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

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| **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** | ) | |
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## Errata for Respondents' Motion for Summary Decision

Counsel attaches hereto a new copy of Respondents' Motion for Summary Decision to correct only the inadvertent clerical errors on page 4 of Respondents' Motion for Summary Decision, and to properly reflect the accurate footnote numbering that results from this correction.

Dated February 25, 2009.

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**Respondents' Motion for Summary Decision and Memorandum in Support**

COME NOW Respondents Daniel Chapter One and James Feijo (hereinafter collectively, "DCO") who move this Court for an Order on Summary Decision declaring that the FTC lacks sufficient evidence at the close of discovery to proceed with its charges against DCO as a matter of law.

This Motion is based on the Memorandum below, on the records and files herein, and on the Sworn Declarations of DCO's counsel supplied herewith.

## I. Introduction

DCO is a religious ministry, organized as such under the laws of Washington State.[1] The DCO website states that DCO was formed "as a health and healing ministry in the summer of 1986."[2] The organizing principle of DCO's ministry is reflected by its very name. Daniel Chapter One is a book from the

[1] DCO incorporates herein the details of its ministry and history as a religious organization as described in its companion Motion to Dismiss on Constitutional grounds, which is filed contemporaneously with this Motion.

[2] dc1pages.com/danielchapterone/index.php?option=com_content&task=view&id=57&Itemid=76

Bible's Old Testament, the text of which states that proper religious practice includes a natural diet. This principle is reflected throughout DCO's religious and educational communications, which are accessible to DCO followers and constituents via the DCO website and other media.

Part of DCO's religious ministry involves the supply of natural dietary supplements. It is these DCO supplements, and DCO's claims about them, that prompt the FTC's Complaint here. In light of the connection between DCO's ministry and its dietary supplements, this case is unlike any to have come before the FTC to date.

The FTC's Complaint against DCO contends that DCO has created an "overall net impression" that four specific supplements are offered to cure or treat cancer. The FTC Complaint charges that this activity is therefore false and misleading under 15 USC § 52, and unfair and deceptive under 15 USC §45.

DCO disputes the FTC charges as a matter of substance, and based on several Constitutional grounds. However, this Motion is not about the substantive controversy involved in the FTC's charges. There are no issues of material fact relevant to the legal issue raised in this Motion.

By this Motion, DCO will show that the FTC's charges must be dismissed due to the FTC's inability at this stage of the proceedings to meet its evidentiary burden of proof. There can be no factual dispute. Discovery is now closed, and the record reveals that the FTC has ignored or otherwise failed to produce the evidence required to prove essential elements of the statutory charges against DCO. Instead, the FTC has relied almost exclusively on presumptions. A

defendant/respondent is entitled to summary judgment when it can show the plaintiff/prosecution lacks the necessary evidence to sustain its burden at trial. Such is the case here.

## II. Analysis of the DCO Mosaic

In the present case, the FTC's Complaint is based on charges that DCO has created an "overall net impression" of cancer cures via its website.[3] The FTC does not contend that DCO has made express claims of cancer cures. FTC case law, guidelines and policy statements have stated clearly over the years that when allegations of deception are based on the "overall net impression," the entire framework and context of the representations must be considered, along with other important factors.

> "It is necessary in these cases to consider the advertisement in its entirety, and not to engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately." *FTC v. Sterling Drug*, 317 F. 2d. 669, 674 (2nd Cir. 1963).

To evaluate the DCO mosaic, it is important to know two things: first, what the FTC's Complaint omits about DCO claims; and second, what the FTC's Complaint misrepresents about DCO claims.

### A. What the Complaint Omits

[3] See FTC Answers to DCO Interrogatories # 1 and 3 through 10, attached as Exhibit A to the McCormack Declaration.

The FTC Complaint is based on DCO representations that appear in the DCO website and other media. The DCO representations on which the FTC relies are contained in the Exhibits attached to the Complaint.[4] FTC investigators and legal staff discovered DCO by means of an "internet surf" (i.e., google search) that targeted DCO along with over a hundred other dietary supplement manufacturers. The investigators who designed the surf, who targeted DCO and who researched DCO's claims had no background in health care. The FTC administrator who instigated this particular web surf testified that the decision to pursue the DCO Complaint was based on "common sense" and FTC policy. The FTC's only disclosed expert did not review this case until after the Complaint in this matter was filed.

