

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

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

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=7

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

⁵dc1pages.com/danielchapterone/index.php?option=com_content&task=view&id=16&Itemid=3

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
<p><u>About Bioshark:</u></p> <p><i>"Bioshark inhibits tumor growth"</i></p> <p><i>"Bioshark is effective in the treatment of cancer"</i></p>	<p><i>"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 . . ."</i></p>
<p><u>About 7 Herb Formula:</u></p> <p><i>"7 Herb Formula is effective in treating and curing cancer"</i></p> <p><i>"7 Herb Formula inhibits tumor formation"</i></p>	<p><i>"purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria"</i></p>

<p><u>About GDU:</u></p> <p><i>"GDU eliminates tumors"</i></p>	<p><i>"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. . ."</i></p>
<p><u>About BioMixx:</u></p> <p><i>"BioMixx is effective in the treatment of cancer"</i></p> <p><i>"BioMixx heals the destructive effects of radiation and chemotherapy"</i></p>	<p><i>"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."</i></p>

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 *Beneficial 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

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

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

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

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

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.

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 to 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.

⁴⁸ 424 U.S. 319, 332 (1976)

DCO's companion Motion amply addresses the constitutionally protected First Amendment and Religious interests and deprivations involved in this case. For the purpose of this Motion, the third of the *Mathews* factors deserves an especially close look, i.e. the added fiscal and administrative burden that additional due process procedures would entail, i.e. the requirement to produce extrinsic evidence instead of presumptions. Mindful of the pages of FTC policy statements and guidelines that are devoted to First Amendment protections and the risk of deprivation, it is this third factor that especially drives the FTC to adopt "trial by presumption."

Trial by presumption has been explicitly considered and explicitly rejected by the U.S. Supreme Court. Indeed, almost in anticipation of this 3rd element of the *Mathews* test, the U.S. Supreme Court decided *Stanley v. Illinois*⁴⁹ just a few years earlier than *Mathews*. 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 in the interest of efficiency by adopting a presumption in lieu of meeting a burden of proof. Here, in a quote that seems to have anticipated not only *Mathews* but this case also, the *Stanley* court said this:

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 concern for efficiency and

⁴⁹ 405 U.S. 645, 656-657 (1972).

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

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.

Allowing the FTC to try this case by presumption in the absence of actual harm, wherein the standard is a subjective “overall net impression,” improperly shifts the primary burden of proof to DCO in violation of DSHEA, *Matthews* and *Stanley*.

A. Adjudication by presumption is the unauthorized use of *parens patriae* under the guise of police power.

The FTC uses its police power to protect citizens from harm and the unreasonable risk of harm. A similar power is conferred on a government agency as *parens patriae* – government as parent – to determine what is good and healthy for citizens who are deemed unfit to care for themselves. See e.g. *Addington*.

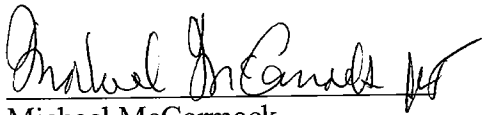
When a government agency exploits its police power in the absence of harm, and in the absence of authentic, qualified and credible extrinsic evidence, that agency casts itself not as the arbiter of what is harmful, but as the arbiter of what is good and healthy. It casts itself as the *parens patriae* of healthcare for all citizens. Nothing could be more systemically damaging and offensive, much less unconstitutional, to the burgeoning and valuable healthy effects offered by dietary supplements to consumers, to say nothing of the actual users of DCO

products who benefited from their faith in DCO when they were left with nowhere else to turn.

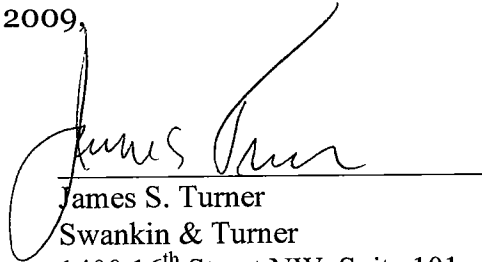
CONCLUSION

For the foregoing reasons, the Motion to Dismiss should be granted and the Complaint dismissed.

