studies misses the mark. The FTC Act does not require double blind, placebo-controlled studies as the basis for reasonable substantiation. In fact 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.<sup>1</sup>

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<sup>1</sup> The Dietary Supplement Health and Education Act of 1994 (DSHEA) added section 403(r)(6) to the Federal Food, Drug, and Cosmetic Act.

*“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 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.

Furthermore, notwithstanding impressive credentials, 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.

As described more fully below, the single-minded prosecution that Complaint Counsel has undertaken here ignores the following express FTC policies and Guidelines for dietary supplements:

- “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.

**B. Complaint Counsel Failed to Meet Other Necessary Elements of Proof Altogether.**

The shortcomings in Complaint Counsel’s case extend to other elements of required proof, for Complaint Counsel has ignored its burden on several key elements, which it must prove with clear, cogent and convincing evidence.<sup>2</sup>

1. General Elements of Proof.

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

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<sup>2</sup> The standard of proof required of the FTC in this case is *clear, cogent and convincing* evidence in light of the Constitutional liberty and property interests involved in this case. *Addington v. Texas*, 441 U.S. 418 (1970).

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.

Complaint Counsel offered not a shred of evidence to meet the requirements of 15 USC §45(n). As the relevant case law and FTC policy show, these same standards apply also to false, deceptive and misleading charges under 15 U.S.C. §45(a) and 52.

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

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.

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.

As with the standards required by 15 USC §45(n), Complaint Counsel produced no evidence at the hearing to meet its requirements under the “reasonable basis” test.

### 3. 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*<sup>3</sup>, 791 F. 2d at 197. Accord, *Thompson* Policy Statement at p. 2.

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; and
- The amount of substantiation experts in the field believe is reasonable.

See *Thompson* Policy Statement at p. 2.

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.]”

These factors are identical to the statutory requirements of 15 USC 6§45(n) applicable to claims of unfairness. In other words, Complaint Counsel must effectively

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<sup>3</sup> *Thompson Medical*, 104 FTC 648 (1984), aff’d 791 F. 2d 189 (D.C Cir 1986).

meet the same standards of proof for false advertising and deception, as §45(n) requires for unfairness. Agency presumptions and policy guidance alone will not suffice.

The Commission must also examine the allegedly deceptive practice from the perspective of a reasonable consumer. If the representation is directed *primarily* to a particular group, the FTC is required to examine reasonableness from the perspective of that group.<sup>4</sup> *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.<sup>6</sup>

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."

#### 4. Specific Elements of Proof for Dietary Supplement Claims.

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 describes general well-being from consumption of a nutrient or dietary ingredient,

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<sup>4</sup> Note that the representation need not be directed *exclusively* to a particular group.

<sup>6</sup> *Cliffdale* Statement at footnotes 13 and 29.

(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.

Here, Complaint Counsel has tried to ignore DSHEA and the FTC’s own guidelines for dietary supplement claims. Dr. Miller’s testimony related to the approval by the FDA of chemotherapeutic agents and made no reference to or claimed any

relevance to the standards that govern claims made for dietary supplements. Dr. Miller's 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.<sup>7</sup> This is consistent with the qualifications required of an expert under the relevancy prong of the *Daubert* standard.<sup>8</sup> Dr. Miller did not even know what a structure or function claim is! (Miller, Tr. 173-174.)

In contrast, Respondents' experts Dr. Duke and Dr. LaMont are specifically qualified to testify about dietary supplements. The FTC's need for qualified expert testimony from the field of dietary supplements is drawn from the sharp distinction expressed 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 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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<sup>7</sup> *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.

<sup>8</sup> *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

**C. Respondents' Substantiation Is More Than Adequate To Meet The Required Legal Standards.**

Respondents substantiated their structure or function claims. As Dr. LaMont testified, the substantiation that Respondents used is supported by considerable literature in the field that constitutes adequate and reasonable corroboration for the claimed “biological mechanism underlying the claimed action.” (LaMont, Tr. 587, 599.)

**D. In The Absence Of Actual Harm, The FTC Must Prove Its Case With Actual Evidence Or Otherwise Violate Due Process.**

There is a final point to be made about Complaint Counsel’s flawed reliance on presumptions in a case involving dietary supplement structure or function claims. The principle of DSHEA is that dietary supplements are presumed safe unless and until they are proved harmful. The burden to prove harm is on the government. Complaint Counsel’s approach in this case turns Congressional promulgation of DSHEA on its head by emasculating the dietary supplement providers’ rights, and by ignoring the government’s burden to prove harm.

Even without DSHEA, Complaint Counsel’s near-exclusive reliance on presumptions in a case like this violates due process. It bears repeating: there are many factors that the FTC must consider in order to maintain charges of unfair, deceptive and misleading advertising. In circumstances like those presented here, those factors must be addressed with extrinsic evidence, including but not limited to consumer surveys, expert testimony about consumer perceptions and expert testimony qualified in the specific field of dietary supplements.