The FTC's myopic pursuit of DCO resulted in at least two errors in the DCO Complaint. The first of these errors is an error of omission, i.e. what the FTC Complaint leaves out about DCO's website. The second error is one of commission, i.e. what the FTC misrepresents about the DCO website and other materials.

In the first instance, the FTC has omitted several indisputable features from the mosaic that is DCO and its claims. The first omission is the name Daniel Chapter One itself, a book of the Old Testament. The following comes from the DCO website:

> Welcome to Daniel Chapter One Online!

[4] See FTC Answers to DCO Interrogatories 1 at Exhibit A to McCormack Declaration.

> Daniel Chapter One got its name from the Old Testament, book of Daniel, first chapter. In that account, Daniel and his men were being held in Babylonian captivity, and were expected to eat the king's food -so as to be fit and strong servants.
>
> But Daniel asked permission to eat a vegetable diet and to drink only water, rather than partake of the rich meats and wine of the king. The king's men said no; surely Daniel would get sick, maybe die! So Daniel asked for a trial of 10 days. At the end of Chapter One, it is recorded that Daniel and men, after that trial, were strong in flesh, with bright eyes, and continued to grow in knowledge and wisdom.
>
> So it was that the founders of Daniel Chapter One®, since trying their own "Daniel Chapter One" diet for 10 days and discovering that indeed they felt fantastic, decided to name the health food store they began, after that portion of the bible. The company, then and now, does not push a vegetarian diet for wellness, but simply a healthy diet of wholesome, natural foods - rather than the unwholesome, artificial food of the modern world. It's about eating with purpose, and partaking of the good food God has given us for health and healing. Good food for physical, mental, and emotional health includes herbs and nutrients.
>
> The tiny health food supplement store Daniel Chapter One® grew and grew, from one to several locations. As the store grew, so the founders grew - in knowledge and wisdom, as in fact Daniel had experienced! The store quickly became more of a natural healing center. From their hands-on expertise, the couple began next to design the nutritional supplement product line now known world over as Daniel Chapter One.[5]

Every page of the DCO website contains the following statement:

> The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose a disease. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs or supplements should not be mixed with certain medications.

The description of every product offered on the DCO website includes the following language:

> **These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease.* (Italics and "*" supplied in original.)[6]

From this more complete picture of the DCO mosaic, it cannot reasonably be disputed that the DCO ministry – including but not limited to its product

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[5] dc1pages.com/danielchapterone/index.php?option=com_content&task=view&id=16&Itemid=33

[6] See e.g. dc1store.com/component/page,shop.product_details/category_id,46/flypage,shop.garden_flypage/product_id,25/option,com_virtuemart/Itemid,44/

offerings – is directed to a unique religious constituency. This indisputable fact bears on the burden of proof that the FTC is required to meet.

### B. What the Complaint Misrepresents

The FTC Complaint also contains errors of commission, i.e. what the Complaint misrepresents. The Complaint identifies DCO representations about 4 DCO products: (1) Bioshark; (2) 7 Herb Formula; (3) GDU; and (4) BioMixx. At ¶18 of the Complaint, the FTC sets forth the representations attributed to DCO for each product.

The following chart juxtaposes what the FTC attributes to DCO with what DCO actually wrote on its website. This juxtaposition is important not only to a fair evaluation of DCO's "structure/function" claims and the substantiation for those claims, but also to an understanding of the "overall net impression" that the FTC must now prove with substantial evidence consistent with the required standards of proof.

| The FTC's attribution to DCO | DCO's actual claim |
|---|---|
| About Bioshark:<br><br>*"Bioshark inhibits tumor growth"*<br><br>*"Bioshark is effective in the treatment of cancer"* | *"Bioshark is pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis -- the formation of new blood vessels. This can stop tumor growth and halt the progression of eye diseases . . ."* |
| About 7 Herb Formula:<br><br>*"7 Herb Formula is effective in treating and curing cancer"*<br><br>*"7 Herb Formula inhibits tumor formation"* | *"purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"* |

| | |
|---|---|
| About GDU:<br><br>*"GDU eliminates tumors"* | *"contains natural proteolytic enzymes (from pineapple source bromelain to help digest protein --even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . .GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."* |
| About BioMixx:<br><br>*"BioMixx is effective in the treatment of cancer"*<br><br>*"BioMixx heals the destructive effects of radiation and chemotherapy"* | *"boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."* |

Each of the statements that DCO actually made about its products is truthful and substantiated, as explained in more detail below. In contrast, the FTC has no qualified proof to the contrary that will support its charge of "overall net impression."