Respectfully submitted February 24, 2009,



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

In the Matter of
DANIEL CHAPTER ONE,
a corporation, and
JAMES FEIJO,
individually, and as an officer of
Daniel Chapter One

) Docket No.: 9329
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**[PROPOSED] ORDER GRANTING RESPONDENTS' MOTION FOR
SUMMARY DECISION**

Based on the Motion of Respondents' for Summary Decision supported by the Sworn Declaration of Michael McCormack and related documents, and based upon the Response of Complaint Counsel, the Court makes the following Findings of Fact and Conclusions of Law.

1. Respondent Daniel Chapter One (DCO) is a religious ministry founded pursuant to the "corporation sole" laws of Washington State.

2. Respondent's primary purpose is to serve constituents of its ministry.

3. One means by which Respondent serves the constituents of its ministry is by providing dietary supplements through sale and/or donation.

1 4. Respondent makes claims about four of their dietary supplements as
2 follows:
3
4

5 About Bioshark:

6 *"Bioshark is pure skeletal tissue of sharks which provides a*
7 *protein that inhibits angiogenesis -- the formation of new*
8 *blood vessels. This can stop tumor growth and halt the*
9 *progression of eye diseases . . ."*

10 About 7 Herb Formula:

11 *"purifies the blood, promotes cell repair, fights tumor*
12 *formation, and fights pathogenic bacteria"*

13 About GDU:

14 *"contains natural proteolytic enzymes (from pineapple*
15 *source bromelain to help digest protein --even that of*
16 *unwanted tumors and cysts. This formula also helps to*
17 *relieve pain and heal inflammation. . .GDU is also used for.*
18 *. .and as an adjunct to cancer therapy. GDU possesses a*
19 *wide range of actions including anti-inflammatory and*
20 *antispasmodic activity. . ."*

21 About BioMixx:

22 *"boosts the immune system, cleanses the blood and feeds the*
23 *endocrine system to allow for natural healing. It is used to*
24 *assist the body in fighting cancer and in healing the*
25 *destructive effects of radiation and chemotherapy*
26 *treatments."*
27
28

1 5. The claims identified in Finding of Fact #4 contain no express claims
2 about the diagnosis, mitigation, treatment, cure or prevention of any disease. These
3 claims are structure/function claims as defined by 21 USC §343(r)(6).
4

5 6. The Respondents' structure/function claims are substantiated by adequate
6 scientific evidence.

7 7. The Commission must meet its burden of proof by clear, cogent and
8 convincing evidence.
9

10 8. Complaint Counsel has the burden to prove that Respondents lacked a
11 reasonable basis for their claims.
12

13 9. Complaint Counsel provided insufficient evidence to meet the burden of
14 proving that that Respondents lacked a reasonable basis for their claims.

15 10. Complaint Counsel has the burden to the standards of proof required by 15
16 USC §45(n).
17

18 11. Complaint Counsel provided no evidence to meet the standard of proof
19 required by 15 USC §45(n).
20

21 12. Complaint Counsel has the burden to prove with extrinsic evidence the
22 overall net impression of Respondents' claims. That extrinsic evidence must include
23 evidence about consumer perceptions of a reasonable member of Respondents'
24 constituency.
25

26 13. Complaint Counsel provided no extrinsic evidence to prove the overall net
27 impression of Respondents' claims.
28

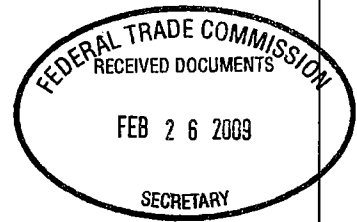
1 14 Complaint Counsel had the burden to prove with extrinsic evidence that
2 Respondents lacked adequate substantiation for their claims. That extrinsic evidence
3 must include expert testimony from an expert specifically qualified in the fields of
4 herbal medicine, phyto-nutrition and/or dietary supplement effect on structure and
5 function of the human body.
6

7 15. Complaint Counsel provided no qualified extrinsic evidence that
8 Respondents lacked adequate substantiation for their claims.
9

10 Based on the foregoing, IT IS ORDERED that Respondents' Motion for Summary
11 Decision is granted. The Commission's Complaint is dismissed with prejudice.
12