## III. Basis and Standard for Summary Decision

It bears emphasizing that this Motion for Summary Decision is based on the FTC's lack of competent, qualified evidence altogether, notwithstanding some potential factual issues that are not relevant to this Motion. To survive this Motion, the FTC must offer sufficient qualified evidence, not mere allegations. A "scintilla" of evidence, evidence that is "merely colorable", and evidence that "is not significantly probative" will not defeat the motion. See e.g. *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986). It is also true, according to the elements of

proof described below, that presumptions about the facts will not defeat this Motion.

This Brief shows that the FTC does not have the evidence to meet its burden in this case under the *preponderance of evidence* standard. Nevertheless, DCO contends that 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. See e.g. *Addington v. Texas*, 441 U.S. 418 (1970). This standard applies even in the summary judgment context, i.e. the FTC must produce clear, cogent & convincing evidence to defeat DCO's Motion. See *Anderson*.

*Addington* articulated the reasons for the *clear, cogent & convincing* standard in a case like this one. Though that case concerned the standard of proof in an involuntary civil commitment proceeding, the *Addington* Court's analysis properly fits the circumstances here. For instance, *Addington* states that the nature and importance of the Constitutional interest determines the proper standard of proof. In this case, the Constitutional interests include the First Amendment rights to free speech and religious freedom possessed by both DCO and its constituents.

*Addington* states that proper standard of proof flows from the relative importance attached to the ultimate decision, i.e., the more important the decision, the higher the burden of proof. Id. at 423. *Addington* established that there is a constitutional necessity for an intermediate standard of proof (i.e., "clear," "cogent," "unequivocal," and/or "convincing") in circumstances where the interest is greater than a mere money judgment but less than a generic

criminal proceeding. *Id.* at 424. The intermediate *clear, cogent & convincing* standard is required in a variety of civil situations "to protect particularly important individual interests," namely Constitutional interests that are more important than the interest against erroneous imposition of a mere money judgment. *Id.*

*Addington* also noted that while the interest of the individual may dictate a higher standard of proof to avoid erroneous deprivation, important interests of the state are likewise vindicated by the higher burden because state interests would be compromised by a lower burden of proof, thus needlessly increasing the incidents of erroneous results. *Addington*, at 425.

Indeed, it is not just DCO's constitutional interests that are at stake. Also involved here is the interest of the public, constituents of DCO's ministry who exercise their right to access DCO's religious and educational messages, and the related wellness products and information. The public's interest is as much a part of this case as is DCO's interest.

In any event, now that discovery has closed, DCO contends that the FTC charges are wholly unsupported by the required evidence as a matter of law, even if this Court applies a *preponderance* standard.

## IV. The Law Requires the FTC to Produce Extrinsic Evidence

There are a number of factors that bear on the FTC's burden of proof, and the elements of that proof required in a case like this one. First, in evaluating the FTC charges under 15 USC §§ 45 and 52, the Commission employs a "reasonable basis" test for evaluating whether claims about Challenged Products are unfair, deceptive and/or misleading. See, e.g. *FTC v. Pharmatec*, 576 F. Supp. 294

(D.C.D.C. 1983); accord, FTC Policy Statement appended to *Thompson*[7]. This test requires the FTC to consider whether there is a "reasonable basis" for the claims, i.e. is there reliable and competent information to substantiate the efficacy claims made for the Products. *Thompson*, 791 F. 2d at 193-194.

The FTC must also address several other considerations in order to prove violations of §§45 and 52. For instance, where the charges against a respondent are based on the "overall net impression" rather than on any express claims, those charges must be proved by substantial evidence of consumer expectations in order for the FTC to prevail. *Thompson*, 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

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

costs of substantiating a particular claim. These factors include [the 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, the FTC must effectively meet the same standards of proof for false advertising and deception, as §45(n) requires for unfairness.