13 Dated _____, 2009.
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16 D. Michael Chappell
17 Chief Administrative Law Judge
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4 **IN THE UNITED STATES OF AMERICA**
5 **BEFORE THE FEDERAL TRADE COMMISSION**
6 **OFFICE OF ADMINISTRATIVE LAW JUDGES**

7 **In the Matter of**) **Docket No.: 9329**
8 **DANIEL CHAPTER ONE,**)
9 **a corporation, and**)
10 **JAMES FEIJO,**) **PUBLIC DOCUMENT**
11 **individually, and as an officer of**)
12 **Daniel Chapter One**)
13)

14 **ERRATA TO**
15 **RESPONDENTS' MOTION TO DISMISS FOR LACK OF JURISDICTION**
16 **AND VIOLATION OF RESPONDENTS' CONSTITUTIONAL RIGHTS**
17 **AND MEMORANDUM IN SUPPORT**
18 **(Motion originally filed on February 24, 2009)**

19 Attached to this errata sheet is a corrected copy of Respondents' Motion to Dismiss for
20 Lack of Jurisdiction and Violation of Respondents' Constitutional Rights and Memorandum in
21 Support. The corrected copy incorporates the following changes:

22 1. The last two sentences in footnote 2 on page 10 should read:

23 By one 1986 survey, 73 percent of responding Canadian physicians who treated
24 non-small-cell lung cancer stated that if they had that condition, they would not
25 participate in any of six then-available randomized chemotherapy trials. "Their
26 main reasons? The ineffectiveness of chemotherapy and its unacceptable degree
of toxicity." Ralph W. Moss, Questioning Chemotherapy, Equinox Press, 2000,
p. 40.

27 2. Footnote 3 on page 11 should read:

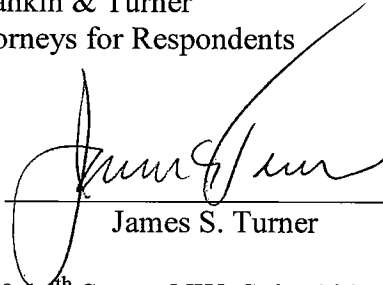
28 ³ See, e.g., *John* 9:1-34.

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Dated this 25th day of February, 2009.

Swankin & Turner
Attorneys for Respondents

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

In the Matter of)
DANIEL CHAPTER ONE,)
a corporation, and)
)
JAMES FEIJO,)
individually, and as an officer of)
Daniel Chapter One.)
_____)

DOCKET NO. 9329

PUBLIC DOCUMENT

**Respondents' Motion to Dismiss for Lack of Jurisdiction and Violation of Respondents
Constitutional Rights and Memorandum in Support**
(Including Errata Change of Feb. 25, 2009)

COME NOW Respondents Daniel Chapter One and James Feijo (hereinafter collectively, "DCO") and move this Court for Orders to Dismiss for Lack of Jurisdiction declaring that the FTC has failed to establish that it has jurisdiction over DCO, a religious non profit organization, or to offer evidence supporting its restrictions on Respondents' Constitutional rights, as a matter of law.

This Motion is based on the Memorandum below and on the records and files herein.

I. INTRODUCTION

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

II. THE FTC HAS NO LEGAL AUTHORITY TO PROCEED ON ITS COMPLAINT AGAINST DANIEL CHAPTER ONE IN THIS MATTER.

A. There is No Evidence that Daniel Chapter One is a Nonprofit Religious Corporation of a Type Over Which the FTC Has Jurisdiction.

The FTC "has only such jurisdiction as Congress has conferred upon it by the Federal Trade Commission Act ("the Act")." Community Blood Bank of the Kansas City Area, Inc. v. FTC., 405 F.2d 1011, 1015 (8th Cir.1969). "[I]f the jurisdiction of the Commission is challenged, it bears the burden of establishing its jurisdiction." *Id.* The FTC has failed to carry that burden.