The *Thompson* Policy Statement goes on to say that "extrinsic evidence" is useful, including qualified expert testimony and consumer surveys. In fact, under 15 USC §45(n), extrinsic evidence is required. Presumptions and policy guidance alone will not suffice.

The Courts and the Commission have explained why extrinsic evidence about these factors is required in a case like this one. For instance, at the outset, evaluation of the 6 factors in an "overall net impression" case involves a "highly factual inquiry. "[8] One reason for that inquiry is because even the most orthodox commercial advertisers "are not required to substantiate claims that were not made." *Thompson* Policy Statement at footnote #3. Only a "highly factual inquiry" can justify overall net impression claims.

### A. Extrinsic Evidence is Required to Prove Deception and Unfairness.

As an adjunct to the required evidence that bears on the 6 factors of the *Thompson* Policy Statement, the FTC 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

[8] Bene*ficial Corp. v. FTC*, 542 F.2d 611, 617 (3rd Cir. 1976).

reasonableness from the perspective of that group.[9] See FTC Policy Statement appended to *Cliffdale Associates*[10] (hereinafter *Cliffdale* Statement). That is, the FTC must determine the effect of the challenged claims on a reasonable member of the target group, e.g. constituents of a religious ministry devoted to natural health and wellness.[11]

When such a specific group of recipients is involved, extrinsic evidence about that group's reasonable perceptions is necessary. *Id.* See e.g. *Thompson*, 791 F. 2d at 197, where the Circuit Court made special note that "The issue of [consumer perception of the claims] was extensively addressed by expert testimony." This is just one of the reasons why understanding the full mosaic of DCO as a religious ministry is so important, because it underscores the requirement for actual extrinsic evidence.

The FTC understands why it's necessary to prove consumer perception with actual extrinsic evidence:

> "[Consumer perception scores] may reflect basic consumer skepticism of promotional claims, however worded."[12]
>
> "Although some variations in consumer interpretation of qualified health claims is inevitable given what are almost certainly broad differences in [consumers'] background beliefs, the degree of variation observed in the research is nonetheless surprising . . ."[13]

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[9] Note that the representation need not be directed *exclusively* to a particular group.
[10] See FTC Statement on Deception, appended to *Cliffdale Associates*, 103 FTC 110, 174 (1984), hereinafter *Cliffdale* Statement.
[11] See *Cliffdale* Statement at footnotes 13 and 29.
[12] See p. *In the Matter of Assessing Consumer Perceptions of Health Claims*, FTC Staff Comments, p. 10. Complaint Counsel produced this document as indicative of FTC policy bearing on this matter under Bates document nos. FTC-DCO 870 to 894. See Appendix 1 attached hereto.
[13] Id, at footnote 39.

These statements reveal an understanding that consumer perceptions vary greatly, and in surprising ways. Presumptions about consumer perception do not pass muster under the standards of the *Thompson* and *Cliffdale* Policy Statements, just as they do not pass muster under §45(n). The FTC must produce substantial evidence about consumer perception, and the 6 factors articulated by the *Thompson* and *Cliffdale* Policy Statements. This requirement is in accord with, as well as independent from §45(n).

### B. Qualified Expert Evidence is Required to Challenge Substantiation.

Qualified expert testimony or other extrinsic evidence is required not just to satisfy the FTC's burden on the issue of consumer perception. Qualified expert testimony is also required to address the substantiation for "overall net impression" claims. This is especially true for cases involving natural dietary supplements, where science and law has prompted standards for dietary supplement claims that are dramatically different from the standards applied to drugs.

As a general matter, the FTC's Official Guidance to the Dietary Supplement Industry says that the amount and type of substantiation evidence required for dietary supplements is determined by what experts *in the relevant field* would consider to be adequate.[14] This is consistent with the qualifications required of an expert under the relevancy prong of the *Daubert* standard.[15]

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[14] *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-DCO 1041 to 1070. See p. 1052, specifically.

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

In other words, without testimony from experts who are specifically qualified about dietary supplements (e.g. naturopaths and phyto-nutritionists), the FTC cannot meet its burden of proof about DCO's claims and the alleged lack of substantiation for those claims as a matter of law.