1. DCO is Organized as a Nonprofit Religious Corporation.

The Complaint alleges that Daniel Chapter One ("DCO") "is a Washington Corporation." Complaint, Para. 1. In fact, DCO is a "corporation sole ... formed under the laws of the State of Washington," having been "issued a Certificate of Incorporation in Washington on October 30, 2002." *See* State of Washington, Secretary of State, Certificate of Existence/Authorization of Daniel Chapter One. On that same date, the Secretary of State of the State of Washington "issued ...Articles of Incorporation to Daniel Chapter One ("the Articles")," attesting to the fact that such Articles "were filed for record" with the Secretary of State. *See* State of Washington, Secretary

of State, Articles of Incorporation to Daniel Chapter One (UBI Number 602 245 097) and RCW 24.12.030. According to the Important Notice and Articles 1 and 2, of these documents and as provided for in Revised Code of Washington (RCW) 24.12.030, DCO is a “private religious corporation sole,” established “in perpetuity,” the sovereign head and director of which is the “Lord God Almighty and His Son the Lord Jesus Christ,” recognized, but not created by, the State of Washington. According to Article 3, and as provided for in RCW.12.010, DCO is authorized to engage only in activities that “promote the Kingdom of God, All Righteousness and the principles of Liberty and Justice.” To that end, it has authority to “provide for the comfort, happiness and improvement of an indefinite number of natural men and women,” but not the financial interests of any individual or group. Rather, it may only act to “provid[e] lawful advice, educat[e] people in the fundamental principles of liberty and the common law, research[], develop[] and implement[] remedies at law for any problem [and further] “other worthwhile projects for the common good.” Indeed, as a corporate sole, and according to Article 4 and RCW 24.12.030, 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].”

In short, DCO is a nonprofit religious corporation. It is not operated for the profit of itself, nor for the profit of any “member.”

2. DCO Operates as a Nonprofit Religious Ministry.

DCO is decidedly not a business enterprise engaged in commerce. Rather, it is a Christian ministry fully engaged in taking the saving and healing gospel of Jesus Christ to the world. . Deposition J. Feijo p. 45, 46, 190, 223, P. Feijo p, 29, 30, 52, 82, 117. For two hours

each day, Monday through Friday, DCO conducts a Health Watch radio program addressing current public policy issues regarding the spiritual and physical health of people, all the while maintaining that healing can only take place by the power of the Great Physician, Jesus Christ. *See* Response to First Set of Interrogatories No. 5.

As Overseer of DCO, James Feijo is not a corporate CEO. Rather, he is God's servant, receiving no personal income from DCO or any other source, and owning no real property, no personal bank accounts, health insurance, investment accounts or retirement funds. While DCO defrays his expenses, Feijo holds all moneys in trust for the religious and educational purposes of Daniel Chapter One, in accordance with the statutory requirements of a corporate sole. *See* Response to First Set of Interrogatories No. 3.

As Secretary of DCO, Patricia Feijo is God's servant, receiving no personal income from DCO or any other source and owning no personal or real property. She has no personal bank accounts, health insurance, life insurance, investment accounts, or retirement funds. *See* Response to First Set of Interrogatories No. 6.

While DCO raises funds through its promotion of a variety of health enhancing products and dietary supplements, such promotion is an integral part of DCO's overall religious ministry of providing people with educational and religious information. *See* Response to First Set of Interrogatories No. 13. Its income from such promotions "is devoted exclusively to the purposes of [DCO] and not distributed to [any] members or shareholders." *See* Community Blood Bank of the Kansas City Area, Inc. v. FTC, 405 F.2d at 1019-1020. Rather, all receipts of funds are considered donations to a religious organization and are expended in accordance with DCO's

religious purposes and to support its charitable and educational activities. *See* Response to First Set of Interrogatories No. 26. *See also* J. Feijo Deposition, pp. 209-12.

3. DCO is Not Within the Class of Nonprofit Corporations Over Which the FTC Has Jurisdiction.

In order for the FTC to exercise jurisdiction over a non profit corporation such as DCO, the FTC must affirmatively demonstrate that DCO is a “[c]orporation ... which is organized for its own profit or that of its members.” *See* 15 U.S.C. Section 45(a)(2).

In Community Blood Bank of the Kansas City Area, Inc. v. FTC, 405 F.2d 1011, the FTC contended that its jurisdiction under this provision applied to any nonprofit corporation “organized to engage in some undertaking for which it will receive compensation in the form of fees, prices, or dues and is not prohibited by its charter from devoting any excess of income over expenditures or other benefit derived from doing business to its own use; i.e., *for its own self-perpetuation or expansion.*” *Id.*, 405 F.2d at 1016 (italics original). The court of appeals rejected this argument, observing that:

The interpretation of the Commission means ... that any corporation engaged in business **only for charitable purposes** and which is forbidden by law to carry on business for profit, that receives income in excess of expenses, is in fact carrying on business for its own profit if it is capable of self-perpetuation or expansion. [*Id.* (emphasis added).]

Instead, the court ruled that “Congress did not intend to bring within the reach of the Commission any and all nonprofit corporations regardless of their purposes and activities.” *Id.*, 405 F.2d at 1018.

As DCO is operated exclusively for charitable and educational purposes, fully engaged in the national debate regarding health care and totally committed to bringing the Christian message of natural healing and spiritual rejuvenation, the FTC has no statutory authority over DCO, or over its Overseer, James Feijo.

B. The FTC Has Placed Unconstitutional and Unlawful Burdens Upon Respondents.

1. The FTC Has Unconstitutionally Burdened Respondents' Commercial Speech.

In its Complaint, the FTC seeks an Order requiring Respondents not to make any representation about any of its products “unless the representation is true [and] non-misleading.” Complaint, Orders I and II. Indeed, as shown in Respondent accompanying Motion for Summary Judgment, the FTC has sought to impose upon Respondents the burden of proving that they had a “reasonable basis” for making the representations about the products itemized in the Complaint. By seeking to place the burden upon Respondents to show that they had a reasonable basis for their representations, the FTC disregards the fact that **the First Amendment imposes upon the FTC the burden** to show that there was no reasonable basis for the representation.

As the United States Supreme Court has consistently ruled since Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976), even commercial speech receives First Amendment protection, unless “as a threshold matter ... the commercial speech concerns unlawful activity or is misleading.” See Thompson v. Western States Med. Ctr., 535 U.S. 357, 366-67 (2002). Under the court’s commercial speech doctrine, **the burden is clearly upon the FTC** to demonstrate affirmatively that Respondents’ representations are

unlawful or misleading. If the FTC is to apply its standard of “competent and reliable scientific evidence” to health-related claims or claims related to dietary supplements, then constitutionally it would be required to prove by such evidence that the Respondents’ product claims are **not** supported. There is no such evidence in this case.

There being no evidence that Respondents’ representations are misleading, the FTC would be required, under the commercial speech doctrine, to establish that its application of the “competent and reliable scientific evidence” rule is required by a “substantial government interest, and not more extensive than necessary to advance that interest.” *Id.*, 535 U.S. at 367. The FTC has failed to meet that standard in this proceeding.

2. The FTC Has Placed an Unconstitutional Burden on Respondents’ Religious and Political Speech.

In its attempt to shut down DCO’s promotion of its health-care products, the FTC has attempted to isolate DCO’s promotional material in relation to those products from its overall educational and religious ministry. Its effort is obviously calculated to extract such promotional material out of the context of DCO’s ministry in order to establish that “[t]he speech at issue in this case is commercial speech, not political or religious speech.” *See* Complaint Counsel’s Memorandum in Opposition to Respondents’ Motion to Dismiss (“Opposing Memo to Motion to Dismiss”), p. 12. Otherwise, the constitutional standard that would be applied to the FTC action here would be much higher than that applied to commercial speech. The FTC seeks to avoid application of a rule recently suggested by Justice Stevens that — when communications are a “blending of commercial speech, noncommercial speech and debate on an issue of public

importance” — such First Amendment activity might well deserve the kind of constitutional protection afforded “misstatements about public figures that are not animated by malice.” *See Nike, Inc. v. Kasky*, 539 U.S. 654, 656, 664 (2003) (*per curiam* opinion dismissing writ of certiorari as improvidently granted, Stevens, J., concurring).

As Complaint Counsel points out, the normal rule governing the application of the Act’s prohibition of “deceptive” practices does not turn on the communicator’s “intent.” *See* *Opposing Memo to Motion to Dismiss*, p. 12. If, however, such communications are so intertwined with political and religious communications on an issue of public importance, application of that normal rule would infringe upon First Amendment rights. As the Supreme Court has put it in *New York Times v. Sullivan*, 376 U.S. 254 (1964), the freedom of speech commits the nation to the “unfettered interchange of ideas for the bringing about of political and social change.” *Id.*, 376 U.S. at 271. Thus, in the constitutionally-guaranteed marketplace of ideas where the “debate on public issues should be uninhibited, robust and wide-open,” there is no room for government suppression of a communication even on the grounds that it is deceptive or false:

That **erroneous statement is inevitable in free debate**, and that it must be **protected** if the freedoms of expression are to have the ‘breathing space’ that they ‘need ... to survive. [*Id.*, 376 U.S. at 271-72 (emphasis added).]