1. DCO's Structure/Function Claims are Not the Same as Health Claims for Drugs.

The FTC's need for expert testimony from the field of dietary supplements is drawn from the sharp distinction expressed by Congress between the regulation of dietary supplements claims on the one hand, and the regulation of drugs and drug claims on the other hand. Few, if any, FTC cases have addressed this distinction, as this case now must.

The Dietary Supplement Health and Education Act (DSHEA) authorizes dietary supplement manufacturers to make "structure/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,
>
> (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.

See 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-function claims describing how a particular nutrient or dietary supplement may affect a structure or function of the human body. See *Pearson v. Shalala*, 164 F. 3d 650 (1999); and *U.S. v. Lane Labs*, 324 F. Supp. 2d 547, 565 (2004). A fair reading of the actual DCO claims, as opposed to the inferences drawn by the FTC Complaint, shows that DCO claims are proper structure/function claims. Nowhere on the face of the actual DCO statements does DCO state that its products "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," which are the claims prohibited by DSHEA. Each of the DCO statements on their face describe how the products and/or their constituent ingredients support the structure/function of the human body, as "adjuncts" to – not in lieu of - cancer treatment. The efficacy of these DCO claims is corroborated by DCO's experts qualified in natural healing modalities, as discussed below.

It is well settled, and self-evident, that FTC law corresponds with DSHEA. Logic dictates that DSHEA influences FTC actions just as significantly as it does FDA actions. Lest there be any doubt as to the role DSHEA must play on FTC law, the FTC's own words put the issue to rest:

> "[S]tructure/function claims . . . refer to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health . . . This [FDA] requirement is fully consistent with the FTC's standard that advertising claims be truthful, not misleading and substantiated."[16]

[16] FTC Dietary Supplement Advertising Guide, footnotes 2 and 3; Bates page FTC-DCO 1068.

In light of DSHEA, it stands to reason that expertise on health claims for drugs is not the same field as expertise on structure/function claims for dietary supplements. Without expert testimony properly qualified for dietary supplements, the FTC does not meet its burden of proof.

To summarize this section, the FTC must address the 6 factors identified by the *Thompson* Policy Statement. It must do so with substantial evidence. These factors apply to FTC charges of deception, just as they apply to charges of unfairness. These factors mirror the requirements of 15 USC §45(n). As part of this inquiry, the FTC must also produce extrinsic evidence bearing on these factors especially when the charges are based on the "overall net impression," as opposed to express claims. The required extrinsic evidence must address the perceptions of a reasonable person within the target audience to whom the Respondent's activity is primarily directed. And the extrinsic evidence must include qualified expert testimony about dietary supplements, about the structure/function claims made for those dietary supplements, and about the substantiation that supports those claims.

The record of discovery taken in this case reveals that the FTC has not met any of these requirements.

## V. The FTC Lacks the Evidence to Sustain the Charges.

The FTC has properly identified only three witnesses in this case. Two of those are FTC investigators who are identified as fact witnesses. The third witness is an expert witness qualified in the area of conventional cancer treatment and

research. As revealed by their testimony, as well as the testimony of the FTC administrator who conceived of the internet surf that resulted in this action, the FTC has failed to address the required elements of proof in almost every instance.

### A. The FTC did not consider the required elements of proof.

1. FTC witness Michael Marino is an investigator whose role was limited to gathering evidence: he "recorded" the DCO website; he made an undercover website purchase of DCO products; he purchased recordings of two radio programs, and he did BBB, Lexis and Dunn & Bradstreet searches for DCO.[17] Mr. Marino had virtually no experience that he could recall investigating dietary supplement manufacturers before this DCO matter.[18] He played no role in the evaluation of DCO claims, and exercised no discretion about the investigation. That is, he did what he was told to do.[19]

Mr. Marino has no training in health matters, and no understanding of what a structure/function claim is.[20] He has no understanding of what is meant by "overall net impression."[21] He investigated, but could not find any complaints about DCO products.[22] He has no knowledge about any consumer injury connected with DCO or its products.[23]

2. FTC witness Lynne Colbert was the supervising investigator for the internet surf involved here; her role includes supervision of FTC staff paralegals