Therefore, the Court ruled that there is “no ... warrant for repressing speech that would otherwise be free [because of] factual error.” *Id.*, 376 U.S. at 272. Instead, it ruled that even untrue communications were constitutionally protected unless they were made knowing them to be false or in reckless disregard of their truth or falsity. *Id.*, 376 U.S. at 279-80.

While the Court has not applied the “actual malice” rule of New York Times v. Sullivan in every case involving issues of public importance, the Court has consistently ruled against the imposition of “liability without fault” for the publication of a false statement. *See Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 347 (1974). Additionally, the Court has assiduously followed its rule that “the government may not regulate speech based upon its substantive content or the message that it contains.” *See Rosenberger v. Rector and Visitors of Univ. of Va.*, 515 U.S. 819, 828 (1995). Complaint Counsel asserts that this rule does not apply because “[t]he FTC’s well-recognized substantiation standards, with which the Respondents now take issue, apply equally to all parties, regardless of viewpoint.” *See* Opposing Memo to Motion to Dismiss, p. 11, n.4. This is not true. The FTC applies its “competent and reliable scientific evidence” standard only to statements that “implicate health concerns.” *See FTC v. National Urological Group, Inc.*, 2008 U.S. Dist. LEXIS, * 43-44.

.Respondents are entitled to constitutional protection afforded false statements, or against subject matter content. ..Their statements promoting their products are so integral to the ongoing debate on public health that they cannot fairly be isolated from DCO’s overall religious and political ministry of health freedom and healing. .

3. The FTC Has Unconstitutionally Burdened Respondents’ Freedom of Religion.

DCO is not just engaged in communications promoting the use of its health-improving products. As evidenced to the world by its name — Daniel Chapter One — DCO is engaged in an ongoing conflict with the nation’s governing authorities regarding the standard by which the public health is promoted and achieved. Just as Daniel refused to eat the “king’s meat,” opting

for a health regimen that was consistent with God’s revelation and his religious convictions¹, DCO promotes an approach to health based upon God’s revealed word and the natural law, in contrast to the empirically-bound “scientific” one sanctioned by the federal government. Thus, as in the case of Daniel, DCO relies upon God’s word, divine providence, and personal testimonials . to demonstrate the efficacy of its products. *See Daniel 1:15-20.*

According to the FTC “standard of truth,” however, there is no room for the spiritual — God’s revelation and personal testimonials. There is only room for the secular — “competent and reliable scientific evidence,” that is, “tests, analyses, research, studies, or other evidence based on the expertise of **professionals** in the relevant area, that has been conducted and evaluated in an objective manner by **persons qualified** to do so, using procedures generally accepted in **the profession** to yield accurate and reliable results.”² *See Complaint, Order Definition 1.* (emphasis added). Such blind adherence to the empirical method used by ”professionals” in 2009 —as the sole source of truth about the healing effects that a product might have on the

¹ *See Daniel 1:3-14.*

² History demonstrates again and again the folly of deferring blindly to the medical profession on matters of healthcare. Based on learning drawn from “procedures generally accepted by in the profession to yield accurate and reliable results,” and after examining the four humors (yellow bile, black bile, phlegm, and blood), “the prudent Hippocratic physician would prescribe a regimen of diet, activity, and exercise, designed to “void the body of the imbalanced humor.” <http://www.ancienthistory.about.com/cs/hippocrates/a/hippocraticmeds.htm> The founders who saw George Washington die after being bled repeatedly by Drs. James Craik and Elisha Dick, presumably the best the medical profession had to offer, may have had a different view than the FTC about the “expertise of professionals in the relevant area.” <http://www.gwpapers.virginia.edu/project/exhibit/mourning/scene.html> By one 1986 survey, 73 percent of responding Canadian physicians who treated non-small-cell lung cancer stated that if they had that condition, they would not participate in any of six then-available randomized chemotherapy trials. "Their main reasons? The ineffectiveness of chemotherapy and its unacceptable degree of toxicity." Ralph W. Moss, *Questioning Chemotherapy*, Equinox Press, 2000, p. 40.

human body — presupposes that the therapeutic effects of DCO’s products are to be governed solely by materialistic measurements.

But the human body is not just a physical phenomenon. Rather, man is made in the image of God who is Spirit. *See Genesis 1:26-28 and John 4:24.* And the Holy Scriptures reveal through testimonies God’s healing power.³ According to the FTC’s secular world view, as explained and adopted by the United States Court of Appeals for the Seventh Circuit, healing testimonies are “not a form of proof because most testimonials represent a logical fallacy: post hoc ergo propter hoc,” since a person who uses a product that has not been scientifically tested may have “enjoyed the same” healing effect without it. *See FTC v. QT, Inc.*, 512 F. 3d 858, 862 (7th Cir. 2008).

It is not, however, within the jurisdiction of the FTC or any court to impose its scientific orthodoxy upon Respondents. As the Supreme Court stated in *United States v. Ballard*, 322 U.S. 78, 86 (1944), “[t]he law knows no heresy, and its committed to the support of no dogma,” even the scientific dogma of the FTC, as articulated by the U.S. Court of Appeals for the Seventh Circuit. In short, so-called “science” may not be used by the federal government to shut down alternative health-care messages based upon knowledge other than that possessed by the licensed medical profession or the FDA-approved pharmaceutical approach to healing. Such close-minded use of science is, in fact, the misuse of the empirical method as the sole source of truth.⁴

³ *See, e.g., John 9:1-34.*

⁴ *See H. Schlossberg, Idols for Destruction* 142-46 (Thomas Nelson: 1983) (“Now science ... has been found to have some of the same disabilities as its rivals ; reliance on unproved assumptions, subjectivity, and the propensity to make pronouncements on questions that lie outside its field of competence.”)

And it is contrary to the First Amendment guarantees against an establishment of religion and the prohibition of its free exercise:

Men may believe what they cannot prove. They may **not be put to the proof of their religious doctrines or beliefs. Religious experiences which are as real to life to some may be incomprehensible to others.** Yet the fact that they may be beyond the ken of mortals does not mean that they can be made **suspect before the law.** [Ballard, 322 U.S. at 86-87 (emphasis added).]

4. The FTC Seeks to Substantially Burden Respondents' Exercise of Religion in Violation of 42 U.S.C. Section 2000bb-1.

In its Complaint, the FTC seeks an Order prohibiting Respondents from making any claim about the products named in the indictment “unless ... at the time it is made Respondents **possess and rely upon** competent and reliable scientific evidence that substantiates the representation.” Complaint, Order I (emphasis added). Additionally, the FTC seeks an Order that Respondents make no claim about any product, present or future, “unless ... at the time that it was made Respondents **possess and rely upon** competent and reliable scientific evidence that substantiates the representation.” Complaint, Order II (emphasis added). Furthermore, the FTC seeks an Order requiring Respondents to send a letter to every person who obtained one of the products named in the indictment, informing them that: (a) “scientific studies ... do not demonstrate that any [of these products] are effective when used for prevention or treatment of cancer”; and (b) that before taking anything containing certain ingredients in these products, they must consult their “doctor.” Complaint, Order IV, Attachment A.

By design and effect, these Orders would force Respondents to adopt the FTC’s faith in the scientific method and the medical profession as if it were their own. As such, these Orders, if imposed on Respondents would violate:

“[T]he heart of the First Amendment [wherein] lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence.... Government action that ... requires the utterance of a particular message favored by the Government, contravenes this essential right. Laws of this sort pose the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information or manipulate the public debate through coercion rather than persuasion. [Turner Broadcasting System, Inc. v. FCC, 512 U.S. 622, 641 (1994).]

In the depositions of Respondent Feijo, as DCO overseer, and Tricia Feijo, as DCO secretary, the FTC has made every attempt to impose its scientific orthodoxy upon them, notwithstanding their protestations of Christian faith. In so doing, and in so seeking the Orders set forth above, the FTC has laid a substantial burden upon the Feijos’ exercise of religion in violation of 42 U.S.C. Section 2000bb-1(a).