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[17] See Deposition of Michael Marino, at p20:line 5-7; 34:1-5; 37:8-10 and 38:19-25. Exhibit E to the McCormack Declaration.
[18] Marino dep at 28:24-29:15.
[19] Id., at 30:17-31:17.
[20] Id. at 43:6-25.
[21] Id. at 53:20-54:1.
[22] Id., 49:16-25.
[23] Id., 52:11-20.

and legal technicians.[24] Ms. Colbert was the one primarily in charge of the internet surf involved in this case, including the development and direction of the internet search parameters, using google and other search engines.[25] She performed the preliminary evaluation of all claims discovered in the internet surf, and it was based on her discretion whether a particular target case moved on in the administrative process toward a Complaint.[26] She spent an average of 10 to 15 minutes evaluating the data from each dietary supplement provider's web site.[27]

She has paralegal training, but no background, training or qualifications in health care.[28] She has no training or education about consumer perceptions of health claims.[29] She has no training in regard to structure/function claims other than what she has read on her own.[30] She does not consider any religious speech that may exist in the context of alleged advertising claims.[31]

The investigators whom Ms. Colbert supervised received no instructions about how to evaluate implied claims, or how to evaluate consumer perceptions; the investigators used their own discretion in making those evaluations.[32] The FTC's Division of Advertising Practices has no health care experts on staff.[33]

Ms. Colbert generally uses an online data base accessible to FTC staff to search for information about dietary supplements; she cannot remember doing

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[24] See Colbert deposition at p. 7; lines 1-7. Exhibit B to McCormack Declaration.
[25] Id., at 8:1-15; 10:16-11:7
[26] Id,. 23:14-18; 24:1-16.
[27] Id. 28:9-18
[28] Id., at 7:21-25; 44:18-25
[29] Id. at 24:15-25:5
[30] Id. at 34:1-24; 36:21-37-8
[31] Id. 60:2-22
[32] Id. at 14:5-16; 17:14-25
[33] Id. 44:18-25

so in regard to the DCO products.[34] She does not know if DCO was ever asked to provide substantiation for its claims.[35]

3. Richard Cleland is the Assistant Director for the Division of Advertising Practice at the FTC.[36] He testified for the FTC in this case as a designee on FTC policies and procedures. Mr. Cleland supervised the internet surf involved here, and he was the one who titled it "Operation False Cures."[37] He participated in the exercise of prosecutorial discretion in this case.[38]

Mr. Cleland testified that it is within the FTC's discretion to evaluate implied claims based on policy and case law; the Commission on its own determines the perspective of a reasonable consumer, and the target audience is presumed from the face of the ad alone.[39]

Mr. Cleland testified that he FTC conducted its "reasonable basis" analysis on the basis of presumptions about consumer perceptions and consumer harm; he testified that those presumptions are based on common sense and general FTC institutional knowledge.[40]

Mr. Cleland has no knowledge of economic or physical injury that resulted from DCO activity, and the FTC made no effort to evaluate the users of DCO products.[41] The FTC conducted no analysis under 15 USC §45(n) about whether there were benefits to users of the DCO products, nor did the FTC conduct any

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[34] Id. 42:2-43:6
[35] Id. 40:13-22
[36] Cleland Deposition, at p. 10, line 23 to page 11:line 2. Exhibit C to McCormack Declaration.
[37] Id. 11:9-19; 16:15-19.
[38] Id. 15:13-18.
[39] Id. 18:23-19:22; 20:5-13; 60:10-19; 60:21-61:4.
[40] Id. 68:21-69:21; ; 70:19-71:12.
[41] Id. 61:5-23; 67:17-68:7

analysis about the costs of substantiating dietary supplements.[42] He testified that the FTC used an expert in the field of cancer treatment to evaluate the DCO claims in this case.[43]

4. Dr. Denis Miller is the FTC's testifying expert. Dr. Miller's credentials as a cancer researcher for large pharmaceutical companies, and as a professional expert witness, are impressive. See Exhibit H to the McCormack Declaration. Dr. Miller conducted his analysis on the basis of the FTC's version of the implied claims, not on the basis of DCO's structure/function claims. See Exhibit H, p.4 and see e.g. Miller Deposition, p. 97:7-24, Exhibit D to McCormack Declaration. To be more specific, Dr. Miller only evaluated substantiation for whether DCO products "treat, cure and prevent cancer," and not the actual DCO claims themselves. Exhibit H, §IV at p. 7. See also, e.g. Miller Dep, 142:15-25.