According to 42 U.S.C. Section 2000bb-2 and 2000cc-5, “[t]he term ‘religious exercise’ includes any exercise of religion, whether or not compelled by, or central to, a system of religious belief.” Respondents have established in the discovery process that their “exercise of religion” includes their conviction that their healthcare products are given to them by God, not by scientific or medical experts and, thus, they cannot be beholden to any man or group of men, such as would be the case if Orders I, II and IV were imposed upon them.

According to 42 U.S.C. Section 2000bb-1(a) and 2000bb-2(1) the FTC “shall not substantially burden Respondents’ exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection b of this section.” There is no question that Respondents’ exercise of religion would be substantially burdened by Orders I, II, and III, in that such orders would “require Respondents to utter a particular message favored by the Government,” namely, that only those claims about healthcare products that conform to

“competent and reliable evidence” may be made — that any claim based upon God’s revelation would be forbidden.

According to 42 U.S.C. 2000bb-1(b) the FTC may place such a burden upon Respondents only “if it demonstrates that application of the burden to the person — (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.” And as the Supreme Court has recently ruled the government may sustain this burden only if it “demonstrate[s] that the compelling interest test is satisfied through application of the challenged law “to the person” — the particular claimant whose sincere exercise of religion is being substantially burdened.”

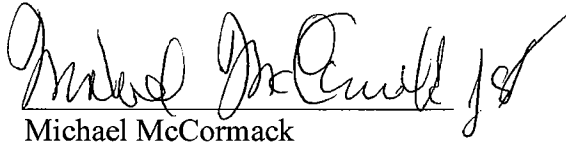
Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal, 546 U.S. 418, 430-31 (2006). It is thus not enough for the FTC to articulate a “broadly formulated interest[]” in the prohibition of deceptive practices “justifying the general applicability” of that mandate. Rather, it must show that it has a compelling interest **not** to grant a “specific exemption” from its scientific standard “to particular religious claimants.” *Id.*, 546 U.S. at 431. And that it has no other reasonable alternative but to enforce its “scientific” standard against these Respondents.

The FTC has not sustained, and cannot sustain, such a statutorily-imposed burden.

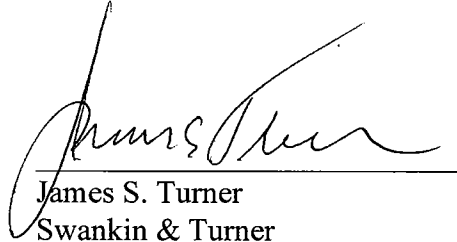
CONCLUSION

For the foregoing reasons, the Motion to Dismiss should be granted and the Complaint dismissed.

Respectfully submitted February 24, 2009,



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COPY

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

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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[PROPOSED] ORDER
GRANTING RESPONDENTS' MOTION TO DISMISS COMPLAINT
(Lack of Jurisdiction)

On February 24, 2009, counsel for Respondents filed a motion to dismiss in the administrative action *In the Matter of Daniel Chapter One*, Docket No. 9329. The Court being fully advised,

IT IS ORDERED that Respondents' Motion for dismissal of the complaint in the administrative action *In the Matter of Daniel Chapter One*, Docket No. 9329, be, and is hereby GRANTED.

Dated this ___ day of _____, 2009.

D. Michael Chappell
Administrative Law Judge

1
2 **IN THE UNITED STATES OF AMERICA**
3 **BEFORE THE FEDERAL TRADE COMMISSION**
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6 **DANIEL CHAPTER ONE,**)
7 **a corporation, and**) **PUBLIC DOCUMENT**
8 **JAMES FEIJO,**)
9 **individually, and as an officer of**)
10 **Daniel Chapter One**)

11
12 **CERTIFICATE OF SERVICE**

13
14 I certify that on February 25, 2009, I served or caused to be served the following
15 documents on the individuals listed below by electronic mail, followed by Federal Express
16 delivery:

17 Errata to Respondents' Motion to Dismiss for Lack of Jurisdiction and Violation of
18 Respondents' Constitutional Rights and Memorandum in Support
19 Errata to Respondents' Motion for Summary Decision


20 Service to:

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

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