Dr. Miller has no training or certification in nutrition. His credentials are in oncology and hematology.[44]

The sum of this testimony shows that the FTC has brought the charges against DCO based on presumptions, and erroneous presumptions at that. These presumptions include:

- A presumption that DCO was not authorized to make structure/function claims;
- A presumption that DCO's claims were directed to the general population, rather than a specific constituency related to its ministry;
- A presumption that the DCO constituency was deceived by DCO structure/function claims;

[42] Id. 72:16-27; 85:20-86:3
[43] Id. 86:17-87:2
[44] Miller Dep, 14:18-25.

- A presumption that DCO products offered no benefits;
- A presumption that DCO had no substantiation for its structure/function claims;
- A presumption that the substantiation required for dietary supplements is equivalent to the substantiation required for prescription drugs.

Reliance on these presumptions does not meet the FTC's burden of proof required by the applicable statutes, guides and policy statements. Yet, the FTC has no other evidence to offer other than these presumptions. As a matter of law, the FTC's charges must be dismissed.

### B. DCO's substantiation is more than adequate to meet the required legal standards.

Lest this Court be left with concern that the FTC's failings will allow a miscreant to walk free, DCO has substantiated its structure/function claims. And it has done so more than adequately. DCO supplied considerable substantiating documents to the FTC in discovery. Experts highly qualified in naturopathy and phyto-nutrition considered this substantiation, as well as additional confirming research, which allowed them to conclude that DCO's claims were proper and accurate structure/function claims.

By way of example, DCO expert witness Dr. Sally LaMont is a licensed naturopath and acupuncture practitioner. Her expertise includes the use of natural dietary supplements for healing and wellness. Dr. LaMont, who has testified before the California State Legislature in support of naturopathic

licensing and efficacy, has issued a written opinion in this case, stating that DCO's actual claims are accurate and substantiated by competent evidence.[45]

DCO expert witness Dr. Jim Duke is a world-renowned ethnobotanist who has written and lectured extensively on the medicinal qualities of plants and herbs. Dr. Duke co-authored the book *Herbs of the Bible: 2000 Years of Plant Medicine*.[46] Dr. Duke worked for 30 years at the USDA, where he established the USDA's ethnobotanical and phytochemical data base. Like Dr. LaMont, Dr. Duke is qualified about the qualities and effects on structure and function of natural products like those used in DCO products. Dr. Duke has also issued a written opinion in this case, stating that DCO's actual claims are accurate and substantiated by competent evidence.[47]

## VI. 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 the FTC's flawed reliance on presumptions in a case involving dietary supplement structure/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. The FTC'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.

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[45] See LaMont Report, p. 40, attached to McCormack Declaration as Exhibit F.

[46] Duke & Telatnik, *Herbs of the Bible: 2000 Years of Plant Medicine* Interweave Press, 1999.

[47] See Duke Report, §IV at p. 3, and §VI at p. 13, attached to McCormack Declaration as Exhibit G.

Even without DSHEA, the FTC'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 consumer surveys, expert testimony about consumer perceptions and expert testimony qualified in the specific field of dietary supplements.

Without such extrinsic evidence, in the absence of actual harm and in the context of an "overall net impression" case, the ability of the FTC to meet nearly every element of proof by means of presumption effectively shifts the burden of proof to the Respondent DCO. This type of procedural approach absolves the government of the most basic obligation to put on a prima facie case with competent evidence. This is unconstitutional, as it violates due process in the most fundamental of ways.

In *Mathews v. Eldridge*[48], the U.S. Supreme Court developed a three-part test to evaluate the minimum constitutional process due in a variety of procedural situations. In *Mathews* at p. 335, the Court considered whether a hearing prior to administrative termination of social security benefits was constitutionally required. The Court structured its consideration of procedural due process on three relevant factors: (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.

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[48] 424 U.S. 319, 332 (1976)